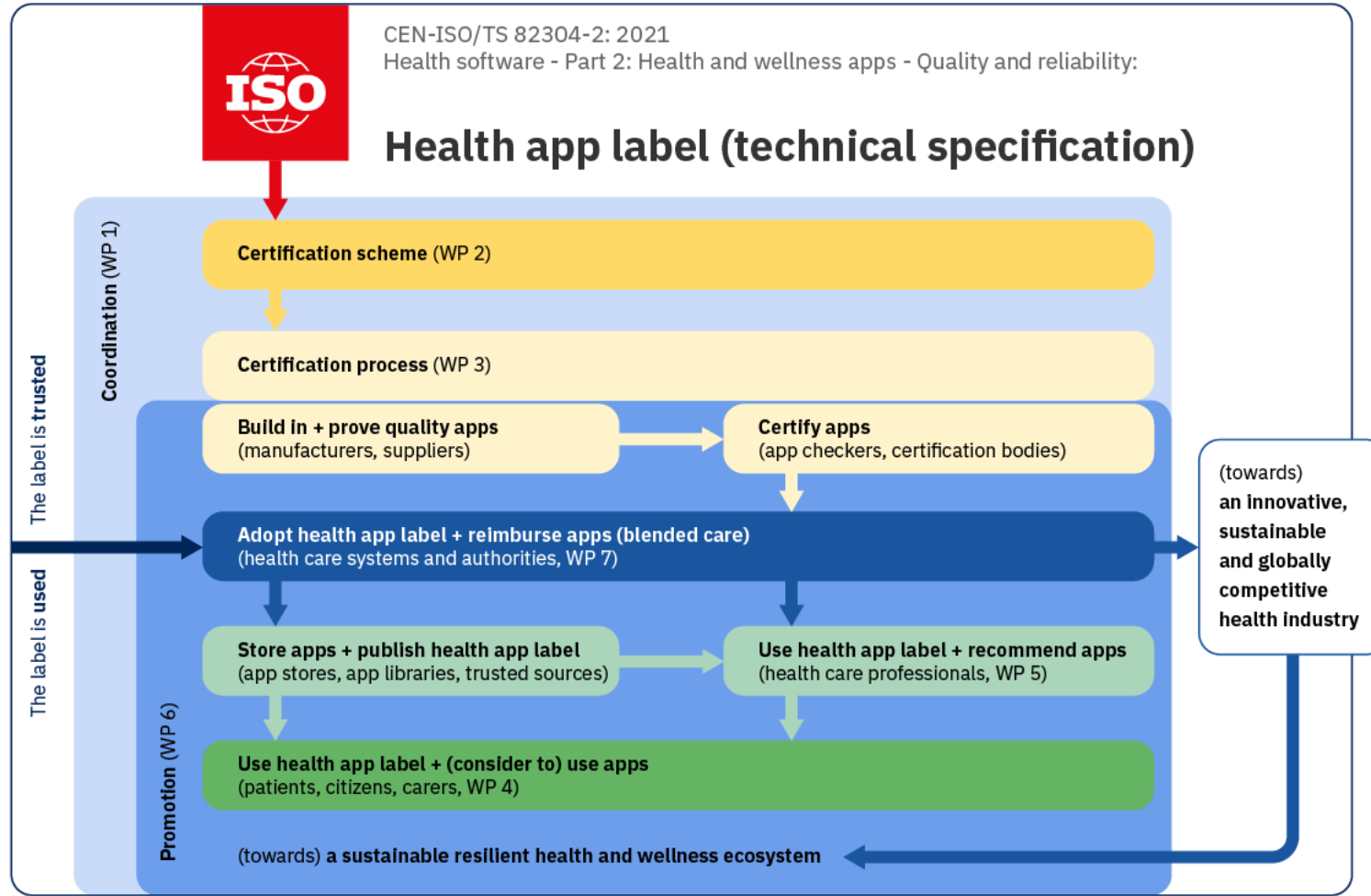


# **(Solutions to) challenges in reimbursement of health apps**

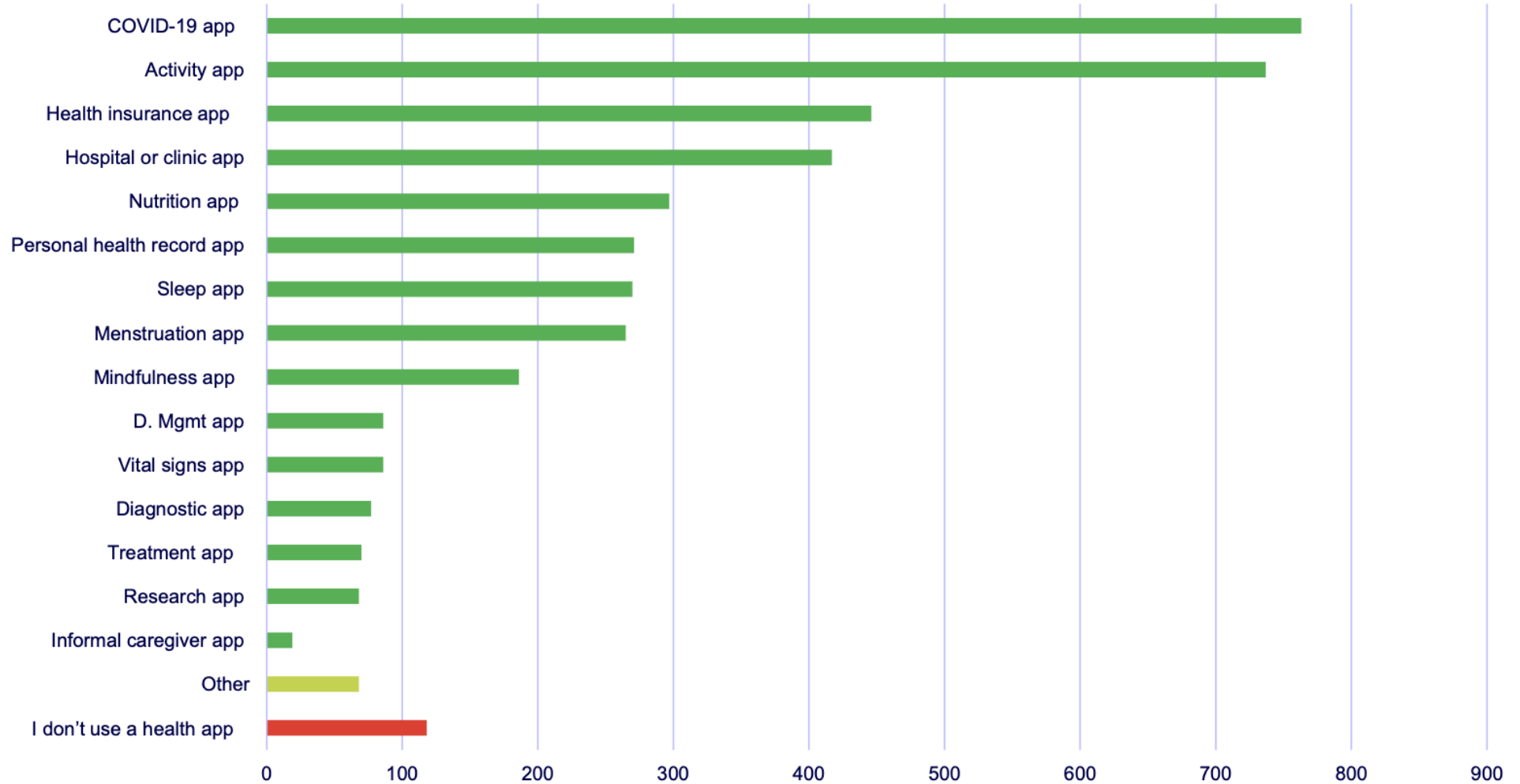
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Petra Hoogendoorn – Leiden University Medical Center / National eHealth Living Lab

