

Real Value of Patient-Centered Positive Health Effects of Digital Medical Devices: Lessons from the German DiGA

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Background

Digital Healthcare Act (DVG): A “**fast track**” regulatory and reimbursement pathway for **digital health applications (DiGAs)** in the German market.

In order to qualify for reimbursement, **DiGAs** are required to demonstrate **positive care effects** through either:

- Medical benefits or
- Positive Structural and Process Improvements (PSVV).^[1]

PSVV domains represent areas such as **health literacy**, **adherence**, **access**, and **safety**, where addressing inefficiencies could lead to significant healthcare cost savings beyond traditional medical interventions.

Yet, despite their crucial role in enhancing healthcare delivery, **PSVV** domains remain starkly **underutilized**.

This study provides evidence of the economic value of **DiGAs** in addressing **PSVV** domains, thereby supporting their case for reimbursement and broader adoption within healthcare systems.

Objectives

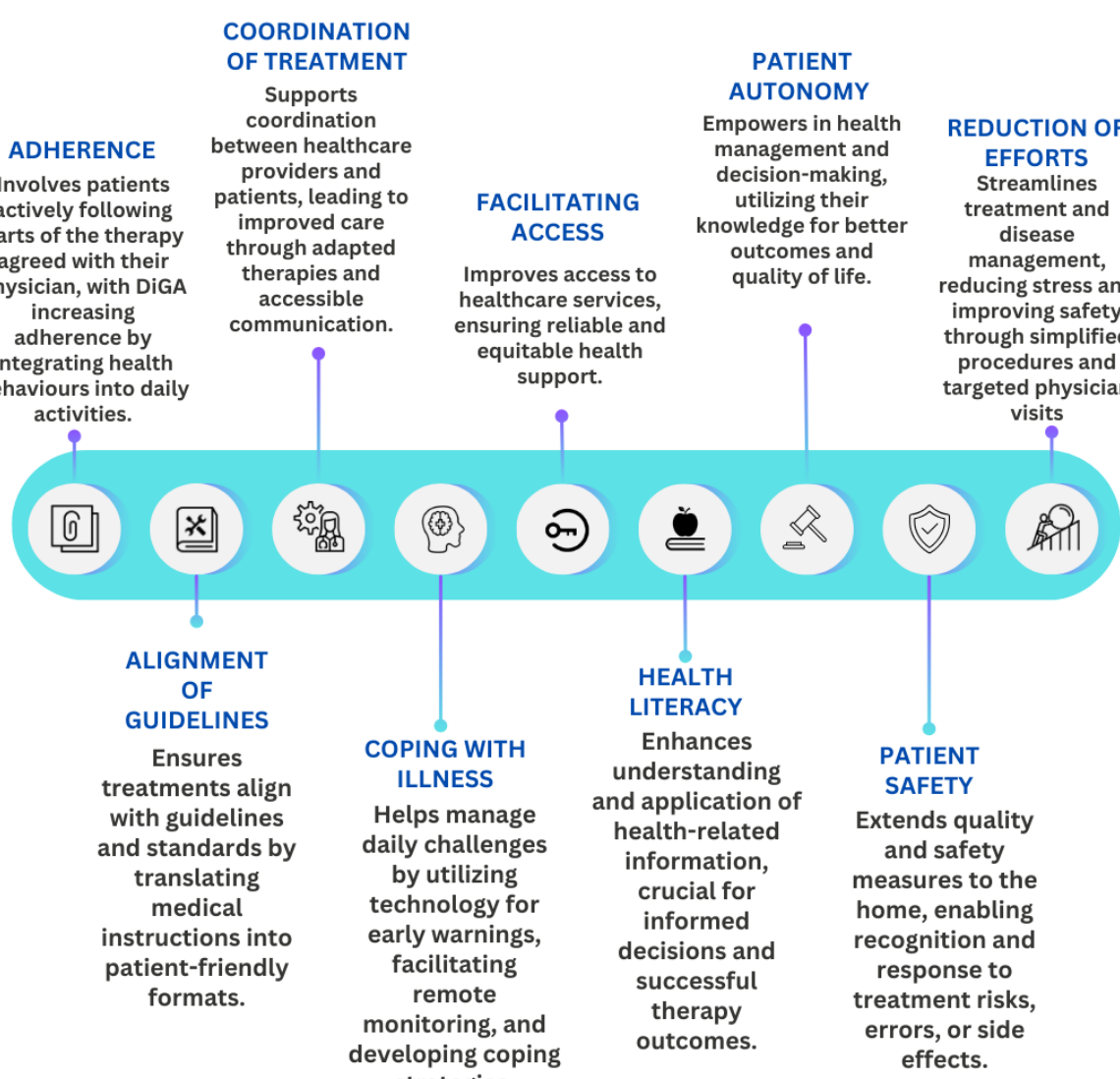
- How do **DiGAs** contribute to cost savings and efficiency improvements within the healthcare system across the **PSVV** domains?
- What indirect economic benefits are associated with **DiGAs** in the **PSVV** domains, and how do these benefits support long-term health outcomes?

