



Patient-Reported Outcome Measures – an International Comparison

Challenges and success strategies for the
implementation in Germany

Patient-Reported Outcome Measures – an International Comparison

Challenges and success strategies for the
implementation in Germany

Authors

Viktoria Steinbeck,
Sophie-Christin Ernst,
Dr. Christoph Pross
Technical University Berlin,
Department of Healthcare Management

Preface

Patients seek medical care trusting that their treatment will be successful. But whether and to what extent a treatment was indeed successful from a patient's point of view is often unknown. There is no systematic assessment of self-perceived treatment outcomes in Germany. Instead, the quality of outcomes is determined almost exclusively via clinical indicators or from administrative data. This means that a central building block for assessing quality in the German health care system is missing, both from an individual and a systemic perspective.

Patient Reported Outcome Measures (PROM) can fill this gap in the evaluation of medical success. They transfer a patient's perspective into an objectively measurable framework. With PROMs in the case of hip replacement surgery, patients are periodically asked to report on the surgery's outcomes regarding mobility or pain. The fundamental idea is that what really matters is the health-related quality of life: every medical intervention should ultimately contribute to improving or maintaining the patient's quality of life or to mitigating an impending deterioration.

On an individual level, PROMs can be used to adjust ongoing treatments. In addition, aggregated PRO-data allow future patients and their doctors a better consideration of possible treatment risks and potential health gains. On a systemic level, PROMs can contribute to more quality transparency and thus support internal and external quality assurance.

PROMs are already in use in many countries, both in singular initiatives and in systematic programmes. In the German healthcare system, a number of forward-looking initiatives have emerged in recent years in the private, scientific and public sectors. However, the German PROM landscape is fragmented, there is little coordination between stakeholders, and a supporting health policy framework is missing. Germany can learn from the experiences and success strategies of international role models and draw on numerous validated generic and disease-related PROM instruments.

This report presents the results of a study conducted by the Technical University of Berlin. It shows the state of PROM implementation in ten countries with regards to five overarching themes (status of implementation, forms of data use, key indication areas, challenges and success factors). We would like to take this opportunity to thank the authors, Viktoria Steinbeck, Sophie-Kristin Ernst and Dr Christoph Pross. They present valuable insights for policy makers, stakeholders and academia, which they have gained through in-depth interviews with 28 national and international experts as well as a systematic literature review. The authors are convinced that the international examples and experiences in using PROMs can inform and support the systematic implementation of PROMs in Germany.

With this international comparison of the implementation status of Patient Reported Outcomes, we at the Bertelsmann Stiftung would like to provide orientation and enrich the ongoing discussion about patient-centred healthcare in Germany.



A handwritten signature in black ink that reads "Brigitte Mohn".

Dr. Brigitte Mohn
Member of the
Executive Board



A handwritten signature in black ink that reads "Uwe Schwenk".

Uwe Schwenk
Director Program
Improving Healthcare –
Informing Patients

Content

Executive Summary	8
Key terms	12
1 Introduction	14
2 Methods	17
3 Results	18
3.1 Australia	19
3.2 Canada	24
3.3 Denmark	28
3.4 England	32
3.5 The Netherlands	38
3.6 Norway	42
3.7 Sweden	46
3.8 Switzerland	50
3.9 United States (of America)	55
3.10 Germany	59
4 Discussion	69
4.1 Common themes across countries	69
4.2 Challenges and success factors	74
4.3 Lessons learned for Germany	76
References	88
Appendix	98
Question guide	98
Interviewee List	99
Authors	100
Acknowledgements	101
Disclaimer	102
Imprint	103

Executive Summary

Introduction: Healthcare quality is predominantly assessed using clinical or process indicators such as blood pressure or mortality rates, with the patient perspective often missing. Patient-Reported Outcome Measures (PROMs) have been developed to measure a patient's subjectively perceived health status in an objective manner. PROMs have generated wide stakeholder interest globally, and several countries have implemented PROMs into their health systems to different degrees. In Germany, although some healthcare providers, payers and research projects have already initiated the use of PROMs, this was on a one-off basis and has not formalized into the healthcare system. There has been no extensive regional or national adoption of PROMs for individual use, e.g. to improve patient-physician interaction, or system-level use, e.g. research into the improvement of care quality.

To identify trends and common themes in introducing PROMs as well as success strategies for its implementation, this report looks at ten countries that have shown significant activity related to PROMs. Lessons learned can be translated into the German context to support a transition towards the greater use of patient-guided quality data and patient-informed feedback loops with providers for continuous improvement, and ultimately to ensure a more patient-centered approach to medical care.

Methods: Based on their PROMs activity level, ten countries were selected for deeper analysis: Australia, Canada, Denmark, England, the Netherlands, Norway, Sweden, Switzerland, the USA and Germany. To understand the diverse country contexts and their experiences with PROMs, interviews with 28 PROMs experts were held. Interviewees were chosen on the basis of their expertise regarding PROMs and their familiarity with the clinical and/or health policy aspects of the respective country either by active involvement in research or their professional commitment. A literature review was conducted and complemented with gray literature including policy reports. Findings are summarized in country profiles covering five overarching themes: 1. the level of PROMs implementation; 2. the forms of PRO-data utilization; 3. disease and treatment areas of focus, 4. challenges, and 5. success factors.

Results: The extent of the PRO-data utilization forms used, as well as the scope of PROMs coverage nationally, regionally or on a pilot level, differ widely across countries. How integrated PROMs are into a health system's quality assurance mechanisms and process is strongly determined by the general level of focus on the quality of care and outcome transparency a country has, as well as on the available infrastructure for data collection and sharing in the respective health system. While one country has already implemented a national PROMs approach (England), some, on the other hand, are implementing a regional PROMs strategy (e.g. Switzerland, Australia). Others again include PROMs in national disease registries (e.g. Sweden, Norway, Denmark, USA, the Netherlands) and in larger hospital networks (USA, the Netherlands). In Germany, in the meantime, the PROMs

landscape is currently dominated by individual or cross-provider pilot and research projects, with some recent payer pilot activity.

To develop best practice examples in their national contexts, all countries started with pilot and research projects, predominantly in the treatment areas of orthopedics and oncology, and frequently expanded them to chronic care initiatives afterwards. Over time, a mixture of bottom-up and top-down strategies evolved, with some countries showing more top-down initiatives than others, often depending on the level of health system centralization and political will. Some countries have achieved almost a national use of PROMs, such as the Netherlands, through a predominant bottom-up clinician-driven and voluntary strategy, whereas in other countries, such as Sweden, government institutions (top-down) were a driver for using PROMs and establishing public collection and reporting mechanisms.

Each country is at a different stage on its PROMs implementation, adoption and utilization journey. In those without a national PROMs framework (Australia, Germany, Switzerland, USA, Norway), PROMs utilization for more holistic patient monitoring and improved patient-physician communication in a shared decision-making process prevails. In countries with national registries that include PROMs or a national PROMs standard (Norway, Denmark, the Netherlands, Sweden, England, Canada), aggregated PRO-data is additionally used for external quality assurance and for generating evidence to identify the best practices. In countries with a regional or national framework or supporting infrastructure for PROMs (England, Denmark, Australia and Switzerland), standard question sets and a PRO-data collection infrastructure have been established, yet utilization of PRO-data remains challenging.

Discussion: Overall, similar challenges were faced by those trying to implement PROMs in daily clinical practice and on a wider scale. These challenges were recurrent in interviews and the literature and can be summarized as follows. Firstly, the selection of PROMs questionnaires and their patient focus, usability and comparability. Secondly, the varying perception of the value of and benefit from PROMs among stakeholders, particularly on the clinical side. Thirdly, high barriers to data collection and analysis due to lacking IT and digital health infrastructures and/or integration as well as data privacy regulations. Fourthly, lacking guidance, standardization and systematic best practice identification at a regional or national level; and lastly lacking political support and cooperation between different levels of government and providers. How country health systems and their stakeholders handled these challenges and the subsequent progress achieved in each country allows identification of the following six success factors: 1. level of patient focus, 2. existence of clinical champions, 3. standardization efforts, 4. IT infrastructure, 5. incentives, and 6. political will.

Status of and recommendations for Germany: In Germany, the absence of a national policy explicitly mandating the collection and utilization of PROMs currently coincides with a growing number of bottom-up initiatives with few stakeholders attempting to create alignment among each other. While several organizations such as Qualitätskliniken.de are exploring ways of introducing PROMs for nationwide quality assessment and public reporting for specific treatments, some hospitals are also testing the use of PROMs for clinical decision-making. Meanwhile, the “Hospital Care Structure Reform Act” of 2016 has introduced the option for insurers and hospitals to negotiate quality contracts, in part based on PROMs. Established programs today focus primarily on orthopedics and oncology. They can lead the way to a wider PROMs rollout, while other treatment areas, especially chronic care, can closely follow suit and utilize the lessons learned.

Based on the experiences of other countries, different utilization forms for PRO-data can be anticipated in Germany. To generate a direct benefit for patients and clinicians, the individual use of shared decision-making and its integration into the care pathway as clinical decision support should be primary utilization forms. However, to draw insights that can improve the quality of care over time, it is important that PRO-data facilitates benchmarking and research as well. With sufficient experience, research and a wider basis of trust, further utilization forms such as public reporting, wider selective contracting or pay-for-performance can follow. Piloting PROMs rollouts beyond individual providers on a regional level can generate additional lesson to be learned prior to a national scale-up. Looking forward, a balance needs to be achieved in Germany between a top-level support structure, on the one hand, that prevents fragmentation and over time will enable benchmarking to benefit patients nationwide and innovative bottom-up solutions, on the other hand, that best serve and are driven by healthcare professionals and patients.

Guided by six common success factors for implementing PROMs that emerged from this study, potential strategies and recommendations to aid different stakeholders in overcoming implementation hurdles in Germany, include:



Patient focus

PRO measurement, collection and reporting should involve patient representatives and commitment in patient societies, in the development of PROMs as well as the identification and scaling of best practices. Patients should have access to their own PROMs results to promote involvement and self-management and be able to share this data with their care network. Although, public reporting of PROMs is important for achieving transparency in the health sector over time, it should not be the first step in PROMs usage, as clinical trust needs to be established prior to this.



Clinical champions

Nationwide support and incentives for clinicians can increase the uptake across providers, such as a PROMs scholarship or dedicated research funds, national roundtables of clinicians sharing PROMs best practices, a curriculum for PROMs training of medical staff and dedicated conferences, and online portals to identify, highlight and spread best practices.



Standardization

A nationwide standard for a common PROMs questionnaire framework can provide guidance on common sections and questionnaires; a multi-stakeholder, national expert body can support guideline development and guide implementation and best practice identification.



IT infrastructure

An open, common and basic national health IT infrastructure as well as standards for interoperability, data governance and clinical use should be established to offer support and guidance for the integration, scaling and implementation of digital health and in particular apps for PROMs collection and use in clinical practice. PROMs initiatives should influence the possibilities of digital health tools for the collection, data integration, automatic analyses and use by patients and providers in a more reliable and efficient manner relative to paper-based PROMs collection.