# our aim: a sustainable resilient health ecosystem



# patient and citizen facing health apps



# the consortium: intentionally multi-stakeholder

- **Title** Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.
- **Duration** June 2022 – May 2024
- **Instrument** Horizon Europe
- **Type** Coordination and Support Action
- **Grant Agreement number** 101057522
- **Partners**

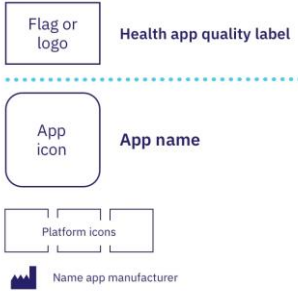


## the context: EU policy

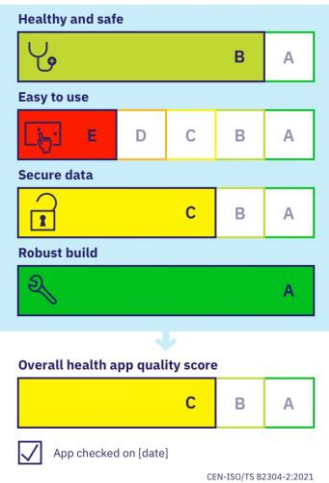
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- The *Green Paper on mobile health* (2014) addresses the potential benefits and risks of health apps, questioning **how to verify or ensure the efficacy of health apps** (e.g. certification schemes) and **how to better inform users** on the quality and safety of these apps
- The *Communication on enabling the digital transformation of health and care in the Digital Single Market* (2018) highlights “digital tools and data for citizen empowerment and person-centred care” as a key priority and proposes **common principles and certification** to facilitate supply of these tools, also by Small and Medium-sized Enterprises
- *CEN-ISO/TS 82304-2:2021 (health and wellness apps – quality and reliability)*, an assignment from the European Commission to the European Committee for Standardization (CEN), International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), delivers a **common health app assessment framework and label**
- The Proposal for a *Regulation on the European Health Data Space* (2022) calls for **voluntary labelling of wellness apps** (Article 31) and a **cascading effect in medical devices** that aim to be interoperable with Electronic Health Record systems
- *Horizon Europe project Label2Enable* creates **ISO 17067 EU certification scheme** for CEN-ISO/TS 82304-2 aligned with EU values and EU legislation, enabling accredited app assessors (third party assessment) to issue **trusted CEN-ISO/TS 82304-2 health app quality labels, scores and reports**

# ISO/TS 82304-2 helps deliver, review and choose apps



**Benefit of the app**  
 With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]  
 ⚠ Check [here] when app requires approval from a health professional before use



- Comprehensive** For wellness and medical device apps, not duplicating the work of notified bodies
- Evidence-informed** Inspired by the EU energy label: used by 85% EU consumers and in 59 non-EU countries
- Inclusive** Label tested with people with low health literacy
- Informative** Score, label and report communicate quality in a glance to the needed detail
- Proportionate** At most 81 questions, of which at most 67 score-impacting yes/no questions
- Testable** Yes-answers require evidence to be assessed by accredited app assessors
- Relevant** Assessment framework founded in a Delphi study with 83 experts from 8 stakeholder groups

**Maintained**



European Commission (2019) New energy efficiency labels explained

# 'the EU energy label but then for health apps'

**Health app quality label**

Flag or logo

App icon

Platform icons

Name app manufacturer

**Benefit of the app**  
With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]

Check [here] when app requires approval from a health professional before use

**Healthy and safe** A

**Easy to use** B A

**Secure data** C B A

**Robust build** D C B A

**Overall health app quality score** E D C B A

App checked on [date]

CEN-ISO/TS 82304-2:2021

**Egészségügyi alkalmazás minőségi címke**

Zászló vagy logó

Alkalmazás ikon

Platform ikonok

Alkalmazás gyártójának neve

**Az alkalmazás előnyei**  
Ezzel az alkalmazással [céltott felhasználók] [tervezett felhasználás] / Ezzel az alkalmazással [x 10-ből] [céltott felhasználók] [egészségre gyakorolt hatás] [használat esetén]

Jelölje be [itt], ha az alkalmazás használatához egészségügyi szakember jóváhagyása szükséges.

**Egészséges és biztonságos** A

**Könnyen használható** C B A

**Biztonságos adatok** D C B A

**Robusztus felépítés** B A

**Általános egészségügyi alkalmazás minőségi pontszám** B A

Az alkalmazás ellenőrzése [ dátum]

CEN-ISO/TS 82304-2:2021

**Label qualité pour appli de santé**

Drapeau ou logo

Icône de l'appli

Icônes des plateformes

Nom du fabricant de l'appli

**Bienfait de l'appli**  
Avec cette appli, [utilisateurs prévus] peuvent [utilisation prévue] / Avec cette appli, [x sur 10] [utilisateurs prévus] [effet sur la santé] [si utilisée]

Cochez [ici] si l'appli nécessite l'approbation d'un professionnel de la santé avant d'être utilisée

**Saine et sûre** B A

**Facile à utiliser** E D C B A

**Données sécurisées** C B A

**Design robuste** A

**Score global de qualité de l'appli de santé** C B A

Appli vérifiée le [date]

CEN-ISO/TS 82304-2:2021

**Marchio di qualità dell'app per la salute**

Bandiera o logo

Icona dell'app

Icone della piattaforma

Nome del produttore dell'app

**Vantaggio dell'app**  
Con questa app [utenti previsti] possono [uso previsto] / Con questa app [x in 10] [utenti previsti] [effetto sulla salute] [se utilizzato]

Controlla [qui] quando l'app richiede l'approvazione di un operatore sanitario prima dell'uso

**Sano e sicuro** D C B A

**Facile da usare** A

**Dati protetti** E D C B A

**Costruzione solida** D C B A

**Punteggio di qualità complessivo dell'app per la salute** D C B A

App controllata il [data]

CEN-ISO/TS 82304-2:2021

**Sundhedsapp kvalitetsmærke**

Flag eller logo

App ikon

Platformsikoner

Navn på leverandør af app

**Fordel ved appen**  
Med denne app kan [tilsigtede brugere] [tilsigtede brugere] / Med denne app oplever [x ud af 10] [tilsigtede brugere] [sundhedseffekt] [ved brug]

Tjek [her], når appen kræver godkendelse fra en sundhedsperson inden brug

**Sund og sikker** E D C B A

**Let at bruge** B A

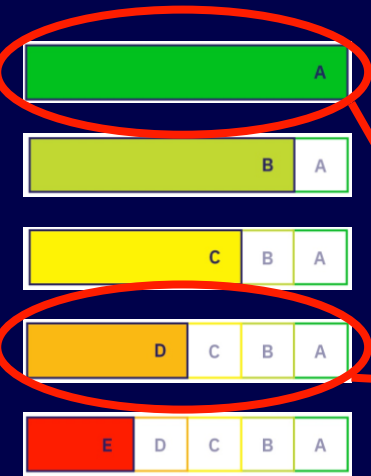
**Sikrer data** D C B A

**Robust konstruktion** E D C B A

**Samlet kvalitetsscore for sundhedsapp** E D C B A

App tjekket den [dato]

