A cost/benefit analysis of self-care systems in the European Union

Final report

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Abstract

Due to the recent economic environment and the accompanying financial pressure on public payers, European health systems are confronted to implement cost containment measures and simultaneously maintain the quality of health care services for the population. Fostering initiatives that promote patient involvement ("self-care") is considered as a possible policy to achieve efficiency increases.

As first step, a definition of self-care was developed based on a literature review and a two-stage Delphi process with the project's expert panel. To determine the added value of self-care, a systematic literature review was conducted for five minor ailments (i.e. athlete's foot, cold, cough, heartburn and urinary tract infection). As a next step, existing self-care initiatives in Europe have been identified and analysed according to the RE-AIM framework (i.e. reach, effectiveness, adoption, implementation and maintenance) in order to identify best-practices. For identified best-practice initiatives a cost benefit-analyis has been conducted from the patient's, the supplier's, the system's and the societal perspective. Finally, a methodology of the transferability of best-practices was developed, which was based on a combination of literature search and expert interviews. Finally, a dissemination strategy for the results gained was developed.

Concerning the added value of self care, good evidence is given for the effectiveness of topical treatments of athlete's foot (i.e. allylamines and azoles), treatments of cold (i.e. Acetylsalicylic acid, nasal sprays/topical treatments, Echinacea), treatments against heartburn including lansoprazole and H2-receptor antagonists. No clear evidence could be found for the effectiveness of over-the counter (OTC) medicines against cough and also the evidence of self-care strategies for urinary tract infection (UCI) was unclear. Concerning the cost-benefit analysis, the results suggest that from the societal persective NHS Choices representing internet based information systems and MAS representing legislative change being favourable policy options, with different benefit levels regarding patient groups exempt/non-exempt of paying prescription charges. The impacts of NMP show no difference concerning the obligation of patients to pay prescription charges. Concerning the methodology of transferability of best-practice self-care initiatives, a four step approach was developed consisting of: 1.) identification of best-practices in self-care, 2.) identification of key features of best-practice initiatives, 3.) assessment of the feasibility of transferring best-practice initiatives, 4.) deduction of policy options.

The study offers added value to existing literature on self-care, which tends to focus on pharmaceutical treatments for the use in self-care. By assessing the effectiveness of self-care treatments, assessing self-care initiatives in cost-benefit analysis and developing a methodlogy for transferability of best-practice self-care initiatives, scientific evidence could be supplemented by a practical guide for policy-makers for identifying and transferring best-practices in self-care. The results highlight that political commitment to self-care is essential for the implementation and uptake of self-care. Further, it shows that for successful self-care initiatives a change in "culture" is necessary, so that patients take responsibility for their own health. In this context, patient information and clear communication is of particular relevance. Also, successful self-care requires a re-thinking of health care professionals involved related to the definition of their professional identity. This may concern particularly the cooperation between physicians and pharmacists.

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List of Abbreviations

AMC/DCBA	Amylmetacrsol/2.4-dichlorobenzyl alcohol
ARI	Acute Respiratory Infection
AT	Austria
A&E	Accident & Emergency
BEUC	Bureau Européen des Unions de Consommateurs/The European Consumer Organisation
BMI	Body Mass Index
CAP	Community-Acquired Pneumonia
CBA	Cost-Benefit Analysis
CHAFEA	Consumer, Health, Agriculture and Food Executive Agency
CNAMTS	Caisse Nationale de l'Assurance Maladie des Travailleurs salariés / National Health Insurance Fund for Employees (France)
COPD	Chronic Obstructive Pulmonary Disease
CQC	Care Quality Commission (United Kingdom)
CRD	Centre for Reviews and Dissemination (United Kingdom)
CZ	Czech Republic
D	Deliverable
DE	Germany
DG SANTE	Direction générale de la santé et des consommateurs/Directorate-General for Health and Food Safety
DIMDI	Deutsches Institut für medizinische Dokumentation und Information/German Institut of Medical Documentation and Information (Germany)
DK	Denmark
DoPHER	Database of Promoting Health Effectiveness Reviews (United Kingdom)
DM	Dextromethorphan
ENT	Ear, Nose, Throat
EU	European Union
FR	France
GER / GOR	Gastro-Esophageal Reflux/Gastro-Oesophageal Reflux
GERD / GORD	Gastro-Esophageal Reflux Disease/Gastro-Oesophageal Reflux Disease
GI	Gastro-Intestinal
GKV	Gesetzliche Krankenversicherung/National Health Insurance (Germany)

GP	General Practitioner
H_2RA	H_2 Receptor Antagonists
HSCIC	Health & Social Care Information Centre (United Kingdom)
IDSA	Infectious Diseases Society of America (USA)
IQWIG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen/Institute for quality and efficiency in Healthcare (Germany)
LES / LOS	Lower Oesophageal Sphincter/Lower Esophageal Sphincter
LUTI	Lower Urinary Tract Infection
LV	Latvia
MAS	Minor Ailment Scheme
MeSH	Medical Subject Headings
NHS	National Health Service
NL	Netherlands
NMP/PIP	Non-Medical Prescribing / Pharmacist independent Prescribing
OECD	Organisation for Economic Co-operation and Development
ONB	Österreichische Nationalbibliothek/Austrian National Library (Austria)
OTC	Over-the-counter
PCR	Polymerase Chain Reaction
PIP	Pharmacist Independent Prescribing
PMAS	Pharmacy Minor Ailment Scheme (England)
POM	Prescription Only Medicine
PPI	Proton Pump Inhibitors
PT	Portugal
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trial
RE-AIM	Reach, Efficiecy, Adoption, Implementation, Maintenance
RSV	Respiratory Syncytial Virus
RTI	Respiratory Tract Infection
RUTI	Recurrent Urinary Tract Infection
Rx	Prescription
SARS	Severe Acute Respiratory Syndrome
SI	Slovenia
SMS	Short Message Service
UK	United Kingdom
URTI	Upper Respiratory Tract Infection

USA	United States of America
UTI	Urinary Tract Infection
VAT	Value Added Tax
WHO	World Health Organization
WP	Work package
WW	Watchful Waiting

Executive summary

Background

The traditional provider-centred structure within most European health care systems is primarily designed for delivering acute care, and less targeted for the care of patients with chronic, minor and/or self-limiting diseases. For these patients other concepts of care may be more suitable and may also contribute to enhanced cost containment within health care systems.

One approach which promotes patient involvement and is expected to lead to savings in health care budgets is the concept of self-care. The areas of action for self-care are twofold: First, self-care is regarded as a suitable approach for dealing with chronic conditions, as the day-to-day management is already carried out by patients and their families. Second, there are also further, typically self-limiting and minor conditions which can be handled with simple actions and low risk by the patients or other lay-persons (such as relatives). These conditions are referred to as minor ailments.

At EU level, the issue of self-care was particularly addressed through processes related to self-medication or non-prescription medication. In Commission Decision C(2013) 4940 of 2 August 2013 concerning the financial contribution by the Community towards a pilot project in the field of self-care systems in EU, the Budget Authority asked the Commission to fund initiatives which put in place a framework for action to enhance self-care at EU level and develop strategies to support the broader implementation of effective self-care.

These objectives shall be achieved by:

1. A cost/benefit analysis of patient self-care oriented health care systems in the European Union and the current frameworks in place to enhance self-care oriented health care systems and patients' empowerment;
2. Transferability of best-practices; and
3. The creation of a platform of experts in self-care and health care.

Objectives 1) and 2) are covered by this study at hand. Objective 3) will be addressed by the 'Pilot project on the promotion of self-care systems in the European Union: Platform of experts' (PISCE).

Rationale and objectives of the study

The general objective of the study was to explore the added value of self-care systems in Europe. As such, this study aimed to provide a basis for assessing the economic and societal impacts of self-care, as well as to offer guidance on how to transfer and implement self-care initiatives that had proven to be effective on the grounds of existing evidence. Accordingly, the specific objectives are:

- to provide scientific evidence of the added value of self-care for five selected minor ailments (i.e. athlete's foot, cold, cough, heartburn, urinary tract infection);
- to analyse potential costs and savings of self-care initiatives;
- to develop a methodology of the transferability of best-practices in self-care and assess it; and
- to develop a strategy to disseminate the benefits of self-care.

Definition of self-care

For all activities undertaken in this project, such as the literature review of minor ailments and the cost/benefit analysis, the following **definition** of self-care was applied:

"Self-care is what individuals, families and communities do with the intention to promote, maintain, or restore health and to cope with illness and disability with or without the support of health professionals such as pharmacists, doctors, dentists and nurses. It includes but is not limited to self-prevention, self-diagnosis, self-medication and self-management of illness and disability."

This definition was developed based on a literature review and a two-stage Delphi process with the project's expert panel.

Added value of self-care

A systematic literature review was conducted for five selected minor ailments. Key results were:

For the ailment of **athletes' foot**, the included studies contained good evidence for the effectiveness of almost all topical treatments of athlete's foot which can be used by the patient in self-care. Strong evidence was available for allylamines and azoles. For butenafine, ciclopiroxolamine, tolciclate and tolnaftate as well as for terbinafine evidence was less strong.

For **cold**, the included studies showed that there was sound evidence for the effectiveness of treatments (e. g. Acetylsalicylic acid, nasal sprays/topical treatments, Echinacea, etc.) against the symptoms of the common cold which can be used by patient. However, some caution is required with regard to products where the effectiveness is not proven, as the placebo effect together with the natural resolving of the common cold might lead patients to misperceive the actual added value of these products.

With regard to **cough**, the systematic search revealed a lack of evidence for the effectiveness of Over-the-Counter (OTC) medicines which can be used by patients in self-care. Despite a high evidence grade of an included review, its results have to be interpreted cautiously as it is based on too few studies with too many methodological issues making generalisations difficult. Aligned with WHO recommendations, home remedies like a spoon of buckwheat honey can be used as a first line treatment against minor ailments, especially against nocturnal cough symptoms.

For the ailment of **heartburn**, there was good evidence for the effectiveness of some treatments of heartburn, which can be used for self-care. Evidence found mostly referred to products, which can usually be purchased over the counter and have little side-effects such as lansoprazole and H2-receptor antagonists. However, future evaluations on self-care for heartburn should pay more attention to clearly distinguish between heartburn, gastroesophageal symptoms and Gastro-Esophageal Reflux Disease.

Referring to **urinary tract infection (UTI),** no clear evidence could be identified if and how different preventive self-care strategies can reduce the risk of (recurrent) UTI. The reasons are diverse: non-compliance with juice and syrup products, no statements about how much of the active ingredient (if any) is inside non-juice products. Antibiotics are the most effective treatment in the presence of UTI, but the added value for self-management is limited, as it is not possible to draw inferences from symptoms to bacteriuria or bacterial counts.

Analysis of self-care initiatives

Initially, eight self-care initiatives were considered to be analysed according to the RE-AIM+ framework. During the course of the project, one of these initially selected initiatives (i.e. 'Grünes Rezept') was excluded in accordance with the project commissioners. It did not target towards the avoidance/substitution of GP contacts by self-care in first place, and thus did not completely comply with the definition of self-care used in this project.

The following self-care initiatives were analysed:

- Ameli santé (Health information – website; France)
- Latvian tele-helpline (Health information - telephone hotline; Latvia)
- Zelfzorg.nl (Health information – website; the Netherlands)
- **NHS Choices** (Health information – website; UK)
- **NHS 111 (NHS direct)** (Health information - telephone hotline; UK)
- **Minor ailment scheme** (Legislative change; UK)
- **Non-medical prescribing** (Legislative change; UK)

According to the proposed framework the latter four UK-based initiatives were identified as best-practice. A cost-benefit analysis was performed for NHS Choices, Minor ailment scheme and Non-Medical Prescribing. For the case of NHS 111, sufficient cost data was not available to undertake a cost-benefit analysis.

Economic evaluation of self-care initiatives

For the five selected minor ailments, costs and savings of the identified best-practice self-care initiatives were analysed from four different perspectives: patient, provider, system, society.

Minor ailment schemes (MAS) have the potential to lead to a positive societal net benefit if shift rates exceed 27.5 percent. As prescription charges are relatively high (£ 8.05 or 10.87 € per item) compared to the prices of OTC medicines, patients not exempt from these charges tend to benefit to a larger extent than those exempt. Still, the latter group of patients also tends to benefit from MAS, and even more than from merely using an internet-based information service such as NHS Choices.

Concerning **Non-medical prescribing (NMP),** costs at providers' level are too high to allow for a positive net benefit at the societal level. Patients, however, regardless as to whether they are exempt from prescription charges, tend to benefit from NMP, as they are likely to save time due to the avoided GP encounter while the medication as well as possible (co-)payments remain the same.

With regard to **NHS Choices**, a positive net societal benefit appears to exist despite comparatively low rates of overall shift (break-even of the initiative at 4.4 percent shift rate). Patients exempt from prescription charges benefit from time savings only, while patients obliged to pay prescription charges additionally benefit from lower (co-)payments, as they have to pay fully out-of-pocket for OTC medicines instead paying the prescription fee of £ 8.05 per item for a similar prescription-only medicine.

In a nutshell, from a societal perspective the results suggest NHS Choices and MAS being favourable policy options, with NHS Choices primarily benefiting patients obliged to pay prescription charges, whereas MAS appears to be designed more towards patients exempt from prescription charges.

The impacts of NMP show no difference concerning the obligation of patients to pay prescription charges. From a societal perspective, though, a widespread adoption of pharmacist independent prescribing is very unlikely.

Transferability of best-practices

Based on the frameworks for policy transfer in health as well as in other settings identified in literature, a four-step approach was developed, consisting of:

1. Identification of best-practices in self-care
2. Identification of key features of best-practice initiatives
3. Assessment of the feasibility of transferring best-practice initiatives
4. Deduction of policy options

The identification and selection of best-practices (**step 1**) in self-care was based on the RE-AIM framework (i.e. criteria for reach, effectiveness, adoption, implementation and maintenance). In order to identify the features and characteristics of best-practice self-care initiatives in **step 2**, each best-practice initiative was assessed by a framework consisting of four dimensions: 1) Population/Patient, 2) Providers, 3) Government/System and 4) Technology.

Based on steps 1 and 2, the feasibility of best-practices' transferability was assessed (**step 3**). This step aims to examine the conditions that have to be met for a best-practice initiative to function successfully in the importing setting. The assessment links the above mentioned four dimensions to other works in that field and covers three aspects:

1. Factors supporting policy success in the exporting setting (i.e. **"favourable conditions"**).
2. Assessment of the success factors' relevance in the exporting setting (**"relevance"**).
3. Assessment of the situation in relation to the success factors in the importing setting (**"feasibility"**).

Based on the assessment results gained by following the first three steps, policy-makers decide in **step 4** if, and how a best-practice initiative should be implemented in their country.

In order to critically reflect the feasibility of the methodology for transferability a SWOT and risk analysis was conducted.

Dissemination strategy of best-practice in self-care

In order to allow for learning and a transfer of best-practices in self-care, the findings of the study about the benefits of self-care and the methodology for transferability should be appropriately disseminated.

Major **target groups** include policy-makers and stakeholders at EU and national levels, representatives of similar projects, in particular the PISCE (pilot project on the promotion of self-care) consortium as well as the general public.

In addition to this report at hand, which comprises in a comprehensive way scientific results and a practical tool of the methodology for transferability aimed at policy-makers, further dissemination activities are recommended.

Highly recommended **dissemination tools** for this project include a press release and a leaflet in order to raise awareness. Furthermore, the proposed dissemination plan for this

report suggests making use of existing newsletters and websites of the consortium and of other institutions to disseminate the results. The scientific community can be reached through articles in peer-reviewed journals, presentations and posters at conferences.

A major **dissemination activity** would be the organisation of a large-scale conference targeted at policy-makers and stakeholders, either as a stand-alone event or together with similar projects, such as the PISCE project.

Conclusions and recommendations

The study at hand highlighted the increasing relevance of self-care, both in literature as well as in practice, and, at the same time, the need for further evidence and knowledge, and their dissemination.

Our study offers added value to existing literature that tends to be focused on the effectiveness of the pharmaceutical treatments for self-care use. We explored the benefits of self-care by critically assessing self-care initiatives in cost-benefit analyses. Scientific evidence is supplemented by a practical guide for policy-makers that allows identifying best-practices in self-care and transferring them to their own setting.

While several factors in the setting of the importing and exporting countries playing a role to facilitate the implementation and uptake of self-care, our study has outlined that a **political commitment to self-care**, such as in the UK, supports best-practices in self-care.

A prerequisite for successful self-care initiatives is the **change in "culture"** so that patients take responsibility for their own health. In order to do so, patients have to be "empowered", and they require access to reliable and understandable information about how to engage in self-care. An inevitable part of patient information related to self-care must be clear communication that self-care cannot substitute health care by professionals. Patients have to be taught to distinguish minor ailments from serious cases.

Self-care also requires **re-thinking of the involved health care professionals** related to the definition of their professional identity. In particular, the cooperation between physicians and pharmacists may need to be re-organised since these health care professionals should engage more in collaborative care.

Our study is a basis for follow-up work in this field, especially for the development of a guideline for the promotion of self-care and a guideline for the development and production of communication tools as well as a proposal of policy actions on self-care at EU level that will be done in the PISCE project. It is highly recommended that our results are fed into the PISCE project and that the experts of the PISCE platform consider our findings in their work.

Résumé

Contexte

La structure traditionnelle centrée sur le fournisseur, au sein de la plupart des systèmes de soins de santé européens, est principalement conçue pour la prestation de soins aigus de courte durée, et moins ciblée sur le soin des patients atteints de maladies chroniques, mineures et/ou spontanément résolutives. Pour ces patients, d'autres concepts de soins peuvent être plus appropriés et peuvent également contribuer à la maîtrise des coûts accrue dans les systèmes de soins de santé.

Une approche, qui favorise la participation des patients et peut conduire à des économies dans les budgets de soins de santé est le concept des soins personnels («self care»). Les domaines d'action pour les soins personnels sont de deux ordres: d'abord, les soins personnels sont considérés comme une approche appropriée pour traiter des conditions chroniques, étant donné que la gestion au jour le jour est déjà effectuée par les patients et leurs familles. Deuxièmement, il y a aussi plus de maladies, spontanément résolutives et mineures, qui peuvent être traitées avec des actions simples et à moindre risque par les patients ou l'entourage. Ces conditions sont appelées maladies mineures («minor ailments»).

Au niveau européen la question des soins personnels a été particulièrement abordée à travers des processus liés à l'automédication ou à la médication sans ordonnance. La décision C(2013) 4940 de la Commission, datant du 2 Août 2013, concerne la contribution financière de la Communauté Européenne à un projet pilote dans le domaine des systèmes de soins personnels dans l'UE. Dans cette décision l'autorité budgétaire a demandé à la Commission de financer des initiatives qui mettent en place un cadre pour des mesures d'amélioration des soins personnels au niveau de l'UE et pour développer des stratégies visant à soutenir la mise en œuvre plus large de soins personnels efficaces.

Ces objectifs seront atteints par:

1. Une analyse des coûts/avantages des systèmes de santé orientés sur les soins personnels des patients dans l'Union européenne et les structures actuellement en place pour améliorer ces systèmes ainsi que la responsabilisation des malades;
2. La transférabilité des meilleures pratiques; et
3. La création d'une plate-forme d'experts en soins personnels et en santé.

Les objectifs 1) et 2) sont couverts par cette étude. L'objectif 3) sera traité par le «Projet pilote sur la promotion des systèmes de soins personnels dans l'Union européenne: plate-forme d'experts» (PISCE).

Motifs et objectifs de l'étude

L'objectif général était d'explorer la valeur ajoutée des systèmes de soins personnels en Europe. Cette étude vise à fournir une base pour évaluer les impacts économiques et sociaux de soins personnels, ainsi que d'offrir des conseils sur la façon de mettre en œuvre des initiatives de soins personnels qui se sont montrées efficaces selon les preuves existantes. Les objectifs spécifiques sont:

- de fournir des preuves scientifiques de la valeur ajoutée des soins personnels pour cinq maladies mineures sélectionnés (pied d'athlète, le rhume, la toux, les brûlures d'estomac, l'infection des voies urinaires);
- d'analyser les coûts potentiels et les économies des initiatives de soins personnels;

- de développer une méthodologie de transmission des meilleures pratiques en soins personnels et de l'évaluer; et
- de développer une stratégie visant à diffuser les avantages des soins personnels.

Définition des soins personnels

Dans ce projet la **définition** suivante des soins personnels a été appliquée:

«*Les soins personnels sont ce que les individus, les familles et les communautés font avec l'intention de promouvoir, maintenir ou rétablir la santé et de faire face à la maladie et l'invalidité avec ou sans le soutien des professionnels de santé tels que les pharmaciens, les médecins, les dentistes et les infirmières. Il inclut, mais n'est pas limitée à, l'auto-prévention, l'autodiagnostic, l'automédication et l'autogestion de la maladie et du handicap.*»

Cette définition a été élaborée sur la base d'une revue de la littérature et d'un processus Delphi en deux étapes avec un panel d'experts.

Valeur ajoutée des soins personnels

Une revue systématique de la littérature a été réalisée pour cinq maladies mineures:

Pour la maladie du **pied d'athlète (mycose des pieds)**, les études considerées contenaient une forte indication de l'efficacité de presque tous les traitements topiques du pied d'athlète qui peuvent être utilisés par le patient en soins personnels. Des preuves solides étaient disponibles pour les allylamines et azoles. Pour la buténafine, ciclopiroxolamine, tolciclate et tolnaftate ainsi que pour la terbinafine, les indications étaient moins fortes.

Pour le **rhume**, les études ont montrés qu'il y avait de fortes indications de l'efficacité des traitements (par exemple de l'acide acétylsalicylique) contre les symptômes du rhume qui peuvent être appliqués par le patient. Toutefois, une certaine prudence est nécessaire en ce qui concerne les produits pour lesquels l'efficacité n'est pas prouvée. L'effet placebo lié à la guérison naturelle du rhume pourrait conduire les patients à mal percevoir la valeur ajoutée réelle de ces produits.

En ce qui concerne la **toux,** la recherche systématique a révélé un manque de preuves en ce qui concerne l'efficacité des médicaments sans ordonnances qui peuvent être utilisés par les patients en termes de soins personnels. Malgré de fortes indications, ses résultats doivent être interprétés avec prudence, car ils sont basés sur trop peu d'études avec trop de problèmes méthodologiques rendant les conclusions difficiles. En accord avec les recommandations de l'OMS, les remèdes maison comme une cuillère de miel de sarrasin peuvent être utilisés comme un traitement de première intention contre les maladies mineures.

Pour les **brûlures d'estomac**, il y avait une forte indication de l'efficacité de certains traitements, qui peuvent être utilisés pour les soins personnels. Les éléments trouvés font souvent référence à des produits qui peuvent généralement être achetés sans ordonnance et qui ont peu d'effets secondaires tels que le lansoprazole et les antagonistes récepteurs H2. Toutefois, les évaluations futures devront accorder plus d'importance au fait de distinguer clairement les brûlures d'estomac des symptômes de la gastro et de la maladie de reflux gastro-oesophagien.

En ce qui concerne **l'infection des voies urinaires (IVU)**, aucune indication claire n'a pu être identifiée pour savoir si et comment les différentes stratégies de soins personnels

préventifs peuvent réduire le risque (récurrent) d'IVU. Les raisons sont diverses: non-respect des produits de type jus et sirop, aucune déclaration sur le nombre d'ingrédient actif (le cas échéant) à l'intérieur des produits de type non-jus. Les antibiotiques sont le traitement le plus efficace en présence de l'IVU, mais la valeur ajoutée pour les soins personnels est limitée, car il n'est pas possible de tirer des conclusions à partir de symptômes à bactériurie ou à numération bactérienne.

Analyse des initiatives de soins personnels

Initialement, huit initiatives de soins personnels ont été considérées pour être analysées selon le cadre RE-AIM+ (l'efficacité, l'adoption, la mise en œuvre et la maintenance). Au cours du projet, l'une de ces initiatives initialement sélectionnée (en l'occurrence «Grünes Rezept») a été exclue en accord avec les commissaires du projet parce qu'elle ne visait pas à éviter/substituer les contacts avec les médecins dans le cadre des soins personnels, et n'est donc pas complètement conforme avec la définition des soins personnels utilisée dans ce projet.

Les initiatives de soins personnels suivants ont été analysées:

- Ameli santé (information sur la santé - site; FR)
- Télé-assistance téléphonique Lettone (information sur la santé - ligne téléphonique; LV)
- Zelfzorg.nl (information sur la santé - site; NL)
- **NHS Choices** (information santé - site; RU)
- **111 NHS (NHS Direct)** (information sur la santé - ligne téléphonique; RU)
- **Minor ailment scheme** (changement législatif; RU)
- **Non-medical prescribing** (changement législatif; RU)

Les quatre dernières initiatives basées au Royaume-Uni ont été identifiées comme les meilleures pratiques. Une analyse des coûts-avantages a été effectuée pour NHS Choices, Minor Ailment Scheme (le service des maladies mineures) et Non-medical-prescribing (la prescription sans ordonnance). Pour le cas de NHS 111, les données sur les coûts n'ont pas été suffisantes pour entreprendre une analyse des coûts-avantages.

L'évaluation économique des initiatives de soins personnels

Pour les cinq maladies mineures sélectionnées, les coûts et les économies des meilleures pratiques identifiés ont été analysés à partir de quatre points de vue différents: celui du patient, du fournisseur, du système et de la société.

Minor ailment scheme (MAS) a le potentiel d´apporter une contribution avantageuse dans la société (avantage net) si les taux de changement dépassent 27,5%. Comme les frais d'ordonnance sont relativement élevés dans le Royaume-Uni (£ 8,05 ou 10,87 € par article) par rapport aux prix des médicaments en vente libre, les patients non exemptés de ces frais ont tendance à en profiter plus largement. Pourtant, ce dernier groupe a également tendance à bénéficier de services de maladies mineures, et même plus que de la simple utilisation d'un service d'information sur Internet tels que NHS Choices.

En ce qui concerne la **Non-medical prescribing (NMP)**, les coûts au niveau des fournisseurs sont trop élevés pour permettre une contribution avantageuse pour la société. Les patients, cependant, indépendamment de savoir s'ils sont exemptés de frais d'ordonnance, ont tendance à bénéficier de NMP, car ils sont susceptibles de gagner du temps en raison de la non-consultation de médecin tandis que la médication ainsi que les (co)paiements possibles restent les mêmes.

En ce qui concerne **NHS Choices**, une contribution avantageuse dans la société semble exister en dépit des taux de changement relativement faibles (seuil de rentabilité de l'initiative taux de changement de 4,4%). Les patients bénéficiant de la franchise de prescription ne bénéficient que d'un gain de temps, alors que les patients tenus de payer les frais d'ordonnance supplémentaires bénéficient de (co)paiements plus bas, car ils doivent payer intégralement de leur poche les médicaments en vente libre, au lieu de payer les frais de prescription de £ 8,05 par article pour un médicament similaire uniquement sur ordonnance.

En un mot, pour la société les résultats suggèrent NHS Choices et MAS comme étant des options politiques favorables, avec NHS Choices bénéficiant principalement aux patients qui sont obligés de payer des frais d'ordonnance, alors que MAS semble être plutôt conçu pour des patients exemptés de frais d'ordonnance.

Les impacts des NMP ne montrent aucune différence concernant l'obligation des patients à payer les frais d'ordonnance. Pour la société cependant, une adoption généralisée d'une prescription indépendante du pharmacien est très peu probable.

Transférabilité des meilleures pratiques

Une approche en quatre étapes a été élaborée, comprenant:

1. Identification des meilleures pratiques en soins personnels
2. Identification des caractéristiques clés des initiatives de meilleures pratiques
3. Évaluation de la faisabilité du transfert des initiatives de bonnes pratiques
4. Déduction des options politiques

L'identification et la sélection des meilleures pratiques (**étape 1**) dans les soins personnels a été basée sur le cadre RE-AIM. Afin d'identifier les spécificités et les caractéristiques des initiatives de meilleures pratiques dans **l'étape 2**, chaque initiative a été évaluée par un cadre composé de quatre dimensions: 1) Population/Patient, 2) Fournisseurs, 3) Gouvernement/système et 4) la Technologie.

Basé sur les étapes 1 et 2, la faisabilité de la transmission et réalisation des meilleures pratiques a été évaluée (**étape 3**). Cette étape vise à examiner les conditions qui doivent être remplies pour qu'une initiative des meilleures pratiques puisse fonctionner avec succès dans le cadre de l'importation. L'évaluation relie les quatre dimensions mentionnées ci-dessus à d'autres travaux dans ce domaine et couvre trois aspects:

1. Facteurs soutenant la réussite de la politique pour l'exportation («**conditions favorables**»).
2. L'évaluation de la pertinence des facteurs de succès dans l'exportation (la «**pertinence**»).
3. Évaluation de la situation par rapport aux facteurs de succès dans l'importation («**faisabilité**»).

Basé sur les résultats de l'évaluation obtenus en suivant les trois premières étapes, les décideurs politiques décident à **l'étape 4** si, et comment une initiative de meilleures pratiques devrait être mise en œuvre dans leur pays. Afin de réfléchir de manière critique à la faisabilité de la méthodologie pour la transmission et réalisation, une analyse SWOT et une analyse des risques ont été menées.

Stratégie de diffusion des meilleures pratiques en matière de soins personnels

Afin de permettre l'apprentissage et le transfert des meilleures pratiques, les résultats de l'étude sur les avantages des soins personnels et la méthodologie de transmission

devraient être diffusés de manière appropriée.

Les principaux **groupes cibles** sont les décideurs politiques et les parties prenantes au niveau européen et nationaux, des représentants de projets similaires, en particulier le projet PISCE ainsi que le grand public.

Les Outils de diffusion fortement recommandés comprennent un communiqué de presse et un dépliant pour sensibiliser le public. En outre, le plan de diffusion proposé pour ce rapport suggère de faire usage de bulletins d'information et des sites Web existants du consortium et d'autres institutions pour diffuser les résultats. La communauté scientifique peut être atteinte par des articles dans des revues évaluées par des pairs, des présentations et des affiches à des conférences.

Une des principales **activités de diffusion** serait l'organisation d'une grande conférence destinée aux décideurs politiques et aux parties prenantes, que ce soit comme un événement autonome ou avec des projets similaires, tels que le projet PISCE.

Conclusions et recommandations

Cette étude a souligné l'importance croissante des soins personnels, à la fois dans la littérature ainsi que dans la pratique, le besoin de plus d'indications, de connaissances et de leur diffusion.

Notre étude apporte une valeur ajoutée à la littérature existante qui se concentre sur l'efficacité des traitements pharmaceutiques pour un usage personnel. Nous avons exploré les avantages des soins personnels par une évaluation critique des initiatives de soins personnels dans les analyses de coûts-avantages. Les preuves scientifiques sont complétées par un guide pratique pour les décideurs politiques. Notre étude permet d'identifier les meilleures pratiques dans les soins personnels et de les transférer vers leur propre milieu.

Bien que plusieurs facteurs dans le cadre des pays importateurs et exportateurs jouent un rôle pour faciliter la mise en œuvre et l'utilisation des soins personnels, notre étude a souligné qu'un **engagement politique aux soins auto-administrés**, comme en Royaume-Uni, soutient les meilleures pratiques dans les soins personnels.

Une condition préalable pour le succès des initiatives de soins personnels est le **changement de «culture»** afin que les patients prennent en charge leur propre santé. Pour ce faire, les patients doivent être «habilités», et doivent avoir accès à une information fiable et compréhensible sur la façon de s'engager dans l'autogestion. Une communication claire sur ce type de soins ne peut se substituer aux soins de santé délivrés par des professionnels. Les patients doivent apprendre à distinguer les maladies mineures des cas graves.

Prendre soin de soi nécessite également **une réflexion des professionnels de santé impliqués,** liée à la définition de leur identité professionnelle. Une coopération entre les médecins et les pharmaciens doit permettre de tendre vers une collaboration au niveau des soins.

Notre étude est une base de travail qui doit être suivie dans ce domaine, en particulier pour l'élaboration de recommandations pour la promotion des soins personnels et pour le développement et la production d'outils de communication; ainsi que d'une proposition de mesures politiques sur les soins personnels au niveau de l'UE qui sera faite dans le projet PISCE. Il est fortement recommandé que nos résultats soient introduits dans le projet PISCE.

Zusammenfassung

Hintergrund

Die traditionell Anbieter-zentrierte Struktur der meisten europäischen Gesundheitssysteme ist in erster Linie auf Akutversorgung ausgelegt und zielt weniger auf die Betreuung von Patienten/innen mit chronischen, minderschweren und/oder selbstlimitierenden Erkrankungen ab. Für diese wären andere Konzepte der Versorgung besser geeignet. Ein Ansatz, der Patientenbeteiligung fördert und voraussichtlich auch zu Einsparungen bei den Gesundheitskosten führen wird, ist das Konzept der Selbstbehandlung („Self Care"). Es gibt zwei Handlungsfelder für Selbstbehandlung: Zum einen chronischen Erkrankungen, deren tägliches Management ohnehin bereits jetzt von den Erkrankten und ihren Familien durchgeführt wird. Zum anderen selbstlimitierende kleinere Erkrankungen, die mit einfachen Maßnahmen und mit geringem Risiko von den Patienten/innen selbst. Diese werden als minderschwere Beschwerden (minor ailments) bezeichnet.

Auf EU-Ebene wurde die Frage der Selbstbehandlung bisher vor allem mit Prozessen der Selbstmedikation in Zusammenhang gebracht. In der Entscheidung C(2013)4940 vom 2. August 2013 über die finanzielle Beteiligung der Gemeinschaft an einem Pilotprojekt im Bereich von Selbstbehandlungssystemen in der EU forderte die Haushaltsbehörde die Kommission auf, Initiativen zu finanzieren, die einen Handlungsrahmen für Maßnahmen in diesem Bereich auf EU-Ebene einrichten, und Strategien für eine umfassende Umsetzung wirksamer Selbstbehandlung zu entwickeln.

Diese Ziele sollen erreicht werden durch:

1. eine Kosten-Nutzen-Analyse von patienten- und selbstbehandlungsorientierten Gesundheitssystemen in der EU sowie einer Analyse der bestehenden Rahmenbedingungen, um selbstbehandlungsorientierte Pflegesysteme zu stärken und Patientenbefähigung zu erhöhen;
2. die Übertragbarkeit von Best Practices;
3. die Schaffung einer Experten-Plattform zum Thema ‚Selbstbehandlung und Gesundheit'.

Die vorliegende Studie beschäftigt sich mit den Zielen 1 und 2. Das Ziel 3 wird von dem Pilotprojekt 'Pilot project on the promotion of self-care systems in the European Union: Platform of experts' (PISCE) adressiert.

Begründung und Ziele der Studie

Das allgemeine Ziel der Studie ist, den Mehrwert von etablierten Selbstbehandlungssystemen in Europa zu erkunden. Sie soll eine Grundlage für die Beurteilung der wirtschaftlichen und gesellschaftlichen Auswirkungen von Selbstbehandlung schaffen sowie eine Anleitung zur Übertragung und Umsetzung von Selbstbehandlungsmaßnahmen entwickeln. Die spezifischen Ziele sind daher:

- wissenschaftliche Evidenz für den Mehrwert von Selbstbehandlung für fünf ausgewählte minderschwere Erkrankungen (Fußpilz, Schnupfen, Husten, Sodbrennen, Harnwegsinfektion) zu liefern;
- potenzielle Kosten und Einsparungen von Selbstbehandlungsinitiativen zu analysieren;
- eine Methodik für die Übertragbarkeit von Best Practices im Bereich ‚Selbstbehandlung' zu entwickeln und zu bewerten; und
- eine Strategie zur Verbreitung von erfolgreicher Selbstbehandlung zu entwickeln.

Definition von Selbstbehandlung

Für alle Aktivitäten, die im Zuge dieses Projekts durchgeführt wurden wurde folgende Definition von Selbstbehandlung angewendet:

"Selbstbehandlung ist, was Einzelpersonen, Familien und Gemeinschaften mit der Absicht tun, Gesundheit zu fördern, zu erhalten oder wiederherzustellen und Krankheit und Behinderung zu bewältigen. Dies kann mit der oder ohne die Unterstützung durch Gesundheitsberufe, wie etwa Apotheker, Ärzte, Zahnärzte und Pflegepersonal erfolgen. Der Begriff Selbstbehandlung beinhaltet, ist aber nicht beschränkt auf Selbstprävention, Selbstdiagnose, Selbstmedikation und Selbstmanagement von Krankheit und Behinderung."

Diese Definition wurde entwickelt auf Basis einer Literaturrecherche in Kombination mit einem zweistufigen Delphi-Prozess, welcher mit Hilfe eines Expertengremiums durchgeführt wurde.

Mehrwert von Selbstbehandlung

Für fünf ausgewählte minderschwere Beschwerden wurde eine systematische Literaturrecherche durchgeführt. Die wichtigsten Ergebnisse waren:

Hinsichtlich **Fußpilz** zeigen die eingeschlossenen Studien eine gute Evidenz für die Wirksamkeit von fast allen topischen Behandlungen, die von Patienten/innen in Selbstbehandlung angewendet werden können. Starke Evidenz liegt für Allylamine und Azole vor. Für Butenafin, Ciclopiroxolamin, Tolciclat und Tolnaftat sowie Terbinafin war der Evidenzgrad niedriger.

In Bezug auf **Erkältungen** liefern die eingeschlossenen Studien klare Evidenz für die Wirksamkeit von Selbstbehandlungen bei Erkältungssymptomen (z. B. Acetylsalicylsäure, Nasensprays / topische Behandlungen, Echinacea etc.). Eine gewisse Skepsis ist in Bezug auf Produkte angebracht, bei denen die Wirksamkeit nicht erwiesen ist, da der Placebo-Effekt zusammen mit dem natürlichen Abklingen der Erkältung dazu führen kann, dass der tatsächliche Mehrwert dieser Produkte falsch wahrgenommen wird.

In Bezug auf **Husten** zeigt die systematische Literatursuche einen Mangel an Evidenz für die Wirksamkeit rezeptfreier Arzneimittel. Trotz des hohen Evidenzgrades einer inkludierten Übersichtsarbeit sind die Ergebnisse mit Vorsicht zu interpretieren, da die wenigen eingeschlossenen Studien methodische Ungenauigkeiten aufweisen, was die Verallgemeinerbarkeit der Ergebnisse schmälert. Den Empfehlungen der WHO folgend können Hausmittel wie ein Löffel Buchweizenhonig als First-Line-Behandlung, insbesondere gegen die Symptome nächtlichen Hustens, eingesetzt werden.

Zu **Sodbrennen** gibt es Evidenz für die Wirksamkeit einiger Selbstbehandlungsmethoden (z. B. Lansoprazol und H2-Rezeptorantagonisten). Bei künftigen Untersuchungen zum Thema ‚Selbstbehandlung bei Sodbrennen' sollte zwischen Sodbrennen, gastroösophagealen Symptomen und gastroösophagealer Reflux-Krankheit genauer unterschieden werden.

Keine Evidenz konnte identifiziert werden hinsichtlich präventiver Selbstbehandlungsstrategien, die das Risiko einer (wiederkehrenden) **Harnwegsinfektion** reduzieren. Die Gründe dafür sind vielfältig und können z. B. mangelnde Einnahmetreue bei Saft- und Sirup-Produkten oder mangelnde Klarheit hinsichtlich der aktiven Wirkstoffmenge (falls vorhanden) in Nicht-Saft-Produkten sein. Antibiotika sind die effektivste Behandlung, jedoch ist der Mehrwert in Hinblick auf

Selbstbehandlung limitiert, da es Patienten/innen nur bedingt Rückschlüsse von den Symptomen auf eine Bakteriurie oder die Bakterienanzahl ziehen können.

Analyse der Selbstbehandlungsinitiativen

Zunächst sollten acht Selbstbehandlungsinitiativen anhand der RE-AIM+ Kriterien (Reichweite, Wirksamkeit, Übernahme, Implementierung, Aufrechterhaltung, Zugang, Gerechtigkeit und Einsparungspotenzial) analysiert werden. In Abstimmung mit den Projektauftraggebern wurde im Projektverlauf eine der ursprünglich ausgewählten Initiativen („Grünes Rezept") aufgrund der mangelnden Übereinsprechung mit der in diesem Projekt verwendeten Definition von Selbstbehandlung ausgeschlossen. Folgende Initiativen wurden untersucht:

- Ameli santé (Gesundheitsinformation - Website; FR)
- Lettische Tele-Helpline (Gesundheitsinformation - Telefon-Hotline, LV)
- Zelfzorg.nl (Gesundheitsinformation - Website, NL)
- **NHS Choices** (Gesundheitsinformation - Website; UK)
- **NHS 111 (NHS Direct)** (Gesundheitsinformation - Telefon-Hotline, UK)
- **Minor Ailment Scheme** (Gesetzesänderung, UK)
- **Non-Medical Prescribing** (Gesetzesänderung, UK)

Die vier in Großbritannien ansässigen Initiativen wurden als Best Practices identifiziert. Eine Kosten-Nutzen-Analyse wurde für NHS Choices, Minor Ailment Scheme und Non-Medical Prescribing durchgeführt. Für NHS 111 standen nicht genügend Kostendaten zur Verfügung, um eine Kosten-Nutzen-Analyse durchführen zu können.

Ökonomische Bewertung von Selbstbehandlungsinitiativen

Für die fünf ausgewählten minderschweren Beschwerden wurden Kosten und Einsparungen durch die identifizierten Best-Practice-Selbstbehandlungsinitiativen analysiert. Die Bewertung erfolgte aus vier unterschiedlichen Perspektiven: Patient, Anbieter, öffentlicher Zahler und Gesellschaft.

Minor Ailment Schemes (MAS) führen aus gesellschaftlicher Sicht potenziell zu einem positiven Nettonutzen, wenn die Verschiebungsrate 27,5 Prozent überschreitet. Aufgrund der relativen Höhe von Rezeptgebühren (£ 8,05 oder € 10,87 pro Stück in GB) im Vergleich zu den Preisen von OTC-Arzneimitteln profitieren Patienten/innen ohne Rezeptgebührbefreiung in einem größeren Umfang als jene, die befreit sind. Dennoch profitiert auch die letztere Patientengruppe tendenziell von MAS, mehr sogar als durch die alleinige Nutzung eines internetbasierten Informationsdiensts (wie NHS Choices).

Für **Non-Medical-Prescribing (NMP)** sind die Kosten auf Anbieterebene zu hoch, um einen positiven Nettonutzen aus gesellschaftlicher Sicht zu ermöglichen. Der tendentielle Nutzen von NMP für Patienten/innen ist unabhängig von der Rezeptgebührenpflicht, da sie aufgrund der vermiedenen ärztlichen Konsultationen Zeit eingesparen, während die Kosten für Medikamente sowie mögliche Selbstbehalte gleich bleiben.

Im Hinblick auf **NHS Choices** wurde trotz vergleichsweise niedriger Verschiebungsraten (Break-even der Initiative bei 4,4 Prozent Verschiebungsrate) ein positiver gesellschaftlicher Nettonutzen identifiziert. Jene Patienten/innen, die von der Rezeptgebühr befreit sind, profitieren ausschließlich von der Zeitersparnis, während die übrigen zusätzlich durch niedrigere Selbstbehalte profitieren (da sie die Kosten für OTC-Arzneimittel gänzlich selbst zu tragen haben und somit die Rezeptgebühr von £ 8,05 pro Stück wegfällt).

Aus gesellschaftlicher Sicht stellen NHS Choices und MAS günstige politische Optionen dar, wobei von NHS Choices in erster Linie jene Patienten/innen profitieren, die verpflichtend Rezeptgebühren zu leisten haben, während sich MAS eher an Rezeptgebühr befreite Patienten/innen richtet. Die Effekte von NMP zeigen keinen Unterschied hinsichtlich der Rezeptgebührenpflicht. Allerdings ist aus gesellschaftlicher Sicht eine umfassende Einführung von NMP durch Apotheker/innen sehr unwahrscheinlich.

Übertragbarkeit von Best-Practice-Selbstbehandlungsinitiativen

Basierend auf den in der Literatur identifizierten Rahmenwerken für Politik-Transfer im Bereich Gesundheitspolitik (und anderen Bereichen) wurde ein Vier-Stufen-Modell entwickelt. Es besteht aus:

1. Identifikation von Best Practices in Selbstbehandlung
2. Identifikation der wichtigsten Charakteristika von Best-Practice-Initiativen
3. Bewertung der Machbarkeit der Übertragung von Best-Practice-Initiativen
4. Ableitung von Politik-Optionen

Die Identifizierung und Auswahl von Best Practices im Bereich Selbstbehandlung (Schritt 1) basierte auf den RE-AIM Kriterien. Um die Merkmale und Eigenschaften der Best-Practice-Selbstbehandlungsinitiativen zu identifizieren (Schritt 2), wurde jede Best-Practice-Initiative anhand von vier Dimensionen bewertet: 1) Bevölkerung/Patient, 2) Leistungserbringer, 3) Regierung/System und 4) Technologie.

Ausgehend von den Schritten 1 und 2 wurde die Machbarkeit der Übertragbarkeit von Best Practices beurteilt (Schritt 3). Dieser Schritt untersucht jene Bedingungen, die gegeben sein müssen, damit eine Best-Practice-Initiative im Zielland erfolgreich ausgeführt werden kann. Die Beurteilung umfasst drei Aspekte:

1. Faktoren, die den politischen Erfolg im Ursprungsland unterstützen (**"günstige Bedingungen"**);
2. Bewertung der Relevanz von Erfolgsfaktoren im Ursprungsland (d. h. **"Relevanz"**);
3. Bewertung der Rahmenbedingungen des Ziellandes in Bezug auf die Erfolgsfaktoren (**"Machbarkeit"**).

Basierend auf den Bewertungsergebnissen können politische Entscheidungsträger/innen in Schritt 4 beurteilen, ob und wie eine Best-Practice-Initiative in ihrem jeweiligen Land durchgeführt werden soll.

Die Anwendbarkeit der Methode für die Übertragbarkeit von Best-Practice-Initiativen wurde in einer SWOT- und Risikoanalyse kritisch reflektiert.

Verbreitungsstrategie für Best Practices in der Selbstbehandlung

Um das Lernen im Bereich ‚Selbstbehandlung' und die Übertragung von Best Practices zu ermöglichen, sollten die Ergebnisse hinsichtlich des Nutzens von Selbstbehandlung sowie die Methodik für die Übertragbarkeit angemessen verbreitet werden.

Die **wichtigsten Zielgruppen** für die Studienergebnisse sind Entscheidungsträger/innen und Akteure auf europäischer und nationaler Ebene, Vertreter von ähnlichen Projekten - insbesondere das PISCE-Konsortium - und die allgemeine Öffentlichkeit.

Zu den empfohlenen **Verbreitungsinstrumenten** gehören Pressemitteilungen und Flyer. Außerdem sieht ein für das Projekt entworfener Verbreitungsplan die Nutzung bestehender Newsletter und Websites des Konsortiums sowie anderer Institutionen vor.

Die wissenschaftliche Gemeinschaft soll durch Artikel in Fachzeitschriften, Vorträge und Posters auf Konferenzen erreicht werden.

Eine wichtige **Verbreitungsmaßnahme** wäre die Organisation einer Konferenz, die sich speziell an politische Entscheidungsträger/innen und Interessengruppen richtet. Die Organisation kann entweder als eigenständige Veranstaltung oder zusammen mit ähnlichen Projekten (wie dem PISCE-Projekt) erfolgen.

Schlussfolgerungen und Empfehlungen

Die vorliegende Studie zeigt die steigende Relevanz von Selbstbehandlung sowohl in der Literatur als auch in der Praxis auf und verweist gleichzeitig auf die Notwendigkeit weiterer Evidenz und deren Verbreitung.

Bestehende Literatur zum Thema Selbstbehandlung konzentriert sich weitgehend auf die Wirksamkeit pharmazeutischer Behandlungen. Die vorliegende Studie bietet darüber hinaus einen Mehrwert, indem sie den Nutzen von Selbstbehandlung durch eine Kosten-Nutzen-Analyse von Selbstbehandlungsinitiativen kritisch beurteilt. Die Aufbereitung wissenschaftlicher Evidenz wurde durch einen praktischen Leitfaden für politische Entscheidungsträger/innen ergänzt. Dieser ermöglicht, Best Practices im Bereich Selbstbehandlung zu identifizieren und sie in das jeweilige Umfeld zu übertragen.

Während diverse Umfeldfaktoren der Ursprungs- und Zielländer einer zu übertragenden Initiative eine Rolle bei Implementierung und Aufnahme von Selbstbehandlung spielen, hat die Studie gezeigt, dass eine **politische Verpflichtung zur Selbstbehandlung** - wie etwa in Großbritannien - Best Practices im Bereich ‚Selbstbehandlung' unterstützt.

Voraussetzung für eine erfolgreiche Initiative im Bereich Selbstbehandlung ist die **Veränderung der "Kultur**", so dass Patienten/innen Verantwortung für ihre eigene Gesundheit übernehmen. Damit sich Patienten/innen zur Selbstbehandlung verpflichten können, müssen sie "ermächtigt" werden und müssen Zugang zu verlässlichen und verständlichen Informationen erhalten. Patienteninformationen zu Selbstbehandlung müssen klar kommunizieren, dass Selbstbehandlung Gesundheitsversorgung durch Profis nicht ersetzen kann. Patienten/innen müssen lernen, kleinere Erkrankungen von schweren Fällen zu unterscheiden.

Selbstbehandlung erfordert auch ein **Umdenken der beteiligten Gesundheitsberufe** in Bezug auf die Definition ihrer beruflichen Identität. Insbesondere die Zusammenarbeit zwischen Ärzteschaft und Apothekerschaft muss neu organisiert werden, da sich diese Gesundheitsberufe in der Versorgung kooperativer engagieren sollen.

Die vorliegende Studie stellt eine Grundlage für zukünftige Arbeiten in diesem Bereich dar. Erwähnenswert sind vor allem die Entwicklung einer Richtlinie für die Förderung von Selbstbehandlung und ein Leitfaden für die Entwicklung und Produktion von Kommunikationsmitteln sowie ein Vorschlag für politische Maßnahmen im Bereich ‚Selbstbehandlung' auf EU-Ebene. Es wird dringend empfohlen, dass die Ergebnisse dieser Studie in das PISCE-Projekt einfließen und dass die Experten/innen der PISCE-Plattform die gewonnenen Erkenntnisse bei ihrer Arbeit berücksichtigen.

1 Introduction

The report at hand is the final report of the request for Specific Services № EAHC/2013/Health/26 for the implementation of Framework Contract № EAHC/2013/Health/01 "Health economic reports – analysis and forecasting" (Lot 2) for a cost/benefit analysis of self-care systems in the European Union, commissioned by CHAFEA/DG SANTE.

1.1 Activities and deliverables

The project consisted of three work packages with 15 tasks in total. It started with work package 0 (WP0) during which the kick-off meeting was held, an inception report written and an expert group formed. Work package 1 (WP1) was mainly concerned with finding scientific evidence for the added value of self-care and analysing the costs and benefits of selected self-care initiatives which were reported in Deliverable 1 (D1). During work package 2 (WP2) the transferability of best-practice examples of self-care and the associated risks were evaluated and presented in Deliverable 2 (D2).

1.2 Outline of this report

This report is split into four content chapters which follow, to a great extent, the defined work packages of the Specific Service. However, the in-depth methodology and results already presented in earlier documents (Deliverable 1 and 2) will not be described in detail again in this report but are shortly outlined.

Section 2 – Background and context: This section sets the scene for the following study and elaborates on minor ailments in general and on the relevance of self-care in particular. Also, the rationale and objectives of the study are presented.

Section 3 – Methodology: The methodology used in WPs 1 and 2 is presented including the methodology for developing a clear definition of self-care (task 5), the systematic literature search (task 6), for the general analysis (task 7) and for the cost/benefit analysis of self-care initiatives (task 8) and for the identification of best-practice initiatives (task 9), as well as the methodology for the assessment of the transferability of self-care initiatives including a SWOT analysis (task 11).

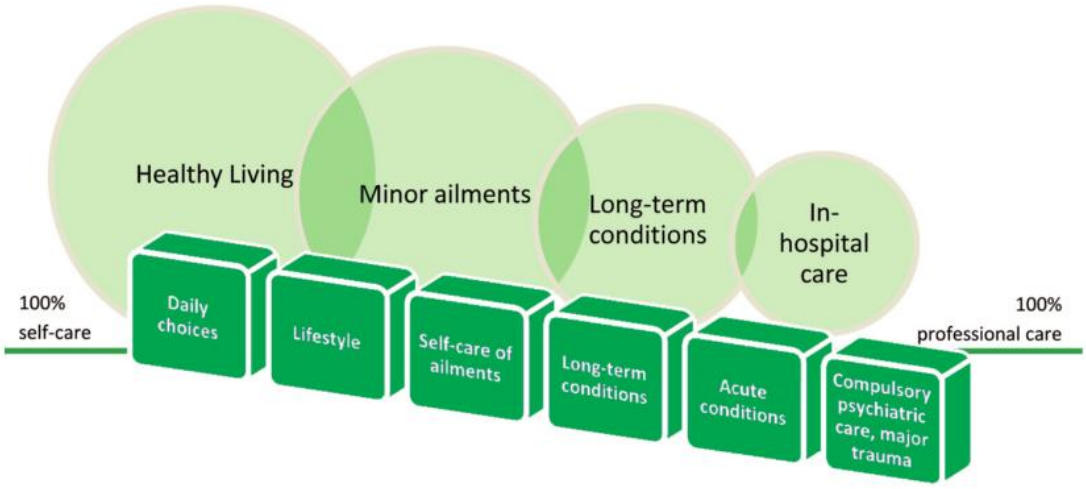
Section 4 – Results and analysis: in this section the results of the tasks outlined in the methodology section are presented. Furthermore, the limitations of the analyses are discussed.

Section 5 – Conclusions and recommendations: Based on the study results, conclusions and recommendations will be drawn in this section.

2 Background and context

The traditional provider-centred structure within most European health care sectors is designed for delivering acute care, and less for the care of patients with chronic, minor and/or self-limiting diseases. For these patients other concepts of care may be more suitable and may also contribute to cost containment within health care systems. One approach which promotes patient involvement and may lead to savings within health care budgets is the concept of self-care. The areas of action of this concept are twofold: First, self-care is regarded as a suitable approach for dealing with chronic conditions, as the day-to-day management is carried out by patients and their families already. Second, there are also other – self-limiting and minor – conditions which can be handled by patients themselves or other lay-persons (such as relatives), with simple actions and low risk. In the literature these conditions are referred to as minor ailments (Welle-Nilsen et al. 2011).

Figure 1: Continuum of care



Source: (Yiangou 2011)

2.1 Minor ailments

Minor ailments are usually defined as self-limiting and manageable by patients. It is therefore a condition that patients can handle by themselves with simple actions that do not necessarily require a doctor. The actions taken could include, for instance: seeking advice from a pharmacist, taking non-prescription medication or staying in bed (Welle-Nilsen et al. 2011).

In literature and practice, including an EU-funded research project (AESGP 2012; Jensen 2010; NHS Scotland; PAGB 2009; Welle-Nilsen et al. 2011; Yiangou 2011), the following ailments are considered minor and/or self-limiting (in alphabetical order):

- Acne
- Allergic and/or bacterial conjunctivitis
- Athlete Foot
- Cold
- Cold sores

- Constipation
- Cough
- Dermatitis/eczema
- Diarrhoea
- Erectile dysfunction
- Flu (prevention and treatment)
- Haemorrhoids
- Hay fever (prevention and treatment)
- Headache (including migraine)
- Indigestion/heartburn
- Lower urinary tract infection
- Mild/moderate pain (e.g. back pain)
- Mouth ulcers
- Nausea from known causes
- Sore throat
- Topical bacterial infections
- Vaginal thrush

This list includes both "traditional" as well as "new" indications which can be addressed by self-management. In the 1970s and 1980s the conditions considered as suitable for being treated without the intervention of a doctor were limited to mild to moderate pain, coughs and colds, constipation and minor skin problems such as cuts and bruises. Since then, the range of minor ailments which can be treated via self-care has been considerably extended following technological advances, patient empowerment as well as the reclassification of prescription-only medicines to the non-prescription status (Vogler et al. 2012a; Vogler et al. 2012b).

A preliminary shortlist of ten minor ailments was created by the project team together with a primary care physician and public health experts (see Annex 1). This shortlist served as a basis for the further selection of five minor ailments in agreement with DG SANTE during the kick-off meeting. The following minor ailments have been selected for further analysis:

- Athlete's foot
- Cold
- Cough
- Heartburn (without indigestion)
- Lower urinary tract infection

2.2 Relevance of self-care

The issue of self-care gains a lot of attention as there is a trend in health care towards consumer empowerment and increasing access to information about health via the internet. The starting point of this trend was a change in the understanding of health care as "patient-centred" care which the World Health Organization (WHO) expressed in some documents from the 1970s on. In 1975, the WHO organised the first international symposium on the role of the individual in primary care (WSMI 2010). Key concepts for health care adopted by the WHO such as the "Alma Ata Declaration" in 1978 (International Conference on Primary Health Care 1978) and the Ottawa Declaration for health promotion in 1986 (WHO 1986) stressed the importance of patients' participation in health care.

In parallel to these developments related to patient participation, patient empowerment and patient rights, the role of the health professional also changed. Since more than two decades ago, (HeplerStrand 1990) had advocated a patient-focused role and had called on pharmacists to adopt pharmaceutical care as professional mission. The role of pharmacists has extended from being dispensers of medicines to health professionals who are responsible for safe, effective and rational use of medicines (Ellitt et al. 2009; Mossialos et al.; Nkansah et al. 2010).

Individuals want to play an active role in managing their health and should no longer be seen as passive recipients of health care (Pablickova/Bowman-Busato 2013). However, self-care does not mean the absence of professional health care, but combining the professional expertise of all medical professions (including pharmacists) and the experiences and individual knowledge of the patient and his acquaintances in order to maintain good health or treat (chronic) diseases (Coulter/Ellins 2006).

2.3 EU and international framework

At EU level the issue of self-care was particularly addressed through processes related to self-medication or non-prescription medication. The G10 Medicines1 Report from 2002 suggests reviewing existing mechanisms for moving medicines from prescription to non-prescription status (Recommendation 5). The G10 Report also indicated that medicines should move from prescription to non-prescription status wherever possible, as long as such a reclassification does not compromise patient safety (Council of the European Union 2008).

The High Level Pharmaceutical Forum[2] (2005-2008) devoted one of its working groups to the issue of 'Patient Information' which aimed to advise the Commission on ways to improve the quality of, and access to, information on authorised medicines and related health areas to European patients. This was understood as to supplement the key role of health professionals in providing information to patients on medicines and health issues more generally (Council of the European Union 2008): In 2008, the European Commission, published the Communication `Safe, innovative and accessible medicines: A Renewed Vision for the Pharmaceutical Sector' which explicitly addressed the role of self-medication as a lever for patient empowerment: 'Self-medication empowers patients to treat or prevent short term or chronic illnesses which they consider not requiring the consultation of a physician or which may be treated by the people after an initial medical diagnosis' (European Commission 2008).

As a follow-up process of the High Level Pharmaceutical Forum the Process on Corporate Responsibility in the Field of Pharmaceuticals ('Tajani Initiative') was launched in 2010, with three different platforms[3]. Under the platform on 'Access to Medicines in Europe',

1
G10 Medicines is a High Level Group on Innovation and the Provision of Medicines composed of selected private and governmental health stakeholders, created in 2001 by the European Commission.

2
The High Level Pharmaceutical Forum was established as a three year process and involved EU institutions, all EU Member States, industry, healthcare professionals, patients and insurance funds being represented in different Working Groups.

3
Transparency and ethics in the sector, Access to medicines in Europe, in the context of pricing and reimbursement, and Access to medicines in developing countries with a focus on Africa

five Working Groups were put in place in order to exchange ideas and knowledge between competent authorities and stakeholders as well as to explore non-regulatory approaches. One of the working groups was devoted to 'Promoting good governance for non-prescription medicines'. It aimed to gain a better understanding of the different approaches and attitudes to availability and use of non-prescription medicines across the EU. The objective of the project of that Working Group was to identify the necessary elements to ensure availability, uptake, and informed use of choice of non-prescription medicines, including medicines after a change of classification. The findings of Working Group and their recommendations were summarized in a final report (EU 2013).

In Commission Decision C(2013) 4940 of 2 August 2013 concerning the financial contribution by the Community towards a pilot project in the field of self-care systems in EU, the Budget Authority asked the Commission to fund initiatives which put in place a framework for action to enhance self-care at EU level and develop strategies to support the broader implementation of effective self-care.

These objectives shall be achieved by:

1) A cost/benefit analysis of patient self-care oriented health systems in the European Union and the current frameworks in place to enhance self-care oriented health care systems and patients' empowerment;
2) Transferability of best-practices, and
3) The creation of a platform of experts in self-care and health care.

Objectives 1) and 2) are intended to be covered by this study at hand (see below). Objective 3) will be addressed by the 'Pilot project on the promotion of self-care systems in the European Union: Platform of experts' (PISCE).

While these two projects have a particular focus on self-care, there are further on-going and previously finalized EU projects that related to, some aspects of, self-care. These include the Joint Action on Chronic Diseases (CHRODIS) that addresses chronic diseases and promoting healthy ageing across the life cycle. It aims to map new innovative actions (social media, behavioural science and new technologies) as well as more traditional actions on risk factors across Europe, to examine barriers to uptake for prevention in screening risk groups, and treatment of major chronic diseases (using diabetes as an example) (Riese 2014). Other examples are the 'Empowering Patients in the management of chronic diseases' (EMPATHiE) project, which aims to achieve a common understanding of the concept of patient empowerment and identify good practices, success factors and barriers, the Joint Action of Patient Safety and Quality of Care (PaSQ) that aims to facilitate the exchange of information on issues related to quality of health care, including patient safety and patient involvement and establish common principles at the EU level through the integration of existing knowledge, experiences and expertise gathered from Member States and EU stakeholders (EU Network for Patient Safety and Quality of Care (PaSQ) 2012) and the EU-WISE project "Self-care for Long-Term Conditions in Europe" under the 7th Framework Programme of the European Commission which aimed to understand the role and influences of resources external to health services which have an impact on people's capacities to manage long-term conditions (EU-WISE: Selfcare for Long-Term Conditions in Europe)

The WHO Regional Office for Europe has also embedded patient empowerment in a new European health policy "Health 2020": Under the priority area "Strengthening people centred health systems, public health capacity and emergency preparedness, surveillance and response". Its aim is as follows: "achieving high-quality care and improved health

outcomes requires health systems that are financially viable, fit for purpose, people centred and evidence-informed". This initiative requires reorientation of health care systems to give priority to disease prevention, foster continual quality improvement, integrate service delivery, ensure continuity of care, support self-care by patients, relocate care as close to home as is safe and cost-effective (World Health Organization Regional Office for Europe 2013)

2.4 Rationale and objectives

This project shall provide a basis for assessing the economic and societal impact of self-care, as well as providing information on how to transfer self-care initiatives which proved to be effective on the grounds of scientific evidence. Therefore, one key aim of the study is to identify as to whether self-care initiatives can lead to a reduction in health care resources. In order to follow up on possible best-practice examples that may also contribute to savings, the safety and effecitiveness of these initiatives have to be ensured. If these three criteria (safety / effectiveness / cost-effectiveness) have been positively evaluated, the transferability of best-practices can be examined.

The general objective of the study is to explore the added value of self-care systems in Europe. Accordingly, the specific objectives are:

- to provide scientific evidence of the added value of self-care for five selected minor ailments (i.e. athlete's foot, cold, cough, heartburn, urinary tract infection);
- to analyse potential costs and savings of self-care initiatives;
- to develop a methodology of the transferability of best-practices in self-care and assess it; and
- to develop a strategy to disseminate the benefits of self-care.

3 Methodology

The study consisted of three work packages which are the basis for the final report at hand. WP 0 (tasks 1-4) was concerned with agreeing on a work plan with DG SANTE, the kick-off meeting and the formation of the expert group. WP 1 (task 5-9) aimed to develop a definition of self-care – this was done with the support of the expert panel (see above "Definition of self-care") –in order to find evidence on the added value of self-care and to analyse selected self-care initiatives regarding their overall and their economic benefit. The aim of WP 2 was to assess the transferability of best-practice initiatives (task 11). The methodology of the tasks within both work packages is described in detail in the following section.

3.1 Definition of self-care (task 5)

There are currently various definitions of self-care used throughout the literature. For the purpose of the study it was required to develop a clear definition of self-care. The development of the definition was based on existing definitions used in the literature (see Annex 2) and a Delphi process with an expert panel whose main task was to provide input comments to the definition.

To ensure impartiality and quality throughout the study, the project team aimed to achieve a balance in the composition of the expert panel, including experts in the fields of the health promotion, health literacy, patients´ rights and pharmaceutical markets. Furthermore, it was strived for a balance in terms of EU member states' experts (see Table 1).

Table 1: Expert panel

Expert	Country	Institution	Field of expertise
Expert 1	PT	Pharmaceutical Group of the European Union (PGEU)	Representative of community pharmacists
Expert 2	AT	National association for self-help (*ARGE Selbsthilfe*)	CEO of the consortium of self-help groups
Expert 3	DK	University of Southern Denmark	Patients' rights and Health technology assessment
Expert 4	DE	World Health Organization (WHO) European Observatory	Health policy expert
Expert 5	CZ	State Institute for Drug Control (SUKL)	Pharmaceutical pricing expert
Expert 6	NL	Maastricht University	Health literacy, public health and health diplomacy
Expert 7	SI	General practitioner and researcher	Primary health care
Expert 8	EU	The European Consumer Organisation (BEUC)[4]	Expert on consumer rights

4 Involved on a sub-contract basis

The Delphi process was organised in two rounds. In the **first round,** the experts commented on existing definitions from the literature (see Annex 2) and provided their own preferred definitions. The experts were explicitly asked for their relevant view on the respective elements of the definitions that might be particularly or – on the contrary – less relevant. For the proposal of their own preferred definition three options were possible. First, it could be one of the existing definitions. Second, the preferred definition could be an adaption of existing definitions. Third, the preferred definition could be an entirely different one. The experts were invited to elaborate on their own preferred definition as well (i.e. the rationale of the definition).

In the **second round,** the experts received the compiled comments and all suggested definitions. They had the opportunity to provide further feedback on the comments from the first round and the suggested definitions from the other experts. Furthermore, they had the chance to revise their own preferred definition based on the comments and the other suggested definitions of the first round.

The definitions, comments and feedback received in round 1 and 2 of the Delphi process were incorporated into the development of a clear definition of self-care.

3.2 Added value of self- care (task 6)

To provide scientific evidence of the added value of self-care for the five selected minor ailments and for analysing potential costs and savings of self-care initiatives a systematic literature search was conducted.

The systematic literature search was conducted by linking different search terms regarding the intervention (self-care), the minor ailments (athlete's foot, cold, cough, heartburn (without indigestion), lower urinary tract infection), outcomes (e.g. effectiveness, safety, cost/benefit) and study type (systematic reviews, meta-analysis, randomized controlled trials, comparative studies, evaluation studies, observational studies, validation studies, multicenter studies, etc.). For the search terms subject headings (e. g. Medical Subject headings (MeSH) and free-text (e. g. truncation like self treat* for self treatment or self treated or self treating) were used. The search covered a period of ten years (2004-2014). Studies in English, German, French and Italian language were considered. The detailed search strategies are outlined in Annex 3.

The following international databases were searched: Ovid MEDLINE, Embase Cochrane, CRD, CINAHL and Scopus. The decision on the relevant databases was made after the five conditions have been selected in agreement with CHAFEA and DG SANTE.

Additionally, a thorough hand search was conducted including a systematically search on the internet, the reference lists of the identified studies and on websites of the international organisations (e.g. European Union, WHO, OECD) and networks for relevant literature. Furthermore, the SelfCare ("The journal of consumer-led health"), the King´s Fund, the Campbell Collaboration, DoPHER, Austrian National Library (ONB), DIMDI and IQWIG Databases were searched.

The first selection of publications was based on available abstracts and titles (if abstracts were not available) using eligible pre-defined criteria. The inclusion/exclusion followed formal criteria, contextual criteria, criteria concerning study design, medical criteria or other inclusion criteria (see Table 1 in Annex 4). For the second selection, the criteria for the first selection were adapted and enhanced by quality and validity criteria and criteria for relevant endpoints. The full texts of all included abstracts were thoroughly read (in-depth review) and selected using the pre-defined criteria (see Table 2 in Annex 4).

The internal (risk of bias) and external validity (applicability of study results to patients outside the study population) of the selected studies was assessed after the second selection. The overall grading of the evidence was conducted in three steps: (1) evaluation of internal validity (risk of bias), (2) evaluation of external validity and (3) evaluation of the overall grade of evidence synthesizing the internal and external validity (for details see Tables 1-4 in Annex 5).

The results of the included studies are displayed (per ailment) in a summary table containing information on the authors, the year of publication, the study design and population, the intervention, the indication and the results of the study. The results are then synthesised for each possible self-care treatment for the respective ailment.

3.3 Analysis of self-care initiatives (task 7)

Under task 7, the first step was to identify European self-care initiatives through a thorough hand search (listed in Annex 6).

Initiatives were considered relevant for this analysis if they corresponded to the following attributes:

- Information based (e.g. media campaigns to increase health literacy), or
- Action based (such as legal changes e.g. shift of competences of providers or shift from prescription to non-prescription medicines, but also provision of new technologies), and
- National or regional, but not local, and
- Public, private or semi-private

Efforts were made to choose and analyse a balanced set of initiatives with regard to the above mentioned factors (See table 3 below).

Table 2: Selected initiatives for economic evaluation

Country	Name of the initiative	Type of initiative	Year of implementation
UK	NHS Choices	Health information - website	2007
UK	Minor ailment scheme	Legislative change	2006 (Scotland)
UK	Non-medical prescribing	Legislative change	2006 (independent prescribing for nurses and pharmacists)
UK	NHS 111	Health Information - telephone hotline	2014

The initiatives that were included in the analysis generally covered more than one of the selected minor ailments. Therefore, integrated analyses for the entire initiatives (i.e. for all selected ailments covered by the initiative) were conducted.

The selected initiatives were analysed based on the RE-AIM framework developed by (Glasgow et al. 2001). The methodology of RE-AIM was adapted to fit the purpose of this study. This allows an analysis of the self-care initiatives selected at the individual level (R=reach and E=effectiveness), the organisational level (A=adoption, I=implementation, M=maintenance) and the societal level (accessibility and equity). The adapted framework will be called RE-AIM+ in the remainder of the report, as accessibility and equity were added to the original RE-AIM criteria. The RE-AIM+ criteria were operationalized using

one or two questions/statements per criteria that could be answered either with yes (✓), no (!), partly (≈) or unclear (?).