Incentives

In a first stage, financial support should incentivize the collection and use of PROMs by providers without being tied to the outcomes achieved. In a second step, additional incentives can include certificates/excellence labels for providers assessing and reporting PRO-data as well as incentives for patients to fill out PROMs. In a third step, selective contracts and payment systems connected to outcome quality should be adjusted and expanded based on emerging evidence, practical insights into the utility of first selective contracts and the involvement of a variety of stakeholders.



Political will

A combined top-down and bottom-up approach is vital as well as large-scale pilots to identify and scale best practices and establish an at-scale proof of concept in the German context, creating political traction and health system focus. A supportive top-down framework includes components such as standardization, allocation of financial resources and establishment of incentives as well as an independent body auditing the results and a bottom-up-approach commitment of clinical champions and providers to integrate PROMs in clinical practice.

Key terms

AMNOG **Act on the Reform of the Market for Medicinal Products** (Arzneimittelmarktneuordnungsgesetz): a 2010 German act that revised pricing regulations for and the reimbursement of new medicinal products. In accordance with the act, pharmaceutical companies are required to submit a dossier that proves an added benefit for patients when they launch a product with new active ingredients onto market. The G-BA and the IQWiG conduct the benefit assessment

CROMs **Clinician-reported outcome measures**: tools for assessing patient outcomes based on objective or subjective data evaluated by healthcare professionals

DeQS-RL **Guideline for data-supported quality assurance across institutions** (Richtlinie zur datengeschützten einrichtungübergreifenden Qualitätssicherung): a German policy introducing patient surveys to assess the quality of care for designated procedures and disease areas as part of the mandatory external quality assurance procedures. The guideline will come into effect in 2021

EHR/ePA **Electronic health record** (elektronische Patientenakte): a digital and cross-institutional version of a patient's health record. An EHR system describes the infrastructure that enables the electronic collection of patient data

G-BA **Federal Joint Committee** (Gemeinsamer Bundesausschuss): a German public legal entity comprising the four umbrella organizations of the self-governing bodies of payers and providers in the German healthcare system. The G-BA is the highest decision-making body of the joint self-government and issues directives that are legally binding for all actors in the statutory health insurance system. It is under the supervision of the Ministry of Health

ICHOM **International Consortium for Health Outcomes Measurement**: an international nonprofit organization developing global standard sets of PROMs for various conditions

Innovation fund (Innovationsfond): a German innovation fund managed by the G-BA and funded by the statutory health insurance providers and by health insurance contributions that allocates funding to projects in two areas: health services research and innovative care models

IQM **Initiative Quality Medicine** (Initiative Qualitätsmedizin): an initiative launched by hospitals and hospital groups in 2008 aiming to improve the quality of diagnostics and patient care through outcome measurement, public reporting, and continuous improvement measures

IQTIG Institute for Quality Assurance and Transparency in Healthcare (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen): an independent German scientific institute established in 2015 to work by order of the G-BA on cross-sectoral quality assurance and transparency measures

IQWiG Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen): an independent German institute established in 2004 to support the G-BA by offering scientific recommendations and performing benefit and cost-effectiveness assessments

PARIS Patient-reported Indicator Surveys: an OECD initiative to advance and standardize the international monitoring of PROMs and to conduct an international survey of people living with chronic conditions using PROMs and PREMs

PEQ Patients' experience questionnaire: an initiative of the Bertelsmann Stiftung and Weisse Liste to measure patient experience during a hospital stay. Data is collected together with statutory health insurance funds, predominantly the AOK (Allgemeine Ortskrankenkassen) – a system of regional sickness funds – and BARMER making it the largest patient satisfaction survey in Europe

PREMs Patient-reported experience measures: tools for assessing healthcare experiences from the patient's perspective

PRO Patient-reported outcome: a health outcome directly reported by the patient

PROMs Patient-reported outcome measures: tools for assessing health outcomes from the patient's perspective. In this report, PROMs do not only refer to outcomes assessed at the end or after completion of a treatment, but to the continuous assessment of a patient's subjectively perceived status of health and functionality along the care pathway including before treatment. PROMs belong to the broader category of Patient Reported Indicators.

PROMIS Patient-Reported Outcomes Measurement Information System: an initiative established in 2004 with funding from the US National Institute of Health to develop and validate PROMs sets for use in clinical research and routine care

QSR Quality assurance with routine data (Qualitätssicherung mit Routinedaten): an initiative of the WiDo (Wissenschaftliches Institut der AOK) – the research institute of the AOK sickness fund – to measure clinical outcome quality using routine hospital data

Quality contracts (Qualitätsverträge): exclusive quality contracts between health insurance providers and hospitals in accordance with the German Hospital Care Structure Reform Act of 2016. The aim is to test new incentive models to improve the quality of inpatient care. The IQTIG is entrusted with evaluating the success of the quality contracts

SDM Shared Decision Making: Shared decision making (SDM) is a process in which clinicians and other health professionals and patients work together to select tests, treatments, or procedures, based on clinical evidence and the patient's informed preferences

VBHC Value-based healthcare: a concept that encompasses all healthcare models in which patient value is at the center of the care delivery system and payments to providers are based on patient health outcomes

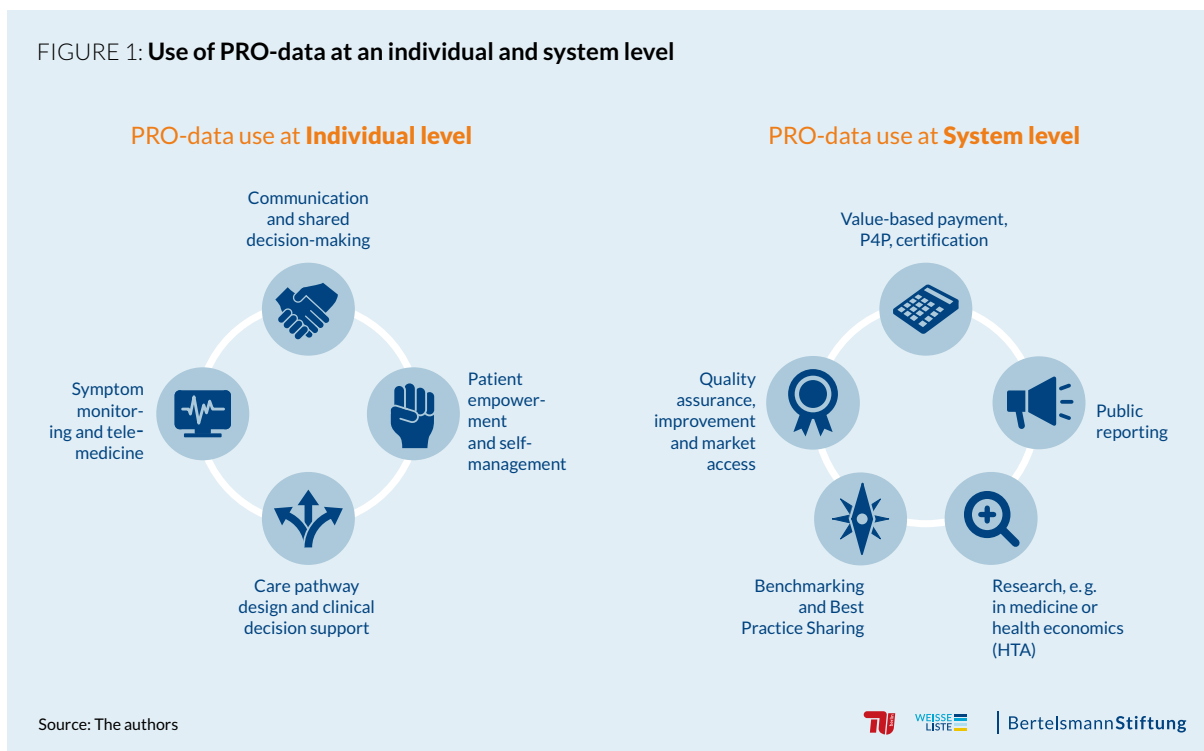
1 Introduction

Healthcare should theoretically improve what matters most to patients, their psycho-physical wellbeing and ability to perform everyday tasks. However, the actual attainment of this objective has not been measured historically. In the past, the metrics, results and success of medical care have predominantly been defined and measured using clinical parameters such as tumor growth, blood pressure, mortality rate or other indicators. A systematic assessment of how patients perceive their own health status before, during and after medical treatment is generally lacking in routine care. To address this lack of involvement of those at the center of healthcare, i.e. patients, in the definition, design and assessment of its success, Patient-Reported Outcomes (PROs) questionnaires have been developed. These aim to objectively measure a patient's own subjectively-perceived health status over time to complement Clinician-Reported Outcomes (CROs). PROMs can be seen as part of the broader category of Patient Reported Indicators and in this report are referred to as outcome measures which can be continuously measured before and along the care pathway. Patient Reported Outcome Measures (PROMs), the tools to assess PROs, help patients to self-assess their quality of life, daily functioning and symptom severity, in relation to a specific disease and their overall health status. Well-designed PROMs are valid, reliable and responsive (Wells, G.A. et al, 2011).

A multitude of applications exist for PROMs and many different ways in which they can advance care improvement (see Figure 1). On an individual level, PRO-data can help create a more holistic representation of the impact an illness or a medical treatment has on a patient's experienced health status and thus support routine care. PROMs collected along the care pathway may reveal changes in a patient's quality of life or symptom severity that would otherwise have been missed, e.g. because of limited time or a lack of follow-ups. Identifying these changes in time and feeding the information back to clinicians can improve symptom monitoring, enhance patient-physician communication personalized healthcare, and support clinical and shared decision-making. For instance, a study from the US has shown that the integration of PROMs into the routine care of cancer patients led to the earlier identification of critical care pathways, which allowed the possibility of scheduling earlier follow-ups, thereby improving patients' overall survival rates (Basch, E. et al., 2017). Two systematic reviews from the field of oncology have further shown that routine PROMs collection and feedback facilitated patient-physician communication and led to better pain management and a reduction in pain intensity (Yang, L.Y. et al., 2017, Adam, R. et al., 2016). PRO-data helps involve patients and empowers them to take charge of their own care, for instance by self-managing their illness (Mejdahl, C.T. et al., 2018). Finally, it can be used for AI-based decision support.

On a system level, the various types of PRO-data use range from public reporting to supporting patients' choice to medical and health policy research. In addition to the strong unwarranted clinical outcome variation that has been identified in recent years in many

FIGURE 1: Use of PRO-data at an individual and system level



countries and treatment areas, PROMs at scale further facilitates detecting and addressing variation in the quality of care from a patient perspective (Pross, C., Geissler, A, Busse, R., 2017). The design of care pathway adjustments and comparisons is also possible based on PROMs benchmarking. PRO-data analysis can further inform quality assurance strategies across providers or in specific disease areas or care units. Although still rarely used internationally, the option of value-based payment models partially based on PRO-data is another form of applying PRO-data. The use of PROMs for benchmarking and payment models requires a combination of this type of data with CROMs to support risk-adjustment which enables fairer comparisons.