CEN-ISO/TS 82304-2:2021



# the EU energy score



5 jaar garantie

★★★★★ (91)

**Siemens WM14N295NL  
iQ300 extraKlasse  
wasmachine**

**577,-** Adviesprijs 759,-

✓ Op voorraad



- Energieklasse C
- Vulgewicht 8 kg
- max. 1400 toeren
- 72 dB centrifugeren

Vergelijk product



Ariel Allin1 PODS cadeau

★★★★★ (1)

**Whirlpool FFD6E 9638  
BCEV F wasmachine**

**497,-** Adviesprijs 629,-

✓ Op voorraad



- Energieklasse D
- Vulgewicht 9 kg
- max. 1600 toeren
- 85 dB centrifugeren

Vergelijk product



Black Friday Deal

★★★★★ (84)

**AEG L8FEN96CAD OKOMix  
AutoDose wasmachine**

**866,-** Adviesprijs 1.329,-

✓ Op voorraad



- Energieklasse A
- Vulgewicht 9 kg
- max. 1600 toeren
- 76 dB centrifugeren

Vergelijk product



Black Friday Deal

**Miele WED 174 WPS  
wasmachine**

**1.379,-**

✓ Op voorraad




- Energieklasse A
- Vulgewicht 9 kg
- max. 1400 toeren
- 70 dB centrifugeren

Vergelijk product



# the EU energy label



**ENERGY LABEL**

Siemens WM14N295NL

5 jaar garantie

★★★★★

Siemens iQ300 ext wasmachine

577,- Adviesprijs 629,-

✓ Op voorraad

**62 kWh / 100**

8.0 kg 3:29 43 L

72dB

AB CDEFG



★★★★★ (84)

**AEG L8FEN96CAD OKOMix AutoDose wasmachine**

866,- Adviesprijs 1.329,-

✓ Op voorraad

- A**
- Energieklasse A
  - Vulgewicht 9 kg
  - max. 1600 toeren
  - 76 dB centrifugeren

Vergelijk product



**Miele WED 174 WPS wasmachine**

1.379,-

✓ Op voorraad

- A**
- Energieklasse A
  - Vulgewicht 9 kg
  - max. 1400 toeren
  - 70 dB centrifugeren

Vergelijk product

An official website of the European Union How do you know? ▾

 European Commission EN English

**EPREL - European Product Registry for Energy Labelling**

Home > Washing machines > 335652

## Washing machines

COMMISSION DELEGATED REGULATION (EU) 2019/2014 with regard to energy labelling of household washing machines and household washer-dryers

Siemens  
**WM14N295NL**

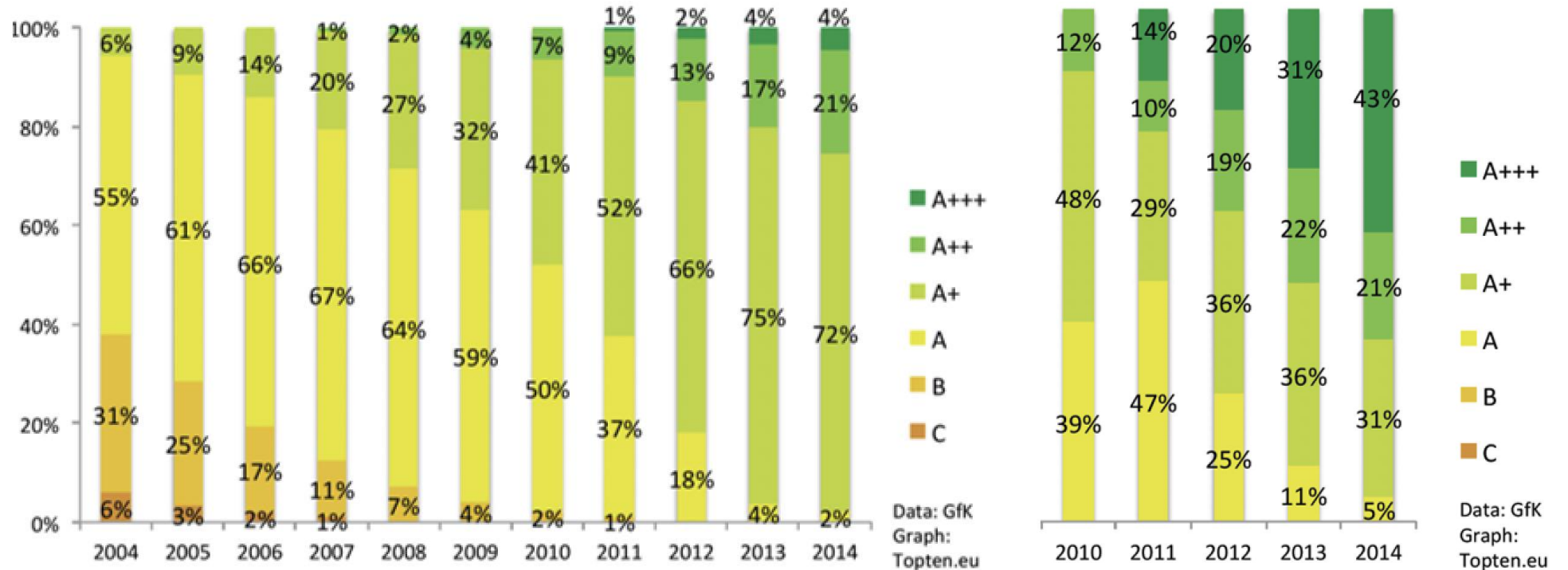
**General information**

	Overall dimensions	85 (Height) x 60 (Width) x 63 (Depth)	cm
	Energy efficiency Index (EEI)	68,6	
	Washing efficiency index	1,04	
8 Kg	Rinsing effectiveness	4,5	g/kg
	Energy consumption [per cycle, eco 40-60 programme]	0,624	kWh
	Weighted energy consumption [per 100 cycles, eco 40-60 programme]	62	kWh
	Water consumption [per cycle, eco 40-60 programme]	43	litres
	Maximum temperature inside the treated textile (Rated capacity)	44	°C
	Maximum temperature inside the treated textile (Half)	37	°C
	Maximum temperature inside the treated textile (Quarter)	23	°C
	Weighted remaining moisture content	52	%
	Spin speed (Rated capacity)	1 400	rpm



The energy label shows a class C rating, 62 kWh energy consumption per cycle, 8.0 kg capacity, 3:29 cycle time, 43 L water consumption, and 72 dB noise level.