Table 3: Operationalization of Criteria

Criteria	Question
Reach	▪ Was the participation as a proportion of all people affected high?
Efficacy/Effectiveness	▪ Is there any evidence for the effectiveness of the initiative?
Adoption	▪ Could the initiative be adopted in other regions/settings of the country? ▪ Was the initiative carried out in a setting that is transferable to other European settings?
Implementation	▪ Was the initiative carried out as planned?
Maintenance	▪ Was the initiative successfully integrated in the system – institutionalized or part of routine work?
Accessibility	▪ Could the initiative be used without any barriers?
Equity	▪ Was it ensured that no socio-economic group was excluded from participating/utilising the initiative's benefits.

3.4 Economic evaluation of self-care initiatives (task 8)

The methodology of the cost/benefit analysis that was developed in WP1 was revised in accordance with the project's commissioners. For the report at hand cost-benefit analyses have been conducted for above presented self-care initiatives.

With regard to NHS choices, Minor ailment scheme as well as Non-medical prescribing sufficient information on relevant cost categories as well as potential user rates was available in order to perform a cost benefit analyses. With regard to NHS 111, neither authoritative figures on costs nor on user potential could be identified. This made it impossible to conduct a specific cost/benefit analysis. However, it can be reasoned that from a patient's, system's as well as providers' perspective, telephone-based information services may lead to similar results as internet-based information services (such as NHS Choices) in terms of costs/benefits. Whether NHS 111 turn out to be beneficial from a societal perspective depends to a large extent on the average operating costs of the service itself, which were in fact the most frequent points of critique for the former service offered under NHS Direct (Wales Audit Office 2009). Thus, an analysis from the societal perspective can be easily integrated at a later point.

3.4.1 Conceptualization and general assumptions

To compare the costs and savings of the different initiatives a cost-benefit-analysis was conceptualized and an extensive data collection was carried out. As with any economic evaluation, some general assumptions had to be made where inconclusive or no evidence was found.

As a starting point, it was assumed that a patient suffering from a minor ailment has three options which are mutually exclusive. First, the patient can see a primary care physician/ general practitioner (GP) and treat the ailment with OTC medication as advised by the physician. The second option is that the patient practises self-care by visiting a

pharmacy and receiving counselling and OTC products by the pharmacist. The last option is, the patient practising self-care by using home remedies or lifestyle modifications. In the remainder of this report the three options described above are denoted as follows:

- Option 1: Physician contact
- Option 2: Self-care with medication
- Option 3: Self-care without medication

It was further assumed that the patient changes health care utilization due to the self-care initiatives. More precisely, fewer patients were assumed to seek the advice of a physician in case of a minor ailment, whereas more patients will practice self-care with or without the support of a pharmacist. The share of patients choosing the third behavioural option, self-care without medication, was assumed to remain constant despite the implementation of a new initiative. This assumption is quite sensible, as this group probably consists of patients, who are either only mildly impaired or who are generally not prone to use medications, or modern western medicine. Therefore, though Option 3 is likely to be highly relevant in the field of minor and self-limiting ailments, it will not show an effect in the CBA.

The objective of the cost/benefit analysis[5] was not to compare the three options, but to assess the savings for the patient and the health care system following the introduction of a self-care initiative and to compare these savings with the (capital and operating) costs of the initiative. The costs that were considered in the cost-benefit analysis are the following:

Direct (medical) costs

- Cost for consultation and treatment by GP (incl. diagnosis)[6] and / or other health professionals (pharmacy)
- Cost for medication (depending on the system these costs are carried by the health care system or the patient or both)
- Costs of the initiative

Non-medical costs for the patient

- Travelling time and costs (to GP and/or pharmacy)
- Time spent at encounter (GP and/or pharmacy)

The cost-benefit analyses were performed from the patient's and the payer's perspective. Depending on the chosen perspectives different cost items might be applicable in different health care systems (e.g. in the UK the GP visit is free for at patient and therefore the cost item "Outpatient treatment by GP" is irrelevant for the patient's perspective).

Several studies (White et al. 2008) have shown that patients' measurable health outcomes under Option 1 and Option 2 are similar. In other words, the effectiveness of the treatment – in the case of self-limiting minor ailments these are mostly medicines – is

5
The term cost/benefit analysis is frequently used as a rather generic description of any economic evaluation, covering all forms of an economic evaluation: cost/cost, cost/utility, cost/effectiveness analysis, and cost/benefit analysis.

6
Covering all expenses at general practice (including services of healthcare assistants, nurses, etc.)

unaffected by the health professional who delivers the care. This also implies that the same medicines are consumed regardless of whether a primary care physician is contacted or not. Furthermore, it has been shown for certain self-care initiatives that the quantity of work of the primary care physicians does not change due to an initiative, but that the share of encounters due to minor ailments decreases (Bojke et al. 2004). The assumption of interchangeability was also taken for the cost-benefit analyses conducted in this report.

Besides the aforementioned assumptions, some more general assumptions about minor ailments had to be made. Despite some evidence that minor ailments lead to sickness leaves (Bramley et al. 2002), this possibility was disregarded in the presented model. The reason for this is that the mentioned evidence does not differentiate between patients seeing a doctor and patients using self-care with or without medication. If the loss of productivity due to sickness leave was factored in, it would have been necessary to assume the same loss of productivity for all treatment options and has therefore no impact on the resulted savings.

With regard to the cost/benefit analyses conducted, the authors decided to apply a multi-dimensional model which allows for the integration of different perspectives for each of the initiatives assessed. Cost as well as benefit categories were mainly derived from (Farnfield 2008) and (Latter et al. 2010) with pharmacy training costs, pharmacy time costs, governance costs, medicine prices, and remuneration to pharmacies for specific initiative-induced activities included as cost categories and non-monetary benefits, such as time savings to patients and cost savings from reduced GPs' time included as benefits (for the case of non-monetary benefits, a monetization was waived due to data issues).

Regarding the broad classification of costs and benefits it has to be noted, though, that the additional benefit due to the implementation of a particular self-care initiative for one stakeholder (e.g. cost savings for the health care system due to reduced GPs' time) may have detrimental effects to other stakeholders leaving them worse off after the introduction of the initiative (e.g. less income for GPs and/or less GP positions due to less GP contacts). If the additional benefit for one stakeholder group were linked to the additional costs for another (e.g. remunerations to community pharmacies for MAS consultations paid by the health care system) these effects would be factored out from a societal perspective. The classification of all costs and benefits regarded in terms of its relevance and direction for the assessed perspective is shown in Table 4[7].

7
Also, NHS 111 (formerly NHS Direct telephone service) was considered as best-practice, but due to missing data it was possible to apply the conceptual framework on it.

Table 4: Conceptual framework for the cost/benefit-analysis of self-care initiatives

		Cost and benefits for each initiative			Relevance and direction of costs and benefits depending on perspective				
		MAS	NHS Choices	NMP/PIP	Patient	Provider (Pharmacy)	Provider (Physician)	Public Payer	**Society**
Costs	Pharmacy training costs	x	n/a	x		x (-)			x (-)
	Pharmacy time costs	x	x	x		x (-)			x (-)
	Governance costs	x	x	x				x (-)	x (-)
	Medicine prices	x	x	x	x (+/-) *			x (-/+) *	**
	Remuneration of pharmacies	x	n/a	n/a		x (+)		x (-)	**
Benefits	Non-monetary benefits	non monetised			*x (+)*				*x (+)*
	Time savings to patients	x	x	x	x (+)				x (+)
	Cost savings from reduced GPs' time	x	x	x			x (-)	x (+)	**

x ... relevant; n/a ... non applicable; x (+) ... relevant with positive effect (additional benefits outweigh additional costs); x (-) relevant with negative effect (additional costs outweigh additional benefits); x (+/-) relevant with positive or negative effect depending on the particular ailment/patient group; * ... no effect in the case of non-medical prescribing; ** ... effects factored out on societal level

3.4.2 Data collection

Data availability, in particular on the capital and operating costs of the initiative, the cost items listed in the previous section and data on the health care utilization in case of minor ailments is a major prerequisite for conducting a reliable cost-benefit analysis. Despite all possible efforts to receive valid data, some estimations, imputations and assumptions about certain parameters had to be made.

Data and information for the calculation of the potential savings due to the different initiatives were taken from publications, identified by the systematic literature review, by web-based hand search and citation tracking.

Extensive attempts were made to use published unit costs for the costing of the resource use data, such as a web-based search to identify international and national sources of cost data (e.g. national statistics). Where no information was publicly available, institutions associated with the selected initiatives were contacted[8]. Variability in the

8
Requests were sent to institutions and persons associated with the Dutch website zelfzorg.nl, the French website ameli santé and the German initiative "Grünes Rezept"

availability of unit cost data made it necessary to make several assumptions that were based on available information from other countries.

3.4.3 Sensitivity analyses

A parametric sensitivity analysis was conducted with respect to uncertainties regarding patients' behaviour and changes in utilization patterns, travelling time to the physician and the pharmacy, utilization of medication, and the costs of the initiatives.

The sensitivity analysis of the cost/benefit analysis from the patient's perspective was conducted by using the price of the least and the most expensive medicine for each ailment, and by varying the time a patient spends at the pharmacy under one of the analysed ailments.

With regard to the costs and benefits from the providers' and system's perspectives the lowest and highest (co-)payments for pharmaceuticals were again included for each ailment. Moreover, in terms of costs of each initiative a lower and upper boundary was applied (if applicable) to pharmacy training time and costs, pharmacists' hourly wages as well as governance costs.

3.5 Definition and assessment criteria for the best-practice of self-care (task 9)

For identifying best-practices in self-care, assessment criteria were selected and a definition for best-practices in self-care was set up in WP 1.

The selection of the assessment criteria for best-practices in self-care was based on the overall analyses of the initiatives in chapter "Analysis of self-care initiatives (task 7)" and the cost/benefit analysis (task 8) in the previous chapter. Thus, the selection is a synthesis of the results gained through the literature review conducted for tasks 6-8 in WP 1. Based on the assessment criteria selected a definition for best-practices in self-care was set up and best-practices on self-care in EU Member States were identified.

3.6 Transferability of best-practices (task 11)

In WP 2 a methodology for assessing the transferability of best-practice self-care initiatives identified in task 9 transferability was developed, which was revised in accordance with the project's commissioners.

3.6.1 Methodology of transferability

For the development of a methodology of transferability, two concepts are relevant:

- **Policy transfer**, describes the process of transferring knowledge and good practices between two political entities (i.e. countries) (Dolowitz/Marsh 2000). It focuses on the process of transfer.
- **Transferability analysis**, assesses the (technical and political) feasibility of the successful implemented policies (i.e. best-practice self-care initiatives) from one country to another. It focuses on the outcome of an intervention after transferring it (Wang et al. 2006).

The methodology of transferability proposed is the theoretical backbone of transferability analysis. It provides guidance for analysing the feasibility of transferring self-care best-

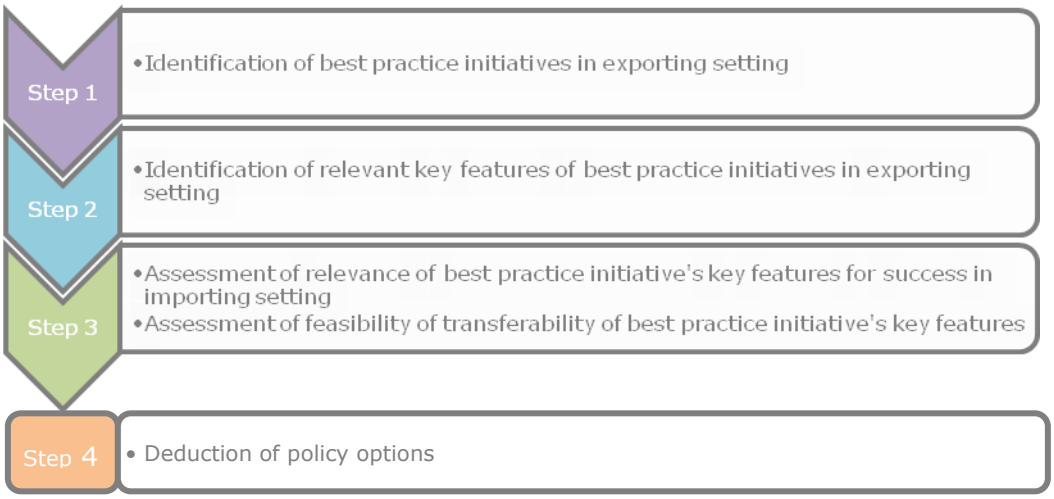
practices from one EU Member State to another. Hence, it focuses on the procedural aspect.

Based on the frameworks for policy transfer in health (Figueras 2014; Nolte 2014) as well as in other settings (Beecroft 2011; TURBLOG 2011) identified in literature, a basic four step approach was developed (see Figure 2: Methodology for transferability) consisting of:

1. Identification of best-practices
2. Identification of best-practices' key features
3. Assessment of the feasibility of transferring best-practices
4. Deduction of policy options

By following these steps, policy-makers should be able to assess, if a best-practice self-care initiative can be implemented in their country or if adjustments are necessary.

Figure 2: Methodology for transferability



Exporting setting refers to the country, for which the initiative was originally developed.
Importing setting refers to the country/setting, to which the best-practice initiative should be transferred

3.6.2 SWOT and risk analysis

The **SWOT analysis** aims for internal critical reflection of the proposed methodology's (see Figure 2) feasibility. In general, the concept of SWOT analysis has its roots in strategic management and originally aimed to facilitate a firm's strategy setting by analysing internal strengths and weaknesses as well as external opportunities and threats (Kessler 2013; Thompson/Strickland 2003).

In the context of this study, the SWOT framework was adopted (see Table 5) in order to serve as appropriate analysis tool for assessing the internal strengths and weaknesses of the methodology of transferability as well as the external opportunities and threats for its application.

Table 5: Framework for SWOT analysis

	Positive aspects	**Negative aspects**
Internal factors	What are internal factors strengthening the methodology for transferability of best-practice initiatives?	What are internal factors weakening the methodology for transferability of best-practice initiatives?
External factors	What are opportunities that can promote the applicability of the methodology for transferability of best-practice initiatives?	What are threats that can jeopardise the applicability of the methodology for transferability of best-practice initiatives?

Based on the findings of the SWOT analysis, a risk analysis was performed to match strengths and opportunities in order to determine its competitive advantage, and to convert weaknesses or threats into strengths and opportunities. In cases where conversion is not possible, weaknesses and threats should be minimized or avoided (Piercy/Giles 1989). The framework used for the risk analysis consisted of eight relationships between internal and external factors and is depicted in Figure 3.

Figure 3: Framework for the risk analysis

			Internal approach		
			List of strengths	**List of weaknesses**	***Study of reasons why strengths overcome weaknesses?***
			How can strengths be maximised?	How can weaknesses be minimised?	
External approach	**List of opportunities**	How can opportunities be maximised?	How can strengths be used to take advantage of opportunities?	How can weaknesses be corrected to take advantage of opportunities?	
	List of threats	How can threats be minimised?	How can strengths be used to reduce threats?	How can weaknesses and threats be minimised?	
	Study of reasons why opportunities minimise threats?				

The SWOT analysis was fed by the knowledge gained during the prior tasks of the project including findings of the literature (Figueras 2014; Hardee et al. 2012; Nolte 2014). To gain additional insights and a better understanding for country-specific issues related to the transferability of best-practices initiatives, telephone interviews were conducted with the project's expert panel members (see Table 1). The interview results (see Annex 16), the information were incorporated into the risk analysis. These inputs – which were the major source of information, and due to its practical hands-of character the experience of the panel members provide an added value - supplemented the information identified in literature (Lavis et al. 2013a; Lavis et al. 2013b; Lavis et al. 2013c)

3.7 Dissemination strategy of good practice initiatives (Task 14)

The general aim of the strategy is to disseminate best-practices in self-care identified in this project as well as to disseminate the method for transferability of best-practices.The choice of the most appropriate dissemination instrument and the development of a dissemination plan depends on five dimensions:

- the purpose of dissemination
- the target group(s) addressed
- the timing
- the choice of dissemination tools
- the evaluation of the dissemination strategy

Particular **purposes of dissemination** activities related to this project are:

- to **raise awareness** about possible benefits as well as costs of practices in self-care (e.g. via a press release),
- to **inform** policy-makers and stakeholders at EU and national levels (e.g. based on the findings presented in the technical report, disseminated through websites and scientific articles),
- to **engage** policy-makers and possible providers of practices (e.g. through an information event such as a workshop or a large conference),
- to **promote** existing best-practices and the method for transferability in order to instigate further good self-care practices (e.g. through presentation at different occasions).

Each purpose of dissemination can address different stakeholders of the initiative, therefore it is important to identifiy the relevant stakeholders in the dissemination process and the rationale of why they should be targeted. This was done by performing a basic stakeholder analysis which is provided in Annex 14. Due to overlaps in stakeholder groups some dissemination tools directed at one **target group** will therefore be able to achieve more than one purpose. To achieve the best effects, a mix of dissemination tools, as suggested in the dissemination plan for this project, is required.

An important dimension of dissemination consists of deciding when different dissemination activities should take place. **Timing** is an inherent part of dissemination, and determines at which stage of the project which target audience should be reached with which dissemination tool.

Given these considerations with regard to purpose, target groups and timing of planned dissemination activities, different **dissemination tools** may be available. In order to select the most adequate instrument a framework is needed. For that reason common selection criteria frequently used in EC funded projects (European Commission 2013; Peace Research Institute Oslo 2012) were applied. These are the criteria:

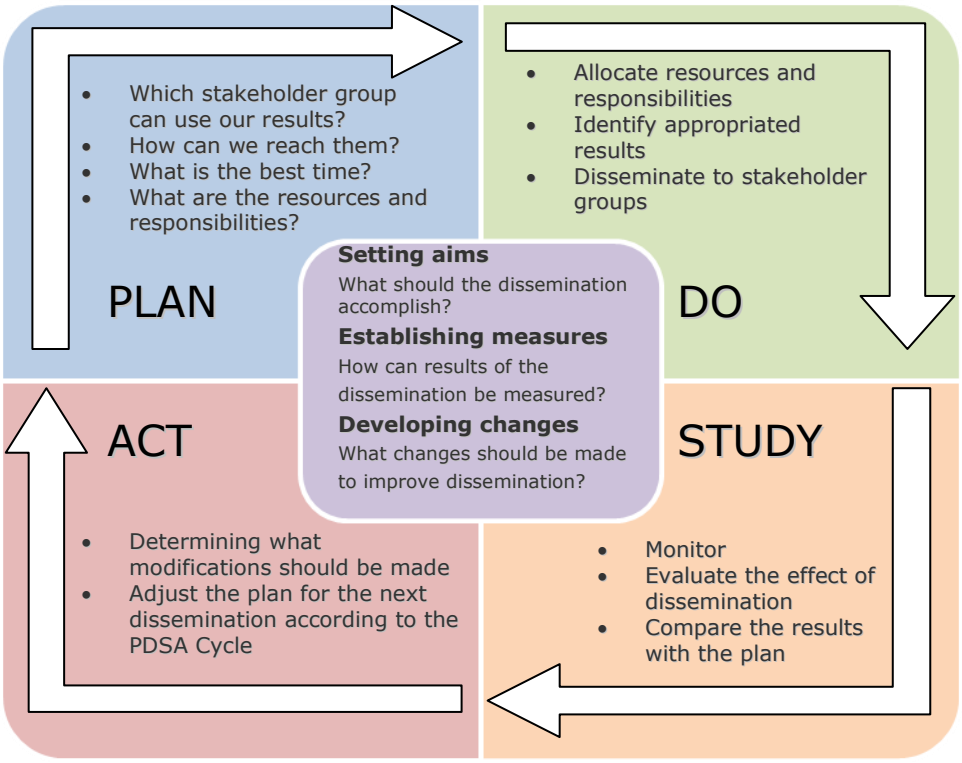
- **Appropriate**: Suitable for a particular stakeholder segment,
- **Effective**: Capable of eliciting a strong response or call to action from the particular stakeholder segment,
- **Targetable**: Capable of direction to a stakeholder segment,
- **Economical**: Disseminating the Deliverable efficiently both operationally and technically without burdensome aspect or cost,

- **Measurable**: Capable of being measured and distinguishable with reasonable amount of effort and accuracy.

In addition, contractual commitments of the consortium to the EC (as, for instance, specified in the tender specification and in the proposal for this service) are included to the list of criteria.

A dissemination strategy should be designed as an evolving and constantly developing process as not only the environment around the dissemination strategy may change. It is thus good practice to provide suitable mechanisms for reviewing the progress of the dissemination strategy and, eventually, the extent to which the strategy supports the uptake of self-care. This is only possible if clear and measureable targets were established at the outset of the transferability and dissemination process. A good framework work for a continuous **evaluation** process provides the Plan-Do-Study-Act (PDSA) process (Deming/Renmei 1952; Food Processing Initiative 2010; Langley et al. 2009). In the dissemination plan below, we thus included, where appropriate and possible, outcome measures.

Figure 4: Plan-Do-Study-Act (PDSA) process



4 Results

4.1 Definition of self-care (task 5)

The following definition of self-care has been developed for further use throughout the whole project:

"Self-care is what individuals, families and communities do with the intention to promote, maintain, or restore health and to cope with illness and disability with or without the support of health professionals such as pharmacists, doctors, dentists and nurses. It includes but is not limited to self-prevention, self-diagnosis, self-medication and self-management of illness and disability."

This definition was used in the subsequent literature review, analysis of initiatives and cost/benefit analysis.

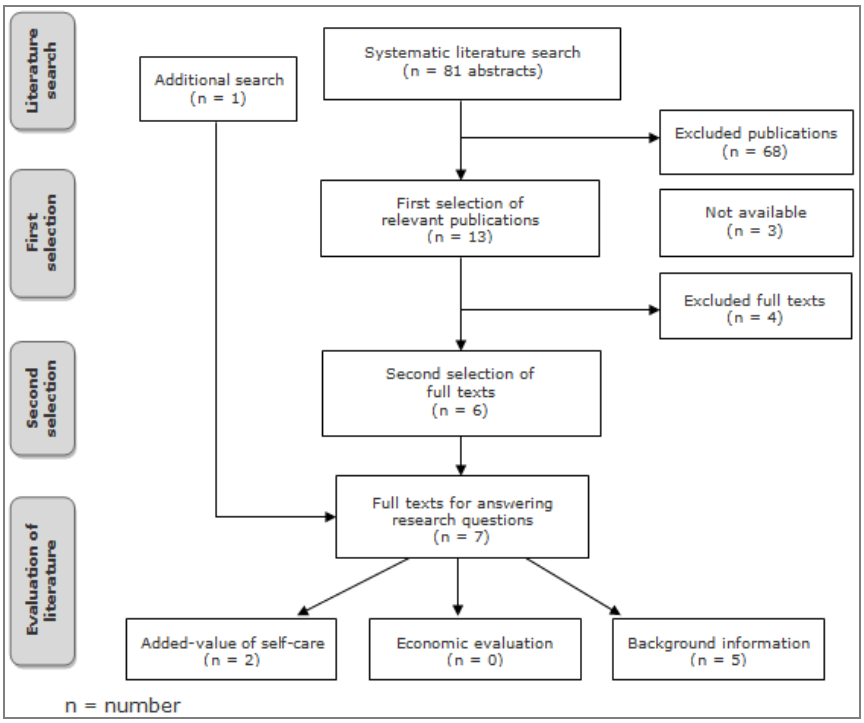
4.2 Added value of self-care (task 6)

The systematic literature review conducted in WP 1 contained for each ailment general information about the ailment, an overview of the included literature, the quality evaluation of each study (internal and external validity), an overview of the results of the included studies, and a synthesis of the study results and their overall evidence grades for the most common self-care interventions found in the literature (see Annex 7 and 8). In the following section an overview of the results the five selected ailments and limitations or the literature review are presented.

Athlete's foot

The systematic literature review for the ailment **"Athlete's foot"** delivered a total of 81 abstracts (duplicates were excluded). In Figure 5, the selection process is illustrated.

Figure 5: Graphical illustration of the selection process for the ailment of athlete's foot



After the selection of abstracts and full texts, two publications (Crawford/Hollis 2007; Ortonne et al. 2006) were identified to provide evidence about the added value of self-care (see Table 6). No publications about an economic evaluation was found and five publications were included for background and context information (Bell-Syer et al. 2012; Gensthaler 2004; Gupta et al. 2013; Morien 2013; Stock 2008).

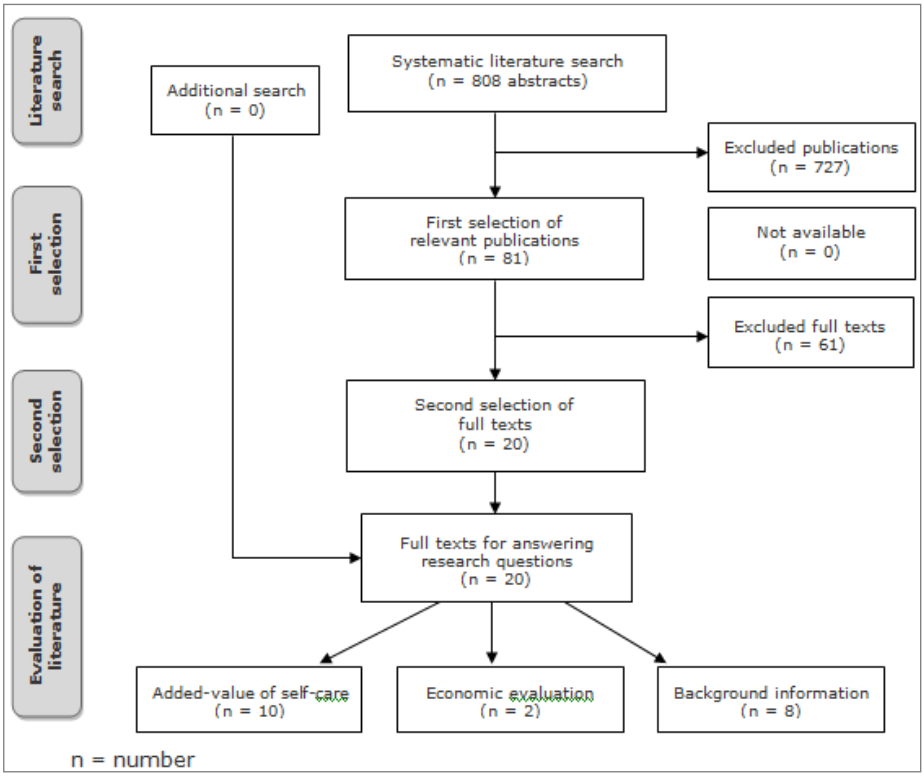
Table 6: Results of the literature review about the added value of self-care for the ailment of athlete's foot

Author (year)	Study design	Study population	Intervention	Indication	Results
Crawford et al. (2007)	Systematic literature review (Cochrane)	Not stated	Topical treatments of the skin and nails of the feet	Fungal infections of the skin and nails of the feet	Best results with the use of allylamines; small evidence for similar effect of butenafine Limited evidence about efficacy of tea tree oil for skin infections
Ortonne et al. (2006)	Multicentre RCT	273 patients between 12/18 (depending on country) and older	4-g tube of terbinafine 1% film-forming solution and placebo	Tinea pedis	Terbinafine 1% film-forming solution is compared to the control significant with respect to symptom relief and rates of effective treatment, negative microscopy, negative culture, mycological cure and complete cure.

The included studies contain good evidence (one Cochrane Review and one RCT) for the effectiveness of almost all topical treatments of athlete's foot which can be used by the patient in self-care because the side-effects are little and the products can usually be purchased over the counter. Strong evidence is available for allylamines and azoles. For butenafine, ciclopiroxolamine, tolciclate and tolnaftate as well as for terbinafine evidence is less strong. Additional literature searches on the specific substances for the treatment of athlete's foot are recommendable in order to get a full picture of the available evidence.

The systematic literature search for the ailment **"Cold"** in total delivered 808 abstracts. The selection process is depicted in Figure 6.

Figure 6: Graphical illustration of the selection process for the ailment of cold



After the selection of abstracts and full texts, ten publications (AlBalawi et al. 2013; Chaudhry et al. 2006; Häcker et al. 2010; KarschVolk et al. 2014; Lanas et al. 2011; McNally et al. 2010; Riebeling/Unkauf 2004; Theurer/Gessner 2011; Wade et al. 2011; Yardley et al. 2010) were identified to provide evidence aobth the added value of self-care (see Table 7), two publications (Rohrer et al. 2010; Svensson et al. 2012) about an economic evaluation were found and 8 publications were included for background and context information (Altiner et al. 2007; Arroll 2011; Decker/Herring 2011; Demicheli et al. 2014; Eccles 2005; Heikkinen/Järvinen 2003; Mäkelä et al. 1998; Simasek/Blandino 2007).

Table 7: Results of the literature review about the added value of self-care for the ailment of cold

Author (year)	Study design	Study population	Intervention	Indication	Results
AlBalawi et al. (2013)	Systematic literature review (Cochrane)	2,144 patients between 12 and 70 years	Intranasal ipratropium bromide	Common cold (rhinorrhoea and nasal congestion)	Consistent results favouring IB over placebo for rhinorrhoea but not for nasal congestion
Karsch-Völk et al. (2014)	Systematic literature review (Cochrane)	1,822 healthy people in prevention trials and 3,448 patients in treatment trials.	Echinacea for prevention and treatment	Common cold, influenza like syndrome of Upper respiratory tract infection	Evidence from prevention trials of slightly reduced risk of getting a cold, but only weak evidence of clinically relevant treatment effect from treatment trials. No evidence on safety or efficacy of parental application of Echinacea products on children.
Lanas et al. (2011)	Literature review and meta-analysis	13,222 patients between 18 and 81 years	Short-term acetylsalicylic acid (Aspirin)	Pain, fever or colds	Acetylsalicylic acid slightly increases risk of mild to moderate dyspepsia and abdominal pain compared to placebo. No significant occurrence of major gastrointestinal complications was observed. No statistically significant differences regarding adverse events occurred compared to other active agents (acetaminophen or ibuprofen)
Chaudry et al. (2006)	Cluster RCT	22 physicians with 212 patients	Nurse-based telephone treatment following a protocol (without physician involvement)	Upper respiratory tract infection	Compared to usual care models (with direct or indirect physician contact) the intervention leads to fewer antibiotics prescriptions, acceptable rates of adverse events and need for subsequent care. Patients stated a preference for telephone care with future similar illnesses.
McNally et al. (2010)	RCT	310 patients between 18 an 75 years	AMC/DCBA lozenges	Acute sore throat	Compared to placebo lozenges, the medicated lozenges significantly reduce soreness of throat and difficulty in swallowing and show significantly better sore throat relief and overall treatment ratings.
Wade et al. (2011)	Multicentre RCT	225 patients between 16 and 75 years	AMC/DCBA Warm lozenges and AMC/DCBA Cool lozenges (Strepsils)	Acute sore throat	Compared to placebo lozenges AMC/DCBA Warm and Cool lozenges significantly reduced the severity of throat soreness, difficulty in swallowing and increased sore throat relief, throat numbness and total sum of pain relief ratings.

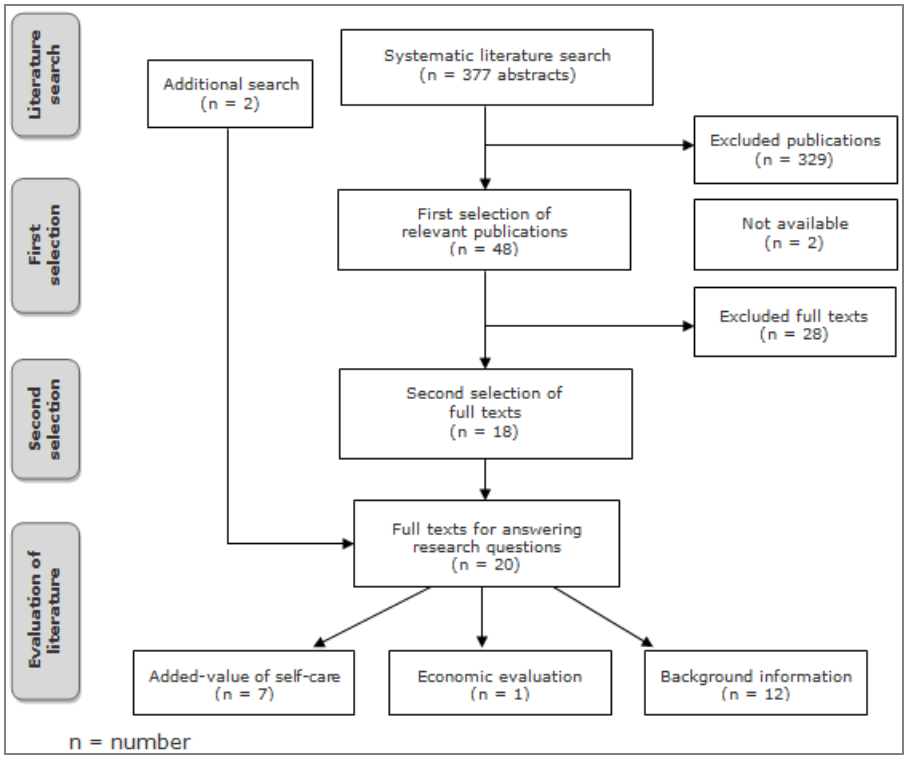
Author (year)	Study design	Study population	Intervention	Indication	Results
					Consumers evaluated the effect of the treatment on functional impairment, sensorial benefits, speed and duration of effects, emotional benefits and overall treatment as positive. No statistically significant difference in adverse events between treatment groups and placebo group.
Yardley et al. (2010)	RCT	714 people aged 18 to 79 years	Web-based triage system	minor respiratory symptoms	Initial evidence that tailored web-based advice could improve patients' ability to self-manage minor symptoms compared to a static, booklet-based information website. The effect on consultation rates was modest.
Häcker et al. (2010)	Non-interventional pre-post-study without control	64 patients between 18 and 79 years	Katimun (homeopathic remedy)	Common cold	Most patients taking Katimun suffer from mild colds and are generally very satisfied. As mild common cold resolves naturally and no control group was included, no clear statement can be made about the effect of Katimun
Riebeling and Unkauf (2004)	Non-interventional pre-post-study without control	196 patients between 14 and 82 years	Combination of Xylometazolin (Otrivin nasal spray) with Dexpanthenol (Otrivin care)	Common cold/ rhinitis	Nasal spray shows quick onset and long duration of effect, with low risk of side effects if the user instructions are followed. Care product speeds up and supports healing of lesions of nasal mucosa. The variable and flexible treatment corresponds to the needs of patients.
Theurer and Gessner (2011)	Non-interventional pre-post-study without control	1,053 patients with average age of 39.2 years	Combination product of acetylsalicylic acid and pseudoephedrine (Aspirin complex)	Common cold	The treatment is well tolerated and reduces main symptoms of common cold after 2 hours. The patient satisfaction regarding effectiveness, side effects, convenience and global satisfaction is high compared to other substances for other indications

The included studies show that there is good qualitative evidence for the effectiveness of treatments against the symptoms of the common cold which can be used by patient as self-care because the side-effects are little and the products can usually be purchased over the counter. However, some caution is necessary with regard to products where the effectiveness has not been proven, as the placebo effect together with the natural

resolving of the common cold might lead patients to misperceive the actual added value of these products.

The systematic literature search for the ailment **"Cough"** in total delivered 377 abstracts. The selection process is depicted in Figure 7.

Figure 7: Graphical illustration of the selection process for the ailment of cough



After the selection of abstracts and full texts, seven publications (Conrad et al. 2007; Gonzales et al. 2005; Paul et al. 2007; Schulz 2008; Smith et al. 2012b; Timmer et al. 2013; White et al. 2012) were identified to provide evidence abouth the added value of self-care (see Table 8), one publication (Oppong et al. 2011) about an economic evaluation was found and 12 publications were included for background and context information (Acute bronchitis 2006; Altiner et al. 2007; Chung/Pavord 2008; Eccles 2005; Fischer et al. 2005; Morice 2002; Mostov 2007; Schroeder/Richards 2013; Smith et al. 2012a; Wenzel/Fowler III 2006; Widdicombe 2003; World Health Organization 2001).

Table 8: Results of the literature review about the added value of self-care for the ailment of cough

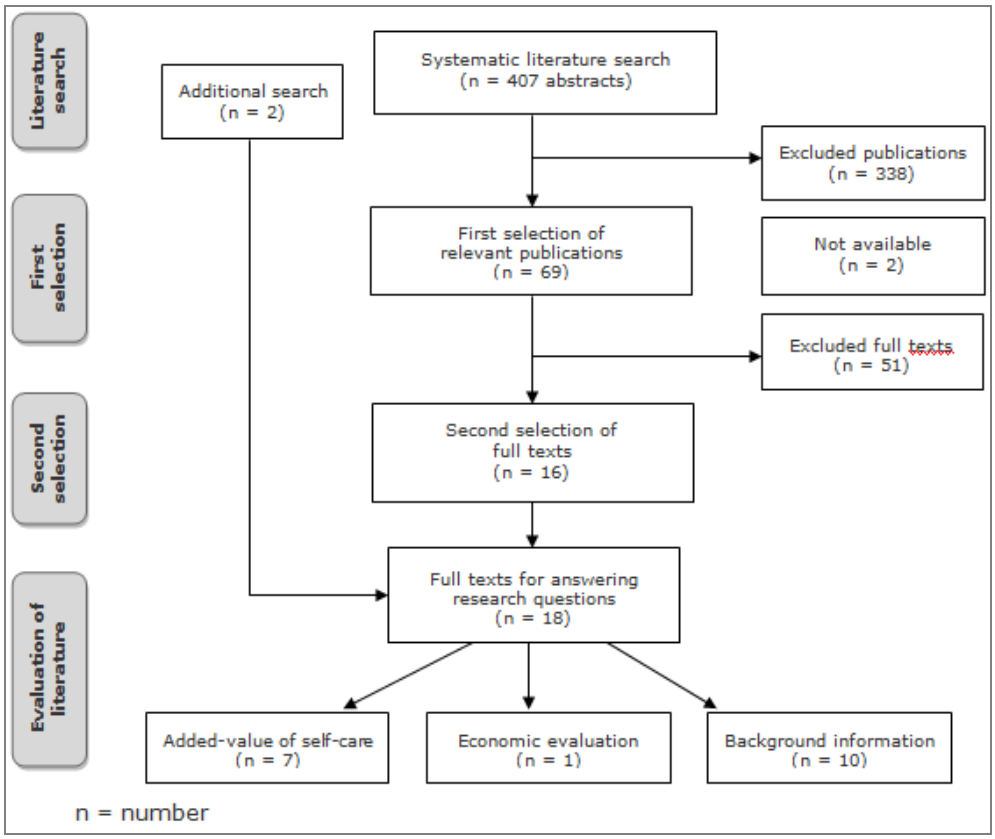
Author (year)	Study design	Study population	Intervention	Indication	Results
Conrad et al. 2007	Literature Review	Not summarised	Pelargonium sidoides-extract (EPs® 7630)	Acute Bronchitis	Efficacy on adults → Compared to placebo the rate of eradication was significant higher; Efficacy on children → Similar rate of eradication as Acetylcysteine; high practicability and tolerance; In General → A 10-days treatment result in 1 report per every 100,000 treatment cases; the study suggests a low therapy risk
Smith et al. 2012	Systematic literature review	4037 people (3421 adults and 616 children) ranging from 1 year to 71 years	Different OTC cough preparations	Acute cough	No good evidence for or against the effectiveness of OTC medicines in acute cough; the results of this review have to be interpreted with caution due to differences in study characteristics and quality; Studies often showed conflicting results with uncertainty regarding clinical relevance
Timmer et al. 2014	Systematic literature review	Not explicitly stated	Pelargonium sidoides-extract (EPs® 7630)	Acute Bronchitis	Pelargonium sidoides-extract (EPs® 7630) may be effective in alleviating symptoms of acute rhinositis and the common cold on adults. It may be effective in relieving symptoms on acute bronchitis on adults and children, and sinusitis on adults; the overall quality of the evidence was considered either low (acute bronchitis on children and adults) and very low (acute sinusitis & common cold)
Schulz 2007	Randomi-sed Controlled Trial	341 patients	Pelargonium sidoides-extract (EPs® 7630)	Acute Bronchitis	eradication of symptoms with EPs® 7630 treatment was significantly better at any point of time compared to the placebo; Patients treated with EPs® 7630 reported a higher satisfaction with their treatment than patients in the placebo group; undesired side effects were for both groups of the same size (21% and 22%)
Gonzales et al. 2005	Observational Study / Pre-Post Study	7 intervention practices with approximatel y 400	Patient education through information materials including a	Acute respiratory infections (ARI)	Primary endpoint of the study was the reduction of antibiotic prescription rates; provided valuable insights how information materials contributed to a reduction of

Author (year)	Study design	Study population	Intervention	Indication	Results
		patient visits each	reference card with facts about symptoms and treatment for ARI		GP visits: 3 percentage point decrease of pharyngitis visits of total ARI visits for children and a four percentage point decrease of bronchitis visits for adults, whereas the percentage rate in control practices remained the same.
Paul et. al. 2007	Pre-Post Study	105 children between 2 to 18 years	Buckwheat honey or honey flavoured Dextromethorphan (DM)	Nocturnal Cough and Sleep Quality	Significant differences on symptom improvement between treatment groups; honey consistently scores the best and no treatment scores the worst; Honey was significantly superior to no treatment for cough frequency. DM was not significantly better than no treatment for any outcome.
White et al. 2012	Pre-Post study	1568 participants	Training programme	Minor Ailments	Reduction in health service usage was not evident in the medium run, but there were small improvements in participants' knowledge and the confidence in self-care was still evident 12 months later. Self-care training offers benefits when people are encouraged to take greater responsibility for their health.

The systematic search revealed a lack of evidence for the effectiveness of OTC available preparations against cough which can be used by patients for self-care. Although one included review has a high evidence grade, its results have to be interpreted cautiously. Smith et al. (2013) point out that the results are based on too few studies with too many methodological issues as to allow generalisation. The situation for cough treatment with Pelargoniumsidoides extract (EPs® 7630) is similar to the treatment with OTCs: Literature reports significantly better rates of symptom eradication on adults compared to placebos and similar rates on children compared to Acetylcysteine, but the evidence grade of the included studies is in the best case moderate (Conrad et al. 2007; Schulz 2008; Timmer et al. 2013). Patient education provided through training programmes, does not alter the usage of health services in the medium run. It only results in improvements on patients' knowledge about ailments and the confidence in self-care. Another study which reported fewer GP visits for patients with acute respiratory infections, had a medium to low evidence grade due to its focus on different endpoints. Aligned with WHO recommendations, home remedies such as a spoon of buckwheat honey can be used as a first line treatment against minor ailments. Honey contributed to an improvement of nocturnal cough symptoms by reducing the cough frequency and scored better in doing so, compared to Dextromethorphan (DM) or no treatment.

The systematic literature search for the ailment **"Heartburn"** in total yielded 407 abstracts. The selection process is depicted in Figure 8.

Figure 8: Graphical illustration of the selection process for the ailment of heartburn



After the selection of abstracts and full texts, seven publications (Bruley Des Varannes et al. 2010; Hacker/Morck 2012; Konturek et al. 2007; Labenz/Willmer 2012; Mehuys et al. 2009; Närhi et al. 2005; Peura et al. 2009) were identified to answer the research questions concerning the added value of self-care (see Table 9), one publication (Mason/Hungin 2005) was identified for the economic evaluation and ten publications were included for background and context information (Della Casa et al. 2010; Fass 2007; Hegar/Vandenplas 2013; Kahrilas 2008; Katz et al. 2013; Khan et al. 2013; Pettit 2005; Rockafellow/Berardi 2009; Truter 2012; Wilson 2008).

Table 9: Results of the literature review about the added value of self-care for the ailment of heartburn

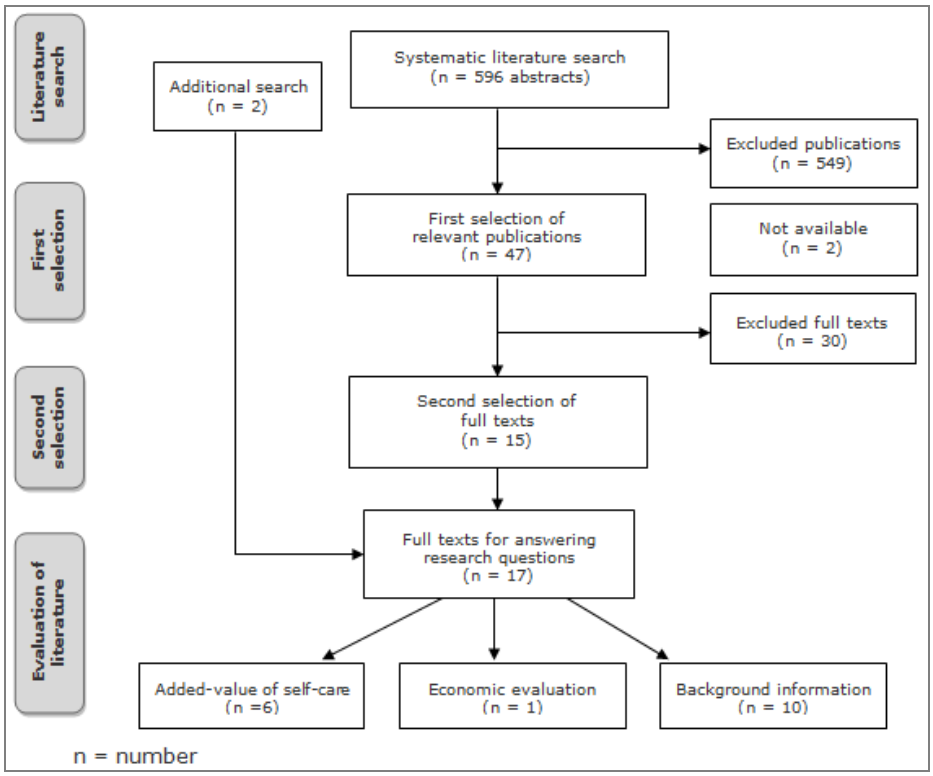
Author (year)	Study design	Study population	Intervention	Indication	Results
Bruley des Varannes et al. (2010)	Literature review	Not stated	PPI short-term and long-term treatment	GORD	No major differences between various PPIs used at standard licensed doses No evidence that long-term PPI therapy increases mortality, as compared with general population No evidence of additional risk with OTC PPI compared with other existing anti-reflux therapies
Häcker, et al. (2012)	Non-interventional pre-post study without control group	548 patients	500 or 1,000mg hydrotalcite (chewable tablets) or 1,000mg hydrotalcite as oral suspension Patient satisfaction questionnaire	Purchase of medication including hydrotalcite as active agent in pharmacy setting	Hydrotalcite led to symptom relief on patients (after 15/90min); Patients' expectations were met by the antacid hydrotalcite.
Konturek, et al. (2007)	Randomized, parallel group comparison	53 patients between 20-75 years	Single dose of the 1,000mg hydrotalcite (antacid) chewable tablets on occasion of a symptomatic reflux episode	GORD (frequent reflux symptoms, moderate/severe heartburn)	Results indicate that hydrotalcite relieves the symptoms of gastroesophageal reflux significantly faster than OTC famotidine; between 60-120 min both pharmaceuticals equal efficacy It is a safe and effective self-medication for on-demand treatment of heartburn
Peura et al. (2009)	Multicentre randomized controlled trial	864 patients 18 years and older	15mg lansoprazole (one 15mg active capsule and one matched control capsule), 30mg lansoprazole (two 15mg lansoprazole active capsules)	Nighttime heartburn	Lansoprazole 15mg and 30mg were superior to placebo for the treatment of frequent night-time heartburn, as well as 24-h heartburn and were well tolerated in a self-treating population

Author (year)	Study design	Study population	Intervention	Indication	Results
Labenz et al. (2012)	Non-interventional observation study	2,718 participants (no age range stated)	Treatment with omeprazole 20mg (Antra®) for maximum intake period of 14 days	Purchase of omeprazole 20mg (Antra®) in pharmacy setting	The study confirms the efficacy and compatibility of omeprazole in self medication.
Mehuys, et al. (2009)	Non-interventional pre-post-study without control	592 patients between 18 and 80 years	Self-treatment non-pharmacological advice plus antacid or pharmacological advice and antacid plus domperidone 10mg (dyspeptic symptoms)	Gastro-Intestinal (GI)symptoms	Mild GI symptoms can be solved mostly safely and effectively with self-treatment using OTC medicines and lifestyle modification
Närhi et al. (2005)	Non-interventional observation study	Inhabitants Finland	Data base analysis on the consumption and number of adverse events before and after H2 receptor antagonists' switch	GORD	The number of adverse effects of H2-receptor antagonists decreased after switch, although consumption increased, which gives indication that they do not have serious adverse effects and can be regarded as safe

There is sound evidence for the effectiveness of some treatments of heartburn, which can be used for self-care. Evidence found mostly refers to medicines, which can usually be purchased over the counter, that have little side-effects. A lesson learnt in the evaluation on self-care for heartburn was, that caution must be paid on the distinction between heartburn, gastroesophageal symptoms and GERD. As distinction was not always easy, additional literature searches on the substances identified might be necessary in order to get a full picture of the available evidence.

The systematic literature search for the ailment **"Urinary tract infection"** in total resulted in 596 delivered abstracts. The selection process is depicted in Figure 9.

Figure 9: Graphical illustration of the selection process for the ailment of urinary tract infection



After the selection of abstracts and full texts, six publications (Albert et al. 2009; Eells et al. 2014; Falagas et al. 2006; Ferry et al. 2004; Hudson 2006; Jepson et al. 2012) were identified to answer the research questions concerning the added value of self-care (see Table 10), one publication (Griebling 2005) was identified for the economic evaluation and ten publications were included for background and context information (Colgan/Williams 2011; Dielubanza/Schaeffer 2011; Epp et al. 2010; French 2006; Gupta et al. 2011; Hooton 2012; Jackson 2007; Kubik/McCarter 2012; Moore/Spence 2014; O'Shea 2010).

Table 10: Results of the literature review about the added value of self-care for the ailment of Urinary tract infection

Author (year)	Study design	Study population	Intervention	Indication	Results
Albert et al. (2004)	Systematic literature review and meta analysis (Cochrane)	1,120 participants between 12 and 83 years	Any Antibiotic regimen	Recurrent UTI	Continuous antibiotic prophylaxis for 6-12 months reduced the rate of UTI during prophylaxis-period compared to placebo; patients treated with antibiotics reported more adverse events (digestive problems, skin rash and vaginal irritation); daily prophylaxis compared to post-coital intake of antibiotics showed no significant difference;
Eells et al. (2014)	Systematic Literature Review + Model simulation	Not stated	Daily antibiotics, estrogen, cranberry pills or monthly acupuncture	Recurrent UTI	Daily antibiotic use is the most effective strategy for the prevention of recurrent UTI compared to daily cranberry pills, daily estrogen therapy, and acupuncture. Cost savings to payers and patients were seen for most regimens, and improvement in QALYs was seen with all. findings provide clinically meaningful data do guide the physician-patient partnership in determining a preferred method of prevention for this common clinical problem
Falagas et al. (2006)	Literature review	Not stated	Oral or vaginal administration of different probiotics	Recurrent UTI	Evidence for the beneficial effect of some strains of lactobacilli on the restoration of vaginal flora; use of probiotics for the prophylaxis of UTI is still controversial because only a few case-controlled, double blind clinical trials using strains carefully selected have been carried out so far.
Hudson (2006)	Literature review	Not stated	Various preventive behaviours (cranberry & blueberry juice, fermented milk products)	Uncomplicated UTI	Lower extrogen states result in lower amounts of lactobacilli in the vagina and bladder, and therefore to more RUTI; intravaginal estriol has shown to be an effective treatment for recurring UTI on postmenopausal women, as it restores the normal vaginal flora.

Author (year)	Study design	Study population	Intervention	Indication	Results
Jepson et al. (2012)	Systematic literature review and meta analysis (Cochrane)	4,473 participants with 7.5 years as lowest and 81 years as highest mean age	Cranberry juice or any Cranberry product	Uncomplicated or recurrent UTI	Lack of evidence that cranberry products significantly reduce the risk of repeated symptomatic UTI compared to placebo or no treatment in groups of people at risk of (recurrent) UTI for any of the subgroups analysed; greatest effect on children and smaller effects on elderly, pregnant women, patients with spinal injury or neuropathic bladder, people with multiple sclerosis and people receiving radiant therapy; all of these effects are not significant.
Ferry et al. (2004)	Randomised controlled trial	1,143 women consulting in 18 primary health care centres between 18 and above (up to 55+)	No intervention compared to 3 different regimens of pivmecillinam	Uncomplicated UTI	Association between symptoms and bacteriuria or bacterial counts were unpredictable, an thus rapid and patient near-laboratory tests are required for diagnosis of UTI; spontaneous resolution of all symptoms and bacteriuria was surprisingly low (24%)

There is no reliable evidence if and how different preventive strategies could reduce the risk of (recurrent) UTI. The reasons for that are diverse: For instance, many studies on cranberries report problems with compliance as juice and syrup seem to be not acceptable over long periods of time. Non-juice products, on the other hand, do not suffer from such problems, but are not able to state how much of the active ingredient (if any) is inside the tablet or capsule (Jepson et al. 2012). Probiotics lack randomised controlled trials to investigate the effectiveness of some lactobacilli strains (Falagas et al. 2006). Antibiotics are the most effective treatment in the presence of UTI, but the prospects for self-management are limited: It is not possible to draw inferences from symptoms to bacteriuria or bacterial counts (Ferry et al. 2004). Therefore laboratory test provide the most reliable diagnosis but take, despite major improvements, still some time. Self-administered dipsticks can lead to positive effects in shorter time, but they can be subject to specimen collection errors.

There were some **limitations** of the literature review on the added value of self-care for the five selected minor ailments. Due to the search strategy the literature review is limited to studies on the effectiveness with regard to self-care, self-management and self-medication. Consequently, studies focussing exclusively on the efficacy of products and substances against minor ailments were not included. Further research would benefit from a focus on specific OTC substances in order to get a full picture of the available evidence as some of these studies might not be detectable under the keyword "self-care" or its synonyms. As this study was commissioned to cover a broad range of ailments and their possible treatments, a search strategy for each available treatment for all included ailments was beyond the scope of the study.

Concerning the ailments "cough" and "cold", the search terms and the results were overlapping because the two ailments are closely related (cough is often mentioned as a symptom of the common cold) and existing literature did not clearly separate them. Nevertheless, a literature review was conducted for the aliments "cough" and "cold" separately and overlapping studies for the relevant ailment were exchanged.

4.3 Analysis of self-care initiatives (task 7)

Initially, eight self-care initiatives were considered to be analysed according to the RE-AIM+ framework in WP 1. For the report at hand, one initially selected initiative (i.e. Grünes Rezept) was excluded in accordance with the project commissioners as it did not target towards the avoidance/substitution of GP contacts by self-care in first place, and therefore not completely fit the definition of self-care developed in task 5,. Table 11 gives an overview of the selected and analysed initiatives.

Table 11: Selected self-care initiatives

Country	Name of the initiative	Type of initiative
FR	Ameli santé	Health information - website
LV	Latvian tele-helpline	Health information - telephone hotline
NL	Zelfzorg.nl	Health information - website
UK	NHS Choices	Health information - website
UK (England)	NHS 111 (NHS direct)	Health information - telephone hotline
UK	Minor ailment scheme	Legislative change
UK	Non-medical prescribing	Legislative change

Améli-Santé (webpage)

Améli-Santé (www.ameli-sante.fr) is the French public health information portal, similar to UK's NHS Choices. It is maintained by the National Health Insurance Fund for Employees (CNAMTS) and completely funded by the CNAMTS. Améli-Santé was launched in May 2010 for the purpose of informing the French population of a variety of different topics on health. The portal provided general information but, as specified, it is not intended to substitut advice from health care providers and cannot be used to establish a diagnosis or a medical treatment (Caisse nationale de l'Assurance Maladie des travailleurs salariés 2010).

In 2010, Améli-Santé comprised 16 health subjects. Now, it contains more than 200 health subjects and 25 symptoms. Relevant information on minor ailments is supplied in order to create better understanding of the pathology so that patients can more easily deal with an ailment. Information comprises description of the pathology, symptom(s) and possible complications and health care offered by the Insurance Fund. Also, information regarding prevention is provided in a separate section of the homepage. Furthermore, Améli-Santé provides direct access to Améli-direct, a tool for finding information on health care providers (i. e. fees, contact details).

According to the 2012 activity report of the CNAMTS, 366,000 visits per month were recorded. In 2012, the most accessed section was for 'Antibiotics' for which 249,400 visits were documented (Caisse nationale de l'Assurance Maladie des travailleurs salariés

2012). In 2011, 2,730,632 visits were counted over the year, whereas only 619,852 were recorded in 2010 (Caisse nationale de l'Assurance Maladie des travailleurs salariés 2011). Thus, visit rates more than quadrupled between 2010 and 2011.

Latvian tele-helpline service

The Tele-helpline service (66016001) was implemented in Latvia in 2011 with the aim to improve access to basic health services and to provide advice for people during GPs' out-of work hours. The service is organised and ran by the Latvian Ministry of Health and the National Health Service. It is available on working days from 5.00 p. m. to 8.00 a. m. and 24 hours during weekends and on holidays. Calls are charged according to regular phone call tariffs (Nacionālais Veselības Dienests 2012).

Tele-consultations are provided by medical staff: GPs or their assistants. The main aim is to give patients the opportunity to get medical advice and educational support for minor illnesses, which do not require immediate medical care outside of GPs' working hours. Self-care advice or direction to other service providers is given and calls can be re-directed immediately to Emergency ambulance service, if considered appropriate by the operator. E-mail or Skype communication is also available. Consultations are provided in Latvian, English or Russian (Nacionālais Veselības Dienests 2012)

Zelfzorg.nl (webpage)

Zelfzorg.nl (www.zelfzorg.nl) is the most popular Dutch information portal on self-care issues. It is run by Neprofarm, the Dutch branch association of the Dutch producers and importers of self-care products. Altogether, Neprofarm involves 25 members[9] (Zelfzorg.nl n.d.-a). The website was launched in March 2003. By providing patients/consumers with relevant information, Zelfzorg.nl aims to enable patients to autonomously take care of their health. Besides this, another aim is to provide information on medication, for which no advice is given at the point of purchase, as their selling points are supermarkets, gas stations and other (Neprofarm 2003; Neprofarm 2006).

The self-care information provided by Zelfzorg.nl is based on medical standards of GPs and pharmacists, and covers the following:

- General information about minor ailments and their prevention and treatment
- Specific information on almost 1,000 self-care products (i. e. application, dosage and composition). For further information, the patient information leaflet can be downloaded. All products recommended on the homepage can be compared with each other.
- Self-care related information for pregnant women and children
- Information about self-care related issues (e.g. information on correct usage, market authorisation and availability of self-care medication, etc.)

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Neprofarm's members: Bayer B. V., Bayer B. V. (Steigerwald), BioClin B. V., Biohorma B. V., Boehringer Ingelheim B. V., GlaxoSmithKline Consumer Healthcare B. V., Heel Biologische Geneesmiddelen B. V., Holland Pharma, Imgroma B. V., Johnson & Johnson Consumer B. V., Meda Pharma B. V., Medical Brands, Novartis Consumer Health B. V., Omega Pharma Nederland B. V., Pfizer bv Consumer Healthcare, Reckitt Benckiser Healthcare B. V., Remark Pharma B. V., Sanofi Consumer Healthcare, Timm Healthcare B. V., Vemedia B. V., VSM Geneesmiddelen B. V., WALA Nederland B. V., Weleda Benelux SE, Will-Pharma B. V., YouMedical, Zambon Nederland B. V.

During its 13 years of existence, Zelfzorg.nl went through several phases of re-structuring and renewal (Neprofarm 2005; Neprofarm 2007), during which the homepage's topics were extended and new applications (e.g. symptom checker, mobile app) have been introduced (Neprofarm 2009; Neprofarm 2010; Neprofarm 2011).

In the second half of 2004 – the first year for which usage data is available – between 10,218 and 16,241 visitors were reported per month (Neprofarm 2004). Since then visitor numbers have risen continuously. In 2011 about 1.1 million visitors were counted. The average visitor stays between 1.5 and 2 minutes on the homepage (Neprofarm 2011).

NHS Choices (webpage)

NHS Choices (www.nhs.uk) is Europe's most popular health website and the third biggest government website in the UK (NHS Choices 2012b). It is run by the NHS, thus a programme of UK's Department of Health and accessible across all parts of the UK. In case of non-availability of services, users are referred to other equivalents (e.g. NHS 24 for Scotland). NHS Choices was established in 2007 (Nelson et al. 2010a) to provide comprehensive medical and lifestyle information to both the public as well as health care professionals. Its aim is "to develop a world-leading, multi-channel service that will create a 'front door' for everyone to engage with the NHS and social care." (NHS Choices 2013a). Therefore, it compiles the knowledge and expertise of various health care organisations (e. g. NHS Evidence, Health & Social Care Information Centre, Care Quality Commission, etc.).

Health information is provided by means of several features of the website (e. g. "Health A-Z", or "Services near you"), social media and different electronic tools such as the symptom checker, mobile apps or a BMI calculator to name just a few. In 2012, the website received more than 27 million visits per month. Regarding usage, NHS Choices users access the website mostly to receive medical information (39%) and to check their symptoms (26%) (NHS Choices 2012b).

Within the remit of providing health information, the support and improvement for primary care consultations is of particular importance. NHS Choices tries to facilitate this in several ways. First, GPs are provided with a single, complete portal for clinical information (e.g. Health A-Z). Thus, they can easily find necessary information for reference or discussion with patients and are able to easily dispense Information prescriptions.[10] Second, users are offered access to reliable health information and materials, which prepared them better for GP consultations. An informed patient can make a consultation more effective and more efficient. Third, by providing clear information about appropriate time, place and reasons for consultations, unnecessary consultations might be avoided (Nelson et al. 2010a).

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Information prescriptions provide up-to-date and accurate information regarding patients' specific condition, treatment options, local care services, benefits to be claimed, housing support and self help and support groups. It can be created by patients themselves. Patients can also discuss information prescription needs with healthcare professionals or social care workers (NHS Choices 2012a).

NHS 111

NHS 111 is England's current telephone based triage and signposting service for helping people to access appropriate health care for urgent medical problems, which are not 999 emergencies. In 2014, it replaced the former telephone helpline of NHS Direct (NHS Direct 2014). There are also telephone based helplines in Scotland (NHS 24) or Wales (NHS Direct Wales) (NHS 24 2014; NHS Direct Wales n.d.), whereby plans are discussed by the Welsh government to launch a NHS 111 telephone helpline (Martin 2013).

NHS 111 is a 24/7 service providing response to health care requests for non life threatening situations, care access out of hours and to insecurities regarding services needed. The main objective as defined is to simplify access to consistent information about non-emergency health care by use of a memorable number (111) free of charge. Besides, it provides clinical assessment at the first point of contact and routs patients to the right NHS service (NHS 111 programme team 2011; NHS Choices 2013b). To achieve this, NHS 111 is staffed with a team of trained advisers, supported by experienced nurses and paramedics. The core of the service is based on a triage system, thus by asking questions, symptoms are assessed, on which basis health care advice is given or callers are directed directly to local services, such as accident an emergency (A&E) departments, out-of-hour doctors, urgent care centres or walk-in centres. Where possible, appointments are booked by the NHS 111 team (NHS Choices 2013b).

In 2014, NHS 111 service in England was divided into 45 catchment areas. In May 2014, 1,112,633 calls were directed to the NHS 111 service. Extrapolating the numbers for the whole year would yield 13.1 million calls per year. In May 2014, waiting times for callers were less than 60 seconds (NHS England 2014a).

Minor Ailment Schemes

Community pharmacy minor ailment schemes (MAS) are locally tailored schemes to provide public access to NHS treatment and/or advice via a pharmacist or pharmacy personnel, or, where appropriate, to refer to other health professionals. The idea is to encourage patients to use community pharmacies as first access point for minor ailments rather than a general practitioner (GP). Their establishment as well as their management is up to the four different regional entities (NHS 2000). Originally proposed by the UK Department of Health, the schemes were introduced in all community pharmacies in Scotland and Northern Ireland in 2006 and 2009, respectively. In Wales, a MAS was rolled out nationwide in 2013. In England, the community pharmacy contract specifies MAS as 'enhanced' services, which can be commissioned by the primary care trusts (today NHS England Area Teams after the 2013 healt care reform) after a local needs assessment.[11] The schemes have an agreed list of ailments to be treated and treatment supply is based on an agreed formulary – a list of products which gives instruction about which product can be prescribed for which minor ailment – (National Public Health Service for Wales 2007).

MAS can be open to patients, who normally pay prescription charges but usually they focus on those patients, who are exempt from NHS prescription charges. For the latter

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The Community Pharmacy Contractual Framework in England divides pharmacy services into three categories: Essential Services (which are provided by all NHS pharmacies, e.g. filling prescriptions), Advanced Services which pharmacies may choose to provide (e.g. medicines management review programs) and Enhanced Services locally commissioned (e.g. public health programs).

medicines are supplied free of charge. Thus, the payment barrier, which might hinder patients to consult a pharmacist instead of a GP, is removed. There are also differences regarding access to MAS. Some schemes are only open to patients registered with a participating GP practice (i.e. GP practice referral); others are open to all patients regardless of registration (i.e. patient self-referral). As registering with a GP is required for GP-practice referrals, the substitution of GP consultations by pharmacy consultation is supported. Accessing MAS by self-referral makes pharmacies the first point of access and thus, promotes the role of pharmacies and makes access easier. MAS often use a combination of GP practice referrals and self-referrals, with pharmacies checking patient's eligibility (National Prescribing Centre 2004). MAS enables monitoring of individual medication utilisation through the pharmacy (Community Pharmacy n.d.). Further benefits refer to minimising the work of GP practice staff and avoidance of unnecessary GP visits each time a patient wishes to use the scheme. However, as patients can only register with one community pharmacy, patient choice is reduced following this strategy (National Prescribing Centre 2004).

Regarding payment of MAS, costs of medicines and consultation costs need to be differentiated. Costs for medicines are reimbursed for all pharmacies, whereas the payment of the consultation varies across schemes (e.g. fee for service payment or annual and one-off retainers, respectively). Furthermore, the funding of these schemes must account also for stationery, printing costs, marketing, training events and evaluations of the scheme (National Prescribing Centre 2004).

In the Scottish MAS, over two million items were dispensed between April 2011 and March 2013. The most often dispensed medicines were Paracetamol, followed by Ibuprofen and simple Linctus. The ten most often dispensed pharmaceuticals accounted for 53% of all prescribings (Pharmacy Research UK 2014).

Non medical prescribing / Pharmacist independent prescribing

Since 1998 Non-medical prescribing (NMP) has been a common practice in the UK. The intention of NMP was to make the NHS workforce more effective, as evidence suggested that it was ineffective if nurses had to request and wait for prescriptions from GPs (Department of Health 1999). Independent nurse prescribers – now called community practitioners – have been the first health professionals apart from physicians provided with the right to prescribe (Hacking/Taylor 2010). Since then, NMP developed in several waves, by extending authorities, number of medicines prescribable and number of health professionals provided with the right of prescribing (Courtenay et al. 2012). This development was supported by several legal actions (i. e. the new General Medical Services contract, the new Community Pharmacy Contractual Framework and the application of statutory working time limits in line with the EU working time Directive for doctors in training). The changes strengthened the position of NMP, especially for services formerly provided by junior doctors in hospitals or the management of long-term conditions. In practice, three types of NMP can be distinguished (Hacking/Taylor 2010):

1. *Community practitioner prescribers* (i. e. nurses), who prescribe medications and dressings from the Community Practitioner Prescriber Formulary which contains a rather limited number of products.
2. *Supplementary prescribing* (i. e. nurses, midwives, health visitors, pharmacists, optometrists, physiotherapists, podiatrists and radiographers)

3. *Independent prescribers*[12] (i. e. nurses, midwifes, health visitors, pharmacists and optometrists)

According to (Courtenay et al. 2012), in 2011 approximately 33,000 community practitioner prescribers, 23,000 nurse independent and/or supplementary prescribers 2,000 pharmacist independent and/or supplementary prescribers as well as several hundred optometrists and allied health care professionals equipped with prescribing capacities work across the UK.

Those five initiatives were comprehensively analysed based on published evaluations, reports and articles (see Annex 9). A summary of the analysis' results is presented in Table 12.

Table 12: Summary of analysis of initiatives

Name of initiative	R	Eff	Ad	I	M	Acc	Eq
Améli-Santé	?	?	?	?	?	?	?
Latvian tele-helpline	≈	?	≈	?	✓	?	≈
Zelfzorg.nl	?	?	?	?	?	?	?
NHS Choices	✓	✓	≈/?	✓	✓	≈/?	≈/?
NHS 111	✓	?	≈	≈	✓	✓	✓
Minor ailment scheme	?	✓	≈	✓	✓	≈	✓
NMP/PIP	✓	✓	✓	✓	✓	✓/≈	?

✓: high; ≈: moderate; ?: unclear; !: low

R: Reach; Eff: Effectiveness; Ad: Adoption; I: Implementation; M: Maintenance; Acc: Access; Eq: Equity

General limitations of the analysis refer to lacking evaluations and information relevant for the analysis. Hence, an assessment of the Latvian tele-helpline was only partly possible. Regarding the Dutch and the French web portals, contacting the providers for further information and potential evaluations did not yield any results. Thus, an evidence-based assessment of Améli-Santé and zelfzorg.nl was not possible at the time of this report.

4.4 Economic evaluation of self-care initiatives (task 8)

In the following sections the costs and savings of the identified best-practice self-care initiatives MAS, NHS-Choices and NMP/PIP (all UK-based) will be analysed according to the previously outlined methodology from different perspectives (patient, provider,

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NMP refers in the further course of the report to non-medical independent prescribing by pharmacists and nurses. This is due to missing cost data for NMP services provided by professions other than pharmacists and nurses in the CBA. For better clarity, the abbreviation NMP/PIP is used non medical independent prescribing by pharmacists.

system, society). Due to a lack of solid data in particular on costs but also user rates, no cost-benefit analysis could be performed for the other self-care initiatives presented above.

However, as the assessed initiatives cover all possible "generic" types of self-care initiatives (see also Table 11) and due to the fact, that costing information (in particular on medication and unit costs for various providers) is always country specific, the performed cost/benefit analyses meet the criteria of representativeness from a methodological perspective. The conducted analyses can therefore serve as a blueprint for the analysis of the other initiatives listed in Table 11 if further information is available as well as for specific national initiatives not covered by this report.

The cost/benefit analysis of WP 1 has been revised and completed. The results of the economic literature review conducted in WP 1 can be found in Annex 10.

4.4.1 Costs and benefits from patient's perspective

The **travelling time** (both ways) to a physician's office was assumed to be 30 minutes and an additional 10 minutes to go to a pharmacy directly afterwards to fill the prescription. The travelling time to the pharmacy was assumed to be 20 minutes (both ways). As there are fewer GP offices than pharmacies in England, it is reasonable to assume that the average travelling time to the pharmacy is shorter than to the closest GP (Farnfield 2008).