PROMs have generated wide stakeholder interest globally, and several countries have implemented PROMs into their health systems to different degrees. In 2017, the OECD set out recommendations to strengthen the international comparison of health system performance through PROMs. The International Consortium for Health Outcomes Measurement (ICHOM) has so far published outcome measurement standardsets including PROMs and CROMs. These are developed by panels of experts and patient representatives in relevant fields. Additionally, the Patient-Reported Outcomes Measurement Information System (PROMIS) is an initiative for the improvement and standardization of the self-reported physical, psychological and social health of patients in the form of PRO-data. Internationally, PROMs have experienced growing utilization in recent years, with initiatives ranging from pilots and research projects to implementation at national scale in countries such as England, the Netherlands and Denmark.

In Germany, healthcare quality is currently recorded primarily via a mandatory quality assurance system on clinical process and outcome parameters and ICD-10-classified morbidity, length of stay and readmission rate for hospital care. Some additional large-scale stakeholder initiatives record clinical outcome quality via hospital or administrative data (e.g. QSR and IQM). In addition, some sickness funds measure patient experience

during their hospital stay (e.g. patient satisfaction survey PEQ by Weisse Liste with BARMER and AOK). However, PROMs are gaining considerable attention, particularly in the field of oncology and orthopedics. Various pilot and research projects have been completed or are currently being conducted. Several projects focusing on PROMs use at an individual provider level as well as across providers, such as PRO-B in the area of breast cancer (led by Charité Berlin), or across providers and institutions as is the case of PROMoting Quality in the area of joint replacement (led by Technical University Berlin) receive funding through the G-BA Innovation Fund. Moreover, the G-BA announced an additional funding round for research specifically targeted at PROMs and PREMs in October 2020. Organizations already involved in the quality assessment of providers and public reporting at national scale such as Initiative Qualitätsmedizin und Qualitätskliniken.de are also exploring ways to introduce PROMs. In February 2021, Initiative Qualitätsmedizin (IQM) signed a framework agreement with a German IT-provider for large-scale collection of PROMs, enabling nationwide and cross-state quality benchmarking. Furthermore, a policy enacted as part of the “Hospital Care Structure Reform Act” (Krankenhausstrukturgesetz, 2016) has created the option of negotiating exclusive quality contracts between health insurance companies and hospitals, in part based on PROMs. The aim is to test how agreements on higher quality targets and incentives could drive further improvements in inpatient care. In four service areas, contractual partners can decide on the quality instruments – including indicator results or results of patient surveys – and incentive models.

The IQTIG (National Institute for Quality and Transparency in Healthcare), established by the German federal government in 2015 and entrusted with the advancement of quality measurement in healthcare and the transparency of results for all stakeholders, developed a first policy for patient surveys in designated indication areas as part of quality assurance, including questions for PROMs and PREMs (DeQS-RL). The DeQS-RL takes effect in 2021 as a guideline for data-based quality assurance and a first attempt to introduce PROMs into routine care, at national scale. However, PROMs will be collected only from a small fraction of all patients within the selected treatment areas and utilisation of PROMs within this framework will be limited to external quality assurance DeQS-SL is a step in the right direction, but the current underdevelopment and fragmentation of the PROMs landscape within Germany, a lack of standardization and large-scale comparability and the emerging demand for guidance on PROMs implementation necessitate an international comparative analysis of PROMs adoption and possible lessons for Germany. Already in 2019, the German health minister, Jens Spahn, called for a discussion about the definition of the quality of care looking at international examples of quality measurements (Deutsches Ärzteblatt, 2019).

To identify the further potential for PROMs implementation in Germany and learn from the way different countries have implemented PROMs so far, an international comparative analysis of PROMs adoption in 10 countries has been conducted based on expert interviews, a literature review and an online search to identify barriers and facilitating factors for the successful implementation of PROMs (see guiding questions below). This is of particular interest due to the dynamic development in this field throughout the last 5-10 years.

Guiding questions for this report:

- » What trends can be characterized based on the recent PROMs development and dynamics in different countries?
- » How can successful strategies identified for PROMs implementation be translated to the German context to provide better patient-centered, data-driven care?

2 Methods

This report compiles PROMs country profiles based on expert interviews, review of academic and gray literature and online research. It outlines implications of the international findings for Germany to initiate a dialog on how PROMs can be best used for the benefit of patients and to inform and improve the care practice within the German healthcare system.

Based on their prominent activity in the PROMs arena, the following countries were selected for this review: Australia, Canada, Denmark, England, the Netherlands, Norway, Sweden, Switzerland and the USA. Selecting countries that are among the most advanced in terms of PROMs implementation allows the authors to draw conclusions based on existing projects, implementation strategies and lessons learned from real experiences. For each country, the authors conducted 2-3 semi-structured interviews between August and October 2020 with academic, regulatory and/or clinical experts (Appendix I), following a predetermined question guide (Appendix II). The authors aimed at addressing both the practical implementation perspective (by interviewing an expert from a clinical setting) and the political viewpoint (by including an expert from the country's health policy environment). Core topics discussed in the interview were the level of implementation across medical indications, the form of PROMs utilization, stakeholders and driving forces as well as the political framework and anticipated trends. The authors engaged experts both at the start of the country analysis to understand the respective countries' PROMs status and critical elements of PROMs implementation, as well as at later points in the study to review and comment on finalized country profiles and the recommendations derived for Germany. Each country profile also includes two summary boxes for quick reference information, on the one hand about the country's use of and approach to PROMs, and on the other hand to present the challenges to implementation and factors for success.

In addition to the interviews, a literature review was conducted to capture PROMs initiatives, policy frameworks and registries in the nine countries. The PubMed and Medline search strategy included terms such as "PROMs", "PROs", and "value-based healthcare" linked with the terms „registries", "policy", "implementation", "public health", "hospital" and "healthcare" and the respective country names. In addition, the authors investigated gray literature (e.g. reports, documentations, and press releases) found on the websites of the relevant portals and agencies. The report includes literature from 2010 onward, with a stronger emphasis on more recent material to account for the rapidly changing policy environment, new PROMs initiatives being implemented and the subsequently evolving expert positions concerning this topic. The country experts also shared literature from their own as well as from other countries and international comparisons. The interview results were challenged and broadened based on the PROMs expertise that the TU Berlin team has built up in the past years, based both on academic research projects as well as the PROMs implementation and best practice identification as part of the PROMoting Quality Project, of which the TU Berlin is the consortium leader.

3 Results

The following country profiles reflect how, in the context of different national healthcare systems, PROMs are implemented and utilized in different ways for different reasons, from aiming to improve the patient-physician interaction to public reporting. Across countries, PROMs are often applied in similar disease and treatment areas. Countries either use a predominantly bottom-up, a predominantly top-down or a mixed implementation style. The large amount of pilot projects, registry initiatives, state-level or national movements reveal challenges in the implementation of PROMs at various levels. Similarly, elements for success and projects were identified that show a promising direction of continuous improvement to evolve towards more patient-centered care and improvement in the quality of care. There is as yet no clear, widely recognised policy angle for PROMs, but several policy trends and lessons learned can be identified.

The extent and depth of PROMs as well as the scope and coverage of use differ widely by country and are strongly determined by the general focus on quality and outcomes as well as data collection and data-sharing infrastructure in a respective health system. Thus, the experience reported by country experts and reflected in the literature reveals that countries are at different stages in the PROMs implementation cycle. For example, whereas Denmark already has a national agency responsible for PROMs questionnaire standardization and Canada a national institute collecting and managing health system data, other countries are challenged by a lack of standardization and common data infrastructure. Countries approached widening the scale of implementation differently, but common themes for scaling up PROMs could be identified. All countries started with pilot and research projects to create best practice examples for their national context. These often took place within the treatment areas orthopedics or oncology. Some countries are still following this approach and have achieved an almost national use of PROMs, such as in the Netherlands, through a predominantly bottom-up clinician-driven strategy. In other countries, such as Sweden, government institutes were a driver for the use of PROMs by establishing public collection and reporting mechanisms for PROMs.



3.1 Australia

PROMS APPROACH

- » **Level of implementation:** Mainly bottom-up pilot projects but also state-wide implementation in NSW
- » **Disease and treatment areas:** cancer, hip and knee replacement, rheumatology, chronic conditions, mental health
- » **Use for:** research, service improvement, benchmarking, shared decision-making
- » **Key challenges:** IT infrastructure, divide between federal and state level

Australia has a universal public health insurance scheme called Medicare that provides mandatory health service coverage. It is financed through general tax and a government levy. Half of Australians purchase supplementary private insurance that is incentivized by the government. The fiscal responsibility over Medicare and the regulation of private health insurance lies with the federal government. The actual organization of healthcare services in public and private clinics, however, takes place on a state level, in six states and two territories. Besides federal funds, states contribute their own funding to sustain and improve health services. Lastly, local governments are in charge of community health and preventive health programs (Commonwealth Fund, 2020a and Australian Government, Department of Health, 2020).

In Australia, there were 38.4 hospital beds per 10.000 inhabitants in the year 2016, a 5% decrease from the year 2000 (WHO, 2020). Overall, there are currently 693 public hospitals with a total of 61,647 beds and 657 private hospitals with 34,300 beds (Commonwealth Fund, 2020a). The government provides 41% of public hospital funding and 24% of private hospital funding. The National Health Performance Authority reports on hospital performance in terms of effectiveness, efficiency and equity measures.

3.1.1 PROMs Implementation

A public healthcare reform in 2010–2014 invested 7.8 billion Australian dollars (4.8 billion €) in various improvement strategies, primarily to enhance accountability and performance (Australian Government Department of Health, 2011). A central reform element was the Performance and Accountability Framework, which aimed at improving quality of care, enhancing patients' choice and creating quality transparency via public reporting. PROMs were not yet included. The first Australian Atlas on Healthcare Variation in 2015 recommended research into the role of PROMs to identify low-value care (ACSQHC, 2016a). Following this recommendation, the Australian Commission on Safety and Quality in Healthcare commissioned a scoping review to map the existing PROMs landscape throughout Australia. Its goal was to gain information about an appropriate role the government could play in supporting the consistent and routine use of PROMs at national level. Following the publication more and more programs emerged, and e.g. a wider use of digital PROMs collection was observable according to PROMs expert Melissa Tinsley at the Agency for Clinical Innovation (ACI) in New South Wales (NSW).

As of today, the national role in PROMs is not yet observable. However, on a state level there is more development, with one frontrunner in terms of a state-based system being New South Wales (NSW). Nationally, although various organizations are interested in



PROMs, the development, collection and utilization is currently fragmented and inconsistent. Pilot projects exist in the private and public hospital sector, some are paper-based, and others use online questionnaires with a trend towards more digital collection. The organizations most frequently engaged in the development and implementation of PROMs are academic institutions or research centers in collaboration with clinicians and university-based clinical registries, e.g. Monash Clinical Registries (ACSQHC, 2016b). Moreover, some PROMs projects in Australia are implemented across hospitals nationwide, such as in the AOANJRR project consisting of 45 hospitals across the country collecting PROMs data in the field of joint replacement (AOANJRR, 2020).

In some states or territories, PROMs are higher on the political agenda than in others. In NSW, a state-based PROMs program focusing on integrated care was launched in 2014 (NSW Government, 2020a). Starting with 4 pilot sites initially, the program grew continuously and is now covering 25 disease areas in different provider settings from primary care to hospital care (Interview: Melissa Tinsley). In the past year, the ACI, leading the PROMs program in NSW, co-developed an IT platform in cooperation with a private provider to provide more functions for clinicians, service management level and patients alike. In a co-design process involving patients, physicians and supporting staff, program aspects and IT functions were continually taken into consideration for readjustment. The rollout of the new IT system is planned for the beginning of 2021. Other states which are commencing a PROMs program are South Australia, Victoria, Northern Territory, Western Australia and lastly Queensland. In the latter, the data collection commenced in September 2020.