# EU Energy label: refrigerator & washing machine sales



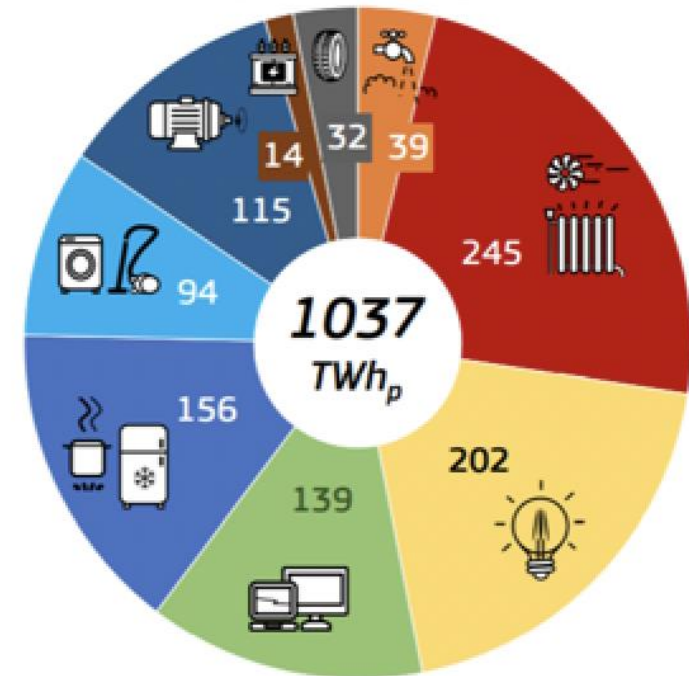
# EU Energy label: impacts estimates

## Impacts estimates (2020 vs BaU)

- **1037 TWh** primary energy  $\cong$  7% of total EU 27 primary energy demand
- Electricity: ca. **1000 kWh**/household (27%)  $\cong$  total EU wind production
- **€60 billion/y** in consumer expenditure (€ 210/household) based on pre-2021 energy price estimates
- Additional **business revenue 21 billion** euros and related **jobs increase** by **324 thousand**

Source: Ecodesign Impact Accounting 2020

## Energy savings 2020



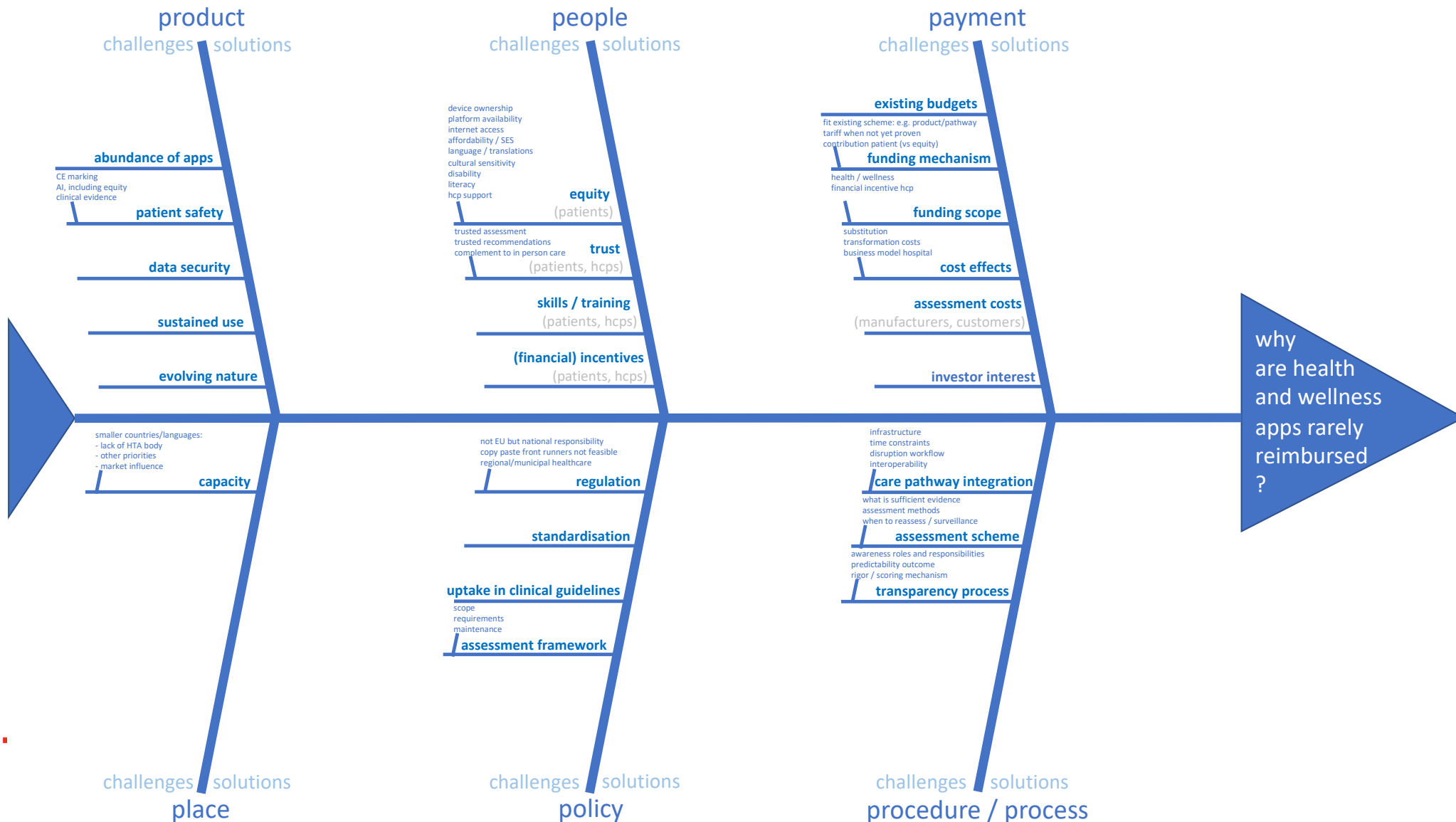
# importance reimbursement: telemedicine

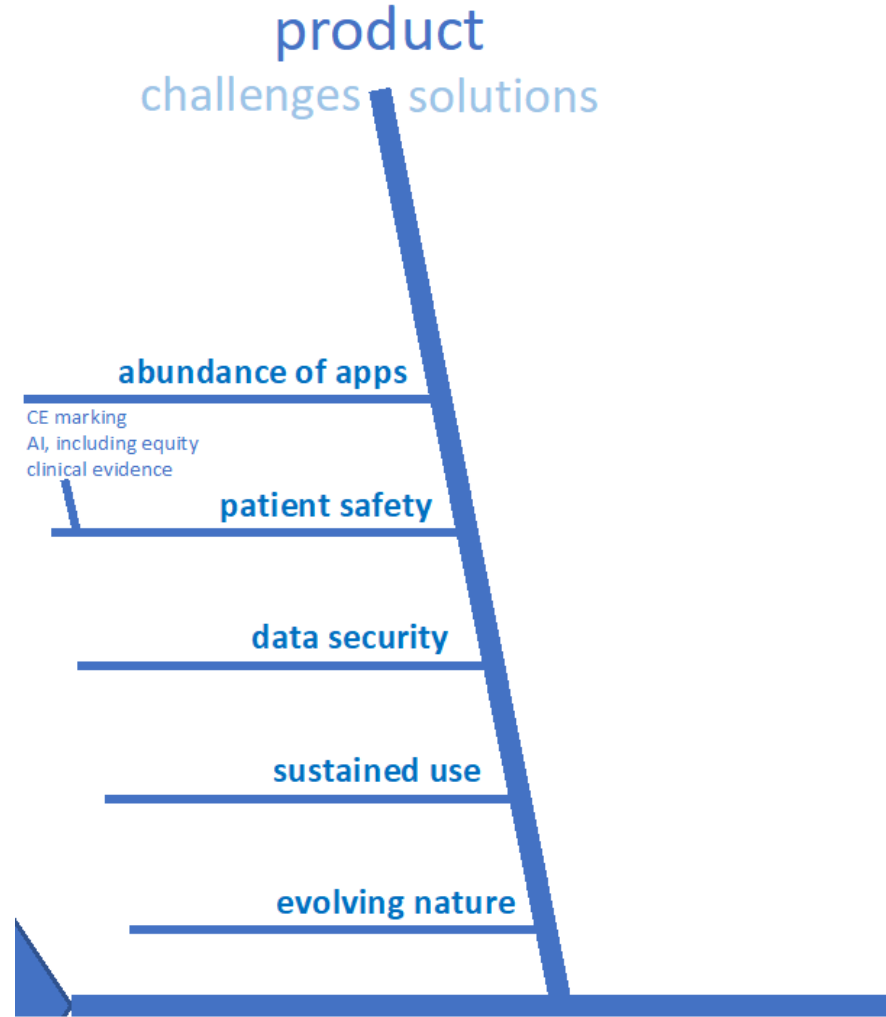
Themes of barriers to adoption	References	Occurrences (n=64)	Probability of occurrence
Increased cost (to provider) because reimbursement does not cover the technology	[20,27,28,34,37,39,40,50,51,57,60]	11	17%
Patient privacy	[1,40,51,57,58,60]	7	9%
Technical literacy	[9,28,40,51,53]	6	9%
State licensing	[10,51,[55], [56], [57]	5	8%
Data security	[1,27,28,34,39]	5	8%
Socioeconomics	[24,38,42,49,52]	5	8%
Limited reimbursement	[37,46,51,56]	4	6%
Issues of interoperability	[11,39,40,60]	4	5%
Patient safety	[28,34,43]	3	5%
Less personal	[20,39,51]	3	5%
Misaligned incentives	[3,37,51]	3	5%
Can raise ethical issues	[3,28,34]	3	5%