The **average time** a patient spends at the **GP's office** is assumed to be around 30 minutes (including waiting time) (Curtis 2012; May/Bauer 2013). There is no definite evidence on the length of an encounter at the pharmacy but it can be assumed that a contact with the purpose of only purchasing a prescribed medicine is shorter than a consultation with the pharmacist. Some evidence from Austria suggests that a consultation at a pharmacy lasts five minutes if the patient saw a physician first (Option 1) and seven minutes if the pharmacist is the first contact point in the case of a minor ailment (May/Bauer 2013). The time spent at the pharmacy with one of the initiatives in place depends on the function of the pharmacist within this initiative, and will be considered in the sensitivity analysis (British Columbia Pharmacy Association 2013; Curtis 2012; Farnfield 2008; Latter et al. 2010; May/Bauer 2013). Table 13 depicts the assumed average time spent at the GP's office or the pharmacy under the different self-care initiatives and the travelling time to the encounters.

Table 13: Average time spent at encounter in minutes

	GP's office	Pharmacy after GP	Pharmacy only	Pharmacy with initiative
Minor ailment scheme	30	5	7	12 (10;15)
NHS Choices	30	5	7	7 (5;10)
Non-medical prescribing	30	5	7	18 (15;20)
Travelling time (both ways)	30	10	20	20

The physician and pharmacy visits are assumed to be undertaken by the patient during his working time, as these are the common office hours for health professionals. The time spent is therefore priced using the median hourly earnings excluding overtime of all employees in the UK in 2012 (Levy 2013), which was 11.21 £.

The **average costs** a patient has to pay for **pharmaceuticals** in case of one of the selected minor ailments, the mean prices of the most common OTC and Rx products for athlete's foot, common cold, cough, heartburn and urinary tract infection have been calculated (see tables 1-5 in Annex 11 for detailed calculation basis).

Table 14: Average pharmaceutical prices used in the CBA

		Average pharmaceutical price for patient (in UK £)… (minimum price; maximum price)		
Minor ailment (pharmaceu-ticals)	**Rx or OTC**	***… without prescription (OTCs only)***	***… with prescription if obliged to pay prescription charges***	***… with prescription if exempt from prescription charges***
Athlete's foot (Lamisil, Canesten, Daktarin, Sporanox,, Griseofulvine)	OTC	5.08 (3.58; 7.33)	5.08 (3.58; 7.33)	1.24 (0;4.38)
	POM	n.a.	8.05 (8.05; 8.05)	0.00 (0.00; 0.00)
Cold (Paracetamol, Aspirin, Ibuprofen, Strepsils, Vicks Vaporup, Vicks Decongestant, Vicks First Defence)	OTC	2.72 (0.69; 7.09)	2.72 (0.69;7.09)	1.10 (0.00; 7.09)
	POM	n.a.	n.a.	n.a.
Cough (Benylin, Robitussion, Lemsip Mucus, Erythroped A, Azithromycin, Doxycycline)	OTC	4.52 (2.99; 6.78)	4.52 (2.99; 6.78)	4.52 (2.99; 6.78)
	POM	n.a.	8.05 (8.05; 8.05)	0.00 (0.00; 0.00)
Heartburn (Alka-Seltzer, Rennie, Antacid, Magnesium Trexiclicate, Omeprazole)	OTC	2.32 (1.69; 3.69)	2.32 (1.69;3.69)	1.84 (1.69;3.69)
	POM	n.a.	8.05 (8.05; 8.05)	0.00 (0.00; 0.00)
Urinary tract infection (Amoxicilin, Nitrofurantion, Co-Trimoxazole)	OTC	n.a.	n.a.	n.a.
	POM	n.a.	8.05 (8.05; 8.05)	0.00 (0.00; 0.00)

The average pharmacy retail price for OTC products against **athlete's foot, cold, cough, and heartburn** is £ 5.08 , £ 2.72, £ 4.52, and £ 2.32, respectively. This is the price an average patient would have to pay if he goes to a pharmacy. As all relevant pharmaceuticals against **urinary tract infection** are prescription only products, a patient who consults a pharmacist can only be advised to lifestyle modifications (e.g. increase water intake) and/or to purchase non-medical products with potentially mediating effects (e.g. cranberry juice). If a patient who is exempt from prescription charges gets a prescription, the average price for OTC products would be £ 1.24, £ 1.1, £ 4.52 and 1.84 £ for the afore-mentioned four ailments. The prices are lower because in the UK

some OTC products are prescribable and can be dispensed free of charge by the pharmacy. This means that on average, patients who are exempt from prescription charges pay £ 3.8, £ 7.4, and £ 0.5 less in case of an athlete's foot, a cold or heartburn. The average price of OTC products for patients with a cough remains unchanged (£ 4.52) as the relevant pharmaceuticals are not prescribable. For the share of the population that is not exempt from prescription charges, nothing changes regarding the price of the purchased OTC medicines.

Average prescription charge is set at £ 8.05 for each medication prescribed (NHS England 2014b) regardless whether the pharmacy retail price is lower than the prescription charge. For simplification and clarity reasons and due to the objective of assessing "generic" initiatives other forms of financial arrangements regarding prescription charges (e.g. certificates, payment ceilings, etc.) are excluded from the analysis. These arrangements might impact, however, the average pharmaceutical prices paid by specific subsets of the population and have to be taken into account if assessing a specific initiative in a defined setting. If a patient is exempt from prescription charges, no co-payment is required for POMs as well as for OTC products (if prescribable).

With regard to the **average number and types of pharmaceuticals** dispensed to the patient, it was assumed that on average patients would be handed out two pharmaceuticals specialties regardless whether they would consult a GP before the pharmacy encounter or not (Bojke et al. 2004). However, if seeing a GP before visiting the pharmacy, the two recommended pharmaceuticals were assumed to consist of one Rx and one OTC product (if medication of both types were available for the particular minor ailment), which was also assumed to be the case for a pharmacy that only encounters with NMP in place. For the case of cold, for which no Rx medication was found to be available, two OTC products, were assumed to be dispensed to the patient in any case, whereas for urinary tract infection, the patient would only receive one Rx product (no OTC product available) if he either decided to consult a GP prior to going to the pharmacy or directly consulted a pharmacy independent prescriber (for an overview of the sample medication for all minor ailments assessed see Table 15).

Table 15: Number and type of pharmaceuticals dispensed to patient

	Number and type pf pharmaceuticals dispensed to patient				
Minor ailment	***GP + pharmacy***	***Pharmacy only* (without initiative)**	***Pharmacy only (with MAS)***	***Pharmacy only (with NHS Choices)***	***Pharmacy only (with NMP/PIP)***
Athlete's foot	1 OTC + 1 Rx	2 OTC	2 OTC	2 OTC	1 OTC + 1 Rx
Cold*	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC
Cough	1 OTC + 1 Rx	2 OTC	2 OTC	2 OTC	1 OTC + 1 Rx
Heartburn	1 OTC + 1 Rx	2 OTC	2 OTC	2 OTC	1 OTC + 1 Rx
Urinary tract infection**	1 Rx	-	-	-	1 Rx

* ... no Rx products for cold available

** ... no OTC products for urinary tract infection available

As the subject of the study is self-limiting minor ailments by definition, it can be assumed that there is no long-term difference in health outcomes whether an OTC or an Rx product was used. There might of course be a short-term difference, as some conditions might resolve faster when using certain pharmaceuticals. For the case of UTI only Rx products are available.

In the following section the results of the cost/benefit analysis from the perspective of the patient for MAS, NHS Choices and NMP are summarized. Detailed calculations for all minor ailments can be found in Annex 12.

Minor ailment schemes

Experiences from Scotland, where MAS have been introduced almost ten years ago, show that pharmacy-based MAS have the potential to substitute for other health service and to reduce GP consultations for minor ailments (Baqir et al. 2011; Paudyal et al. 2013). However, it is important to note that there are various forms of MAS across the UK with different characteristics. The joint goal of all schemes is to encourage patients with minor ailments to consult a local pharmacy instead of a GP.

MAS are expected to be associated with two potential benefits for the patient: first, the waiting time in the pharmacy is usually shorter than at the GP's office. Therefore, the patient has to spend less time for a consultation if he uses the pharmacy under the MAS as the first point of service. Second, patients who are exempt from the prescription charges would usually visit the GP to get a prescription, which gives them access to pharmaceuticals free of any (co-)payment.

It is therefore assumed for the subsequent cost-benefit analysis of MAS, that – on the condition that certain scheme-inherent requirements are met (e.g. registration with GP, etc.) – medicines for minor ailments which can be prescribed by a physician can also be handed out free of charge by the pharmacist to patients exempt from prescription charges. Hence, one incentive for the patient to visit a GP rather than a pharmacy is eliminated by the MAS.

Table 16: MAS: Average patient's savings who sees pharmacist instead of GP

		Average savings for patient due to shift from GP to pharmacy (in UK £) … (lowest; highest prices and time spent)		
	Minor ailment	**… without initiative**	**… with MAS**	**Difference**
Patient exempt from prescription charges	Athlete`s foot	0.04 (1.81; -1.32)	6.80 (8.41; 3.10)	6.75 (6.60; 4.41)
	Cold	5.73 (7.59; 8.97)	8.03 (8.41; 7.47)	2.30 (0.82; -1.50)
	Cough	4.45 (5.98; 2.19)	3.52 (5.42; 0.69)	-0.93 (-0.56; -1.49)
	Heartburn	6.18 (7.28; 5.28)	6.19 (6.72; 3.78)	0.01 (-0.56; -1.49)
	Urinary tract infection	8.97 (8.97; 8.97)	8.97 (8.97; 8.97)	0.00 (0.00; 0.00)
Patient obliged to pay prescription charges	Athlete`s foot	11.94 (13.44; 9.69)	11.94 (13.44; 9.69)	0.00 (0.00; 0.00)
	Cold	8.97 (8.97; 8.97)	8.97 (8.97; 8.79)	0.00 (0.00; 0.00)
	Cough	12.50 (14.03; 10.24)	12.50 (14.03; 10.24)	0.00 (0.00; 0.00)
	Heartburn	14.70 (15.33; 13.33)	14.70 (15.33; 13.33)	0.00 (0.00; 0.00)
	Urinary tract infection	17.02 (17.02; 17.02)	17.02 (17.02; 17.02)	0.00 (0.00; 0.00)

The cost/benefit analysis showed that before the implementation of MAS a patient who was exempt from prescription charges could save £ 0.04 if going to the pharmacist instead of the GP in case of an **athlete's foot** (in this case he/she would not receive any Rx medicnes). After the implementation, the same patient could save almost £ 7 with the decision to consult a pharmacist instead of a GP. From an economic view it is therefore likely that more patients who are exempt from prescription charges will consult a pharmacist in the case of athlete's foot due to the MAS. This is not the case for patients who are not exempt from prescription charges, as they are unaffected in terms of individual co-payment as well as additional MAS-induced consultation time at pharmacy and would therefore save the same amount before and after the implementation of the MAS (see Table 16).

The benefit for a patient exempt from prescription charges with a common **cold** who consults a pharmacist with the MAS in place instead of a GP amounts to around £ 8. If no MAS was established this benefit were £ 5.73 making it very likely from an economic point of view that more patients will consult a pharmacist in case of a common cold due to MAS. The same is true for exempt patients with **heartburn**, but at a considerably smaller scale. In the case of **cough**, however, no prescribable OTC products are available resulting in a lower relative advantage for the shifting patient as costs for medication remains the same with or without MAS in place but pharmacy consultation time is longer due to MAS requirements (such as registration, handling costs). For the case of **UTI**, for which it is evident that no OTC medication regardless of being prescribable or not exists, no additional pharmacy consultation time has been assumed. Therefore the average

savings of a shift from GP to pharmacy consultation only for exempt patients do not differ whether an MAS is in place or not.

To check the robustness of these results a parametric sensitivity analysis was conducted. The smallest and highest pharmaceutical (co-)payments were used for each ailment and the time at the pharmacy under the MAS was adapted to a minimum of 10 and a maximum of 15 minutes (Curtis 2014; Farnfield 2008). The findings presented above seem to be fairly robust to these changes, deviations of the upper and lower boundary with regard to the difference presented in the last column are due to the impact the alternated parameters (payments, time) have on a shift under the two observed scenarios, namely before and after the implementation of the MAS.

NHS Choices

NHS Choices has the goal to inform patients about their specific ailments and to increase health literacy in general, and consequently, to make patients more confident in taking care of themselves with or without the help of a health professional. However, from a patient's economic point of view there is no difference in the savings from seeing a pharmacist instead of a GP before and after NHS Choices has been implemented. For example, a patient with heartburn who is exempt from prescription charges safes around £ 6 by consulting a pharmacist instead of a GP regardless of whether NHS Choices has been implemented or not, because there is no change in the legislation regarding prescriptions which may impact her (co-)payments (see Table 17 below).

Table 17: NHS Choices: Average patient's savings who sees pharmacist instead of GP

		Average savings for patient due to shift from GP to pharmacy (in UK £) … (lowest; highest prices and time spent)		
	Minor ailment	**… without initiative**	**… with NHS Choices**	**Difference**
Patient exempt from prescription charges	Athlete`s foot	0.04 (1.81; -1.32)	0.04 (2.18; -1.88)	0.00 (0.37; -0.56)
	Cold	5.73 (7.59; 8.97)	5.73 (7.96; 8.41)	0.00 (0.37; -0.56)
	Cough	4.45 (5.98; 2.19)	4.45 (6.36; 1.63)	0.00 (0.37; -0.56)
	Heartburn	6.18 (7.28; 5.28)	6.18 (7.65; 4.72)	0.00 (0.37; -0.56)
	Urinary tract infection	8.97 (8.97; 8.97)	8.97 (9.34; 8.41)	0.00 (0.37; -0.56)
Patient obliged to pay prescription charges	Athlete`s foot	11.94 (13.44; 9.69)	11.94 (13.81; 9.13)	0.00 (0.37; -0.56)
	Cold	8.97 (8.97; 8.97)	8.97 (9.34; 8.41)	0.00 (0.37; -0.56)
	Cough	12.50 (14.03; 10.24)	12.50 (14.41; 9.68)	0.00 (0.37; -0.56)
	Heartburn	14.70 (15.33; 13.33)	14.70 (15.70; 12.77)	0.00 (0.37; -0.56)
	Urinary tract infection	17.02 (17.02; 17.02)	17.02 (17.39; 16.46)	0.00 (0.37; -0.56)

Despite these results, as already mentioned, there might be other than economic reasons why NHS Choices impacts a patient's decision to see a pharmacist instead of a GP. It has been shown in a user survey that users of NHS Choices are likely to decrease their physician visits (Murray et al. 2011; Nelson et al. 2010b).

Non-medical prescribing

The CBA of the NMP refers to pharmacist independent prescribing (PIP) only. Similar to the MAS, the saving effects of this initiative are based on the sensible assumptions that patients reduce their physician visits if they receive prescriptions for the same medicines from their pharmacist. This assumption is facilitated by the fact that the waiting time and hence the time spent at the encounter is lower at the pharmacy compared to a visit to the GP's office.

Table 18: NMP/PIP: Average patient's savings who sees pharmacist instead of GP

		Average savings for patient due to shift from GP to pharmacy (in UK £) … (lowest; highest prices and time spent)		
	Minor ailment	**… without initiative**	**…. with NMP/PIP**	**Difference**
Patient exempt from prescription charges	Athlete`s foot	0.04 (1.81; -1.32)	6.91 (7.47; 6.54)	6.87 (5.67; 7.85)
	Cold	5.73 (7.59; 8.97)	6.91 (7.47; 6.54)	1.18 (-0.11; -2,43)
	Cough	4.45 (5.98; 2.19)	6.91 (7.47; 6.54)	2.46 (1.49; 4.35)
	Heartburn	6.18 (7.28; 5.28)	6.91 (7.47; 6.54)	0.73 (0.20; 1.26)
	Urinary tract infection	8.97 (8.97; 8.97)	6.91 (7.47; 6.54)	-2.06 (-1.49; -2.43)
Patient obliged to pay prescription charges	Athlete`s foot	11.94 (13.44; 9.69)	6.91 (7.47; 6.54)	-5.02 (-5.96; -3.15)
	Cold	8.97 (8.97; 8.97)	6.91 (7.47; 6.54)	-2.05 (-1.49; -2.43)
	Cough	12.50 (14.03; 10.24)	6.91 (7.47; 6.54)	-5.59 (-6.56; -3.70)
	Heartburn	14.70 (15.33; 13.33)	6.91 (7.47; 6.54)	-7.79 (-7.85; -6.79)
	Urinary tract infection	17.02 (17.02; 17.02)	6.91 (7.47; 6.54)	-10.11 (-9.54; -10.48)

When comparing the savings from consulting a pharmacist instead of a GP with NMP/PIP in place to the potential savings without NMP/PIP it becomes obvious that especially patients who are exempt from prescription charges would benefit in the cases of **athlete`s foot, cold, and cough**. From an economic view it is therefore likely that more patients with these ailments who are exempt from prescription charges would shift to pharmacy consultations if NMP/PIP was implemented. For patients who are obliged to pay prescription charges consulting a prescribing pharmacist instead of a GP involves higher (co-payments) when compared to shifting from a pharmacist to a GP without NMP/PIP in place due to the assumption, that instead of receiving 2 OTC products when visiting a

regular pharmacist only, a prescribing pharmacist would hand out 1 OTC and 1 Rx product. Obviously, the prescription fee of £ 8.05 would be charged for the latter (see Table 18 above).

The sensitivity analysis shows that the results of all minor ailments assessed are fairly robust for both, exempt patients and patients obliged to pay prescription charges. As for the sensitivity analysis for MAS, the smallest and highest (co-)payments for pharmaceuticals were included. With regard to the time spent for consultation, the lower boundary was set at 15 minutes and the upper boundary at 20 minutes (British Columbia Pharmacy Association 2013).

4.4.2 Costs and benefits from the providers' and system's perspective

The following selected self-care initiatives will be assessed in terms of their benefits and costs from a provider's and system's perspective in order to identify which economic impacts an initiative-induced shift of a particular case from GP+pharmacy consultation to pharmacy consultation only has on various cost categories. With regard to the categories assessed (pharmacy training costs, pharmacy time costs, governance costs, costr related to medicine prices, remuneration of pharmacies, time savings to patients, cost savings from reduced GPs' time) the authors build on the evaluation schemes deployed by (Latter et al. 2010) and (Farnfield 2008). The attribution of the monetary categories to each perspective as well as its direction (cost or benefit) is presented in Table 4 in the methods section and represents the basis for the calculation of the net benefits (including an overall societal perspective) at the end of this chapter.

To identify the costs and benefits per shift case for each initiative, the authors built on various sources to ultimately come up with a robust model. In cases of assumptions and/or differing values found in literature lower and upper boundaries were defined for the parametric sensitivity analysis. For clarity reasons, the authors will start by presenting general assumptions as well as cost calculations for categories, which are relevant to all initiatives assessed (e.g. number of shifts, cost savings from GPs' time). Then specific cost calculations for each initiative are presented along with overall tables summing up costs and benefits per shift case for each initiative (Table 19-21) for 3 different scenarios with regard to the share of shifts (5% / 10% / 20% of current GP contacts due to minor ailments only).

General assumptions

Discounting of operating costs and savings

As the main results of the cost-benefit analysis are calculated on a case basis taking into consideration the economic effect of shift from GP and pharmacy contact (option 1: physician contact) to a pharmacy contact only (option 2: self-care with medication) from different perspectives (patients' perspective, providers' perspective, system's perspective and overall societal perspective) all operating costs as well as savings are calculated on an annual basis without discounting.

Initial training and infrastructure costs

Initial training costs (for NMP/PIP and MAS) are calculated on the basis of a sufficient share of pharmacies in the UK participating in the respective schemes (50% for the base scenario, 25% for the lower boundary and 75% for the upper boundary) in order to ensure sufficient access for the targeted population - number of pharmacies taken from

Croft 2013 - with one pharmacist trained in each pharmacy. As these training costs can be regarded as an initial investment, these costs are divided by the factor 10 (lower boundary 20) to derive annual training costs assuming that after ten years, new pharmacists have to be trained due to turnover and/or retirements or for those a training update is required to account for new developments.

As the mere costs of the initiatives *before* the actual establishment are regarded, already existing infrastructure (such as trained pharmacists or IT infrastructure) is not taken into account and has therefore no (diminishing) impact on infrastructure costs.

Number of shifts

In order to derive the effective operating costs of the initiatives analysed on a case basis, it is necessary to assume a plausible number of overall shifts due to the implementation of a particular self-care initiative. According to the IMS estimates for England presented by Farnfield 2008, approximately 51,4 million visits to the GP can be attributed to minor ailments only resulting in roughly 1 GP consultation per inhabitant and year (in fact, for 2007 the mid-year population estimate for England equalled to 51,4 million persons (Wright 2010)). These findings are also in line with Yadav 2008 who estimates that 18% of GPs' time is spent for the treatment of minor ailments. Assuming that the consultation time does not vary significantly between minor ailments and other diseases dealt in general practice, the number of approximately 300 million GP consultations in England (Gregory 2009) would translate into 54 million visits due to minor ailments. The authors therefore assumed, that overall 50 million GP visits were conducted in England in order to seek relief from a minor ailment only and could potentially be substituted by a pharmacy contact (option 2: self-care with medication).

Regarding the number of shifts, we estimate for each initiative that for the base scenario 10 % (5 million cases) of the consultations at GP for minor ailments will shift to self-care with medication resulting in a pharmacy encounter only. This assumption is rather conservative compared to Farnfield 2008 who assumes that for the case of a MAS that up to 50% of the consultations due to minor ailments of the population exempt from prescription charges (61% of total population in England) would shift if fully operational after the third year resulting in an overall number of shifts of approximately 15,7 million cases. However, for the first year (Farnfield 2008) assumes a shift of only 20% of the population exempt for prescription charges resulting in approximately 6,3 million GP consultations was effectively avoided. With regard to NHS choices, the assumption of 10% shifted consultations is supported by Nelson et al. 2010b who concluded, based on an empirical enquiry, that with the increased use of NHS choices 5.7 million GP consultations can be saved.

As participation rates in terms of shift cases for all the initiatives assessed appear to have a major impact on the cost-benefit ration, the results for the assumption of 5 % of the minor ailment cases (lower boundary) as well as 20% of the minor ailment cases (upper boundary) shifting are also presented in the subsequent summary of findings. With regard to the combination of initiatives (e. g. implementation of a MAS and NMP for pharmacists) it has to be noted, that participation rates are unlikely to sum up to the full share of each initiative if introduced exclusively in a setting, where no other self-care initiative is in place yet.

Medicine costs

Average additional savings or costs with regard to (co-)payment for pharmaceuticals are included on an ailment-specific basis with distinction whether the patient is exempt from prescription charges or not. The corresponding results are taken from the authors' own calculations as presented in the section "*Costs and benefits from patient's perspective"* and are presented in detail Annex 12 for each initiative assessed.

Time savings to patients

Time savings to patients are estimated on the basis of the average time saved due to the avoided physician encounter (11.7 minutes) and the average additional time spent in pharmacy due to requirement posed by the initiative (for MAS and NMP/PIP) and/or consultation time. The time saved is priced using the median hourly earnings on the UK of £ 11.21 £ (Levy 2013). As for medicine costs the calculations are taken from the tables 1-5 in Annex 11 for each initiative assessed.

Cost savings from reduced GPs' time

In the UK, the costs of the outpatient treatment by a general practitioner or physician (incl. diagnosis) are assumed to be around £ 36 as on average a physician spends 11.7 minutes on a patient and earns £ 3.1 per minute (Curtis 2012). Consequently, if a patient suffering from a minor ailment decided to consult the pharmacist immediately (option 2) instead of visiting the GP prior to the pharmacy encounter (option 1), resources at the level of £ 36 are freed which can either be used for efficiency gains or adjustment in the provision of GPs.

Non-monetary benefits and costs

Possible non-monetary benefits to patients such as improved access to treatment for different income, age or ethnic groups as well as possible non-monetary costs to patients such as differences in pain relief due to different medication (Rx vs. OTC) have not been monetised.

Minor ailment scheme

The specific cost categories for the MAS have been derived as follows:

Pharmacy training costs

Course fees for training on MAS have been assumed to amount to £ 100 for each pharmacy (Farnfield 2008) (£ 120 for the upper boundary (Philips et al. 2001), £ 100 for the lower boundary). With regard to time costs due to training, we estimated based on (Aiello 2013) that training time would amount to 25,5 hours (including one 8-hours training course and 3 evening shifts (6,5 hours each)). Costs per community pharmacist hour were set in line with (Curtis 2012; Latter et al. 2010) at £ 64 per hours with £ 51 for the lower boundary and £ 71 for the upper boundary resulting in total training costs for community pharmacies at £ 1,732 (£ 1,401; £ 1,931).

Pharmacy time costs

As shown in Table 19 it is assumed, that the average time spent at encounter when receiving consultation under a MAS equals to the average surgery consultation and is therefore set at 12 minutes (10 minutes for the lower boundary and 15 minutes for the upper boundary (Curtis 2012; Farnfield 2008). Taking into consideration the average time costs for a community pharmacist, additional operating cost for a shift case under the MAS regime (as compared to a 5 minute time span for a regular pharmacy encounter with prescription (May/Bauer 2013)) amount to £ 7.47 (4.25; 11.83).

Governance costs

Governance costs (i.e. costs for operating the scheme in terms of overall promotion, clinical supervision and financial governance) are set based on the estimations of (Farnfield 2008) at a level of £ 6.8 million.

Remuneration of pharmacies

Remuneration of pharmacies participating in the MAS are estimated on a consultation basis and are subject to the concrete arrangement of the various MAS in place. The authors set the level of £ 3.50 per MAS consultation as presented by (Aiello 2013) as a base scenario with £ 3.00 remuneration for the lower boundary and £ 4.50 for the upper boundary (Ailments 2014; Baqir et al. 2011; Paudyal et al. 2013; The National Pharmaceutical Association Limited 2003).

Table 19: MAS: Summary of costs and benefits per shift case

			Summary of costs and benefits per shift case (in UK £) … (lower boundary; upper boundary)		
	Share of shifts		**5%** (n=2,500,000)	**10%** (n=5,000,000)	**20%** (n=10,000,000)
Costs	Pharmacy training costs		0.40 (0.08; 0.67)	0.20 (0.04; 0.33)	0.10 (0.02; 0.17)
	Pharmacy time costs		7.47 (4.25; 11.83)		
	Governance costs		2.72 (2.72; 2.72)	1.36 (1.36; 1.36)	0.68 (0.68; 0.68)
	medicine costs: Patient exempt from prescription charges	Athlete`s foot	1.24 (0.00; 4.38)		
		Cold	0.00 (0.00; 0.00)		
		Cough	4.52 (2.99; 6.78)		
		Heartburn	1.84 (1.69; 3.69)		
		Urinary tract infection	0.00 (0.00; 0.00)		
	medicine costs: Patient obliged to pay prescription charges	Athlete`s foot	-2.97 (-4.47; -0.72)		
		Cold	0.00 (0.00; 0.00)		
		Cough	-3.53		

			Summary of costs and benefits per shift case (in UK £) … (lower boundary; upper boundary)		
	Share of shifts		**5%** (n=2,500,000)	**10%** (n=5,000,000)	**20%** (n=10,000,000)
			(-5.06; -1.27)		
		Heartburn	-5.73 (-6.36; -4.36)		
		Urinary tract infection	-8.05 (-8.05; -8.05)		
	Remuneration of pharmacies		3.50 (3.00; 4.50)		
Benefits	Non-monetary benefits		- (not monetised)		
	Time savings to patients		8.03 (8.41; 7.47)		
	Cost savings from reduced GPs' time		36.27 (36.27; 36.27)		

The costs of MAS in England were estimated in a partial impact assessment by the Department of Health in 2008. The pharmacy training and governance were estimated to employ one-off costs of £ 1 Mio, and annual costs of £ 6.8 Mio (Farnfield 2008).

The total savings associated with the MAS equals the costs for the share of patients who would use the MAS (potential "shifters", p) but go to a GP if the initiative has not been established[13]. The total costs equal the capital operating costs of the service plus the consultation fees that are paid to the pharmacists per consultation multiplied by the number of patients that might use the service.

NHS Choices

The specific cost categories for NHS Choices have been derived as follows:

Pharmacy training costs

Not applicable.

Pharmacy time costs

As shown in Table 20, average time spent at encounter when receiving consultation at a pharmacy after having consulted the internet-based services offered by NHS Choices was assumed to equal the average pharmacy consultation when handing out OTC-medication (May/Bauer 2013). With regard to the lower boundary, the consultation time was set to the level of average consultations when handing out Rx-medication (5 minutes (May/Bauer 2013)) assuming that well informed patients might be able to articulate their needs in a better way hence saving time at an OTC-encounter. For the upper boundary the average consultation time was set to 10 minutes reasoning that patients having already consulted NHS Choices may have more specific needs which may draw on a larger share of the pharmacist's time. Including average time costs for the pharmacist,

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Costs of Option 1 x share of patients who shifted from Option 1 to Option 2

additional operating costs for a shift case having consulted NHS Choices before the pharmacy encounter amount to £ 2.13 (0.00; 5.92).

Governance costs

Governance costs of the NHS Choice initiative are mainly associated with operating costs of the core services provided on the website (in particular information on conditions and treatments including the symptom checking algorithms as well as information health services and social care and support). Due to its nature of a web-based information portal these costs can be mainly regarded as fixed costs which decrease on an average basis when overall use of services rises. In terms of annual costs for the internet-based NHS Choices services (Murray et al. 2011) estimate the overall level at around £ 25 million. NHS Choices itself published some information on costs in the 2011 annual report stating that an average visit to the NHS Choices costs 12p (NHS Choices 2011). Taking into consideration overall monthly user numbers for the same period (on average 10 million users) it can be derived that operating costs for NHS choices would annually equal £ 14.4 million. We therefore assumed for the base scenario annual governance costs for NHS Choices at the amount of £ 15 million and included the figure estimated by (Murray et al. 2011) in the sensitivity analysis for the upper boundary (for the lower boundary we applied the base scenario).

Remuneration of pharmacies

Not applicable.

Table 20: NHS Choices: Summary of costs and benefits per shift case

			Summary of costs and benefits per shift case (in UK £) … (lower boundary; upper boundary)		
	Share of shifts		**5%** (n=2,500,000)	**10%** (n=5,000,000)	**20%** (n=10,000,000)
Costs	Pharmacy training costs		n/a		
	Pharmacy time costs		2.13 (0.00; 5.92)		
	Governance costs		6.00 (6.00; 10.00)	3.00 (3.00; 5.00)	1.50 (1.50; 2.50)
	medicine costs: Patient exempt from prescription charges	Athlete`s foot	8.93 (7.16; 10.28)		
		Cold	3.23 (1.38; 0.00)		
		Cough	4.52 (2.99; 6.78)		
		Heartburn	2.79 (1.69; 3.69)		
		Urinary tract infection	0.00 (0.00; 0.00)		
	Medicine costs: Patient obliged to	Athlete`s foot	-2.97 (-4.47; -0.72)		
		Cold	0.00 (0.00; 0.00)		

			Summary of costs and benefits per shift case (in UK £) … (lower boundary; upper boundary)		
	Share of shifts		**5%** (n=2,500,000)	**10%** (n=5,000,000)	**20%** (n=10,000,000)
	pay prescription charges	Cough	-3.53 (-5.06; -1.27)		
		Heartburn	-5.73 (-6.36; -4.36)		
		Urinary tract infection	-8.05 (-8.05; -8.05)		
	Remuneration of pharmacies		n/a		
Benefits	Non-monetary benefits		- (not monetised)		
	Time savings to patients		8.97 (9.34; 8.41)		
	Cost savings from reduced GPs' time		36.27 (36.27; 36.27)		

Non-medical prescribing

The specific cost categories for NMP/PIP have been derived as follows:

Pharmacy training costs

Course fees for training on NMP were taken from (Latter et al. 2010) and amount to £ 1,236 for each pharmacy. Regarding training time, we assumed in line with (Latter et al. 2010), that training for NMP requires in total 140 hours (40 hours face-to-face training and 90 hours distance learning in practice). Costs per community pharmacist hour were set as for MAS in line with (Curtis 2012; Latter et al. 2010) at £ 64 per hours (£ 51 for the lower boundary; £ 71 for the upper boundary). Total training costs for community pharmacies for medical prescribing therefore equal £ 10,223 (£ 8,403; 11,203).

Pharmacy time costs

As presented in Table 21, that average time spent at encounter when receiving consultation at a pharmacy including NMP was observed to be 18 minutes (Latter et al. 2010). With regard to the estimates of (British Columbia Pharmacy Association 2013)the lower and upper boundaries for consultation length with NMP/PIP are set to 15 and 20 minutes respectively. With regard to the average time costs for a community pharmacist, additional operating cost for a shift case under the NMP/PIP regime (as compared to a 5 minute time span for a regular pharmacy encounter with GP prescription (May/Bauer 2013)) amount to £ 13.87 (£ 8.50; 17.75).

Governance costs

As no reliable information on governance costs (i.e. costs for operating the scheme in terms of overall promotion, clinical supervision and financial governance) was available, the authors reasoned, that governance costs of a comprehensive implementation of NMP/PIP in English pharmacies would equal the costs documented for the governance of a MAS. Due to increased supervisory requirements, this estimate can be deemed to be rather conservative.

Remuneration of pharmacies

Remuneration of pharmacies offering NMP do currently not appear to be in integral feature of NMP/PIP initiatives and are rather a matter of individual bargaining between the pharmacy and the initiative-operating entity. Moreover, participation rate of pharmacies offering NMP/PIP is currently quite low (17 out of 11,495 pharmacies in 2012/13 (Croft 2013)), that no further information on remuneration mechanisms and levels could be retrieved.

Table 21: NMP/PIP: Summary of costs and benefits per shift case

			Summary of costs and benefits per shift case (in UK £) … (lower boundary; upper boundary)		
	Share of shifts		**5%** (n=2,500,000)	**10%** (n=5,000,000)	**20%** (n=10,000,000)
Costs	Pharmacy training costs		2.35 (0.48; 3.86)	1.18 (0.24; 1.93)	0.59 (0.12; 0.97)
	Pharmacy time costs		13.87 (8.50; 17.75)		
	Governance costs		2.72 (2.72; 2.72)	1.36 (1.36; 1.36)	0.68 (0.68; 0.68)
	Medicine costs: Patient exempt from prescription charges	Athlete`s foot	0.00 (0.00; 0.00)		
		Cold	0.00 (0.00; 0.00)		
		Cough	0.00 (0.00; 0.00)		
		Heartburn	0.00 (0.00; 0.00)		
		Urinary tract infection	0.00 (0.00; 0.00)		
	Medicine costs: Patient obliged to pay prescription charges	Athlete`s foot	0.00 (0.00; 0.00)		
		Cold	0.00 (0.00; 0.00)		
		Cough	0.00 (0.00; 0.00)		
		Heartburn	0.00 (0.00; 0.00)		
		Urinary tract infection	0.00 (0.00; 0.00)		
	Remuneration of pharmacies		- (matter of individual bargaining)		
Benefits	Non-monetary benefits		- (not monetised)		
	Time savings to patients		6.91 (7.47; 6.54)		
	Cost savings from reduced GPs' time		36.27 (36.27; 36.27)		

4.4.3 Net benefits from patients', providers', system's and societal perspective

Table 22-24 ultimately presents the net benefits per shift case, which are realised when implementing one of the self-care initiatives assessed from a patients', providers', system's as well as societal perceptive. For clarity reasons, the results of the parametric sensitivity analysis were excluded from the illustration in the subsequent Tables 22-24. The calculations for the different share of shift cases (5%; 10%; 20%) were however included in the tables as the share of shift cases has shown to have a major impact on the overall effectiveness of self-care initiatives in particular of initial costs and/or fixed operating costs are high. Consequently, the authors also calculated the share of shifts necessary to gain a net positive benefit from a societal perspective. This "break even" share of shifts represents a valuable information for policy-makers, it indicates the benchmark for a successful implementation of self-care initiatives not only in technical terms but also in terms of sufficient user acceptance hence enabling the initiatives to nurture their expenditure-saving potential.

Minor ailment scheme

With regard to the implementation of a MAS, Table 22 shows, that from a societal perspective patient participation rates have to succeed 20% in order to show a positive net impact and would have to reach a target rate of 27.5% at least. At a level of 5% shift cases net benefit would be negative at an amount of £ -2.50 per case, at a level of 10% (base scenario) at an amount of £ -0.99 and at a level of 20% at an amount of £ -0.21 for each case shifted from GP+pharmacy encounter to pharmacy consultation only due to the MAS.

With regard to the patients' perspective, patients are better off shifting from GP contact + pharmacy consultation to pharmacy consultation only. As prescription fees amount to £ 8,05, patients obliged to pay prescription charges benefit on average from higher savings as consulting the pharmacist would only result in a delivery of 2 OTC-products (instead of 1 Rx and 1 OTC product). Consequently, patients not exempt from prescription charges benefit the most in the case of UTI (£ 16.08) whereas exempt patients receive the most moderate benefit in the case of cough (£ 3.52) for which no Rx medication is available.

Regarding the providers' perspectives, pharmacists are facing higher costs due to the implementation of a MAS because of a higher amount of time needed for consultations performed under the scheme (see Table 13) as well as due to training costs. The remuneration for pharmacies for providing MAS services on a case based basis (£ 3.00 – £ 4.50) does obviously not compensate for the total amount of the additional costs to pharmacies associated with the participation in the MAS. Overall, pharmacies are affected by a net negative benefit ranging from £ -4.07 to £ -4.36 for each shift case.

As far as physicians are concerned, the implementation of a MAS effectively leads to reduced physicians time hence leaving the physician in total worse off at the amount of £ 36.27 for each shift case. The immediateness of this impact, however, is depending on the payment mechanism applied: if, for instance, GPs are paid on a fee-for-service (FFS) basis or receive lump-sum payments for every patient contact, then a reduction of the physician's consultations, due to self-care initiatives, immediately results in a reduced income. If, on the other hand, physicians receive fixed budgets or salaries for performing their services, a reduction of GP consultations must not immediately lead to a net negative benefit for physicians. However, on the medium term, the health system is likely to adapt the capacities of GPs and use the freed resources for alternative uses (with a

higher benefit) ultimately resulting in a net negative benefit for GPs if regarded as a whole.

With regard to the system's perspective, it can be seen from Table 22, that the health system as a financing agent benefits from the implementation of a MAS. This is mainly due to – at least for the medium term – reduced GP payments for treating minor ailments. Furthermore, the changes in the distributed medication also impact the public payer's net benefit as due to the shift from 1 Rx and 1 OTC medication to 2 OTC medications only, the payer no longer benefits from prescription charges in the case of patient not exempt from prescription charges. With increasing participation rates the net benefit from a system perspective slightly increases due to the degression of fixed governance costs of the scheme. Overall, the net benefit various depending on the ailment as well as shift rate from £ 22.00 to £ 36.61 per shift case.

Table 22: MAS: Summary of net benefit per shift case

			Summary of net benefit per shift case (in UK £) …				
	Perspective		Patient	Provider (Pharmacy)	Provider (Physician)	System	**Society**
Share of shifts: **5%**	Patient exempt from prescription charges	Athlete`s foot	6.80	-4.36	-36.27	31.29	**-2.50**
		Cold	8.03			30.05	
		Cough	3.52			34.57	
		Heartburn	6.19			31.89	
		UTI	8.03			30.05	
	Patient obliged to pay prescription charges	Athlete`s foot	11.00			27.08	
		Cold	8.03			30.05	
		Cough	11.57			26.52	
		Heartburn	13.77			24.32	
		UTI	16.08			22.00	
Share of shifts: **10%**	Patient exempt from prescription charges	Athlete`s foot	6.80	-4.17	-36.27	32.65	**-0.99**
		Cold	8.03			31.41	
		Cough	3.52			35.93	
		Heartburn	6.19			33.25	
		UTI	8.03			31.41	
	Patient obliged to pay prescription charges	Athlete`s foot	11.00			28.44	
		Cold	8.03			31.41	
		Cough	11.57			27.88	
		Heartburn	13.77			25.68	
		UTI	16.08			23.36	

			Summary of net benefit per shift case (in UK £) …				
	Perspective		Patient	Provider (Pharmacy)	Provider (Physician)	System	Society
Share of shifts: **20%**	Patient exempt from prescription charges	Athlete`s foot	6.80	-4.07	-36.27	33.33	**-0.21**
		Cold	8.03			32.09	
		Cough	3.52			36.61	
		Heartburn	6.19			33.93	
		UTI	8.03			32.09	
	Patient obliged to pay prescription charges	Athlete`s foot	11.00			29.12	
		Cold	8.03			32.09	
		Cough	11.57			28.56	
		Heartburn	13.77			26.36	
		UTI	16.08			24.04	

Non-medical prescribing / pharmacist independent prescribing

Concerning the introduction of NMP, the net benefits for each case shifted are summarized in Table 23 from various perspectives. Regarding the societal level it has to be noted, that under the assessed effective shift rates of 5%, 10% and 20% of the minor ailment only GP consultations, net societal benefits is always negative ranging from £ -8.22 to £ -12.02. It is also remarkable, that even at an assumed rate of shift cases at the level of all (i.e. 100%) minor ailment GP consultations avoided, net societal benefits would still be negative (£ -7.21).

As far as the patients' perspective is concerned, one can derive from the figures presented in Table 23, that the medication dispensed as well as subsequent patients' (co-) payments are not affected by the introduction of NMP. These findings are in line with table 15, as from a medication perspective it does not make a difference whether the patient receives Rx medication with or without seeing the GP first. However, patients are likely to save some time to the avoided GP encounter if they decide to visit a NMP/PIP pharmacist instead, whereby some the time gained is counterweighted by increased pharmacy consultation time. Overall, our calculations show, that the patients' benefit from an average gain of £ 6.91 if shifting form a GP+pharmacy encounter to a NMP/PIP pharmacy consultation instead.

With regard to the providers' perspectives, pharmacists are facing substantially higher costs due to the implementation of NMP as consultation time increases and training costs have to be factored in. Overall, pharmacies are affected by a net negative benefit ranging from £ -14.45 to £ -16.22 for each case in which a patient decided to consult a NMP/PIP pharmacist instead of seeing the GP first. As pointed out above, evidence for the remuneration of NMP/PIP pharmacists on a case-base was insufficient, which could in theory counterbalance the net negative impact to pharmacies on the account of the system's perspective, as this would most likely result in a transfer of funds from the health system to the pharmacies.

Regarded from a physicians' perspective, again GPs are affected by fewer consultations due to the share of patients visiting a NMP/PIP pharmacy instead of a GP, as triggered by the initiative (negative net benefit of £ 36.27 per shift case). The immediateness of the

economic impact on GPs has already been discussed when presenting the results of the net benefits likely to be caused when implementing a MAS.

Table 23: NMP/PIP: Summary of net benefit per shift case

			Summary of net benefit per shift case (in UK £) ...				
	Perspective		Patient	Provider (Pharmacy)	Provider (Physician)	System	**Society**
Share of shifts: **5%**	Patient exempt from prescription charges	Athlete`s foot	6.91	-16.22	-36.27	33.55	**-12.02**
		Cold					
		Cough					
		Heartburn					
		UTI					
	Patient obliged to pay prescription charges	Athlete`s foot					
		Cold					
		Cough					
		Heartburn					
		UTI					
Share of shifts: **10%**	Patient exempt from prescription charges	Athlete`s foot	6.91	-15.04	-36.27	34.91	**-9.49**
		Cold					
		Cough					
		Heartburn					
		UTI					
	Patient obliged to pay prescription charges	Athlete`s foot					
		Cold					
		Cough					
		Heartburn					
		UTI					
Share of shifts: **20%**	Patient exempt from prescription charges	Athlete`s foot	6.91	-14.45	-36.27	35.59	**-8.22**
		Cold					
		Cough					
		Heartburn					
		UTI					
	Patient obliged to pay prescription charges	Athlete`s foot					
		Cold					
		Cough					
		Heartburn					
		UTI					

As far as the perspective of the health system is concerned, it can be derived from Table 23 that overall the health system in its role as a financing agents benefits from consultations shifted from GP-pharmacy to pharmacy only under the regime of NMP (net benefit ranging from £ 33.55 to 35.59). This benefit is foremost due to the savings generated by avoided GP contacts adjusted for a small share of governance costs, which regress with higher participation rates.

NHS Choices

Concerning the introduction of an internet-based information portal such as NHS Choices, Table 24 shows that from a societal perspective a positive net benefit is generated for all the assessed levels of shift cases (5%; 10%; 20%) ranging from £ 0.83 to £ 5.33 for each shift case. In fact, a minimum shift rate of 4.4% is required in order to result in a positive net benefit.

With regard to the patients' perspective, patients are better off from shifting from GP contact + pharmacy consultation to pharmacy consultation only, even though the benefits are smaller in particular for patients exempt from prescription charges as compared to the other initiatives assessed above. As for the minor-ailment scheme, a patient obliged to pay prescription charges benefit to a larger extend from a shift to pharmacy consultation only as (co-)payments for 2 OTC medications tend to be lower than the prescription charge for 1 Rx product plus the price for 1 OTC product. Overall patients' net benefits vary on an ailment and prescription exemption basis and range from £ 0.04 (athlete's foot for exempt patients) to £ 17.02 (UTI for patients obliged to pay prescription charges).

Concerning the providers' perspective, pharmacists are facing slightly higher costs (£ -2.13 loss of net benefit) due to the implementation of an internet based information portal as the time needed for consultations increases (see Table 13). With regard to the results of the sensitivity analysis it has to be kept in mind, though, that for the lower boundary no additional consultation time is assumed hence leaving the pharmacists unaffected.

With regard to the physicians' perspective, the introduction of NHS choices again leads to reduced physicians time in the case of shifts from GP+pharmacy (option 1) to pharmacy consultations only (option 2) hence leaving the physician in total worse off at the amount of £ 36.27 for each shift case.

As far as the system's perspective is concerned, it can be shown, that the health system benefits from the effective introduction of NHS choices quite substantially (in fact exceeding the net benefits attainable by the implementation of MAS or NMP/PIP). This is mainly due to two mechanisms: first, and as for all the other initiatives assessed the health system benefits from reduced GP time resulting in lower expenditure for GP services and/or higher efficiency of service delivery. Second, for the particular case of NHS Choices, the health system saves expenditure on medication, if a patient exempt from prescription charges decides to consult a pharmacist directly without corresponding prescriptions hence paying the full price for the OTC products handed out. Moreover, overall fixed operating costs for running the NHS choices service regress with increasing participation rates ultimately resulting in a range of net benefits to the health system between £ 22.22 (urinary tract infection for patient not exempt from prescription charges at an overall shift rate of 5%) and £ 43.70 per shift case (athlete's foot for exempt patients at 20% shift rate).

Table 24: NHS Choices: Summary of net benefit per shift case

			Summary of net benefit per shift case (in UK £) …				
	Perspective		Patient	Provider (Pharmacy)	Provider (Physician)	System	**Society**
Share of shifts: **5%**	Patient exempt from prescription charges	Athlete`s foot	0.04	-2.13	-36.27	39,20	**0.83**
		Cold	5.73			33,50	
		Cough	4.45			34,79	
		Heartburn	6.18			33,06	
		UTI	8.97			30,27	
	Patient obliged to pay prescription charges	Athlete`s foot	11.94			27,30	
		Cold	8.97			30,27	
		Cough	12.50			26,74	
		Heartburn	14.70			24,54	
		UTI	17.02			22,22	
Share of shifts: **10%**	Patient exempt from prescription charges	Athlete`s foot	0.04	-2.13	-36.27	42,20	**3.83**
		Cold	5.73			36,50	
		Cough	4.45			37,79	
		Heartburn	6.18			36,06	
		UTI	8.97			33,27	
	Patient obliged to pay prescription charges	Athlete`s foot	11.94			30,30	
		Cold	8.97			33,27	
		Cough	12.50			29,74	
		Heartburn	14.70			27,54	
		UTI	17.02			25,22	
Share of shifts: **20%**	Patient exempt from prescription charges	Athlete`s foot	0.04	-2.13	-36.27	43,70	**5.33**
		Cold	5.73			38,00	
		Cough	4.45			39,29	
		Heartburn	6.18			37,56	
		UTI	8.97			34,77	
	Patient obliged to pay prescription charges	Athlete`s foot	11.94			31,80	
		Cold	8.97			34,77	
		Cough	12.50			31,24	
		Heartburn	14.70			29,04	
		UTI	17.02			26,72	

4.4.4 Discussion of the results of the CBA

In this final section on the cost-benefit analysis the authors will briefly discuss the main findings of the CBA and will also focus on its methodological as well as conceptual limitations which have to be borne in mind when interpreting the results.

Limitations

As pointed out in the methods section, the developed CBA is – as any other CBA – based on a number of assumptions, which are important in order to come up with an operational framework, but must not necessarily be met in practice.

The first fundamental assumption relates to the fact, that all the assessed minor ailments are self-limiting by nature and that the effectiveness of the medication handed out is the same regardless whether Rx or OTC products are used. In fact, as sickness leaves due to minor ailments are excluded in the model and as we have decided in line with Farnfield 2008 not to monetise non monetary patient benefits or costs (such as harm caused by longer periods of pain), it is irrelevant in terms of the health outcome, whether a patient suffering from one of the selected minor ailments choses to visit a GP (option 1) or decides to rely on self-care with (option 2) or without medication (option 3).

This assumption, though, might be challenged as there is some evidence, that minor ailments may also lead to sickness leaves (Bramley et al. 2002). Moreover, at least for the case of urinary tract infection but also with regard to the other minor ailments assessed, it is very likely that different treatment options might at least result in different sequences of pain relief hence also impacting individual productivity. On the other hand, systematic evidence for the impact of minor ailments on productivity as well as for the effectiveness of the various medication included in the study is heterogenous (see also chapter 4.2); so the authors ultimately felt more confident assuming equal levels of effectiveness for all three options and not factoring in non monetary costs.

The second assumption which has to be scritinized is included in the conceptualization of the model: As indicated above, a patient suffering from a minor ailment faces three treatment options: (1) physician contact, (2) self-care with medication and (3) self-care without medication. In the case of the implementation of one of the analysed self-care initiatives, a change in the patient's behaviour only takes place from option 1 to option 2. This can be reasoned by the mere mechanism of the initiatives assessed, which for the case of MAS and NMP/PIP effectively intends to replace GP visits caused by prescription considerations with pharmacy encounters. However, as pharmacy encounters may be easier to access for patients (no need to arrange appointment, fewer waiting times), self-care initiatives might also excert some impacts on patients, who originally decided the conduct self-care without medication hence resulting in shift cases from option 3 to option 2. Ultimately, the internet information provided by NHS choices might have a similar impact incentivicing patients to consult a pharmacy instead of doing nothing, as patients are informed on treatment options they would not have considered prior to consulting NHS choices.

From a methodological point, thus, the authors were also well aware of the relevance of this second shift scenario (from option 3 to option 2). With regard to the available data, however, it was not possible to extract sufficient and/or consistent information of the prevalence of minor ailments in general and the share of each treatment option in particular, which would have been a prerequisite for integrating this second scenario in the cost-benefit analysis. Consequently, the authors decided to only include shifts from

treatment option 1 to treatment option 2 in the CBA, as valid information could be identified for the number of patients visiting a GP due to minor aiments only allowing for the calculation of a minimum share of shift cases required for each initiative in order to generate a societal net benefit (if feasable).

The third fundamental assumption of the CBA conducted is related to the average number and type of pharmaceuticals prescribed or handed out if one decided to visit a GP (option 1) or a pharmacy only (option 2). Based on the (scarce) evidence presented in literature (Ashworth et al. 2005; Fischer 2003; May/Bauer 2013; Pillay et al. 2010) we reasoned, that on average 2 products are dispensed to the patient in case he or she suffered from a minor ailment. Moreover, we assumed, that if the patient visited a GP (or an independent pharmacy prescriber), 1 Rx and 1 OTC product would have been prescribed instead of 2 OTC products if he or she had contacted the pharmacy only (all assumption for the case, that OTC and Rx products are available for a particular minor ailment; for details see table 15).

In the first draft, the authors also considered to ailment-specifically adjust the number and type of medication. However, due to lacking data in particular on the medication handed out in pharmacies for a particular minor ailment we decided to rely on the approximation of 2 items prescribed or handed out bearing in mind, that both different (co-)payments and their mere number for a particular medication has an impact, in particular, on the net benefits generated on the patients' and system's level.

The forth relevant assumption is also linked to the issue of medication and becomes evident when presenting the results of the CBA from a patients perspective. With regard to the average savings a patient would generate if he decided to shift from option 1 (GP visit) to option 2 (self-care with medication), the authors compare two different shift scenarios: without and with the initiative assessed in place (Tables 16-18). This differential analysis of the effects of a particular self-care initiative from a patients' perspective is of relevance when it comes to the interpretation of the results and takes into consideration the fact that a patient is free to opt for self-care with medication instead of a GP consultation even if there is no self-care initiative in place. Consequently, if one wants to assess the additional benefit a particular self-care initiative might have for a patient suffering e.g. from athlete's foot, one cannot simply derive this effect by solely regarding a shift from option 1 to option 2 with the particular self-care initiative in place. Instead, it has to be assessed how much the patient may be better or worse off, if he or she performs the shift under the conditions of the particular self-care initiative as opposed to a shift in scenario of no self-care initiative in place.

Apart from these four major assumptions presented above, some further limitations have to be kept in mind when interpreting the results of the CBA:

First, it is assumed, that all the self-care initiatives assessed are exclusively effective with regard to minor ailments. This means, that only GP consultation which are due to minor ailments are avoided leaving other GP contacts unaffected. However, for all three initiatives assessed cases might be created, in which patients decide to conduct self-care with medication instead of visiting a GP even if they suffer from a more severe disease, which would actually require a GP contact. Due to unsufficient evidence, this potential non-monetary harm was not explicitely included into the analysis. As patients are known to adapt their behaviour quite irrationally (Loewenstein et al. 2012) it has to be kept in mind though, that the implementation of a self-care initiative might also distract those patients who suffer from more serious disease from visiting a GP.

Second, the results of the CBA presented above are highly context specific. Of course, this does not come as a suprise and is at least somewhat balanced by the sensitivity analysis performed. On the other hand, it has to be kept in mind, that reimbursement mechanisms of prescription charges and other co-payments for pharmaceuticals are, in particular, a matter of constant change and highly impact the findings as presented in the CBA from patients' and system's perspectives. Take for instance the regulation on prescription charges with regard to Rx products with lower prices than the level of the prescription fee (currently 8.05). In the current study, we assumed that patients had to pay the full prescription charge regardless of the actual price of the Rx product hence subsidising the NHS if the price of the medication prescribed is lower than the prescription fee. Moreover, we also excluded alternative payment mechanisms for prescriptions charges, such as prepayment certificates, from our analysis as this would have led to increased complexity and less clear-cut results.

Also, the initiatives assessed are very specific, as MAS and to a lesser extent NMP/PIP are often being implemented regionally allowing for a number of variations in the mere governance of the schemes as well as remuneration. It therefore has to be kept in mind that the purpose of this cost-benefit analysis was to provide an assessment framework for generic self-care initiatives, which can´then be adapted and supplemented if particular other initiatives are to be assessed (also in contexts other than the UK). As such, it was essential, the come up with a rather universial cost-benefit analysis (see Tables 19-21) which accounts for the relevant cost components on the one hand and makes the basic assumptions in terms of the costs calculated transparent and also consistent on the other hand.

Ultimately it has to be noted that, with regard to the limitations of the cost benefist analysis, the results are only calculated for one particular self-care initiatve implemented on a large-scale national basis (in this case: throughout England). If countries decide to implement a combination of self-care initiatives, then a number of effects would overlap; with regard to user participation rates it might be also questionable, if the full potential of shift cases for each initiative - if regarded isolated - equals to the potential of the initiative if implemented alongside another initiative already in existence for a sufficient period of time.

Results of the CBA

With regard the results of the cost-benefits analysis, a number of key findings have to be discussed:

First, and despite the fact, that all the initiatives assessed in the CBA were England-based, the availability of data was a critical issue. With regard to various cost assumptions and estimates, the authors benefited from unit costs available for health and social care (Curtis 2012) and also prices for pharmaceuticals could be distracted by the authors' own run pharmaceutical price information system (Gesundheit Österreich GmbH n.d.). However, whenever the authors faced unsufficient data (in particular on the pravelence and treatment of minor ailment), assumptions had to be made in order to conduct the CBA as intended.

Second, the status of the patient in terms of exemption from prescription charges or not has an essential impact on the results of the CBA for MAS and NHS Choices. As it is assumed, that patients in general receive 1 OTC and 1 Rx product if they decide to visit a GP (option 1) and 2 OTC products if they decide to opt for self-care with medication (option 2), patient not exempt from prescription charges tend to benefit more from a shift

to pharmacy consultation only as on average OTC products are priced below the level of current prescriptions charges for England. With regard to the MAS, it has to be borne in mind, though, that patients not exempt from prescription charges are explicitely targeted only by some schemes and that the rational of MAS is rather geared towards the avoidance of GP consultations, which are currently held as the patient exempt from prescription charges needs a prescription in order to obtain the medication needed free of charge (Baqir et al. 2011). For the case of NMP/PIP, a shift case under this self-care initiative does not lead to a change in medication; consequently patient exempt from prescription charges as well as patients obliged to pay prescription charges benefit from time savings but not from reduced (co-)payments for medication.

Third, the availability of Rx and/or OTC medication for specific minor ailments as well as for the case of OTC medication the question, whether this medication can be reimbursed for exempt patients - if prescribed or handed out under a MAS - has an impact on the fact, whether a patient is prone to higher or lower out-of-pocket payments for pharmaceuticals (see medicine costs as listed in Table 19 and 20). Generally speaking, NHS choices lead to the highest increase in out-of-pocket payments for pharmaceuticals for the population exempt from prescription charges whereas this effect is somewhat mitigated within the MAS as reimbursable OTC-products are usually covered by the scheme. For the case of patients not exempt from prescription charges, medicine costs except for the case of cold, for which no Rx medication is available, tend to decrease if they shift from GP consultation to self-care with medication.

Fourth, evaluations of self-care initiatives (including cost-benefit analysis) are rather scarce. For the development of the CBA the authors mainly relied on the methodological approaches devised by Farnfield 2008, Latter et al. 2010, Nelson et al. 2010a, with the latter two representing officially mandated evaluation studies of a broader scope whereas Farnfield 2008 can rather be classified as grey literature representing an internal CBA to the DoH with regard to the introduction of a nationwide MAS. Even though the authors finally felt quite confident for the CBA and were able to identify at least two different sources for most cost components (at similar scales), it still appears that the conduction of a cost-benefit-analysis as well as an overall evaluation in general is rather the exemption than the norm if a particular self-care initiative was to be implemented.

Fifth, with regard to the overall identified societal benefit of the self-care initiatives assessed, it can be concluded, that the more elaborated an initative appears to be in terms of handling at a pharmacy level as well as in terms of its governance, the less likely the initiative will achieve a positive net societal impact. In terms of the MAS, it appears to be possible, that increased patient benefit tends to outweigh relatively modest training and operating costs on a pharmacy level with increasing levels of shift rates. With regard to the "brake-even" participation rate of 27.5% it has to be borne in mind, however, that almost half of the patients exempt from prescription charges would have to decide to participate in the MAS and effectively shift from GP contact to self-care with medication if they would exclusively suffer from a minor ailment next time.

Regarding NMP handling costs and in particular time and training costs to pharmacies currently appear to be too high in order to promote widespread adoption of pharmacist independent prescribing but also in order to contribute to a positive net societal benefit as a whole. For the case of NHS Choices, however, net societal benefit appears to be positive even at a low rate of shift cases. This is mainly due to the fact, that NHS Choices does not require a high amount of adoption and/or investment at the pharmacist level on the one hand and features relatively low operating costs. Moreover NHS Choices appears to be the most attractive policy option from a system's perspective as it leaves the prescription

mechanism including the exemptions untouched hence resulting in average savings up to £ 43.70 per shift case.

4.5 Definition and assessment criteria for the best-practice of self-care (task 9)

Based on the knowledge gained from the analyses of self-care initiatives conducted in chapter "Analysis of self-care initiatives (task 7)" and the cost/benefit analysis in the previous chapter (task 8) of WP 1, following definition for best-practices in self-care is proposed:

A self-care initiative is defined as best-practice example if its reach, effectiveness, adoption, implementation, maintenance, accessibility and equity are regarded as high. Furthermore, the potential savings of the initiative estimated in the cost/benefit analysis are factored in.

Following this definition, the following assessment criteria and their definitions/operationalization can be used to identify best-practice examples of self-care initiatives:

- **Reach**: High user rates of people affected by minor ailments
- **Effectiveness**: The initiative is effectively facilitating and supporting self-care
- **Adoption**: The initiative is adopted in other settings and regions, respectively
- **Implementation**: Successful implementation of an initiative in a specific setting
- **Maintenance**: The initiative is successfully integrated into the formal system
- **Accessibility**: No potential barriers impede the utilisation of the initiative
- **Equity**: No socio-economic group is potentially excluded from participating/utilising the initiative's benefits
- **Cost-saving potential**: The initiative causes potential cost-effects on patients, providers, the health care system and/or the society as a whole

A Self-care initiative qualifies as candidate for best-practice if it fulfils this set of eight criteria (i. e. reach, effectiveness, adoption, implementation, maintenance, accessibility, equity and the potential savings caused by the initiative). Following these criteria, three European self-care initiatives were identified to comply with these criteria and can be regarded as best-practice initiatives (see Table 25):

- NHS Choices
- NMP/PIP
- MAS

Also, NHS 111 (formerly NHS Direct telephone service) was considered as best-practice, although no statements regarding its cost saving potential could be made at the time of the report (see methods section of Economic evaluation of self-care initiatives (task 8)). This decision can be justified by the assessment results of the non-monetary criteria (i.e. reach, effectiveness, adoption, etc.), which still indicate high relevance of telephone based initiatives in the field of self-care.

Table 25: Matrix of best-practices identified

Name of initiative	R	Eff	Ad	I	M	Acc	Eq	CBA				
								Pat	Sys	Prov Phar	Prov GP	Soc
NHS Choices	✓	✓	≈/?	✓	✓	≈/?	≈/?	✓/≈*	✓	≈	!	✓/≈
NHS 111	✓	?	≈	≈	✓	✓	✓	Cost data not available				
MAS	?	✓	≈	✓	✓	≈	✓	✓/≈*	✓	≈	!	≈
NMP/PIP	✓	✓	✓	✓	✓	✓/≈	?	✓/≈	✓	!	!	!

✓: high; ≈: moderate; ?: unclear; !: low

* higher benefit for patients exempt from prescription charges

R: Reach; Eff: Effectiveness; Ad: Adoption; I: Implementation; M: Maintenance; Acc: Access; Eq: Equity; CBA: cost benefit analysis; Perspectives: Pat: patient; Soc: society; Sys: system; Prov Phar: pharmacy provider; Prov GP: GP provider

There are some **general limitations and remarks** regarding the best-practice initiatives identified. As depicted in Table 25, all best-practices identified are UK-based, which may not show a true and accurate picture of European best-practice self-care initiatives. The results for best-practice initiatives are based on the information identified during the literature review (including a hand search for identifying relevant grey literature). Thus, this findings do not necessarily mean that the UK is the only European Member State developing best-practice initiatives in the field of self-care, only that initiative-specific evidence is available best for the UK.

4.6 Transferability of best-practices (task 11)

The following sections present the proposed methodology of transferability developed under WP 2, together with the results of a SWOT and risk analysis targeting the methodology proposed.

4.6.1 Methodology of transferability of best-practices

Step 1: Identification of best-practice self-care initiatives

The identification and selection of best-practices in self-care corresponds with the previous chapter "Definition and assessment criteria for the best-practice of self-care" (task 9) of WP 1. Thus, for avoiding repetition it is referred to Table 25 in the previous chapter.

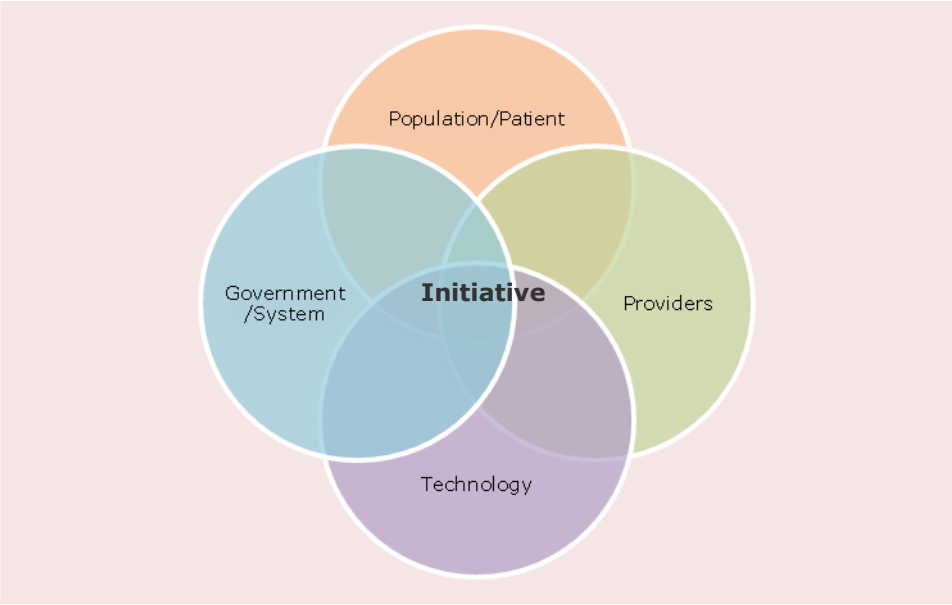
Step 2: Identification of the features and characteristics of best-practice self-care initiatives

In Step 2, each best-practice initiative will be analysed in terms of its features and characteristics. It should contribute to a better understanding of the initiatives and facilitate further analyses, since features and characteristics are the basis for assessing the feasibility of transferability. The assessment framework for this task is based on the WHO Health Systems Framework (WHO 2007) and a framework developed by (Simmons et al. 2007), and consists of four different dimensions (see Figure 10):

- **Population/Patient:** reflects those people who are addressed by the initiative

- **Providers**: covers directly involved providers as well as other health care providers (or stakeholders) affected by the initiative
- **Government/System**: includes issues related to governance, pharmaceutical policy and legal aspects
- **Technology**: reflects the medium used for encounter and accessibility, whereby time and place are issues to be addressed in this context.

Figure 10: Key features of best-practices



To identify the key features and characteristics of each dimension, several questions have to be considered with regards to each initiative assessed. An exemplary illustration of the assessment frameworks' applicability, thus a sketch of key features of NHS Choices, NHS 111, NMP/PIP and MAS is provided in Table 1 of Annex 15.

Table 26: Assessment framework for identification of initiative's key features and characteristics

Dimensions of initiatives		Questions for identifying key features (exemplary)
Population/ Patient	Population addressed	▪ Who is addressed by the initiative? ▪ Does the initiative target the total population? ▪ Does the initiative target explicitly a subgroup of the population? ▪ Does the initiative implicitly target a subgroup of the population?
Providers	Providers involved	▪ Who has to be involved for operating the initiative? ▪ What are the specific tasks for operating the initiatives? ▪ Are the providers of the best-practice initiatives centrally organised? ▪ Are the providers of the best-practice de-centrally organised? ▪ In case of de-centralised organisation of the providers, who is in charge of governance/control?
	Providers affected	▪ Who is affected by the best-practice initiatives? ▪ Is the effect positive? ▪ Is the effect negative?
Government/ System	Governance	▪ What tasks have to be performed from a governance perspective? ▪ Which mechanisms are in place to control undesired events/undesired effects/malfunctions
	Pharmaceutical policy	▪ Is the pharmaceutical reimbursement system relevant for the best-practice? ▪ What aspects of the pharmaceutical reimbursement policies are relevant for the best-practice initiative? ▪ Is the share of OTC products on the total pharmaceutical market relevant for the best-practice initiative? ▪ How easy/difficult is it to switch from POM to an OTC product? ▪ How are exemptions from prescription charges regulated? ▪ What products and/or specific population groups are exempt from prescription charges? ▪ What is the level of prescription charges in relation to the average OTC price?
	Legal aspects addressed	▪ What legal aspects are affected by the initiative? ▪ Are changes in professional law necessary? ▪ Does the initiative affect liability issues?
Technology	Medium of encounter and accessibility (time and place)	▪ By which medium is the encounter facilitated? ▪ How does the medium affect accessibility with regards to time? ▪ How does the medium affect accessibility with regards to place?

Step 3: Assessment of the feasibility of transferability

Based on Steps 1 and 2, the feasibility of best-practices' transferability is assessed. This step aims to examine the conditions that have to be met for a best-practice initiative to work well in the importing setting. Also in this step, an assessment framework (see Table 27) proves to be a helpful tool for identifying factors which support the success of self-care initiatives in the exporting setting. The assessment links the above mentioned four dimensions to other works in that field (Figueras 2014; Gyergyay/Boehler-Baedeker 2014; TURBLOG 2011) and covers three aspects:

1. Factors supporting policy success in the exporting setting (i.e. "**favourable conditions**"). The list of favourable conditions was derived from the initiative-focused literature review conducted for task 7 under WP 1. If necessary, decision-makers are recommended to adapt and complement factors supporting the initiative's success.
2. Assessment of the success factors' relevance in the exporting setting ("**relevance**"). The relevance of the different factors will be evaluated on three-range scale, consisting (1) High Relevance (H), (2) Medium relevance (M), and (3) Low relevance (L)
3. Assessment of the situation in relation to the success factors in the importing setting ("**feasibility**"). This aspect is country specific and aims to set the identified favourable conditions in relation to the context of the importing country. Three different situations are possible (1) high feasibility (H), (2) moderate feasibility (M), and (3) low feasibility (L).

Also for Step 2, an exemplary illustration of the assessment framework's applicability, thus a sketch of the feasibility assessment of the transferability of NHS Choices, NHS 111, NMP/PIP and MAS is provided in table 2 Annex 16.

Table 27: Assessment framework for the feasibility assessment of transferability

Dimensions of initiatives		**Favourable conditions in exporting setting (exemplary)**	**Relevance** ***exporting*** **setting**	**Feasibility** ***importing*** **setting**
Population/ Patients	**Population addressed**	▪ Universal approach of population addressed (without particular focus on subgroups) ▪ Universal approach focusing on subgroups (e.g. informal carers, patients, elderly, health literate, internet) ▪ Focus on one particular subgroup only (e.g. population exempt from prescription charges) ▪ *If relevant: Consideration of vulnerable groups and equality impacts* ▪ *...*		

Dimensions of initiatives		Favourable conditions in exporting setting (exemplary)	Relevance *exporting* setting	Feasibility *importing* setting
Providers	**Providers involved**	▪ Institutional capacity on operator level (e.g. central and/or de-central) ▪ Provision of training (e.g. pharmacists, telephone operators) ▪ Institutional capacity for training provision (e.g. professional bodies and/or formal education) ▪ ...		
Providers	**Providers affected**	▪ Cooperative relationship with relevant providers' professional organisation ▪ Limited influence of providers' professional organisation on political decision-making process ▪ Support/barrier of providers' professional organisation in the policy implementation ▪ ...		
Government/System	**Governance**	▪ Governmental capacity to promote (use of) initiative via various media ▪ Institutional capacity to govern initiative in terms of regulatory aspects and control ▪ Institutional capacity to govern initiative in terms of clinical supervision (e.g. patient safety issues) ▪ Institutional capacity to govern providers of professional training required ▪ ...		
	Pharmaceutical policy	▪ Share of OTCs covering relevant minor ailments (high vs. low) ▪ Sufficient accessibility of OTCs ▪ Sufficient affordability of OTCs ▪ Ease to switch from Rx products to OTC products ▪ High level of prescription charges ▪ High share of population exempt from prescription charges ▪ If relevant: Other allowances in place (e.g. co-payment limits) ▪ ...		
	Legal aspects addressed	▪ Distinct and transparent liability of operators/providers ▪ Clearly defined framework for professional competences (e.g. defined list of minor ailments, medicines to be dispensed) ▪ Sufficient/extended professional competencies for service providers ▪ ...		

