Towards reimbursement of mobile digital health applications?

An international comparison of practices

EUPHA Conference | 16 October 2020

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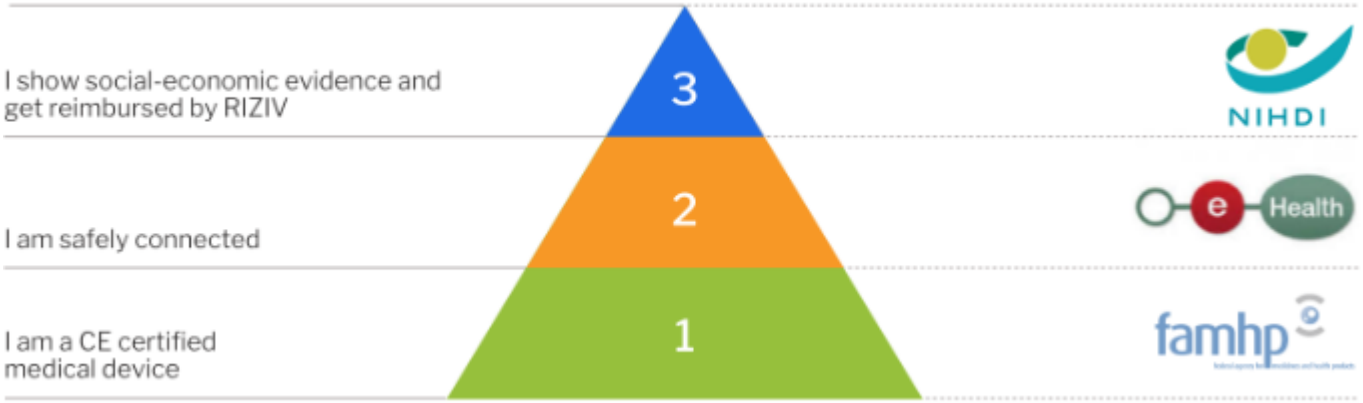
Background and research question

- Mobile digital health solutions abound
- Necessary to determine what apps are effective, safe, etc. → assessment challenge
- How to incentivize the use of apps deemed effective?
  - No public sector intervention?
  - User guidance, e.g. through app registries
  - Financial incentives/reimbursement
    - National solutions
    - Individual payers
  - Lack of clear reimbursement pathways

Current state-of-play: Belgium

mHealth Belgium platform:

- Three-level pyramid
  1. Level 1: CE certified, GDPR compliant
  2. Level 2: safely connected (risk assessment performed)
  3. Level 3: reserved for apps for which the social-economic added value has been demonstrated and which are financed, after approval by National Institute for Health and Disability Insurance (NIHDI) of their funding request.
- As per August 2020: 21 apps, of which 17 at level 1 and 0 at level 3
- Level 3 funding model currently being developed by NIHDI
- NIHDI funds clinical study for apps focusing on rehab after knee/hip surgery; one level 2 app is currently eligible (moveUp) → app already available for free for study participants