3.1.2 Disease and treatment areas of focus

In NSW different treatment areas are covered in the state-based value-based healthcare programs “Leading Better Value Care”, which are collecting PREMs and PROMs. The first ones, which were implemented from 2017 – 2018, are osteoarthritis, osteoporosis, chronic heart failure, chronic obstructive pulmonary disease, diabetes mellitus, diabetes high-risk foot care service, falls in hospitals and renal supportive care (NSW Government, 2020b). From 2019 – 2020 the following initiatives were added: hip fracture care, wound management, bronchiolitis, hypofractionated radiotherapy for breast cancer and direct access colonoscopy. In the future, additional treatment areas are planned to be added continuously, including neonatal and maternal care, drug and alcohol-related care and mental health.

Moreover, various disease areas are currently covered by pilot PROMs projects; the most prominent ones are oncology, hip and knee replacement, rheumatology, mental health and chronic diseases. The PromptCare project focusing on oncology in NSW is gaining national attention due to its successful implementation and continuous learning. Additionally, since 2012 the Flinders Medical Centre has been using the BREAST Q PROMs questionnaire for plastic and breast reconstructive surgery and the Australian Mental Health Outcomes and Classification Network (AMHOCN) has implemented the MHQ-14 to record symptoms of fatigue, anxiety and depression. Registries that collect PROMs data currently exist for joint replacement, prostate cancer, rheumatology, lung cancer, breast cancer, dementia and pain.



3.1.3 Forms of data utilization

PROMs are used in various ways throughout Australia, for benchmarking, research, service improvement and to support patient-physician interactions.

There are several well-established consortia in Australia that provide leadership on benchmarking. For example, government-funded entities such as the Palliative Care Outcomes Collaboration (PCOC), the electronic Persistent Pain Outcomes Collaboration (ePPOC) and the Australian Rehabilitation Outcomes Centre (AROC) provide patient outcome reports to participating clinical services on a six-monthly basis that facilitate comparison with state/territory and national benchmarks. The clinicians receive a comparative analysis of their outcomes regularly on a clinical level. Benchmarking workshops are held every six months to increase understanding of how clinicians can use outcome data to drive quality improvement. The data collected by clinical registries such as the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) is further used for peer-review, quality assurance and research (ACSQHC, 2020). Some registries allow participating clinicians to audit their patient outcomes, anonymously comparing results with other clinicians. Researchers can also apply for access to specific data sets (ACSQHC, 2016a).

The state-based PROMs program in NSW encourages PRO-data use in real time by clinicians to provide information for patient-physician interaction and treatment decisions. Moreover, improvement cycles are implemented on a provider level in which data is continuously reevaluated and care adjustments are made based on the PRO-data. This process is supported by the ACI, e.g. through training programs. State-wide public reporting is not currently taking place.

Across Australia, PROMs are increasingly being used at the level of individual healthcare organizations to support clinical practice and patient-centered care in pilot projects. For instance, in the Flinders Medical Centre (FMC) aggregated data from the PROMs questionnaire BREAST-Q are used to give patients insights into the differences in long-term patient satisfaction and wellbeing associated with various clinical procedures, thus enabling informed choices (ACSQHC, 2020). PRO-data is further collected to demonstrate the clinical effectiveness of the breast reconstruction clinic to both internal and external stakeholders. Some organizations also provide advice and training about the use and implementation of PROMs (e.g. AHOC; ISOQOL Australian Special Interest Group).

3.1.4 Challenges in the implementation of PROMs

A primary challenge is the cooperation between state, territory and federal government to ensure that the financial means for a common electronic recording infrastructure are available across Australia. With four different health IT systems currently being used throughout the country, the integration, collection and public reporting of PROMs is not feasible on a national level. State-based efforts to create new IT structures have been delayed in NSW, but a private-public-partnership has emerged to combat the functional deficiencies of the previous system. In addition, there is a fragmentation of registries which is not yet interoperable with EHRs. Currently, the financial means of the health sector are limited, especially due to recent widespread fires and the COVID-19 pandemic. Simultaneously, however, the COVID-19 pandemic has highlighted the need for more investments into remote consultations and the use of self-reported measures by patients.



Various challenges were faced at the start of the PROMs program to integrate PROMs along the care continuum in NSW. Initially there was resistance from clinicians as they perceived PROMs as unhelpful, too complex and time-consuming. Moreover, clinicians reported about lacking expertise on how to talk to patients about the results of their PROMs assessment. A further hurdle was demonstrated by the lack of interoperability and transparency of data between provider types. Primary care providers are funded differently than hospitals, making the transparency between systems especially hard to achieve.

Beyond the macro-level challenges of cooperation among stakeholders, inadequate or nonexistent IT infrastructure and limited financing, additional challenges exist at a clinical level. These include the selection of appropriate measurement instruments as well as designing and choosing appropriate systems to collect, store, process and report data efficiently, securely and accurately. For reporting purposes, a core challenge is the development of sophisticated methods of risk-adjustment to ensure fair comparisons among providers.

Furthermore, language, cultural and health literacy barriers challenge a broad patient participation in PROMs collection, according to PROMs expert, Prof. Delaney, Director of Cancer Services at the South Western Sydney Clinical School. Moreover, due to the separate use of PROMs questionnaires for different diseases and multiple providers, patients with multimorbidities or those needing to see various professionals for one disease can be faced with a large number of repetitive questionnaires. Hence, coordination and integration of PROMs systems is highly recommended. In addition, most pilot projects currently take place in a clinical setting, leading to general practitioners (GPs) not having been involved in its implementation or follow-up. This is now being addressed in NSW by integrating PROMs in community healthcare services such as GP practices, hospitals and rehabilitation centers, but other states and territories are yet to follow.

3.1.5 Success factors

According to the Australian Commission on Safety and Quality in Healthcare (2018), a successful implementation of PROMs initiatives relies on equitable access for all consumers, minimizing disruptions to the clinical workflow, and maximizing data quality and relevance. Various pilot projects also reported the commitment of clinical and non-clinical staff to be a main facilitator for successful PROMs implementation together with a long-running partnership with a registry (BreastQ, AOANJRR). A sentiment analysis showed that most healthcare professionals regard PROMs as neutral, but identified the following aspects as facilitating factors for successful implementation in routine clinical practice: how PROMs fit into an existing practice, how PROMs are valued, capacity to respond to PROMs and the support in place (Easpaig, B. N. G. et al., 2020).

The integrated care strategy which commenced in 2014 in NSW is a frontrunner in terms of PROMs implementation in Australia. The strategy's three key enablers are: PROMs, risk stratification and digital technologies. In focus groups with patients, healthcare professionals and administrative staff, core aspects for a successful PROMs implementation were identified. These included the importance of real-time data that is presented in an intuitive way to inform about immediate care adjustments. Patients reported that the general quality of life questionnaires were more important to them as they felt less associated with their disease characteristics, favoring their overall wellbeing and mental health aspects to be addressed. PROMs questionnaires were validated over an 18-month period and translated into different languages. Investing in a co-design process up front was



reported as especially relevant to ensure long-term commitment from all sides according to Melissa Tinsley, Manager Clinical Information and Decision Support at ACI. This enables the successful launch at four proof-of-concept sites, starting with the implementation in NSW. In addition, capability programs were introduced to train and educate healthcare professionals. Based on the stakeholder feedback, more functionalities will be added in the new IT solution being implemented in the beginning of 2021, including the access to disease self-management information for patients, the possibility for carers to log into the system for patients and the access to longitudinal data across different providers.

Successful projects that have generated national interest include the PromptCare project. It was initially designed, developed and tested in South Western Sydney and Illawarra in NSW, before then being adopted by the NSW Cancer Institute as their statewide solution to PROMs collection in oncology. PROMs answers are directly shown to medical staff on an online interface so that they can easily identify critical aspects in their patient's wellbeing. One of the leading researchers in this field Prof. Delaney is spreading the message in other states to advocate the benefit of a common IT data infrastructure and the practical use on a clinical level. A recent study by Girgis and Delaney (2020) integrating the PromptCare system into clinical workflows has highlighted the following success factors. Firstly, an automation of alerts to review patients who have passed a predefined PRO-threshold. Secondly, the important role of nurses in managing those alerts, and finally to provide resources for self-management to patients.

Another success story is the Arthroplasty Clinical Outcomes Registry (ACORN), a multisite initiative set up to monitor, evaluate and report on clinical outcomes and PROMs for knee and hip arthroplasty in a standardized fashion. Included questionnaires were EQ-5D, and Oxford Knee and Hip, together with clinical data and broader satisfaction questions. On this data basis, the registry produced and delivered comprehensive reports of patient outcomes to prospective surgical patients, surgeons and the hospital departments of participating institutions (ACORN, 2014). It allowed risk-adjusted comparisons between surgeons and institutions.

Several challenges have been identified in the Australian context regarding PROMs implementation, but strategies also emerged from the discussion with experts and literature that could help overcome these hurdles.

Implementation challenges	Success factors
PROMs implementation in the clinical sector is fragmented	<ul style="list-style-type: none"> » Involvement of various stakeholders to advocate the benefits of PROMs and the need for national financial support » Educate GPs on the use of PROMs and the value it adds for patients and physicians » An enhanced federal government role in steering policy, funding, co-ordination and performance monitoring (OECD recommendation) » Champions who promote the use of PROMs in hospitals
PROMs questionnaires: too many questions, replication for patients with comorbidities, too general	<ul style="list-style-type: none"> » Disease-specific PROMs, suitable questionnaire selection » Centers should determine thresholds for clinical action for each PRO in collaboration with clinicians to set realistic thresholds and develop recommendations which consider the availability of existing services and resources in a clear, concise and manageable way, based on evidence-based guidelines (Girgis, A. et al. 2019)



Way of collection and timeliness of data: Follow-up rates are low for paper-based questionnaires	» Digital PROMs collection led to higher response rates for follow-ups » The Centre for Advances in Epidemiology and Information Technology develops a web-based 'real-time' IT platform (DiscoverQuick) for health outcomes monitoring and assessment.
Low Health Literacy/ Language & cultural barriers	» An app that provides questions in different languages /culturally adjusted and has voice recognition prompts overcoming poor literacy skills (PromptCare)
IT infrastructure: Separate IT systems, IT systems developed by the state are delayed and do not fulfil new technology standards	» Private public partnerships to build IT tools for PROMs collection and data sharing » Financing top-down from the federal level to adjust IT infrastructure in the different states

3.2 Canada

PROMS APPROACH

- » **Level of implementation:** Mix of top-down and bottom-up: predominantly bottom-up and province-based implementation
- » **Disease and treatment areas:** focus on elective surgeries and chronic diseases, national standard for hip and knee replacement.
- » **Use for:** performance monitoring, research, shared decision-making
- » **Key challenge:** implementation in the provider setting due to IT integration and manpower needed, government commitment for PROMs implementation varies across provinces

Canada has a universal healthcare system for all citizens via Canadian Medicare and two-thirds of the population have supplementary private insurance. Health insurances are publicly administered and funded separately in the 13 provinces and territories leading to varying service coverage. The federal government supports the provinces and territories financially on a per-capita basis. Other than that, the province and territory governments have the core responsibility for financing, organizing, and delivering Medicare programs as well as for quality assurance of the self-governing providers (Commonwealth Fund, 2020b).