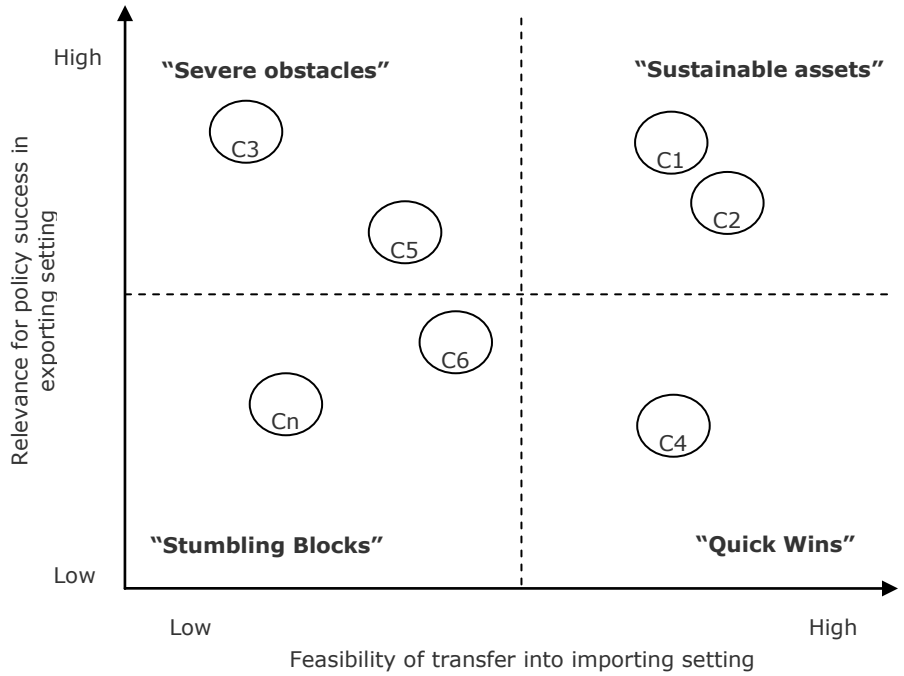
Dimensions of initiatives		Favourable conditions in exporting setting (exemplary)	Relevance *exporting* setting	Feasibility *importing* setting
Technology	**Medium of encounter and accessibility (time and place)**	▪ Sufficient access to ICT (e.g. internet, telephone) ▪ Sufficient ICT capacity ▪ Comprehensive participation at provider level (e.g. voluntary vs. legal enforcement) ▪ Comprehensive accessibility of service at operator/provider level (e.g. operating/opening hours according to patient needs) ▪ ...		

Step 4: Deduction of Policy Options

Based on the findings of Steps 1-3, results can be translated into a strategic mapping. The basic framework for the strategic mapping is based on the assessment schemes suggested by (McLaughlin/McLaughlin 2008) (see

Figure 11).

Figure 11: Strategic mapping of initiative-relevant conditions



C1, C2, C3... Cn: Initiative-relevant conditions

Figure 11 depicts four quadrants relevant for the identification of suitable policy options for each condition addressed:

- **"Sustainable assets":** comprising those conditions of a particular self-care initiative, which have been identified as being relevant for its success in the exporting setting and which are also deemed to be in place in the importing context. Thus, these factors have the potential to strongly promote the effectiveness if an initiative is going to be transferred.
- **"Quick wins":** including those conditions, which have a low impact on the initiative's success in the exporting context but are in place in the importing country. Thus, these conditions could facilitate the transfer of initiatives, but it is unlikely that they contribute to sustainable success of the transferred initiatives.
- **"Stumbling Blocks":** describing conditions of low relevance for policy success in the exporting setting and are of low feasibility in the importing setting. Consequently, these conditions may have the potential to – but not necessarily must - impede the successful transfer of a particular self-care initiative. From a policy perspective, such conditions demand high attention. It is possible to transfer initiatives with a number of less relevant conditions not met in the importing setting. However, policy-makers have to be aware that less relevant conditions, which are not managed properly might also turn into relevant factors seriously compromising policy success.
- **"Severe obstacles":** containing conditions which have been identified to be of high relevance for initiative success in the exporting context but are not in place in the importing setting. In terms of policy options, alternative approaches can be considered. One option is adapting the initiative to be transferred in order to decrease the relevance if the conditions identified are unfavourable in the importing setting. The second option is to adapt the context in the importing setting in order to increase the feasibility of the conditions in the importing context. It is evident, that the second approach of changing the importing context is more time consuming and poses also higher challenges in terms goal attainment. However, if the initiative to be transferred cannot be adapted easily or if the adaption would change or even alienate its intended effects, it appears advisable to assess the second policy option. If the latter turns out to be unattainable either, successful transfer of the self-care initiative is not possible.

4.6.2 SWOT and risk analysis

The second part of task 11 refers to conducting a SWOT and risk analysis for assessing and critically reflecting the feasibility of the methodology for transferability proposed. The results of the **SWOT analysis** are depicted in Table 28.

Table 28: Results of the SWOT analysis

		Positive aspects		Negative aspects

Internal factors	Strengths	▪ **Initiative sensitive** and **context sensitive** approach
		▪ Incorporation of **stakeholders' claims and issues** possible due to analysis of importing setting
		▪ **Policy learning** fostered due to differentiated analysis of characteristics and features
		▪ **Flexible approach** for adoption allows for different policy options/strategies:
		  ▪ Tailor initiative to context
		  ▪ Change context
		  ▪ Dismiss policy
			Weaknesses	▪ **Limitation to existing/reported evidence** only due to best-practice focus; policy innovation not yet manifested are not covered
				▪ **Quality of analyses** is determined by involvement of experts and/or representativeness of health system
				  ▪ Analyses of key features
				  ▪ Assessment of their feasibility to transfer
				▪ **Political priorities** and/or **opportunistic behaviour** of decision makers in terms of overall aim of initiative are not factored in
				  ▪ Promotion of self-care itself
				  ▪ Means to another end (e.g. limitation of bargaining power of GPs)
				▪ **Limited data/information availability** may bias the analyses results.
				▪ Not all **factors** relevant for transferability captured, as they may be **outside the scope** of the methodology

External factors	Opportunities	▪ Current **debates about transferability** of **health reform innovation** at European level (in various expert groups) might encourage use of standardised methods for transferability. ▪ Enhanced use of transferability methods allows to assess feasibility of the applied approaches and fosters **methodological advancement** ▪ Available literature on **comparative health systems research** improves quality of application of transferability methods ▪ Awareness of potential **health care cost savings** stimulates the use of transferability methods	Threats	▪ **Developments outside** the **methodology's scope** might jeopardise its applicability ▪ Factors supporting policy success in exporting setting may not work in importing setting due to: e.g. changing preferences, resource availability, priorities ▪ **Technological developments** cannot be taken into account due to static view of the methodology

The different relationships between internal strengths and weaknesses and external opportunities and threats have been examined by using a **risk analysis** consisting of a framework of eight questions:

1. How can strengths be maximised?
2. How can weaknesses be minimised?
3. How can opportunities be maximised?
4. How can threats be minimised?
5. How can strengths be used to take advantage of opportunities?
6. How can weaknesses be corrected to take advantage of opportunities?

7. How can strengths be used to reduce threats?
8. How can weaknesses and threats be minimised?
9. How can weaknesses and threats be minimised?

The complete findings of the risk analysis conducted under WP 2 are provided in Annex 16. Based on its findings, the following **general conclusions** on the methodology for transferability can be drawn.

1. The methodology's accuracy can be increased by the comprehensive use of information and by ensuring the level of topicality. Increased accuracy in turn promotes its use compared to other methodologies.
2. A major weaknesses of the methodology is its limited scope. The exclusion of relevant factors might distort the analysis and hinder the production of results reflecting the reality in the best possible way. Therefore, it might be necessary to widen the focus of the methodology and/or to include new perspectives by involving experts and decision-makers of different fields. Also, the provision of transparent and up-to-date data and information is important in this context.
3. Opportunities for the methodology refer to external factors promoting its application and its quality. Most important in this context is to put the topic of transferability on national political agendas. Quality can be improved by incorporating results of comparative health system research into the analyses, especially in the analysis of the importing setting. In order to do so, publications including appropriate forms of information-packaging as well as availability of literature needs to be fostered.
4. The threats jeopardizing the applicability of the methodology are related to its static view of reality. Thus, monitoring and adapting the methodology are important tools to avoid or overcome threats. Furthermore, the inclusion of experts with different backgrounds as well as in-time interactive knowledge sharing can help to anticipate and account for developments in technology or in the importing setting.
5. As opportunities relate to factors fostering the applicability of the methodology, strengths need to be used in terms of promoting factors. By disseminating the methodology and sharing its success, increased application by different interest groups can be achieved. Both will be facilitated by the methodology's ability to produce accurate and reliable results.
6. By ensuring/increasing the quality of the analysis, the utilisation of the methodology might be encouraged, which subsequently enables the assessment of the methodology's feasibility and might foster methodological advancement. An advanced methodology in turn might be noticed and eventually applied by expert groups discussing the transfer of health reform innovations at EU level.
7. The strengths of the methodology are used in terms of anticipating developments outside its scope. This can be facilitated by a comprehensive analysis of the importing setting in combination with the inclusion of expert's and stakeholder's view on technological and other relevant developments. If anticipation is not possible, the flexibility of the methodology regarding policy adoption needs to be ensured.

8. In order to reduce the impact of the methodology's limited scope, steering towards regular assessment of the methodology and its results and adapting the methodology (if necessary) are possible options.

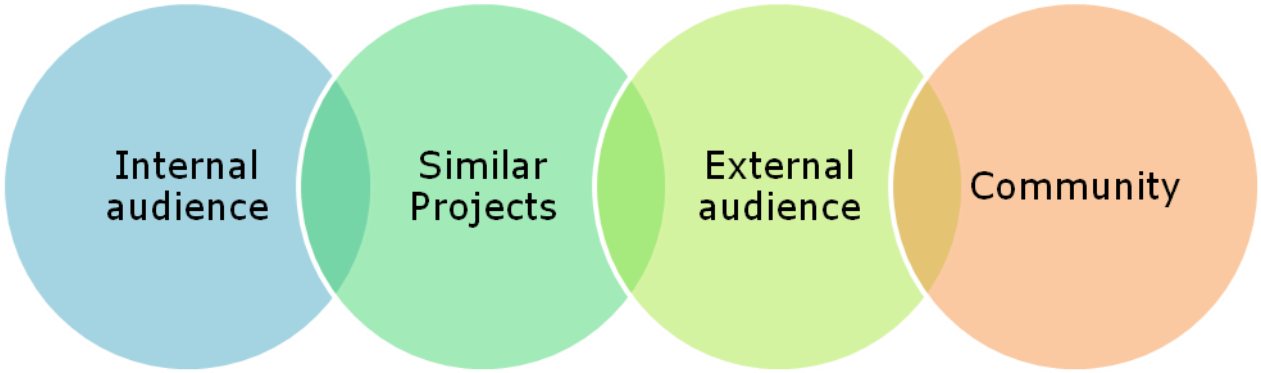
General limitations refer to difficulties in conceiving the concept of capturing positive and negtative internal and external factors of a methodology. This was especially an issue for the interviews. As a consequence, the interviewees showed a tendency to loose track and focused more on initiative level which might have biased the results. Furthermore, as the methodology is based on evidence identified, its development relies on the literature found, which was especially in the field of health not so much.

4.7 Dissemination strategy of good practice initiatives (task 14)

The choice of the most appropriate dissemination instrument depends on the purpose (raise awareness, inform, engage, promote), but also on the target group(s) addressed and the timing. Due to overlaps some dissemination tools will be able to achieve more than one purpose. To achieve the best effects, a mix of dissemination tools, as suggested in the dissemination plan for this project, is required.

Based on a basic stakeholder analysis (see Annex 14), the following key target groups for this project were identified (see Figure 12).

Figure 12: Target groups addressed



Internal audience: members of the consortium, expert group of this project

WHY?: The reason for including members of the consortium or expert group of this project is to ensure a common understanding and to make use fo the 'catalyst' effect i.e. the experts can open channels for dissemination in their country or constituencies and themselves will also desseminate

HOW?: Dissemination tools for this target groups are the report, websites, internal fact sheets, presentations, conferences or courses.

Similar projects: members of the EU funded PISCE project 'Pilot project on the promotion of self-care systems in the European Union; members of the working Group on promoting good governance of Non-Prescription medicines in Europe of the Platform on

Access to Medicines in Europe under the Process on Corporate Responsibility in the Field of Pharmaceuticals (2010 – 2013)

WHY?: Similar projects are considered as stakeholder since they enable a 'learning from' effect between them. The PISCE project was designed to be a framework for action to enhance self-care at EU level and develop strategies to support the broader implementation of effective self-care.

HOW?: 'Learning from' effects should be achieved through presentation to other projects or invitations to information events.

External audience: policy-makers and stakeholders at EU and national levels (e.g. Commission Services, Member States competent authorities, representatives of consumers (BEUC, HAI), patients (EFP, EPHA, health care industry, including self-medication industry (AESGP), providers of self-care practices, health professionals such doctors (CPME), pharmacists (PGEU), etc.), public payers (ESIP, AIM) and further researchers as catalysts

WHY?: Policy-makers have various policy instruments at their disposal to prioritise developments in health care. In order to do so, the need information inputs which focus on the importance of self-care initiatives on preserving public health, their potential to contribute to cost-containment in health expenditures.

HOW?: To address policy-makers and stakeholders reports, websites, leaflets, information events, scientific articles, posters, educational outreach visits, computerised support systems or training for practioners can be used as dissemination channels.

Community: general public, general press as catalysts

WHY?: Considering the general public and general press as target group stems from the need to raise awareness for self-care initiatives and to communicate the benefits that self-care brings in to daily life.

HOW?: Appropriate dissemination instruments are leaflets, press releases, videos, education materials, interactive small group meetings, workshops, open days, public events, blogs or social media.

Given these considerations with regard to purpose, target groups and timing of planned dissemination activities, different tools may be applied, some of them already listed above. Possible dissemination tools in the context of this project include:

- Report,
- Fact sheet,
- Case studies,
- Website,
- Press release,
- Leaflet / flyer / brochure,
- Newsletter,
- Presentations (at workshops of similar projects, at stakeholders meetings, at scientific conferences),
- Scientific articles in scientific peer-review journals,

- Posters at scientific conferences,
- Information event(s)
- Articles addressed to general public,
- Videos.

In order to select dissemination activities, a framework for selection was applied which included:

- criteria which are also frequently used in EC funded projects (Appropriate, Effective, Targetable, Economical, Measurable) (European Commission 2013; Peace Research Institute Oslo 2012)
- further criteria the contractual commitments of our consortium to the EC (as, for instance, specified in the tender specification and in the proposal for this service).

In Table 29, the mentioned dissemination activities are assessed according to the mentioned criteria. Based on the assessment, dissemination acitivities will be included in the dissemination plan according to their priority and are further described in Table 30. In this table, and below, it will also be explained if these activities have already been implemented in the course of the project, or whether they are to be launched after the approval of the final technical report by the EC.

Table 29: Selection of tools to be included the dissemination plan

Diss. activity	Selection criteria						Assessment
	Appropriate	**Effective**	**Targetable**	**Economical**	**Measurable**	**Contractual**	
Report	Yes, for different target groups	Basic for further, projects	Yes, at IA, projects, EA	Yes, if electronically available	Yes	Yes	High priority
Fact sheet	Yes, for IA and projects	Yes	Yes, at IA, projects	Yes (particularly in electronic version)	No	No	Medium priority
Case studies	Yes, for all target groups	Yes, very effective due to the illustrative effect	Yes, at IA, projects, EA; community (if case studies are used to illustrate the message)		Yes	Yes (as part of technical report)	High priority
Website	Yes, for all target groups, depending on the message and language	Yes, easy access	Yes, particularly at EA (policy-makers, stakeholders, researchers) and project, also at community	Yes, existing websites are used; No, if a separate project website is set up	Yes	No	Use of existing websites as dissemination portal – high priority Setting up a separate project website – not part of the diss. plan of this project
Press release	Yes, for community in particular	Yes, if disseminated through the right media and drafted with clear message	Yes, particularly targeted at community	Yes, no article / dissemination fees are charged by the media. However, it takes skills to write a good PR.	Yes	Yes	High priority
Leaflet / flyer	Yes, for all target groups	Yes	Yes, at IA, projects, EA; community	No if large-scale distribution of glossy hard copies	Yes	Yes	High priority

Diss. activity	Selection criteria						Assessment
	Appropriate	**Effective**	**Targetable**	**Economical**	**Measurable**	**Contractual**	
Newsletter	Yes, for all target groups	Yes	Yes, at IA, projects, EA; community	Yes	Yes	No	Disseminating through existing newsletters – high priority Established a project newsletter – not part of the diss. plan of this project High priority
Presentations (projects, stakeholders, conferences)	Yes, for all target groups	Yes	Yes, at IA, projects, EA; community	Yes (unless high travel expenses	Yes	Yes (partially)	Depending on the request: medium and high priority High priority if channelled through CHAFEA / DG SANTE, e.g. if invited by the PISCE project
Posters	Yes, particularly for the scientific community	Yes	Yes, at researchers	Yes	Yes	No	Medium priority
Info. event	Yes, for all target groups	Yes, highly effective due to the involvement of the stakeholders	Yes, at IA, projects, EA; community	No	Yes	No	High priority
Articles (addressed at community)	Yes, for community in particularly	Yes	Yes, particularly targeted at community	Yes	Number of downloads, number of letter to the editor	No	Low priority since the purpose (awareness raising) might also be targeted through the press release → not included in the dissemination plan
Video	Yes, for different target groups	Yes	Yes, particularly targeted at community	No	Number of downloads	No	Low priority due to high costs, long preparation time → not included in the dissemination plan

diss. = dissemination, EA = External audience (e.g. policy-makers, stakeholders), IA = internal audience, info. = information

Table 30: Dissemination plan –Key features of dissemination activities and proposed implementation

Diss. activity	Key features						Status of and plan for
	Key purpose	Target group	Actor	Timing	Cost estimate	Outcome mea.	implementation
Report	Inform	IA, projects, EA	Contractor	At the end of the project	No separate cost estimate provided (part of the contract)	No. of downloads, no. of copies distributed, no of citations	Apart from internal fact sheet and internal presentations, this is one of the first diss. deliverable of this project. Basis for further diss. activities.
Fact sheet	Engage	IA, projects	Contractor	During the course of the project	No separate cost estimate provided (part of the contract)	Not measurable (primary purpose: to inform and educate internal audience / expert group) and projects	An internal fact sheet about the project was produced and circulated with the candidates for the expert group to motivate them to join.
Case studies	Inform Raise awareness	IA, projects, EA; community (if case studies are used to illustrate the message)	Contractor	During the course of the project	No separate cost estimate provided (part of the contract)	No. of similar initiatives as case studies launched and/or discussed in other countries, no. of references to case studies in literature	The contractor produced case studies about SC initiatives in HC in European countries. They are included in the final technical report. The case studies may be further used for further diss. activities, for the leaflet, the PR and for the info. event, for instance.
Website	Inform Raise awareness	IA, projects, EA, (community)	Contractor in case of making use of existing websites	After approval of the final technical report by the EC	In case of use of existing websites: working time (e.g. drafting texts, communication to website providers)	Number of visits of the specific information on the website during a certain period, number of download, no. of citations in social media	The set-up of a project website has not been part of the diss. Plan of this project. For suggestions of relevant websites to disseminate the project's outcomes see below.

Diss. activity	Key features						Status of and plan for
	Key purpose	**Target group**	**Actor**	**Timing**	**Cost estimate**	**Outcome mea.**	**implementation**
Press release	Raise awareness	Particularly community	Contractor will draft the press release; EC will approve it. To be discussed with the EC who will contact the media	After approval of the final technical report by the EC.	Working time for drafting and revising the PR: included as part of the project Possible article / dissemination charges	No. of PR circulated, no. of media communications issued, number published, contact with media (requests), geographical scope and range of publication, size of distribution list	At request of the EC. For further information on the implementation, including possible target media and content of the PR see below
Leaflet / flyer	Raise awareness Inform	IA, projects, EA, (community)	Contractor will draft the leaflet; EC will approve it	After approval of the final technical report by the EC.	Working time for drafting and revising the leaflet: included as part of the project. Printing cost	No of leaflets / flyers distributed, no. of downloads of the leaflet on websites	At request of the EC. For further information on the implementation, including possible target media and content of the PR see below
Newsletter	Raise awareness	IA, projects, EA, (community)	Contractor in case of existing newsletters, including its own newsletter.	After approval of the final technical report by the EC.	Working time for communication with editors and drafting texts	No. of newsletters which informed about the project, geographical scope and range of publication; size of the respective mailing list	No project newsletter, but plan to disseminate through other newsletters, including the one of the contractors.
Presentations (projects, stakeholders, conferences)	Engage Promote	IA, projects, EA	Contractor	After approval of the final technical report by the EC.	Working time, travel expenses	No. of national or international conferences and further events at which the initiative is presented	Contractor was already approached by the PISC project and AESGP if we could give a presentation (however, PISCE meeting in autumn 2014 was too short-term, further cooperation is planned)

Diss. activity	Key features						Status of and plan for
	Key purpose	**Target group**	**Actor**	**Timing**	**Cost estimate**	**Outcome mea.**	**implementation**
Posters (at conferences)	Promote	Particularly scientific community	Contractor	After approval of the final technical report by the EC.	Working time, travel expenses	Number of national or international conferences at which a poster about the initiative is presented	Not started yet.
Info. event	Engage	IA, projects, EA; (community)	To be commissioned by the EC	Around one year after the end of the project	High-cost event: venue rent, travel and accommodation cost of around 100 participants, equipment, translation, printing. Working time for preparation. Estimate of around € 100,000 – 150,000	Participation rate, media coverage, follow-up activities at national level	Not in the scope of this project. An outline for a large-scale conference is provided below.

EA = External audience (e.g. policy-makers, stakeholders), EC= European Commission, IA = internal audience, mea. = measure(s), no. = number, PR = press release

5 Conclusions and recommendations

Self-care has become an important concept in modern health care settings. This has been promoted in European countries, at EU level and internationally. Some countries have taken the lead in launching self-care initiatives whereas policy-makers in other countries tend to still lack experience and knowledge and are therefore interested in learning from their peers. As a matter of fact, knowledge transfer is an important issue in this field.

The literature review undertaken in this study has shown that a body of literature has been produced in recent years related to this topic. However, literature is predominantly focused on the effectiveness of medical, often pharmaceutical, treatments that could also be used in self-care under specific conditions.

The literature review in the study provides an overview of the evidence of the effectiveness of treatment options for the five selected ailments and also highlights the variability of the results for the different treatments. While there is good evidence for the effectiveness of treatments against the symptoms of the common cold that can be used in self-care, there is limited evidence for the effectiveness of Over-the-Counter medicines against cough, for instance. The identified limitations and variations in the effectiveness of treatment options for minor ailments are not caused by methodological shortages of the studies assessed but they are rather caused by the key characteristic of a minor ailment as being self-limiting by definition. As such, treatment options for minor ailments can primarily result in quicker pain relief or remedy. For most cases, however, the ultimate outcome in terms of health gain remains the same whether an intervention is taking place or not.

Building on the evidence gained in this project, a follow-up study could review literature for each available treatment for all included ailments. Further research could also be expanded to further than the five ailments covered in this report. Still, we believe that these five selected ailments cover essential ailments that are relevant in self-care.

Apart from variations in the effectiveness of treatment options for minor ailments, the literature review also revealed that hardly any profound epidemiological dataset or at least estimations for minor ailments existed. This is partly due to difficulties in the distinction from one episode of illness to another (in particular in the case of recurring ailments such as athlete's foot or heartburn) which would be necessary to derive numbers for annual incidence rates. Moreover, the documented cases of minor ailments mostly refer to the number of GP visits due to minor ailments only without any information or estimates given on the number of ailments dealt with in a self-care setting with or without consultation of the pharmacist. As shown in the cost-benefit analysis, the authors therefore decided to solely analyse "shift cases" from GP consultation to pharmacy consultation only. However, if further studies on the issue of self-management of minor ailments are to be conducted, and if these studies should also include an evaluation at population level, a sound epidemiological framework for quantifying the incidence of minor ailments appears to be of particular importance. Further coordinated research could add a valuable contribution in this respect.

Ultimately, variability is also an issue related to the existence of self-care initiatives given the different extent and progress of self-care initiatives between countries as well as the different levels of information and in particular evaluation studies available on self-care initiatives. Most of the selected self-care initiatives studied in the cost-benefit analysis related to projects in England. On the one hand England being a "champion" in self-care is not surprising since patient empowerment and self-care has been high on the political agenda. On the other hand, a homogenous, well introduced and widely accepted set of unit costs for health and social care exists for England

hence allowing for comparable and transparent approximations applied in the evaluation studies. However, if self-care initiatives, once successfully transferred to other settings, are intended to be evaluated by using similar approaches as in the exporting country in order to facilitate comparability of results, similar catalogues of unit costs for the importing contexts would be a valuable asset. It is advised considering promoting at least a minimum subset of common unit costs in the EU Member States. These data should be regularly updated and published.

The effectiveness of the self-care initiatives assessed and their economic impacts for different stakeholder groups are both highly sensitive with regard to the context of the importing setting and in particular to the pharmaceutical policies in place. Policy relevant issues concern the availability and pricing of prescription-only medicines and Over-the-Counter (OTC) medicines as well as their reimbursement status and extent (e.g. the mechanisms applied in terms of co-payments and their exemptions, the criteria for defining which medicines are eligible for reimbursement). As a matter of fact, these policies impact as to whether patients, as a whole or a defined subgroup, will be better or worse off if they decide to shift from GP consultation to self-care with medication under the regime of a particular self-care initiative.

It could be shown that MAS in England (i.e. locally tailored schemes to provide public access to NHS treatment and/or advice in a pharmacy or, where appropriate referral to other health care professional) have the potential to lead to a positive net societal benefit for the ailments assessed if shift rates exceed 27.5 percent. As prescription charges are relatively high as compared to prices for OTC products, patients obliged to pay charges tend to benefit to a larger extend, if they decide to avoid contacting a GP and directly visit the pharmacy instead. On the other hand, patient exempt from prescription charges also tend to considerably benefit from MAS and it has to be noted, that their benefit as on average larger as compared to the mere implementation of an internet-based information service such as NHS choices.

Concerning pharmacist independent prescribing, costs on a providers' level are too high in order to allow for a positive net impact on a societal level. From a patients' perspective however, benefits exist: Patients, both those exempt and those not exempt from prescription charges, tend to benefit from the NMP initiative as they are likely to save time due to the avoidance of the GP encounter whereas they are likely to get the same medication at the same extent of (co-)payments as if they had been visiting a GP.

With regard to NHS Choices, a positive net societal benefit appears to exist even at comparable low rates of the shift (break-even of the initiative at a 4.4 percent shift rate). Patients exempt from prescription charges tend to benefit from time savings, but since reimbursements do not change, their benefit is lower as compared to MAS (MAS) where this is not the case. Patients obliged to pay prescriptions charges, however, benefit from time savings as well as from cheaper (co-)payments for OTC pharmaceuticals as compared to Rx products at a prescription fee of 8.05 GBP per item, which would have been prescribed if they had first consulted a GP.

From a societal perspective and with regard to England, therefore, NHS choices as well as the MAS could be identified as favourable policy options with NHS choices rather favouring patients obliged to pay prescription charges whereas MAS appears to be geared more towards benefits of patient exempt from prescription charges. The impacts of NMP show no difference concerning the obligation of patients to pay prescription charges, from a societal perspective, though, a widespread adoption of pharmacist independent prescribing is very unlikely.

With regard to its mere incentives, the selected initiatives cover different possible types of self-care projects, such as a telephone hotline, a health information website and pharmaceutical access schemes. They thus fulfil the criterion of

representativeness and may serve as good-practice for other countries. To be considered best-practice, however, a set of defined criteria as suggested in this report has been fulfilled, which limits the list of best-practice initiatives in self-care to few initiatives. Applying this framework, we identified the health information website NHS Choices, NMP, MAS and the telephone hotline NHS 111a as best-practices which help policy-makers and patients to better understand the benefits in self-care.

Best-practices can serve to provide ideas but initiatives cannot be "copied" identically from one country to another since the policy context, including the legal framework and the "culture", differ between countries. In order to support policy-makers to transfer self-care to other countries, they require, in addition to knowledge about best-practices, guidance for the implementation. We developed a methodology of transferability for best-practices in self-care which is intended to serve as a guide for the policy-makers.

It is important that the findings of this study, including this practical guidance of the methodology of transferability for best-practices in self-care, are disseminated appropriately. Information should particularly be circulated to policy-makers at EU and national levels and to patients but also to further stakeholders and the scientific community. In order to reduce possible redundancy, the dialogue and cooperation to projects in this field shall be sought, particularly with the PISCE (pilot project on the promotion of self-care) consortium project that aims to build on the results of this project. A large-scale conference on self-care, during which findings of this study are disseminated is, though beyond the scope of this project, highly recommended and should address policy-makers and stakeholders at national and EU levels.

The promotion of self-care and the implementation of successful initiatives require changes at several levels. Self-care should be accompanied with enhanced patient empowerment, improved patient information and an appropriate organisation and financial health care framework. Promoting self-care also has an impact on health professional and their collaboration, as pharmacists, for instance, will play an increasingly important role as first contact points. This implies a change in the definition of pharmacists, expanding from a "dispenser" to an integrated health care professional offering counselling, advices and new pharmacy services. This change has already been undertaken in many countries. Self-care allows physicians to focus on patients with serious illnesses in such a setting, and, at the same time, they will be required to be more strongly involved in collaborative care.

Our study is a basis for further follow-up work in this field, especially for the development of a guideline for the promotion of self-care and a guideline for the development and production of communication tools as well as a proposal of policy actions on self-care at EU level that will be done in the PISCE project. It is highly recommended that our results are fed in the PISCE project and that the experts of the PISCE platform consider our findings in their work.

Though our study has shown benefits of successful self-care initiatives it needs to be understood and clearly communicated that self-care is addressed to specific conditions, such as minor ailments, but it cannot substitute health care by professionals in more serious cases

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Annex 1: List of Minor Ailments

Table A 1: Shortlist of Minor Ailments

Minor ailment	Selected (yes/no)
Allergic and/or bacterial conjunctivitis	No
Athlete´s Foot	Yes
Cold	Yes
Cold sores	No
Constipation	(Back-up)
Cough	Yes
Haemorrhoids	(Back-up)
Indigestion/heartburn	Yes (without indigestion)
Lower urinary tract infection	Yes
Vaginal thrush	No

This shortlist of ten minor ailments was created by the project team together with a primary care physician and public health experts based on the following criteria: (1) feasibility to identify/distinguish from other (harmful) conditions; (2) potential treatability (3) necessity/benefit of treatment; and (4) self-care potential.

This shortlist served as a basis for the further selection of five minor ailments in agreement with DG SANTE during the kick-off meeting. This selection is indicated in the column "Selected (yes/no)".

Annex 2: Definitions of self-care used for the Delphi process

Table A 2: Proposed set of definitions found in the literature

No	Definition	Source (year)
1	Self care is defined as the actions people take for themselves, their children and their families to prevent and care for minor ailments and long-term conditions and maintain health and well-being after an acute illness or discharge from hospital	Tender Specifications (EAHC/2013/ Health/26) (2013)
2	Self-care is what people do for themselves to establish and maintain health, and to prevent and deal with illness. It is a broad concept encompassing hygiene (general and personal), nutrition (type and quality of food eaten), lifestyle (sporting activities, leisure etc.), environmental factors (living conditions, social habits, etc.), socio-economic factors (income level, cultural beliefs, etc.) and self-medication	Report of the 4th WHO consultative group on the role of pharmacists (1998)
3	Self-care is the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a health-care provider	WHO, regional consultation (2009)
4	Practices undertaken by individuals towards maintaining health and managing illness	QQUIP (Coulter: Patient-focused interventions - A review of the evidence) (2006)
5	Self care is about people`s attitudes and lifestyle, as well as what they can do to take care of themselves when they have a health problem. […] Self care is a continuum, starting from the individual responsibility people take in making daily choices about their lifestyle, and risk taking. […] Next along the continuum (is) […] the self management of ailments without and with advice and guidance from family, peers and voluntary groups, or assistance from health professionals such as pharmacists, general practitioners, dentists or nurses.	European forum for primary care (Position paper) (2006)

Annex 3: Search Strategies

Search strategy: Urinary tract infection

Search strategy Medline, Cochrane, CRD, Embase via OVID – urinary tract infection:

Search date: 26th June 2014

Databases:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present,
- Embase 1988 to 2014 Week 25,
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to May 2014,
- EBM Reviews - ACP Journal Club 1991 to May 2014,
- EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2014,
- EBM Reviews - Cochrane Central Register of Controlled Trials May 2014,
- EBM Reviews - Cochrane Methodology Register 3rd Quarter 2012,
- EBM Reviews - Health Technology Assessment 2nd Quarter 2014,
- EBM Reviews - NHS Economic Evaluation Database 2nd Quarter 2014

1	exp Self Care/	88569
2	exp Self Medication/	10597
3	exp Self Administration/	17367
4	exp Patient Education as Topic/	155129
5	exp Patient Participation/	34927
6	exp self efficacy/	124781
7	exp Telemedicine/	36175
8	exp Self-Assessment/	30681
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	441593
10	self care.ab,ti,tw.	24461
11	self medication.ab,ti,tw.	5645
12	self management.ab,ti,tw.	21808
13	patient education.ab,ti,tw.	27752
14	patient empowerment.ab,ti,tw.	1305
15	self administration.ab,ti,tw.	15479
16	health awareness.ab,ti,tw.	1651
17	patient awareness.ab,ti,tw.	1390
18	self help.ab,ti,tw.	10987
19	self monitoring.ab,ti,tw.	10312
20	home monitoring.ab,ti,tw.	2642
21	tele monitoring.ab,ti,tw.	150
22	telemonitoring.ab,ti,tw.	1861
23	self treatment.ab,ti,tw.	2213
24	patient participation.ab,ti,tw.	3127
25	self efficacy.ab,ti,tw.	31572
26	telecare.ab,ti,tw.	947

27	telemedicine.ab,ti,tw.	13923
28	tele medicine.ab,ti,tw.	154
29	tele care.ab,ti,tw.	56
30	self assessment.ab,ti,tw.	16397
31	self diagnosis.ab,ti,tw.	569
32	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31	179363
33	9 or 32	517760
34	exp Urinary Tract Infections/	95191
35	exp Lower Urinary Tract Symptoms/	37403
36	exp Cystitis/	22438
37	exp Urethritis/	7878
38	cystitis.ab,ti,tw.	18366
39	urethritis.ab,ti,tw.	6956
40	acute cystitis.ab,ti,tw.	853
41	lower urinary tract infectious disease.ab,ti,tw.	0
42	urinary tract infection.ab,ti,tw.	34842
43	bladder infection.ab,ti,tw.	343
44	lower urinary tract infection.ab,ti,tw.	769
45	lower urinary tract infections.ab,ti,tw.	801
46	urinary tract infections.ab,ti,tw.	31659
47	bladder infections.ab,ti,tw.	234
48	Chronic lower urinary tract infection.ab,ti,tw.	6
49	Chronic lower urinary tract infections.ab,ti,tw.	6
50	acute lower urinary tract infection.ab,ti,tw.	29
51	acute lower urinary tract infections.ab,ti,tw.	38
52	Lower urinary tract symptom.ab,ti,tw.	451
53	Lower urinary tract symptoms.ab,ti,tw.	54
54	34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or47 or 48 or 49 or 50 or 51 or 52 or 53	184957
55	33 and 54	2744
56	55 and 2004:2014.(sa_year).	1608
57	remove duplicates from 56	1337
58	57 and "Systematic Review" [Publication Type]	32
59	57 and "Journal: Review" [Publication Type]	187
60	57 and "Review" [Publication Type]	255
61	57 and "Journal: Article" [Publication Type]	847
62	57 and "Journal Article" [Publication Type]	847
63	57 and "Randomized Controlled Trial" [Publication Type]	42
64	57 and "Comparative Study" [Publication Type]	35
65	57 and "Evaluation Studies" [Publication Type]	21
66	57 and "Observational Study" [Publication Type]	2
67	57 and "Validation Studies" [Publication Type]	12
68	57 and "Multicenter Study" [Publication Type]	22

69	59 or 61 or 62	1021
70	exp Safety/	324976
71	exp treatment outcome/	1719163
72	exp Comparative Effectiveness Research/	12121
73	exp Program Evaluation/	62168
74	exp "Outcome Assessment (Health Care)"/	1034036
75	exp Pharmacology, Clinical/	11569
76	exp Quality Assurance, Health Care/	2159603
77	70 or 71 or 72 or 73 or 74 or 75 or 76	3219100
78	69 and 77	366

Search strategy Scopus – urinary tract infection

Search date: 27th June 2014

Database: Scopus

13 Search Terms INDEXTERMS("urinary tract infection") OR TITLE-ABS-KEY("urinary tract infection") OR TITLE-ABS-KEY("lower urinary tract infection") OR TITLE-ABS-KEY("Lower urinary tract symptoms") OR INDEXTERMS(cystitis) OR TITLE-ABS-KEY(cystitis) OR INDEXTERMS(urethritis) OR TITLE-ABS-KEY(urethritis) OR TITLE-ABS-KEY("acute cystitis") OR TITLE-ABS-KEY("bladder infection") OR TITLE-ABS-KEY("acute lower urinary tract infection") OR TITLE-ABS-KEY("Chronic lower urinary tract infection") OR TITLE-ABS-KEY("lower urinary tract infectious disease") AND INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed") AND PUBYEAR > 2003 AND LANGUAGE(english OR german OR italian OR french) AND NOT INDEX(medline)

165 document results

14 History Search Terms INDEXTERMS("urinary tract infection") OR TITLE-ABS-KEY("urinary tract infection") OR TITLE-ABS-KEY("lower urinary tract infection") OR TITLE-ABS-KEY("Lower urinary tract symptoms") OR INDEXTERMS(cystitis) OR TITLE-ABS-KEY(cystitis) OR INDEXTERMS(urethritis) OR TITLE-ABS-KEY(urethritis) OR TITLE-ABS-KEY("acute cystitis") OR TITLE-ABS-KEY("bladder infection") OR TITLE-ABS-KEY("acute lower urinary tract infection") OR TITLE-ABS-KEY("Chronic lower urinary tract infection") OR TITLE-ABS-KEY("lower urinary tract infectious disease") AND INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed") AND PUBYEAR > 2003 AND LANGUAGE(english OR german OR italian OR french) AND NOT INDEX(medline) AND (LIMIT-TO(DOCTYPE, "ar") OR LIMIT-TO(DOCTYPE, "re")) 131 document results

Search strategy CINAHL available via EBSCO – urinary tract infection

Search date: 27th June 2014

Database: CINAHL available via EBSCO

S52	S33 AND S49 Eingrenzungen-Erscheinungsdatum: 20040101-20141231; MEDLINE-Datensätze ausschließen; Sprache: English, French, German, Italian	66
S51	S33 AND S49 Eingrenzungen-Erscheinungsdatum: 20040101-20141231	171
S50	S33 AND S49	290
S49	S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48	6,441
S48	"lower urinary tract infectious disease"	0
S47	"Chronic lower urinary tract infections"	0
S46	"Chronic lower urinary tract infection"	0
S45	"acute lower urinary tract infections"	3
S44	"acute lower urinary tract infection"	1
S43	"bladder infections"	25
S42	"bladder infection"	10
S41	"acute cystitis"	35
S40	(MH "Urethritis") OR "urethritis"	185
S39	(MH "Cystitis+") OR "cystitis"	797
S38	""Lower urinary tract symptom""	25
S37	"Lower urinary tract symptoms"	360
S36	"lower urinary tract infections"	67
S35	"lower urinary tract infection"	24
S34	(MH "Urinary Tract Infections+") OR "urinary tract infection"	5,297
S33	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32	112,779
S32	"self diagnosed"	... (17)
S31	"self diagnosis"	... (635)
S30	"self diagnose"	... (27)
S29	"self assessment"	... (6,349)
S28	"self efficacy"	... (11,442)
S27	"patient participation"	... (613)
S26	"self treated"	... (27)
S25	"self treatment"	... (240)
S24	"telemedicine"	... (3,460)
S23	"telecare"	... (213)
S22	"telemonitoring"	... (196)
S21	"home monitoring"	... (219)
S20	"self monitoring"	... (2,781)
S19	"self help"	... (1,838)
S18	"patient awareness"	... (154)
S17	"health awareness"	... (305)

S16	"self administration"	... (2,026)
S15	"patient empowerment"	... (337)
S14	"patient education"	... (40,902)
S13	"self management"	... (4,746)
S12	"self medication"	... (1,033)
S11	"self care"	... (15,327)
S10	(MH "Telehealth+")	... (7,675)
S9	(MH "Self-Efficacy")	... (8,961)
S8	(MH "Consumer Participation")	... (9,976)
S7	(MH "Self Assessment")	... (4,688)
S6	(MH "Self Diagnosis+")	... (8,534)
S5	(MH "Self Administration+")	... (3,089)
S4	(MH "Empowerment")	... (7,035)
S3	(MH "Patient Education+")	... (46,522)
S2	(MH "Self Medication")	... (793)
S1	(MH "Self Care+")	... (24,230)

Search strategy: Athlete's Foot

Search strategy Medline, Cochrane, CRD, Embase via Ovid –athlete's foot

Search date: 1st July 2014

Databases:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present,
- Embase 1988 to 2014 Week 25,
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to May 2014,
- EBM Reviews - ACP Journal Club 1991 to May 2014,
- EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2014,
- EBM Reviews - Cochrane Central Register of Controlled Trials May 2014,
- EBM Reviews - Cochrane Methodology Register 3rd Quarter 2012,
- EBM Reviews - Health Technology Assessment 2nd Quarter 2014,
- EBM Reviews - NHS Economic Evaluation Database 2nd Quarter 2014

1	exp Self Care/	88569
2	exp Self Medication/	10597
3	exp Self Administration/	17367
4	exp Patient Education as Topic/	155129
5	exp Patient Participation/	34927
6	exp self efficacy/	124781
7	exp Telemedicine/	36175
8	exp Self-Assessment/	30681
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	441593
10	self care.ab,ti,tw.	24468
11	self medication.ab,ti,tw.	5645
12	self management.ab,ti,tw.	21817
13	patient education.ab,ti,tw.	27756
14	patient empowerment.ab,ti,tw.	1306
15	self administration.ab,ti,tw.	15480
16	health awareness.ab,ti,tw.	1652
17	patient awareness.ab,ti,tw.	1391
18	self help.ab,ti,tw.	10988
19	self monitoring.ab,ti,tw.	10316
20	home monitoring.ab,ti,tw.	2642
21	tele monitoring.ab,ti,tw.	150
22	telemonitoring.ab,ti,tw.	1862
23	self treatment.ab,ti,tw.	2213
24	patient participation.ab,ti,tw.	3128
25	self efficacy.ab,ti,tw.	31578
26	telecare.ab,ti,tw.	947
27	telemedicine.ab,ti,tw.	13932

28	tele medicine.ab,ti,tw.	154
29	tele care.ab,ti,tw.	56
30	self assessment.ab,ti,tw.	16399
31	self diagnosis.ab,ti,tw.	569
32	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31	179404
33	9 or 32	517801
34	exp Tinea Pedis/	3079
35	"tinea pedis".ab,ti,tw.	2260
36	"tinea pedum".ab,ti,tw.	27
37	"foot ringworm".ab,ti,tw.	4
38	"Ringworm of the foot".ab,ti,tw.	4
39	"Athlete's foot".ab,ti,tw.	331
40	"athlete foot".ab,ti,tw.	10
41	"athletes foot".ab,ti,tw.	331
42	"moccasin foot".ab,ti,tw.	15
43	"Tinea pedis interdigitalis".ab,ti,tw.	40
44	"interdigital tinea pedis".ab,ti,tw.	133
45	"interdigital mycosis".ab,ti,tw.	23
46	"plantar mycosis".ab,ti,tw.	1
47	"mycosis pedis".ab,ti,tw.	3
48	"pedal mycosis".ab,ti,tw.	5
49	"moccasin tinea".ab,ti,tw.	7
50	Dermatophytosis.ab,ti,tw.	2710
51	foot.ab,ti,tw.	133527
52	exp Foot/	66828
53	51 or 52	175697
54	50 and 53	117
55	"fungal infection".ab,ti,tw.	15688
56	53 and 55	241
57	34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or47 or 48 or 49 or 54 or 56	4180
58	33 and 57	87
59	58 and 2004:2014.(sa_year).	57
60	remove duplicates from 59	44
61	from 59 keep 1-57	57

Search strategy Scopus –athlete's foot

Search date: 2nd July 2014

Database: Scopus

9 History Search Terms (((INDEXTERMS(foot) OR TITLE-ABS-KEY(foot)) AND (INDEXTERMS(mycosis) OR TITLE-ABS-KEY(mycosis) OR INDEXTERMS("mycotic infection") OR TITLE-ABS-KEY("mycotic infection") OR INDEXTERMS("fungal infection") OR TITLE-ABS-KEY("fungal infection") OR INDEXTERMS(dermatomycoses) OR TITLE-ABS-KEY(dermatomycoses) OR INDEXTERMS("cutaneous candidiasis") OR TITLE-ABS-KEY("cutaneous candidiasis") OR INDEXTERMS(tinea) OR TITLE-ABS-KEY(tinea))) OR (INDEXTERMS("tinea pedis") OR TITLE-ABS-KEY("tinea pedis") OR INDEXTERMS("tinea Pedum") OR TITLE-ABS-KEY("tinea Pedum") OR INDEXTERMS("foot ringworm") OR TITLE-ABS-KEY("foot ringworm") OR TITLE-ABS-KEY("Ringworm of the foot") OR INDEXTERMS("athletes foot") OR TITLE-ABS-KEY("athletes foot") OR INDEXTERMS("athlete foot") OR TITLE-ABS-KEY("athlete foot") OR INDEXTERMS("Athlete's foot") OR TITLE-ABS-KEY("Athlete's foot") OR INDEXTERMS("moccasin foot") OR TITLE-ABS-KEY("moccasin foot") OR INDEXTERMS("Tinea pedis interdigitalis") OR TITLE-ABS-KEY("Tinea pedis interdigitalis") OR INDEXTERMS("interdigital tinea pedis") OR TITLE-ABS-KEY("interdigital tinea pedis") OR INDEXTERMS("interdigital mycosis") OR TITLE-ABS-KEY("interdigital mycosis") OR INDEXTERMS("plantar mycosis") OR TITLE-ABS-KEY("plantar mycosis") OR INDEXTERMS("mycosis pedis") OR TITLE-ABS-KEY("mycosis pedis") OR INDEXTERMS("pedal mycosis") OR TITLE-ABS-KEY("pedal mycosis") OR INDEXTERMS("moccasin tinea") OR TITLE-ABS-KEY("moccasin tinea"))) AND (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) AND (LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004)) 59 document results

8 History Search Terms (((INDEXTERMS(foot) OR TITLE-ABS-KEY(foot)) AND (INDEXTERMS(mycosis) OR TITLE-ABS-KEY(mycosis) OR INDEXTERMS("mycotic infection") OR TITLE-ABS-KEY("mycotic infection") OR INDEXTERMS("fungal infection") OR TITLE-ABS-KEY("fungal infection") OR INDEXTERMS(dermatomycoses) OR TITLE-ABS-KEY(dermatomycoses) OR INDEXTERMS("cutaneous candidiasis") OR TITLE-ABS-KEY("cutaneous candidiasis") OR INDEXTERMS(tinea) OR TITLE-ABS-KEY(tinea))) OR (INDEXTERMS("tinea pedis") OR TITLE-ABS-KEY("tinea pedis") OR INDEXTERMS("tinea Pedum") OR TITLE-ABS-KEY("tinea Pedum") OR INDEXTERMS("foot ringworm") OR TITLE-ABS-KEY("foot ringworm") OR TITLE-ABS-KEY("Ringworm of the foot") OR INDEXTERMS("athletes foot") OR TITLE-ABS-

KEY("athletes foot") OR INDEXTERMS("athlete foot") OR TITLE-ABS-KEY("athlete foot") OR INDEXTERMS("Athlete's foot") OR TITLE-ABS-KEY("Athlete's foot") OR INDEXTERMS("moccasin foot") OR TITLE-ABS-KEY("moccasin foot") OR INDEXTERMS("Tinea pedis interdigitalis") OR TITLE-ABS-KEY("Tinea pedis interdigitalis") OR INDEXTERMS("interdigital tinea pedis") OR TITLE-ABS-KEY("interdigital tinea pedis") OR INDEXTERMS("interdigital mycosis") OR TITLE-ABS-KEY("interdigital mycosis") OR INDEXTERMS("plantar mycosis") OR TITLE-ABS-KEY("plantar mycosis") OR INDEXTERMS("mycosis pedis") OR TITLE-ABS-KEY("mycosis pedis") OR INDEXTERMS("pedal mycosis") OR TITLE-ABS-KEY("pedal mycosis") OR INDEXTERMS("moccasin tinea") OR TITLE-ABS-KEY("moccasin tinea"))) AND (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) 91 document results

7 History Search Terms ((INDEXTERMS(foot) OR TITLE-ABS-KEY(foot)) AND (INDEXTERMS(mycosis) OR TITLE-ABS-KEY(mycosis) OR INDEXTERMS("mycotic infection") OR TITLE-ABS-KEY("mycotic infection") OR INDEXTERMS("fungal infection") OR TITLE-ABS-KEY("fungal infection") OR INDEXTERMS(dermatomycoses) OR TITLE-ABS-KEY(dermatomycoses) OR INDEXTERMS("cutaneous candidiasis") OR TITLE-ABS-KEY("cutaneous candidiasis") OR INDEXTERMS(tinea) OR TITLE-ABS-KEY(tinea))) OR (INDEXTERMS("tinea pedis") OR TITLE-ABS-KEY("tinea pedis") OR INDEXTERMS("tinea Pedum") OR TITLE-ABS-KEY("tinea Pedum") OR INDEXTERMS("foot ringworm") OR TITLE-ABS-KEY("foot ringworm") OR TITLE-ABS-KEY("Ringworm of the foot") OR INDEXTERMS("athletes foot") OR TITLE-ABS-KEY("athletes foot") OR INDEXTERMS("athlete foot") OR TITLE-ABS-KEY("athlete foot") OR INDEXTERMS("Athlete's foot") OR TITLE-ABS-KEY("Athlete's foot") OR INDEXTERMS("moccasin foot") OR TITLE-ABS-KEY("moccasin foot") OR INDEXTERMS("Tinea pedis interdigitalis") OR TITLE-ABS-KEY("Tinea pedis interdigitalis") OR INDEXTERMS("interdigital tinea pedis") OR TITLE-ABS-KEY("interdigital tinea pedis") OR INDEXTERMS("interdigital mycosis") OR TITLE-ABS-KEY("interdigital mycosis") OR INDEXTERMS("plantar mycosis") OR TITLE-ABS-KEY("plantar mycosis") OR INDEXTERMS("mycosis pedis") OR TITLE-ABS-KEY("mycosis pedis") OR INDEXTERMS("pedal mycosis") OR TITLE-ABS-KEY("pedal mycosis") OR INDEXTERMS("moccasin tinea") OR TITLE-ABS-KEY("moccasin tinea")) 4,591 document results

6 History Search Terms (INDEXTERMS(foot) OR TITLE-ABS-KEY(foot)) AND (INDEXTERMS(mycosis) OR TITLE-ABS-KEY(mycosis) OR INDEXTERMS("mycotic infection") OR TITLE-ABS-KEY("mycotic infection") OR INDEXTERMS("fungal infection") OR TITLE-ABS-KEY("fungal infection") OR INDEXTERMS(dermatomycoses) OR TITLE-ABS-KEY(dermatomycoses) OR INDEXTERMS("cutaneous candidiasis") OR TITLE-ABS-KEY("cutaneous candidiasis") OR INDEXTERMS(tinea) OR TITLE-ABS-KEY(tinea)) 2,460 document results

5 History Search Terms INDEXTERMS(foot) OR TITLE-ABS-KEY(foot)
182,821 document results

4 INDEXTERMS(mycosis)OR TITLE-ABS-KEY(mycosis)OR INDEXTERMS("mycotic infection")OR TITLE-ABS-KEY("mycotic infection")OR INDEXTERMS("fungal infection")OR TITLE-ABS-KEY("fungal infection")OR INDEXTERMS(Dermatomycoses) OR TITLE-ABS-KEY(Dermatomycoses)OR INDEXTERMS("cutaneous candidiasis")OR TITLE-ABS-KEY("cutaneous candidiasis")OR INDEXTERMS(tinea)OR TITLE-ABS-KEY(tinea) 83,820 document results

3 INDEXTERMS("tinea pedis")OR TITLE-ABS-KEY("tinea pedis")OR INDEXTERMS("tinea Pedum") OR TITLE-ABS-KEY("tinea Pedum")OR INDEXTERMS("foot ringworm")OR TITLE-ABS-KEY("foot ringworm")OR TITLE-ABS-KEY("Ringworm of the foot")OR INDEXTERMS("athletes foot")OR TITLE-ABS-KEY("athletes foot")OR INDEXTERMS("athlete foot")OR TITLE-ABS-KEY("athlete foot")OR INDEXTERMS("Athlete's foot")OR TITLE-ABS-KEY("Athlete's foot")OR INDEXTERMS("moccasin foot")OR TITLE-ABS-KEY("moccasin foot")OR INDEXTERMS("Tinea pedis interdigitalis")OR TITLE-ABS-KEY("Tinea pedis interdigitalis")OR INDEXTERMS("interdigital tinea pedis")OR TITLE-ABS-KEY("interdigital tinea pedis")OR INDEXTERMS("interdigital mycosis")OR TITLE-ABS-KEY("interdigital mycosis")OR INDEXTERMS("plantar mycosis")OR TITLE-ABS-KEY("plantar mycosis")OR INDEXTERMS("mycosis pedis")OR TITLE-ABS-KEY("mycosis pedis")OR INDEXTERMS("pedal mycosis")OR TITLE-ABS-KEY("pedal mycosis")OR INDEXTERMS("moccasin tinea")OR TITLE-ABS-KEY("moccasin tinea")
3,067 document results

2 INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed") 286,885 document results

Search strategy CINAHL available via EBSCO – athlete's foot

Search date: 2nd July 2014

Database: CINAHL available via EBSCO

S83	S33 AND S80 Eingrenzungen - Erscheinungsdatum: 20040101-20131231; MEDLINE-Datensätze ausschließen	...(17)
S82	S33 AND S80 Eingrenzungen - Erscheinungsdatum: 20040101-20131231	...(24)
S81	S33 AND S80	...(34)
S80	S78 OR S79	...(505)
S79	S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64	...(484)
S78	S76 AND S77	...(30)
S77	S65 OR S66 OR S67 OR S68 OR S69 OR S70 OR S71 OR S72 OR S73 OR S7 OR S75	...(1,100)
S76	(MH "Foot+")	...(8,572)
S75	AB mycosis	...(101)
S74	TI mycosis	...(71)
S73	TI "mycotic infection"	...(0)
S72	AB "mycotic infection"	..(7)
S71	AB "fungal infection"	...(325)
S70	TI "fungal infection"	...(93)
S69	(MM "Dermatomycoses")	...(187)
S68	AB Dermatophytosis	(21)
S67	TI Dermatophytosis	..(10)
S66	(MH "Candidiasis, Cutaneous")	...(93)
S65	(MM "Tinea")	...(323)
S64	AB "pedal mycosis"	...(0)
S63	TI "pedal mycosis"	...(0)
S62	AB "mycosis pedis"	...(0)
S61	TI "mycosis pedis"	...(0)
S60	AB "plantar mycosis"	...(0)
S59	TI "plantar mycosis"	...(0)
S58	AB "interdigital mycosis"	...(1)
S57	TI "interdigital mycosis"	...(0)
S56	TI "interdigital tinea pedis"	...(2)
S55	AB "interdigital tinea pedis"	..(3)
S54	AB "Tinea pedis interdigitalis"	...(0)
S53	TI "Tinea pedis interdigitalis"	...(1)
S52	TI moccasin tinea	...(0)
S51	AB moccasin tinea	...(1)
S50	AB moccasin foot	...(1)
S49	TI moccasin foot	...(0)
S48	AB "Athlete foot"	...(1)
S47	TI "Athlete foot"	...(0)
S46	TI "Athletes foot"	...(0)

S45	AB "Athletes foot"	...(2)
S44	AB "Athlete's foot"	...(15)
S43	TI "Athlete's foot"	...(26)
S42	TI Ringworm of the foot	...(1)
S41	AB Ringworm of the foot	...(1)
S40	AB "foot ringworm"	...(1)
S39	TI "foot ringworm"	...(0)
S38	AB "tinea pedum"	...(0)
S37	TI "tinea pedum"	...(0)
S36	AB "tinea pedis"	...(53)
S35	TI "tinea pedis"	..(30)
S34	(MH "Onychomycosis")	...(388)
S33	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32	(112,779)
S32	"self diagnosed"	...(17)
S31	"self diagnosis"	...(635)
S30	"self diagnose"	...(27)
S29	"self assessment"	...(6,349)
S28	"self efficacy"	...(11,442)
S27	"patient participation"	...(613)
S26	"self treated"	...(27)
S25	"self treatment"	...(240)
S24	"telemedicine"	...(3,460)
S23	"telecare"	...(213)
S22	"telemonitoring"	...(196)
S21	"home monitoring"	...(219)
S20	"self monitoring"	...(2,781)
S19	"self help"	...(1,838)
S18	"patient awareness"	...(154)
S17	"health awareness"	...(305)
S16	"self administration"	...(2,026)
S15	"patient empowerment"	...(337)
S14	"patient education"	...(40,902)
S13	"self management"	...(4,746)
S12	"self medication"	...(1,033)
S11	"self care"	...(15,327)
S10	(MH "Telehealth+")	...(7,675)
S9	(MH "Self-Efficacy")	...(8,961)
S8	(MH "Consumer Participation")	...(9,976)
S7	(MH "Self Assessment")	...(4,688)
S6	(MH "Self Diagnosis+")	...(8,534)
S5	(MH "Self Administration+")	...(3,089)
S4	(MH "Empowerment")	...(7,035)
S3	(MH "Patient Education+")	...(46,522)
S2	(MH "Self Medication")	...(793)
S1	(MH "Self Care+")	...(24,230)

Search strategy: Cough

Search strategy Medline, Cochrane, CRD, Embase via OVID –cough

Search date: 2nd July 2014

Databases:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present,
- Embase 1988 to 2014 Week 25,
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to May 2014,
- EBM Reviews - ACP Journal Club 1991 to May 2014,
- EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2014,
- EBM Reviews - Cochrane Central Register of Controlled Trials May 2014,
- EBM Reviews - Cochrane Methodology Register 3rd Quarter 2012,
- EBM Reviews - Health Technology Assessment 2nd Quarter 2014,
- EBM Reviews - NHS Economic Evaluation Database 2nd Quarter 2014

1	exp Self Care/	88569
2	exp Self Medication/	10597
3	exp Self Administration/	17367
4	exp Patient Education as Topic/	155129
5	exp Patient Participation/	34927
6	exp self efficacy/	124781
7	exp Telemedicine/	36175
8	exp Self-Assessment/	30681
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	441593
10	self care.ab,ti,tw.	24468
11	self medication.ab,ti,tw.	5645
12	self management.ab,ti,tw.	21817
13	patient education.ab,ti,tw.	27756
14	patient empowerment.ab,ti,tw.	1306
15	self administration.ab,ti,tw.	15480
16	health awareness.ab,ti,tw.	1652
17	patient awareness.ab,ti,tw.	1391
18	self help.ab,ti,tw.	10988
19	self monitoring.ab,ti,tw.	10316
20	home monitoring.ab,ti,tw.	2642
21	tele monitoring.ab,ti,tw.	150
22	telemonitoring.ab,ti,tw.	1862
23	self treatment.ab,ti,tw.	2213
24	patient participation.ab,ti,tw.	3128
25	self efficacy.ab,ti,tw.	31578
26	telecare.ab,ti,tw.	947
27	telemedicine.ab,ti,tw.	13932
28	tele medicine.ab,ti,tw.	154
29	tele care.ab,ti,tw.	56
30	self assessment.ab,ti,tw.	16399
31	self diagnosis.ab,ti,tw.	569

32	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31	179404
33	9 or 32	517801
34	exp Cough/	77091
35	cough.ab,ti,tw.	71265
36	bronchitis.ab,ti,tw.	34297
37	"chronic bronchitis".ab,ti,tw.	16361
38	"acute bronchitis".ab,ti,tw.	2720
39	"chest cold".ab,ti,tw.	28
40	bronchiolitis.ab,ti,tw.	18357
41	exp Bronchiolitis/	19966
42	tussis.ab,ti,tw.	28
43	exp Bronchitis/	61588
44	exp Bronchitis, Chronic/	7484
45	34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44	185877
46	32 and 45	894
47	46 and 2004:2014.(sa_year).	631
48	47 and "Journal: Article" [Publication Type]	367
49	47 and "Journal Article" [Publication Type]	367
50	47 and "Journal: Review" [Publication Type]	63
51	47 and "Systematic Review" [Publication Type]	52
52	47 and "Clinical Trial" [Publication Type]	12
53	47 and "Review" [Publication Type]	78
54	47 and "Comparative Study" [Publication Type]	11
55	47 and "Controlled Clinical Trial" [Publication Type]	6
56	47 and "Evaluation Studies" [Publication Type]	3
57	47 and "Trade Journal: Article" [Publication Type]	4
58	51 or 52 or 54 or 55 or 56 or 57	84
59	48 or 49 or 50 or 53	430
60	exp Safety/	325757
61	exp treatment outcome/	1720933
62	exp Comparative Effectiveness Research/	12229
63	exp Program Evaluation/	62220
64	exp "Outcome Assessment (Health Care)"/	1034915
65	exp Pharmacology, Clinical/	11573
66	exp Quality Assurance, Health Care/	2163095
67	exp Cost-Benefit Analysis/	135262
68	exp Economics/	694902
69	exp "Costs and Cost Analysis"/	434033
70	60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69	3958323
71	remove duplicates from 59	312
72	from 58 keep 1-84	84
73	from 59 keep 1-430	430
74	70 and 71	139

Search strategy Scopus –cough
Search date: 2nd July 2014
Database: Scopus

15 History Search Terms (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) AND (INDEXTERMS(cough) OR TITLE-ABS-KEY(cough) OR INDEXTERMS(tussis) OR TITLE-ABS-KEY(tussis) OR INDEXTERMS(bronchitis) OR TITLE-ABS-KEY(bronchitis) OR INDEXTERMS("chronic Bronchitis") OR TITLE-ABS-KEY("chronic Bronchitis") OR INDEXTERMS("acute Bronchitis") OR TITLE-ABS-KEY("acute Bronchitis") OR INDEXTERMS(bronchiolitis) OR TITLE-ABS-KEY(bronchiolitis) OR INDEXTERMS("chest cold") OR TITLE-ABS-KEY("chest cold")) AND NOT (INDEX(medline)) AND (LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004) OR LIMIT-TO(PUBYEAR, 2004)) AND (LIMIT-TO(LANGUAGE, "English") OR LIMIT-TO(LANGUAGE, "German") OR LIMIT-TO(LANGUAGE, "French") OR LIMIT-TO(LANGUAGE, "Italian")) 152 document results

14 History Search Terms (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) AND (INDEXTERMS(cough) OR TITLE-ABS-KEY(cough) OR INDEXTERMS(tussis) OR TITLE-ABS-KEY(tussis) OR INDEXTERMS(bronchitis) OR TITLE-ABS-KEY(bronchitis) OR INDEXTERMS("chronic

Bronchitis") OR TITLE-ABS-KEY("chronic Bronchitis") OR INDEXTERMS("acute Bronchitis") OR TITLE-ABS-KEY("acute Bronchitis") OR INDEXTERMS(bronchiolitis) OR TITLE-ABS-KEY(bronchiolitis) OR INDEXTERMS("chest cold") OR TITLE-ABS-KEY("chest cold")) AND (LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004) OR LIMIT-TO(PUBYEAR, 2004)) AND (LIMIT-TO(LANGUAGE, "English") OR LIMIT-TO(LANGUAGE, "German") OR LIMIT-TO(LANGUAGE, "French") OR LIMIT-TO(LANGUAGE, "Italian"))

543 document results

13 History Search Terms (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) AND (INDEXTERMS(cough) OR TITLE-ABS-KEY(cough) OR INDEXTERMS(tussis) OR TITLE-ABS-KEY(tussis) OR INDEXTERMS(bronchitis) OR TITLE-ABS-KEY(bronchitis) OR INDEXTERMS("chronic Bronchitis") OR TITLE-ABS-KEY("chronic Bronchitis") OR INDEXTERMS("acute Bronchitis") OR TITLE-ABS-KEY("acute Bronchitis") OR INDEXTERMS(bronchiolitis) OR TITLE-ABS-KEY(bronchiolitis) OR INDEXTERMS("chest cold") OR TITLE-ABS-KEY("chest cold")) AND (LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004) OR LIMIT-TO(PUBYEAR, 2004)) 567 document results

12 History Search Terms (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR

INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) AND (INDEXTERMS(cough) OR TITLE-ABS-KEY(cough) OR INDEXTERMS(tussis) OR TITLE-ABS-KEY(tussis) OR INDEXTERMS(bronchitis) OR TITLE-ABS-KEY(bronchitis) OR INDEXTERMS("chronic Bronchitis") OR TITLE-ABS-KEY("chronic Bronchitis") OR INDEXTERMS("acute Bronchitis") OR TITLE-ABS-KEY("acute Bronchitis") OR INDEXTERMS(bronchiolitis) OR TITLE-ABS-KEY(bronchiolitis) OR INDEXTERMS("chest cold") OR TITLE-ABS-KEY("chest cold")) 998 document results

10 INDEXTERMS(cough)OR TITLE-ABS-KEY(cough)OR INDEXTERMS(tussis)OR TITLE-ABS-KEY(tussis)OR INDEXTERMS(bronchitis)OR TITLE-ABS-KEY(bronchitis)or INDEXTERMS("chronic Bronchitis")OR TITLE-ABS-KEY("chronic Bronchitis")OR INDEXTERMS("acute Bronchitis")OR TITLE-ABS-KEY("acute Bronchitis")OR INDEXTERMS(bronchiolitis)OR TITLE-ABS-KEY(bronchiolitis) OR INDEXTERMS("chest cold")OR TITLE-ABS-KEY("chest cold") 103,713 document results

2 INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed") 286,885 document results

Search strategy CINAHL available via EBSCO – cough
Search date: 2nd July 2014
Database: CINAHL available via EBSCO

S56	S33 AND S53 Eingrenzungen - Erscheinungsdatum: 20040101-20141231; MEDLINE-Datensätze ausschließen	... (42)
S55	S33 AND S53 Eingrenzungen - Erscheinungsdatum: 20040101-20141231	... (127)
S54	S33 AND S53	... (207)
S53	S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52	... (6,933)
S52	AB "chest cold"	... (5)
S51	TI "chest cold"	... (2)
S50	AB bronchiolitis	... (576)
S49	TI bronchiolitis	... (495)
S48	(MH "Bronchiolitis+")	... (774)
S47	AB "acute bronchitis"	... (110)
S46	TI "acute bronchitis"	... (78)
S45	(MH "Bronchitis, Acute")	... (4)
S44	AB "chronic bronchitis"	... (455)
S43	TI "chronic bronchitis"	... (187)
S42	(MH "Bronchitis, Chronic")	... (182)
S41	AB bronchitis	... (871)
S40	TI bronchitis	... (367)
S39	(MH "Bronchitis+")	... (1,668)
S38	TI tussis	... (0)
S37	AB tussis	... (1)
S36	AB cough	... (2,796)
S35	TI cough	... (1,521)
S34	(MH "Cough")	... (2,403)
S33	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32	(112,779)
S32	"self diagnosed"	...(17)
S31	"self diagnosis"	...(635)
S30	"self diagnose"	...(27)
S29	"self assessment"	...(6,349)
S28	"self efficacy"	...(11,442)
S27	"patient participation"	...(613)
S26	"self treated"	...(27)
S25	"self treatment"	...(240)
S24	"telemedicine"	...(3,460)
S23	"telecare"	...(213)
S22	"telemonitoring"	...(196)

S21	"home monitoring"	...(219)
S20	"self monitoring"	...(2,781)
S19	"self help"	...(1,838)
S18	"patient awareness"	...(154)
S17	"health awareness"	...(305)
S16	"self administration"	...(2,026)
S15	"patient empowerment"	...(337)
S14	"patient education"	...(40,902)
S13	"self management"	...(4,746)
S12	"self medication"	...(1,033)
S11	"self care"	...(15,327)
S10	(MH "Telehealth+")	...(7,675)
S9	(MH "Self-Efficacy")	...(8,961)
S8	(MH "Consumer Participation")	...(9,976)
S7	(MH "Self Assessment")	...(4,688)
S6	(MH "Self Diagnosis+")	...(8,534)
S5	(MH "Self Administration+")	...(3,089)
S4	(MH "Empowerment")	...(7,035)
S3	(MH "Patient Education+")	...(46,522)
S2	(MH "Self Medication")	...(793)
S1	(MH "Self Care+")	...(24,230)

Search strategy: heartburn

Search strategy Medline, Cochrane, CRD, Embase via OVID –heartburn
Search date: 1st July 2014
Databases:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present,
- Embase 1988 to 2014 Week 25,
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to May 2014,
- EBM Reviews - ACP Journal Club 1991 to May 2014,
- EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2014,
- EBM Reviews - Cochrane Central Register of Controlled Trials May 2014,
- EBM Reviews - Cochrane Methodology Register 3rd Quarter 2012,
- EBM Reviews - Health Technology Assessment 2nd Quarter 2014,
- EBM Reviews - NHS Economic Evaluation Database 2nd Quarter 2014