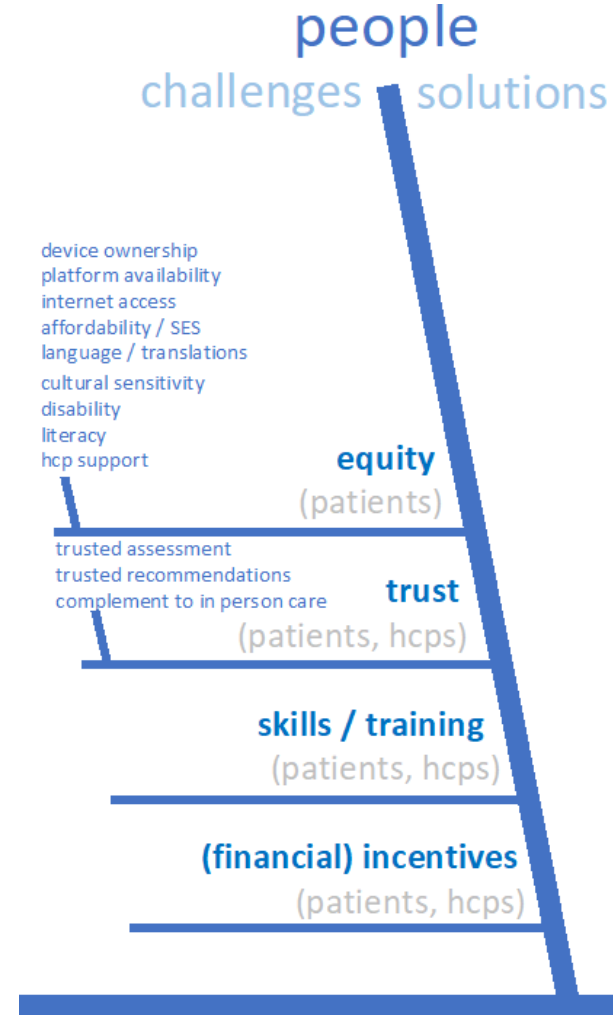
“Reimbursement mechanisms must exist to enable this modality in the healthcare industry of nations. In the U.S., 50 states establish their own standards for the practice of telemedicine, and many of these states require the provider to reside in the state in which telemedicine is being utilized: The situation is similar in Europe [64] Such practices defeat telemedicine's purpose to heal at a distance, through the Internet or mobile device, and in a secure manner [1,4,7,9,32,35,43]. As this new modality of care becomes more widely accepted and preferred, the health policy of nations will have to adjust and expand to govern and monitor it while incentivizing providers and patients to use it.”

Scott Kruse et al (2021) Telemedicine and health policy: A systematic review

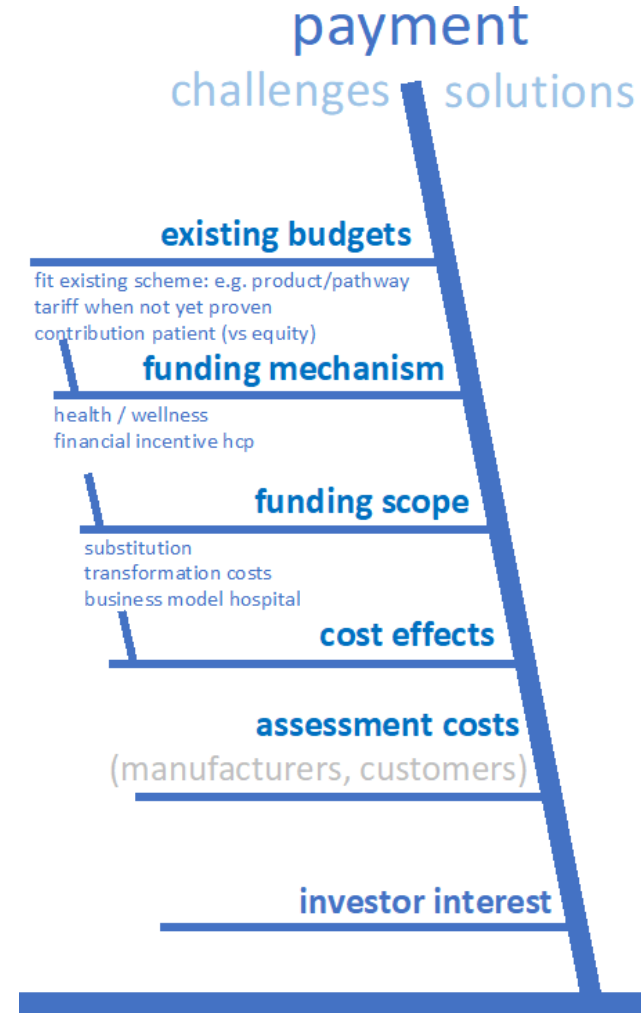
# challenges – initial analysis (fishbone diagram)