Methods

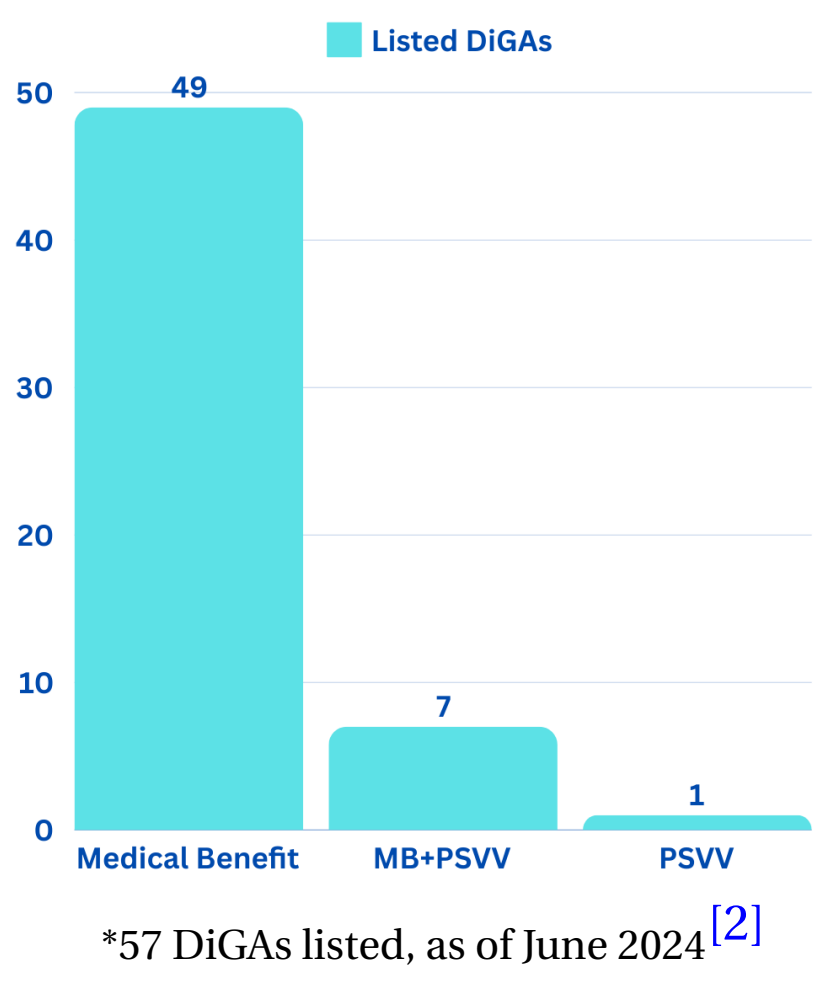
- Systematic Review**
We gather cost-impact estimates for each **PSVV** domain, identifying relevant benchmarks for cost reduction.
- Data**
We sourced demographic, epidemiological, and healthcare expenditure databases, specifically focusing on Germany.
- Estimation**
Used human capital and cost-of-illness methods to project **DiGAs**’ cost-saving potential.