Hospitals are mostly public nonprofit organizations. Private hospitals are, however, more common in the province of Ontario. According to the Canadian Institute for Health Information (CIHI), an independent, non-profit organization that provides essential data on Canada's health system and the health of Canadians, 91,325 operating hospital beds exist throughout Canada (CIHI, 2019a). According to the WHO (2020) there are 25.2 hospital beds per 10.000 inhabitants, a 33% decrease from 2000. Hospitals are mostly managed by delegated health authorities or hospital boards representing the community.



3.2.1 PROMs Implementation

Canada is in the process of establishing nationwide standards for the collection of PROMs in certain disease areas; however, these are only at the start of being rolled out in some states. The central organization promoting and establishing the national PROMs standards is the CIHI. As the main responsibility for healthcare lies with the provinces and territories, CIHI can give recommendations but not establish a national mandate. In 2013–2014, CIHI conducted an environmental scan of the Canadian and international PROMs landscape. The analysis showed that, while there are some regional-level PROMs initiatives in Canada, a standardized program for routine PRO-data collection and reporting does not exist. The need for PROMs information to support a range of healthcare goals has been identified as a high priority, including at the October 2014 Consensus Conference co-hosted by CIHI and Statistics Canada (CIHI, 2015). In 2015, a pan-Canadian PROMs Forum was hosted by CIHI to identify opportunities for the standardization of PROMs collection and reporting, which resulted in the recommendation to establish a pan-Canadian PROMs program. To advance this idea, an advisory group with stakeholders from jurisdictions, researchers and health professionals has been set up. Consequently, disease specific working groups as well as one to establish generic PROMs tools have been established (CIHI, 2017). So far, a national standard has been established for hip and knee replacement and was published in 2019. “The Patient-Reported Outcome Measures Data Collection Manual: Hip and Knee Arthroplasty standards” were first implemented in Ontario. In collaboration with the CIHI, a Quality-Based Procurement Program is being piloted and PROMs data is currently being collected. This was made possible due to the commitment and financing of the province Ontario (CIHI, 2019b).

The national effort for standardization builds upon the fact that PROMs have been widely used in various initiatives, registries, in clinical trials and in other research settings, at a province and provider level. Alberta and British Columbia have advanced towards establishing full province-based PROMs programs. These provinces have invested in centralized data collection as well as in the integration of PROMs into EHRs. Whereas some states have seen a more widescale implementation of PROMs, there are still observable PROMs developments in other provinces as well. In Quebec, for instance, quality of life indicators are being used to measure program effectiveness and for pain and symptom management in cancer and palliative care. The Canadian Organ Replacement Registry (CORR) carried out an exploratory project collecting PROMs for renal dialysis, but have no ongoing PROMs collection for the registry. Moreover, diverse research projects use PROMs, for instance the Canadian Multi-center Osteoporosis Study, which already started using PROMs in 1995 (CAMOS, 2020).

3.2.2 Disease and treatment areas of focus

Various disease and treatment areas are covered across national, regional and pilot level projects. A CIHI PROMs standard set exists for hip and knee replacement and is planned for chronic kidney disease (CIHI, 2018). With these treatment areas being the most advanced in terms of PROMs implementation, CIHI is also chairing the International Hip and Knee Replacement Surgery Working Group of the Patient Reported Indicator Survey (PaRis) survey by the OECD. Moreover, according to a comparative study by Lunney, M. et al. (2019) on kidney care services, PROMs are already measured in most (51% - 75%) hemodialysis centers in Canada, but in few (1% - 10%) peritoneal dialysis centers, and no centers measure and report PROMs on transplantation.



At province level, the Registry Cancer Care Ontario collects data on psychological stress across oncology centers in Ontario (ACSQHC, 2016b). Other projects cover chronic diseases such as kidney failure (Northern Alberta Renal Program) or knee arthroplasty (PEAK Project) (University Hospital Foundation, 2020, CIHI, 2015). The RESIO project moreover covers various elective surgeries, including prostatectomy, hysterectomy, cholecystectomy, lumbar discectomy and cataract surgery. In Alberta, it is planned to expand the routine collection and use of PROMs for cardiovascular disease, chronic obstructive pulmonary disease and primary healthcare with a focus on chronic diseases.

3.2.3 Form of data utilization

The ways PRO-data is utilized varies strongly by province and provider setting. In Alberta, PROMs are, for instance, used in annual reporting, performance monitoring, benchmarking and the province's annual population health survey (Alberta Government, 2020). Since 2016 primary care networks have incorporated PROMs into their accountability frameworks as performance indicators and have directly integrated it into the workflow. In 2015 a PROMs and EQ-5D Research and Support Unit (APERSU) was built to coordinate and support the use of the EQ-5D questionnaire. In British Columbia, a study with 5,000 patients was conducted that evaluated the advantages and cost-effectiveness of PROMs in routine care (RESIO Project: Regional Evaluation of Surgical Indications and Outcomes) (Mcgrail, K. et al., 2011). Some states are experimenting with digitalized data collection, but paper-based collection is still more common.

Moreover, there are local, regional and provider-level PROMs programs, but their use of PROMs in routine care varies. For instance, in one of the smaller provinces, Manitoba, PROMs data in hip and knee replacement is reported back to physicians to improve shared decision-making. Based on the initial use of PROMs in Manitoba, in 2019 the Provincial Patient-Reported Measurement Strategy Advisory Committee was convened to help advance the collection, analysis and use of PROMs and PREMs in Manitoba (Centre for Healthcare Innovation, 2020). Thus, a wider more standardized use is anticipated.

As the collection of PROMs by CIHI based on common standards is just being rolled out for hip and knee replacement in Ontario, PRO-data has not yet been utilized or shared at national level. Currently aggregated data is returned to the ministry of health and private reports are sent to individual data providers and hospitals in Ontario. Once more provinces have joined, the reporting could evolve to include comparative provincial reporting.

3.2.4 Challenges

The large variation between implementation levels across Canada means that different provinces are facing different barriers in the implementation of PROMs. In Alberta, British Columbia, Ontario and Manitoba, a strong government push for PROMs collection and utilization can be observed, especially for hip and knee arthroplasty. Some other provinces and territories lack a similar governmental commitment to centralize data collection and provide additional resources for providers to collect and utilize PROMs. In some cases, this commitment exists for other treatment areas, such as in primary care (Saskatchewan), and in some provinces there is no observable push for centralized PRO-data collection. The CIHI has reported a common interest in collecting across provinces, which now needs to be translated into regional practical action.

The collection and use of PROMs at a provider level have been described as challenging by experts, especially when it comes to the follow-up with patients if they are not in the provider setting. The often paper-based collection of PROMs complicates the collection of PRO-data. Moreover, as each provider often has a different electronic health record (EHR) system, data integration and comparison between different facilities is hardly possible. Province and territory-level standards to make the integration of PROMs in EHR possible and thereby facilitate their use are often lacking. Differing priorities, budgets and infrastructures create additional challenges.

3.2.5 Success factors

The collection and use of hip and knee replacement PROMs data is a frontrunner in Canada, due to strong support from the clinical community, existing scientific evidence of pain, function and quality of life improvements, a high prevalence and comparative international programs. The lessons learned after implementing the 'Patient-Reported Outcome Measures Data Collection Manual: Hip and Knee Arthroplasty set standards' that could be used in the rollout in other disease areas. Chronic renal care and organ transplantation are anticipated to be the next area for common national standards.

Recommendation by the RESIO research team for a continuous successful implementation of PROMs include starting on a small-scale in coordinated experiments on the care of chronic conditions and convening a pan-Canadian working group to help coordinate and organize these activities (Mcgrail, K. et al., 2011). The CIHI has already focused on hip and knee replacement, chronic kidney disease and a general standard questionnaire; additional ones will be continuously added to expand the scope of implementation.

A drive for centralization by province governments is described to make Ontario, Alberta and British Columbia the leading provinces in the use of clinical and PROMs data at the moment according to Nicole de Guia, PROMs expert at the CIHI. Having even established a form of data integration, these provinces' success stories can encourage effective implementation across the country.

Implementation challenges	Success factors
IT infrastructure different per provider	<ul style="list-style-type: none"> » Centralized data collection and data infrastructure at province level supported by province government (e.g. Alberta) » Financial support by province government for provider IT infrastructure (e.g. tablets in Ontario for the implementation of hip and knee replacement PROMs)
Actual implementation in the provider setting is complicated by low response rates, lack of data integration and lacking manpower	<ul style="list-style-type: none"> » The integration of patient information/caregivers' information in the EHR could not only facilitate targeted digital follow-up but also facilitate the use of the comprehensive information by staff and the CIHI » Financial support should not only target the IT infrastructure but also financial means for additional staff





3.3 Denmark

PROMS APPROACH

- » **Level of implementation:** Top-down recommendations and infrastructure, national PROMs recommendations and support organization
- » **Disease and treatment areas:** chronic diseases, orthopaedics, cancer, mental health
- » **Use for:** outcome improvement, patient remote monitoring, reporting to quality registries, (P4P)
- » **Key challenge:** tracking and on-site support of PRO implementation, cross-sector PROMs implementation

Denmark provides universal coverage, free and equal access to public healthcare for its citizens (Commonwealth Fund, 2019c). The public healthcare system is primarily tax-funded and organized in two main sectors: The primary healthcare and the hospital sector for specialized treatment, with general practitioners often having a gatekeeper function between those two: For specialist treatment except for cases of acute illness or accidents, patients need a referral from their GP. The Danish healthcare system is run and organized across three levels: The State, the Danish Regions and the 98 Municipalities. At state level, the national governments provide the regulatory framework for all health services. It is responsible for the general planning and monitoring of care quality, collecting of taxes and allocation of funding to regions and municipalities which play key roles in delivering health services.

The five Danish regions plan and deliver specialized healthcare services as well as social care. The regions own and manage public hospitals and enter into contracts with GPs, dentists and other specialists in the private practice sector. The Municipalities are responsible for a broad range of health services including home care, general rehabilitation, public health and prevention.

Almost all hospitals are publicly owned. There are only a few, small private hospitals providing predominantly specialty care including elective surgery. In 2019, the country had 26 hospital beds per 10.000 inhabitants, which represents a 39% decrease from the year 2000 because of a major reorganization of the hospital system (WHO, 2020).

3.3.1 PROMs Implementation

Quality of care and patient safety have been high on the agenda of Danish governments for more than two decades and an array of national guidelines and programs have led to the implementation of PROMs at regional or national scale in selected disease areas.

In 2005, the Danish Institute for Quality and Accreditation (IKAS) was founded as part of the Danish Healthcare Quality Program (DDKM) and given the responsibility for establishing and organizing the Danish provider accreditation system (Commonwealth Fund, 2020c). In 2015, however, the Ministry of Health decided to end the program to focus on quality improvement rather than on quality control. A new scheme, The National Quality Program was implemented: It demands the sharing of best practices across sectors and regions, the timely implementation of best clinical practice and systematic work with real-time data as well as with leaders driving improvement.