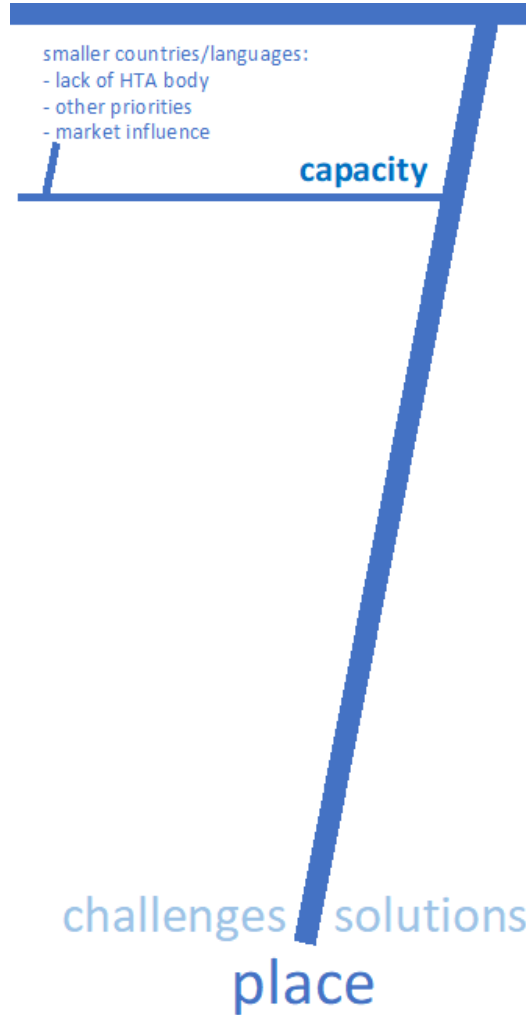


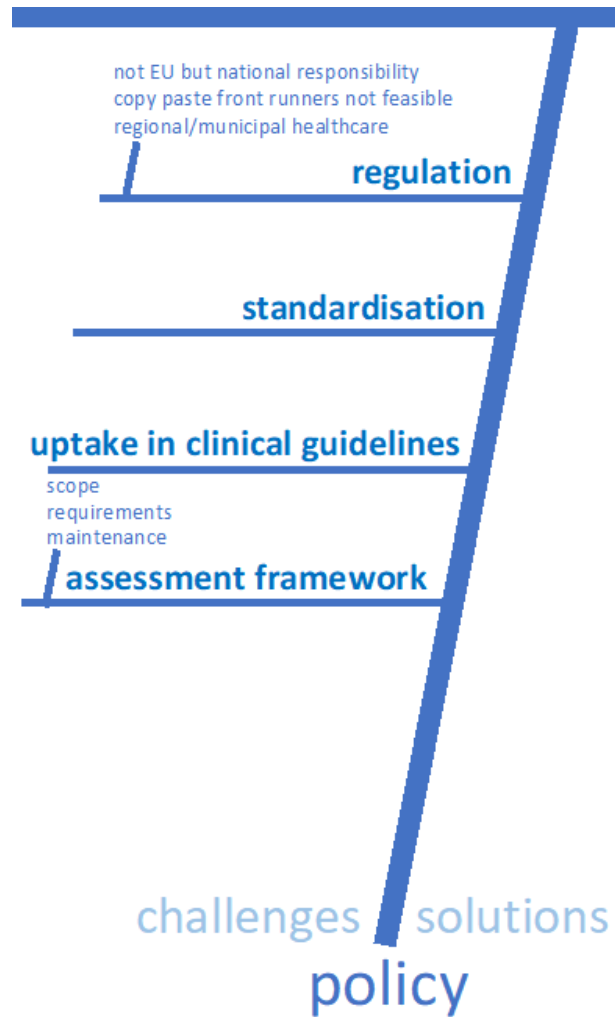




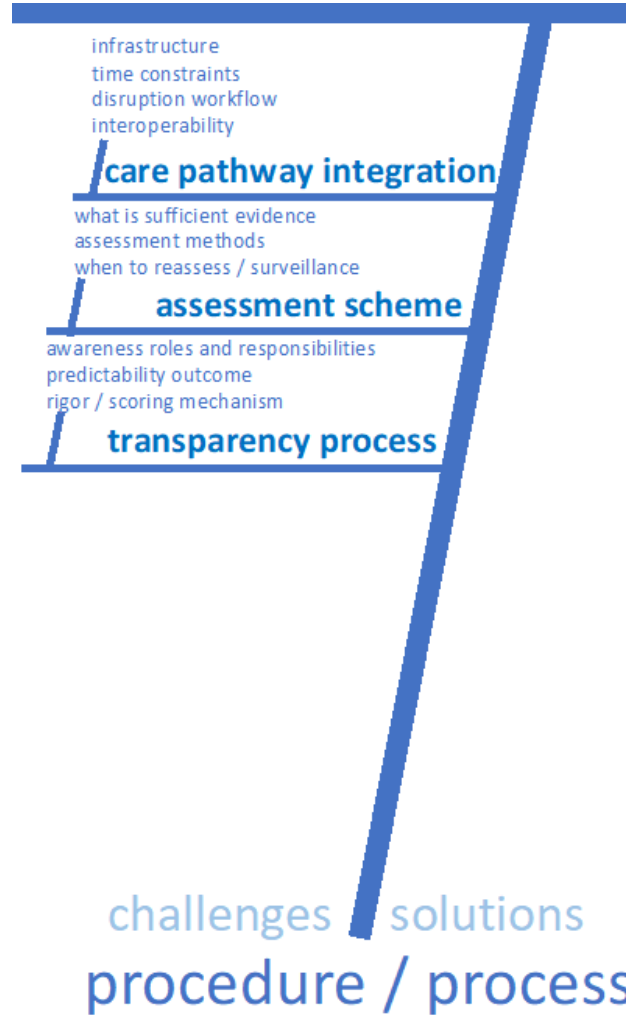








# procedure / process





**Email** [info@label2enable.eu](mailto:info@label2enable.eu) / [a.p.y.hoogendoorn@lumc.nl](mailto:a.p.y.hoogendoorn@lumc.nl)

**Website** [label2enable.eu](http://label2enable.eu)

**Twitter (X)** @label2e

**LinkedIn** [linkedin.com/company/label2enable](https://linkedin.com/company/label2enable)

**Facebook** [facebook.com/label2enable](https://facebook.com/label2enable)

# Survey

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2<sup>nd</sup> Label2Enable roundtable on reimbursement of health apps

## 5.2.5.1 Is evidence available of a **societal benefit** of using the app?

EVIDENCE: Societal benefit evidence. Where many resources are available, provide the most important 5 to 10.

Evidence can include evidence relating to non-digital versions of the health intervention and evidence of demonstrably equivalent health apps.

Societal benefit can refer to Reference [55]:

- **Information**, which includes a positive effect on lack of population denominator, delayed reporting of events, lack of reliable data, communication roadblocks, lack of access to information or data, insufficient utilization of data and information and lack of unique identifiers;
- **Availability**, which includes a positive effect on insufficient supply of commodities, services, equipment and/or qualified health professionals;
- **Quality**, which includes a positive effect on poor experiences for persons with health needs, health issues, at risk for health issues or informal carers, insufficient health professional competence, low quality health commodities, low health professional motivation, insufficient continuity of care, inadequate supportive supervision and poor adherence to guidelines;
- **Acceptability**, which includes a positive effect on lack of alignment with local norms and programs which do not address individual beliefs and practices;
- **Utilization**, which includes a positive effect on low demand for services, geographic inaccessibility, low adherence to treatments and loss to follow up;
- **Efficiency**, which includes a positive effect on inadequate workflow management, lack of or inappropriate referrals, poor planning and coordination, delayed provision of care and inadequate access to transportation;
- **Cost**, which includes a positive effect on high cost of manual processes, lack of effective resource allocation, expenses of persons with health needs, health issues, at risk for health issues or informal carers and lack of a coordinated payer mechanism;
- **Accountability**, which includes a positive effect on insufficient engagement of persons with health needs, health issues, at risk for health issues or informal carers, unawareness of service entitlement, absence of community feedback mechanisms, lack of transparency in commodity transactions, poor accountability between the levels of the health sector, and inadequate understanding of the beneficiary populations.

[55] WHO 2018. *Classification of digital health interventions v1.0 (WHO/RHR/19.06)*. <https://www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/>

# societal benefit – reference DiGA

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‘patientenrelevante Struktur- und Verfahrensverbesserungen (pSVV):

- coordination of treatment procedures
- alignment of treatment with guidelines and recognized standards
- adherence
- facilitating access to care
- patient safety
- health literacy
- patient autonomy
- coping with illness-related difficulties in everyday life
- reduction of therapy-related efforts and strains for patients and their relatives

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[https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/Interesting-facts/\\_node.html](https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/Interesting-facts/_node.html)

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Open your smartphone browser and go to

**live.voxvote.com**

enter the following numbers

**PIN: 25785**

Voting is **anonymous**.