1	exp Self Care/	88569
2	exp Self Medication/	10597
3	exp Self Administration/	17367
4	exp Patient Education as Topic/	155129
5	exp Patient Participation/	34927
6	exp self efficacy/	124781
7	exp Telemedicine/	36175
8	exp Self-Assessment/	30681
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	441593
10	self care.ab,ti,tw.	24468
11	self medication.ab,ti,tw.	5645
12	self management.ab,ti,tw.	21817
13	patient education.ab,ti,tw.	27756
14	patient empowerment.ab,ti,tw.	1306
15	self administration.ab,ti,tw.	15480
16	health awareness.ab,ti,tw.	1652
17	patient awareness.ab,ti,tw.	1391
18	self help.ab,ti,tw.	10988
19	self monitoring.ab,ti,tw.	10316
20	home monitoring.ab,ti,tw.	2642
21	tele monitoring.ab,ti,tw.	150
22	telemonitoring.ab,ti,tw.	1862
23	self treatment.ab,ti,tw.	2213
24	patient participation.ab,ti,tw.	3128
25	self efficacy.ab,ti,tw.	31578
26	telecare.ab,ti,tw.	947
27	telemedicine.ab,ti,tw.	13932
28	tele medicine.ab,ti,tw.	154
29	tele care.ab,ti,tw.	56
30	self assessment.ab,ti,tw.	16399
31	self diagnosis.ab,ti,tw.	569
32	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31	179404
33	9 or 32	517801

34	exp Heartburn/	10903
35	exp Esophagitis, Peptic/	12502
36	exp Gastroesophageal Reflux/	61900
37	heartburn.ab,ti,tw.	10414
38	"heart burn".ab,ti,tw.	280
39	"peptic esophagitis".ab,ti,tw.	384
40	pyrosis.ab,ti,tw.	608
41	pyroses.ab,ti,tw.	0
42	agita.ab,ti,tw.	34
43	peratodynia.ab,ti,tw.	0
44	"acid reflux".ab,ti,tw.	4762
45	"gastric acid reflux".ab,ti,tw.	91
46	"gastric acid reflux disease".ab,ti,tw.	2
47	"reflux oesophagitis".ab,ti,tw.	1980
48	"reflux esophagitis".ab,ti,tw.	6130
49	"esophageal reflux".ab,ti,tw.	3997
50	"gastro?esophageal reflux".ab,ti,tw.	32488
51	"gastro?esophageal reflux disease".ab,ti,tw.	18592
52	"gastro oesophageal reflux".ab,ti,tw.	8036
53	"gastro oesophageal reflux disease".ab,ti,tw.	4500
54	"oesophageal reflux".ab,ti,tw.	8326
55	34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54	82786
56	33 and 55	997
57	remove duplicates from 56	802
58	57 and 2004:2014.(sa_year).	550
59	58 and "Randomized Controlled Trial" [Publication Type]	6
60	58 and "Meta-Analysis" [Publication Type]	1
61	58 and "Comparative Study" [Publication Type]	4
62	58 and "Patient Education Handout" [Publication Type]	1
63	58 and "Systematic Review" [Publication Type]	14
64	58 and "Review" [Publication Type]	149
65	58 and "Journal Article" [Publication Type]	298
66	58 and "Journal: Review" [Publication Type]	142
67	58 and "Journal: Article" [Publication Type]	298
68	65 or 66 or 67	440
69	59 or 60 or 61 or 62 or 63 or 64	173
70	exp Safety/	325757
71	exp treatment outcome/	1720933
72	exp Comparative Effectiveness Research/	12229
73	exp Program Evaluation/	62220
74	exp "Outcome Assessment (Health Care)"/	1034915
75	exp Pharmacology, Clinical/	11573
76	exp Quality Assurance, Health Care/	2163095
77	exp Cost-Benefit Analysis/	135262
78	exp Economics/	694902
79	exp "Costs and Cost Analysis"/	434033
80	70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79	3958323

81 68 AND 80 211

Search strategy Scopus –heartburn
Search date: 1st July 2014
Database: Scopus

12 History Search Terms ((INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed"))) AND (INDEXTERMS(heartburn) OR TITLE-ABS-KEY(heartburn) OR TITLE-ABS-KEY("heart burn") OR INDEXTERMS("peptic esophagitis") OR TITLE-ABS-KEY("peptic esophagitis") OR INDEXTERMS(pyrosis) OR TITLE-ABS-KEY(pyrosis) OR INDEXTERMS(agita) OR TITLE-ABS-KEY(agita) OR INDEXTERMS(peratodynia) OR TITLE-ABS-KEY(peratodynia) OR INDEXTERMS("acid reflux") OR TITLE-ABS-KEY("acid reflux") OR INDEXTERMS("gastric acid reflux") OR TITLE-ABS-KEY("gastric acid reflux") OR INDEXTERMS("gastric acid reflux disease") OR TITLE-ABS-KEY("gastric acid reflux disease") OR INDEXTERMS("reflux oesophagitis") OR TITLE-ABS-KEY("reflux oesophagitis") OR INDEXTERMS("reflux esophagitis") OR TITLE-ABS-KEY("reflux esophagitis") OR INDEXTERMS("Gastroesophageal Reflux") OR TITLE-ABS-KEY("Gastroesophageal Reflux") OR INDEXTERMS("Gastro esophageal Reflux") OR TITLE-ABS-KEY("Gastro esophageal Reflux") OR INDEXTERMS("Gastroesophageal reflux disease") OR TITLE-ABS-KEY("Gastroesophageal reflux disease") OR INDEXTERMS("Esophageal Reflux") OR TITLE-ABS-KEY("Esophageal Reflux") OR INDEXTERMS("Oesophageal Reflux") OR TITLE-ABS-KEY("Oesophageal Reflux") OR INDEXTERMS("Gastro oesophageal Reflux") OR TITLE-ABS-KEY("Gastro oesophageal Reflux") OR INDEXTERMS("gastro oesophageal reflux disease") OR TITLE-ABS-KEY("gastro oesophageal reflux disease")) AND NOT (INDEX(medline)) AND (LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004) OR LIMIT-TO(PUBYEAR, 2004)) AND (LIMIT-TO(LANGUAGE, "English") OR LIMIT-TO(LANGUAGE, "German") OR LIMIT-TO(LANGUAGE, "French") OR LIMIT-TO(LANGUAGE, "Italian")) 125 document results

7 History Search Terms ((INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR

INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed"))) AND (INDEXTERMS(heartburn) OR TITLE-ABS-KEY(heartburn) OR TITLE-ABS-KEY("heart burn") OR INDEXTERMS("peptic esophagitis") OR TITLE-ABS-KEY("peptic esophagitis") OR INDEXTERMS(pyrosis) OR TITLE-ABS-KEY(pyrosis) OR INDEXTERMS(agita) OR TITLE-ABS-KEY(agita) OR INDEXTERMS(peratodynia) OR TITLE-ABS-KEY(peratodynia) OR INDEXTERMS("acid reflux") OR TITLE-ABS-KEY("acid reflux") OR INDEXTERMS("gastric acid reflux") OR TITLE-ABS-KEY("gastric acid reflux") OR INDEXTERMS("gastric acid reflux disease") OR TITLE-ABS-KEY("gastric acid reflux disease") OR INDEXTERMS("reflux oesophagitis") OR TITLE-ABS-KEY("reflux oesophagitis") OR INDEXTERMS("reflux esophagitis") OR TITLE-ABS-KEY("reflux esophagitis") OR INDEXTERMS("Gastroesophageal Reflux") OR TITLE-ABS-KEY("Gastroesophageal Reflux") OR INDEXTERMS("Gastro esophageal Reflux") OR TITLE-ABS-KEY("Gastro esophageal Reflux") OR INDEXTERMS("Gastroesophageal reflux disease") OR TITLE-ABS-KEY("Gastroesophageal reflux disease") OR INDEXTERMS("Esophageal Reflux") OR TITLE-ABS-KEY("Esophageal Reflux") OR INDEXTERMS("Oesophageal Reflux") OR TITLE-ABS-KEY("Oesophageal Reflux") OR INDEXTERMS("Gastro oesophageal Reflux") OR TITLE-ABS-KEY("Gastro oesophageal Reflux") OR INDEXTERMS("gastro oesophageal reflux disease") OR TITLE-ABS-KEY("gastro oesophageal reflux disease"))
727 document results

6 History Search Terms (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) 286,870 document results

5 History Search Terms INDEXTERMS(heartburn) OR TITLE-ABS-KEY(heartburn) OR TITLE-ABS-KEY("heart burn") OR INDEXTERMS("peptic esophagitis") OR TITLE-ABS-KEY("peptic esophagitis") OR INDEXTERMS(pyrosis) OR TITLE-ABS-KEY(pyrosis) OR INDEXTERMS(agita) OR TITLE-ABS-KEY(agita) OR INDEXTERMS(peratodynia) OR TITLE-ABS-KEY(peratodynia) OR INDEXTERMS("acid reflux") OR TITLE-ABS-KEY("acid reflux") OR INDEXTERMS("gastric acid reflux") OR TITLE-ABS-KEY("gastric acid reflux") OR INDEXTERMS("gastric acid reflux disease") OR TITLE-ABS-KEY("gastric acid reflux disease") OR INDEXTERMS("reflux oesophagitis") OR TITLE-ABS-

KEY("reflux oesophagitis") OR INDEXTERMS("reflux esophagitis") OR TITLE-ABS-KEY("reflux esophagitis") OR INDEXTERMS("Gastroesophageal Reflux") OR TITLE-ABS-KEY("Gastroesophageal Reflux") OR INDEXTERMS("Gastro esophageal Reflux") OR TITLE-ABS-KEY("Gastro esophageal Reflux") OR INDEXTERMS("Gastroesophageal reflux disease") OR TITLE-ABS-KEY("Gastroesophageal reflux disease") OR INDEXTERMS("Esophageal Reflux") OR TITLE-ABS-KEY("Esophageal Reflux") OR INDEXTERMS("Oesophageal Reflux") OR TITLE-ABS-KEY("Oesophageal Reflux") OR INDEXTERMS("Gastro oesophageal Reflux") OR TITLE-ABS-KEY("Gastro oesophageal Reflux") OR INDEXTERMS("gastro oesophageal reflux disease") OR TITLE-ABS-KEY("gastro oesophageal reflux disease") 51,782 document results

Search strategy CINAHL available via EBSCO – heartburn
Search date: 1st July 2014
Database: CINAHL available via EBSCO

S82 S33 AND S77 Eingrenzungen - Erscheinungsdatum: 20040101-20141231; MEDLINE-Datensätze ausschließen; Publikationstyp: Clinical Trial, Corrected Article, Journal Article, Meta Analysis, Meta Synthesis, Randomized Controlled Trial, Review, Systematic Review; Sprache: English, French, German, Italian ... (43)

S81 S33 AND S77 Eingrenzungen - Erscheinungsdatum: 20040101-20141231; MEDLINE-Datensätze ausschließen; Sprache: English, French, German, Italian ... (44)

S80 S33 AND S77 Eingrenzungen - Erscheinungsdatum: 20040101-20141231 (80)

S79 S33 AND S77 Eingrenzungen - Erscheinungsdatum: 20040101-20141231 (80)

S78 S33 AND S77 ... (138)

S77 S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69 OR S70 OR S71 OR S72 OR S73 OR S74 OR S75 OR S76 ... (4,617)

S76 AB "reflux esophagitis" ... (88)

S75 TI "reflux esophagitis" ... (49)

S74 TI "reflux oesophagitis" ... (24)

S73 AB "reflux oesophagitis" ... (26)

S72 AB "Gastro oesophageal reflux disease" ... (179)

S71 TI "Gastro oesophageal reflux disease" ... (111)

S70 TI "Gastro oesophageal reflux" ... (185)

S69 AB "Gastro oesophageal reflux" ... (245)

S68 TI "Oesophageal Reflux" ... (186)

S67 AB "Oesophageal Reflux" ... (250)

S66 AB "Esophageal Reflux" ... (58)

S65 TI "Esophageal Reflux" ... (28)

S64 AB "Gastro esophageal reflux disease" ... (22)

S63 TI "Gastro esophageal reflux disease" ... (7)

S62 AB "Gastroesophageal reflux disease" ... (634)

S61 TI "Gastroesophageal reflux disease" ... (414)

S60 TI "Gastro esophageal Reflux" ... (15)

S59 AB "Gastro esophageal Reflux" ... (41)

S58 AB "Gastroesophageal Reflux" ... (1,009)

S57 TI "Gastroesophageal Reflux" ... (715)

S56 (MH "Gastroesophageal Reflux") ... (3,398)

S55 TI "gastric acid reflux disease" ... (0)

S54 AB "gastric acid reflux disease" ... (0)

S53 AB "gastric acid reflux" ... (8)

S52 TI "gastric acid reflux" ... (0)

S51	AB "acid reflux"	... (115)
S50	TI "acid reflux"	... (60)
S49	AB peratodynia	... (0)
S48	TI peratodynia	... (0)
S47	AB agita	... (5)
S46	TI agita	... (3)
S45	TI Pyroses	... (0)
S44	AB Pyroses	... (0)
S43	AB pyrosis	... (8)
S42	TI pyrosis	... (1)
S41	AB "peptic esophagitis"	... (2)
S40	TI "peptic esophagitis"	... (1)
S39	(MH "Esophagitis+")	... (593)
S38	TI "heart burn"	... (2)
S37	AB "heart burn"	... (4)
S36	TI heartburn	... (286)
S35	AB heartburn	... (315)
S34	(MH "Heartburn")	... (474)
S33	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32	(112,779)
S32	"self diagnosed"	...(17)
S31	"self diagnosis"	...(635)
S30	"self diagnose"	...(27)
S29	"self assessment"	...(6,349)
S28	"self efficacy"	...(11,442)
S27	"patient participation"	...(613)
S26	"self treated"	...(27)
S25	"self treatment"	...(240)
S24	"telemedicine"	...(3,460)
S23	"telecare"	...(213)
S22	"telemonitoring"	...(196)
S21	"home monitoring"	...(219)
S20	"self monitoring"	...(2,781)
S19	"self help"	...(1,838)
S18	"patient awareness"	...(154)
S17	"health awareness"	...(305)
S16	"self administration"	...(2,026)
S15	"patient empowerment"	...(337)
S14	"patient education"	...(40,902)
S13	"self management"	...(4,746)
S12	"self medication"	...(1,033)
S11	"self care"	...(15,327)
S10	(MH "Telehealth+")	...(7,675)

S9	(MH "Self-Efficacy")	...(8,961)
S8	(MH "Consumer Participation")	...(9,976)
S7	(MH "Self Assessment")	...(4,688)
S6	(MH "Self Diagnosis+")	...(8,534)
S5	(MH "Self Administration+")	...(3,089)
S4	(MH "Empowerment")	...(7,035)
S3	(MH "Patient Education+")	...(46,522)
S2	(MH "Self Medication")	...(793)
S1	(MH "Self Care+")	...(24,230)

Search strategy: Cold

Search strategy Medline, Cochrane, CRD, Embase via OVID –cold
Search date: 30th June 2014
Databases:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present,
- Embase 1988 to 2014 Week 25,
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to May 2014,
- EBM Reviews - ACP Journal Club 1991 to May 2014,
- EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2014,
- EBM Reviews - Cochrane Central Register of Controlled Trials May 2014,
- EBM Reviews - Cochrane Methodology Register 3rd Quarter 2012,
- EBM Reviews - Health Technology Assessment 2nd Quarter 2014,
- EBM Reviews - NHS Economic Evaluation Database 2nd Quarter 2014

1	exp Self Care/	88569
2	exp Self Medication/	10597
3	exp Self Administration/	17367
4	exp Patient Education as Topic/	155129
5	exp Patient Participation/	34927
6	exp self efficacy/	124781
7	exp Telemedicine/	36175
8	exp Self-Assessment/	30681
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	441593
10	self care.ab,ti,tw.	24461
11	self medication.ab,ti,tw.	5645
12	self management.ab,ti,tw.	21808
13	patient education.ab,ti,tw.	27752
14	patient empowerment.ab,ti,tw.	1305
15	self administration.ab,ti,tw.	15479
16	health awareness.ab,ti,tw.	1651
17	patient awareness.ab,ti,tw.	1390
18	self help.ab,ti,tw.	10987
19	self monitoring.ab,ti,tw.	10312
20	home monitoring.ab,ti,tw.	2642
21	tele monitoring.ab,ti,tw.	150
22	telemonitoring.ab,ti,tw.	1861
23	self treatment.ab,ti,tw.	2213
24	patient participation.ab,ti,tw.	3127
25	self efficacy.ab,ti,tw.	31572
26	telecare.ab,ti,tw.	947
27	telemedicine.ab,ti,tw.	13923
28	tele medicine.ab,ti,tw.	154
29	tele care.ab,ti,tw.	56
30	self assessment.ab,ti,tw.	16397

31	self diagnosis.ab,ti,tw.	569
32	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31	179363
33	9 or 32	517760
34	exp Nasopharyngitis/	6633
35	exp Common Cold/	9248
36	exp Respiratory Tract Infections/	522989
37	exp Sinusitis/	41940
38	exp Rhinitis/	82275
39	Nasopharyngitis.ab,ti,tw.	1555
40	rhinopharyngitis.ab,ti,tw.	303
41	Sinusitis.ab,ti,tw.	25671
42	Rhinitis.ab,ti,tw.	48438
43	nasal catarrh.ab,ti,tw.	114
44	nasal catarrhs.ab,ti,tw.	0
45	acute nasal catarrh.ab,ti,tw.	2
46	acute rhinitis.ab,ti,tw.	190
47	common cold.ab,ti,tw.	5734
48	acute coryza.ab,ti,tw.	11
49	Coryza.ab,ti,tw.	832
50	cold.ab,ti,tw.	170114
51	head cold.ab,ti,tw.	26
52	respiratory tract infection.ab,ti,tw.	14918
53	respiratory tract infections.ab,ti,tw.	22771
54	upper respiratory tract infection.ab,ti,tw.	5491
55	upper respiratory tract infections.ab,ti,tw.	4897
56	viral upper respiratory tract infection.ab,ti,tw.	229
57	viral upper respiratory tract infections.ab,ti,tw.	246
58	34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57	783730
59	33 and 58	5940
60	59 and 2004:2014.(sa_year).	4012
61	remove duplicates from 60	3304
62	34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57	783730
63	33 and 62	5940
64	remove duplicates from 63	4797
65	64 and 2004:2014.(sa_year).	3304
66	65 and "Validation Studies" [Publication Type]	7
67	65 and "Systematic Review" [Publication Type]	61
68	65 and "Randomized Controlled Trial" [Publication Type]	37
69	65 and ": Article" [Publication Type]	1556
70	65 and "Trade Journal: Article" [Publication Type]	27
71	65 and "Comparative Study" [Publication Type]	41
72	65 and "Journal Article" [Publication Type]	1926
73	65 and "Journal: Article" [Publication Type]	1926

74	65 and "Journal: Review" [Publication Type]	513
75	69 or 72 or 73	1934
76	74 or 75	2447
77	exp Safety/	325757
78	exp treatment outcome/	1720933
79	exp Comparative Effectiveness Research/	12229
80	exp Program Evaluation/	62220
81	exp "Outcome Assessment (Health Care)"/	1034915
82	exp Pharmacology, Clinical/	11573
83	exp Quality Assurance, Health Care/	2163095
84	exp Cost-Benefit Analysis/	135262
85	exp Economics/	694902
86	exp "Costs and Cost Analysis"/	434033
87	77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86	3958323
88	76 and 87	1085
89	exp Pharyngitis/	31852
90	pharyngitis.af.	21743
91	exp Laryngitis/	7327
92	laryngitis.ab,ti,tw.	2744
93	exp Pharyngitis/	31852
94	pharyngitis.af.	21743
95	exp Laryngitis/	7327
96	laryngitis.ab,ti,tw.	2744
97	34 or 35 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 51 or 54 or 55 or 56 or 57 or 93 or 94 or 95 or 96	176273
98	33 and 97	2336
99	98 and 2004:2014.(sa_year).	1587
100	remove duplicates from 99	1325
101	100 and "Journal: Article" [Publication Type]	742
102	100 and "Journal: Review" [Publication Type]	285
103	100 and "Journal Article" [Publication Type]	742
104	100 and "Comparative Study" [Publication Type]	15
105	100 and "Evaluation Studies" [Publication Type]	6
106	100 and "Systematic Review" [Publication Type]	29
107	100 and "Trade Journal: Article" [Publication Type]	19
108	100 and "Clinical Trial" [Publication Type]	5
109	100 and "Multicenter Study" [Publication Type]	8
110	100 and "Randomized Controlled Trial" [Publication Type]	13
111	100 and "Review" [Publication Type]	305
112	101 or 102 or 103 or 111	1031
113	87 and 112	480
114	104 or 105 or 106 or 107 or 108 or 109 or 110	83

Search strategy Scopus –cold
Search date: 30th June 2014
Database: Scopus

19 History Search Terms (INDEXTERMS(pharyngitis) OR TITLE-ABS-KEY(pharyngitis) OR INDEXTERMS(nasopharyngitis) OR TITLE-ABS-KEY(nasopharyngitis) OR INDEXTERMS(rhinopharyngitis) OR TITLE-ABS-KEY(rhinopharyngitis) OR INDEXTERMS(sinusitis) OR TITLE-ABS-KEY(sinusitis) OR INDEXTERMS(rhinitis) OR TITLE-ABS-KEY(rhinitis) OR TITLE-ABS-KEY("acute Rhinitis") OR TITLE-ABS-KEY("nasal catarrh") OR TITLE-ABS-KEY("acute nasal catarrh") OR INDEXTERMS("common cold") OR TITLE-ABS-KEY("common cold") OR INDEXTERMS(laryngitis) OR TITLE-ABS-KEY(laryngitis) OR TITLE-ABS-KEY("upper respiratory tract infection") OR TITLE-ABS-KEY("viral upper respiratory tract infection") OR TITLE-ABS-KEY("head cold") OR INDEXTERMS(coryza) OR TITLE-ABS-KEY(coryza) OR TITLE-ABS-KEY("acute coryza")) AND (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) AND NOT (INDEX(medline)) AND (LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004)) AND (LIMIT-TO(LANGUAGE, "English") OR LIMIT-TO(LANGUAGE, "German") OR LIMIT-TO(LANGUAGE, "French") OR LIMIT-TO(LANGUAGE, "Italian")) AND (LIMIT-TO(DOCTYPE, "ar") OR LIMIT-TO(DOCTYPE, "re")) 278 document results
18 History Search Terms (INDEXTERMS(pharyngitis) OR TITLE-ABS-KEY(pharyngitis) OR INDEXTERMS(nasopharyngitis) OR TITLE-ABS-KEY(nasopharyngitis) OR INDEXTERMS(rhinopharyngitis) OR TITLE-ABS-KEY(rhinopharyngitis) OR INDEXTERMS(sinusitis) OR TITLE-ABS-KEY(sinusitis) OR INDEXTERMS(rhinitis) OR TITLE-ABS-KEY(rhinitis) OR TITLE-ABS-KEY("acute Rhinitis") OR TITLE-ABS-KEY("nasal catarrh") OR TITLE-ABS-KEY("acute nasal catarrh") OR INDEXTERMS("common cold") OR TITLE-ABS-KEY("common cold") OR INDEXTERMS(laryngitis) OR TITLE-ABS-KEY(laryngitis) OR TITLE-ABS-KEY("upper respiratory tract infection") OR TITLE-ABS-KEY("viral upper respiratory tract infection") OR TITLE-ABS-KEY("head cold") OR INDEXTERMS(coryza) OR TITLE-ABS-

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17 History Search Terms (INDEXTERMS(pharyngitis) OR TITLE-ABS-KEY(pharyngitis) OR INDEXTERMS(nasopharyngitis) OR TITLE-ABS-KEY(nasopharyngitis) OR INDEXTERMS(rhinopharyngitis) OR TITLE-ABS-KEY(rhinopharyngitis) OR INDEXTERMS(sinusitis) OR TITLE-ABS-KEY(sinusitis) OR INDEXTERMS(rhinitis) OR TITLE-ABS-KEY(rhinitis) OR TITLE-ABS-KEY("acute Rhinitis") OR TITLE-ABS-KEY("nasal catarrh") OR TITLE-ABS-KEY("acute nasal catarrh") OR INDEXTERMS("common cold") OR TITLE-ABS-KEY("common cold") OR INDEXTERMS(laryngitis) OR TITLE-ABS-KEY(laryngitis) OR TITLE-ABS-KEY("upper respiratory tract infection") OR TITLE-ABS-KEY("viral upper respiratory tract infection") OR TITLE-ABS-KEY("head cold") OR INDEXTERMS(coryza) OR TITLE-ABS-KEY(coryza) OR TITLE-ABS-KEY("acute coryza")) AND (INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-

KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed")) AND (LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004) OR LIMIT-TO(PUBYEAR, 2014) OR LIMIT-TO(PUBYEAR, 2013) OR LIMIT-TO(PUBYEAR, 2012) OR LIMIT-TO(PUBYEAR, 2011) OR LIMIT-TO(PUBYEAR, 2010) OR LIMIT-TO(PUBYEAR, 2009) OR LIMIT-TO(PUBYEAR, 2008) OR LIMIT-TO(PUBYEAR, 2007) OR LIMIT-TO(PUBYEAR, 2006) OR LIMIT-TO(PUBYEAR, 2005) OR LIMIT-TO(PUBYEAR, 2004)) AND (LIMIT-TO(LANGUAGE, "English") OR LIMIT-TO(LANGUAGE, "German") OR LIMIT-TO(LANGUAGE, "French") OR LIMIT-TO(LANGUAGE, "Italian"))

1,128 document results

2 INDEXTERMS("self care") OR TITLE-ABS-KEY("self care") OR INDEXTERMS("Self Medication") OR TITLE-ABS-KEY("Self Medication") OR INDEXTERMS("Self Administration") OR TITLE-ABS-KEY("Self Administration") OR INDEXTERMS("Patient Education") OR TITLE-ABS-KEY("Patient Education") OR INDEXTERMS("Patient Participation") OR TITLE-ABS-KEY("Patient Participation") OR INDEXTERMS("self efficacy") OR TITLE-ABS-KEY("self efficacy") OR INDEXTERMS("Telemedicine") OR TITLE-ABS-KEY("Telemedicine") OR INDEXTERMS("Self Assessment") OR TITLE-ABS-KEY("Self Assessment") OR INDEXTERMS("self management") OR TITLE-ABS-KEY("self management") OR INDEXTERMS("Patient empowerment") OR TITLE-ABS-KEY("patient empowerment") OR TITLE-ABS-KEY("health awareness") OR TITLE-ABS-KEY("patient awareness") OR TITLE-ABS-KEY("self help") OR TITLE-ABS-KEY("self monitoring") OR TITLE-ABS-KEY("home monitoring") OR TITLE-ABS-KEY("tele monitoring") OR TITLE-ABS-KEY("self treatment") OR TITLE-ABS-KEY("self treated") OR TITLE-ABS-KEY("telecare") OR TITLE-ABS-KEY("self diagnose") OR TITLE-ABS-KEY("self diagnosis") OR TITLE-ABS-KEY("self diagnosed") 286,885 document results

Search strategy CINAHL available via EBSCO – cold
Search date: 30th June 2014
Database: CINAHL available via EBSCO

S73	S33 AND S70 Eingrenzungen - Erscheinungsdatum: 20040101-20141231; MEDLINE-Datensätze ausschließen; Sprache: English, French, German, Italian	... (115)
S72	S33 AND S70 Eingrenzungen - Erscheinungsdatum: 20040101-20141231; MEDLINE-Datensätze ausschließen	... (118)
S71	S33 AND S70	... 355
S70	S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69	... (10,057)
S69	AB laryngitis	... (89)
S68	TI laryngitis	... (64)
S67	(MH "Laryngitis+")	... (627)
S66	TI "viral upper respiratory tract infections"	... (4)
S65	AB "viral upper respiratory tract infections"	... (16)
S64	AB "viral upper respiratory tract infection"	... (19)
S63	TI "viral upper respiratory tract infection"	... (2)
S62	TI "upper respiratory tract infections"	... (116)
S61	AB "upper respiratory tract infections"	... (236)
S60	AB "upper respiratory tract infection"	... (289)
S59	TI "upper respiratory tract infection"	... (71)
S58	AB "head cold"	... (0)
S57	TI "head cold"	... (2)
S56	AB "acute coryza"	... (0)
S55	TI "acute coryza"	... (0)
S54	TI coryza	... (0)
S53	AB coryza	... (28)
S52	TI "common cold"	... (291)
S51	AB "common cold"	... (259)
S50	(MH "Common Cold")	... (1,540)
S49	AB "acute nasal catarrh"	... (0)
S48	TI "acute nasal catarrh"	... (0)
S47	TI "nasal catarrh"	... (1)
S46	AB "nasal catarrh"	... (2)
S45	AB nasopharyngitis	... (70)
S44	TI nasopharyngitis	... (5)
S43	TI rhinopharyngitis	... (4)
S42	AB rhinopharyngitis	... (6)
S41	AB Sinusitis	... (785)
S40	TI Sinusitis	... (692)
S39	TI rhinitis	... (1,251)

S38	AB rhinitis	... (1,494)
S37	AB ""acute rhinitis"	... (36)
S36	TI ""acute rhinitis"	... (36)
S35	(MH "Sinusitis+") OR (MH "Rhinitis+")	... (5,290)
S34	(MH "Pharyngitis") OR (MH "Tonsillitis")	... (1,312)
S33	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32	(112,779)
S32	"self diagnosed"	... (17)
S31	"self diagnosis"	... (635)
S30	"self diagnose"	... (27)
S29	"self assessment"	... (6,349)
S28	"self efficacy"	... (11,442)
S27	"patient participation"	... (613)
S26	"self treated"	... (27)
S25	"self treatment"	... (240)
S24	"telemedicine"	... (3,460)
S23	"telecare"	... (213)
S22	"telemonitoring"	... (196)
S21	"home monitoring"	... (219)
S20	"self monitoring"	... (2,781)
S19	"self help"	... (1,838)
S18	"patient awareness"	... (154)
S17	"health awareness"	... (305)
S16	"self administration"	... (2,026)
S15	"patient empowerment"	... (337)
S14	"patient education"	... (40,902)
S13	"self management"	... (4,746)
S12	"self medication"	... (1,033)
S11	"self care"	... (15,327)
S10	(MH "Telehealth+")	... (7,675)
S9	(MH "Self-Efficacy")	... (8,961)
S8	(MH "Consumer Participation")	... (9,976)
S7	(MH "Self Assessment")	... (4,688)
S6	(MH "Self Diagnosis+")	... (8,534)
S5	(MH "Self Administration+")	... (3,089)
S4	(MH "Empowerment")	... (7,035)
S3	(MH "Patient Education+")	... (46,522)
S2	(MH "Self Medication")	... (793)
S1	(MH "Self Care+")	... (24,230)

Annex 4: Inclusion/Exclusion Criteria

Table A 3: First selection (abstracts)

Exclusion criteria	
Formal criteria	
E1	Study is not published in English, French, German, or Italian
E2	Duplicates
E3	Study is not relevant for the Member States of European Union
E4	Publication date
Contextual criteria	
E5	Different research question
E6	Different ailment, i.e. other medical focus(e.g. catheter-associated urinary tract infection or in combination with other (chronic) diseases)
E7	Different intervention (e.g. not self-care)
E8	(Primary) Prevention studies
E9	Diagnostic studies
Study design	
E10	Congress presentations, posters, comments, letters etc. (i.e. abstracts not based on a study)
E11	Case studies/case series
E12	Studies that do not focus on human medicine (animal studies) or in-vitro studies
Inclusion criteria	
Medical criteria	
I1	Basic prerequisites fulfilled (according to abstract, title, key words)
I2	HTA/systematic reviews/meta analysis
I3	Intervention studies
I4	Observational studies
Other inclusion criteria	
I5	Relevant initiatives
I6	Relevant background information

Table A 4: Second selection (full texts)

Exclusion criteria	
Formal criteria	
E1	Study is not published in English, French, German, or Italian
E2	Duplicates
E3	Study is not relevant for the Member States of European Union
E4	Publication date
Contextual criteria	
E5	Different research question (e.g. how can the use of antibiotics be reduced?)
E6	Different ailment, i.e. other medical focus(e.g. catheter-associated urinary tract infection or ailment in combination with other (chronic) diseases)
E7	Different intervention (e.g. tele-consultation with primary physician, nurse´s prescription)
E8	(Primary) Prevention studies
Study design	
E10	Congress presentations, posters, comments, letters, "how to"-articles etc. (i.e. abstracts not based on a study)
E11	Case studies/case series (cut-off point to be defined)
E12	Studies that do not focus on human medicine (animal studies) or in-vitro studies
E13	Only endpoint is the reduction of use of antibiotics
E14	Study population is limited to children or geriatric patients
Inclusion criteria	
Medical criteria	
I1a	Study is concerned with selected ailment and self-care
I1b	Study investigates relevant endpoints (efficacy, effectiveness, safety, costs)
I2	HTA/systematic reviews/meta analysis
I3	Intervention studies
I4	Observational studies
Other inclusion criteria	
I5	Relevant initiatives in the European Union
I6	Relevant background information (e.g. possible treatments of the selected ailment)

Annex 5: Grade of Evidence

Table A 5: Risk of bias - Definitions

Low risk of bias	It is unlikely that the outcome of the study is significantly distorted by confounding factors. The confidence in the correctness of the results is high.
Moderate risk of bias	It is unclear to what extent the results of the study are distorted by confounding factors. Confounders are possible and could provide the correctness of the results into question.
High risk of bias	It is very likely that the result of the study is significantly distorted by confounding factors. The confidence in the correctness of the results is very low.
Unclear risk of bias	The risk of bias cannot be evaluated because of missing information in the study.

Source: (HigginsGreen 2011); presentation: own

Table A 6: Criteria for evaluation of external validity

Relevant question	**Explanation**
Did the study refer to populations in primary care?	Many studies are conducted in a highly specialised inpatient setting (such as university clinics) and the results are therefore not transferable to other settings such as primary care.
Were the eligibility criteria not too stringent?	The inclusion and exclusion criteria for patients of clinical trials are often very stringent (age, co-morbidities etc.) and do not reflect the actual patient population. The transferability of the results to average patients is therefore low.
Were endpoints assessed that are relevant for the patient (health outcomes)?	In clinical trials the primary endpoints are often surrogate endpoints from laboratory data that might not be relevant to the patient. Patient relevant endpoints are health outcomes that the patient can subjectively experience and feel (such as reduction of symptoms).
Were the study period and the modes of treatment clinically relevant (resembling conditions of daily living)?	The study period and mode of treatment should resemble treatment situations in real life. This means that the mode and duration should be flexible and according to patient´s behaviour in real life.
Was the sample size sufficiently large to assess minimally important differences from a patient perspective?	Statistical significance is usually ensured by a sufficiently large study population; however, this does not mean that the population is large enough to assess relevant differences that can be experienced by the patient. The minimal clinically important difference should be taken into account when calculating the necessary size of the study population.

Source: (Gartlehner et al. 2006); presentation: own

Table A 7: Evidence grade

	Internal validity				
External validity		**Low**	**Moderate**	**Unclear**	**High**
	Low	Very low	Low	Very low	Low
	Moderate	Low	Low/moderate	Unclear	Moderate/high
	Unclear	Low	Low	Unclear	Moderate
	High	Low	Moderate	Unclear	High

Table A 8: Overall evidence grade – Definitions

Evidence Grade	Definition
High	It is unlikely that further research changes the confidence in the observed results.
Moderate	Further research is likely to have an impact on the confidence in the observed results and the intervention effect might change.
Low	Further research is very likely to have a significant impact on the confidence in the observed results and the intervention effect might change.
Very low	The observed intervention effect is very uncertain.

Source: (Guyatt et al. 2008); presentation: own

Annex 6: List of Initiatives

Country	Name	Type of initiative
Austria	Gesundheit.gv.at	health information platform
Austria	Initiative Insektengift Allergie	information campaign
Austria	Netdoktor.at	health information platform
France	Ameli Santé	health information platform
Germany	Deutsche Gesundheitshilfe e.V.	several information campaigns
Germany	Grünes Rezept	legislation and/or regulatory changes
Germany	Initiative Schmerzlos	information campaign
Germany	Jucknix	health information platform
Germany	MigräneLiga e.V.	health information platform
Germany	Silometer Cough Testing App	innovative technology
Ireland	Feel better	information campaign
Ireland	Self-Care first	legislation and/or regulatory changes
Italy	Cultura dell' automedicazione responsabile	health information platform
Italy	Enciclopedia salute	health information platform
Italy	Erboristeria	information platform
Italy	Guida all' utilizzo dei farmaci generici	information platform
Latvia	Tele-helpline	telehotline
Malta	Educate yourself about your Health	health information platform
Malta	Ministry Campaigns	information campaign
Spain	Automedicación. Factores de riesgo para la salud	information campaign
The Netherlands	Maagzuur.nl	information platform
The Netherlands	zelfzorg.nl	information platform
United Kingdom	Ask your pharmacist week	information campaign
United Kingdom	Choose Well - Manchester	information campaign
United Kingdom	Choose Well - Wales	information campaign
United Kingdom	Choose Well summer campaign	information campaign
United Kingdom	Choose Well' winter campaign	information campaign

Country	Name	Type of initiative
United Kingdom	Dispensing Health	awareness campaign
United Kingdom	Home care is best	information campaign
United Kingdom	Making sense of health	education campaign
United Kingdom	Minor Ailment Service/Scheme Scotland	legislation and/or regulatory changes
United Kingdom	NHS 111	telehotline
United Kingdom	NHS choices	health information platform
United Kingdom	NHS direct Wales	health information platform
United Kingdom	Patient.co.uk	health information platform
United Kingdom	Quick reference guide of the Consumer Health Information Centre	health information platform
United Kingdom	Self Care Aware: Joining Up Self Care in the NHS	information campaign
United Kingdom	Self Care Campaign	awareness campaign
United Kingdom	Self Care Forum (based on Self Care Campaign)	information campaign
United Kingdom	Self Care Week	awareness campaign
United Kingdom	Sickness Certification	legislation and/or regulatory changes
United Kingdom	The earlier the better	information campaign
United Kingdom	Treat yourself better without antibiotics	information campaign
United Kingdom	WiPP = Working in partnership program	Strategy/ awareness campaign

Annex 7: Quality tables

Assessment of included studies: Athlete's foot

Systematic reviews/HTA/meta analysis

Table A 9:Crawford & Hollis, 2012

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?	X		
METAANALYSEN			
Was the publication bias evaluated?			X
Was the heterogeneity evaluated statistically?	X		
Was the reason for the heterogeneity analysed?	X		
Was the statistical model chosen adequately?	X		
Assessment of the risk of bias	**Low**	**Unclear / moderate**	**High**
	X (systematic review)	X (meta-analysis)	
Comments • Cochrane review			

Interventional studies

Table A 10: Ortonne et al., 2006

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?			X
Was the allocation concealment ensured?			X
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?	X		
Were the study participants blinded?	X		
Were the persons who administered the intervention blinded?	X		
Were the persons who surveyed the end points blinded?	X		
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?	X		

Criteria to assess the quality of RCTs	Yes	No	Unclear
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?		X	
Is it reasonable to assume that all gathered endpoints have been reported?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
		X	
Comments ▪ Funding by Novartis ▪ Double blinded, clinical trial, but nothing was mentioned about randomisation and allocation concealment ▪ demographic and disease characteristics of treatment groups were similar ▪ endpoint evaluation was 1 week and 6 weeks after treatment plus 12 weeks for those with effective treatment ▪ low drop-out rate: 7.8% in the intervention group and 7.2% in the control group			

Assessment of included studies: Cold

Systematic reviews /HTA /meta-analysis

Table A 11: AlBalawi ZH et al., 2013

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?	X		
METAANALYSEN			
Was the publication bias evaluated?			X
Was the heterogeneity evaluated statistically?	X		
Was the reason for the heterogeneity analysed?		X	
Was the statistical model chosen adequately?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
	X (literature review)	X (meta-analysis)	
Comments: ▪ Cochrane review (update) ▪ Metaanalysis was only conducted for adverse events as this was the only outcome that was reported in all included studies.			

Table A 12: Karsch-Völk, 2014

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?	X		
METAANALYSEN			
Was the publication bias evaluated?	X		
Was the heterogeneity evaluated statistically?	X		
Was the reason for the heterogeneity analysed?			X
Was the statistical model chosen adequately?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
	X	X (meta-analysis)	
Comments ▪ The meta-analysis was only exploratory and all studies (regardless of the echinacea product used) were pooled ▪ Findings of the included studies were highly consistent, although it is unclear whether the author did not analyse the reason for the heterogeneity			

Table A 13: Lanas et al., 2011

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?		X	
Did at least two researchers decide on the exclusion and inclusion of the studies?			X
Did at least two researchers evaluate the methodological quality of the included studies?			X
Was the methodological quality considered in the synthesis of the evidence?			X
METAANALYSEN			
Was the publication bias evaluated?		X	
Was the heterogeneity evaluated statistically?	X		
Was the reason for the heterogeneity analysed?			X
Was the statistical model chosen adequately?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
			X
Comments ▪ Most relevant inclusion and exclusion criteria are listed ▪ All studies were conducted by Bayer Health Care by 31 March 2008 ▪ No heterogeneity was found			

Intervention studies

Table A 14: Chaudry et al., 2006

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?			X
Was the allocation concealment ensured?			X
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?			X
Were the study participants blinded?			X
Were the persons who administered the intervention blinded?		X	
Were the persons who surveyed the end points blinded?		X	X
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?	X	X	
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?			X
Is it reasonable to assume that all gathered endpoints have been reported?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
		X (unclear)	

Comments

- The study protocol (randomization, collection of endpoints) and the characteristics of the treatment groups are insufficiently described.
- As the intervention is the use of a protocol for a nurse-based telephone management the blinding of the care givers was impossible.
- It is not clear whether the patient´s new about the trial/intervention.
- The drop-out rate for the clinical evaluation was lower than 20% but not for the participants of the survey
- the satisfaction with the intervention was collected by a survey filled in by the patient

Table A 15: McNally et al., 2010

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?	X		
Was the allocation concealment ensured?	X		
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?	X		
Were the study participants blinded?	X		
Were the persons who administered the intervention blinded?	X		

Criteria to assess the quality of RCTs	Yes	No	Unclear
Were the persons who surveyed the end points blinded?	X		
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?	X		
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?	X		
Is it reasonable to assume that all gathered endpoints have been reported?	X		
Assessment of the risk of bias	**Low**	**Unclear/moderate**	**High**
	X		
Comments ▪ Study was blinded / placebo controlled			

Table A 16: Wade et al., 2011

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?	X		
Was the allocation concealment ensured?	X		
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?	X		
Were the study participants blinded?		X	
Were the persons who administered the intervention blinded?	X		
Were the persons who surveyed the end points blinded?			X
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?	X		
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?	X		
Is it reasonable to assume that all gathered endpoints have been reported?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
		X	
Comments ▪ Biggest problem of the study are the different flavours of the lozenges ▪ No drop-outs ▪ Patient diaries → persons who surveyed the endpoints were not blinded			

Table A 17: Yardley et. al, 2010

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?	X		
Was the allocation concealment ensured?	X		
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?	X		
Were the study participants blinded?	X		
Were the persons who administered the intervention blinded?	X		
Were the persons who surveyed the end points blinded?	X		
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?		X	
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?		X	
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?		X	
Is it reasonable to assume that all gathered endpoints have been reported?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
		X	

Comments

- A major drawback of this intervention study was the substantial dropout before the follow-up study, which is a common problem in internet studies.
- ITT was precluded as online volunteers could not be followed up rigorously
- Participants were automatically assigned to the intervention and control groups and were blind to group assignment
- Presumptively the allocation concealment was ensured and the persons who administered the intervention were blinded since the assignment to the groups was done automatically

Observational studies

Table A 18: Häcker et al., 2010

Criteria to assess the quality of pre-post studies	Yes	No	Unclear
DESIGN			
Was the research question clearly defined and stated?	X		
Were eligibility criteria for the study population prespecified and clearly described?	X		
Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?			X
Were all eligible participants that met the prespecified entry criteria enrolled?	X		
Was the sample size sufficiently large to provide confidence in the findings?		X	X
Was the intervention clearly described and delivered consistently across the study population?		X	
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?			X
COMPARABILITY			
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment described sufficiently?		X	
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment similar?			X
ENDPOINTS			
Were the people assessing the outcomes blinded to the participants' interventions?		X	
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?		X	
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		X	
Was the general drop-out-rate lower than 20 %?		X	
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
			X

Comments

- No eligibility criteria were specified/everybody was eligible; Some participants have taken the drug before; this implies high expectations to the effects of the drug and is therefore a high bias risk
- No power calculations are presented but the sample size seems quite small (64 persons)
- As this was an observational study, no instructions were given to the patient how to use the drug
- the outcomes were prespecified, but as the data was collected through a questionnaire, the answers might not be reliable and consistent across the participants

Table A 19: Riebling and Unkauf, 2004

Criteria to assess the quality of pre-post studies	Yes	No	Unclear
DESIGN			
Was the research question clearly defined and stated?	X		
Were eligibility/selection criteria for the study population prespecified and clearly described?	X		
Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?			X
Were all eligible participants that met the prespecified entry criteria enrolled?	X		
Was the sample size sufficiently large to provide confidence in the findings?			X
Was the test/service/intervention clearly described and delivered consistently across the study population?			X
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?			X
COMPARABILITY			
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment described sufficiently?		X	
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment similar?			X
ENDPOINTS			
Were the people assessing the outcomes blinded to the participants' exposures/interventions?		X	
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?	X		
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		X	
Was the general drop-out-rate lower than 20 %?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
			X
Comments ▪ No power calculations are presented ▪ The intervention was clearly described, but pattern of use was up to patient ▪ Outcomes were assessed with a questionnaire			

Table A 20: Theurer and Gessner, 2011

Criteria to assess the quality of pre-post studies	Yes	No	Unclear
DESIGN			
Was the research question clearly defined and stated?		X	
Were eligibility/selection criteria for the study population prespecified and clearly described?		X	
Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?			X
Were all eligible participants that met the prespecified entry criteria enrolled?		X	
Was the sample size sufficiently large to provide confidence in the findings?	X		
Was the test/service/intervention clearly described and delivered consistently across the study population?	X		
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment described sufficiently?		X	
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment similar?			X
ENDPOINTS			
Were the people assessing the outcomes blinded to the participants' exposures/interventions?		X	
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?		X	
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?	X	X	
Was the general drop-out-rate lower than 20 %?		X	
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
			X

Comments

- every participating pharmacy was allowed to distribute up to 5 questionnaires – not stated if any criteria was used for distribution
- 63% of the participants have taken the drug before → positive expectations → high risk of bias
- The endpoints were assessed by questionnaire / self-assessment
- The outcome measures of interest were taken multiple times after the intake, but only once before the treatment
- The drop-out rate was higher than 20%

Assessment of included studies: Cough

Systematic Reviews/HTA/meta analysis

Table A 21: Conrad et al., 2007

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?			X
Did at least two researchers evaluate the methodological quality of the included studies?			X
Was the methodological quality considered in the synthesis of the evidence?			X
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
		X	
Comments ▪ The study/review focuses on the current pharmacological, toxicological and clinical data covering the efficacy and innocuousness of EPs® 7630 when administered for the treatmentof acute bronchitis ▪ The study is based on several other studies investigating the effects of Pelagornium sidoides extra; The study also includes the results of the study Schulz. (2007) Pelargonium siduoides-Extract (EPs® 7630) for the treatment of 217 patients with acute bronchitis. Publication of an additional double-blind study [German]			

Table A 22: Smith et al., 2012

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
	X		
Comments Cochrane review (update)			

Table A 23: Timmer et al., 2013

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?	X		
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
	X		
Comments ▪ Cochrane review (update) ▪ characteristic of included studies was presented			

Intervention study

Table A 24: Schulz, 2007

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?			X
Was the allocation concealment ensured?			X
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?	X		
Were the study participants blinded?	X		
Were the persons who administered the intervention blinded?			X
Were the persons who surveyed the end points blinded?			X
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?		X	
Was the general drop-out rate lower than 20 %?			X
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?			X
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?		X	
Is it reasonable to assume that all gathered endpoints have been reported?			X
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
			X
Comments ▪ an adequate randomising method is presumed, although it is not exactly described in the study ▪ an proper allocation concealment is not explicitly mentioned ▪ it is not clear what the authors mean with „double-blinded" ▪ Nothing was mentioned			

Table A 25: Gonzales, 2005

Criteria to assess the quality of pre-post studies	Yes	No	Unclear
DESIGN			
Was the research question clearly defined and stated?	X		
Were eligibility/selection criteria for the study population prespecified and clearly described?	X		
Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?	X		
Were all eligible participants that met the prespecified entry criteria enrolled?	X		
Was the sample size sufficiently large to provide confidence in the findings?	X		
Was the test/service/intervention clearly described and delivered consistently across the study population?	X		
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment described sufficiently?	X		
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment similar?	X		
ENDPOINTS			
Were the people assessing the outcomes blinded to the participants' exposures/interventions?		X	
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?		X	
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		X	
Was the general drop-out-rate lower than 20 %?			X
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**

Comments

- The research question of the study was „How to reduce antibiotics"; Therefore a household- and office based patient education intervention was launched; The Intervention included a reference card providing easy-to-read facts about symptoms and treatments for ARIs; Although the research questions focussed on the reduction of antibiotics it also provides valuable insights into the relationship of patient education and self-care.
- the study was only conducted at PCT in the Denver Area
- uthors described the patient and provider characteristics

Pre-Post Studies

Table A 26: Paul et. al., 2007

Criteria to assess the quality of pre-post studies	Yes	No	Unclear
DESIGN			
Was the research question clearly defined and stated?	X		
Were eligibility/selection criteria for the study population prespecified and clearly described?	X		
Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?	X		
Were all eligible participants that met the prespecified entry criteria enrolled?	X		
Was the sample size sufficiently large to provide confidence in the findings?			X
Was the test/service/intervention clearly described and delivered consistently across the study population?	X		
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment described sufficiently?		X	
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment similar?			X
ENDPOINTS			
Were the people assessing the outcomes blinded to the participants' exposures/interventions?	X		
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?		X	
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		X	
Was the general drop-out-rate lower than 20 %?	X		
Assessment of the risk of bias	**Low**	**Unclear/moderate**	**High**
		X	
Comments ▪ *A drawback of* the study was, that the no-treatment group was not blinded to their treatment arm because the received no placebo. ▪ Participants in the study received either a single nocturnal dose of honey or honey-flavored DM or no treatment 30 minutes prior to bedtime ▪ Improving the bothersome nature of cough during bedtime related to its frequency and severity ▪ Questions on frequency, severity, degree how bothersome coughing was regarded and how much cough affected child's or parent's ability to sleep;			

Table A 27: White et al., 2012

Criteria to assess the quality of pre-post studies	Yes	No	Unclear
DESIGN			
Was the research question clearly defined and stated?	X		
Were eligibility/selection criteria for the study population prespecified and clearly described?	X		
Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?	X		
Were all eligible participants that met the prespecified entry criteria enrolled?		X	
Was the sample size sufficiently large to provide confidence in the findings?	X		
Was the test/service/intervention clearly described and delivered consistently across the study population?	X		
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment described sufficiently?			X
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment similar?	X		
ENDPOINTS			
Were the people assessing the outcomes blinded to the participants' exposures/interventions?	X		
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?	X		
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		X	
If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?	X		
Was the general drop-out-rate lower than 20 %?		X	
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
	X		

Comments

- The study had a high dropout rate: 1568 participants were included in the study. 65 participants withdrew form the study or were lost to follow-up. A further 545 participants could not be included in the analysis of the primary outcome, either because they did not provide GP details or because their GP practice was outside the participating PCT area. From the lef 958 participants, only 657 questionnaires were returned at six months and 622 at twelfth months
- Intervention did not aim at a specific ailment but self-care in general through delivering self-care skills courses and creating local self-care networks;
- No p-value was reported, but the author constructed a 95% Confidence intervall

Assessment of included studies: Heartburn

Literature Review

Table A 28: Bruley et al., 2010

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?		X	
Were the selection criteria for the studies clearly defined?		X	
Was a comprehensive systematic literature search conducted?		X	
Did at least two researchers decide on the exclusion and inclusion of the studies?			X
Did at least two researchers evaluate the methodological quality of the included studies?			X
Was the methodological quality considered in the synthesis of the evidence?		X	
Assessment of the risk of bias	**Low**	**Unclear /moderate ?**	**High**
			X
Comments ▪ Method of review was not clear; It was not a systematic review; just a review on PPIs focusing on short-term and long-term treatment; ▪ No clear research question: just "review recent data (published after 2000) on PPI efficacy and to discuss more extensively the long-term strategies available for GERD treatment, as well as the shortcomings and limitations of current PPIs" ▪ No methods section, explaining research approach, literature search ▪ Nothing mentioned about methodological quality of the evidence included; just studies published after 2000			

Interventional studies

Table A 29: Konturek et al.,2007

Criteria to assess the quality of cohort studies	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?			X
Was the allocation concealment ensured?			X
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?			X
Were the study participants blinded?		X	
Were the persons who administered the intervention blinded?		X	
Were the persons who surveyed the end points blinded?		X	
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?	X		
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		

Criteria to assess the quality of cohort studies	Yes	No	Unclear
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?			X
Assessment of the risk of bias	**Low**	**Unclear/ moderate**	**High**
			X
Comments ▪ No blinding: for administration, assessment of endpoints, for patients ▪ no concealed allocation to treatment groups ▪ Prognostic factors only shortly mentioned (obesity, excess weight), but patients show normal weight; thus, not clear if treatment groups similar regarding to prognostic factors ▪ Intervention equally assessed in both groups, equal proceeding of intervention ▪ No drop outs, but relative small intervention groups(n=26; n=27) ▪ Unclear if intention to treat analysis conducted - not mentioned ▪ Study sponsored by Bayer; Bayer also provided statistical plan and analysis			

Table A 30: Peura et al. 2009

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?	X		
Was the allocation concealment ensured?	X		
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?	X		
Were the study participants blinded?	X		
Were the persons who administered the intervention blinded?	X		
Were the persons who surveyed the end points blinded?	X		
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?	X		
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Was an intention-to-treat (ITT-) analysis conducted and was it carried out correctly?	X		
Is it reasonable to assume that all gathered endpoints have been reported?	X		
Assessment of the risk of bias	**Low**	**Unclear/ moderate**	**High**
	X	X	
Comments ▪ Single randomization code 1:1:1 ratio, ▪ Funding by Novartis Health Inc. ▪ Author a consultant and advisory board member for Novartis Consumer Inc.			

Observational studies

Table A 31: Häcker and Morck, 2012

Criteria to assess the quality of pre-post studies	Yes	No	Unclear
DESIGN			
Was the research question clearly defined and stated?	X		
Were eligibility/selection criteria for the study population prespecified and clearly described?	X		
Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?	X		
Were all eligible participants that met the prespecified entry criteria enrolled?		X	X
Was the sample size sufficiently large to provide confidence in the findings?			X
Was the intervention clearly described?	X		
Was the intervention delivered consistently across the study population?		X	
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment described sufficiently?		X	
Is the distribution of prognostic factors between the treatment group and the general population that is affected by the ailment similar?			X
ENDPOINTS			
Were the people assessing the outcomes blinded to the participants' interventions?		X	
Were the endpoints assessed before and after the intervention?		X	
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?	X		
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?		X	
Was the general drop-out-rate lower than 20 %?			X
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
			X
Comments ▪ Endpoints were assessed only after the intervention ▪ Intervention was not delivered consistently: patients could choose between 500 or 1,000mg hydrotalcite as chewable tablets or 1,000mg as oral suspension in sachets ▪ Everybody was eligible, but pharmacies were requested to include up to five participants			

Table A 32: Labenz & Schubert-Zsilavecz, 2012

Criteria to assess the quality of cohort studies	Yes	No	Unclear
SELECTION			
Were the treatment groups recruited from the same population during the same period of time?	X		
Did the authors exclude the possibility that a defined endpoint has already been present at the beginning of the study?	X		
Were interventions in all treatment groups assessed with the same method?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment groups described sufficiently?		X	
Is the distribution of prognostic factors between the treatment groups similar?			X
ENDPOINTS			
Were the endpoints assessed using the same method?	X		
Was the assessment of the endpoints blinded?		X	
Were potential confounders taken into account in the statistical analysis?			X
Was the study duration adequate and identical for all treatment groups?	X		
Was the general drop-out-rate lower than 20 %?		X	
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?			X
Assessment of the risk of bias	**Low**	**Unclear/ Moderate**	**High**
		X	X

Comments

- Selection was appropriate (see above)
- Prognostic factors are not mentioned, consequently not clear if prognostic factors are equally distributed in study population
- Assessment not blinded;
- Study duration adequate for basis questionnaire (14 days as max intake period of Antra), voluntary follow up after 3month (low participation → n=178)
- Not all eligible patients included, as pharmacies received only 5 documentation forms
- Sponsor: Bayer Vitality GmbH

Table A 33: Mehuys et al., 2009

Criteria to assess the quality of cohort studies	Yes	No	Unclear
SELECTION			
Were the treatment groups recruited from the same population during the same period of time?	X		
Did the authors exclude the possibility that a defined endpoint has already been present at the beginning of the study?	X		
Were interventions in all treatment groups assessed with the same method?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment groups described sufficiently?		X	
Is the distribution of prognostic factors between the treatment groups similar?			X
ENDPOINTS			

Criteria to assess the quality of cohort studies	Yes	No	Unclear
Were the endpoints assessed using the same method?		X	
Was the assessment of the endpoints blinded?			
Were potential confounders taken into account in the statistical analysis?			X
Was the study duration adequate and identical for all treatment groups?	X		
Was the general drop-out-rate lower than 20 %?	X		
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Assessment of the risk of bias	**Low**	**Unclear/ moderate**	**High**
		X	
Comments ▪ Possible that different antacids were used for treatment ▪ No blinding due to self-reported efficacy ▪ Low dropout rate ▪ For the management of heartburn just antacid was mentioned, but not which product			

Table A 34: Nähri, et al., 2005

Criteria to assess the quality of cohort studies	Yes	No	Unclear
SELECTION			
Were the treatment groups recruited from the same population during the same period of time?	X		
Did the authors exclude the possibility that a defined endpoint has already been present at the beginning of the study?	X		
Were interventions in all treatment groups assessed with the same method?	X		
COMPARABILITY			
Is the distribution of prognostic factors between the treatment groups described sufficiently?		X	
Is the distribution of prognostic factors between the treatment groups similar?			X
ENDPOINTS			
Were the endpoints assessed using the same method?	X		
Was the assessment of the endpoints blinded?	X		
Were potential confounders taken into account in the statistical analysis?			X
Was the study duration adequate and identical for all treatment groups?	X		
Was the general drop-out-rate lower than 20 %?	X		
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Assessment of the risk of bias	**Low**	**Unclear/ moderate**	**High**
		X	
Comments ▪ H2 receptor antagonists prescription free since 1996, thus data examined 6 years before and after switch; Data was extracted from the Finnish drug consumption data and register for adverse drug			

Assessment of included studies: Urinary Tract Infection

Systematic Reviews/HTA/meta analysis

Table A 35: Albert et al., 2004

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?	X		
METAANALYSEN			
Was the publication bias evaluated?			X
Was the heterogeneity evaluated statistically?	X		
Was the reason for the heterogeneity analysed?		X	
Was the statistical model chosen adequately?	X		
Assessment of the risk of bias	**Low**	**Unclear/ moderate**	**High**
	X (literature review)	X (meta analysis)	
Comments ▪ Cochrane review of 19 studies with a total of 1,120 women; ▪ The literature review examines the effects of antibiotics on recurrent urinary tract infection especially the ailment's prevention			

Table A 36: Eells et al, 2014

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?			X
Assessment of the risk of bias	**Low**	**Unclear/ moderate**	**High**
	X		
Comments: ▪ The article provides a literature review of 5 different prevention and management strategies of RUTI; these comprise: (1) daily antibiotics (2) daily estrogen (3) daily cranberry (4) acupuncture and (5) symptomatic self treatment; ▪ The study assesses the efficiency of each treatment with respect to rise in QALD (quality adjusted life-days) and and lower costs calculated through a Markov Chain Monte Carlo Model ▪ It was not mentioned if the methodological of the included studies was also considered in the literature review			

Table A 37: Falagas, 2006

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?			X)
Did at least two researchers evaluate the methodological quality of the included studies?			X
Was the methodological quality considered in the synthesis of the evidence?		X	
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
		X	
Comments: ▪ The article is a literature review about articles examining the effects of probiotics on urinary tract infection especially their preventive nature ▪ The review has some methodological flaws: It is not reported if two other researchers decided on the exclusion/inclusion and carried out the evaluation of the methodological quality ▪ The study does not address the methodological quality of the articles reviewed			

Table A 38: Hudson, 2006

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?		X	
Were the selection criteria for the studies clearly defined?			X
Was a comprehensive systematic literature search conducted?		X	
Did at least two researchers decide on the exclusion and inclusion of the studies?			X
Did at least two researchers evaluate the methodological quality of the included studies?			X
Was the methodological quality considered in the synthesis of the evidence?			X
Assessment of the risk of bias	**Low**	**Unclear /moderate**	**High**
			X
Comments ▪ The author describes treatment and prevention of bladder infections and underpins his descriptions with different studies ▪ The author did neither mention a literature search, nor considered more than one study on a certain treatment ▪ Presumptively the review does not reflect results of a comprehensive literature search.			

Table A 39: Jepson et al., 2012

Criteria to assess the quality of systematic reviews and meta-analyses	Yes	No	unclear
Is the review based on a clearly defined research question?	X		
Were the selection criteria for the studies clearly defined?	X		
Was a comprehensive systematic literature search conducted?	X		
Did at least two researchers decide on the exclusion and inclusion of the studies?	X		
Did at least two researchers evaluate the methodological quality of the included studies?	X		
Was the methodological quality considered in the synthesis of the evidence?			X
METAANALYSEN			
Was the publication bias evaluated?			X
Was the heterogeneity evaluated statistically?	X		
Was the reason for the heterogeneity analysed?		X	
Was the statistical model chosen adequately?	X		
Assessment of the risk of bias	**Low**	**Unclear/moderate**	**High**
	X (Literature Review)	X (meta analysis)	
Comments ▪ Cochrane review (update) of 24 studies with a total of 4,473 participants; ▪ Meta-analysis included only 13 studies, because either the design was not adequately chosen (cross-over study) data were not reported separately, for the first phase, or a lack of relevant data.			

Intervention study

Table A 40: Ferry et al., 2004

Criteria to assess the quality of RCTs	Yes	No	Unclear
SELECTION			
Was an adequate randomising method applied, in order to assign participants in the study to different treatment groups?		X	
Was the allocation concealment ensured?		X	
COMPARABILITY			
Were the treatment groups after randomisation similar with respect to essential prognostic characteristics or confounder?	X		
Were the study participants blinded?	X		
Were the persons who administered the intervention blinded?	X		
Were the persons who surveyed the end points blinded?	X		
Did all treatment groups receive identical treatments apart from the evaluated intervention?	X		
ENDPOINTS			
Were the endpoints in all treatment groups evaluated at the same point in time?	X		
Was the general drop-out rate lower than 20 %?		X	
Was the differential drop-out-rate between treatment groups lower than 15 percentage points?	X		
Was an intention-to-treat (ITT-) analysis conducted	X		

Criteria to assess the quality of RCTs	Yes	No	Unclear
and was it carried out correctly?			
Is it reasonable to assume that all gathered endpoints have been reported?	X		
Assessment of the risk of bias	**Low**	**Unclear/moderate**	**High**
	X		
Comments ▪ The study did not explain the randomisation process; In Addition, it also had a high drop-out rate ▪ Patients were randomly assigned to three different regimens of pivmecillinam (Selexid); However a fourth of the patients (i.e. 288) received placebos instead of antibiotics; Thus, the intervention was defined „no-intervention" to assess the natural course of UTI; ▪ Prior to inclusion, all patients received written and verbal information concerning the study and gave written consent to participate ▪ apparently there was a randomisation, but nothing is mentioned how it worked ▪ Presumptively it is a double-blinded study, but nothing exactly is mentioned; The same holds for the allocation concealment			

Annex 8: Extraction Tables

Table A 41: Athlete's foot: included publications second selection

Author/year	Titel	Type	Risk of bias
Crawford et al., 2007	Topical treatments for fungal infections of the skin and nails of the foot. (Review)	Systematic review	Low
Ortonne, et al., 2006	Efficacy and safety of a new single-dose terbinafine 1% formulation in patients with tinea pedis (athlete's foot): a randomized, double-blind, placebo-controlled study	Randomized control trial	Moderate

Table A 42: Crawford and Hollis, 2003

Author(s)	Crawford F, Hollis S
Title	Topical treatments for fungal infections of the skin and nails of the foot. (Review)
Journal	The Cochrane Library
Research question	▪ To identify and evaluate the evidence for topical treatmens for fungal infections of the skin and nails of the foot. ▪ To establish the effectiveness of topical treatments used for fungal infections of the skin and nails compared with other treatments or untreated controls
Country	USA, Belgium, Finland, Germany, Spain, Europe, Latin America,
Study design	Systematic literature review
Literature search	Databases: ▪ Cochrane Skin Group Specialised Register, ▪ Cochrane Central Register of Controlled Trials (CENTRAL), ▪ MEDLINE (OVID), ▪ EMASE From January 2005 onwards ▪ Science Citation Index and Social Science Citation Index within BIDS ▪ CAB-Health and Healthstar ▪ DARE ▪ NHS Economic Evaluation Database ▪ EconLit ▪ CINAHL From *March 2005* onwards Search period: Till March 2005 Study period: 1970-2003
Selection criteria	Inclusion criteria: ▪ RCTs of topical treatment for fungal infections of the skin and nails of the foot ▪ Men and women of any age who have a fungal infection of the skin or nails of human foot identified by microscopy and growth of dermatophytes in culture ▪ Any programme of treatment administered topically to treate fungal infections of the feet compared with other treatment, placebo, no treatments Exclusion criteria: ▪ Combined data from fingernails and toenails ▪ Combined evaluation of systemic and topical treatments for infected nails

Interventions	Any dose of topical testament for fungal infection of the skin and nails of the foot.
	Skin trials:
	▪ Two different allylamines (naftifine 1% and terbinafine 1%) vs. placebo
	▪ Six different azoles (bifonazole, clotrimazole, miconazole nitrate, oxiconazole nitrate, sulconazole nitrate and tioconazole) vs. placebo
	▪ Other topical antifungal treatment vs. Placebo
	▪ Comparison between azoles regimens
	▪ Allylamines 1 or 2 weeks vs. Azoles 1 or 2 weeks
	▪ Allylamines 1 week vs. Azoles 4 week
	▪ Allylamines vs. Other antifungal topical skin treatments
	▪ Azoles v. Other antifungal topical skin treatments
	▪ Other topical treatments:
	  ▪ Salicylic acid
	  ▪ Tea tree oil
	  ▪ Halprogen
	  ▪ tolnaftate

Endpoint	Rate of treatment failure ▪ Short-term: 2 weeks ▪ Medium-term: 6 weeks ▪ Long-term: 12 weeks
Results	▪ Good evidence that allylamines, azoles, butenafine, ciclopiroxolamine, tolciclate and tolnaftate are efficacious relative to placebo ▪ Allylamines produced evidence of greater effectiveness when used for longer; effectiveness increases over time ▪ Effectiveness of azoles also improves over time (six weeks after baseline greater than outcome after two weeks) ▪ Due to strengths of evidence and narrow CI placebo controls in future RCTs not recommended ▪ Butenafine, ciclopiroxolamine, tolciclate and tolnaftate also greater effectiveness than placebo, but based on limited number of trials including small numbers of people ▪ Length of treatment affects the success of azoles creams: clotrimzole used for four weeks instead of two improves effectiveness ▪ Direct comparison shows allylamines generally more efficacious than azoles; effect becomes detectable at 6 weeks after treatment begins ▪ No evidence to support the use of tea tree oil found ▪ The six trials of nail infections provided evidence that topical ciclopiroxolamine has poor cure rates and that amorolfine might be substantially more effective but more research is required.
Bias-risk subject to type of study	Low
Limitations	None stated by authors
Sponsors	First version of review funded by the Wales Office of Research and Development for Health and Social Care (WORD) For this version no sources of support
Conclusions of the authors	▪ Azoles also very effective and participants should be advised to take azole cream for four weeks (likely to produce better results than a one week cream) ▪ Little evidence that topical anti-fungals are effective in the management of onychomycosis or fungally infected toe nails ▪ Further research into the effectiveness of antifungal agents for nail infections is required.

Comments (own)	Cochrane Review ▪ Research question was clearly defined ▪ Selection criteria were stated ▪ Comprehensive literature search conducted ▪ Two researchers decided on exclusion and inclusion and evaluated methodological quality ▪ Methodological quality considered ▪ Meta analyses done

Table A 43: Ortonne et al., 2006

Author(s)	Ortonne JP, Korting HC, Viguié-Vallanet C, Larnier C, Savaluny E.			
Title	Efficacy and safety of a new single-dose terbinafine 1% formulation in patients with tinea pedis (athlete's foot): a randomized, double-blind, placebo-controlled study			
Journal	European Academy of Dermatology and Venereology			
Research question	Report [...] efficacy and safety of terbinafine 1% FFS and to determine the potential for relapse/re-infection during 12 weeks' follow-up			
Country	France, Germany			
Study design	Multicentre RCT (randomisation ratio 2:1)			
Study period, follow Up	▪ Post-treatment follow-up evaluations were conducted 1 and 6 weeks after treatment. ▪ A follow-up evaluation at 12 weeks was scheduled for patients effectively treated at week 6, to evaluate relapse/re-infection.			
Study size	• 324 enrolled (51 excluded due to negative cultures); • efficacy analysis conducted for 273 patients			
Population selection	**Inclusion criteria:** France: patients 12 years and older Germany: patients 18 years and older ▪ With clinically diagnosed tinea pedis (total sign/ symptom score > 2), ▪ lesion between the toes, with possible extension to the lateral surfaces and soles of the feet ▪ confirmed by a positive microscopy prior to dosing **Exclusion criteria:** ▪ Signs of systemic or other superficial fungal disease (e.g. onychomycosis), clinically relevant abnormal findings upon physical examination of the foot or previous treatment with a disallowed medication (such as corticosteroids)			
Characteristics of the study population		Terbinafine 1% FFS	Placebo	P-value
	Age (Ø ± SD)	42.8 ± 14.8	43.2 ± 15.9	n.s.
	Male n(%)	134 (70.5)	68 (81.9)	n.s.
Sites of tinea pedis lesions n (%)	Bilateral n(%)	150 (78.9)	68 (81.9)	n.s.
	Extension to sole/lateral faces	80 (42.1)	30 (36.1)	n.s.
Species identified on culture (all collection areas): n(%)	Trichophyton rubrum	141 (74.2)	58 (69.9)	n.s.
	Trichophyton mentagrophytes (interdigitale)	37 (19.5)	18 (21.7)	n.s.
	Trichophyton rubrum + T. Mentagrophytes (interdigitale)	5 (2.6)	4 (4.8)	n.s.