In parallel, the Transparency Reform, a political agreement part of the financial agreement (“Mere borger, mindre patient” – “More citizen, less patient”) with the regions in 2013 was introduced to promote the vision of “Better healthcare through better use of data” (Ministeriet for Sundhed og Forebyggelse, 2013). Its triple aim is to achieve 1. Increased cost effectiveness, 2. Improved patient-experienced quality and 3. Improved health for the Danish population. The agreement supports better practice and knowledge-sharing, relevant and better documentation and improved data-sharing across sectors (Lauritsen, 2017).

In 2016, the National Quality Program was followed by the Danish Value-based Healthcare Initiative. It comprises several tracks with the goal of increasing the value of care with a focus on patients and allocating resources more wisely (Danske Regioner, 2016). To explore opportunities of shifting to VBHC, seven treatment sites were selected for trials. By 2017, all five Danish regions had implemented or decided to implement elements of VBHC at a departmental, hospital or regional level to explore effects on patient outcomes and costs. Moreover, an IT solution to systemize and present data is to be developed and tested in a comprehensible and operational way, using both PROMs and clinician-reported outcome measures (CROMs) for hospital management and clinicians.

Through the financial agreement between the state, regions and municipalities of 2017, Denmark further committed itself to PROMs at national scale: A steering group was established to support the standardization and broad application of PROMs across all healthcare sectors (PRO Secretariat, 2019). The steering group (consisting of members of the Ministry of Health, the Danish Regions, Local Government Denmark, The Danish Health Data Authority, The Danish Health Authority and the association of Danish Patients) was given the responsibility of developing standardized PRO questionnaires, developing guidelines and promoting the sharing of knowledge on the use of PRO-data in clinical practice and quality assurance. The committee is supported by the PRO Secretariat and located in the Danish Health Data Authority. Under guidance of the PRO Secretariat, clinical coordination groups representing all relevant stakeholders, including patients, are developing standardized questionnaires and protocols for nationwide use. In the course of 3–5 workshops, the group first identifies when and how it would be beneficial to integrate PROMs into a care pathway. The group then develops the questionnaire for a disease area based on clinical experience, patient insights and, if available, validated questionnaires. Established questionnaires are tested on two levels: Patients test for comprehensibility and meaningfulness, whereas health professionals test whether the questionnaire and associated algorithms support their clinical practice as intended. In addition, an IT infrastructure to facilitate the sharing and comparing of data across sectors was set up. Furthermore, questionnaires are made accessible through a national questionnaire bank. Providers can download individual questionnaires and integrate them into their local electronic health record system.

3.3.2 Disease and treatment areas of focus

In Denmark, the number of disease areas in which PROMs are collected at national scale has been growing over the last five to ten years. The seven areas which were selected for trials as part of the Danish Value-Based Healthcare Initiative included, among others, diabetes, anxiety and depression, prostate cancer and epilepsy (Skovlund, S. and Ejsskjær, N., n. d.). The work of the PRO Secretariat focussing on the areas of apoplexy, knee and hip osteoarthritis, as well as early detection of depression started in 2017 (PRO Secretariat, 2019). In the subsequent years, PROMs questionnaires and recommendations for their





implementation in daily practice were developed for diabetes, heart rehabilitation, pregnancy and maternity, and later for psoriasis and palliative care. So far, standardized PROs for knee & hip arthrosis have been developed, tested and released for nationwide use. Other national PROs are currently in pilot testing and will be released for all regions and communities. Areas for PRO development addressed by the work of the steering committee and PRO Secretariat were in part defined based on ongoing value-based healthcare pilots at Danish hospitals. PROMs in the field of cancer care has been addressed by Danish researchers such as Prof. Helle Pappot (Pappot & Taarnhøj, 2020) and has been implemented at provider level for some types of cancer.

Disease or indication areas for which PRO-data is also transmitted to the Danish Clinical Quality Program – National Clinical Registries (RKKP) include urology, rheumatoid arthritis, palliative care, bariatric surgery, spinal surgery, shoulder arthroplasty and cardiac rehabilitation. PROMs collection in these areas is predominantly paper-based. Results are entered manually by physicians in a separate IT-system, which serves exclusively the purpose of transmitting the PRO-data to RKKP. New areas for PROMs on a system level include hip and knee surgery, prostate cancer, bladder cancer, sarcoma and palliative care. In contrast to the current process, PROMs for these areas will be entered into an IT-system by the patients directly, used as a part of the patient treatment in the clinical setting and transferred directly to RKKP through the national IT infrastructure.

3.3.3 Form of data utilization

PRO-data is used at different levels in Denmark. At an individual level, PRO-data is used to improve patient-physician communication (e.g. to put more emphasis on the patient's needs during consultations) and to support shared decision-making. Moreover, PRO-data is applied in remote monitoring as a decision aid for identifying outpatients in need of more clinical attention. For instance, PROMs has been used in the field of epilepsy treatment since 2011 in the Central Denmark Region (Schougaard, L.M.V. et al., 2016). There, PRO-data from a questionnaire (including the WHO-5 Well-Being Index, items from the Short-Form 36 and the Symptom Checklist 92) are completed by outpatients, and PROMs results are used by health professionals to decide whether a patient needs to be seen at an outpatient clinic based on an algorithm. This solution has been extended to other disease areas: AmbuFlex, a solution for telehealth that uses PROMs as a basis for the follow-up of patients with chronic diseases first established in 2004, is applied today within 28 different groups of chronic and malignant illnesses (Hjollund, 2019). While at the beginning of AmbuFlex projects were predominantly registry-based, epidemiologic cohort studies, from 2015 onwards the use of PRO-data for clinical use at the individual patient's level took over. Similarly, direct use of PROMs in the care process is perceived as the primary purpose of other PROMs collection systems. Other purposes such as quality assurance and research are considered secondary.

Hence, at system level, aggregated PRO-data is used for provider-level, internal and external quality assurance only in some disease areas. In these areas, PRO-data is reported to the RKKP, where data can be made available for research or be used to promote improvement of the overall quality of patient treatment in Danish hospitals and medical practices (RKKP, n.d.). The process of data collection, reporting and discussion of results can be visualized as a system of Plan-Do-Study-Act (PDSA) cycles: Data collected in the registries is analyzed by epidemiologists and discussed in multidisciplinary in the national steering groups and regional audits. These audits also determine indicators and standards for good

clinical practice. They issue recommendations that are reported back to clinical personnel and management for improvement and also released to the public to ensure transparency and accountability. RKKP supplies feedback to management and clinical staff on at least a monthly basis. In a yearly report for each of the registries, the steering group comments on every quality indicator and if necessary issues recommendations. Each region can subsequently use audits to analyze data from their region only that is made available through monthly reports from RKKP to regional business intelligence units. One of the advantages of the RKKP system is a strong anchoring of each clinical quality registry in clinical practice through the professional board.

Currently about 8 % of the quality registries, for instance the rheumatology registry, are already including PROMs in their indicator set. Standard sets are designed by the multi-disciplinary boards which, in an increasing number of registries, are complemented by two patient representatives to promote stronger patient orientation. Currently, educational programs for patients who are eligible for this position are being run.

Based on first experiences with registries including PROMs directly transferred from patients to registries, changes were made to the process of PRO collection and reporting: Collection of PRO-data is now managed by clinical staff in order to make reported outcomes requiring medical attention actionable. Variables of the PRO-dataset are now transferred into the registries simultaneously or subsequently. RKKP also promotes stronger commitment of clinical staff in improving the quality of care as a reaction to monthly reports. Furthermore, RKKP acts as a counterpart for public and private stakeholders who would like to use part of the data for research purposes. For instance, life science industrial players can apply and be provided access to requested data by RKKP if their application meets the criteria. This option is frequently used due to the high-quality data Denmark has to offer.

3.3.4 Challenges

A main challenge concerns the fragmented IT infrastructure in the country, as not all regions have the same quality of IT systems and not all communities have an established PRO system to work with. A further challenge concerning the cross-sectorial use of PROMs is to find hospitals and communities that are willing to participate and have sufficient patient overlap to be able to follow patients across the care pathway, from the hospital to rehabilitation. Moreover, the PRO Secretariat develops and tests PRO questionnaires but has currently no capacities for tracking and accompanying the implementation of established PROMs recommendations at provider sites. Since there is no legislation mandating its use, PROMs is used in all regions to varying degrees, and implementation depends on the commitment of individual providers or health professionals.

3.3.5 Success factors

Denmark has been successful in developing recommendations for nationwide PROMs in a number of indications and providing an IT infrastructure for PRO-data collection in some of its regions.

To establish PRO questionnaires and recommendations for implementation, the PRO Secretariat follows a participatory approach involving all actors in the process. Strong



involvement of both patients and physicians ensures relevance and applicability in clinical settings. Initially, workshops are conducted with patients only to identify their needs. Results of these workshops are used to guide subsequent ones with clinicians and PROMs researchers as well as representatives of the respective quality registries if possible. After a questionnaire is developed, it is piloted in different settings for approximately 6 months, and feedback is collected before it is made available for nationwide use. For instance, PRO questionnaires for hip and knee osteoarthritis have been successfully tested and released for nationwide use. Validated PRO questionnaires can be downloaded and administered via electronic health records, and results can be seen and used by the patient. In the Capital Region and in the region of Zealand PROMs are very well integrated in the e-health systems.

Implementation challenges	Success factors
PROMs implementation in the clinical sector depends on commitment and preferences of individual providers	<ul style="list-style-type: none"> » First identifying the need for PROMs in a specific area from a patient and clinician perspective » Providing guidelines for PROMs implementation and supporting integration into clinical pathways » Decreasing barriers for implementation (e.g. providing tools and infrastructure for PROMs) » Leaving room for the commitment of clinical staff and involving both patients and clinicians in the design of questionnaires
Cross-sector PROMs: Testing and implementation of PRO questionnaires in cross-sector care delivery remains difficult	<ul style="list-style-type: none"> » Common IT infrastructure to facilitate follow-up and increase the connectivity of sectors
IT infrastructure and integration of PROMs in EMR across regions varies	<ul style="list-style-type: none"> » Two regions (Capital Region and Zealand) have integrated PROMs in their e-health systems, lowering the administrative burden » AmbuFlex: PROMs as tools for telemedicine / remote monitoring of patients to trigger intervention if necessary

3.4 England

PROMS APPROACH

- » **Level of implementation:** Top-down implementation but also bottom-up initiatives and registries
- » **Disease and treatment areas:** hip and knee replacement focus
- » **Use for:** public reporting, research, quality improvement
- » **Key challenge:** public trust, utilization and integration in clinical care, resource allocation, data interoperability, IT infrastructure

England – where 80 % of the United Kingdom’s population live – has a national tax-funded healthcare system called the National Health Service (NHS). Responsibility for health policy rests with the UK Parliament and the Department of Health. Day-to-day responsibility for the NHS lies with NHS England, a government-funded body that is separated from the Department of Health. The Care Quality Commission ensures that government-set safety and quality standards are met by providers.