Screen name or **(nick)name** is optional.

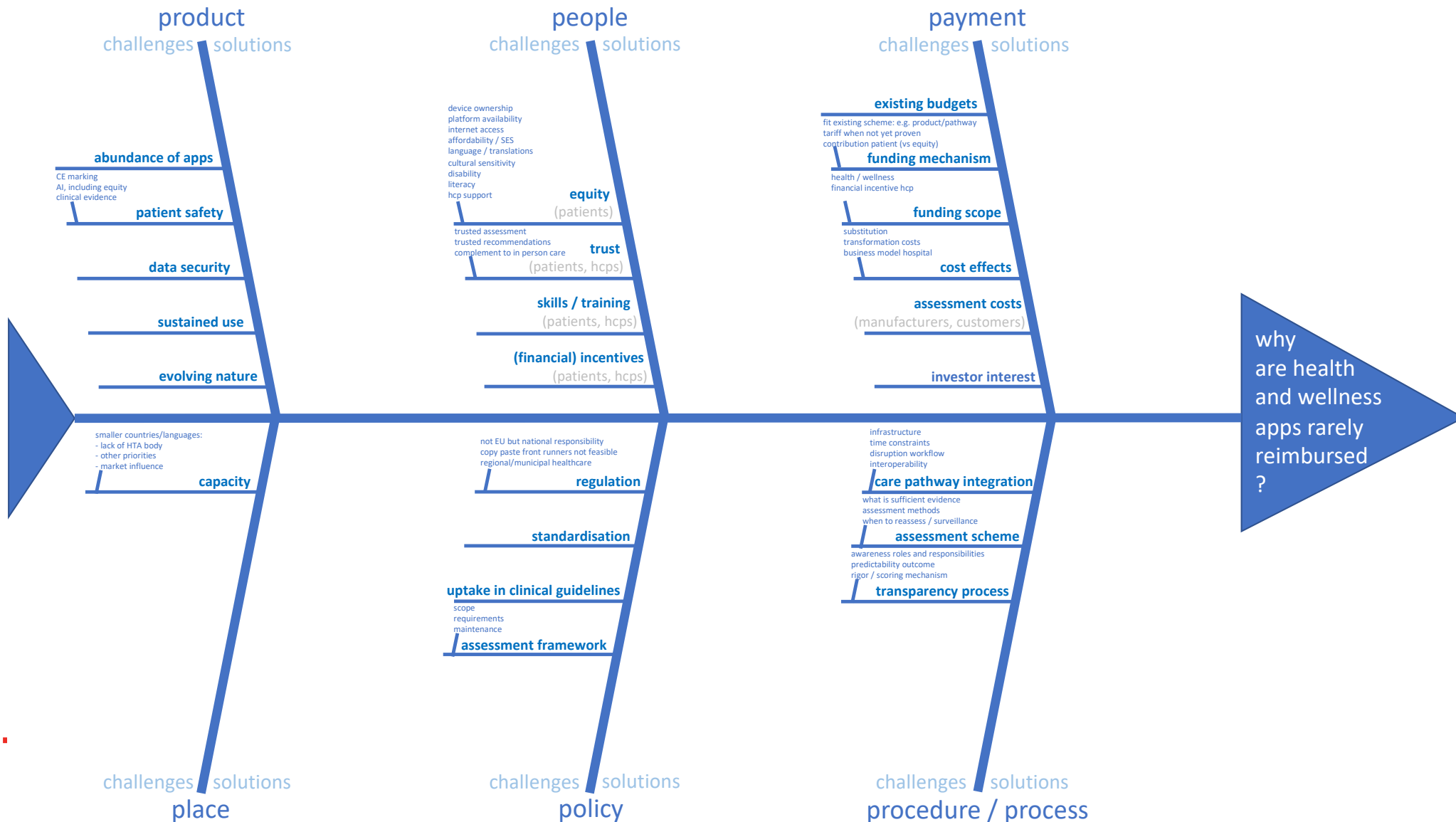


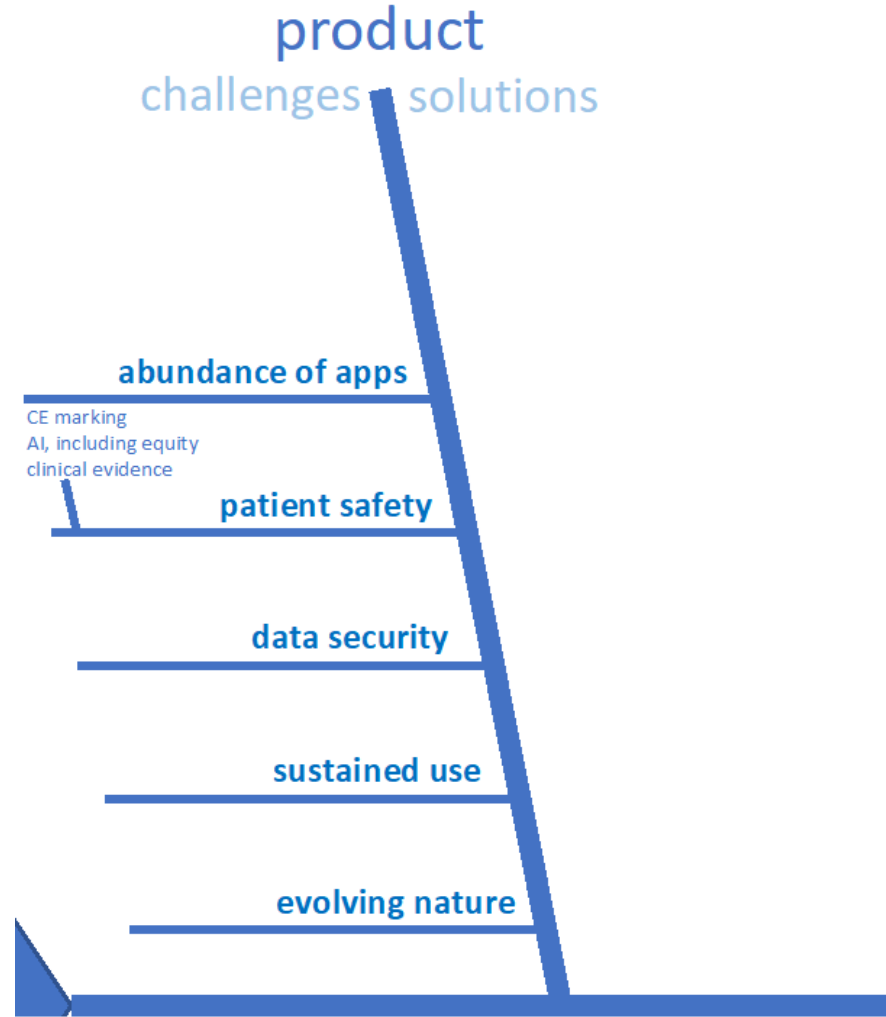
# Discussion

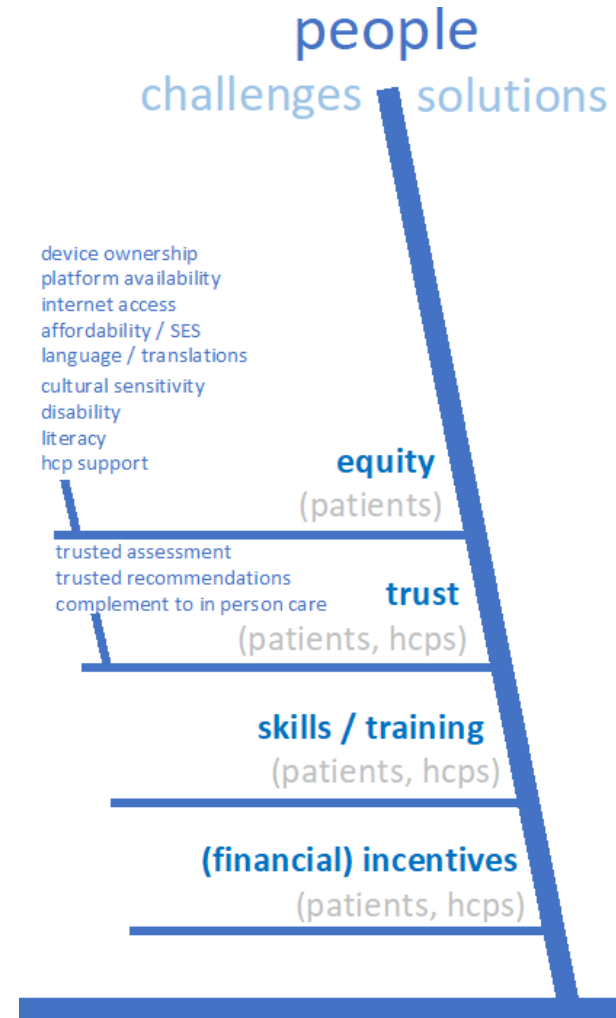
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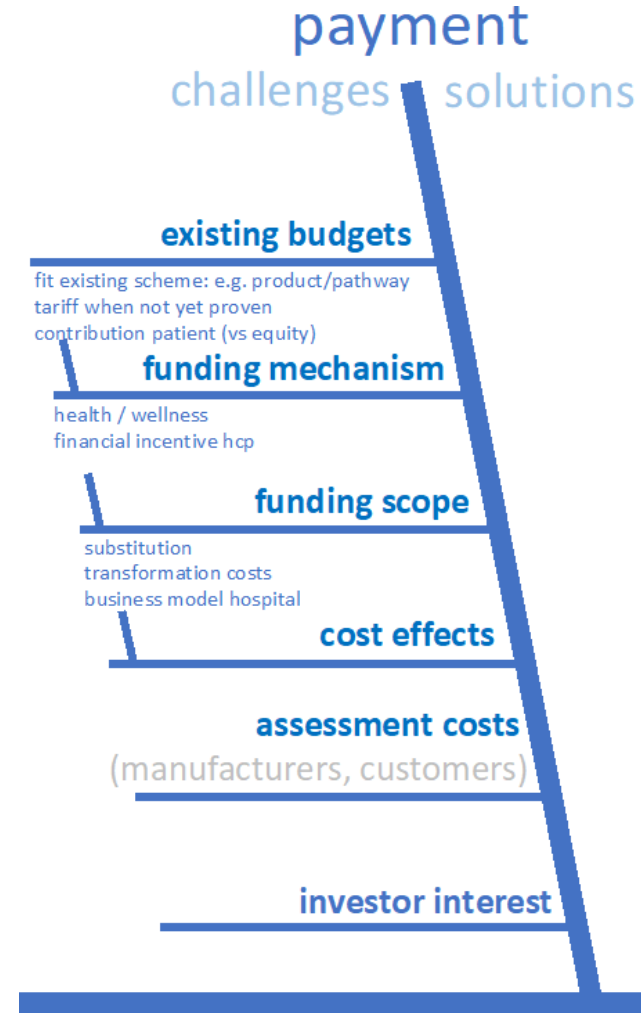
