Boosting digital health through legislative initiatives in Germany

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some decisive steps towards widespread uptake of Digital Health..

Assets: Digital/digitised hospital EHRs, imaging, reimbursement, telehealth;
Barriers: Lack of integration, life-long EHRs, Data-driven care, Apps/mHealth
NB: Specialist care dominated by office-based specialists, many single-handed

Digitisation initiatives:

- Secure network covering ambulatory services, hospitals, pharmacies
  Health Telematics Infrastructure (TI) completely rolled-out, hardware connectors.

- Service roll-out for emergency data management, electronic medication plan, secure
  email communication (KIM – obligatory from October for sickness leave certificates)
  [KIM will usher in the end of fax, doctor's letters paid via KIM only]

- Upcoming: EHR, secondary data use, a secure messenger (Matrix), DiGA, DIPA
E-Health-Act (EHG) [21.12.2015] Act for secure digital communication and applications in the health sector
Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen


Digital Healthcare Act (DVG) [19 December 2019]
Act to Improve Healthcare Provision through Digitalisation and Innovation / Digitales Versorgungsgesetz

Digital Health Applications Ordinance (DiGAV) [21 April 2020]

Hospital Future Act (KHZG) Krankenhauszukunftsgesetz [18 September 2020]
Digitisation programme supported by € 4.3 bn jointly funded by Federal (3 bn) and states (1.3 bn)

German Patient Data Protection Act (PDSG) [20 October 2020]
Sharing Data for research purposes, integrating medications/eRx, image files

Digital Care and Nursing - Modernisation Act (DVPMG) [9 June 2021]
Digital Therapeutics (DiGA) – prescribing Apps for reimbursement

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Digital Health Applications Ordinance (DiGAV) – Fast Track Procedure

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Drawing © Federal Institute for Drugs and Medical Devices, Germany (BfArM)
Digital Health Applications Ordinance (DiGAV) – Proof of Evidence

Proof of general requirements:
- Safety
- Functionality
- Quality
- Data Protection
- Information Security

Proof of positive care effects:
- Structural and procedural effects
- and/or
- Medical benefit

12-months trial period where applicable

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Hospital Future Act / Hospital Funding and Digital Maturity

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Hospital Future Act: Domains in focus of funding and Digital Maturity

1. Adaptation of emergency rooms*
2. Establishment of patient portals
3. Electronic documentation
4. Clinical decision support systems
5. Digital medication management
6. Digital performance request process
7. Regional coordination of the range of services
8. Supply verification system
9. Telemedicine network structures
10. IT security
11. Adaptation of patient rooms (epidemic)

Promotion of (building) technical structures
Promotion of special IT systems
Promotion of regional network structures
Promotion of IT security

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Hospital Future Act: Digital Maturity and (distinct) penalty assessments

30.6.2021
Reifegradmessung

2 Jahre, um „Digitale Reife“ zu erlangen, falls nicht vorhanden

30.6.2023
Reifegradmessung

Ab 1.1.2025:
-2 % Erlösverlust

Self Assessment

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Smart, mobile platforms – putting health data in patients’ hands

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ePA (Electronic Health Records) Germany: Roadmap 2021 - 2024

- ePA 1.1 – from January 2021 (roll-out just getting pace as of September 2021)
  Comprehensive digital support of the patient-doctor relationship

- ePA 2.0 – from January 2022
  Involving more health professional groups (physiotherapists, midwives)

- ePA 3.0 – from January 2023
  Sharing Data for research purposes, integrating medications/eRx, image files

- ePA 4.0 – from January 2024
  Options for connecting cross-border eHealth applications
MIO – Medical Information Objects (Semantic Building Blocks) -> IPS

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