Regulating AI in Healthcare and Perspectives for Reimbursement

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It’s not if but how – Shape Digitalisation of Healthcare together

Main tasks
• Think Tank for the Ministry of Health
• Identification of innovative solutions, their evaluation and support of their implementation
• Platform for dialogue with stakeholders

Broad Expertise
• Big Data & AI
• Digital Health
• Interoperability
• Outpatient and Inpatient Care
• Data Privacy / Medical and Medical Device Law
Team hih: sparring partner & think tank

Unique interdisciplinary digital competence in the German healthcare system

Nataliya Bogdanova-Dochev
Events

Claudia Dirks
Communications

Julia Hagen
Regulatory & Politics

Lars Roemheld
AI & Data

Dr. med. Philipp Stachwitz
Medical Care

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Data protection, IT-security & Medical Law

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Hospital Care

Dr. med. Kai Heitmann
Interoperability

Selma Oppermann
Advisory Board: Home Care

Prof. Dr. med. Jörg Debatin
Chairman
Assessing New Products: Drugs & AI

- retrospective data / in silico clinical trials → chance for hypotheses building / early validation

- gold standard: randomized control trials → accounting for complexity of human metabolism etc. and lack of appropriate data

- retrospective data / test data (different from training data) → offer High Level of Confidence

- account for limitations of test data:
  - re-certification / validation
  - prospective clinical trials

→ test data: chance for collaboration on high quality, representative test data sets
Perspectives for Reimbursement

Currently no or little re-assessment / understanding of performance for authorities
→ German Initiative for some drugs: continuous data collection

Inherent incentive for HCP to use new drugs once their medical benefit has been shown

Need for re-assessment
→ chance for pay for performance
→ incentive to innovate
→ Increased transparency about performance

Chance to improve quality of care using AI but currently little to no incentive to integrate AI in standard care
→ Need for new incentives: initiatives for digitalisation of hospitals and use of pay for performance / VBH
Example: Reimbursement of Digital Health Applications
Definition of a DiGA (digital health application)

**DiGA according to § 33a SGB V**

- Medical product class I or IIa under MDR (incl. transitional periods for MDD)
- Main function relies on digital technologies
- Intended use is centered around the patient, possible to include the physician
- Product functionalities: Detection (monitoring), treatment, palliation / abatement of pain, compensation of diseases, injuries, disability
The Fast Track Process for Digital Health Applications

- Application of DiGA manufacturer to be registered in DiGA-listing (§ 139e SGB V)
- BfArM analyses and decides within 3 months (netto)
- Preliminary listing & trial period of 12 months (§139e SGB V)
- 12-months trial in first healthcare market
- Pricing negotiations with GKV-SV

**Fundamental Requirements**
- Security | Quality | Functionality | Data Privacy | Cyber Security

**Positive Effects on Care Delivery**
- Medical benefits | Procedural and structural improvements (patient related)

- Final Listing in DiGA-Registry

- Arbitration body if negotiations stuck after 1 year
Requirements to apply for DiGA registration

Details will be specified in a regulation by the Federal Health Ministry
Beyond low-risk Digital Health Applications: Reflexions on Closed-Loop Systems
DVG Fast Track: Experiment with iterative approach

- Low risk classes allow for fast track approach
- Assigned to a new player (Federal Institute for Drugs and Medical Devices BfArM)
- Potential for better care delivery beyond IIa and in the use by HCP only
Reflexions on Closed-Loop Systems

Preparations by Joint Federal Committee, German Diabetes Association, Patient Organisations, Health Ministry & hih:
- Organisation of continuous data collection?
- Governance of a Diabetes / Closed-Loop – Registry
- Chances for health services research, comparability → better quality of care (delivery)
FDA-Approach (Regulatory Proposal)

- FDA: assess the culture of quality and organizational excellence of a particular company and have reasonable assurance of the high quality of their software development, testing, and performance monitoring
  → Pragmatic approach
  → Risk of dependence on manufacturers

Figure 2: Overlay of FDA’s TPLC approach on AI/ML workflow

FDA (2019)
Health Data – a European model

- Availability and use of data decided and managed by state
- State wins over individual → lack of self determination

Social market economy
European data space
- The individual decides
- State creates governing model, sanctions abuse
- Research possible based on data donation

- Availability and use of data determined by market
- Economic interests more relevant than individuals → lack of self determination
Conclusion & Discussion

- AI – Chance to improve care delivery
- Focus on continuous monitoring / re-certification instead of focusing on strict initial assessment (only) → balance patient safety and innovation
- Perspective for collaboration: high quality test data sets
- Chance for Pay for Performance & Incentive to innovate
- Remaining challenges: integration into standard care
- Combining different approaches, iteration: requirements for internal processes (FDA approach), requirements for test data, requirements for clinical (prospective) trials, requirements for re-certification / continuous monitoring