https://mhealthbelgium.be/validation-pyramid

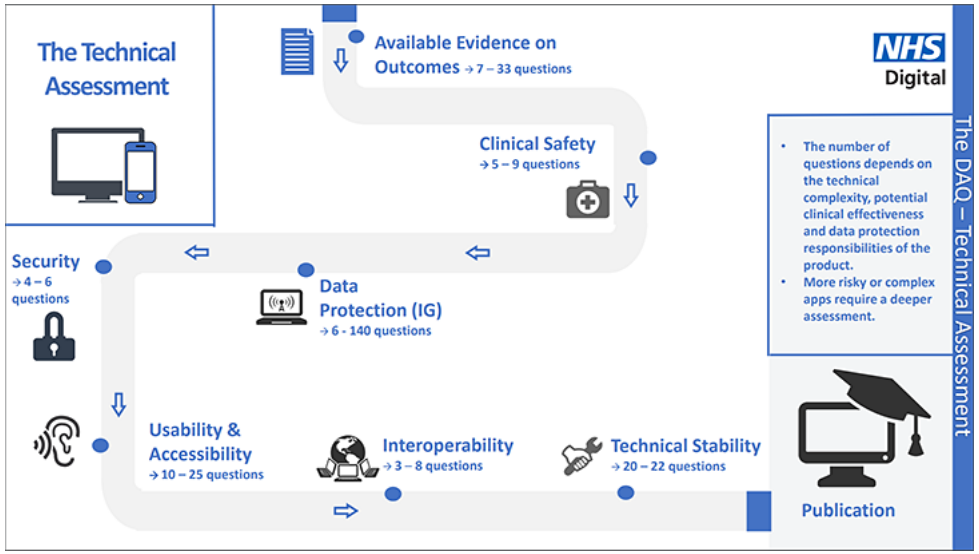
Current state-of-play: England

- NHS Apps Library (NHS Digital)
- Collecting all the apps assessed against national standards
- Inclusion in the Library != reimbursement
- Facilitates decision-making on reimbursement by the Clinical Commission Groups and NHS Trusts
- In addition as guidance for CCGs/Trusts and developers: NICE Evidence standards framework and Medical Technologies Evaluation Programme
- myCOPD as the only nationally reimbursed app (via an instrument called Innov. and Tech. Payment)

Sleepio

An online sleep improvement programme, clinically proven to help you fall asleep faster

Free in some areas



https://digital.nhs.uk/services/nhs-apps-library/guidance-for-health-app-developers-commissioners-and-assessors/how-we-assess-health-apps-and-digital-tools#how-the-assessment-works

Current state-of-play: France

- Reimbursement via inclusion in the French List of Products and Healthcare Services Qualifying for Reimbursement (LPPR list)
- Evidence requirements specified in the HAS Assessment principles to determine the reimbursement eligibility of medical devices for individual use, evaluated by the Medical Device and Health Technology Committee (CNEDIMTS)

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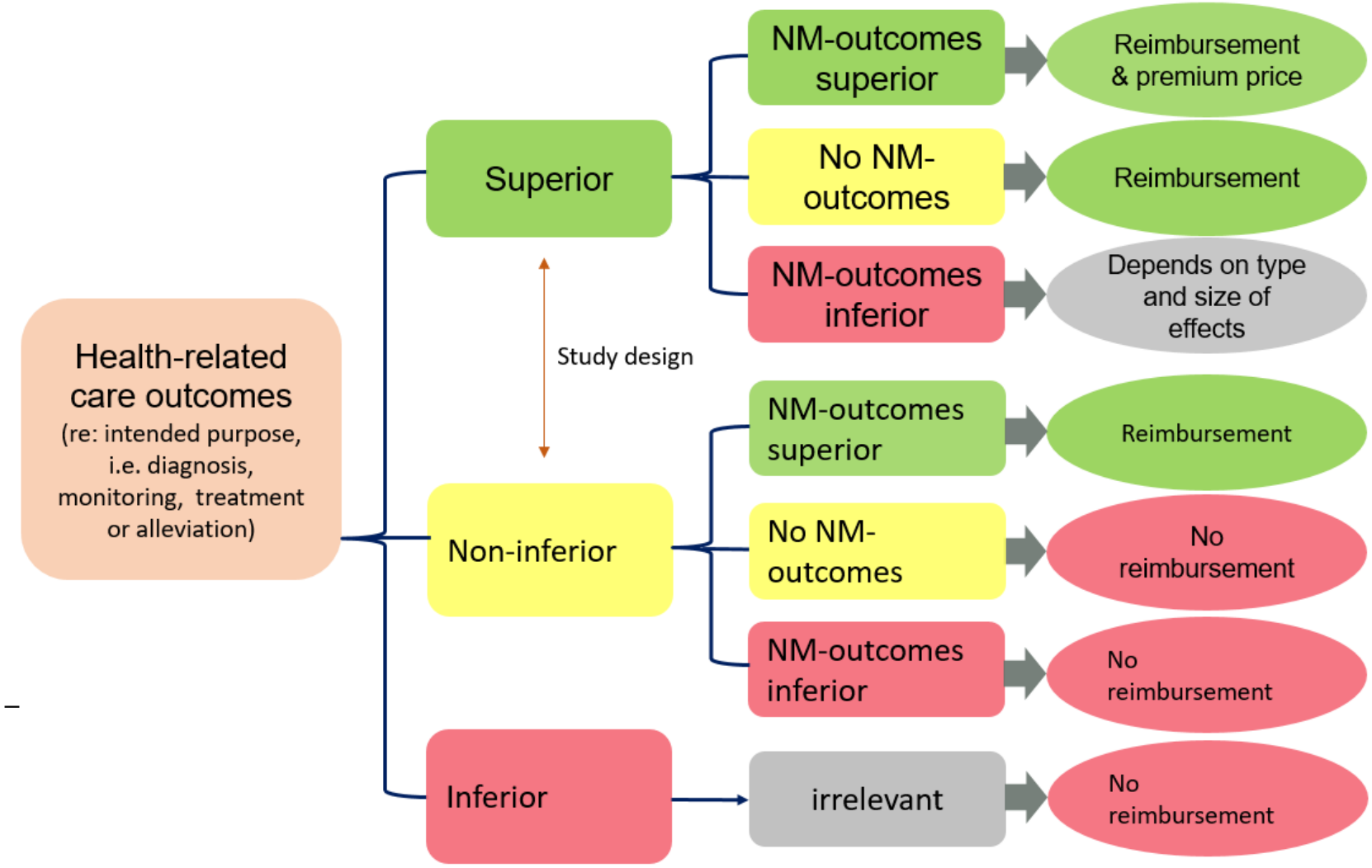