	Epidermophyton floccosum	7 (3.7)	3 (3.6)	n.s.
	▪ Baseline demographic and disease characteristics of treatment groups similar ▪ Epidemiological pattern of disease observed was representative of a typical tinea pedis population (80% bilateral lesions, 40% lesions on the sole and/or lateral area			
Intervention	**<u>Intervention group:*</u>** ▪ 214 patients supplied with a 4g tube of terbinafine FFS to be applied once at home on the evening of day 1; **<u>Control group:*</u>** ▪ 107 patients supplied with a placebo to be applied at home on the evening of day 1 *including the 51 excluded patients			
Endpoints	**<u>Efficacy:</u>** **Primary Efficacy endpoints:** ▪ Rate of effective treatment at week 6, defined as negative microscopy and culture, plus absent or minimal signs and symptoms; ▪ mild or no erythema, desquamation or pruritus (individual scores ≤ 1), no pustules, incrustation or vesiculation, and a total sign/symptom score **Secondary Efficacy endpoints:** ▪ mycological cure (negative microscopy and culture), changes in clinical signs/symptoms scores and complete cure (mycological cure and no signs or symptoms), evaluated at weeks 1 and 6 **<u>Safety:</u>** Monitoring and recording all adverse events 8including severity and relationship to study rug) ▪ at 6 weeks, investigator and patient provided overall assessments of safety and tolerability using a five-point scale (very good, good, moderate, poor, very poor)			
Results		Terbinafine 1% FFS	Placebo	P-value
Effective treatment after 6 weeks	Incl. Patients with missing values	120/190, 63.2%	14/83 16.9%	<0.0001
	Excl. Patients with missing values	120/175 68.6%	14/77 18.2%	<0.0001
Patients with missing data treated as failure 6 weeks	Negative culture	83.2	32.5	<0.0001
	Negative microscopy	74.2	25.3	<0.0001
	Mycological cure	71.6	20.5	<0.0001
Patients with missing data excluded 6 weeks	Negative culture	90.8	35.1	<0.0001
	Negative microscopy	81	27.3	<0.0001
	Mycological cure	78.2	22.1	<0.0001
Safety	Adverse effects such as mild burning, moderate peripheral oedema and mild pain and moderate aggravated pruritus	1%	11%	n.s.
Bias-risk subject to type of study	Moderate			
Limitations	Not stated			
Sponsors	Novartis Consumer Health, Nyon, Switzerland			
Conclusions of the authors	▪ Terbinafine 1% FES is compared to the control significant with respect to symptom relief and rates of effective treatment, negative microscopy, negative culture, mycological cure and complete cure.			

	▪ The relapse/re-infection rate 3 months after the end of single-dose therapy is similar to that previously demonstrated in a study using terbinafine 1% cream for 7 days
Comments (own)	▪ no intention-to-treat analysis conducted ▪ randomization method unclear ▪ allocation concealment unclear

Table A 44: Cold: included publications second selection

Author/year	Title	Type	Risk of bias
AlBalawi et al., 2013	Intranasal ipratropium bromide for the common cold (Review)	Systematic review and meta-analysis	Low (moderate for the meta-analysis)
Karsch-Völk et al., 2014	Echinacea for preventing and treating the common cold (Review)	Systematic review and exploratory meta-analysis	Low (moderate for meta-analysis)
Lanas et al., 2011	Short-term acetylsalicylic acid (Aspirin) use for pain, fever, or colds – Gastrointestinal adverse effects – A meta-analysis of randomized clinical trials	Meta-analysis	Moderate
Chaudry et al., 2006	Nurse-based telephone protocol versus usual care for management of URI and acute sinusitis: a controlled trial	(Cluster) randomized controlled trial	Unclear
McNally et al., 2010	Rapid relief of acute sore throat with AMC/DCBA throat lozenges: randomised controlled trial	Randomized controlled trial	Low
Wade et al., 2011	A multicentre, randomised, double-blind, single-dose study assessing the efficacy of AMC/DCBA Warm lozenge or AMC/DCBA Cool lozenge in the relief of acute sore throat	Randomized controlled trial	Moderate/high
Yardley et al., 2010	Evaluation of a web-based intervention providing tailored advice for self-medication of minor respiratory symptoms: Exploratory randomized controlled trial	Randomized controlled trial	Moderate
Häcker et.al, 2010	Selbstmedikation von Erkältungssymptomen mit Katimun	Pre-post study	High
Riebling and Unkauf, 2004	Rhino-Studie: Schnupfenbehandlung in der Selbstmedikation	Pre-post study	Unclear/Moderate
Theurer and Gessner, 2011	Zufriedene Patienten bei der Selbstmedikation von Erkältungsbeschwerden	Pre-post study	Moderate/ high

Table A 45: AlBalawi et al., 2013

Author(s)	AlBalawi ZH, Othman SS, AlFaleh K
Title	Intranasal ipratropium bromide for the common cold (Review)
Journal	The Cochrane Library
Research question	What is the effect of intranasal ipratropium bromide (IB) versus placebo or no treatment on severity of rhinorrhoea and nasal congestion in children and adults with the common cold?
Country	Denmark, Finland, Norway, Sweden, United Kingdom, United States,
Study design	Systematic literature review with a meta-analysis for adverse events
Literature search	Databases: CENTRAL (Cochrane Central Register of Controlled Trials), MEDLINE, EMBASE, AMED, Biosis, LILIACS Search period: until 2013 Study period: 1981 - 2007
Selection criteria	Inclusion criteria: ▪ Randomised controlled trials comparing intranasal IB with placebo or no treatment ▪ Children > 5 years and adults > 18 years ▪ Participants with recent symptoms suggestive of the common cold (self diagnosed by runny or stuffy nose, sneezing with or without symptoms of malaise, headache and cough) ▪ Naturally occurring and experimental rhinovirus infections Exclusion criteria: ▪ Allergic rhinitis ▪ Perennial non-allergic rhinitis and other concurrent respiratory infections ▪ Asthma, sinusitis and other chronic diseases ▪ Influenza and myalgia
Interventions	Any dose of intranasal IB as a single active agent and trials permitting co-interventions if equally balanced in both groups. Doses: three studies using 84 micrograms (µg) per nostril, two studies using 80 per nostril and one using 200 µg per nostril and one comparing different doses (42, 84 and 168 µg). Dosing frequency: three times a day in four studies and four times a day in three studies
Endpoint	Primary outcomes ▪ Change in severity of symptoms of rhinorrhoea and congestion (subjective assessment by validated scales) ▪ Overall improvement e.g. in health related quality of life (assessed by standardised questionnaire) Secondary outcome: ▪ Type and frequency of adverse events (e.g. epistaxis, dry mucous membranes, systematic anticholinergic effects)
Results	The included seven RCTs involved a total of 2,144 participants with patients between 12 and 70 years of age. ▪ Change in severity of symptoms: Rhinorrhoea (addressed in four studies): intranasal IB was found to be effective in ameliorating rhinorrhoea across the studies ▪ Nasal congestion (addressed in four studies): no significant difference between intervention and placebo group

	▪ Overall improvement (addressed in two studies): statistically significant improvement with IB was shown in one of the two studies.
	▪ Adverse events/ side events (odds ratios calculated in meta-analysis):
	  ▪ Epistaxis (addressed in four studies): 3.21 [1.68; 6.13]
	  ▪ Nasal dryness (addressed in all seven studies): 2.55 [1.5; 4.33]
	  ▪ Eye dryness (addressed in one study): 3.18 [0.13; 80.79]
	  ▪ Mouth dryness (addressed in four studies): 3.59 [1.38; 9.38]
	  ▪ Nasal irritation/burning (addressed in three studies): 0.77 [0.07; 8.00]
	  ▪ Headache (addressed in three studies): 0.55 [0.23; 1.28]
	  ▪ Tachycardia (addressed in two studies): 0.44 [0.04; 5.19]
	  ▪ Total adverse events/side effects: 2.09 [1.40; 3.11]

Bias-risk subject to type of study	For the primary endpoints: low risk of bias For the secondary endpoints (meta-analysis): moderate risk of bias
Limitations (stated by the authors)	The authors of the systematic review point out that despite the inclusion of seven RCTs, there was incomplete outcome data in two studies, randomisation and allocation concealment were unclear in four studies, blinding was insufficiently described in five studies, extent of involvement of funding provider (Boehringer Ingelheim Pharmaceutical Company) was not addressed in two studies,
Sponsors	-
Conclusions of the authors	"All seven studies showed consistent results favouring IB over placebo for rhinorrhoea. They also all reported side effects to be more frequent in the IB group but that they were generally well tolerated"
Comments (own)	

Table A 46: Karsch-Völk et al., 2014

Author(s)	Karsch-Völk M, Barrett B, Kiefer D, Bauer R, Ardjomand-Woelkart K, Linde K
Title	Echinacea for preventing and treating the common cold (Review)
Journal	The Cochrane Library
Research question	Is there evidence that Echinacea preparations are effective and safe compared to placebo in the prevention and treatment of the common cold?
Country	USA, Sweden, Germany, Canada, United Kingdom, Australia,
Study design	Systematic literature review and exploratory meta-analysis
Literature search	Databases: CENTRAL (Cochrane Central Register of Controlled Trials), MEDLINE, EMBASE, CINAHL, AMED, LILACS, Web of Science Search period: until 2013 Study period: 1992 – 2012
Selection criteria	Inclusion criteria: ▪ Study type: ▪ Randomized controlled trials

	▪ Participants
	  ▪ Individuals with non-specific viral upper respiratory tract infections (URTIs) with a clinical diagnosis of common cold, influenza-like syndrome or viral URTI
	  ▪ Volunteers without acute URTIs but treated for preventative purposes (prevention studies)
	  ▪ Volunteers without acute URTIs but challenged with rhinovirus treated for preventative or therapeutic purposes
	▪ Interventions:
	  ▪ Oral Echinacea mono-preparations versus placebo
	▪ Outcome measures:
	  ▪ Clinical outcome measures related to occurrence and severity or duration of infections
	Exclusion criteria:
	▪ Participants:
	  ▪ Individuals suffering from other URTIs with defined etiology (e.g. influenza) or more specific symptomatology (e.g. acute sinusitis, angina tonsillaris)
	▪ Interventions:
	  ▪ Combinations of Echinacea and other herbs
	  ▪ Echinacea versus no treatment or other treatment than placebo
	▪ Outcome measures:
	  ▪ Solely physiological parameters

Intervention	Oral intake of Echinacea mono-preparations
Endpoint	Primary outcomes: ▪ Number of participants experiencing at least one cold episode (prevention trials) ▪ Duration in days (treatment trials) ▪ Acceptability and safety outcome: Number of participants dropping out due to side effects or adverse events Secondary outcomes: ▪ Number of participants experiencing more than one cold episode; cold duration in days; severity scores (prevention trials) ▪ Total severity and duration measures; severity of symptoms at days two to four and at days five to ten; number of participants who developed the "full picture of a cold" (treatment trials) ▪ Acceptability and safety outcome: Total number of drop-outs and the number of participants reporting side effects or adverse events
Results	24 studies were included (15 had been included in the previous version of the review) and in these studies a wide array of different Echinacea preparations were used. The included studies involved a total of 1,822 healthy people in prevention trials and 3,448 patients in treatment trials. ▪ Primary outcomes: ▪ Number of participants experiencing at least one cold episode (addressed in 9 of 10 prevention trials): no statistically significant difference compared to placebo (highly consistent across studies) ▪ Duration in days (addressed in two treatment trials): no statistically significant difference compared to placebo was found ▪ Number of participants dropping out due to side effects or adverse events (addressed in seven studies): no

	significance, but wide confidence intervals due to low drop-out Secondary outcomes Prevention trials: ▪ Number of participants experiencing more than one cold episode (addressed in three trials): no significant difference, but wide confidence intervals ▪ Cold duration in days (addressed in four trials): one small trial reports very large (5.2 days) statistically significant effect over placebo, others range between 1.2 days shorter and 0.6 days longer with Echinacea compared to placebo ▪ Severity scores (addressed by five trials): no statistically significant difference was found ▪ Total number of participants dropping-out (addressed in nine trials): two trials reported significantly higher drop-out in Echinacea group than in placebo group, the other trials found no significant difference ▪ Number of participants reporting side effects or adverse events (addressed in eight trials): only one trial found significantly less adverse events in the placebo group Treatment trials: ▪ Total severity and duration (addressed in nine trials): standard mean difference (SMD) was not significant ▪ Severity of symptoms at days two to four (addressed in seven trials): two comparisons (out of eight) found a significant difference, but generally heterogeneous results ▪ Severity of symptoms at days 5 to 10 (addressed in eight trials): four comparisons (out of 11) found a significant difference, but generally heterogeneous results ▪ Participants who develop "full picture of a cold" (addressed in three trials): no significant differences were found ▪ Total number of participants dropping-out (addressed in nine trials): only one trial reported a significantly higher drop-out in Echinacea group than in placebo group, the other trials found no significant difference ▪ Number of participants reporting side effects or adverse events (addressed in eight trials): no significant differences were found in the trials; one trial showed an increased frequency of rash in children when using Echinacea.
Bias-risk subject to type of study	Low (review) Moderate (exploratory meta-analysis)
Limitations (stated by the authors)	The Echinacea products used in the trials varied a lot in preparation and concentration. Available research suggests that clinical effects of (some) Echinacea preparations are likely to be due to several components which may have synergetic effects. Heterogeneous quality of the included trials: 38% were considered by the authors to have a high risk of bias, 42% where considered to have a low risk of bias Lack of blinding can be a relevant problem in trials of Echinacea products The results of the meta-analysis (pooled estimates) have to be interpreted with caution and should not be interpreted as "average" effects
Sponsors	Non stated
Conclusions of the authors	The available Echinacea products differ greatly and most of them have not been tested in clinical trials. The prevention trials suggest that a number of Echinacea

	products slightly reduce the risk of getting a cold and if this is true, the lack of significance might be due to too few patients included in the single studies (lack of statistical power). The treatment trials suggest that the overall evidence for clinically relevant treatment effects over placebo is weak. Parental application of Echinacea preparations on children should be discouraged, as there is no evidence either on safety or effectiveness.
Comments (own)	-

Table A 47: Lanas et al., 2011

Author(s)	Lanas A, McCarthy D, Voelker M, Bruecker A, Senn S, Baron JA
Title	Short-term acetylsalicylic acid (Aspirin) use for pain, fever, or colds – Gastrointestinal adverse effects – A meta-analysis of randomized clinical trials
Journal	Drugs in R & D
Research question	What is the safety profile of short-term acetylsalicylic acid (ASA) use at the recommended doses for various OTC ASA indications?
Country	different
Study design	Literature review and meta-analysis
Literature search	Databases: all studies conducted by Bayer Health care were included Search period: until March 2008 Study period: 1987-2008
Selection criteria	Inclusion criteria: ▪ Efficacy or pharmacokinetic studies ▪ Adequate data documentation in terms of adverse events available Exclusion criteria: ▪ low-dose ASA for the prevention of cardiovascular diseases
Interventions	Treatment: Acetylsalicylic acid (ASA; Aspirin) alone (including ASA in combination with vitamine C, caffeine, or calcium) Control: placebo or an active comparator (acetaminophen (paracetamol) or ibuprofen)
Endpoint	Primary endpoints: Patient reported gastrointestinal adverse effects (GI AE) such as ▪ GI bleeding ▪ (severe/minor/any) dyspepsia ▪ abdominal pain ▪ gastro-oesophageal reflux disease (GORD)-related symptoms Secondary endpoints: Patient reported non-GI AEs such as ▪ cerebral hemorrhage ▪ non-GI, non-cerebral bleeding ▪ hypersensitivity reactions ▪ headache ▪ dizziness ▪ ipaired hearing abilitiy ▪ tinnitus ▪ mental confusion ▪ oral complications ▪ signs of overdose All endpoints were regarded as treatment related if they occurred in a time window of seven days after drug discontinuation

Results	**ASA versus placebo:** overall incidence of AEs was not statistically different in treatment and placebo group Primary endpoints: Patient reported gastrointestinal adverse effects (GI AE) were slightly but significantly higher in the ASA group than in the placebo group (odds ratio 1.3; 95% confidence interval 1.1, 1.5) ▪ GI bleeding: not reported ▪ severe dyspepsia: no significant differences ▪ minor dyspepsia: significantly higher in ASA group ▪ any dyspepsia: significantly higher in ASA group ▪ abdominal pain: no significant differences ▪ gastro-oesophageal reflux disease (GORD)-related symptoms: no significant differences Secondary endpoints: ▪ cerebral hemorrhage: did not occur ▪ non-GI, non-cerebral bleeding: no significant differences ▪ hypersensitivity reactions: did not occur ▪ headache: significantly lower in ASA group ▪ dizziness: no significant differences ▪ impaired hearing ability: occurred once in ASA group ▪ tinnitus: no significant differences ▪ mental confusion: occurred once in ASA group ▪ oral complications: no significant differences ▪ signs of overdose: no significant differences ASA versus active comparator: No statistically significant differences were found for the primary and secondary endpoints when comparing ASA with acetaminophen or ibuprofen.
Bias-risk subject to type of study	High
Limitations (stated by the authors)	The usage of ASA might vary in different populations (e.g. might be taken on a daily basis as prevention against cardiovascular events and colon cancer). Therefore, the conclusions apply only to very short-term treatment (majority of patients took a single dose of 500-1,000mg in 1 day). Safety data reported may not be valid for the entire population with access to OTC ASA, as patients at risk (elderly and with ulcer history) were excluded from clinical trial. The majority of patients in the included trials was relatively young and healthier than in comparable observational studies. There were very few AE in the included trials, much larger studies would be required to generate enough events to observe statistically significant differences (lack of statistical power)
Sponsors	Bayer HealthCare
Conclusions of the authors	Small increases in the risk of mild to moderate dyspepsia and abdominal pain with ASA, but no significant occurrence of major GI complications were observed.
Comments (own)	The method of the review is not clearly described and only studies from one provider (Bayer HealthCare) are considered, furthermore the study was funded by Bayer HealthCare

Table A 48: Chaudry et al., 2006

Author(s)	Chaudry R, Stroebel RJ, McLeod TG, Von Houten HK, Naessens JM, Jaeger TM, Bartel G, Scheitel SM
Title	Nurse-based telephone protocol versus usual care for management of URI and acute sinusitis: a controlled trial
Journal	Managed Care Interface
Research question	What are the clinical outcomes of patients with URI or sinus infection managed by a nurse-based, telephone treatment protocol using the guidelines of the Institute for Clinical Systems Improvement (ICSI)
Country	USA
Study design	Cluster randomized controlled trial
Study period, follow Up	30 days after initial contact
Study size	Intervention group: 10 physicians with 77 patients Control group: 12 physicians with 135 patients
Population selection	Inclusion criteria: ▪ adult patients of included physicians ▪ from January 2002 to July 2002 ▪ complaining of cough, runny nose, sinus pain, or sinus infection Exclusion criteria: patient does not meet ICSI-guideline criteria for diagnosis of sinusitis or URI
Characteristics of the study population	Diagnosis: URI: 65% of patients in intervention group and 61% of patients in control group Sinusitis: rest
Intervention	Intervention group: telephone treatment protocol: if patient met criteria for URI telephone management, symptomatic treatment measures were advised; if patient met criteria for sinusitits, an antibiotic prescription was called in to the pharmacy; no input from physician was required Control group: usual-care model: either appointment for an physician visit or talk with nursing care team who discussed details with a physician

Endpoints	▪ Use and choice of (first- or second-line) antibiotics
	▪ Telephone calls or visits for similar health problems or complications during 30 days after treatment to:
	  ▪ primary care physician
	  ▪ urgent-care centre
	  ▪ emergency department
	  ▪ hospital
	▪ Patient satisfaction:
	  ▪ Rated care received
	  ▪ Ease to have illness or symptoms evaluated
	  ▪ Ease to understand information received
	  ▪ Evaluation preference for symptoms in the future

Results	▪ Use and choice of (first- or second-line) antibiotics: URI: No antibiotics (Intervention): 72% No antibiotics (Control): 66% (difference not significant) First-line antibiotics prescribed (Intervention): 16% First-line antibiotics prescribed(Control): 12% (P-value not reported) Second-line antibiotics prescribed (Intervention): 12% Second-line antibiotics prescribed(Control): 22% (P-value not reported) Sinusitis: No antibiotics (Intervention): 0% No antibiotics (Control): 9% (P-value not reported)

	First-line antibiotics prescribed (Intervention): 81% First-line antibiotics prescribed(Control): 53% (significant difference) Second-line antibiotics prescribed (Intervention): 19% Second-line antibiotics prescribed(Control): 38% (P-value not reported) ▪ Telephone calls or visits for similar health problems or complications during 30 days after treatment to: ▪ primary care physician: not reported ▪ urgent-care centre: 8% from intervention group and 5% from control group (difference not significant) ▪ emergency department: none in both groups ▪ hospital: none in both groups ▪ Also reported: complications: 1 patient in intervention group and 3 patients in control group were diagnosed with pneumonia (difference not significant) ▪ Patient satisfaction (58% of intervention and 56% of control group completed survey) ▪ Rated care received (Intervention): 40% ▪ Rated care received (Control): 54% (significant difference) ▪ Ease to have illness or symptoms evaluated (Intervention): 58% ▪ Ease to have illness or symptoms evaluated (Control): 70% (significant difference) ▪ Ease to understand information received (Intervention): 73% ▪ Ease to understand information received (Control): 92% (significant difference) ▪ Evaluation preference for symptoms in the future (Intervention): 60% telephone; 31% clinic visit; 9% telephone ▪ Evaluation preference for symptoms in the future (Control):53% telephone (significant difference); 34% clinic visit (difference not significant); 13% no preference
Bias-risk subject to type of study	Unclear
Limitations (stated by the authors)	▪ Small number of subjects assessed ▪ Larger sample sizes might improve ability to detect significant differences ▪ ICSI guideline were made available for physicians and might have affected the choice of antibiotics used ▪ Survey response rate was low, which might have an effect on representativeness of surveyed group
Sponsors	None stated
Conclusions of the authors	Protocol-based nurse telephone management results in: ▪ Comparably low rates of antibiotics use in URI ▪ Increased first-line antibiotic prescribing to treat sinusitis ▪ Acceptably low rate of adverse events and need for subsequent care ▪ Stated preferences for telephone care with future similar illness
Comments (own)	The study population is not described sufficiently and the results could be flawed by the small sample size.

Table A 49: McNally et al., 2010

Author(s)	McNally D, Simpson M, Morris C, Shephard A, Goulder M
Title	Rapid relief of acute sore throat with AMC/DCBA throat lozenges: randomised controlled trial
Journal	The International Journal of Clinical Practice
Research question	What are the analgesic properties of amylmetacresol and dichlorobenzyl alcohol (AMC/DCBA) throat lozenges (Sprepsils®) in the relief of acute sore throat caused by upper respiratory tract infections?
Country	Northern Ireland / United Kingdom
Study design	Multi-centre, randomised, double-blind, parallel-group, placebo-controlled, multiple-dose study
Study period, follow Up	Study period: November 2007 and February 2008 Follow-up: between 4 and 7 Days after the start of the treatment
Study size	310 patients
Population selection	Inclusion criteria: ▪ Men or women aged between 18 and 75 years ▪ Primary diagnosis of sore throat with a recent onset within the past 4 days (i.e. ≤ 4 days) because of URTI ▪ Baseline sore throat score of ≥ 6 on the Throat Soreness Scale (TSS); ▪ Objective findings confirming the presence of tonsillopharyngitis i.e. ≥ 5 points on the expanded 21-point Tonsillopharyngitis Assessment (TPA) ▪ Written informed consent for study participation Exclusion criteria: ▪ History of allergy or known intolerance to the study or rescue medication (paracetamol) and their ingredients ▪ Sore throat present for more than 4 days ▪ Evidence of severe coughing or mouth breathing ▪ Use of any medicated confectionery or any products with demulcent properties, such as boiled sweets, within the previous 2 hours ▪ Use of any analgesic, antipyretic or 'cold' medication within the previous 8 hours ▪ And use of longer-acting or slow-release analgesic during the previous 24 h
Characteristics of the study population	▪ Mean age of all patients was 36.1 years; the age range was 18 to 76 years ▪ The mean TPA score in both treatment groups was similar i.e. 8.8 in the AMC/DCBA group and 9.1 in the placebo group ▪ The mean throat soreness score in the AMC/DCBA group was 7.1 and in the placebo group 7.2 ▪ The mean difficulty in swallowing score was 62.6 in the AMC/DCBA group and 62.5 in the placebo group ▪ 28% of patients reported previous medical condition (21% had psychiatric conditions and 21% had gastrointestinal conditions)
Intervention	Intervention group: AMC/DCBA throat lozenges (active lozenges) Control group: non-medicated sugar-based lozenges (placebo lozenges)
Endpoints	Primary endpoint: ▪ Change in severity of throat at 2 hours after first dose Secondary endpoints: ▪ Throat soreness ▪ Sore throat relief

	▪ Difficulty in swallowing ▪ Symptom free ▪ Overall treatment ▪ Functional impairment ▪ Opinions on pain relief (what it felt like, how sore throat affects daily activities) ▪ Adverse events

Results	Primary endpoint:
	▪ Change in severity of throat at 2 hours after first dose: significantly improved in treatment group
	Secondary endpoints:
	▪ Throat soreness:
	  ▪ Change: significantly higher in treatment group at all assessments from 5 to 120 min after treatment
	  ▪ Area under the curve from baseline to 2 h after first dose: significantly increased
	  ▪ Mean change at day 1, at 24h, end of day 2 and day 3: difference between treatment and placebo increased over 3-day study period.
	▪ Sore throat relief: improved significantly
	▪ Onset of analgesia: 63% of patients in treatment group compared to 22% in control group reported moderate pain relief
	▪ Difficulty in swallowing: significantly improved in treatment group
	▪ Symptom free: no significant difference after 24 hours but at end of day 2 and day 3 significantly higher in treatment group.
	▪ Overall treatment: significantly better in treatment group at 2h and at end of day 3
	▪ Functional impairment: mean total score significantly higher in treatment group
	▪ Opinions on pain relief (what it felt like, how sore throat affects daily activities): Relief provided by the active lozenges was reported to be deeper within the throat, more moisturising/lubricating, soothing and coating than the non-medicated lozenges
	▪ Adverse events: no significant difference

Bias-risk subject to type of study	low
Limitations	The placebos had the same colour, size and shape like the AMC/DCBA, but nothing is mentioned about the flavour;
Sponsors	Research was funded by Reckitt Benckiser Healthcare International (manufacturer of AMC/DCBA throat lozenges)
Conclusions of the authors	Amylmetacresol/dichlorobenzyl alcohol (AMC/DCBA) throat lozenges provide rapid analgesic effects that last for 2 hours, providing ongoing relief long after the lozenge has dissolved. The superior analgesic effects and improvements in functional impairment scores observed with AMC/DCBA throat lozenges translate into pain relief benefits that are clinically meaningful and are thus a suitable OTC treatment option for patients in the self-management of acute sore throat
Comments (own)	The study focuses on sore throat, which is partially related to cough

Table A 50: Wade et al., 2011

Author(s)	Wade AG, Morris C, Shephard A, Crawford GM, Goulder MA
Title	A multicentre, randomised, double-blind, single-dose study assessing the efficacy of AMC/DCBA Warm lozenge or AMC/DCBA Cool lozenge in the relief of acute sore throat
Journal	BMC Family Practice
Research question	What are the analgesic properties of the two AMC/DCBA throat lozenge variants (Warm and Cold) compared with an unflavoured, non-medicated placebo lozenge in patients with acute sore throat?
Country	UK
Study design	Multicentre, randomised, double-blind study
Study period, follow up	Enrolment: 12 January – 20 February 2009 Follow up: 1-3 days after intervention
Study size	225 participants
Population selection	Inclusion criteria: ▪ Confirmed diagnosis of acute sore throat due to upper respiratory tract infection (URTI) ▪ Age between 16 and 75 years ▪ Onset within the previous four days ▪ Sore throat score ≥ 6 on Throat Soreness Scale ▪ Presence of tonsillopharyngitis (i.e. ≥ 3 points on expanded 21-point Tonsillopharyngitis Assessment)
Characteristics of the study population	Mean age: 31.7 years Gender: 40.9% male Race: 96.9% Caucasian Alcohol drinker: 81.8% Current smoker: 36.4% Former smoker: 19.6% Mean duration of sore throat: 2.2 days Mean duration of URTI: 3.0 days All parameters where well balanced between the treatment groups
Intervention	Intervention group 1: AMC/DCBA Cool lozenges Intervention group 2: AMC/DCBA Warm lozenges Control group: Unflavoured, non-medicated lozenge
Endpoints	Primary efficacy endpoint: ▪ Area under the change-from-baseline curve (AUC) in severity of throat soreness from 0 to 2 hours Secondary efficacy endpoints (measured at 1, 5, 10, 15, 30, 45, 60, 75, 90, 105 and 120 minutes): ▪ Severity of throat soreness (11-point Throat Soreness Scale) ▪ Sore throat relief (7-point scale) ▪ Difficulty in swallowing (visual analogue scale) (incl. AUC from baseline) ▪ Throat numbness (incl. AUC from baseline) ▪ Total sum of pain relief ratings (AUC from baseline) ▪ Consumer questionnaire: ▪ Functional impairment ▪ Opinions about type of pain relief ▪ Sensorial benefits ▪ Speed and duration of effects ▪ Emotional benefits ▪ Overall treatment rating

Results	Primary efficacy endpoint:
	▪ Area under the change-from-baseline curve (AUC) in severity of throat soreness from 0 to 2 hours: AMC/DCBA Warm and AMC/DCBA Cool lozenges both significantly reduced severity
	Secondary efficacy endpoints (measured at 1, 5, 10, 15, 30, 45, 60, 75, 90, 105 and 120 minutes post dose):
	▪ Severity of throat soreness (11-point Throat Soreness Scale): significantly reduced between 5 and 120 minutes (AMC/DCBA Warm) and between 1 and 120 minutes (AMC/DCBA Cool)
	▪ Sore throat relief (7-point scale): significantly increased between 5 and 120 minutes (AMC/DCBA Warm) and between 1 and 120 minutes (AMC/DCBA Cool)
	▪ Difficulty in swallowing (visual analogue scale) (incl. AUC from baseline): significantly reduced between 5 and 60 minutes and at 90 minutes (AMC/DCBA Warm) and between 1 and 120 minutes (AMC/DCBA Cool)
	▪ Throat numbness (incl. AUC from baseline): both lozenges induced significant numbness, with a peak at 15 minutes (AMC/DCBA Warm) and 10 minutes (AMC/DCBA Cool)
	▪ Total sum of pain relief ratings (AUC from baseline): significantly increased by AMC/DCBA Warm and AMC/DCBA Cold
	▪ Consumer questionnaire:
	  ▪ Functional impairment: significant improvements in swallowing (both), and in talking and overall score only with AMC/DCBA Warm, no significant differences in concentrating and reading (both)
	  ▪ Opinions about type of pain relief:
	  ▪ Sensorial benefits: significantly more patients indicate immediate cooling/warming relief
	  ▪ Speed and duration of effects: cooling/warming sensation is experienced significantly earlier and lasted significantly longer
	  ▪ Emotional benefits: significantly more patients indicated emotional benefits and felt less distracted, frustrated and happier
	  ▪ Overall treatment rating: significantly higher with AMC/DCBA Warm and AMC/DCBA Cool
	Adverse events (AE):
	▪ 18 patients (8%) reported 23 adverse events
	▪ Highest number of AE was reported in control group
	▪ No treatment-emergent serious adverse events were reported
	▪ Headache was most frequently reported AE
	▪ No statistically significant differences between treatment groups in proportion of patients reporting treatment-emergent AE

Bias-risk subject to type of study	Moderate to high
Limitations (as stated by the authors)	▪ Placebo lozenge was unflavoured, while active lozenges were flavoured
Sponsors	Benckiser Healthcare International, UK (manufacturers of Strepsils)
Conclusions of the authors	AMC/DCBA Warm lozenges and AMC/DCBA Cool lozenges are well-tolerated and effective OTC treatment options
Comments (own)	The blinding of the study population was not given, as the placebo lozenges was not flavoured and the throat numbness, which is a rather well-known effect of Strepsils, was experienced to a lesser extent in the control group

Table A 51: Yardley et al., 2010

Author(s)	Yardley L, Joseph J, Michie S, Weal M, Wills G, Little P
Title	Evaluation of a Web-based Intervention providing Tailored Advice for Self-management of Minor Respiratory Symptoms: Exploratory Randomized Controlled Trial
Journal	Journal of Medical Internet Research
Research question	What are the usage and effects of the 'Internet Doctor' website which provides tailored advice on self-management of minor respiratory symptoms (e.g. cough, sore throat, fever, runny nose)?
Country	United Kingdom
Study design	Exploratory or phase-2 randomised controlled trial
Study period, follow up	Between October 2009 and March 2010 Two Follow-ups: 48 hours after accessing the intervention and the final follow-up after 4 weeks
Study size	714 people
Population selection	Inclusion criteria: all persons logging onto the website and giving informed consent. Exclusion criteria: not stated
Characteristics of the study population	Gender (female): 72.3% Age: 18 to 79 years (62.1% under 25 years) 91.2% were or had completed a university degree
Intervention	Intervention group: fully automated digital triage system providing tailored computer-generated advice Control group: static webpage delivering booklet-based information
Endpoints	▪ Intentions to consult a doctor ▪ Confidence to self-care (self-efficacy for self-management) ▪ Consultation necessity beliefs
Results	368 persons (51.5%) were randomised to the Internet Doctor website and 346 to the static website control **Comparison of Internet Doctor and Control Groups on Primary outcomes at 4-Week Follow-up:** ▪ Self-efficacy: median patient enablement score was significantly greater in the Internet Doctor group than in the control group. ▪ Physician consultations: 11.6 % of treatment group had consulted a doctor or used other health services (e.g. NHS direct), compared to 17.6% in the control group (not significant) **Comparison of Internet Doctor and Control Groups on Intermediate Outcomes at 48-Hour Follow-op:** ▪ Intentions to consult a doctor: decline in intentions was greater in the Internet Doctor group, but not significantly different to control group. ▪ Consultation necessity beliefs and emotional reactions to illness declined at follow-up to a similar extent in both groups. ▪ Reduction in intentions to consult across both groups was predicted by all the baseline measures of cognitions and illness perceptions, except for confidence to self-care ▪ Being < 25 years predicted a reduction in intentions to consult a doctor ▪ The use of the Diagnostic section predicted reduction in intentions ▪ Effect of use of the Treatment section did not quite reach significance.
Bias-risk subject to type of study	Moderate

Limitations	▪ The findings cannot be considered definitive, because the sample size was too small to reliably detect group differences in consultation rates. Furthermore, reported consultation rates were not objectively verified ▪ The study did not permit evaluation of the effectiveness of the website for reducing consultation rates, since the control group was given non-tailored advice that was previously shown to be effective in reducing consultation rates. ▪ There was substantial dropout before follow-up. Those who dropped out had less confidence to self-manage their symptoms, suggesting that the reductions in concern about symptoms seen those who were followed up might not have been observed in those who dropped out. ▪ Women were substantially overrepresented in the sample; However, there is evidence that women tend to have a more positive attitude than men toward self-management of health
Sponsors	Grant from UK Economic and Social Research Council
Conclusions of the authors	The findings provide initial evidence that tailored web-based advice could improve patients' ability to self-manage minor symptoms. Effect sizes on consultation rates were modest, which is consistent with previous research suggesting that often information may be obtained from the Internet in order to supplement rather than replace consultations with doctors.
Comments (own)	A major drawback of this intervention study was the substantial dropout before the follow-up study, which is a common problem in internet studies.

Table A 52: Häcker et al., 2010

Author(s)	Häcker F, Kiefer A, Morck H
Title	Pharmacy-based non-interventional study: Self-medication of cold symptoms with Katimun *(Selbstmedikation von Erkältungssymptomen mit Katimun)*
Journal	Pharamzeutische Zeitung online
Research question	Which complaints are usually reported by patients before and after the intake of Katimun? How do patients use Katimun (length of treatment and co-medication)? How satisfied are patients with Katimun? Did any undesirable effects or pharmaceutical shortages occur?
Country	Germany
Study design	Pre-post study without control (survey of pharmacy customers suffering from common cold)
Study period, follow up	Study period: February to April 2009 Follow up: on average Katimun was taken for 6 days, which was when the endpoints were collected with a survey
Study size	64 patients buying Katimung in a pharmacy agreed to participate in the pilot study, 28 of Katimun purchasers did not agree
Population selection	Inclusion criteria: any customer purchasing Katimun in one of the 16 participating pharmacies and agreeing to partake in the pilot study Exclusion criteria: none
Characteristics of the study population	Gender (female): 77% Age (average): 44 years (18-79 years) Employment: 79% employed, 21% unemployed First time taking Katimun: 73% Duration of symptoms before intake of Katimun: 36% 1 day; 44% 2-3 days; 20% 4 days or longer

Intervention	Intervention group: treatment of common cold with Katimun (homeopathic remedy) as preferred by patient (without restrictions about length or amount of intake) Control group: no control group included
Endpoints	▪ Severity of symptoms ▪ Subjective improvement of complaints ▪ Satisfaction with Katimun ▪ Adverse events

Results	▪ Severity of symptoms:
	  ▪ None or mild: before intake 46%, after intake 84%
	  ▪ Mild to medium: before intake 48%, after intake 14%
	  ▪ Medium to severe: before intake 4%, after intake 2%
	▪ Time until subjective improvement of complaints:
	  ▪ Day 1: 11%
	  ▪ Day 2 or 3: 47%
	  ▪ After day 3: 32%
	  ▪ Stopped intake without improvement: 10%
	▪ Satisfaction with Katimun (scale from 5: completely satisfied to 1: completely unsatisfied):
	  ▪ 5: 32 %
	  ▪ 4: 37%
	  ▪ 3: ~ 14%
	  ▪ 2:~ 7%
	  ▪ 1: ~ 10%
	▪ Adverse events: two patients reported adverse events but these cannot be causally linked to the intervention

Bias-risk subject to type of study	High
Limitations (stated by the authors)	▪ Common colds often resolve naturally, so that the improvement of the symptoms cannot be unambiguously attributed to the intervention ▪ Patients who already took the drug once, were more satisfied with it than first users, which indicates positive expectations ▪ No randomization and no blinding
Sponsors	None stated
Conclusions of the authors	Katimum is used primarily by patients with mild colds and the instructions on the patient information sheet are usually followed The majority of patients is very satisfied with the drug and takes it until the symptoms resolve The realization of non-interventional studies is feasible in public pharmacies, however careful planning is necessary.
Comments (own)	Almost half of the study population (48%) took other medication against the common cold or cough. This and the lack of a control group make the results of this study highly invalid.

Table A 53: Riebeling and Unkauf, 2004

Author(s)	Riebeling A, Unkauf M
Title	Rhinologic study: Treatment of colds in self-medication *(Rhino-Studie: Schnupfenbehandlung in der Selbstmedikation)*
Journal	Deutsche Apotheker Zeitung
Research question	How effective and tolerated is a variable combination of Xylometazolin (Otrivin nasal spray) with Dexpanthenol (Otrivin care)?
Country	Germany
Study design	Pre-post study without control (survey of pharmacy customers suffering from common cold/rhinitis)
Study period, follow up	Study period: January to April 2003 Follow up: after 10 days (+/- 2 days) a follow up-questionnaire was sent to the participants
Study size	196 costumers of 33 pharmacies
Population selection	Inclusion criteria: ▪ Customer presents with common cold/rhinitis at pharmacy ▪ Wish to by a remedy against common cold/rhinitis ▪ Consent to participate in the study ▪ Exclusion criteria: none
Characteristics of the study population	Gender (female): 66.3% Age: between 14 and 82 years Ailment: 83% had a rhinitis associated with the common cold
Intervention	Intervention group: variable combination treatment with Otrivin nasal spray against rhinitis (Xylometazolin) and Otrivin care product (Daxpanthenol) as needed Control group: no control group included
Endpoints	▪ Mode of usage ▪ Tolerability of both products ▪ Satisfaction with effectiveness ▪ Satisfaction with treatment concept

Results	▪ Mode of usage:
	  ▪ 7.61% always used both products together
	  ▪ 46.65% sometimes used the products together sometimes separately
	  ▪ 46.74% used the products independently
	  ▪ 64% indicated that the separate usage corresponds to their needs
	▪ Tolerability of both products:
	  ▪ Kind and number of complaints with Xylometazolin corresponded to commonly known side effects of decongestants
	  ▪ 8 of 15 cases of side effects with Xylometazolin could be causally related to the treatment. The other 9 cases are possibly related to the underlying ailment
	  ▪ The three reported cases of side effects with Dexopanthenol were all possibly related to the underlying ailment
	  ▪ No participant dropped out due to side effects
	▪ Satisfaction with effectiveness:
	  ▪ Decongestant effect of Xylometazolin as very high or high: 91%
	  ▪ Quickness of effect as very high or high: 84%
	  ▪ Caring and healing effects of Daxpanthenol as clearly noticeable: 68%

	▪ Caring effect against dry nose as very good or good: 86% ▪ Satisfaction with treatment concept: ▪ Very high or high: 87% ▪ Would buy at least one product again: 98% ▪ Would buy both products again: 82%
Bias-risk subject to type of study	Unclear/high
Limitations (as stated by the authors)	None stated
Sponsors	Novartis Consumer Health
Conclusions of the authors	Xylometazolin shows a quick onset and a long duration (12 hours) of decongestant effects. If user instructions are followed the risk of side effects and rebound effects (rhinitis medicamentosa) is small Dexpanthenol speeds up and supports the healing of lesions of nasal mucosa. This study documents the effectiveness and tolerability of a variable treatment concept with Otrivin 0.1% nasal spray against rhinitis and Otrivin care with Dexpanthenol under real life conditions. The variable and flexible treatment corresponds to the needs of patients.
Comments (own)	The lack of a control group is a serious flaw of this study and makes it highly susceptible for placebo effects.

Table A 54: Theurer and Gessner, 2011

Author(s)	Theurer C, Gessner U
Title	Aspirin® complex: Satisfied patients in the self-medication of cold symptoms *(Zufriedene Patienten bei der Selbstmedikation von Erkältungsbeschwerden)*
Journal	Pharmazeutische Zeitung online
Research question	How is Aspirin® Complex used for self-medication against the common cold and what are its effects?
Country	Germany
Study design	Pre-post study without control (survey of pharmacy customers suffering from common cold/rhinitis)
Study period, follow up	Study period: November 2009 to June 2010 Follow up: 2 hours after intake of medication
Study size	273 pharmacies distributed 1368 survey of which 1053 (77%) were sent back.
Population selection	Inclusion criteria: costumers purchasing Aspirin ® complex for treating symptoms of the common cold Exclusion criteria: none
Characteristics of the study population	Gender (female): 68.3% Age: between 20 and 40 (average: 39.2 years) Using Aspirin complex for the first time: 37%
Intervention	Intervention group: Aspirin complex (combination product of acetylsalicylic acid and pseudoephedrine) Control group: no control group included
Endpoints	▪ Mode of usage ▪ Severity of symptoms ▪ Satisfaction with medication
Results	▪ Mode of usage: ▪ Average treatment period: 3 days ▪ Average amount of medication: 7.6 sachets ▪ First intake: 60% of patients used 2 sachets ▪ Sixth intake: 80% of patients used 1 sachet ▪ Interval of intake: second intake after 9 hours, subsequent intakes after 8 to 12 hours

Results	▪ Duration of effect: 37.7% of patients indicated at least 4 hours; most patients indicated between 4 and 6 hours ▪ Severity of symptoms: ▪ Intensity of congested nose: reduction from 16 (before) to 9 (after 30 min) to 6 (after 120 min) points at a visual analogue scale (1 = not congested and 20= very congested) ▪ Intensity of other symptoms: the intensity of all other symptoms (nasal catarrh, headache, sore throat, fatigue, sore throat, cough, aching limbs, increased temperature) decreased significantly 120 min after intake ▪ Share of patients with severe symptoms: was especially reduced for the symptoms nasal catarrh, fatigue and aching limbs ▪ Cough: severity of symptoms was only slightly influenced by treatment ▪ Share of patients with improved symptoms ▪ after 0.5 hours: increased with each intake from 43.8% after first intake to 89.1% after sixth intake ▪ after 2 hours: increased with each intake from 80% after first intake to 93.2% after sixth intake ▪ Subjective evaluation of effectiveness: 90.3% of patients indicated very good or good (lower for patients who used medication for first time) ▪ Parallel usage of other medications had little impact on subjective evaluation of effectiveness ▪ Satisfaction with medication (Treatment Satisfaction Questionnaire for Medication Version II with four dimensions and possible score between 0 and 100): ▪ Effectiveness (mean points): 70.2 ▪ Side effects(mean points): 88.6 ▪ Convenience (mean points): 74.4 ▪ Global satisfaction (mean points): 74.9
Bias-risk subject to type of study	Moderate/high
Limitations (as stated by the authors)	No randomization and no blinding
Sponsors	None stated
Conclusions of the authors	Effectiveness and tolerability of Aspirin complex could be confirmed under conditions met under everyday life in a collective of over 1000 patients. Aspirin complex decreases the most common symptoms of the common cold, also after several intakes. High patient satisfaction regarding effectiveness, side effects, convenience and global satisfaction also in comparison with other substances for other indications.
Comments (own)	Even though the study lacks a control group, the bias risk is considered moderate to high because of the high number of participating patients and the low drop-out rate.

Table A 55: Cough: included publications second selection

Author/year	Title	Type	Risk of bias
Conrad et al., 2007	Pelargonium sidoides-extract (EPs® 7630): registration confirms efficacy and safety	Literature review	Moderate
Smith et al., 2012	Over-the-counter (OTC) medications for acute cough in children and adults in ambulatory settings	Systematic literature review	Low
Timmer et al., 2014	Pelargonium sidoides extract for treating acute respiratory tract infections	Systematic literature review	Low
Schulz, 2007	Pelargonoium sidoides extract (EPs® 7630) for the treatment of 217 patients with acute bronchitis. Publication of an additional double-blind study [Germany]	Randomised Controlled Trial	High
Gonzales et al., 2005	The 'Minimizing Antibiotic Resistance in Colorado' Project: Impact of Patient Education in Improving Antibiotic Use in Private Office Practices	Observational Study / Pre-Post study	Moderate
Paul et al., 2007	Effect of Honey, Dextromethorphan, and No Treatment on Nocturnal Cough and Sleep Quality for Couging Children and their Parents	Pre-Post study	Moderate
White et al., 2012	The self-care for people initiative: the outcome evaluation	Pre-Post study	Low

Table A 56: Conrad et. al., 2007

Author(s)	Conrad A, Kolodziej H, Schulz V
Title	Pelargonium sidoides-extract (EPs® 7630): registration confirms efficacy and safety
Journal	Wiener Medizinische Wochenschrift
Research question	To describe the current pharmacological, toxicological and clinical data on EPs® 7630 and to assess its efficacy and innocuousness when administered for the treatment of acute bronchitis
Country	Various
Study design	Literature Review of studies on EPs® 7630
Literature search	Databases: None mentioned Search period: 1998-2007 Study period: 2004-2014
Selection criteria	Inclusion criteria: Studies/RCTs on Pelargonium sidoides extract EPs® 7630 Exclusion criteria: all others
Interventions	Medication consisting of some of EPs® 7630
Endpoint	Eradication of symptoms associated with cough such as rale, fatigue, sputum, sore throat, headache, dyspnoea, chest pain, fever or pain in the limbs
Results	▪ 7 studies have been conducted to underpin the clinical efficacy of EPs® 7630. 2 studies examined the effects in adults and 2 studies in children. 1 study focussed on the practicability of the therapy, 3 case series assessed the tolerance of EPs® 7630 and on study dealt with the exclusion of pharmaceutical interaction. ▪ The placebo-controlled, double blind study in adults found a significant symptom eradication compared to patients taking placebos ▪ The study in children found evidence for the same level of symptom eradication and treatment tolerance of EPs® 7630 like the treatment with acetylcysteines (ACC)
Bias-risk subject to type of study	Moderate
Limitations	▪ No other researcher decided on the exclusion or inclusion of the studies ▪ No other researcher evaluated the methodological quality of the included study; ▪ The author did not assess the risk bias of the used literature
Sponsors	None indicated
Conclusions of the authors	Between 1994 and 2003, 109 million defined daily doses of EPs® 7630 have been distributed. In this period 73 cases of spontaneous undesirable side effects and 79 cases of undesirable side effects in a clinical environment have been reported. A 10 days treatment results in 1 report per every 100,000 treatment cases. These studies suggest a low therapy risk with the respective pharmaceutical (Umckaloabo®)
Comments (own)	The literature review focuses only on an intervention in any form of EPs® 7630. There is no evaluation of the methodological quality of the included studies. Furthermore, the methodological quality was not considered the synthesis of the evidence.

Table A 57: Smith et. al., 2012

Author(s)	Smith SM, Schroeder K, Fahey T
Title	Over-the-counter (OTC) medications for acute cough in children and adults in ambulatory settings
Journal	The Cochrane Library
Research question	To assess the effects of oral OTC cough preparations for acute cough in children and adults
Country	different
Study design	Systematic Literature Review
Literature search	Databases: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, LILACS, Web of Science and the UK Department of Health National Research Register Search period: 2004-2014 Study period: 1966-2012
Selection criteria	Inclusion criteria: ▪ Types of study: All placebo-controlled RCTs of oral OTC cough preparations for acute cough ▪ Types of participants: (1) ambulatory settings in primary care and hospital out-patients (2) Children and adults with acute onset of cough (less than three weeks duration) ▪ Types of intervention: (1) Anti-tussives (2) Expectorants, (3) Mucolytics, (4) Antihistamine-decongestant combinations, (5) other drug combinations and (6) Anti-histamines ▪ Types of outcome measure: (1) Primary outcomes such as frequency, severity, amount of sputum and improvements in cough symptoms (2) secondary outcomes such as significant adverse effects. Exclusion criteria: ▪ Lack of a placebo control ▪ Cough was artificially induced ▪ Lasted longer than three weeks ▪ Cough outcomes were not clearly reported
Interventions	▪ Anti-Tussives → centrally acting opioid derivatives or other peripherally active agents, act by reducing the cough reflex ▪ Expectorants → pharmaceuticals leading to increased bronchial mucus production, make secretions easier to remove by cough or ciliary transport ▪ Mucolytics → i.e. pharmaceuticals aiming to decrease the viscosity of bronchial secretions, act to make secretions easier to clear through coughing ▪ Anti-histamine-decongestant combinations → drugs that are combined antihistamine H1-receptor antagonists and alpha-adrenoceptor agonists, act by causing vasoconstriction of mucosal blood vessels thus reducing congestion ▪ Other combinations of pharmaceuticals → fixed pharmaceutical combinations using different ingredients, have mechanisms of action based on individual ingredients ▪ Anti-histamines → anti-histamine H1-receptor agonists, act by reducing histamine release and thus reducing local congestion and production of secretions
Endpoint	▪ Frequency, severity, amount of sputum and improvement in cough symptoms

Results	▪ The 2012 update included 26 RCTs involving 4037 participants. Eighteen of these trials were in adults and eight in children. Most adult trials were on young adults with mean ages ranging from 23 to 48 years. The ages of participants ranged from six months to over 70 years. Ages in studies on children ranged from six months to 18 years. Six trials were more than 20 years old. ▪ Almost half the studies were carried out in the USA (12 out of 26), with the remaining trials located in the UK (5), Finland (3), Germany (2) Italy, India, South Africa and Thailand (each 1). ▪ Most studies were different in their definition of illness, the content of the pharmaceutical preparation, dosage, the frequency of doses and the treatment duration (ranging from a single dose to 18 days), making comparison of trials and quantitative analysis difficult. ▪ Trials were grouped according to pharmaceutical class into anti-tussives, expectorants, mucolytics, anti-histamine-decongestant combination, other combinations and anti-histamines. The number of studies in each group ranged from one to a maximum of six. Cough outcomes included frequency, severity and night-time symptoms and were measured in many different ways, for example, participant self report by symptom scores, physician assessment, observation by parents, cough sound pressure levels obtained by recordings via microphone and tape recordings ▪ The authors found no good evidence for or against the effectiveness of OTC medications in acute cough. The number of trials in each group of pharmaceuticals was small, there was poor overall quality of the studies, and studies showed conflicting evidence. In total, 11 of the 26 included trials showed a positive result, whereas 15 did not show active active treatment to be superior to placebo. Eight out of the 11 Studies that were supported by the pharmaceutical industry showed positive results compared to three positive studies out of the 15 trials that did not report any conflict of interest. The results did not appear to be related to their sample size or length of follow-up. We did not formally examine the trial efficacy versus trial quality because of the lack of reported data.
Bias-risk subject to type of study	Low
Limitations	Study designs, populations, interventions and outcomes varied markedly between studies, limiting the generalisability of the results. All results were based on a small number of studies. It is also questionable as to whether all of the positive results obtained with unclear outcome measures are clinically relevant.
Sponsors	Eleven of the 26 included studies were funded by the pharmaceutical industry. Studies funded in this way were more likely to report positive results. Despite this potential bias the review does not provide evidence of the effectiveness of OTC cough medicines for acute cough
Conclusions of the authors	There is no good evidence for or against the effectiveness of OTC medicines in acute cough. The results of the review have to be interpreted with caution due to differences in study characteristics and quality. Studies often showed conflicting results with uncertainty regarding clinical relevance. Higher quality evidence is needed to determine the effectiveness of self care treatments for acute cough
Comments (own)	Cochrane Review

Table A 58: Timmer et. al., 2014

Author(s)	Timmer A, Günther J, Motschall E, Rücker G, Antes G, Kern WV
Title	Pelargonium sidoides extract for treating acute respiratory tract infections
Journal	The Cochrane Library
Research question	To assess the efficacy and safety of Pelargonium sidoides for the treatment of Acute Respiratory Infections (ARI) in children and adults
Country	
Study design	Comprehensive literature review
Literature search	Databases: MEDLINE, Journals@Ovid, The Cochrane Library, Biosis, Previews, Web of Science, CINAHL, CCMed, XToxline, Global Health, AMED, Derwent Drug File and Backfile, IPA, ISTPB + ISTP/ISSHP, EMBASE, Cambase, LILACS, PubMed, TRIPdatabase, and the publisher databases: Deutsches Ärzteblatt, Thieme, Springer, ScienceDirect; study registries: ClinicalTrials.gov, Deutsches Register klinischer Studien DRKS (German Clinical Trials Register), International Clinical Trials Registry Platform (ICTRP) – WHO ICTRP, Current Controlled Trials and EU Clinical Trials Register Search period: Study period:
Selection criteria	Inclusion criteria: ▪ Double-blind, randomised controlled trials (RCTs) examining the efficacy of P. Sidoides preparations in ARIs compared to placebo or any other treatment. Complete resolution of all symptoms was defined as the primary outcome Exclusion criteria: ▪ Not explicitly stated
Interventions	Umckaloabo is a herbal remedy derived from the roots of Pelargonium sidoides, which is native to South Africa. It is also sold as Umckabo, Umcka, Kaloba or Zucol. Included studies hat do compare P. Sidoides ethanol extract or other P. Sidoides preparations to placebo or any active comparator. Active comparator could include for example, physical therapy, mucolytics/expectorants or prophylactic antibiotic therapy
Endpoint	Efficacy of P. sidoides in ARI 1. Time to complete resolution of all symptoms (in days), or number of patients not resolved at the pre-defined time 2. Time to complete resolution of key symptoms (in days), or number of patients with key symptoms not resolved at a predefined times.
Results	Of 10 eligible studies eight were included in the analyses; two were of insufficient quality. Three trials (746 patients, low quality of evidence) of efficacy in acute bronchitis in adults showed effectiveness for most outcomes in the liquid preparation but not for tablets. Three other trials (819 children, low quality of evidence) showed similar results for acute bronchitis in children. For both meta-analyses there was no pooling of subtotals due to relevant heterogeneity induced by type of preparation. One study in patients with sinusitis (n=103 adults, very low quality of evidence) showed significant treatment effects) complete resolution at day 21. One study in the common cold demonstrated efficacy after 10 days, but not five days (very low quality of evidence).

Bias-risk subject to type of study	Low
Limitations	▪ The rating of the study quality was moderate for all studies due to unvalidated outcome assessment, minor attrition problems, investigator-initiated trials only, etc. ▪ Based on the funnel plot there was suspicion of publication bias
Sponsors	
Conclusions of the authors	P. sidoides may be effective in alleviating symptoms of acute rhinosinusitis and the common cold in adults, but doubt exists. It may be effective in relieving symptoms in acute bronchitis in adults and children, and sinusitis in adults. The overall quality of the evidence was considered low for main outcomes in acute bronchitis in children and adults, and very low for acute sinusitis and the common cold. Reliable data on treatment for other ARIs were not identified.
Comments (own)	Cochrane Review

Table A 59: Schulz, 2007

Author(s)	Schulz V
Title	Pelargonium sidoides extract (EPs® 7630) for the treatment of 217 patients with acute bronchitis. Publication of an additional double-blind study [German]
Journal	Zeitschrift für Phytotherapie
Research question	To assess whether patients suffering from acute bronchitis have a faster eradication of symptoms when treated with EPs® 7630 compared to placebos
Country	Russia
Study design	Multi-centre, randomised, double blind, placebo-controlled
Study period, follow Up	Between October 2000 and March 2002; 2 follow-ups: 3-5 days after the therapy start and at the end of the treatment
Study size	217 patients
Population selection	Inclusion criteria: ▪ Patients between 18 and 66 years ▪ Presence of an acute bronchitis at the initial consultation with beginning of the symptoms 48 hours prior consultation at maximum ▪ More than 5 points on the severity of symptoms score-card Exclusion criteria:
Characteristics of the study population	▪ Patients were aged between 18 and 66 years ▪ 107 patients were included in the verum group and 109 were included in the placebo group
Intervention	Intervention group: Patients received 3 times per day 30 drops of EPs® 7630 prior or after the meal. Control group: Patients in the control group received a placebo which was similar to the verum with respect to colour, smell and taste.
Endpoints	▪ Eradication of cough symptoms measured through the bronchitis-symptom-scores (BSS) which is the sum of the severity of the five bronchitis typical symptoms: cough, sputum, rale, chest pain and dyspnoea ▪ Patient satisfaction
Results	▪ The initial BSS was 8.9 for the verum group and 8.4 for the placebo group. Until the first follow-up visit the BSS decreased on average by 5.9 points for the verum group and 4.2 for the placebo group. The final examination at the end of the treatment on day 7

	revealed an decline of 7.6 for the verum group and 5.3 for the placebo group. The eradication of symptoms with EPs® 7630 treatment was significantly better at any point of time compared to the placebo. ▪ At the final consultation also patients' satisfaction was surveyed. 84% of all patients treated with EPs® 7630 were satisfied with their treatment compared to 48% of the patients in the placebo group. Undesired side effects were reported by 21% taking the verum and 22% taking the placebo. However, none of the side effects were considered as severe.
Bias-risk subject to type of study	High
Limitations	Not stated
Sponsors	None indicated
Conclusions of the authors	Design and results of this study show similarities to an existing publication dating back to 2006. Especially notable in this study were the diverging responses to treatment of the different symptoms of coughing. An addition to previous studies is the survey of patient satisfaction and its significant results
Comments (own)	▪ High exclusion rate; out of 735 examined patients only 218 were included, but the authors did not mention what was the reason for the exclusion of the other 517. ▪ There is also a mathematical inconsistency with the numbers: 107 persons were in the verum group and 109 were in the placebo group, summing up to 216 patients.

Table A 60: Gonzales et al., 2005

Author(s)	Gonzales R, Corbett KK, Leeman-Castillo BA, Glazner J, Erbacher K, Darr CA, Wong S, Maselli JH, Sauaia A, Kafadar K
Title	The 'Minimizing Antibiotic Resistance in Colorado' Project: Impact of Patient Education in Improving Antibiotic Use in Private Office Practices
Journal	Health Services Research
Research question	To assess the marginal impact of patient education on antibiotic prescribing to children with pharyngitis and adults with acute bronchitis in private office practices
Country	Colorado / United States
Study design	A non-randomised controlled trial
Study period, follow Up	Baseline period → winter 2000 Study period → winter 2001
Study size	7 intervention practices (with approximately 400 patient visits)were compared with 288 local and 53 distant control practices (with 8,575 and 1,162 patients respectively)
Population selection	Inclusion criteria: ▪ Practices eligible for the intervention were required to have 20 or more patient visits for acute respiratory infections (ARIs) ▪ Practices were required to provide a mailing and a telephone list of regular clinic patients (defined as any individual adult having at least two office visits based on the clinic's visit records during the preceding 24 months, or any child having at least two office visits during the preceding 12 months) ▪ Practices were required to review and approve final educational materials to be used in the intervention Exclusion criteria: not stated
Characteristics of the study population	▪ Intervention practices had higher mean patients visits than their local and distant control counterparts, 66 visits compared to 30 and 22 visits respectively ▪ The age structure in all three practices was almost the same for children aged between 0 and 17 years and

	adults between 18 and 64 years. ▪ For children the proportion of female patients equates the proportion of male patients, but with age the fraction of women increases up to 62%
Intervention	Intervention group: Campaign packets were mailed to 'regular' households identified by the participating practices. Each household packet consisted of a bilingual introductory letter from the Colorado Department of Public Health and Environment explaining the 'Be S.M.A.R.T about antibiotics" campaign, CDC brochures on antibiotic resistance, a refrigerator magnet, and a reference card providing easy-to-read facts about symptoms and treatments for ARIs
Endpoints	Reduction of antibiotic use
Results	▪ Adjusted antibiotic prescription rates during baseline and study periods increased from 38 to 39 percent for pediatric pharyngitis at the distant control practices, and decreased from 39 to 37 percent at the local control practices, and from 34 to 30 percent at the intervention practices. Adjusted antibiotic prescription rates decreased from 50 to 44 percent for adult bronchitis at the distant control practices, from 55 to 45 percent at the local control practices and from 60 to 36 percent at the intervention practices. ▪ The campaign is the first to demonstrate that the addition of patient-focused education to an ongoing physician quality improvement programme results in a much larger decrease in antibiotic use for adults with acute bronchitis than the physician programme alone. However, the study cannot quantify the degree to which this effect results from a synergy between physician and patient education, or whether the patient education alone would have resulted in the same effect
Bias-risk subject to type of study	Moderate
Limitations	▪ There are limitations to using administrative MCO data to measure antibiotic prescribing behaviour, since the data fail to detect antibiotics given to patients in the office as samples, antibiotic prescriptions that patients decide not to fill, and antibiotic treatment rendered in an alternative facility such as the emergency department or hospital. ▪ Selection bias because of the non-randomised nature of the study could have affected the results of the study. The practices that agreed to participate in the campaign may represent a group of practices more willing to modify their prescribing behaviours than the comparison practices.
Sponsors	The study was sponsored by the Agency for Healthcare Research and Quality and the Centers for Medicare and Medicaid Services
Conclusions of the authors	In office practices, there appears to be little room for improvement in antibiotic prescription rates for children with pharyngitis. In contrast, patient education helps reduce antibiotic use for adults with acute bronchitis beyond that achieved by physician-directed efforts.
Comments (own)	Although the primary clinical endpoint is the reduction of antibiotic use, the intervention included educational materials on self-care and OTC products for ARI (they are available on the campaigns' homepage www.getsmartcolorado.com) The campaign resulted in a 3 percentage point decrease of pharyngitis visits of total ARI visits for children and a 4 percentage point decrease of bronchitis visits of total ARI visits for adults. In contrast, the percentage of such visits in the distant and local control groups remained the same or increased. It may be presumed that this effect is due to the provided information material, since also the mean visits per practices decreased.

Table A 61: Paul et. al., 2007

Author(s)	Paul IM, Beiler J, McMonagle A, Shaffer ML, Duda L, Berlin CM
Title	Effect of Honey, Dextromethorphan, and No Treatment on Nocturnal Cough and Sleep Quality for Coughing Children and Their Parents
Journal	Archives of pediatrics & adolescent medicine
Research question	To compare the effects of a single nocturnal dose of buckwheat honey or honey-flavoured dextromethorphan (DM) with no treatment on nocturnal cough and sleep-difficulty associated with childhood upper respiratory tract infections
Country	Pennsylvania / United States
Study design	Single center, randomised, partially double-blinded study
Study period, follow Up	Between September 2005 and March 2006 Follow-up at the following day after intake
Study size	105 children
Population selection	Inclusion criteria: ▪ Children between 2 to 18 years ▪ Upper respiratory tract infections i.e. rhinorrhea and cough ▪ Nocturnal symptoms ▪ Illness duration of 7 days or less Exclusion criteria: ▪ If patients had symptoms of a more treatable disease (e.g. asthma, pneumonia, laryngotracheobronchitis, sinusitis, allergic rhinitis) ▪ History of reactive airways disease, asthma, or chronic lung disease ▪ Intake of a pharmaceutical known to inhibit metabolism of DM, such as selective serotonin, reuptake inhibitors ▪ If patients had taken the prior evening a medication that included an anti-histamine or DM hydrobromide within 6 hours of bedtime or DM polistrex within 12 hours of bedtime on the evening prior to or on the day of enrolment.
Characteristics of the study population	▪ Median age of the patients completing the study was 5.22 years, the age range was from 2.22 years to 16.92 years ▪ 53% of the children were female ▪ The participants were ill a mean of 4.64 days before participation, without significant differences in either variable between treatment groups ▪ There were no significant differences between measures of symptom severity at baseline
Intervention	Intervention group: A single dose of buckwheat honey or honey-flavoured Dextromethorphan (DM) Children 2-5 years received 8.5 mg/dose DM (1/2 teaspoon) Children 6-11 years received 17 mg/dose DM (1 teaspoon) Children 12-18 years received 34 mg/dose DM (2 teaspoons) For the honey group, the volume of honey dispensed was equivalent to the age-driven volume dispensed for DM Control group: Received not treatment
Endpoints	Primary Endpoint → eradication of (nocturnal) symptoms related to Upper Respiratory Tract Infection i.e. cough frequency, cough severity and bothersome nature of cough Secondary Endpoint → Child and parent sleep quality

Results	Significant differences in symptom improvement were detected between treatment groups, with honey consistently scoring the best and no treatment scoring the worst. In paired comparisons, honey was significantly superior to no treatment for cough frequency and the combined score, but DM was not better than no treatment for any outcome. Comparison of honey with DM revealed no significant differences.
Bias-risk subject to type of study	low to moderate
Limitations	▪ The study is somewhat limited by the fact that each child had a physician visit between the two nights of the study, which may provide some of the explanation for the improvement in all of the groups, including the no-improvement group. Alternatively, much of the improvement can also be attributed to the natural history of URIs, which generally improves with time and supportive care. ▪ The subjective survey used for this study may also be considered to be a limitation, but clinicians and parents often make decisions based on subjective assessment of symptom severity. ▪ Compliance with medication administration could not be guaranteed even though parent did report that the treatment was taken by their child without difficulty regardless of randomisation arm, but the lack of treatment in one of the study arms could be viewed as causing biased results in that treatment arm
Sponsors	
Conclusions of the authors	In a comparison of Honey, DM and no treatment, parents rated honey most favourably for symptomatic relief of their child's nocturnal cough and sleep difficulty due to upper respiratory tract infection. Honey may be a preferable treatment for the cough and sleep difficulty associated with childhood upper respiratory tract infection.
Comments (own)	▪ A drawback of the study was, that the no-treatment group was not blinded to their treatment arm because the received no placebo ▪ General Problems related to questionnaires ▪ Study focuses on children between 2 an 18 years, but one of our exclusions criteria was an age younger than 12.