Hospitals are mostly public and either organized by NHS trusts accountable to the Department of Health or as foundation trusts regulated by NHS Improvement. The number of public hospital beds was continually reduced in the past years to 141,000 in 2019, which translates to 21.1 beds per 10,000 inhabitants: an approximately 40% reduction from the year 2000 (WHO, 2020). Independent sector providers (ISPs) cover a small part of health services with a bed count of ca. 8,900 beds, but have provided an increasing share of certain elective surgeries, such as hip replacements, hernia repairs and cataract procedures (Stoye, 2019). In addition, private hospital beds exist within NHS hospitals and amount to 1140 (Commonwealth Fund, 2020d).

3.4.1 PROMs Implementation

The Stafford Hospital scandal in 2007, in which preventable high mortality rates were observed, has led to demands for stricter quality controls of healthcare providers. Since then, the Care Quality Commission has started individual inspections in clinics throughout the country. These have now been reduced to give more room to alternative strategies such as improved quality reporting mechanisms that enable value-based healthcare including PROMs. As outlined in the NHS Long Term Plan in 2019, the NHS now aims at making better use of data and digital technology, in particular to enhance integrated care.

The Department of Health introduced the mandatory collection of PROMs for four surgical procedures: hip and knee replacement, groin-hernia and varicose vein treatment in 2009. Thereby, England was the first country to globally implement mandatory PROMs monitoring at national level. The implementation was step-wise, starting with pre-operative measures and adding post-operative data the year after. NHS England took over responsibility for the national PROMs program from the Department of Health in April 2013 and decides on the medical conditions included and the questionnaires used for the assessment. A separate entity, NHS Digital, is appointed to analyze and publish the national PROMs data on their website. Generally, PROMs are collected by private contractors on paper and consequently computerized as well as transferred to NHS Digital by the supplier on a monthly basis.

Providers such as NHS trusts can be certified to collect PROMs data themselves or to contract with an accredited PROMs supplier. Since PROMs reporting is mandatory for hip and knee replacement surgery, all providers, both public and independent, are obliged to collect the PROMs of eligible patients and report their information to NHS Digital. It is voluntary for patients to complete these forms and NHS Digital only publishes case mix-adjusted health gain data for organizations that have a representative number of completed records.

Beyond the national level implementation of PROMs reporting for specified diseases, PROMs are used in various pilot research projects and care provider networks, also in additional disease areas as well as national registries. Although there is interest in PROMs utilization in various provider settings, the political momentum which led to national PROMs implementation in 2009 has faded to some degree and more bottom-up initiatives are observable. Additional political actions on PROMs were complicated by a continuously changing health system infrastructure and changing responsibilities in England.



3.4.2 Disease and treatment areas of focus

The disease areas for which PROMs have been nationally recorded in England since 2009 comprise hip and knee replacement, groin-hernia and varicose vein treatment. Following a consultation of experts by NHS England in 2016, the collection of the latter two procedures was discontinued in October 2017 (NHS England, 2017). Arguments were that varicose veins do not occur frequently and are usually not a cause of major patient debility. For groin-hernia surgery, the lack of condition-specific PROMs combined with the fact that surgery reduces the risk of requiring emergency care rather than relieving symptoms were reasons for the discontinuation.

As part of the 2016 expert consultation, two main clinical areas for future PROMs collection were identified as particularly relevant: cancer and chronic conditions. Although mentioned less frequently, other identified disease profiles include trauma, diabetes, mental health and coronary/vascular diseases.

In addition to NHS England, other organizations have launched projects to measure PROMs for other disease areas. There are, for instance, efforts by the National Cancer Registration and Analysis Service to link routinely measured data with PROMs. Another example is the PROMs collection for rheumatoid arthritis care by the British Society for Rheumatology and the integration of PROMs questionnaires for mental health services at King's Health Partners London.

3.4.3 Form of data utilization

A main form of PROMs utilization at the moment is public reporting and data monitoring via NHS Digital. PROMs national-level headline data are published every month with more detailed data made available each quarter. The published data is provisional until a full year. The PROMs report is published in February every year. Data is shown in various forms such as in a mapping tool, an interactive dashboard and reports.

The nationally reported information was used for benchmarking, quality assurance and improvement purposes by the responsible trusts and private providers. For instance, Northumbria NHS Foundation trust identified reasons for lower-than-average health gains in hip and knee replacement surgery and has since commissioned various studies and adjusted its procedures accordingly. One of those improvement strategies was to make PROMs available locally at surgeon level. Moreover, surgery procedures were adjusted in PDSA cycles to improve the quality of care, and hence PROMs outcomes (Partridge, T. et al., 2016). The NHS Partners Network of independent sector providers (private providers) analyzed the health gain data published by NHS Digital for the time period April 2016 to March 2017 (published March 2018). The average adjusted health gain on PROMs e.g. Oxford knee score was slightly higher for independent providers who are now providing information about quality improvement assessments in the public sector (IHPN, 2019). The accuracy of this direct comparison is, however, affected by the differences between patient groups who go to public providers and those who visit private providers.

Various providers and provider networks are utilizing PROMs in additional treatment areas to inform clinical and shared decision-making such as Kings Health Partners London, where different PROMs were integrated into the mental health program. In an initial trial the aim was to identify how PROMs can be best benefit service users and clinical teams and enable continuous improvement and education for multi-professional teams.

Moreover, PROMs are being collected by registries, such as the National Joint Registry (NJR) which started the PROMs program for shoulder surgery in 2017 with a three-year follow-up having been introduced in 2019. NJR is moreover provided with the information by NHS Digital, merges information and contracts Northgate Public Services to send surgeon-specific reports back to surgeons undertaking hip and knee replacements. In 2018, it was agreed to establish a dedicated NJR PROMs working group, and it is planned to work with NHS Digital to merge data and access surgeon-level information to enhance quality improvement options. Other registries exist, such as the UK bone and joint infection registry tracking PROMs performance over many years, with an aspiration to learn which treatment pathways work best for patients.

A separate platform called NHS Choices enabled an online comparison of healthcare providers according to PROMs for selected procedures. Informing patient choice through a comparison portal was continued, but the PROMs criterion has been taken out of the criteria list. However, in a fragmented way hospital data including PROMs is published at a provider level online. Due to the fragmented nature of the data, comparability of providers by patients is, however, not facilitated.

Research projects into various aspects of PROMs collection and use are taking place throughout England. Moreover, various trusts collect large amounts of PROMs data across different specialties, e.g. at Northumbria trust, where PROMs are collected for 80 different procedures and used to inform individual patient care and the reporting to registries. The collaboration for leadership in applied health research Oxford is looking into developing a new questionnaire for long-term conditions and multi-morbidities and the Wellcome Trust is evaluating how to involve patients in the use of their data in a meaningful way.

In addition, outcome-based payment strategies are implemented for hip and knee replacement in England, i.e. hospitals currently lose ten percent of their income if they do not comply with certain criteria and perform less than 3 standard deviations of the national average. Criteria include a 50% PROMs participation rate, a minimum NJR compliance rate of 85%, use of cemented or hybrid prostheses for at least 80% of patients and an unknown consent rate below 15%.

3.4.4 Challenges

Within the UK and globally, England was the first mover for a national mandatorily implemented PROMs reporting system. The top-down approach did not directly translate into a high use at the provider level for service improvement. Experts have questioned whether the national mandate was implemented in the right way to keep innovation power going in the development, implementation and use of PROMs (NHS England 2017). Hence, discussions are ongoing on the system aspects which require improvement. Adjustments to the national approach have been hampered by the continuous reorganization and responsibility shift of health system actors in England. This has made it difficult to keep up the political movement to improve and expand the PROMs program. Moreover, the expert consultation in 2016 presented many hurdles to successful PROMs utilization which might have slowed down the initial political excitement and the will to make this topic a priority.

Although being perceived as already quite advanced when it comes to data interoperability, due to the centralization of the health care system, data interoperability was reported as a core challenge for successful PRO-data use for the maximum benefit of patients. This



includes the data sharing between hospitals and primary care providers and the use of data from NHS England in the provider setting and in relation to registry data. NHS England currently provides data in a CSV file, which the hospital needs to link to their local patient data in a lengthy and complicated process to make it usable.

While the potential of PROMs to improve healthcare quality is perceived as highly valuable, the current anonymous, slow and paper based national data collection does not facilitate the timely clinical-level use of PROMs (NHS England, 2017). Furthermore, experts such as Tom Foley from NHS Digital and those involved in the NHS consultation question as to whether the current PROMs dashboard shows what providers and patients actually need to improve care. Difficulties in access and interpretation accompany questions on how to act upon the reported data. This is partly due to a missing level of detail and the delayed reporting of full data sets. The identification of a problem's root cause is hence hardly possible via the PROMs reporting and needs to take place in consequent separate studies. Due to an initial delay in publishing the complete PROMs data, the information does not necessarily reflect the clinical reality at the time of publication. Following the expert consultation in 2016, some adjustments have already been implemented, such as shorter reporting timelines, but a variety of hurdles still needs to be addressed. Besides these concerns raised in the expert consultation, the national standards were still a positive driver for provider-level collection of the data and coincided with bottom up initiatives that evaluated PROMs use in the clinical care pathway, especially for hip and knee replacement.

In terms of the questionnaires themselves, the paper-based collection has been reported as a hurdle to achieving high participation rates, especially for the follow-up questionnaire which patients have to fill out at home. The EQ-5D was seen as too generic for informing clinicians or presenting a measure of clinical performance. Some experts criticized the amount of questions and the difficulties for some patients to understand and fill out the questionnaire because of low health literacy, language or cultural barriers (NHS England, 2017).

3.4.5 Success factors

Main success factors reported by experts for the implementation of PROMs in different forms were continuous clinical leadership mixed with a national and regional policy enabling coherence and supporting the provider-level collection and use of PRO-data as well as forming public trust in the data system and financial incentives.

Based on past experiences in England, the national hip and knee surgery PROMs collection was generally considered a success with some room for adjustment. The high disease prevalence and successful examples of using the resulting data were stated as reasons why the national PROMs scheme was continued by NHS England in 2017. Examples include improved surgical treatment (NHS Northumbria), improved care pathways (Circle Bath Hospital), informed patient choice (NHS Vale of York) and adjusted rehabilitation services (Barnsley Hospital NHS Foundation Trust). In the near future, likely developments include the expansion of the disease areas of focus from hip and knee replacement surgery to cancer and chronic conditions and a digitalization of the recording process. Various providers are experimenting with the digitalization of PROMs collection and use. Pilot projects such as the HealthUnlocked tracker at Royal National Orthopaedic Stanmore are being tested as online PROMs tools to analyze PROMs and overall treatment success on the platform. The platform shows data in graphs to physicians and patients alike. In the Neighboring country

Wales a wide spectrum of bottom-up and national PROMs initiatives is observable as part of the “prudent healthcare movement”, which potentially provides inspiration for England’s further PROMs approach.

According to Joseph Casey, leader of the VBHC program at King’s Health Partners London, a core component for enabling digitalization and data interoperability is building knowledge and trust in the public, including due to previous unsuccessful attempts in England in this regard. Prof. Mike Reed at Northumbria Healthcare NHS Foundation Trust states that the financial incentives for the collection and target PROMs-level achievement has been especially helpful in encouraging PROMs collection and quality readjustments across providers. Simultaneously, a trend towards a more regional organization of the healthcare system following examples in Scotland and Wales and a move to accountable care organization models are observable. To build upon success stories from pilot projects and the use of PROMs data on hip and knee replacement, enhancing local-level ownership and improving the usability of data are assumed core goals in England to maximize the use of PROMs for the benefit of patients. Additional success strategies have been summarized below.