Based on French National Authority for Health (HAS) – January 2019: Medical device evaluation by the CNEDiMTS. Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement;

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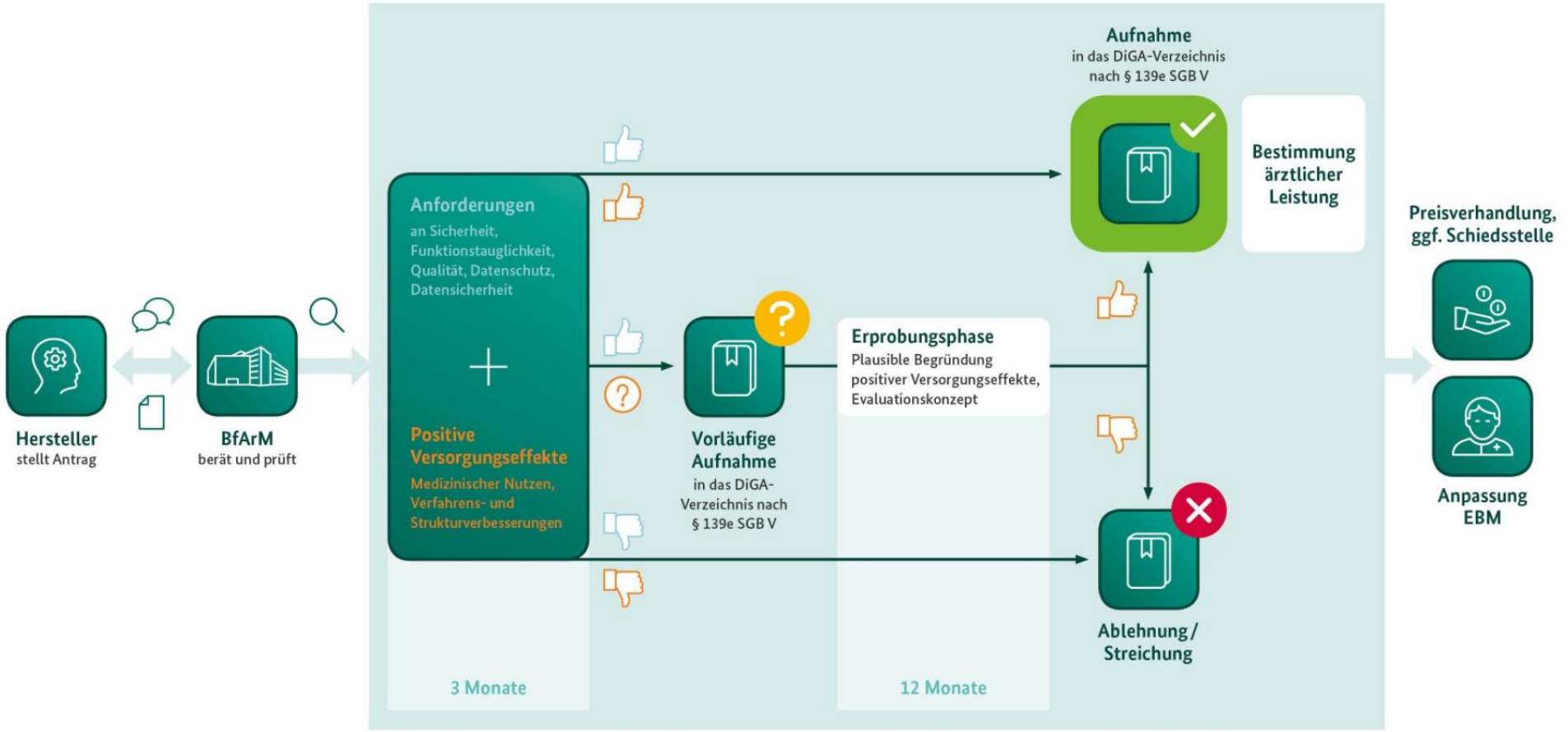
  - → Following this procedure, in August 2020, *Moovcare Poumon* (web and mobile app for telemonitoring of lung cancer patients) is included in the LPPR list;
  - → positively evaluated for three years with Added Clinical Value (ASA) level III (moderate improvement) compared to the conventional care, monitoring by imaging and medical face to face consultations.
  - → A sub-section for "web applications and telemonitoring software" has been added to LPPR; reimbursable tariff of € 500 for a three-month prescription, negotiated between the French Healthcare Products Committee and the manufacturer on the basis of the ASA level
  - → Physicians prescribe the application and inscribe patients