Table A 62: White et al., 2012

Author(s)	White A, South J, Bagnall AM, Forshaw M, Spoor C, Marchant P, Witty K
Title	The self-care for people initiative: the outcome evaluation
Journal	Primary Health Care Research & Development
Research question	To determine the effects of a community-based training programme in self-care on the lay population
Country	England / United Kingdom
Study design	Quasi-experimental longitudinal study
Study period, follow Up	12-month period before and after the intervention Follow-ups 6 and 12 months after the intervention
Study size	1,568 participants
Population selection	Inclusion criteria: Exclusion criteria:
Characteristics of the study population	▪ ,1568 participants were included in the study ▪ The mean age in the intervention group was 40.1 years, and 36.9 years in the comparison group ▪ In the intervention group were less male participants (22% of all participants) than in the comparison group (44%) ▪ The proportion of other ethnicities was in the intervention group more than twice as large as in the control group. (for blacks 2.1% compared to 1.4% and for Asian 11% compared to 4.4% ▪ 45% of all participants considered themselves to have a health condition (45% in the comparison group and 46% in the intervention group)
Intervention	Intervention group: The intervention comprised a training programme which explored attitudes and personal skills in relation to healthcare and self-care. Self Care Support Coordinators in each Primary Care Trust (PCT) were responsible for organising and delivering the self-care skills course and creating local self-care networks. The course was composed of six blocks, each delivered in small group sessions lasting three hours in a non-clinical setting. Control group: The Control group received no intervention.
Endpoints	Efficacy of self-care →Change in the number of GP consultations between baseline and follow-up due to increased self-care knowledge and skills, increased confidence to undertake self-care, and greater intention to self-care.
Results	▪ The study found no impact of the course on the routine health service use for people with long-term conditions. However, the participants in the study did find that being a participant on the course led to moderate gains in self-efficacy, and small gains in energy, quality of life, psychological well-being and partnership with doctors ▪ No changes were seen in usage of General Practitioner services, the primary outcome, however, statistical analysis suggested that being in the intervention group may be associated with increased use of out-of-hours and secondary care services. ▪ At six months' follow-up small but statistically significant positive effects of being in the intervention group were seen on self-esteem, well-being and anxiety scores. ▪ At 12 months' follow-up small but statistically significant positive effects of being the intervention group were also seen on recovery of locus of control, health literacy and self-esteem scores, and on knowledge of adult

	cough. The clinical significance of these very small changes is unclear. ▪ The training programme had a small but positive effect, which was still evident at 12 months, on individuals' knowledge and confidence levels with regard to managing their own health, but did not lead to reductions in health service use.
Bias-risk subject to type of study	Low
Limitations	▪ Tough the included data is accurate, the large amount of missing routine data, particularly from the comparison PCTs, means that these results should be treated with caution. ▪ The response rate for follow-up questionnaires was also low. Recruitment rates were high in the intervention group where there was support for completion of the questionnaire, but reliance on postal questionnaires for follow-up may have proved problematic for those with literacy or language issues. This may have affected representativeness in the follow-up sample. Combined with the first point this is likely to lead to unknown biases being present in the final data set. ▪ Potential for selection bias arises from having practitioners who are involved in the initiative recruiting for the research study. Even with protocols and standardised information, certain types of people, directly or indirectly, may have received more encouragement than others to take part. There was potential selection bias here too in identifying settings and recruiting participants and this may have implications for the applicability of the study findings. ▪ There was a higher number of women, people from black and minority ethnic groups and people recruited from the workplace in the intervention than the comparison group; also higher levels of stress and anxiety, with less perceived social support at baseline, which may be indicative of greater need in the intervention group, and also greater reach of the intervention, as results from the process evaluation would indicate.
Sponsors	
Conclusions of the authors	With the emergence of 'Self Care' within a broad range of policy initiatives, the intervention was an important attempt by official authorities to explore the impact of training on the general population. Tough the primary outcome measure of a reduction in health service usage was not evident in the medium term, there were small but positive improvements in the participants knowledge and the confidence to self-care that were still evident 12 months later. If people are to be expected to take on a greater responsibility for their health then the provision of self-care training may offer some benefits.
Comments (own)	The authors did neither state explicitly exclusion nor inclusion criteria. The only requirement mentioned is that participants would be expected to then have a heightened sense of responsibility for their own health and that of others and be able to proactively manage their health

Table A 63: Heartburn: included publications second selection

Author/year	Title	Study type	Risk of bias
Bruley des Varannes et al., 2010	Short and long-term PPI treatment for GERD. Do we need more-potent anti-secretory drugs?	Literature review	High
Konturek, et al. 2007	The efficacy of hydrotalcite compared with OTC famotidine in the on-demand treatment of gastroesophageal reflux disease: A non-inferiority trial	Randomized parallel group comparison trial	High
Puera et al. 2009	Clinical trial: Lansoprazole 15 or 30mg once daily vs. Placebo for treatment of frequent nighttime heartburn in self-treating subjects	Randomized-control trial	Low/Moderate
Mehuys, et al 2009	Self-medication of upper gastrointestinal symptoms: A community pharmacy study	Non-interventional pre-post study	Moderate/High
Labenz, et al. 2012	Efficacy and safety of OTC omeprazole	Non-interventional observation study	Moderate/High
Närhi, et al. 2005	Switching of H2-Receptor Antagonists to Over-the-Counter Status in Finland. Implications for consumption and adverse effects	Non-interventional observation study	Unclear/High

Table A 64: Bruley et al., 2010

Author(s)	Bruley des Varannes S, Coron E, Galmiche JP
Title	Short and long-term PPI treatment for GERD. Do we need more-potent anti-secretory drugs?
Journal	Best Practice & Research Clinical Gastroenterology
Research question	Review recent data on PPI efficacy and to discuss more extensively the long-term strategies available for GERD treatment, as well as the shortcomings and limitations of current PPIs.
Country	Not stated
Study design	Literature review
Literature search	Databases: not stated Search period: After 2000 (till 2010) Study period: Not stated
Selection criteria	Inclusion criteria: Publishing date after 2000 Exclusion criteria: Not stated
Interventions	▪ Esomeprazole 20mg, Omeprazole 20mg ▪ Rabeprazole 20mg ▪ Esomeprazole 20/40mg, Omeprazole 20mg ▪ Esomeprazole 40mg, Omeprazole 20mg
Endpoint	▪ Short-term PPI therapy in GERD ▪ PPIs long-term safety
Results	Short-term PPI therapy in GERD – healing of GERD: ▪ No significant difference between esomeprazole 20mg and omeprazole 20mg ▪ Significantly higher healing rate with esomeprazole 40mg than with omeprazole 20mg in patients with esophagitis in Los Angeles classification grade C, D but not in patients with grade A or B ▪ 69% of patients with esophagitis Savary Miller Grade 1 healed with rabeprazole 20mg PPIs long-term safety ▪ No evidence that long-term PPI use is a risk factor for development of gastric carcinoids or enterochromaffin-like cell neoplasm

	▪ Bone fractures: modest increase (OR=1.74) in hip fractures in patients with pernicious anemia ▪ Risk of vitamin B12 deficiency ▪ Diarrhea most frequent adverse event
Bias-risk subject to type of study	High
Limitations	Not stated
Sponsors	Not stated
Conclusions of the authors	▪ No major differences between various PPIs used at standard licensed doses ▪ No evidence that long-term PPI therapy increases mortality, as compared with general population ▪ No evidence of additional risk with OTC PPI compared with other existing anti-reflux therapies
Comments (own)	▪ No systematic review ▪ No selection criteria stated ▪ No search strategy mentioned ▪ Inclusion and exclusion criteria not adequately or not at all stated ▪ Unclear, if two researchers decided on inclusion/ exclusion of studies and evaluated methodological quality ▪ Acknowledgements to. Astra Zeneca, Jansen Cilag, , Movetis, Given Imaging, Mauna kea Technologies

Table A 65: Konturek et al., 2007

Author(s)	Konturek J, Beneke M, Koppermann R, Toborg D, Petersen-Braun M, Weingärtner U		
Title	The efficacy of hydrotalcite compared with OTC famotidine in the on-demand treatment of gastroesophageal reflux disease: A non-inferiority trial		
Journal	Medical Science Monitor		
Research question	Investigate the onset and duration of action of the antacid hydrotalcite (1,000mg), a layer lattice antacid, compared with the H2-receptor antagonist famotidine at OTC dosage (10mg) as a positive control in patients suffering from heartburn		
Country	Finland		
Study design	Randomized, parallel-group comparison trial		
Study period, follow Up	May-December 2003 No follow-up		
Study size	53 patients		
Population selection	Inclusion criteria: ▪ Heliobacter-negatie patients ▪ Caucasians aged 20-75 years ▪ Endoscopically diagnosed GERD grade 0-1 according to conventional Savary-miller classification for at least three months ▪ Frequency of reflux symptoms of four days or more per week ▪ Severity of heartburn of "moderate" to "severe" degree Exclusion criteria: ▪ Not mentioned		
Characteristics of the study population		Hydrotalcite	Famotidine
	Male	12 (46%)	16 (59%9
	Age [years]	36.1 ± 13.8	38.8 ± 17.4
	Weight [kg]	71.5 ± 12.7	72.1 ± 11.6
	Height [cm]	170.3 ± 10.0	172.3 ± 8.8
	BMI [kg/m²]	24.5 ± 2.9	24.2 ± 2.2
	Intensitiy of heartburn moderate or severe [yes]	26 (100%)	27 (100%)
Accompanying symptoms	Acid eructation [yes]	26 (96.2%)	27 (100%)
	Epigastric pain [yes]	19 (73.1%)	22 (81.5%9
	Others [yes]	3 (11.5%)	7 (25.9%)
Lesions in the oesophageal mucosa	Stage 0	17 (65.4%)	13 (48.1%)
	Stage 1	9 (34.6%)	14 (51.9%)
Lesions in the duodenal mucosa	No	26 (100%)	27 (100%)
Hiatus hernia	No	4 (15.5%)	5 (18.5%)
	Yes	22 (84.6%)	22 (81.5%)

Intervention	Intervention group: Single dose of 1,000mg hydrotalcite (Talcite(R) forte, chewable tablets, Bayer Vital GmbH) on occasion of a symptomatic reflux episode Control group: Single dose of 10mg famotidine (Pepcid (R) akut, tablets, Mc Neil GmbH & Co. oHG) on occasion of a symptomatic reflux episode Both: ▪ Concomitant GERD treatment was not allowed ▪ Ingest the tablet for the treatment of one heartburn attack and to report the intensity of heartburn and associated symptoms in a predefined time schedule ▪ Documentation at: baseline and after 5, 10, 15, 20, 25, 30, 45, 60, 120, 180, 240 minutes
Endpoints	Primary objective: efficacy variable was onset of action Secondary objective: duration of action
Results	Onset of action ▪ Hydrotalcite was significantly superior to famotidine in increasing proportion of responders within first 45 minutes (starting at 10min) after drug intake ▪ Between 60-120 min both drugs equal efficacy Duration of action: ▪ Response rate at 3hrs after intake: 90.0% of hydrotalcite patients and 92.0% of famotidine patients ▪ Response rate at 4hrs. After intake: 86.4% for hydrotalcite and 96.0% for famotidine
Bias-risk subject to type of study	High
Limitations	▪ Statistical plan and analysis was provided by the Department of Biometry, Bayer Vital GmbH, Germany ▪ Small study population, as a consequence small statistical power ▪ No placebo control, but other medication
Sponsors	Bayer Vital GmbH, Leverkusen, Germany
Conclusions of the authors	▪ Results indicate that hydrotalcite relieves the symptoms of gastroesophageal reflux faster than OTC famotidine and is equally effective for up to two hours. ▪ It is a safe and effective self-medication for on-demand treatment of heartburn
Comments (own)	▪ No blinding: for administration, assessment of endpoints, for patients ▪ no concealed allocation to treatment groups ▪ Prognostic factors only shortly mentioned (obesity, excess weight), but patients show normal weight; thus, not clear if treatment groups similar regarding to prognostic factors ▪ Intervention equally assessed in both groups, equal proceeding of intervention ▪ No drop outs, but relative small intervention groups(n=26; n=27) ▪ Unclear if intention to treat analysis conducted - not mentioned ▪ Study sponsored by Bayer; Bayer also provided statistical plan and analysis

Table A 66: Peura et al., 2009

Author(s)	Peura D, Riff D, Snoddy M, Fennerty M
Title	Clinical trial: Lansoprazole 15 or 30mg once daily vs. Placebo for treatment of frequent nighttime heartburn in self-treating subjects
Journal	Alimentary Pharmacology & Therapeutics
Research question	Investigate the efficacy of Lansopranzole 15- and 30mg dose, compared with placebo, for treatment of night-time heartburn in a self-treating population with frequent night-time symptoms
Country	USA
Study design	Randomized, 3-arm, parallel-group, double-blind, multicentre placebo-controlled trial
Study period, follow Up	Study comprised 4 periods: ▪ 1 week screening for washout ▪ 1 week run-in period for evaluation heartburn frequency and compliance with daily single-blind placebo medication and diary completion ▪ 2 week treatment ▪ 1 week follow up
Study size	864 subjects
Population selection	Inclusion criteria: ▪ Male, female nonpregnant, nonlactating subjects, aged 18 years and older who reported frequent nighttime heartburn ▪ At least partially responded to treatment with antacids, histamine2 receptor antagonists or PPIs ▪ Willing to complete a washout of prior heartburn medication ▪ Heartburn on at least two nights during the week before randomization ▪ No more than one day with missed doses or incomplete or inconsistent entries in pre-randomization diary ▪ Return for the baseline visit within 2 days after the schedule date Exclusion criteria: ▪ Endoscopically confirmed erosive oesophagitis or GERD diagnosed by a physician ▪ Underlying medical condition, concomitant medication which might interfere with evaluation of heartburn ▪ Significant and/or unstable renal or hepatic disease ▪ Need for continuous acid suppressive therapy ▪ Continuous treatment with a prescription antifungal or warfarin or known hypersensitivity to any component of Lansoprazole or or Gelusil antacid ▪ History of alcoholism or illicit drug use or abuse ▪ Other medical condition constituted as a safety concern
Characteristics of the study population	

	Lansoprazole 15mg (n=291)	Placebo (n=277)	Lansoprazole 30mg (n=284)
Age Mean (SD)	48.2 (14.5)	47.4 (13.7)	48.8 (14.1)
Women, n (%)	173 (59.5)	181 (63.7)	183 (66.1)
Race White Black Hispanic Asian Other	 196 (67.4 39 (13.4) 44 (15.1 10 (3.4) 2 (0.7)	 183 (64.4) 38 (13.4) 45 (15.8) 12 (4.2) 6 (2.1)	 191 (69.0) 41 (14.8) 35 (12.6) 9 (3.2) 1 (0.4)

	BMI (kg/m²) Mean	30.5 (7.4)	30.8 (7.5)	29.9 (6.7)
	No days with heartburn in last month, mean (SD)	3.9 (1.4)	4.0 (1.4)	4.0 (1.4)
	Subject's rating of most intense episode of heartburn in last month, n (%) Mild Moderate severe	 29 (10.0) 196 (67.4) 66 (22.7	 22 (7.7) 208 (73.2) 54 (19.0)	 17 (6.1) 197 (71.1) 63 (22.7)
	Subjects received any prescription/OTC treatment for heartburn in past 5 years, n (%)	279 (95.9)	267 (94.0)	260 (93.9)
Intervention	Intervention group: ▪ 15mg lansoprazole (one 15mg active capsule and one matched control capsule), ▪ 30mg lansoprazole (two 15mg lansoprazole active capsules) Control group: ▪ Two matched placebo capsules			
Endpoints	Primary outcomes: ▪ Percentage of nighttimes with no heartburn during 14 days of treatment Secondary outcomes: ▪ Percentage of 24h days with no heartburn during 14 days of treatment ▪ Percentage of subjects with no heartburn during the first 24h ▪ Overall satisfaction with product ▪ Safety and tolerability			
Results	Percentage of nighttimes with no heartburn during 14 days of treatment ▪ Lansoprazole 15mg: 61.7% ▪ Lansoprazole 30mg 61.3% Compared with Placebo, difference highly significant (P<0.0001) Percentage of 24h days with no heartburn during 14 days of treatment ▪ Lansoprazole 15mg 49.7%, ▪ Lansoprazole 30mg 50.9% Compared with placebo 29.5%; difference highly significant Percentage of subjects with no heartburn during the first 24h ▪ Statistically signifianctly higher percentages of lansoprazole recipients reported having no heartburn during day 1 (15mg: 35.4%, 30mg: 36.5%, placebo: 22.5%) Overall satisfaction with product ▪ 87% of subjects getting 15mg, 88% of subjects getting 30mg, 69% of placebo group were satisfied Safety and tolerability			

	▪ Lansoprazole well tolerated; adverse events only mild/moderate
Bias-risk subject to type of study	Low/Moderate
Limitations	▪ No sufficient duration or size to evaluate adequately impact of lansoprazole usage on quality of life and sleep ▪ Placebo response observed; explained by natural variability of disorder
Sponsors	Novartis Consumer Health Inc.
Conclusions of the authors	▪ Lansoprazole 15mg and 30mg were superior to placebo for the treatment of frequent nighttime heartburn, as well as 24-h heartburn and were well tolerated in a self-treating population ▪ As both doses provide similar efficacy, use of lowest dosage considered appropriate in self-treatment
Comments (own)	▪ Selection was adequate ▪ Comparability was ensured ▪ Low drop-out rates ▪ Funding by Novartis ▪ Author a consultant and advisory board member for Novartis Consumer Inc.

Table A 67: Labenz and Willmer, 2012

Author(s)	Labenz J, Willmer C.
Title	[Efficacy and safety of OTC omeprazole] Wirksamkeit und Sicherheit von Omeprazol in der Selbstmedikation. Ergebnisse einer apothekenbasierten nicht-interventionellen Beobachtungsstudie bei Patienten mit Refluxbeschwerden
Journal	MMW-Fortschritte der Medizin
Research question	Documentation of efficacy and safety of omeprazole in daily life conditions of self medication
Country	Germany
Study design	Prospective non-interventional observation study
Study period, follow Up	August 2010 till June 2011 Follow-up after three month of filling in the first questionnaire
Study size	2,718 participants 178 follow up questionnaires
Population selection	Inclusion criteria: Patients who purchased Antra willing to participate Exclusion criteria: not stated
Characteristics of the study population	▪ 51% male ▪ Mean age 43.7 ▪ Mean BMI: 25.3 kg/m² ▪ 36% suffered from heartburn (42% frequently, 40% occasionally) ▪ 8% acid reflux (36% frequently, 42% occasionally) ▪ 56% showed combination of both symptoms (38% frequently, 14% occasionally) ▪ 54% reported medium severe symptoms, 33% reported severe symptoms, 13% reported mild symptoms ▪ 69% reported symptoms during the day, 18% reported during night, 13% reported both day and night
Intervention	<u>Intervention group:</u> Treatment with Omeprazol 20mg (Antra®) for maximum intake period of 14 days <u>Intake diary:</u> Available for patients over period of 14 days for exact

	documentation of type and intensity of symptoms, point of time and frequency as well as dosing of PPI intake TSQM II questionnaire for measuring patients' satisfaction; coverage of effectiveness, side effects, convenience and global satisfaction (voluntary) Follow-up questionnaire: ▪ duration of freedom of symptoms after finishing PPI treatment No control group
Endpoints	Effectiveness Safety Patient satisfaction
Results	Efficacy: ▪ 66% reported relief of symptom intensity after first intake ▪▪ 25% reported freedom of symptoms ▪▪ 41% reported mild symptoms ▪ 74% and 79%, respectively of patients with heartburn or acid reflux reported freedom of symptoms or mild symptoms after first intake ▪ 44% reported relief after 2-4h ▪ After OTC treatment (14days) 71% were free of symptoms; 92% reported max. Mild symptoms Compatibility/Safety: ▪ 2.4% reported side effects during therapy ▪ 0.8% visited physician due to side effects Patient satisfaction: ▪ For all four areas of TSQM II values of 80 and higher reported (100 maximum) Follow-up: ▪ 40% of patients free of symptoms in the three month after therapy ▪ 60% reported symptoms after 5.6 weeks ▪▪ 55% reported medium severe symptoms ▪▪ 41% mild ▪▪ 3% severe
Bias-risk subject to type of study	Moderate/High
Limitations	Not stated ▪ only 5 questionnaire per pharmacy
Sponsors	Bayer Vital GmbH, Leverkusen
Conclusions of the authors	Study confirms efficacy and compatibility of omeprazol in self medication. In compliance with safety instructions, omepracol therapy can be recommended for self medication
Comments (own)	▪ Labenz & Schubert-Zsilavecz, 2012: Wirksamkeit und Vertäglichkeit von Antra bestätigt, Pharmazeutische Zeitung; article based on MMW article Quality assessment: ▪ No blinded assessment ▪ Appropriate selection of participants (those who purchase) ▪ Not all eligible patients included (just 5 per pharmacy)

Table A 68: Mehuys et al., 2009

Author(s)	Mehuys E, Van Bortel L, De Bolle L, Van Tongelen I, Remon JP, De Looze D
Title	Self-medication of upper gastrointestinal symptoms: A community pharmacy study
Journal	The Annals of Pharmacy
Research question	Evaluate the role of the pharmacist as intermediary by investigating: 1) which GI symptoms people intend to self-medicate, 2) the prevalence of alarm symptoms in this population, 3) patients' adherence to referral advice made by the pharmacist, and 4) self-reported efficacy and the frequency of use of OTC medication purchased by subjects eligible for self-care
Country	Belgium
Study design	Non-interventional pre-post study
Study period, follow Up	Conducted in 2007 Follow up after 4 weeks
Study size	592 (m: 199; f: 392)
Population selection	Inclusion criteria: Age 18-80 years Speaking Dutch Agreement for a follow-up visit after 4 weeks Exclusion criteria: Pregnancy
Characteristics of the study population	▪ Mean age: 48.1 ▪ 11.5% under 25 years ▪ 24.5% between 25 and 40 years ▪ 28.2% between 41 and 55 years ▪ 25.3% between 56 and 70 years ▪ 10.5% over 70 years ▪ Mean BMI: 24.5 8range 16.8-43.5)
Intervention	Intervention group: Self treatment 1.) for patients with heartburn ▪ Non-pharmacologic advice ▪ antacid ▪ Filling out a daily diary, recording every dose of OTC product use during 4 week period Self treatment 2.) for patients with dyspeptic symptoms ▪ Non-pharmacologic advice ▪ Propulsive drug (10mg domperidone 20 minutes before each meal) ▪ Filling out a daily diary, recording every dose of OTC product use during 4 week period Self treatment 3.) for patients with heartburn and dyspeptic symptoms: ▪ Non-pharmacologic advice ▪ Antacid plus domperidone ▪ Filling out a daily diary, recording every dose of OTC product use during 4 week period No control group
Endpoints	self-reported efficacy of OTC medication purchased by subjects eligible for self-care
Results	▪ 95.1% participants reported symptom relief ▪ 72.3% still adhered to non-pharmacologic advice
Bias-risk subject to type of study	Moderate to High

Limitations	▪ No records of customers, who refused to participate and their reasons for refusal; no response rate could be calculated ▪ No data on the appropriateness of the referral decisions of the pharmacist to check whether medical consultation was indeed necessary for that patient ▪ However, referral protocol based on current evidence, suggesting appropriateness
Sponsors	Ghent University
Conclusions of the authors	▪ Mild GI symptoms can mostly safely and effectively solved with self-treatment using OTC drugs and lifestyle modification ▪ Findings stress the importance of health professional interaction at the time of purchase of the OTC product ▪ Sale of non-prescription medicines to pharmacies only, where the counselling pharmacist can act as a "filter" by ensuring appropriate referral or proper drug use, seems defensible
Comments (own)	▪ Appropriate selection of participants ▪ consecutive random recruitment ▪ Prediction factors not mentioned ▪ Low drop-out rate ▪ No confounders used ▪ No blinded assessment of endpoints

Table A 69: Närhi et al., 2005

Author(s)	Närhi U, Vanakoski J, Sihvo, S.
Title	Switching of H2-Receptor Antagonists to Over-the-Counter Status in Finland. Implications for consumption and adverse effects
Journal	Clinical Drug Investigation
Research question	Investigate whether there were significant risks related to switching H2-receptor antagonists to self-medication by examining the number and type of reported adverse drug reactions before and after the OTC switch
Country	Finland
Study design	Non-interventional observation study
Study period, follow Up	1990-2003
Study size	Not stated
Population selection	Inclusion criteria: ▪ Adverse drug reaction cases on OTC H2-receptor antagonists (ranitidine, famotidine and nizatidine) ▪ Adverse drug reaction cases on prescription proton pump inhibitors ▪ Consumption data of antacids ▪ Consumption data of drugs for peptic ulcer and gastro-oesophageal reflux disease Exclusion criteria: ▪ Cimetine was excluded due to low consumption rates, market entry 2001
Characteristics of the study population	Not stated
Intervention	Data base search (National Agency of Medicines database on total medicines sold and adverse drug reactions) Descriptive analysis of consumption rates as well as number of adverse drug reactions
Endpoints	Primary outcome: ▪ Number of adverse drug reactions of H2-receptor antagonists before and after OTC switch Secondary outcome:

	▪ Consumption rates of H2-receptor antagonists before and after the OTC switch
Results	Number of adverse drug reactions of H2-receptor antagonists before and after OTC switch: Ranitidine: ▪ 1990-1995: 21 reports before switch ▪ 1996-2003: 18 reports after switch Famotidine, nizatidine: ▪ 1990-1995: 3 report each before switch ▪ 1996-2003: 6 report each after switch *Type of adverse drug reactions: skin reactions(7 before, 8 after), hepatic reactions (6 before, 1 after)* Consumption rates of H2-receptor antagonists before and after the OTC switch ▪ 1990-1996: increase of H2-receptor antagonists 1996-2003: decrease of H2-receptor antagonists ▪ In 1996 OTC consumption was 19% of total H2 receptor antagonist consumption ▪ In 2002, consumption was 41% of total H2-receptor antagonist consumption
Bias-risk subject to type of study	Unclear
Limitations	▪ By use of adverse drug reaction data base possibility of bias due to under-reporting
Sponsors	No external funding
Conclusions of the authors	▪ Number of adverse drug reactions of H2-receptorantagonists decreased after switch, although consumption increased; gives indication that they do not have serious adverse effects and can be regarded as save
Comments (own)	▪ Bias assessment difficult to apply as it was observational study based on data from two databases

Table A 70: Urinary Tract Infection (UTI): included publications second selection

Author/year	Title	Type	Risk of bias
Albert et al. 2004	Antibiotics for preventing recurrent urinary tract infection in non-pregnant women	Systematic review and meta-analysis	Low (moderate for meta-analysis)
Ells et al., 2014	Recurrent Urinary Tract Infections Among Women: Comparative Effectiveness of 5 Prevention and Management Strategies Using a Markov Chain Monte Carlo Model	Systematic Literature Review and Model Simulation	Unclear/ moderate
Falagas et al., 2006	Probiotics for Prevention of Recurrent Urinary Tract Infections	Literature review	Unclear/ moderate
Hudson, 2006	Treatment and Prevention of Bladder infections	Literature review	High
Jepson et. al., 2012	Cranberries for preventing urinary tract infections	Systematic review and meta-analysis	Low (moderate for the meta-analysis)
Ferry et. al., 2004	The Natural Course of Uncomplicated Lower Urinary Tract Infection in Women Illustrated by a Randomised Placebo Controlled Study	Randomized controlled trial	Low

Table A 71: Albert et al., 2004

Author(s)	Albert X, Huertas I, Pereiro I, Sanfélix J, Gosalbes V, Perrotta C
Title	Antibiotics for preventing recurrent urinary tract infection in non-pregnant women
Journal	The Cochrane Library
Research question	To determine the efficacy (during and after) and safety of prophylactic antibiotics used to prevent uncomplicated RUTI in adult non-pregnant women
Country	
Study design	Systematic literature review and meta-analysis
Literature search	Databases: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL) Search period: 2004-2014 Study period: 1966-2004
Selection criteria	Inclusion criteria: Any published randomised control trial (RCT) where antibiotics were used as prophylactic therapy in women with recurrent urinary tract infections. Exclusion criteria: Trials which included women with a history of urological surgery, stones or renal function impairment
Interventions	▪ Any antibiotic regimen administered for at least six months as a preventive strategy for RUTI, where the control group should have received placebo, antibiotic or another pharmacological non-antibiotic treatment
Endpoint	▪ Recurrences occurring during active prophylaxis period; the recurrence needs to be confirmed by a positive urine culture; Recurrence is either measured in number of recurrences/patient-year or proportion of patients who experienced at least one recurrence during prophylaxis. ▪ Recurrences occurring after active prophylaxis period; the recurrence needs to be confirmed by a positive urine culture. Recurrence is either measured in number of recurrences/patient-year or proportion of patients who experienced at least on recurrence after prophylaxis. ▪ Side effects
Results	▪ Overall quality of the included studies was poor. Most studies did not provide any information regarding randomisation and allocation concealment. ▪ 19 studies were included and classified into three groups according to the types of interventions evaluated (1) antibiotics vs. Placebo, (2) Antibiotic vs. Different antibiotic or same antibiotic using different regimen, (3) Antibiotic vs. Another pharmacologic intervention (non-antibiotic) ▪ Ten trials with a total number of 430 women compared antibiotics with placebos; in all of these studies antibiotics showed higher efficacy than placebo to reduce clinical and microbiological recurrences ▪ The recruitment for the antibiotics and placebo comparison study was made from out-patient clinics (urologic, general practice or infection clinics) and one study recruited university students. ▪ The antibiotic vs. antibiotic comparison was undertaken in six studies with a total of 458 women included; Two trials with a total number of 513 women evaluated different regimes of the same antibiotic

	▪ The women in this group were pre- and postmenopausal and recruitment was made from out-patient clinics. ▪ A total number of 177 women were evaluated in two studies which compared antibiotics with other pharmacological strategy. In both studies, women were pre- and postmenopausal and recruitment was made from out-patient UTI clinics.
Bias-risk subject to type of study	Low
Limitations	▪ There is no uniform definition what constitutes recurrence. Most of the studies used microbiological recurrence, others objected that microbiological recurrences are not relevant and the only important outcomes are clinical ones. ▪ The trials did not take into account the ecological impact of preventive long-term antibiotics on bacterial resistance. The local bacterial resistance should also considered when deciding the best strategy
Sponsors	Not stated
Conclusions of the authors	▪ Continuous antibiotic prophylaxis reduces rates of RUTI in non-pregnant women with uncomplicated RUTIs when compared with placebo. The effect lasts during the active antibiotic intake period ▪ Side effects like vaginal or oral candidiasis, skin rash or nausea are frequent ▪ Dropouts and withdrawals are frequent, in some studies more than 20% of the participants decided to discontinue ▪ The decision of the best antibiotic choice must relay on community patterns of resistance, adverse events and local costs ▪ In women with UTI associated with sexual intercourse, post coital prophylaxis seems to be as effective as daily intake ▪ No conclusions can be drawn about the optimal duration of prophylaxis, schedule ore doses.
Comments (own)	Cochrane Review

Table A 72: Eells et al., 2014

Author(s)	Eells S, Bharadwa K, McKinnell J, Miller L
Title	Recurrent Urinary Tract Infections Among Women: Comparative Effectiveness of 5 Prevention and Management Strategies Using a Markov Chain Monte Carlo Model
Journal	Clinical Infectious Diseases
Research question	To assesses the efficiency of different treatment s of UTI with respect to rise in QALD (quality adjusted life-days) and lower costs calculated through a Markov Chain Monte Carlo Model
Country	
Study design	Systematic Literature Review + Model Simulation
Literature search	Databases: Medline, Embase, Cochran Library databases Search period: 2004-2014 Study period: 1966 – 2012
Selection criteria	Inclusion criteria: ▪ The study population was comprised of adult non-pregnant female subjects ▪ The study population had ≥ 3 UTIs per year

	▪ The study was a comparative clinical trial using either an untreated control group or a pre-intervention and post-intervention comparison of UTI incidence Exclusion criteria: Not stated
Interventions	▪ Acupuncture prophylaxis ▪ Cranberry prophylaxis ▪ Oestrogen prophylaxis ▪ Antibiotic (nitrofurantoin) prophylaxis ▪ Self-treatment
Endpoint	Efficacy of prevention methods measured in probability values for risk reduction
Results	▪ All prevention strategies resulted in a reduction in UTI rate; Daily antibiotic prophylaxis was the most effective at UTI reduction. However, from the payer's perspective it was also the most expensive method. Symptomatic self-treatment did not reduce the number of UTIs/year, but mean annual payer cost was the half of compared to antibiotics; All other strategies resulted in a payer cost savings, ranging from $319/year to $502/year ▪ From the patient perspective, self-treatment was the only cost-saving strategy. All other prophylactic interventions incurred additional costs to the patient ranging from the least expensive (antibiotics) to the most expensive (acupuncture) ▪ The sensitivity analysis for the payer model showed that change in the cost of daily oestrogen therapy was the most influential cost variable, followed by daily antibiotic prophylaxis. In the patient perspective model on the other hand, the most influential cost variable was daily cranberry prophylaxis; ▪ Daily antibiotic prophylaxis is the most extensively studied prevention strategy for recurrent UTIs. At the same time, it is also the most effective strategy in preventing UTI; Somewhat surprisingly, acupuncture is the next most effective prevention method.
Bias-risk subject to type of study	low /moderate
Limitations	▪ The risk reduction values for each strategy are based on published studies. Publication bias may result in overestimates of efficacy (e.g. acupuncture). ▪ Additional factors such as infection with multidrug-resistant organism medication adherence, long-term tolerability, toxicity, and uncommon adverse reactions were not explicitly tolerated. ▪ The study did not examine Lactobacillus (probiotic) prophylaxis as a preventive strategy ▪ Comparative clinical trials are the ideal method for determining efficacy, and some of the trials we used to determine probabilities had methodological limitations.
Sponsors	
Conclusions of the authors	Daily antibiotic use is the most effective strategy for recurrent UTI prevention compared to daily cranberry pills, daily oestrogen therapy, and acupuncture. Cost savings to payers and patients were seen for most regimens, and improvement in QALYs were seen with all. The findings provide clinically meaningful data to guide the physician-patient partnership in determining a preferred method of prevention for this common clinical problem
Comments (own)	

Table A 73: Falagas et al., 2006

Author(s)	Falagas M, Betsi G, Tokas T, Athanasiou S
Title	Probiotics for Prevention of Recurrent Urinary Tract Infections in Women; A review of the evidence from microbiological and clinical studies
Journal	Drugs
Research question	To assess the role of probiotics in preventing UTI
Country	
Study design	Literature review
Literature search	Databases: Pub-Med Search period: 2004-2014 Study period: 1950-2005
Selection criteria	Inclusion criteria: Any articles regarding in vitro studies, animal experiments, microbiological studies in healthy women, and clinical trials in women with UTIs Exclusion criteria:
Interventions	▪ Vaginal instillation of different probiotics in women experiencing an episode of UTI ▪ Oral administration different probiotics in healthy women aged 17-50 years who were free from symptomatic urogenital infections
Endpoint	▪ Composition of the vaginal flora towards more lactobacilli; ▪ Lower incidence of UTI
Results	▪ There is a wide range of Probiotics' efficacy. Some probiotic agents restored in only 9,5% of the studied women the vaginal flora whereas other agents could be detected in 80% of the cases. ▪ Probiotic agents can help to convert the vaginal flora from abnormal to normal within 28 days. ▪ Some agents are associated with greater restoration and maintenance of normal vaginal flora than others. ▪ More women treated with lactobacillus reported improvement in vaginal help than those treated with a placebo ▪ Lactobacilli do not adhere to the bladder, meaning a daily intake is necessary ▪ A combined treatment of probiotics results in an increase in the colonisation of vaginal epithelium. ▪ The question of efficacy of antibiotics is still not answered; Two studies casted doubts on the efficacy of antibiotics. In one study he recurrence of UTIs over 6 months decreased to 21% for those receiving lactobacillus compared with 47% for participants which received skimmed mild. Another study suggests no impact of lactobacillus on recurrence. However a third study showed that people which frequently consume fresh juices and fermented milk products containing antibiotics have fewer episodes of UTI ▪ The incidence rate ratio of probiotics between patients treated with probiotics and patients which were give a placebo, was 1.41 ▪ Women reported relief from their symptoms of urogenital infection and had no adverse effects from the administered probiotics.
Bias-risk subject to type of study	Unclear/moderate

Limitations	▪ No evaluation of the studies by two other researchers ▪ Only studies on the oral administration were blinded
Sponsors	None
Conclusions of the authors	▪ Several in vitro and in vivo studies support the beneficial effect of some strains of lactobacilli on the restoration of the vaginal flora and the prevention of recurrent UTI ▪ The use of probiotics for the prophylaxis of UTI is still controversial because only a few case-controlled, double blind clinical trials using strains carefully selected according to their laboratory-proven characteristics have been carried out so far ▪ More RCT should be conducted to confirm the effectiveness of probiotics compared with placebo and antibacterials or other possible preventive agents. Furthermore, research on adverse effects and safety of probiotics is needed.
Comments (own)	-

Table A 74: Hudson, 2006

Author(s)	Hudson T
Title	Treatment and Prevention of Bladder infections
Journal	Alternative & Complementary Therapies
Research question	To describe causes, recurrence and diagnosis of UTI and to assess alternative and complementary treatment s and prevention of UTI.
Country	Not specified
Study design	Literature review
Literature search	Databases: not mentioned Search period: 2004-2014 Study period: 1952-2006
Selection criteria	Inclusion criteria: Exclusion criteria:
Interventions	Various
Endpoint	Efficiency of alternative and complementary treatments of UTI
Results	▪ The highest risk factors of getting an UTI are sexual intercourse, method of contraception, pregnancy. ▪ Recurrence of UTI is related to re-infection from exogenous sources anatomical or functional abnormalities, method of contraception (diaphragm & spermicides) and change in the vaginal microflora. ▪ Diagnosis methods can be based on symptoms and physical examination, urine dipstick, urine analysis and/or urine culture; Cautiousness is required when using a dipstick, because it may produce a false-negative result if bladder bacteria have not had enough time to produce a sufficient amount of nitrite; ▪ Prevention methods include changing nutrition, improving bathroom hygiene, wearing cotton undergarments, using other contraceptives and reducing common bladder irritants (alcohol, chocolate, citrus fruits, coffee, black tea, tomatoes, vinegar and sugar) ▪ Frequent consumption of fresh juices, especially berry juices (cranberry or blueberry), and fermented milk products containing probiotics was associated with a decreased risk of recurring UTIs

	▪ Other supplements for addressing UTIs include Cranberry products (juice or capsule-extract), probiotics, Vitamin C and herbs (bitter wintergreen, Oregon grape, goldenseal, etc.).
Bias-risk subject to type of study	High
Limitations	▪ The author did not conduct (or mention) a thorough literature search guided by inclusion or exclusion criteria. ▪ No other researcher decided on the exclusion or inclusion of the studies ▪ No other researcher evaluated the methodological quality of the included study; ▪ The author did not assess the risk bias of the used literature
Sponsors	
Conclusions of the authors	Other influences are important to consider in post-menopausal women who have chronic recurring UTIs. Lower oestrogen states result in lower amounts of lactobacilli in the vagina an bladder. Fortunately, there are safe and effective solutions in the form of vaginal estrogens. Intra-vaginal estriol has been shown to be an effective treatment for recurring UTIs in postmenopausal women. Vaginal oestrogen has been shown to restore the normal vaginal flora and reduce the risk of vaginal Escherichia Coli colonisation. Other more commercially available oextrogens are also used for this purpose
Comments (own)	The author describes treatment and prevention of bladder infections and underpins his descriptions with different studies; The author did neither mention a literature search, nor considered more than one study on a certain treatment; presumptively the review does not reflect results of comprehensive literature search.

Table A 75: Jepson et al., 2012

Author(s)	Jepson R, Williams G, Craig J
Title	Cranberries for preventing urinary tract infections
Journal	The Cochrane Library
Research question	To assess the effectiveness of cranberry products in preventing UTI in susceptible populations ▪ Cranberry juice/cranberry products are more effective than placebo/no treatment in the prevention of UTIs in susceptible populations ▪ Cranberry juice/cranberry products are more effective than any other treatment in the prevention of UTIs in susceptible populations ▪ Different cranberry products (juice, capsules, tablets, concentrate) may differ in the effectiveness for preventing UTIs in susceptible populations
Country	
Study design	Systematic Literature Review
Literature search	Databases: Cochrane Central Register of Controlled Trials (CENTRAL), Medline Ovid Sp, EMBASE OVID SP, International Clinical Trials Register (ICTRP) PsycLit, LILACS, CINAHL, Biological Abstracts, Current Contents; Search period: 2004-2014 Study period: 1994-2012

Selection criteria	Inclusion criteria: ▪ Participants with a history of recurrent lower UTIs (more than two episodes in the previous 12 months) ▪ Elderly men and women ▪ Participants needing intermittent catheterisation ▪ Pregnant women ▪ Participants with an in-dwelling catheter ▪ Participants with an abnormality of the urinary tract ▪ Children with a first or subsequent UTI Exclusion criteria: ▪ Studies of the treatment of asymptomatic or symptomatic UTI ▪ Studies of any urinary tract condition not caused by bacterial infection (e.g. interstitial cystitis)
Interventions	Cranberry juice or a cranberry product (e.g. cranberry capsules, tablets or extract) taken by participants for at least one month. The amount taken, concentration of the juice/cranberry product and length of treatment was also taken into account in subgroup analyses
Endpoint	▪ Number (incidence) of UTIs in each group (confirmed by a catheter specimen of urine (CSU), midstream specimen of urine (MSU) if possible, or a 'clean catch' specimen ▪ Adherence to therapy ▪ Side effects
Results	▪ The studies had a broad range of participants: participants with a history of recurrent lower UTI or young women with an uncomplicated UTI, elderly men and women, participants needing catheterisation, pregnant women, children or other populations (persons with bladder or cervical cancer) ▪ In all studies, symptomatic UTI and/or positive urine culture were reported as the primary outcome measures ▪ None of the studies described clearly the rationale behind the dosage and concentration of cranberry juice which was delivered to participants ▪ The majority of the reviewed studies used a method of random sequence generation which was considered at low risk of introducing bias, in eight studies it was unclear and two were judged to be at high risk ▪ Allocation concealment was no issue in fifteen studies (low risk of introducing bias), in six studies it was not reported and two studies applied an method that was considered to be at high risk of introducing bias. ▪ Blinding of the participants and study personnel was done in seventeen studies, whereas five had no blinding and for one study it was not clear. 13 studies reported that the outcome assessor was blinded and in nine studies this point was unclear. ▪ There was a considerable variation of the dropout rate ranging from 0% to 55%. Several studies conjectured that the palatability of the cranberry product was the reason for participants discontinuing the study;
Bias-risk subject to type of study	Low
Limitations	▪ Some the studies did not conduct an intention-to-treat analysis, therefore the randomisation process was undermined; ▪ small size of most of the studies. ▪ In studies about non-juice products like capsules, it was not reported how much of the 'active' ingredient if any were in the tablets or capsules they used; ▪ Several studies lacked power to detect a realistic significant difference between treatment groups and

	even combining the few studies with similar populations and treatment, did not greatly improve this issue
Sponsors	Not stated
Conclusions of the authors	▪ There is lack of evidence that cranberry products do significantly reduce the risk of recurrent symptomatic UTI compared to placebo or no treatment in groups of people at risk of (recurrent) UTI for any of the subgroups analysed; ▪ The greatest effect occurs in children, but due to the small sample size of the two studies, this result is not significant; a small - but also not significant effect - is prevalent in women and the elderly; the same holds for studies on pregnant women, patients with spinal injury or neuropathic bladder, people with multiple sclerosis and people receiving radiant therapy ▪ Given the large number of dropouts/withdrawals from studies the small benefit for preventing UTI, Cranberry products cannot be recommended for prevention of UTI
Comments (own)	Cochrane Review

Table A 76: Ferry et al., 2004

Author(s)	Ferry SA, Holm SE, Stenlund H, Lundholm R, Monsen TJ
Title	The Natural Course of Uncomplicated Lower Urinary Tract Infection in Women Illustrated by a Randomised Placebo Controlled Study
Journal	Scandinavian Journal of Infectious Diseases
Research question	To describe the natural course of suspected uncomplicated lower UTI in women by evaluating the presence of symptoms and bacteriuria and their spontaneous cure rates, as well as the combinations of them during 1 week of placebo therapy and a 5-7 weeks follow –up period
Country	Sweden
Study design	Prospective, multicentre, randomised, double-blind and placebo controlled study
Study period, follow Up	Between April 1995 and December 1997 Two follow ups after 8-10 days and 5-7 weeks after first consultation
Study size	1,143 women consulting at 18 primary health care centres
Population selection	Inclusion criteria: ▪ Women aged 18 years and above with symptoms suggestive of lower UTI i.e. urgency, dysuria, suprapubic pain or loin pain Exclusion criteria: ▪ Pregnancy/planned pregnancy ▪ Antibiotic therapy for UTI within the last month or unapproved drug treatment within 3 months prior to inclusion ▪ Known/suspected penicillin allergy ▪ Genital infection ▪ Complicating factors (diabetes or abnormality of the urinary tract) ▪ one or more signs of pyelonephritis ▪ Urine incontinence requiring catheter/pads ▪ Previous participation in the study
Characteristics of the study population	▪ Age distribution: 22% up to 24 years 50% aged between 25 and 54 years 28% 55 years and above ▪ Bacterial counts at inclusion 20% had negative culture 5% had 103 CFU/ml,

	9% had 104 CFU/ml 67% had ≥ 105 CFU/ml ▪ Mixed floras in 55 episodes were classified as negative culture, while 45 episodes with 1 dominating species were classified as uropathogens ▪ Distribution of uropathogens 62.1% Escherichia Coli 4.9% other CNS 2.7% Klebsiella 2.6% Staphylococcus saphrophyticus 2.2% enterococci Young women (< 24 years) had lower frequency of E. Coli (55%) and higher frequency of staphylococci (15%) ▪ Frequency of Symptoms 96% urgency 88% dysuria 60% suprapubic pain 40% loin pain ▪ Among all the 1,143 patients the symptom duration varied considerably (76% ≤7 days and 13% ≥15 days); Women up to 24 years had short symptom duration (78% ≤7 days) compared to women over 55 years (52% ≥15 days)
Intervention	Intervention group: The intervention-group was defined as "no-intervention" combined with an intake of placebo for 7 days. Control group: ▪ Selexid® 200 mg 3 times a day for 7 days ▪ Selexid® 200 mg 2 times a day for 7 days For both groups, symptoms and symptom scores (ranging from 0-3) were registered at inclusion and at the follow-up visits as well as in a patient diary during 7 days of therapy.
Endpoints	Eradication of symptoms and bacteriuria
Results	Of 1,162 enrolled women, 19 were excluded (11 had missed cultures and 8 had a symptom score <2 at consulting); Of the remaining 1,143 included patients, 288 patients were randomised to placebo therapy of whom 11 (4%) patients dropped out before the first follow-up visit. Another 111 (39%) dropped out after the first follow-up visit, mainly due to persisting symptoms and received treatment with other antibiotics than pivmecillinam. The remaining 166 patients fulfilled the study. Another 425 patients fulfilled the inclusion criteria but refused participation in the study and served as controls. The baseline characteristics of placebo treated patients did not significantly differ from the antibiotic treated patients. The natural course of UTI was described among the 288 placebo treated patients. At inclusion no differences in mean symptom scores between patients who dropped out or fulfilled the study plan were found. However, the dropouts had higher bacterial counts. At the first follow-up visit, these patients still had high symptom scores and therefore most of them received antibiotics and left the study. Bacterial species as well as bacterial counts varied considerably during the time of study within the patients. Among the patients with ≥ 10^5 CFU/ml at inclusion, 47% had spontaneous eradication of bacteriuria with negative cultures, while 40% had unchanged counts at the end of the study. Of the 42 patients with negative cultures at inclusion, 83% remained negative after 8-10 days, as did 69% at the end of study. However, among all the 166 patients fulfilling the study, 45% had negative cultures after 8-10 days and 57% at the end of study.

	Patients free from symptoms increased during the first week. At the Day 7, approximately 75% of patients were free from suprapubic and loin pain, 45% from urgency and dysuria, and 30% from all symptoms. Corresponding proportions at the end of study were 90, 70 and 55% respectively. Patients infected with E. Coli and staphylococci had similar and slow eradication rates of all symptoms during placebo therapy compared with patients with other Gram-negatives than staphylococci. The latter groups had eradication rates similar to those with negative cultures. 28% of the patients were cured from all symptoms at the first follow-up visit compared with 54% at the second follow-up visit. Negative culture and no symptoms at those visits were found in 21% and 37% of the patients respectively.
Bias-risk subject to type of study	Moderate (because the study was financed by a pharma company)
Limitations	None stated
Sponsors	The study was financed by LEO Pharma, Denmark, with Ulf Diehl (LEO Sweden) as data reviewer and monitor. The study was also sponsored by grants from the County Council of Västerbotten and Umeå University
Conclusions of the authors	The natural course of uncomplicated lower UTI in women was studied by the presence and eradication of symptoms and bacteriuria and the combinations of them. The association between symptoms and bacteriuria or bacterial counts were unpredictable, and thus rapid and patient near-laboratory tests are required for diagnosis of UTI. 'Other CNS' than S. Saprophyticus was the second most common group of bacteria with a spontaneous eradication similar to that for E. Coli indicating that the present classification in primary, secondary and doubtful uropathogens as in the current guidelines seems not to be clinically relevant and needs to be revised. The spontaneous resolution of all symptoms and bacteriuria was surprisingly low.
Comments (own)	The authors applied a randomising method but did not mention how it worked and how the allocation concealment was ensured. A further drawback of the study was the high dropout rate in the placebo group at the second follow up (39%)

Annex 9: Description and analysis of selected self-care initiatives

Grünes Rezept

Description:

The Grünes Rezept ("Green Prescription") originates in the German health care reform of the year 2004. In this reform, the GKV Modernisierungsgesetz, a law for modernising the German statutory health insurance, was decided. As a consequence, OTC medication was mostly excluded from reimbursement. Exemptions refer to OTC medication for children up to 12 years, adolescents with development disorders and people with serious illnesses, for whom OTC medication is part of their therapy. The rationale for excluding OTC products from reimbursement was cost relief for the health insurance, as the prescription rate of those products made up approximately 40% of total prescriptions in 2000 (Maag 2014). In 2012 the GKV Versorgungsstrukturgesetz, a law aiming for better planning of future demand as well as for securing future health care provision, made OTC medication partly reimbursable again. This refers mainly to natural or homoeopathic products (Bundesverband der pharmazeutischen Industrie e.V. n.d.)

OTC products are regarded as safe with few side effects, and tight monitoring by a physician is not necessary. Therefore, they can be used for self medication. The Green Prescription was developed to prevent the omission of drugs with few side effects from medical treatment. Like regular prescriptions, it is an official document, similar to the red prescription which refers to prescriptions covered by public health insurance. The only difference is that the costs for the medication prescribed by a Green Prescription must be borne by the patient. However, with an average price of € 8, OTC products usually lie below the co-payment limit of prescription drugs. Furthermore, medication prescribed by Green Prescription is tax-deductible (Bundesverband der pharmazeutischen Industrie e.V. n.d.). Physician related advantages connected to the Green Prescription refer to the possibility to use the whole therapeutic diversity, to obligate the patients, to achieve better compliance compared to oral recommendations and to get better information about the patient's range of medication. By prescribing OTC medication with an official document, it is regarded as medically relevant and therefore better accepted by the patient. Furthermore, Green Prescriptions serve as a memory aid helping patients to know when to use what kind of OTC products (Bundesverband der pharmazeutischen Industrie e.V. n.d.; Maag 2014).

Green Prescriptions are most often used by dermatologists, urologists, ear, nose, throat (ENT) specialists as well as GPs. In the fourth quarter of 2013, about 80% of each group of these health care professionals used the Green Prescription. Approximately 95% of prescriptions are handed in by patients (Sauer 2009). Furthermore, it was observed that Green Prescriptions are mostly prescribed for common colds and pain, but also for fungal skin infections (Maag 2012; Maag 2014).

Analysis:

Looking at the utilization of the Green Prescription by both, physicians and patients, its reach can be regarded as high. Evidence confirming the effectiveness could not be found. However, indication is given that the Green Prescription indirectly reduced costs for the German statutory health insurance and enables better patient compliance and functioned as memory aid for patients. Thus, patients are supported in their self-medication, such as when to take which OTC medication (Bundesverband der pharmazeutischen Industrie e.V. n.d.; Maag 2014). The Green Prescription is adopted in outpatient physician practices throughout Germany. If the initiative can be transferred to other European countries remains unclear. Regarding implementation

and maintenance, the Green Prescription receives positive evaluations for both. Implemented in 2004, it is currently in its 10th year of existence and a widely recognised method for prescribing OTC medication among physicians, but at the same time there is evidence that some physicians and patients do not know about the Green Prescription. Thus, lack of knowledge can be considered as one barrier for the use and application of the Green Prescription. Another barrier for patients' application is the fact that patients consider the exemption of OTC products from reimbursement as a sign for missing necessity and effectiveness of drugs prescribed Green Prescriptions (Sauer 2009). Consequently, they do not hand in their Green Prescriptions. Considering equity, financial drawbacks on behalf of families with children over the age of 12 years are conceivable (Ärzte Zeitung n.d.).

Améli-Santé (website)

Description:

Améli-Santé (www.ameli-sante.fr) is the French public health information portal, similar to UK's NHS Choices. It is led by the National Health Insurance Fund for Employees (CNAMTS) and completely funded by the CNAMTS. Améli-Santé was launched in May 2010 for the purpose of informing the French population of a variety of different topics on health. It only deals with general informative facts. As specified on the website, they do not substitute advice from health care providers and cannot be used to establish a diagnosis or a medical treatment (Caisse nationale de l'Assurance Maladie des travailleurs salariés 2010).

In 2010, Améli-Santé comprised 16 health subjects. Now, it contains more than 200 health subjects and 25 symptoms. Relevant information on minor ailments is supplied in order to create better understanding of the pathology so that patients can more easily deal with an ailment:

- Description of the pathology;
- Symptom(s) and possible complications;
- Healthcare offered by the Insurance Fund.

Other parts of the website focus on information regarding prevention (e. g. adult diet) and emergency situations (e. g. snake bite). For more personalised information, it is possible to indicate one's age and sex, which automatically selects the prevention offered in relation to these criteria. Furthermore, Améli-Santé provides direct access to Améli-direct, a tool for finding information on healthcare providers (i. e. fees, contact details).

According to the 2012 activity report of the CNAMTS, 366,000 visits per month were recorded. Of these, 249,400 visits were for "Antibiotics", which was the most accessed section of Améli-Santé in 2012, and 125,900 visits were for "Roseola infantum"[14], which was the second most accessed section of the website in 2012 (Caisse nationale de l'Assurance Maladie des travailleurs salariés 2012). In 2011, 2,730,632 visits were counted over the year, whereas only 619,852 were registered in 2010 (Caisse nationale de l'Assurance Maladie des travailleurs salariés 2011). Thus, visit rates increased more than quadrupled between 2010 and 2011.

Analysis:

An intensive internet research brought no further information on which the assessment of the initiative could have been based. Contacting the French national health insurance agency (CNAMTS) for further information and potential evaluations

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Roseola infantum is a viral infection, which mainly affects young children between six months and two years of age

did not yield any results. Thus, an evidence-based assessment of Améli-Santé is not possible at this time.

Latvian Tele-helpline service

Description:

The Tele-helpline service (66016001) was implemented in Latvia in 2011 with the aim to improve access to basic health services and provide advice for people during GPs' out-of work hours. The service is organized and run by the Latvian Ministry of Health and the National Health Service. It is available on working days from 5.00 p. m. to 8.00 a. m. and 24 hours during weekends and on holidays. Calls are charged according to regular phone call tariffs (Nacionālais Veselības Dienests 2012).

Tele-consultations are provided by medical staff: GPs or their assistants. The main aim is to give patients the opportunity to get medical advice and educational tips for minor illnesses, which do not require immediate medical care outside of GPs' working hours. Where appropriate and/or necessary, self-care advice or direction to other service providers is given. Calls can be re-directed immediately to Emergency ambulance service, if considered appropriate by the operator. E-mail or Skype communication is also available. Consultations are provided in Latvian, English or Russian (Nacionālais Veselības Dienests 2012).

Analysis:

The Latvian Tele-helpline recorded a growing number of calls since its implementation in 2011. The number of calls by 23.7% points to 67,168 in 2013 (latest figures available) (Nacionālais veselības dienests 2013). As the data given do not indicate, if these figures refer to unique users or repeated users, the reach of the initiative is considered as moderate. Introduction of Tele-helpline was also supported by a public campaign. The initiative is considered to be an effective alternative to other service providers and a tool to route customers to the right service. Evidence suggests slightly reduced need for GP visits. Besides, emergency ambulance service calls have decreased as well since the implementation of the initiative. In 2011 706,299 calls have been reported for emergency ambulance services, whereas in 2013 a total number of 524,245 calls have been reported (Disease Control and Prevention Centre 2013). However, it is unclear to what extent this reduction is attributable to the Latvian Tele-helpline service. For this reason and due to missing further evidence, the effectiveness of the initiative is considered as unclear. The Tele-helpline service is a national initiative, thus adoption to other regions/ settings in the country can be considered as good. Transferability to other European settings might be possible, although no evidence supporting this notion was found. Thus, even though transferability of the Latvian Tele-helpline service seems plausible, for the purpose of this assessment it is regarded as unclear. No statement can be made regarding implementation, as no evidence is generalized yet. However, it can be assumed that the Latvian Tele-helpline is successfully integrated into the system. This is indicated by the fact that it is in its third year of existence and shows growing user rates every year. Furthermore, costs per call are decreasing since 2011. In 2011, the implementation year, the average costs per call have been € 9.39, compared to € 2.78 in 2013 (Nacionālais veselības dienests 2013). For these reasons, maintenance is rated as good for the purpose of this report. No evidence could be found regarding access to the Latvian Tele-helpline service. However, potential utilisation barriers might refer to bad health literacy and lack of information. Growing but still low user rates might be an indication for that (Nacionālais veselības dienests 2013). However, no evidence supporting this argument could be found. Thus access is rated as unclear. Equity might be reduced by telephone charges. For people of socioeconomically disadvantaged groups this might be a utilization barrier.

Zelfzorg.nl

Description:

Zelfzorg.nl (www.zelfzorg.nl) is the most popular Dutch information portal on self-care issues. It is led by Neprofarm, the Dutch branch association of the Dutch producers and importers of self-care products. Altogether, Neprofarm involves 25 members[15] (Zelfzorg.nl n.d.-a). In March 2003, the Neprofarm the website was launched to give priority to the consumer. By providing patients/consumers with relevant information, Zelfzorg.nl aims to enable patients to autonomously take care about their health. Besides this, another aim is to provide information on that medication, for which no advice is given at the point of purchase, as their selling points are supermarkets, gas stations and other (Neprofarm 2003; Neprofarm 2006).

The self-care information provided by Zelfzorg.nl is based on medical standards of GPs, pharmacists and chemists and covers the following:

- General information about minor ailments and their prevention and treatment
- Specific information on almost 1,000 self-care products (i. e. application, dosage and composition). For further information, the original patient information leaflet can be downloaded. Besides that, all products recommended on the homepage can be compared with each other.
- Self-care related information for pregnant women and children
- Information about self-care related issues (i. e. information on correct usage, insurance and registration of self-care medication)

During its 13 years of existence, Zelfzorg.nl went through several phases of re-structuring and renewal (Neprofarm 2005; Neprofarm 2007). As part of these phases, the homepage's topics were extended. Furthermore, innovative applications for the provision of self-care information have been introduced. In 2009, an interactive animation – where users can click on the affected body parts – providing information about specific ailments and the necessity for visiting a doctor was launched (Neprofarm 2009). In 2010, the Zelfzorg.nl app was launched to ensure mobile accessibility of information provided. This app gives access to the original patient information leaflet by scanning the bar code of self-care medication (Neprofarm 2010; Neprofarm 2011).

In the second half of 2004, – the first year for which usage data is available – between 10,218 and 16,241 visitors have been reported per month (Neprofarm 2004). Since then visitor numbers have risen continuously. In 2011 about 1.1 million visitors were counted. The average visitor stays between 1.5 and 2 minutes on the homepage (Neprofarm 2011).

Analysis:

An intensive internet research brought no further information on which the assessment of the initiative could have been based. Contacting the provider of the homepage Neprofarm for further information and potential evaluations did not yield any results. Thus, an evidence-based assessment of zelfzorg.nl is not possible at this time.

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Neprofarm's members: Bayer B. V., Bayer B. V. (Steigerwald), BioClin B. V., Biohorma B. V., Boehringer Ingelheim B. V., GlaxoSmithKline Consumer Healthcare B. V., Heel Biologische Geneesmiddelen B. V., Holland Pharma, Imgroma B. V., Johnson & Johnson Consumer B. V., Meda Pharma B. V., Medical Brands, Novartis Consumer Health B. V., Omega Pharma Nederland B. V., Pfizer bv Consumer Healthcare, Reckitt Benckiser Healthcare B. V., Remark Pharma B. V., Sanofi Consumer Health Care, Timm Health Care B. V., Vemedia B. V., VSM Geneesmiddelen B. V., WALA Nederland B. V., Weleda Benelux SE, Will-Pharma B. V., YouMedical, Zambon Nederland B. V.

NHS Choices (website)

Description:

NHS Choices (www.nhs.uk) is Europe's most popular health website and the third biggest government website in the UK (NHS Choices 2012b). It is led by the NHS, thus a programme of UK's Department of Health and accessible across all parts of the UK. In case of non-availability of services via www.nhs.uk, users are referred to their regional equivalents (e.g. NHS 24 for Scotland). It was established in 2007 (Nelson et al. 2010a) to provide comprehensive medical and lifestyle information to both the public as well as health care professionals. "Its aim is to develop a world-leading, multi-channel service that will create a 'front door' for everyone to engage with the NHS and social care." (NHS Choices 2013a). Therefore, it compiles the knowledge and expertise of:

- NHS Evidence (formerly the National Library for Health),
- the Health & Social Care Information Centre (HSCIC),
- the Care Quality Commission (CQC),
- and many other health and social care organisations.

It is certified by The Information Standard – a certification programme run by NHS England for organisations producing evidence-based health and care information for the public – as a producer of reliable health and social care information. Health information is provided by means of several features of the website (e. g. 'Health A-Z', or 'Services near you'), social media and different electronic tools such as the symptom checker, mobile apps or a BMI calculator to name just a few. This is in line with the objective to transform NHS Choices and associated services into a new information, feedback, transactions and participation service delivered through mobile apps, SMS, phone lines and online channels (NHS Choices 2013a). In 2012 the website received more than 27 million visits per month. Regarding usage, NHS Choices users access the website mostly to receive medical information (39%) and to check their symptoms (26%) (NHS Choices 2012b).

Within the remit of providing health information, the support and improvement for primary care consultations is of particular importance. NHS Choices tries to facilitate this in several ways. First, GPs are provided with a single, complete portal for clinical information (e.g. Health A-Z). Thus, they can easily find necessary information for reference or discussion with patients, as well as the ability to easily dispense Information Prescriptions[16]. Second, users are offered access to reliable health information and materials, which makes them better prepare for GP consultations. An informed patient can make a consultation more effective and more efficient. Third, by providing clear information about appropriate time, place and reasons for consultations, unnecessary consultations might be avoided (Nelson et al. 2010a).

Analysis:

With 24 million unique users in 2008, NHS Choices seems to have a high reach. Since then, homepage visits have increased steadily (NHS Choices 2012b). NHS Choices also seems to be effective regarding the reduction of GP visits and the costs for primary care in general (Murray et al. 2011). (Murray et al. 2011) examined the impact of NHS Choices on the frequency of primary care consultations. Their study was two-fold comprising a survey of patients in six GP practices in London as well as an online survey of NHS Choices users. Overall results show that 59% of online (n = 1559) as

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Information prescriptions provide up-to-date and accurate information regarding patients' specific condition, treatment options, local care services, benefits to be claimed, housing support and self help and support groups. It can be created by patients themselves. Patients can also discuss information prescription needs with healthcare professionals or social care workers (NHS Choices 2012a).

well as 8% (n = 125) of GP practice respondents use NHS Choices in relation to primary care services used. Among those, 33% (n = 515) online and 18% (n = 23) of GP practice respondents reported that NHS Choices decreases their number of GP consultations. Another benefit of NHS Choices is that it leads to better informed patients all over the UK. Transferability of NHS Choices to other European countries seems possible, as some European countries are already equipped with online health portals (such as Ameli santé in France or zelfzorg.nl in the Netherlands) (Ameli-santé 2014; NHS Choices 2013a; Zelfzorg.nl n.d.-b) albeit mostly in a more simplified form. Thus, sufficient support and adequate infrastructure given on behalf of national health care authorities can be regarded as necessary preconditions. Considering the implementation of NHS Choices, it can be assumed that the initiative was carried out as planned. This is based on the fact that the website is currently in its 7th year of existence (NHS Choices 2012b). Possible downsides of the health website might be restrictions related to internet access as well as language skills, which can both be hypothesized to be related to lower socioeconomic status. Hence, some people might be excluded from utilization due to their socioeconomic status, nationality and older age. Access restrictions regarding language relate to people with communication difficulties, visual impairments or bad health literacy (Jones/Mays 2009).

NHS 111

Description:

NHS 111 is England's current telephone based triage and signposting service for helping people to access appropriate healthcare for urgent medical problems, which are not 999 emergencies. In 2014 it replaced the former telephone helpline of NHS Direct (NHS Direct 2014). In respect of the other countries of the UK, the telephone based helplines NHS 24 for Scotland and NHS Direct Wales need to be mentioned (NHS 24 2014; NHS Direct Wales n.d.), whereby the Welsh government plans to launch a NHS 111 telephone in the coming year (Martin 2013).

NHS 111 is a 24/7 service providing response to healthcare requests for non life threatening situations, care access out of hours and to insecurities regarding services needed. The main objective as defined is to simplify access to consistent information about non-emergency health care by use of a memorable number (111) free of charge. Besides, it provides clinical assessment at the first point of contact and routs customers to the right NHS service (NHS 111 programme team 2011; NHS Choices 2013b). To achieve this, NHS 111 is staffed with a team of fully trained advisers, supported by experienced nurses and paramedics. By asking questions, symptoms are assessed, on which basis healthcare advice is given or callers are directed directly to local services, such as accident an emergency (A&E) departments, out-of-hour doctors, urgent care centres or walk-in centres. Where possible, appointments are booked by the NHS 111 team (NHS Choices 2013b).

In 2014, NHS 111 service in England was divided into 45 catchment areas. In May 2014, 1,112,633 calls were directed to the NHS 111 service. Extrapolating the numbers for the whole year would yield 13.1 million calls per year. May 2014 waiting times for callers were less than 60 seconds (NHS England 2014a).

Analysis:

Considering the user rate figures of May 2014 and the fact that NHS 111 in its current form is in its second year of existence, reach can be concluded of being good.

As NHS 111 is a relatively new service, no evidence regarding effectiveness from a holistic perspective could be found. However, (Turner et al. 2012) evaluated the impact of the NHS 111 service on the emergency and urgent care system following a controlled before and after approach at four pilot and three control sites in England.

Data of the four NHS 111 pilot sites was collected in 2010/2011. The collection of routine data of use of five emergency and urgent care services started 2 years prior NHS 111 service started. Findings suggest that NHS 111 did not deliver the expected benefits in its first year of operation: no change in overall emergency ambulance calls could be observed, emergency ambulance incidents increased by 2.9% and emergency and urgent care activities increased in the four pilot sites between 4.7% and 12% per month. Considerable noise in the analysis as well as exclusion of in-hours GP services may contribute to the results found. It might be possible that NHS 111 leads to better results regarding system relief by this time, after its nationwide implementation and time for maturing. Evidence for the former NHS Direct supports that assumption (Munro et al. 2000). Munro et al. found that the telephone service of NHS Direct significantly reduced the use of GP out of office consultations, while its impact on the use of emergency departments was insignificant.

Adoption of NHS 111 in other regions of the UK can be considered as high. This can be explained by the existence of other telephone helplines in Wales and Scotland (i.e. NHS Direct Wales, NHS 24). These helplines are quite similar to NHS 111 and replacement by NHS 111 is planned for some regions (i. e. Wales), Transferability of a telephone based health helpline to other European settings might be possible, although no confirmatory evidence was found. Thus, for the purpose of this assessment, NHS 111's transferability is regarded as unclear even though it is plausible. Evidence suggests that the implementation of NHS 111 in England faced some problems after replacing NHS Direct. These problems concerned long waiting times, especially in the evenings and during the weekends, poor quality advice and staff shortages (Walker 2013). Due to these issues, the implementation of NHS 111 is evaluated as being moderate. Yet, NHS 111 seems to have managed the transition into daily routine, with improved response times and sufficient satisfaction rates (NHS England 2014a). Unless people have access to a telephone, accessibility and equity can be regarded as high. The service is free of charge and where necessary an interpreter is provided (NHS Choices 2013b).

Minor Ailment Schemes

Description:

Community pharmacy minor ailment schemes (PMAS) are locally tailored schemes to provide public access to NHS treatment and/or advice via a pharmacist or pharmacy personnel, or, where appropriate, to refer to other health professionals. The idea is to encourage patients to use community pharmacies as first access point for minor ailments rather than a general practitioner (GP). According to a systematic literature review commissioned by the NHS (NHS 2000) PMAs are unique for the UK and their establishment as well as their management is up to the regions. Originally proposed by the UK Department of Health, the schemes were introduced nationally in all community pharmacies in Scotland and Northern Ireland in 2006 and 2009, respectively. In Wales, a PMAS was rolled out nationwide in 2013. In England, the community pharmacy contract specifies PMASs as 'enhanced' services, which can be commissioned by the primary care trusts after a local needs assessment. The schemes have an agreed list of ailments to be treated and treatment supply is based on an agreed formulary – a list of products which gives instruction about which product can be prescribed for which minor ailment – (National Public Health Service for Wales 2007).

PMASs can be open to patients, who normally pay prescription charges. For those patients, who are exempt from NHS prescription charges, medicines are supplied free of charge. Thus, the payment barrier, which might hinder patients to consult a pharmacist instead of a GP, is removed. There are also differences regarding access to PMASs. Some schemes are only open to patients registered with a participating GP

practice; others are open to all patients. If patients can only access a PMAS by registering with a GP (i. e. GP practice referrals), evidence is given that the pharmacy consultation serves as a substitution for GP consultations. Another option are self-referrals to community pharmacies by patients, which makes pharmacies the first point of access and thus promotes the role of pharmacies and makes access easier. PMASs often use a combination of GP practice referrals and self-referrals, with pharmacies checking patient's eligibility (National Prescribing Centre 2004). In Scotland, a patient voluntarily registers with a pharmacy of their choice for minor ailment services and his/her GP is informed. Using this strategy, individual medication utilisation can be monitored through the pharmacy (Community Pharmacy n.d.). Further benefits refer to minimising the work of GP practice staff and avoidance of unnecessary GP visits each time a patient wishes to use the scheme. However, as patients can only register with one community pharmacy, patient choice is reduced following this strategy (National Prescribing Centre 2004).

In the Scottish PMAS, over two million items were dispensed between April 2011 and March 2013. The most often dispensed drugs were Paracetamol, followed by ibuprofen and simple linctus. The ten most often dispensed drugs accounted for 53% of all prescribing (Pharmacy Research UK 2014).

Regarding payment of PMASs costs of medicines and consultation costs need to be differentiated. Costs for medicines are reimbursed for all pharmacies, whereas the payment of the consultation varies across schemes (e.g. fee for service payment or annual and one-off retainers, respectively). Furthermore, funding of these schemes must account also for stationery, printing costs, marketing, training events and evaluations of the scheme (National Prescribing Centre 2004).

Analysis:

It is estimated that approximately 50 million GP consultations in the UK are due to minor ailments (NHS Choices 2014). PMAS have the potential to shift patients from GP practices into community pharmacies for treating their symptoms. As actual user rates were not available the initiative's reach is regarded as unclear. A systematic review of 31 evaluation studies found that PMAS are effective in controlling of symptoms as well as reducing re-consultation rates with GPs. Large variations in the mean costs of PMAS consultations, depending on the methods of cost identification, measurement and valuation could be observed. Costs for PMAS ranged from £ 1.44 to £ 15.90 per consultation. One study estimated that the total cost savings for the NHS could be up to £ 112 million, if all GP consultations for minor ailments are substituted by PMAS. This calculation is based on the mean costs of £ 6.50 for one PMAS consultation (Paudyal et al. 2013). After initial implementation of the first PMAS in Scotland, PMAS are now adopted across all countries of the UK. Transferability of such schemes to other European countries is unclear, as British PMASs are unique in Europe. Transferability to other countries might require changes in legislation as well as support on behalf of medical and pharmaceutical associations. Regarding implementation and maintenance, the initiative is evaluated as being positive. This is based on the fact that PMASs exist for more than ten years, depending on the country. Consequently, PMASs are part of the UK's health care system and it can be assumed that their implementation was carried out as planned. In general, PMASs are easily accessible. However, one potential barrier of the PMASs in Scotland is that patients are requested to be registered with a GP practice to use the PMAS. Equity can be regarded as high, as the design of PMAS takes care of lower socioeconomic groups by exempting them from paying prescription charges (Community Pharmacy n.d.).

Non medical prescribing

Description:

Since 1998 Non Medical Prescribing (NMP) is a common practice in the UK. The intention of NMP was to make the NHS workforce more effective, as evidence suggested that it was ineffective if nurses had to request and wait for prescriptions from GPs (Department of Health 1999). Independent nurse prescribers – now called community practitioners – have been the first health professionals apart from physicians provided with the right to prescribe. In 1998, nurses were able to prescribe medicines from the General Sales List and pharmacy medicines prescribable by GPs as well as 180 prescription only items from the original Nurses Formulary (Hacking/Taylor 2010). Since then, NMP developed in several waves, by extending authorities, number of medicines prescribable and number of health professionals provided with the right of prescribing (Courtenay et al. 2012). This development was supported by several legal actions (i. e. the new General Medical Services contract, the new Community Pharmacy Contractual Framework and the application of statutory working time limits in line with the EU working time Directive for doctors in training). The changes strengthened the position of NMP, especially for services formerly provided by junior doctors in hospitals or the management of long-term conditions. In practice, three types of NMP can be distinguished (Hacking/Taylor 2010):

1. *Community practitioner prescribers* (i. e. nurses), who prescribe medications and dressings from the Community Practitioner Prescriber Formulary which contains a rather limited number of products.
2. *Supplementary prescribing* (i. e. nurses, midwives, health visitors, pharmacists, optometrists, physiotherapists, podiatrists and radiographers) takes place after clinical assessment by a medical practitioner or dentist. It includes a pre-agreed written Clinical Management Plan, in which a list of medicines, which are prescribable by the supplementary prescriber, is outlined. This type of prescribing is best suited for long-term care and when there is necessity for a team approach.
3. *Independent prescribers* (i. e. nurses, midwifes, health visitors, pharmacists and optometrists), who access the whole British National Formulary in their area of competence. Besides independent prescribing, it is also possible for them to practice within a supplementary cooperation with physicians (see above).