Tatjana Prenda Trupec - OptimIT

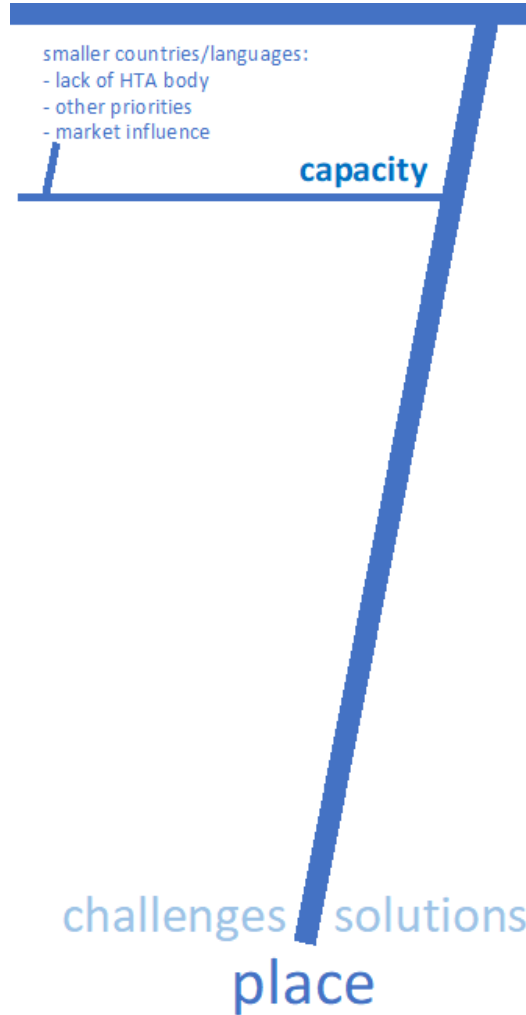
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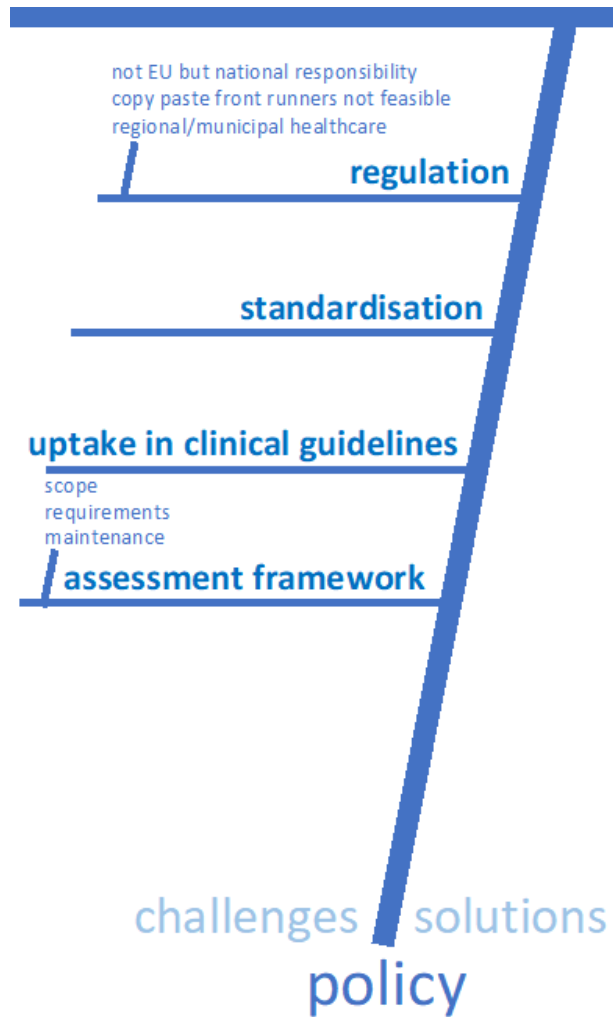














# procedure / process