Current state-of-play: Germany

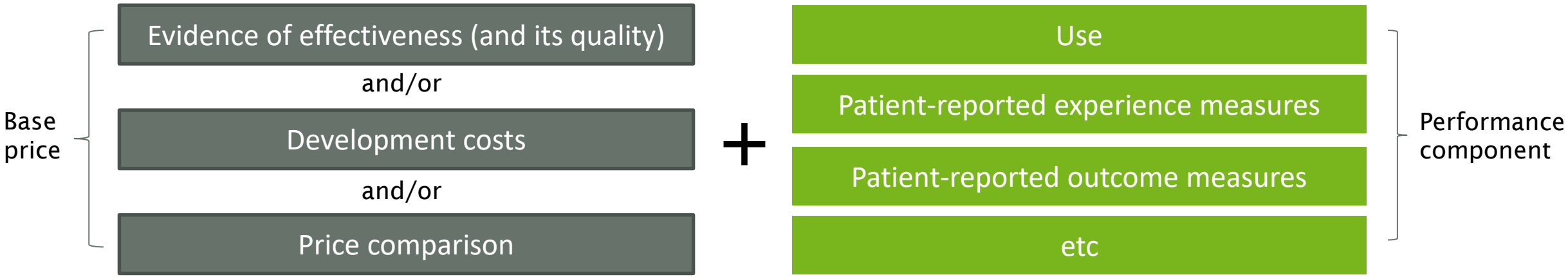
- *Digitale-Versorgung-Gesetz* (DVG), passed in Dec 2019 → 'app by recipe'
- Defining a pathway for the inclusion of digital applications (DiGAs) in the benefit basked of the statutory health system (instead of the earlier practice of individual insurer-level contracts)
- Focusing on patient-facing applications that are classified as class I or IIa medical devices (according to MDR) for
  - diagnosis, monitoring, treatment or alleviation of disease
  - diagnosis, treatment, alleviation of or compensation for injuries and disabilities
- Process
  - Inclusion of DiGA into a national registry (https://diga.bfarm.de/de/verzeichnis) after successful assessment of safety, functionality, quality, data protection and data security → reimbursement
  - One year time window to provide evidence for effectiveness (health effects, but focus can also be on process or structural improvements)
  - Effectiveness proven → continues in the registry and being reimbursed; if not → removed

Current state-of-play: Germany



Current state-of-play: Germany

- Price setting
  - **During** the first year/trial perid, producer price (determined according to common standards) until agreement with GKV-SV is reached; Maximum prices for reimbursement of groups of similar DiGAs (depending on use and effectiveness)
  - **After** the first year/trial period, reimbursed price is negotiated between producer and GKV-SV; negotiations also consider outcomes-based components of the price
  - Below threshold prices, applications are reimbursed without separate negotiations
  - Producers can charge higher prices, patients to pay the difference



Current state-of-play: Germany

» Classifying apps for evaluation and payment according to function and target group
→ evaluation: evidence level defines required study design (cf. NICE Framework)

Categorization based on target group	Categorization based on function		
	4 Diagnosis		
	8 Direct Intervention	7 Indirect Intervention	
	6 komplex monitoring		5 simple monitoring
4 Highly vulnerable, unstable condition	High	High	High
2 acutely ill, not life-threatening/ 3 chronically ill	High	Medium	Medium
1 healthy with risk factors	High	Medium	Low

Current state-of-play: summary

Belgium

Mode of reimbursement			
contract-based	programme-based	catalogue-based	registry-based
Unit of analysis			
individual applications		groups of applications	
Decision-making			
decentralised	mix/conditional		centralised