According to (Courtenay et al. 2012), approximately 33,000 community practitioner prescribers, 23,000 nurse independent and/or supplementary prescribers and 2,000 pharmacist independent and/or supplementary prescribers as well as several hundred optometrists and allied health care professionals equipped with prescribing capacities work across the UK.

Analysis:

Looking at the development of NMP services as well as the growing number of non medical prescribers since its implementation, reach can be assumed to be high. Evidence generally suggests that NMP services are effective regarding competence and safety of NMP practice (Bhanbhro et al. 2011; Latter et al. 2005). Furthermore NMP's benefits such as earlier treatment, better therapeutic management, time savings and higher patient as well as job satisfaction for health care professionals are dominant in the literature (Bhanbhro et al. 2011; Courtenay et al. 2012; Hacking/Taylor 2010; Latter et al. 2005). NMP is adopted throughout the UK. It became a national initiative in 1998, after some pilot projects were run in 1994 (Luker et al. 1998). This positive evaluation is supported by the fact that the UK is one of the countries with the most extended NMP rights (Courtenay et al. 2012). Other countries implemented NMP by non medical healthcare professionals, such as Ireland and the Netherlands in Europe,

but also Australia and the US, where this common practice (Bhanbhro et al. 2011). As the initiative went through some extension waves since its implementation, it can be assumed that it was carried out as planned and NMP is successfully integrated in UK's routine health care working practice. A systematic review investigating NMP from an international perspective identified three studies concerning access for the UK. Results indicate patient satisfaction stemming from nurses being accessible and thus start of medicinal treatment is not delayed. In another study (n=127) focusing on pharmacist supplementary prescribers, 86% of respondents stated that appointments can be made easily and thus, access to medicines is good (Bhanbhro et al. 2011). These studies observed patients already using NMP. Therefore, reduced accessibility due to lack of information was not considered, although it could be an issue. Further barriers mentioned in the literature refer to organisational issues, such as restrictions of local arrangements, inability to computer generate prescriptions, lack of peer support, organisational and policy restrictions and difficulties in fulfilling professional development needs (Courtenay et al. 2012). Equity might be reduced by bad health literacy, but no evidence supporting this argument could be found.

Annex 10: Economic Studies

Athlete's foot:

Non identified

Cold

Table A 77: Rohrer et al., 2010, evidence table for economic studies

Author(s)	**Rohrer JE, Angstmann KB, Adamson SC, Bernard ME, Bachman JW; and Morgan ME**
Title	Impact of Online Primary Care Visits on Standard Costs: A Pilot Study
Journal	Population Health Management
Research question	Do online visits lower the odds of being a cost outlier compared to standard care?
Country / Currency and reference year	USA / 2010 US$
Study design	Cost analysis
Study size	767 patients
Population selection	Inclusion criteria: all patients visiting patient portal or same-day acute medical clinic Exclusion criteria: Codes not included in the CMS (Centers for Medicare and Medicaid Services) fee schedule Illness severity levels high enough to require immediate self-referral to an emergency department Very complex chronic conditions that require longer face-to-face visits
Intervention	Intervention group: visit of a patient portal (i.e. web-based secure interface allowing multiple potential patient/provider interactions) Control group: visit of a standard same-day acute medical clinic
Perspective	Health care system
Endpoints	▪ Median total reimbursable costs per visit ▪ Percentage of cost outliers (exceeding the 75th percentile)
Data sources	Sources for effectiveness data: not collected Sources for cost data: Current Procedural Terminology (CPT) codes from medical records and fee schedules 6 months following the index visit
Methods to calculate effects and costs	Time horizon: 6 months Methods: abstraction of medical records and multiple logistic regression analysis
Results	▪ Median costs per visit: Significant difference between Intervention (patient portal: $ 87.5) and control group (clinic visits: $131.20) ▪ Percentage of cost outliers: significantly lower for intervention (28.5% vs. 21.2%); also after adjusting for previous visit history, case type, age, and sex
Limitations (stated by the authors)	Non-randomization: Patients choosing online option might be more comfortable with not seeing a physician and therefore be more comfortable with less referrals to additional services. Potential other sources of selection bias: ▪ case type (was adjusted for, but should be tested with other methods) ▪ patients choosing online option might be more open to more parsimonious practice styles and this might be

	reflected by different patterns of medical utilization (was adjusted for, so should not impact results too much) ▪ Results might differ in different clinics (e.g. with lower costs) and with other software applications
Sponsors	None stated
Conclusions of the authors	Online visits lowered costs for 6 months after treatment for common medical conditions.
Comments (own)	No sensitivity analysis was performed No exact list of included costs (e.g. not clear whether costs for medication were included)

Source: GÖ FP

Table A 78: Svensson, 2012, evidence table for economic studies

Author(s)	Svensson J, Lundberg J, Olsson P, Stjärne P, Tennvall GR
Title	Cost-effectiveness of mometasone furoate nasal spray in the treatment of acute rhinosinusitis
Journal	Primary Care Respiratory Journal
Research question	What is the cost-effectiveness of mometasone furoate nasal spray (MFNS) compared with amoxicillin or other pharmacological and non-pharmacological treatment (self-medication or non-active treatment) in the treatment of mild to moderate acute rhinosinusitis?
Country / Currency and reference year	Sweden / 2010 Swedish krona (SEK)
Study design	Cost-effectiveness analysis
Study size	Not stated
Population selection	Inclusion criteria: Exclusion criteria:
Intervention	Intervention group: ▪ MFNS 200 µg twice daily Control group: ▪ Amoxicillin 500mg three times daily ▪ Placebo
Perspective	Society
Endpoints	Costs per quality-adjusted life years (QALYs)
Data sources	Sources for effectiveness data: ▪ Efficacy: Randomized clinical study ▪ Health-related quality of life (HRQoL): a observational, multicentre, prospective, non-randomise study in primary care Sources for cost data: ▪ Pharmaceuticals: price of smallest pack size (Swedish association of the Pharmaceutical Industry) ▪ Outpatient visits and inpatient stay: mean of prices from Southern Health Care Region, Northern Health Care Region and Stockholm County Council ▪ Public transportation: mean of prices from Skane and Stockholm regions
Methods to calculate effects and costs	Time horizon: 15 days Health effects: QALYs calculated using Major Symptom Score (MSS)[1] and HRQoL (derived from EQ-5D and EQ-VAS) Costs: ▪ Direct costs: inpatient, outpatient, drugs and transportation ▪ Indirect costs: productivity losses (according to human capital approach) ▪ Modelling methods:

Results	▪ MFNS 200 µg: ▪ Total costs: 7,568 SEK; QALYs: 0.03 ▪ Amoxilin 500 µg: ▪ Total costs: 7,817 SEK (difference: -249); QALYs: 0.0293 (diff.: 0.0005) ▪ Non-active treatment: ▪ Total costs: 7,667 SEK (diff.: -99); QALYs: 0.0326 (diff.: 0.0006 ?) ▪ MFNS 200 µg dominated both alternative treatments, i.e. costs were reduced and QALYs increased in both comparisons.
Limitations (as stated by the authors)	For a disease that often resolves without treatment, it is expected that there is quite some variation in treatment costs and the health outcome does not always reflect these. Generic instruments to evaluate the HRQoL are often not sensitive enough to detect changes in less severe diseases like rhinosinusitis. Lack of significant correlation between costs and the Major Symptom Score (MSS) and between HRQoL and MSS. Only one RCT with MFNS as monotherapy in acute rhinosinusitis from which effect size estimates were taken.
Sponsors	None stated
Conclusions of the authors	MFNS 200 µg twice daily results in lower costs and increased QALYs compared with the alternatives (amoxicillin and non-active treatment).
Comments (own)	

1: MSS reflects the severity of rhinorrhoea, post-nasal drip, nasal congestion, sinus headache, and facial pain.

Cough

Table A 79: Oppong et al., 2011, evidence table for economic studies

Author(s)	**Oppong R, Coast J, Hood K, Nuttall J, Smith R, Butler CC**
Title	Resource use and costs of treating acute cough/lower respiratory tract infections in 13 European countries: results and challenges
Journal	European Journal of Health Economics
Research question	What is the resource use and available cost data of acute cough/lower respiratory tract infections (LRTI) in Europe?
Country / Currency and reference year	Wales, England, the Netherlands, Spain, Germany, Hungary, Belgium, Poland, Italy, Sweden, Norway, Finland and Slovakia / German 2007 Euros converted using purchasing power parities
Study design	Cost analysis
Study size	14 primary care networks; 3,0402 patients (2,690 patient records used for the economic analysis)
Population selection	Inclusion criteria: patients with acute cough/LRTI Exclusion criteria:
Intervention	Intervention group: not applicable Control group: not applicable
Perspective	Society
Endpoints	▪ Total mean costs per patient ▪ Loss of productivity
Data sources	Sources for effectiveness data: Sources for cost data: ▪ self-completed patient diary and case report form completed by physicians ▪ statistical databases for unit costs

Methods to calculate effects and costs	Elements of resource use:
	▪ Health professionals:
	  ▪ visits to nurses and doctors in primary care settings
	  ▪ visits to pharmacists
	  ▪ referrals to specialists
	▪ Investigations (e.g. X-rays, CRP tests)
	▪ Medication (prescribed and over-the-counter products)
	▪ Lost productivity (days off work and lost earnings)
	e.g. calculation and evaluation of health effects, time horizon, modelling methods (type etc.)

Results	▪ Total mean costs per patient in Euros:
	  ▪ Cardiff (Wales): 43.27
	  ▪ Southampton (UK): 59.93
	  ▪ Utrecht (NL): 34.73
	  ▪ Barcelona (ES): 46.53
	  ▪ Mataro (ES): 55.34
	  ▪ Rotenburg (DE): 56.04
	  ▪ Balatonfüred (HU): 20.65
	  ▪ Antwerp (BE): 107.31
	  ▪ Lodz (PL): 16.56
	  ▪ Milan (IT): 40.13
	  ▪ Jonkoping (SE): 73.74
	  ▪ Tromso (NO): 81.03
	  ▪ Helsinki (FI): 72.53
	  ▪ Bratislava (SI): 23.97
	▪ Loss of productivity
	  ▪ Cardiff (Wales): 43.27
	  ▪ Southampton (UK): 213.43
	  ▪ Utrecht (NL): 311.73
	  ▪ Barcelona (ES): 177.8
	  ▪ Mataro (ES): 149.02
	  ▪ Rotenburg (DE): 351.72
	  ▪ Balatonfüred (HU): 111.225
	  ▪ Antwerp (BE): 432.78
	  ▪ Lodz (PL): 116.61
	  ▪ Milan (IT): 237.46
	  ▪ Jonkoping (SE): 400.51
	  ▪ Tromso (NO): 445.29
	  ▪ Helsinki (FI): 424.41
	  ▪ Bratislava (SI): 137.01

Limitations (as stated by the authors)	No information was found on a number of aspects of resource use for some countries Variability in the availability of source unit cost data made it necessary to make number of assumptions Problem of language interpretation as a major hurdle Follow up of patients was only 4 weeks, and therefore some effects (prolonged hospitalization) might not have been captured. Care pathways are likely to be confounded by network and/or country
Sponsors	European Union Framework six Programme
Conclusions of the authors	The mean costs of treating cough/LRTI differ across European regions. The Nordic countries (SE, NO, FI) recorded highest mean total costs, while Eastern European countries (HU, PL, SI) recorded lower costs.
Comments (own)	-

Heartburn

Table A 80: Mason & Hungin, 2005, evidence table for economic studies

<table>
<tr><td>Author(s)</td><td>Mason, J.
Hungin, A. P. S.</td></tr>
<tr><td>Title</td><td>Review article: Gastro-oesophageal reflux disease - The health economic implications</td></tr>
<tr><td>Journal</td><td>Ailment Pharmacological Therapy</td></tr>
<tr><td>Research question</td><td>What is the cost-cost-of illness of GERD in the UK?</td></tr>
<tr><td>Country / Currency and reference year</td><td>UK</td></tr>
<tr><td>Study design</td><td>Literature review</td></tr>
<tr><td>Study size</td><td>Not applicable</td></tr>
<tr><td>Population selection</td><td>Inclusion criteria: not stated
Exclusion criteria: not stated</td></tr>
<tr><td>Intervention</td><td>Intervention group: not applicable
Control group: not applicable</td></tr>
<tr><td>Perspective</td><td>▪ Health care system/financing agent
▪ Patient
▪ Society</td></tr>
<tr><td>Endpoints</td><td>Health care system/financing agent:
▪ cost on prescribed drugs,
▪ costs on consultations of primary/secondary care,
▪ costs on gastrointestinal endoscopy
Patient: costs on self medication
Society: costs due to lost productivity
Cost-effectiveness</td></tr>
<tr><td>Data sources</td><td>Sources for effectiveness data: not stated
Sources for cost data: not stated</td></tr>
<tr><td>Methods to calculate effects and costs</td><td>e.g. calculation and evaluation of health effects, time horizon, modelling methods (type etc.)</td></tr>
<tr><td>Results</td><td><u>Costs for System/financing agent:</u>
▪ prescribed drugs UK £ 625 mio
▪ UK£ 420 million for PPIs
▪ UK £ 46 million for Histamine-2 receptor antagonists
▪ UK £ 22 million for antacids, alginates and proprietary indigestion remedies
▪ consultation in primary care UK £ 53 mio
▪ upper gastrointestinal endoscopy UK £ 185 mio
<u>Patient:</u>
▪ Self medication UK £ 120 mio
<u>Society:</u>
▪ Lost productivity: UK £ 528 mio
<u>Cost-effectiveness review:</u>
Sweden: Oesophagitis
<table>
<tr><td></td><td>PPI on relapse</td><td>PPI continuously (Omeprazole 20mg)</td></tr>
<tr><td>Cost (societal costs)</td><td>6402</td><td>8925</td></tr>
<tr><td>Effect (healthy days)</td><td>290</td><td>353</td></tr>
</table>
▪ ICER: (health service) SEK 40/ healthy days; (societal, 10% sick leave) cost saving
USA: healed erosive oesophagitis</td></tr>
</table>

	Maintenance PPI	Recurrence: PPI then maintenance PPI	PPI maintenance after second recurrence
Cost (direct costs)	1376	908	865
Effect (QALYs	0.18	0.75	1.33

- ICER: varied by grade of oesophagitis, with grade IV oesophagitis
- Maintencance PPI dominates

USA: GERD symptoms

	I1	I2	I3	I4	I5	I6
Cost (direct costs)	0	29,965	27,846	37,641	26,167	41,112
Effect (QALYs)	23.66	24.42	24.37	24.43	24.91	24.65

I1: lifestyle + antacids

I2: maintenance H2 receptor antagonists

I3: step up H2 receptor antagonists – PPI

I4: step down PPI – H2 receptor antagonists

I5: intermittent PPI

I6: maintenance PPI

- ICER: I5 vs. I1: $ 20,934/QALY (severe); $ 37,923/QALY (mild)

All other comparisons dominated

USA: GERD symptoms

	Step up (antacids, H2 receptor antagonists, PPI)	Step down (PPI trial H2 receptor antagonist, antacids
Cost (direct costs)	1,045	1,172
Effect (percentage time symptom free)	50	75

- ICER: favours step down

Canada: acute erosive oesophagitis

	I1	I2	I3	I4	I5	I6
Cost (direct costs CAN $)	678	1093	657	805	748	955
Effect (symptom free months)	10.4	11.1	9.8	9.3	10.8	10.9

I1: Intermittent full dose PPI

I2: Maintenance PPI

I3: Maintenance H2 receptor antagonist

I4: step down prokinetic

I5: step down PPI-H2 receptor antagonist

I6: step down PPI – maintenance PPI

- I4 dominated, I6 extended dominance. I3, I1, I5 then I2 sequentially cost-effective as willingness to pay for a month free from symptoms increases

UK: Healed erosive oesophagitis

		I1	I2	I3	I4	I5	I6
	Cost (direct costs UK £)	125.8	145.3	152.7	166.3	181.8	282.4
	Effect (symptom free months)	10.5	10.25	9.56	11.48	11.53	11.69
	▪ I2 and I3 dominated. ▪ I1, I4, I5 then I6 sequentially cost-effective as willingness to pay for a month free from symptoms increases						
Limitations	Not stated						
Sponsors	Reckitt Benckiser (worldwide producer of cleaning and household products)						
Conclusions of the authors	▪ Financial implications about £ 760 million/year in UK ▪ Regular review and stepping down treatment (while adequate symptom relief can be maintained) links appropriate with resource efficient care ▪ Other cost-effectiveness issues lack objective answers (investment in treatment how much more willing to pay for symptom relief) ▪ Patients with long-term symptoms are willing (to some extent) to trade off symptom relief for greater control over treatment (direction of care) which is resource efficient						
Comments (own)							

Urinary tract infection

Table A 81: Eells et al., 2014, evidence table for economic studies

Author(s)	**Eells SJ, Bharadwa K, McKinnell JA, Miller LG**
Title	Recurrent Urinary Tract Infections Among Women: Comparative Effectiveness of 5 Prevention and Management Strategies Using a Markov Chain Monte Carlo Model
Journal	Clinical Infectious Diseases
Research question	What are the comparative effectiveness and costs of managing recurrent urinary tract infections (UTI) in women with commonly used strategies for management of UTIs?
Country / Currency and reference year	USA / 2014 US$
Study design	Cost-effectiveness analysis (Markov model)
Study size	Not applicable
Population selection	Inclusion criteria: Exclusion criteria:
Intervention	Intervention group: one of 5 prevention (daily antibiotics, daily estrogen, daily cranberry pills, and monthly acupuncture) and management strategies Control group: no intervention
Perspective	Payer and patient
Endpoints	▪ Number of UTIs per year ▪ Annual cost from payer's perspective ▪ Annual cost from patient's perspective ▪ Quality-adjusted life-days (QALD)
Data sources	Literature review
Methods to calculate effects and costs	Time horizon: 1 year Daily UTI risk in non intervention cohort: 3 UTIs / year

	Model: Markov chain model with a Monte Carlo evaluation for 10,000 individuals
Results	▪ Number of UTIs per year: ▪ No strategy: 3 ▪ Daily antibiotics: 0.4 ▪ Daily estrogen: 1.1 ▪ Daily cranberry pills: 1.1 ▪ Acupuncture: 0.7 ▪ Symptomatic self-treatment: 3 ▪ Annual cost from payer's perspective: ▪ No strategy: 771 $ ▪ Daily antibiotics: 821 $ ▪ Daily estrogen: 452 $ ▪ Daily cranberry pills: 444$ ▪ Acupuncture: 269$ ▪ Symptomatic self-treatment: 350 $ ▪ Annual cost from patient's perspective: not presented ▪ No strategy: reference ▪ Daily antibiotics: 821 $ ▪ Daily estrogen: 452 $ ▪ Daily cranberry pills: 444$ ▪ Acupuncture: 269$ ▪ Symptomatic self-treatment: 350 $ ▪ Quality-adjusted life-days (QALD): ▪ Total QALDs in year 1 ▪ No strategy: 353 ▪ Daily antibiotics: 363 ▪ Daily estrogen: 361 ▪ Daily cranberry pills: 360 ▪ Acupuncture: 362 ▪ Symptomatic self-treatment: 355 ▪ Mean payer cost per QUALY gained: ▪ No strategy: reference ▪ Daily antibiotics: 1,859 $ ▪ Daily estrogen: -15,320 $ (dominant) ▪ Daily cranberry pills: -18,079 $ (dominant) ▪ Acupuncture: -22,054 $ (dominant) ▪ Symptomatic self-treatment: -139,828
Limitations	Publication bias may result in overestimates of efficacy (e.g. good results for acupuncture) Model does not explicitly account for factors such as infection with multidrug-resistant organisms, medication adherence, long-term tolerability, toxicity, and uncommon adverse reactions. Disease specific measures for UTIs do not exist.
Sponsors	Not stated
Conclusions of the authors	All 4 prevention strategies (daily antibiotics, daily estrogen, daily cranberry pills, and monthly acupuncture) resulted in lower UTI rates. Self-treatment is the most cost-minimizing and cost-effective strategy for payer and patient, largely due to reduced physician visits and hospitalization.
Comments (own)	-

Source: GÖ FP

Table A 82: Griebling, 2005, evidence table for economic studies

Author(s)	Griebling TL
Title	Urologic diseases in America Project: Trends in resource use for urinary tract infections in women
Journal	The Journal of Urology
Research question	What is the economic impact of care for urinary tract infection (UTI)?
Country / Currency and reference year	USA / 1995, 1998, 1999 and 2000 $
Study design	Cost analysis (review of published studies)
Study size	Not applicable
Population selection	Inclusion criteria: not applicable Exclusion criteria: not applicable
Intervention	Intervention group: treatment of UTI Control group: none
Perspective	health care system and society
Endpoints	▪ Expenditures for female Medicare beneficiaries for UTI treatment in 1998 ▪ Estimated annual expenditure of privately insured workers with and without medical claim for UTI in 1999 ▪ Annual spending and use of outpatient prescription drugs to treat UTI in males and females in 1996 and 1998 ▪ Annual cost of UTI in 1995
Data sources	Sources for effectiveness data: not applicable Sources for cost data: Centers for Medicare and Medicaid, Medical Expenditure Panel Survey, and other studies
Methods to calculate effects and costs	Not applicable
Results	▪ Expenditures for female Medicare beneficiaries for UTI treatment in 1998: 104.9 Mio$ (> 65 years) and 956.5 Mio $ (65 years and older) ▪ Estimated annual expenditure of privately insured workers with and without medical claim for UTI in 1999: 3,099 Mio $ without and 5,470 Mio $ with UTI ▪ Average total expenditure of outpatient prescription drugs to treat UTI in males and females (1996 to 1998): 96,430,407$ ▪ Total annual cost of UTI in 1995: 1,595 Mio $
Limitations	Not stated
Sponsors	None stated
Conclusions of the authors	The economic burden of UTIs in women is significant
Comments (own)	The methods of this study have not been described, thus most methodological issues cannot be stated.

Source: GÖ FP

Annex 11: Pharmaceutical prices UK used for Cost/ benefit analysis

Table A 83: Pharmaceuticals for the treatment of athlete's foot

Price (in £) for patient…			*… without prescription (OTCs only)*	*… with prescription if not exempt from prescription fee*	*… with prescription if exempt from prescription fee*
Pharmaceuticals (active ingredient)	**Form**	**Rx or OTC**	**Retail price**	**Retail Price**	**Retail price**
Lamisil AT (Terbinafine)	7,5 g Creme	OTC (prescribable)	3.99	3.99	0.00
Lamisil AT (Terbinafine)	15 mg Gel	OTC (prescribable)	5.15	5.15	0.00
Lamisil AT (Terbinafine)	15 ml Spray	OTC (prescribable)	5.10	5.10	0.00
Lamisil Once (Terbinafine)	4 mg Solution	OTC (prescribable)	7.79	7.79	0.00
Canesten 1% (Clotrimazole)	20 mg Creme	OTC (prescribable)	3.79	3.79	0.00
Canesten 1% (Clotrimazole)	50 mg Creme	OTC (prescribable)	7.99	7.99	0.00
Daktarin (Miconazole)	15 mg Creme	OTC (non prescribable)	4.35	4.35	4.35
Daktarin (Miconazole)	100 mg Spraypowder	OTC (non prescribable)	4.29	4.29	4.29
Sporanox (Itraconazole)	100 mg Capsules	Rx	-	8.05	0.00
Sporanox (Itraconazole)	150 ml Solution	Rx	-	8.05	0.00
Griseofulvine (Griseofulvine)	125 mg Tablets	Rx	-	8.05	0.00
Lamisil (Terbinafine)	250 mg Tablets	Rx	-	8.05	0.00

Table A 84: Pharmaceuticals for the treatment of cold

Price (in €) for patient…			*… without prescription (OTCs only)*	*… with prescription if not exempt from prescription fee*	*… with prescription if exempt from prescription fee*
Pharmaceuticals (active ingredient)	**Form**	**Rx or OTC**	**Retail price**	**Retail price**	**Retail price**
Paracetamol (Paracetamol)	500 g soluble tabl.	OTC (non prescribable)	1.39	1.39	1.39
Paracetamol (Paracetamol)	60 mg suppositories	OTC (prescribable)	11.28	8.05	0.00
Paracetamol (Paracetamol)	120 mg suppositories	OTC (prescribable)	22.04	8.05	0.00
Paracetamol (Paracetamol)	240 mg suppositories	OTC (prescribable)	36.54	8.05	0.00
Aspirin low dose (Acetylsalicyl)	75 mg tablets	OTC (non prescribable)	0.69	0.69	0.69
Aspirin (Acetylsalicyl)	300 mg tablets	OTC (non prescribable)	0.85	0.85	0.85
Ibuprofen (Ibuprofenum)	400 mg tablets	OTC (prescribable)	3.99	3.99	0.00
Ibuprofen (Ibuprofenum)	200 mg tablets	OTC (prescribable)	1.15	1.15	0.00
Ibuprofen Children (Ibuprofenum)	100 ml solution	OTC (prescribable)	3.60	3.60	0,00
Nurofen Children (Ibuprofenum	200 ml solution	OTC (prescribable)	5.50	5.50	0,00
Strepsils Original (AMC/DCBA)	1.2/0.6 mg Lozenges	OTC (prescribable)	2.22	2.22	0,00
Strepsils Children (AMC/DCBA)	1.2/0.6 mg Lozenges	OTC (prescribable)	3.29	3.29	0.00
Vicks Vaporup (comb.-compound)	500 mg Creme	OTC (non prescribable)	3.25	3.25	3.25
Vicks Decongest. (comb.-compound)	20 ml Nasal Spray	OTC (non prescribable)	3.29	3.29	3.29
Vicks First Defence (comb.-compound)	15 ml Nasal Spray	OTC (non prescribable)	7.09	7.09	7.09

Table A 85: Pharmaceuticals for the treatment of cough

Price (in £) for patient...			*... without prescription (OTCs only)*	*... with prescription if not exempt from prescription fee*	*... with prescription if exempt from prescription fee*
Pharmaceuticals (active ingredient)	**Form**	**Rx or OTC**	**Retail price**	**Retail price**	**Retail price**
Benyl Chesty Cough (Dextromethorphan)	300 ml solution	OTC (non prescribable)	6.78	6.78	6.78
Robitussion (Dextromethorphan)	100 ml solution	OTC (non prescribable)	2.99	2.99	2.99
Lemsip Mucus (Guaifenesin)	100 ml solution	OTC (non prescribable)	3.79	3.79	3.79
Erythroped A (Erythromycin)	250 mg tablets	Rx	-	8.05	0.00
Azithromycin (Azithromycin)	250 mg tablets	Rx	-	8.05	0.00
Doxycycline (Doxycycline)	100 mg tablets	Rx	-	8.05	0.00

Table A 86: Pharmaceuticals for the treatment of urinary tract infection

Price (in £) for patient...			*... without prescription (OTCs only)*	*... with prescription if not exempt from prescription fee*	*... with prescription if exempt from prescription fee*
Pharmaceuticals (active ingredient)	**Form**	**Rx or OTC**	**Retail price**	**Retail price**	**Retail price**
Amoxicillin (Amoxicillin)	500 mg capsules	Rx	-	8.05	0.00
Nitrofurantoin (Nitrofurantoin)	100 mg tablets	Rx	-	8.05	0.00
Co-Trimoxazole (SM/TP)	80/400 mg tablets	Rx	-	8.05	0.00

Table A 87: Pharmaceuticals for the treatment of heartburn

Price (in £) for patient…			*… without prescription (OTCs only)*	*… with prescription if not exempt from prescription fee*	*… with prescription if exempt from prescription fee*
Pharmaceuticals (active ingredient)	**Form**	**Rx or OTC**	**Retail price**	**Retail price**	**Retail price**
Alka Seltzer (comb.-compound)	10 tablets	OTC (non prescribable)	2.29	2.29	2.29
Rennie Spearmint (comb.-compound)	12 tablets	OTC (non prescribable)	1.69	1.69	1.69
Antacid Peppermint (Calciumcarbonat)	96 mg tablets	OTC (non prescribable)	3.69	3.69	3.69
Magn.-Trisilicate (Magnesiumcarbonat)	200 mlg Solution	OTC (prescribable)	1.89	1.89	0.00
Omeprazole (Omeprazole)	20 mg tablets	Rx	-	8.05	0.00

Annex 12: Costs and benefits from a patient's perspective

Table A 88: Non-Medical Prescribing / Pharmacist independent prescribing (NMP/PIP) for athlete's foot

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	1 OTC + 1 Rx
price pharmaceuticals	1.24	1.24	10.16	1.24	13.13	13.13	10.16	13.13
price time at encounter	6.54	6.54	1.31	3.36	6.54	6.54	1.31	3.36
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	15.25	15.25	15.21	8.34	27.14	27.14	15.21	20.23
Savings from pharmacy instead GP								
without NMP/PIP	0.04				11.94			
with NMP/PIP	6.91				6.91			
Difference	6.87				-5.02			
	Before the implementation of NMP/PIP a patient who was exempt from prescription charges could save on average 0.04 pounds by going to the pharmacist instead of the GP in case of an athlete's foot (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save 6.91 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **likely** that more patients which are exempt from p.c. will consult a pharmacist in case of athlete's foot due to NMP/PIP				Before the implementation of NMP/PIP a patient who was NOT exempt from prescription charges could save on average 11.94 pounds by going to the pharmacist instead of the GP in case of an athlete's foot (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save a less, 6.91 pounds with his decision to consult a pharmacist instead of a GP. → despite economic considerations, it is **very likely** that more patients would rather see a pharmacist after the implementation of NMP/PIP as they can now get access to Rx pharmaceuticals which they would not have received at the pharmacy before the implementation of NMP/PIP			

Table A 89: Non-Medical Prescribing / Pharmacist independent prescribing (NMP/PIP) for cold

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used[17]	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC
price pharmaceuticals	2.21	2.21	5.44	2.21	5.44	5.44	5.44	5.44
price time at encounter	6.54	6.54	1.31	3.36	6.54	6.54	1.31	3.36
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	16.22	16.22	10.49	9.31	19.45	19.45	10.49	12.54
Savings from pharmacy instead GP								
without NMP/PIP	5.73				8.97			
with NMP/PIP	6.91				6.91			
Difference	1.18				-2.05			
	Before the implementation of NMP/PIP a patient who was exempt from prescription charges would have to pay on average 5.73 pounds more if she went to the pharmacist instead of the GP in case of a cold (NB: for cold no Rx drugs were included). After the implementation, the same patient could save 6.91 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **very likely** that more patients which are exempt from p.c. will consult a pharmacist in case of a cold due to NMP/PIP				Before the implementation of NMP/PIP a patient who was NOT exempt from prescription charges could save on average 8.97 pounds by going to the pharmacist instead of the GP in case of a cold (NB: for cold no Rx drugs were included). After the implementation, the same patient could save 6.91 pounds with his decision to consult a pharmacist instead of a GP. → despite economic considerations, it is **very likely** that more patients would rather see a pharmacist after the implementation of NMP/PIP as they can now get access to Rx pharmaceuticals which they would not have received at the pharmacy before the implementation of NMP/PIP			

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no Rx products for cold

Table A 90: Non-Medical Prescribing / Pharmacist independent prescribing (NMP/PIP) for cough

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	1 OTC + 1 Rx
price pharmaceuticals	4.52	4.52	9.04	4.52	12.57	12.57	9.04	12.57
price time at encounter	6.54	6.54	1.31	3.36	6.54	6.54	1.31	3.36
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	18.53	18.53	14.08	11.62	26.58	26.58	14.08	19.67
Savings from pharmacy instead GP								
without NMP/PIP	4.45				12.50			
with NMP/PIP	6.91				6.91			
Difference	2.46				-5.59			
	Before the implementation of NMP/PIP a patient who was exempt from prescription charges could save on average 4.45 pounds by going to the pharmacist instead of the GP in case of cough (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save only slightly more, 6.91 pounds, with his decision to consult a pharmacist instead of a GP. → from an economic view it is **likely** that more patients which are exempt from p.c. will consult a pharmacist in case of cough due to NMP/PIP				Before the implementation of NMP/PIP a patient who was NOT exempt from prescription charges could save on average 12.50 pounds by going to the pharmacist instead of the GP in case of cough (NB: in this case he/she would not receive any Rx drugs) . After the implementation, the same patient could save less, 6.91 pounds, with his decision to consult a pharmacist instead of a GP. → despite economic considerations, it is **very likely** that more patients would rather see a pharmacist after the implementation of NMP/PIP as they can now get access to Rx pharmaceuticals which they would not have received at the pharmacy before the implementation of NMP/PIP			

Table A 91: Non-Medical Prescribing / Pharmacist independent prescribing (NMP/PIP) for heartburn

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	1 OTC + 1 Rx
price pharmaceuticals	1.84	1.84	4.63	1.84	10.37	10.37	4.63	10.37
price time at encounter	6.54	6.54	1.31	3.36	6.54	6.54	1.31	3.36
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	15.86	15.86	9.68	8.94	24.38	24.38	9.68	17.47
Savings from pharmacy instead GP								
without NMP/PIP	6.18				14.70			
with NMP/PIP	6.91				6.91			
Difference	0.73				-7.79			
	Before the implementation of NMP/PIP a patient who was exempt from prescription charges could save on average 6.18 pounds by going to the pharmacist instead of the GP in case of heartburn (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save only slightly more, 6.91 pounds, with his decision to consult a pharmacist instead of a GP. → despite economic considerations, it is **very likely** that more patients would rather see a pharmacist after the implementation of NMP/PIP as they can now get access to Rx pharmaceuticals which they would not have received at the pharmacy before the implementation of NMP/PIP				Before the implementation of NMP/PIP a patient who was NOT exempt from prescription charges could save on average 14.70 pounds by going to the pharmacist instead of the GP in case of heartburn (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save less, 6.91 pounds, with his decision to consult a pharmacist instead of a GP. → despite economic considerations, it is **very likely** that more patients would rather see a pharmacist after the implementation of NMP/PIP as they can now get access to Rx pharmaceuticals which they would not have received at the pharmacy before the implementation of NMP/PIP			

Table A 92: Non-Medical Prescribing / Pharmacist independent prescribing (NMP/PIP) for urinary tract infection

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP	no initiative	NMP/PIP
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 Rx	1 Rx	consultation only[18]	1 Rx	1 Rx	1 Rx	consultation only	1 Rx
price pharmaceuticals	0.00	0.00	0.00	0.00	8.05	8.05	0.00	8.05
price time at encounter	6.54	6.54	1.31	3.36	6.54	6.54	1.31	3.36
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	14.01	14.01	5.04	7.10	22.06	22.06	5.04	15.15
Savings from pharmacy instead GP								
without NMP/PIP	8.97				17.02			
with NMP/PIP	6.91				6.91			
Difference	-2.06				-10.11			
	Before the implementation of NMP/PIP a patient with UTI only had one option: see a GP to get a prescription or see a pharmacist without getting medication and save 8.97 pounds. After the implementation of NMP/PIP, the same patient could save the a little less, 6.91 pounds, but she would receive pharmaceutical treatment with her decision to consult a pharmacist instead of a GP, due to less (waiting) time spent at the pharmacy compared to the GP's office. → despite economic considerations, it is **very likely** that more patients would rather see a pharmacist after the implementation of NMP/PIP as they can now get access to Rx pharmaceuticals which they would not have received at the pharmacy before the implementation of NMP/PIP				Before the implementation of NMP/PIP a patient with UTI only had one option: see a GP to get a prescription or see a pharmacist without getting medication and save 17.02 pounds. After the implementation of NMP/PIP, the same patient could save the a little less, 6.91 pounds, but she would receive pharmaceutical treatment with her decision to consult a pharmacist instead of a GP, due to less (waiting) time spent at the pharmacy compared to the GP's office. → despite economic considerations, it is **very likely** that more patients would rather see a pharmacist after the implementation of NMP/PIP as they can now get access to Rx pharmaceuticals which they would not have received at the pharmacy before the implementation of NMP/PIP			

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patients can be advised to drink plenty, wear cotton underwear, etc. by the pharmacists without prescribing any medication

Table A 93: Minor Ailment Scheme (MAS) for athlete's foot

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	MAS	no initiative	MAS	no initiative	MAS	no initiative	MAS
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC
price pharmaceuticals	1.24	1.24	10.16	2.48	13.13	13.13	10.16	10.16
price time at encounter	6.54	6.54	1.31	2.24	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	15.25	15.25	15.21	8.46	27.14	27.14	15.21	15.21
Savings from pharmacy instead GP								
without MAS	0.04				11.94			
with MAS	6.80				11.94			
Difference	6.75				0.00			
	Before the implementation of MAS a patient who was exempt from prescription charges could save 0.04 pounds by going to the pharmacist instead of the GP in case of an athlete's foot (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save over 6.80 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **likely** that more patients which are exempt from p.c. will consult a pharmacist in case of athlete's foot due to MAS				Before the implementation of MAS a patient who was NOT exempt from prescription charges could save 11.94 pounds by going to the pharmacist instead of the GP in case of an athlete's foot (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save the same, 11.94 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are not exempt from p.c. will consult a pharmacist in case of athlete's foot due to MAS			

Table A 94: Minor Ailment Scheme (MAS) for Cold

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	MAS	no initiative	MAS	no initiative	MAS	no initiative	MAS
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used[19]	2 OTC *	2 OTC *	2 OTC	2 OTC	2 OTC *	2 OTC *	2 OTC	2 OTC
price pharmaceuticals	2.21	2.21	5.44	2.21	5.44	5.44	5.44	5.44
price time at encounter	6.54	6.54	1.31	2.24	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	16.22	16.22	10.49	8.19	19.45	19.45	10.49	10.49
Savings from pharmacy instead GP								
without MAS	5.73				8.97			
with MAS	8.03				8.97			
Difference	2.30				0.00			
	Before the implementation of MAS a patient who was exempt from prescription charges would have to pay 5.73 pounds more if she went to the pharmacist instead of the GP in case of a cold (NB: for cold no Rx drugs were included). After the implementation, the same patient could save 8.03 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **very likely** that more patients which are exempt from p.c. will consult a pharmacist in case of a cold due to MAS				Before the implementation of MAS a patient who was NOT exempt from prescription charges could save 8.97 pounds by going to the pharmacist instead of the GP in case of a cold (NB: for cold no Rx drugs were included) . After the implementation, the same patient could save 8.97 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are not exempt from p.c. will consult a pharmacist in case of a cold due to MAS			

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no Rx products for cold

Table A 95: Minor Ailment Scheme (MAS) for Cough

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	MAS	no initiative	MAS	no initiative	MAS	no initiative	MAS
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC
price pharmaceuticals	4.52	4.52	9.04	9.04	12.57	12.57	9.04	9.04
price time at encounter	6.54	6.54	1.31	2.24	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	18.53	18.53	14.08	15.02	26.58	26.58	14.08	14.08
Savings from pharmacy instead GP								
without MAS	4.45				8.97			
with MAS	3.52				8.97			
Difference	-0.93				0.00			
	Before the implementation of MAS a patient who was exempt from prescription charges could save 4.45 pounds by going to the pharmacist instead of the GP in case of cough (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save slightly less, 3.52 pounds, with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of cough due to MAS				Before the implementation of MAS a patient who was NOT exempt from prescription charges could save 8.97 pounds by going to the pharmacist instead of the GP in case of cough (NB: in this case he/she would not receive any Rx drugs) . After the implementation, the same patient could save the same, 8.97 pounds, with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are not exempt from p.c. will consult a pharmacist in case of cough due to MAS			

Table A 96: Minor Ailment Scheme (MAS) for Heartburn

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	MAS	no initiative	MAS	no initiative	MAS	no initiative	MAS
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC
price pharmaceuticals	1.84	1.84	4.63	3.69	10.37	10.37	4.63	4.63
price time at encounter	6.54	6.54	1.31	2.24	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	15.86	15.86	9.68	9.67	24.38	24.38	9.68	9.68
Savings from pharmacy instead GP								
without MAS	6.18				8.97			
with MAS	6.19				8.97			
Difference	0.01				0.00			
	Before the implementation of MAS a patient who was exempt from prescription charges could save 6.18 pounds by going to the pharmacist instead of the GP in case of heartburn (NB: in this case he/she would not receive any Rx drugs) . After the implementation, the same patient could save only slightly more, 6.19 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of heartburn due to MAS				Before the implementation of MAS a patient who was NOT exempt from prescription charges could save 8.97 pounds by going to the pharmacist instead of the GP in case of heartburn (NB: in this case he/she would not receive any Rx drugs) . After the implementation, the same patient could save, 8.97 pounds with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are not exempt from p.c. will consult a pharmacist in case of heartburn due to MAS			

Table A 97: Minor Ailment Scheme (MAS) for urinary tract infection

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	MAS	no initiative	MAS	no initiative	MAS	no initiative	MAS
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 Rx	1 Rx	consultation only[20]	consultation only	1 Rx	1 Rx	consultation only	consultation only
price pharmaceuticals	0.00	0.00	0.00	0.00	8.05	8.05	0.00	0.00
price time at encounter	6.54	6.54	1.31	1.31	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	14.01	14.01	5.04	5.04	22.06	22.06	5.04	5.04
Savings from pharmacy instead GP								
without MAS	8.97				17.02			
with MAS	8.97				17.02			
Difference	0.00				0.00			
	Before the implementation of MAS a patient who was exempt from prescription charges could save 8.97 pounds by going to the pharmacist instead of the GP in case of urinary tract infection (UTI) (NB: in this case she would not receive any drugs) . After the implementation, the same patient could save, 8.97 pounds, with her decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of UTI due to MAS				Before the implementation of MAS a patient who was NOT exempt from prescription charges could save 17.02 pounds by going to the pharmacist instead of the GP in case of UTI (NB: in this case she would not receive any drugs) . After the implementation, the same patient could save, 17.02 pounds, with her decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are not exempt from p.c. will consult a pharmacist in case of UTI due to MAS			

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patients can be advised to drink plenty, wear cotton underwear, etc. by the pharmacists without prescribing any medication

Table A 98: NHS Choices for athlete's foot

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC
price pharmaceuticals	1.24	1.24	10.16	10.16	13.13	13.13	10.16	10.16
price time at encounter	6.54	6.54	1.31	1.31	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	15.25	15.25	15.21	15.21	27.14	27.14	15.21	15.21
Savings from pharmacy instead GP								
without NHS Choices	0.04				11.94			
with NHS Choices	0.04				11.94			
Difference	0.00				0.00			
	Before the implementation of NHS-Choices a patient who was exempt from prescription charges could save 0.04 pounds by going to the pharmacist instead of the GP in case of a cold (NB: in this case he/she would not receive any Rx drugs). After the implementation, the same patient could save the same amount with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of athlete's foot due to NHS Choices				Before the implementation of NHS-Choices a patient who was NOT exempt from prescription charges could save 11.94 pounds by going to the pharmacist instead of the GP in case of a cold (NB: in this case he/she would not receive any Rx drugs) . After the implementation, the same patient could save the same amount with his decision to consult a pharmacist instead of a GP. → from an economic view it is **unlikely** that more patients which are not exempt from p.c. will consult a pharmacist in case of athlete's foot due to NHS Choices			

Table A 99: NHS Choices for cold

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used[21]	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC	2 OTC
price pharmaceuticals	2.21	2.21	5.44	5.44	5.44	5.44	5.44	5.44
price time at encounter	6.54	6.54	1.31	1.31	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	16.22	16.22	10.49	10.49	19.45	19.45	10.49	10.49
Savings from pharmacy instead GP								
without NHS Choices	5.73				8.97			
with NHS Choices	5.73				8.97			
Difference	0.00				0.00			
	Before the implementation of NHS Choices a patient who was exempt from prescription charges would have to pay 5.73 pounds more if she went to the pharmacist instead of the GP in case of a cold (NB: for cold no Rx drugs were included). This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of a cold due to NHS Choices				Before the implementation of NHS Choices a patient who was NOT exempt from prescription charges could save 8.97 pounds by going to the pharmacist instead of the GP in case of a cold (NB: for cold no Rx drugs were included). This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are not exempt from p.c. will consult a pharmacist in case of a cold due to NHS Choices			

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no Rx products for cold

Table A 100: NHS Choices for cough

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC
price pharmaceuticals	4.52	4.52	9.04	9.04	12.57	12.57	9.04	9.04
price time at encounter	6.54	6.54	1.31	1.31	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	18.53	18.53	14.08	14.08	26.58	26.58	14.08	14.08
Savings from pharmacy instead GP								
without NHS Choices	4.45				12.50			
with NHS Choices	4.45				12.50			
Difference	0.00				0.00			
	Before the implementation of NHS Choices a patient who was exempt from prescription charges could save 4.45 pounds by going to the pharmacist instead of the GP in case of cough (NB: in this case he/she would not receive any Rx drugs) . This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of a cough due to NHS Choices				Before the implementation of NHS Choices a patient who was NOT exempt from prescription charges could save 12.50 pounds by going to the pharmacist instead of the GP in case of cough (NB: in this case he/she would not receive any Rx drugs) . This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of a cough due to NHS Choices			

Table A 101: NHS Choices for heartburn

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC	1 OTC + 1 Rx	1 OTC + 1 Rx	2 OTC	2 OTC
price pharmaceuticals	1.84	1.84	4.63	4.63	10.37	10.37	4.63	4.63
price time at encounter	6.54	6.54	1.31	1.31	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	15.86	15.86	9.68	9.68	24.38	24.38	9.68	9.68
Savings from pharmacy instead GP								
without NHS Choices	6.18				14.70			
with NHS Choices	6.18				14.70			
Difference	0.00				0.00			
	Before the implementation of NHS Choices a patient who was exempt from prescription charges could save 6.18 pounds by going to the pharmacist instead of the GP in case of heartburn (NB: in this case he/she would not receive any Rx drugs) . This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of heartburn due to NHS Choices				Before the implementation of NHS Choices a patient who was NOT exempt from prescription charges could save 14.70 pounds by going to the pharmacist instead of the GP in case of heartburn (NB: in this case he/she would not receive any Rx drugs) . This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of heartburn due to NHS Choices			

Table A 102: NHS Choices for urinary tract infection

	Patient 1a	Patient 2a	Patient 1b	Patient 2b	Patient 1c	Patient 2c	Patient 1d	Patient 2d
	exempt	exempt	exempt	exempt	not exempt	not exempt	not exempt	not exempt
	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices	no initiative	NHS Choices
Primary care contact	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only	GP + pharmacy	GP + pharmacy	pharmacy only	pharmacy only
Pharmaceuticals used	1 Rx	1 Rx	consultation only[22]	consultation only	1 Rx	1 Rx	consultation only	consultation only
price pharmaceuticals	0.00	0.00	0.00	0.00	8.05	8.05	0.00	0.00
price time at encounter	6.54	6.54	1.31	1.31	6.54	6.54	1.31	1.31
price travel time	7.47	7.47	3.74	3.74	7.47	7.47	3.74	3.74
sum	14.01	14.01	5.04	5.04	22.06	22.06	5.04	5.04
Savings from pharmacy instead GP								
without NHS Choices	8.97				17.02			
with NHS Choices	8.97				17.02			
Difference	0.00				0.00			
	Before the implementation of NHS Choices a patient who was exempt from prescription charges could save 8.97 pounds by going to the pharmacist instead of the GP in case of urinary tract infection (UTI) (NB: in this case she would not receive any drugs). This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of a urinary tract infection due to NHS Choices				Before the implementation of NHS Choices a patient who was NOT exempt from prescription charges could save 17.02 pounds by going to the pharmacist instead of the GP in case of UTI (NB: in this case she would not receive any drugs). This stays the same after the implementation of the initiative. → from an economic view it is **unlikely** that more patients which are exempt from p.c. will consult a pharmacist in case of a urinary tract infection due to NHS Choices			

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patients can be advised to drink plenty, wear cotton underwear, etc. by the pharmacists without prescribing any medication

Annex 13: Telephone interview results

Table A 103: Results of telephone interview on transferability of best-practice initiatives

Type of initiative	NHS Choices (web portal)	NHS 111 (telephone-based)	MAS, NMP (pharmaceutical access schemes)

Promoting factors for transferability	**Initiative level:**
	▪ Low costs for maintaining the website
	▪ Provision of adequate resources for cultural and textual translations
	▪ Translation of medical information from "GP language" to lay language in order to ensure understanding when accessed via web portal
	▪ Ensure independence of information provided; information should be evidence-based rather than guided by interest groups
	▪ Clear and understandable language for all ages
	▪ Multichannel approach in order to reach all kind of audiences
	▪ Recognised and well known institution behind initiative and quality recognition of authority, respectively
	
	User level:
	▪ High rate of internet access/ number of smart phones (in case service accessible via smart phone app) per capita
	▪ Less dependency on service opening hours
	▪ Less fear in sharing health problems due to anonymity
	▪ Differing accuracy and literacy levels of people among different countries
	
	Stakeholder level:
	▪ Support by different parties (i.e. patient representation, payer, GP)
	▪ Public payer support in order to guarantee independence (trustworthiness)
	▪ Involvement of all relevant stakeholders having expertise in the field (e.g.
		Initiative level:
		▪ Free of charge service provision
		▪ Training of those healthcare professionals who provide service to ensure correct information
		▪ Organisation as triage system: if questions not answerable by trained health staff possibility to transfer to a specialist (e.g. GP)
		▪ Enough staffing capacities
		▪ Centrally organised service embedded in already institutionalised structures
		  ▪ From centralised focal point distribution to regional health care providers if necessary
		  ▪ In order to reach large part of population
		▪ Provision of consistent health information by trustworthy and independent institution;
		  ▪ important as diverse information available, which is often biased by different interest groups
		  ▪ evidence-based information
		▪ Single 5 digit number
		▪ Ensure confidentiality and legal issues
		
		User level:
		▪ Easy access and no equity issues due to the information channel 'telephone'
		▪ 24/7 availability of service
		▪ Trust relationship between patients and the service
		
		Stakeholder level:
		▪ Support of patient associations, as they represent patient needs best
			Initiative level:
			▪ Similar national pilot projects (e.g. GP assistants with prescription permission in Germany, projects strengthening consulting role of pharmacists)
			▪ Clear /transparent regulation, which drugs can be prescribed by healthcare professionals other than GPs
			▪ Capacity building of medical professionals to ensure high quality of service
			▪ Time saving potential
			▪ Potential for better disease management
			▪ Pilot projects before national implementation; learning of bold initiatives
			
			User level:
			▪ High health literacy of national population
			▪ Peoples' awareness of costs of the health system leading to increased use of self care
			▪ Increased patient's proximity to healthcare professionals
			▪ Increased patient autonomy
			
			Stakeholder level:
			▪ Support of pharmacist and nursing representatives, as such systems strengthen their position in health care provision
			▪ Agenda of consumer interest groups and their involvement
			▪ Position of health professionals, pharmacists in national health care systems (superior vs. inferior role)
			  ▪ Upgrading of medical professionals; more medical disciplines are perceived to be qualified in medicine

Type of initiative	NHS Choices (web portal)	NHS 111 (telephone-based)	MAS, NMP (pharmaceutical access schemes)

	providers, patient organisations, pharmaceutical industry, academics) as long as it is transparent
	
	National/system level:
	▪ EU directives for increased mobility of EU citizens; because people might prefer using web portals of their home countries in their mother tongue
		▪ Support of payer (i.e. social health insurance) in order to make information widely available or even finance service
		▪ Support of GP association
		  ▪ Cooperation with GPs during conceptualisation of service, in order to ensure adequate process of triage and to secure support of GPs
		▪ Political support
		
		National/system level:
		▪ Long distances to next healthcare provider (i.e. GP, hospital)
		▪ High work load or even work overload of GPs; probably connected to low GP density
			apart from GPs
			
			National/ system level:
			▪ Low GP density in connection with populations' perception of lacking healthcare provision
			▪ National tradition/attitude of trust into pharmacists as first point of information provision
			▪ Long waiting times in GP's offices; as such schemes enable fast, direct access to healthcare services
			▪ Depending on reimbursement system, potential cost benefits for patients/system to receive prescriptions directly by health care professional
			▪ OTC regulations: broader provision but with limited amount disposed
			▪ Innovative mentality of country
			▪ Social economic crisis as forcing factor
			  ▪ Health care system needs to work with less resources

Barriers for introduction of initiative	**Initiative level:**
	▪ Lacking awareness of the service due to little promotion activities
	▪ Missing face to face contact, which might be preferred by most of the people
	▪ Technically bad web design leading to non-user-friendly web portal
	▪ Preparation of information
	  ▪ Lack of structure
	  ▪ Lack of specificity (e.g. diagnosis specific, population group specific)
	▪ Difficulties to find and understand information
	
	User level:
	▪ Variety of available information of different quality levels leading to high transaction costs on behalf of patients for filtering high-quality information
	▪ Term "self care" might not be known by lay people; they might go from different
		Initiative level:
		▪ Costs higher than at local rate (i.e. 1€ per minute) leading to exclusion of low-income groups
		▪ Administrative barriers (e.g. cross border reimbursement issues due to foreign zip codes not fitting to national forms)
		▪ Shortage of health care professionals, who could provide service
		▪ Lack of translators, especially in the context of migration and tourism
		▪ Lack of staff leading to high waiting times and reduced quality of advice
		▪ Similar coexisting services as barrier
		
		User level:
		▪ Patient's attitude to prefer a personal GP examination
		▪ Low credibility of institution providing the service (e.g. due to private ownership, inconsistent service provision)
			Initiative level:
			▪ Lack of qualified staff
			  ▪ Lack of knowledge on adverse drug events
			▪ Consideration of type of medication necessary; prescription of antibiotics or drugs with (long-term) side effects critical in most countries
			
			User level:
			▪ Traditional notion of GPs knowing best about a patient's ailment, thus GP first point of access
			▪ A strong OTC focus might put a financial burden on people leading to less frequent use of products
			
			Stakeholder level:
			▪ GP representatives hindering factor due to weakening their position; especially in systems emphasising GPs role in

Type of initiative	NHS Choices (web portal)	NHS 111 (telephone-based)	MAS, NMP (pharmaceutical access schemes)

	angle to search for minor ailment issues
	▪ Exclusion of certain societal groups (i.e. elderly people, technology illiterate people)
	  ▪ Danger of reaching only most educated people and not vulnerable population groups
	▪ National habits/culture of health care service utilization preferring face to face treatment and advice
	
	Stakeholder level:
	▪ Involvement of interest groups (e.g. GP association); GPs might perceive the service as competing service
	▪ Possible fear of GPs to lose their unique position in health care provision
	▪ Industry behind initiative steering information in certain direction;
	▪ Private organisations as information source might lead to mistrust on behalf of patients
	
	National/system level:
	▪ Low waiting times in GP practices, as face to face contacts are still the preferable option of patients
	▪ Little pronounced self care culture in a country
	▪ Difficulty to provide consistent health information, due to different platforms
	▪ Missing pool of evidence-based information to feed such kind of service;
	  ▪ Induced by culture characterised by reliance on expert opinions rather than on evidence
	  ▪ Minor internet penetration in eastern European countries
	  ▪ Internet access costs
		▪ Little trust in service if provided by nurses
		▪ Patient's attitude to prefer to look up information on their own
		▪ Lack of knowledge about the service
		▪ Lacking confidence into such services on behalf of patients
		▪ Low need for such kind of service due to good reachability of GPs
		
		Stakeholder level:
		▪ GP as hindering factor, if not considered in implementation process
		
		National/system level:
		▪ Strict and not easily changeable financial models, which might hinder adoption into payment system; of particular importance, if service is provided by GPs
		▪ Difficulties in those countries where emphasis of healthcare provision is laid on GP not on nurses and other healthcare professionals; in those traditional systems, GPs would not agree to power transfer towards nursing staff
		▪ High telephone fees
			healthcare provision
			  ▪ In general, tense relationship between pharmacy and GP associations
			▪ Private interest groups behind initiative might jeopardise trust into schemes
			▪ Professional conflicts
			▪ Not used to work in collaboration (i.e. GPs working together with other healthcare professionals)
			
			National/ system level:
			▪ Restrictive country-specific prescription regulations
			▪ Organisation of the pharmaceutical market (dispensation in pharmacies only vs. Dispensation in drug stores);
			▪ Higher costs due to high utilisation of service
			▪ Hindering national culture and history of healthcare provision

Annex 14: Stakeholder Analysis

Table A 104: Different Stakeholder groups and the rationale for selecting them as dissemination targets for this project

Target Groups	Rationale: Why we want to reach them?	Appropriate dissemination tools
Internal audience: members of the consortium, expert group of this project	To ensure a common understanding, To make use of the 'catalyst' effect of the internal audience (members of the expert group can open channels for dissemination in their country and their constituencies and they themselves will also disseminate)	Report / website/internal fact sheet, presentations, conferences / courses
Similar projects: PISCE project 'Pilot project on the promotion of self-care systems in the European Union: Platform of experts Working Group on 'Good Governance Promoting Good Governance for Non-Prescription Medicines' of the Platform on Access to Medicines in Europe under the Process on Corporate Responsibility in the Field of Pharmaceuticals (2010 – 2013)	To enable a 'learning from' effect between similar projects Why PISCE? In Commission Decision C(2013) 4940 of 2 August 2013 concerning the financial contribution by the Community towards a pilot project in the field of self-care systems in EU, the Budget Authority asks the Commission to fund initiatives which put in place a framework for action to enhance self-care at EU level and develop strategies to support the broader implementation of effective self-care.	Presentation to other project, invitation to information event
Similar projects:	These objectives shall be achieved by a cost/benefit analysis of patient self-care oriented health systems in the European Union and the current frameworks in place to enhance self-care oriented health care systems and patients' empowerment and transferability of best practices (this study) and the creation of a platform of experts in self-care and healthcare (PISCE project). PISCE should consider the results of our project. Why the WG? The WG worked on identifying the necessary elements to ensure availability, uptake, and informed use and choice of non-prescription medicines.	
External audience: Policy makers and stakeholders at EU and national levels (e.g. representatives of consumers, patients, health care industry, including self-medication industry, providers of self-care practices, health professionals, nurses, etc.), public payers and further researchers as catalysts	Policy makers at national and sub-national implement health policies and have strong political and economic incentives. They have various policy instruments at their disposal to prioritise developments in health care. In order to take informed decision they need information inputs. Key messages to political decision makers will focus on the importance of self-care initiatives on preserving public health, their potential to contribute to cost-containment in health expenditures and to make policy makers aware of different approaches of self-care.	Report / website, leaflet, information event, scientific articles / posters / educational outreach visits / computerised decision support systems / training for practitioners

Target Groups	**Rationale:** **Why we want to reach them?**	**Appropriate dissemination tools**
Community: general public, general press as catalysts	To raise awareness, in this cases to communicate the benefits that self-care brings in to daily life	Leaflet / press release / video / educational materials / interactive small group meetings / workshops / open days / public events / blogs / social media

Annex 15: Assessment frameworks for initiatives

Table A 105: Identification of key features and characteristics of self care best-practice initiatives

Dimensions of initiatives		Key features			
		NHS Choices	**NHS 111**	**MAS**	**NMP**
Population/ Patients	**Population addressed**	▪ Total population (in particular health/internet literates)	▪ Total population (in particular non-internet literates)	▪ Population sub-group (population exempt from prescription charges)	▪ Total population
Providers	**Providers involved**	▪ Operator of central service (algorithm/decision tree + web content)	▪ Operator of central service (algorithm/decision tree) ▪ Operator of telephone service (de-central vs. central)	▪ Community pharmacies (training on the job) ▪ Providers of training services (also e-learning services)	▪ Community pharmacies (training on the job) ▪ Providers of training services
	Providers affected	▪ Physicians (payment and/or governance mechanisms determine immediacy of effect) ▪ Community pharmacies	▪ Physicians (payment and/or governance mechanisms determine immediacy of effect) ▪ Community pharmacies	▪ Physicians (payment and/or governance mechanisms determine immediacy of effect)	▪ Physicians (payment and/or governance mechanisms determine immediacy of effect
Govern-ment/ System	**Governance**	▪ Promotion of use of service (via several media channels + health education) ▪ Supervision of initiative (Quality assurance of information provided)	▪ Promotion of use of service (via several media channels + health education) ▪ Supervision of initiative (Quality assurance of information provided)	▪ Promotion of use of service (via several media channels) ▪ Supervision of initiative (minor ailments and medication included, quality assurance of dispensed medication)	▪ Promotion of use of service (via several media channels) ▪ Supervision of initiative (quality assurance of dispensed medication)
	Pharmaceu tical policy	▪ Availability of OTC products ▪ Affordability of OTC products ▪ Switches from Rx products to OTC products ▪ Level of prescription charges compared to average OTC price ▪ Mechanism of prescription charges and allowances	▪ Availability of OTC products ▪ Affordability of OTC products ▪ Switches from Rx products to OTC products ▪ Level of prescription charges compared to average OTC price ▪ Mechanism of prescription charges and allowances	▪ Exemption from prescription charges in place ▪ Possibility to prescribe OTC free of charge under MAS	▪ Availability of OTC products (lower share of OTC products likely to promote NMP) ▪ Level of prescription charges compared to average OTC price ▪ Mechanism of prescription charges and allowances

Dimensions of initiatives		Key features			
		NHS Choices	**NHS 111**	**MAS**	**NMP**
Government/ System	**Legal aspects addressed**	▪ Liability issues in terms of information provided (algorithm/decision tree) ▪ No immediate impact on professional law	▪ Liability issues in terms of information provided (algorithm/decision tree) ▪ Impact on professional law if individual consultation exceeding algorithm possible	▪ No immediate impact on professional law (as long as medication encompassed by imitative is OTC)	▪ Impact on professional law
Technology	**Medium of encounter and accessibility (time and place)**	▪ Internet ▪ 24/7	▪ Telephone ▪ 24/7 (possible)	▪ Community pharmacy (sufficient participation rate required) ▪ Accessibility determined by opening hours and regional distribution of participating pharmacies	▪ Community pharmacy (sufficient participation rate required) ▪ Accessibility determined by opening hours and regional distribution of participating pharmacies

Table A 106: Feasibility assessment of transferability of self care best-practice initiatives

Dimensions of (best-practice) initiatives		NHS Choices			NHS 111			MAS			NMP		
		Favourable condition in exporting setting	Relevance in *exporting* setting	Feasibility in *importing* setting	Favourable condition for bet practice	Relevance in *exporting* setting	Feasibility in *importing* setting	Favourable condition for bet practice	Relevance in *exporting* setting	Feasibility in *importing* setting	Favourable condition for bet practice	Relevance in *exporting* setting	Feasibility in *importing* setting
Population/Patients	**Population addressed**	Universal approach Particular focus on subgroups with specific needs (e.g. informal carers, parents, health literates)	L		Universal approach Particular focus on subgroups with specific needs (e.g. elderly, internet illiterates, etc.)	L		Sub-group specific approach Large share of population exempt from prescription charges, improves impact of MAS	H		Universal approach, Reasonable focus on early adopters	L	
Providers	**Providers involved**	Establishment of institutional capacity for central operation of service	M		Establishment of institutional capacity for central operation of service; if already established: involve de-central providers	H		Provision of sufficient training at pharmacy level (e.g. via professional bodies and/or formal education)	H		Ensure sufficient training at pharmacy level (e.g. via professional bodies and/or formal education)	H	

Dimensions of (best-practice) initiatives		NHS Choices			NHS 111			MAS			NMP		
Providers	**Providers affected**	Cooperation with professionals' lobbies (e.g. physicians' chambers) or identification of strategies to limit their political power	H		Cooperation with professionals' lobbies (e.g. physicians' chambers) or identification of strategies to limit their political power	M		Cooperation with professionals' lobbies (e.g. physicians' chambers) or identification of strategies to limit their political power	H		Cooperation with professionals' lobbies (e.g. physicians' chambers) or identification of strategies to limit their political power	H	
Government/Payer System	**Governance**	General promotion of service by various media	H		Target group specific promotion of service by various media	M		Establishment of institutional capacity to govern scheme (e.g. definition of minor ailments and/or relevant medication), control medication (quality assurance) and training Target group specific promotion of service by various media	H		Establishment of institutional capacity to control medication (quality assurance) and training Target group specific promotion of service by various media	H	
	Pharmaceutical policy	Ensure sufficient share and affordability of OTCs Facilitate switches from Rx products to OTC	M		Ensure sufficient share and affordability of OTCs Facilitate switches from Rx products to OTC if elderly/worse-off are targeted: make sure, that exemption of prescription charges on Rx does not limit shifting behaviour	M		Sufficient share of population covered by exemption from prescription charges Ensure possibility to prescribe OTCs in order to qualify for exemption. If other forms of allowances (co-payment limits, etc.) are in place, total impact not enfolded	H		Small proportion of OTC available for minor ailments Low prescription charges for Rx	M	

Dimensions of (best-practice) initiatives		NHS Choices			NHS 111			MAS			NMP		
Government/Payer System	**Legal aspects addressed**	Clear regulations regarding liability Provision of transparent information/legal disclaimer	M		Clear regulations regarding liability Provision of transparent information/legal disclaimer *In case of individual consultation:* Expansion of competencies of health professionals by law (e.g. nurses)	M		Expansion of competencies of health professionals by law (e.g. pharmacists)	M		Major rearrangement of health professionals' competencies by law (e.g. pharmacists)	H	
Technology	**Medium of encounter and accessibility (time and place)**	Ensure comprehensive access to the internet	M		Promotion of access free of charge Provision of access 24/7 Sufficient capacity to avoid telephone waiting lines	H		Ensure comprehensive accessibility via high participation rates of community pharmacies and (extended) opening hours; particularly in areas with high share of population exempt from prescription charges	M		Ensure comprehensive accessibility via high participation rates of community pharmacies and (extended) opening hours	H	

Annex 16: Risk Analysis

The different relationships between internal strengths and weaknesses and external opportunities and threats have been analysed by answering the following eight questions:

1. How can strengths be maximised?

- Comprehensive use of all information relevant for the analyses available (i.e. literature, experts, stakeholders)
- Fostering the production of evidence based information and promote knowledge-brokering
- Adjust the analyses steps if necessary in order to keep analysis up-to-date

Comprehensive use of information and ensuring level of topicality increases the methodology's accuracy and in turn promotes its use compared to other methodologies.

2. How can weaknesses be minimised?

- Widening of methodology's focus and integrate alternative methods such as horizon scanning, expert consultations, etc.
- Ensure involvement of experts of different fields to avoid limited perspective of analysis
- Tailoring methodology of transferability to specific health care systems in order to get most accurate results
- Participation of decision-makers in the analysis process in order to consider political priorities
- Encourage transparency and publishing of data relevant for analyses, e.g. initiative specific information including cost data, context information of the particular countries
- Adaption of the methodology if factors relevant for transferability obviously not captured

The weaknesses of the methodology mainly refer to the limited scope of the methodology. The exclusion of relevant factors might distort analysis and hinder the production of results reflecting reality best. Therefore, it might be necessary to widen the focus of the methodology and/or to include new perspectives by involving experts and decision-makers of different fields. Also, the provision of transparent and up-to-date data and information is important in this context.

3. How can opportunities be maximised?

- Bring debates about transferability of health reform innovations down to national level
- Promotion of the use of transferability methods parallel to the assessment of their feasibility
- Encourage publications in the field of comparative health system research
- Foster availability of the literature in the field of comparative health system research.

Opportunities for the methodology refer to external factors promoting its application and its quality. Most important in this context is to put the topic of transferability on national political agendas. Quality can be improved by incorporating results of comparative health system research into the analyses, especially in the analysis of the importing setting. In order to do so, publications including appropriate forms of information-packaging as well as availability of literature needs to be fostered.

4. How can threats be minimised?

- Regular monitoring of the context in which the methodology is applied in order to anticipate new and potentially threatening developments.
- Incorporate a surveillance loop for assessing technological developments in regular intervals and allow for interactive in-time knowledge sharing mechanisms
- Participation of experts in the field of self-care to gain insights into technological developments in this field

The threats jeopardizing the applicability of the methodology are related to its static view of reality. Thus, monitoring and adapting the methodology are important tools to avoid or overcome threats. Furthermore, the inclusion of experts with different backgrounds as well as in-time interactive knowledge sharing can help to anticipate and account for developments in technology or in the importing setting.

5. How can strengths be used to take advantage of opportunities?

- Incorporate stakeholders interested in the transferability of health reform innovations and their claims, as they might foster the use of standardised methods for transferability.
- Ensure to produce accurate and reliable results in order to promote the methodology's use and subsequently contribute to the methodology's advancement.
- Share successes via appropriate information formats.

As opportunities relate to factors fostering the applicability of the methodology, strengths need to be used in terms of promoting factors. By disseminating the methodology and sharing its success, increased application by different interest groups can be achieved. Both will be facilitated by the methodology's ability to produce accurate and reliable results.

6. How can weaknesses be corrected to take advantage of opportunities?

- Link health care policy and health research objectives with the aim to improve quality of analysis
- Quality of the assessment of the feasibility to transfer can be increased by not focusing on single sources of information (such as experts' or stakeholders' opinions) only but should be facilitated also by including further sources of information (such as literature on comparative health system research, case reports, etc.)

By ensuring/increasing the quality of the analysis, utilisation of the methodology might be encouraged, which subsequently enables the assessment of the methodology's feasibility and might foster methodological advancement. An advanced methodology in turn might be noticed and eventually applied by expert groups discussing the transfer of health reform innovations at EU level.

7. How can strengths be used to reduce threats?

- Promotion of harmonized methodology to health priority setting and health performance monitoring
- Emphasising the analysis of the importing setting gives chance to anticipate developments outside the scope of the methodology.
- By inclusion of experts and stakeholders especially in Step 1 (i.e. identification of initiatives) technological developments might be anticipated.

- If anticipation of developments either of technological or other nature cannot be anticipated, the methodology's flexible approach of adoption enables to consider those developments during the adaption of the policy strategy.
- Use the patient perspective and patient preferences through initiative development process (target audience of self-care initiatives)

Strengths of the methodology are used in terms of anticipating developments outside its scope. This can be facilitated by a comprehensive analysis of the importing setting in combination with the inclusion of expert's and stakeholder's view on technological and other relevant developments. If anticipation is not possible, the flexibility of the methodology regarding policy adoption needs to be ensured.

8. How can weaknesses and threats be minimised?

- Regular assessment and timely information of the applicability and the results gained by the methodology in order to see if limited scope of the methodology distorts results of the analysis.
- If indication is given that the results of the methodology are distorted due to its scope, the methodology needs to be adapted by means of including further dimensions of analysis.