Results

PSVV Domains



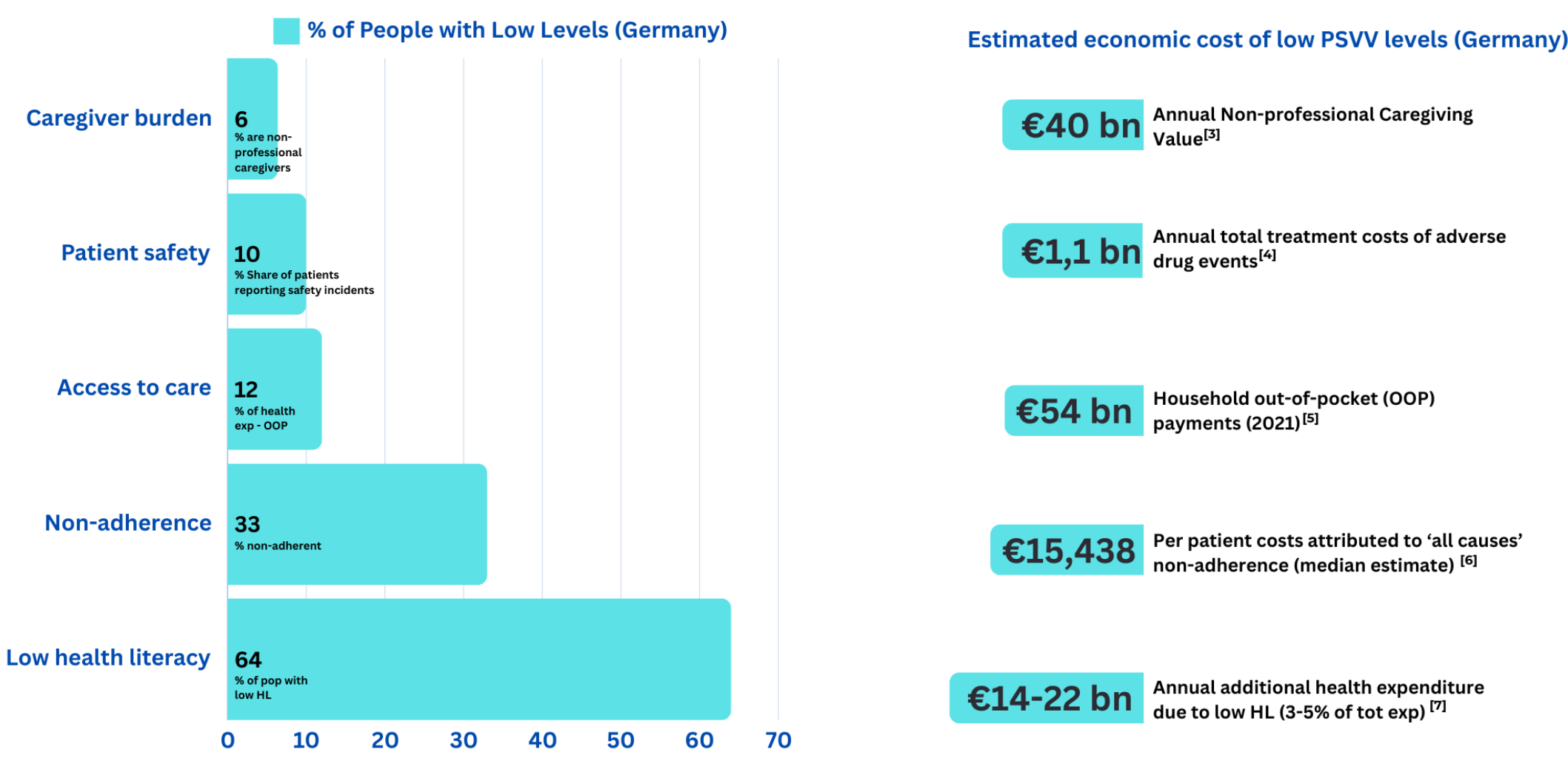
PSVVs in Current DiGAs



Measurement Hurdle

- Evaluation Framework:** Relatively new focus in digital health evaluation.
- Broad Domains:** Some domains are broad and multifaceted.
- Standardized Tools:** Validated measurement instruments are lacking for some.
- Evidence Generation:** Challenging to generate evidence → less clear path to reimbursement.

Estimated Impact of Low Levels in PSVV Domains



How DiGAs Help Reduce Costs

- Functional components:** **DiGAs** serve diagnostic, therapeutic, management & analytic purposes.
- Behavioral Nudges:** Modify patient actions via reminders and feedback.
- Risk Monitoring:** Track real-time health data → earlier detection, risk identification, minimizing emergency care.
- Administrative Streamlining:** Automate scheduling & documentation → reduce bureaucracy, optimize time, & reduce inefficiencies.
- Decision Support:** Guideline-based recommendations → improve patient safety.

Discussion

- The motivation behind adding **PSVVs** was to **empower patients** to become more active and informed, encourage shared decision-making, and promote health literacy.
- Lack of widespread understanding of **PSVVs** among stakeholders
 - PSVVs** are underutilized by **DiGA** applicants
 - Established methods for measuring **PSVV** outcomes are limited
 - Economic value of **PSVVs** not fully demonstrated

Broader Impact of PSVVs: Beyond cost savings, improving patient outcomes and healthcare equity.
Role of DiGAs: Scalable, data-driven solutions to enhance literacy, adherence, safety, and care coordination across key domains.
Economic Value: Significant cost reductions by targeting preventable complications and inefficiencies.
Future Directions: Policy support, reimbursement models, and continued evaluation of long-term benefits.

References

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