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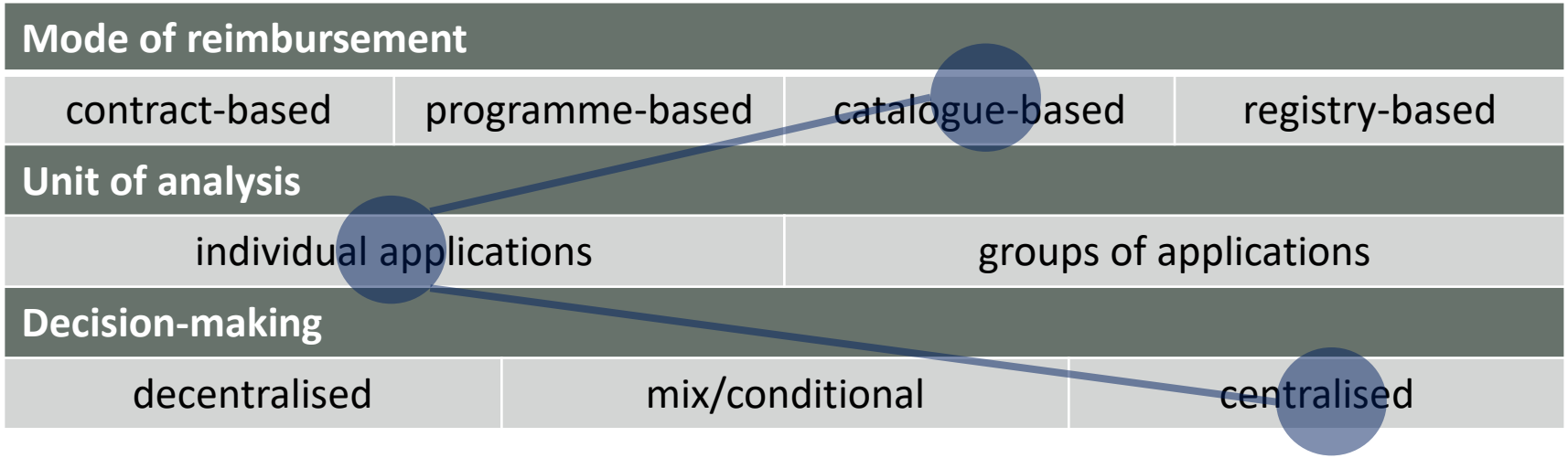

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	Producer	Payer	Physician	Patient
Registry-based reimbursement (vs catalogue inclusion)				
Advantages	Better planning	Transparency, planning	Transparency, orientation	Transparency, orientation
Disadvantages	More formalisation	Register regime has to be set up	New/different regime	-
Groups of applications (vs individual applications)				
Advantages	Less relevant to be first in class	Decreased workload	Guidance	Guidance
Disadvantages	Late entry possible but price fixed	Group definition and revision	How to decide within group?	How to decide within group?
Centralised decision-making (vs decentralised)				
Advantages	Less workload for market entry	Less decision-making costs	NA	Avoids patchy app landscape
Disadvantages	Less room for negotiation	Less flexibility	NA	Less tailored to local needs

Reimbursing health apps – key questions

- What evidence is required and who is paying for the evidence provision? If the producer/supplier is paying, how to avoind piggybacking by new/second entrants?
- How to set prices?
  - Fee for app? Fee for subscription? Fee for usage? Fee for care package? Fee for Outcomes?
  - Fixed maximum prices? On what basis: development and production cost component? Costs for evidence provision? ‚Innovation bonus' (for being first and paying for evidence; also in light of a lack in patent protection)?
  - Thresholds?
  - How do different types of effect (improved medical outcomes vs social or organisational effects) affect reimbursability and pricing?
  - How to set prices for apps that are replacing other treatment vs apps that are complementary or even additional?
- How to deal with market scale (physicians navigating increasing n° of reimbursable apps)?
- Regulating/limitin market entry (e.g. medication diaries)? On what basis?
- International dynamics: what does a market entry in Germany entail for a specific application's pricing in another country?

References

- Gerke, Sara, Ariel D. Stern and Timo Minssen (2020): Germany's digital health reforms in the COVID-19 era: lessons and opportunities for other countries, in: npj Digital Medicine, 3(94), https://doi.org/10.1038/s41746-020-0306-7.
- HAS (2019): Medical device evaluation by the CNEDiMTS (Medical Device and Health Technology Evaluation Committee) Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement, online: https://www.has-sante.fr/upload/docs/application/pdf/2019-04/guide_to_the_specific_feactures_of_clinical_evaluation_of_connected_medical_device_cmd_in_viewof_its_application_for_reimbur.pdf, accessed 20 Sep 2020.
- MTRC (2020): Reimbursement landscape for health apps in Europe, March 2020.