Implementation challenges	Success factors
Using PROMs for care improvement: provider-level usage varies highly and is generally low	<ul style="list-style-type: none"> » Local interests should drive the national program, e.g. by creating greater local ownership of the collection, enabling immediate access to their own data before allowing it to be collated nationally » NHS England agreed to work with NHS Digital to make the national PROMs data easier to use and to provide a range of automated outputs that are tailored to the needs of stakeholders
PROMs as measure: Not enough detail to identify the cause of problems or identify problems that are actually relevant to patients	<ul style="list-style-type: none"> » A newer approach named Patient-Centred Outcome Measures (PCOMs) – a system to allow patients and their families/carers to identify, describe, prioritize and monitor their own health problems, and the impact this has on their quality of life – has been explored at 7 sites across England » A narrative approach is also suggested to include more detail and leave room for patients to report what is important to them
Way of collection and timeliness of data: paper-based	<ul style="list-style-type: none"> » Routine electronic collection » Various apps and online portals have been used in pilot studies and show potential for wider use
Questionnaire: The EQ5D is too dependent on other factors and too generic Patient asked too many questions	<ul style="list-style-type: none"> » Keeping the EQ5D to compare across diseases, but adding condition-specific metrics especially for more complex conditions such as the Oxford Hip and Knee » Integrating PROMs and PREMs in order to ensure that patients are not asked to complete numerous questionnaires or feedback forms » Integrating questionnaires for patients with multi-morbidities and chronic conditions
Low Health Literacy	<ul style="list-style-type: none"> » A study in Scotland has identified the following levers (Health Improvement Scotland, n.d.): <ul style="list-style-type: none"> – larger font sizes and tick boxes – giving patients a choice of where to complete the questionnaire – providing a quiet space – offering assistance



3.5 The Netherlands

PROMS APPROACH

- » **Level of implementation:** Bottom-up implementation & top-down support
- » **Disease and treatment areas:** specialty care – cancer, diabetes, heart diseases etc.
- » **Use for:** benchmarking, research, quality improvement, shared decision-making
- » **Key challenge:** resource allocation, common IT solutions and PROMs standards

The Netherlands has a statutory and mandatory health insurance program offered by 11 different private nonprofit insurance companies. Financing is mostly public via general tax revenue and government grants as well as private via employer financed payroll tax and premiums paid by individuals. The national government is responsible for setting the strategic direction of the healthcare system and well as monitoring its quality and costs. There is a degree of cost sharing with individuals via deductibles, coinsurance and copayments for selected services and medication (Commonwealth Fund, 2020f).

Hospitals in the Netherlands are private nonprofit organizations. In 2018, there were 79 hospital organizations including University Medical Centers (UMCs); these organizations consist of 120 hospital locations and 134 outpatient clinics. The country had 31.7 hospital beds per 10.000 inhabitants in 2018, of which more than 80 % were in general hospitals. This represents a 36 % reduction from the year 2000 (WHO, 2020). In addition to hospitals, there are 76 disease-specific care institutions and 229 independent treatment centers (ZBCs) (Volksgezondheidszorg, 2020).

3.5.1 PROMs Implementation

In the Netherlands, a multitude of PROMs initiatives exist, of which some have already reached national coverage such as registries including the Dutch Institute for Clinical Auditing (DICA) or national programs from large hospital networks. Recently, the government has also launched an outcome-driven healthcare program including PROMs, which builds upon existing initiatives and infrastructure (Mjåset, C. et al., 2020). Core goals include enhancing shared decision-making and enabling better access to up-to-date outcome information (Government of the Netherlands, 2018a). Research initiatives exist that promote the standardization of PROMs indicators such as COSMIN (CONsensus-based Standards for the selection of health Measurement INSTRuments). Moreover, for specialty medical care, various stakeholders (medical professionals, patients, clinics, insurers, ministries and nurses) reached an agreement, stating that outcome data will be made available for 50 % of the disease burden (Government of the Netherlands, 2018b).

DICA is a nonprofit organization that collects, analyzes and reports hospital data including clinical indicators, PROMs and PREMs at a national level. DICA works together with medical specialists, healthcare providers, patients and health insurers. It was founded in 2010 by three surgeons, who saw the need for broader outcome-based evaluations for quality improvement. Today, DICA has 22 clinical quality registrations and covers multiple

disciplines and various diseases with clinical data collection. Since 2015, registries for various conditions were expanded with PROMs and PREMs. At the moment the total number of DICA registries that include PROMs data is nine. Each registry has its own board, the Clinical Audit Board, consisting of mandated delegates of the relevant professional societies. Many scientific societies of medical specialists have become involved in the DICA registries. DICA data provides insight into qualitative factors and patient-reported outcomes, which enables hospitals to target these very aspects in their management decisions. In 2018, DICA introduced the Codman Dashboard, a new and intuitive benchmark instrument. DICA is financed through research grants and since 2016 is financed on a more long-term basis by the healthcare insurance companies (ZN) (Beck, N. et al., 2020). Participation is voluntary and some hospitals participate for a multitude of disease/treatment categories and some for individual ones. Hospitals can access their own and benchmark data for quality improvement purposes on a daily basis through the Codman Dashboards. A similar approach for heart diseases is followed by the National Heart Registry (NHR), which has close ties with DICA.

The NHR is also a physician-driven registry that initially collected PROMs and CROMs for various heart diseases in one provider setting, soon expanded to additional providers, and now covers 23 hospitals and 300,000 patients. The registry shares a comprehensive set of information with participating providers for benchmarking purposes. More recently, mandatory participation for all hospitals offering the service area interventional cardiology services was introduced. A value-based payment model that incentivizes improvements in outcomes and rewards high data quality has also been implemented.

In the year 2006, a reform to improve care quality and efficiency, and managed competition was introduced. This reform allowed the development of new types of care organizations, such as Diabeter, a care organization specializing in Diabetes care. Diabeter is a frontrunner in value-based healthcare in the Netherlands. This clinic network with its six sites provides e-health tools that support patient-centered diabetes care and has established a real-time reporting system that integrates CROMs and PROMs data collection, analysis and reporting. Newly developed bundled payment plans with all national insurers are partly based on PROMs. At Diabeter, physicians can retrieve PROMs data in real time, to inform their own decisions and support shared decision-making with patients. Patients at Diabeter are reported to have significantly improved clinical outcomes, e.g. in the form of HbA_{1c} level, while costs are contained.

Santeon is a group of 7 hospitals throughout the Netherlands implementing value-based healthcare (VBHC) in multiple disease areas, with the most advanced being in breast cancer. Santeon shares clinical and PRO quality indicators among its seven hospitals to enable continuous improvement, with reporting and utilization formats continuously being adjusted based on user feedback (ICHOM, 2017). After completing various improvement cycles, data for breast cancer is now also shared publicly, and the rollout in additional treatment areas has commenced.

Overall, there are a variety of initiatives mostly originating at provider level and from physicians. Health insurances and the government have taken up these bottom-up initiatives and are scaling them for national adoption. The Netherlands has become a leader in VBHC models according to ICHOM, and the Ministry of Health has made a multi-year commitment (2018–2022) to provide insight into PROMs for 50% of the disease burden by 2022 (ICHOM, 2019). Although this has not become a complete reality as of now, patients are already benefiting from the improved quality of care via the various PROMs initiatives.



3.5.2 Disease and treatment areas of focus

Projects, from clinic network-based projects, e.g. Santeon, to registries such as the National Heart Registry, have focused on different disease areas. DICA mainly focused on those which require surgery. Jacqueline Hartgerink, director of DICA has reported that especially breast and intestinal cancer have profited highly from the measurement of PROMs according to patient and physician feedback. Santeon's VBHC approach is currently implemented in 15 disease areas, with the most advanced being in the field of breast cancer, in hip arthrosis, lung and prostate cancer, and cerebrovascular diseases. With Diabeter working on diabetes and a collaboration between Xpert Clinics, Handtherapie Nederland and the Erasmus MC Rotterdam working on specialist hand and wrist care, the disease area focus for PROMs is already wide in the Netherlands.

3.5.3 Form of data utilization

The forms of data utilization are as varied as the focus on the disease areas. At DICA, the main focus lies on benchmarking and internal quality improvement, facilitated through real-time data sharing. Moreover, as hospitals can ask for additional data from DICA, they can identify problems in the treatment of individual patients and generate lessons learned at a physician and patient level as well. DICA is continuously evolving and establishing additional standard sets and utilization forms for the retrieved data. It is planned to enable access to real-time data for providing information for patient treatment decisions in the near future. This means that the platform accessible by clinicians summarizes the outcomes for patients with similar characteristics for different treatment options (Looking Forward Together program). This will enable shared decision-making and a common framework for integrating PROMs in the clinical care pathway. Finally, half of the indicators are being used for public reporting once a year by the government.

In a collaboration between Xpert Clinics, Handtherapie Nederland and the Erasmus MC Rotterdam, specialist hand and wrist care is being optimized using PROMs across 12 hand clinics (VBHC Centre Europe, n.d.). Patient and therapist-reported health outcomes are recorded pre intervention and several times post intervention. The results are integrated into EHRs via a link and are easily accessible for HCPs in this way. Patients have access to their outcomes through their own personal web page. In order to maximize the benefit of having outcome data available, real-time feedback loops have been created including an extreme value threshold detection system, the presentation of norm data relative to patient data, and the option to benchmark at a clinic, therapist and treatment level.

At Diabeter, PROMs data already facilitates shared decision-making today. The Diabeter IT platform which integrates EMRs, PROMs and CROMs was coded by its founder Dr. Veeze himself, and retrieved data is used to inform a multidisciplinary care team as well as patients in the consultation. Based on the improved outcome scores, Diabeter has developed a long-term partnership with all health insurers in the Netherlands and has introduced a new form of value-based payment as the first organization in the Netherlands.

An additional form of utilization of PROMs data in the Netherlands is for scientific research. This is, for instance, enabled through the data collected at national registries such as the National Heart Registry, DICA or through various research grants. The Dutch COSMIN initiative furthermore has been aiming to improve the selection of outcome measurement instruments of health outcomes since 2005.

3.5.4 Challenges

When Diabeter first started sharing the results of their quality outcomes publicly, there was low acceptance of this level of transparency and criticism from the healthcare professional community that results were not valid. Some physicians are reported to be afraid of measurement and losing their professional autonomy. This especially stems from the fear of management using data that does not reflect the reality of what is going on, especially if there is no risk adjustment. This, however, is changing as more value-based care is implemented and data-sharing has led to quality improvement in cases such as Diabeter. Besides, Dr Veezes promotes not using risk adjustment to better understand underlying reasons for low outcomes, e.g. deprived neighborhoods.

A study from 2019 on shared decision-making based on PROMs in the Netherlands reflected that in the physician-patient interaction it is well implemented in conversations on monitoring and managing symptoms (Damman, O. C. et al., 2019). However, aggregated PROMs information was rarely utilized due to common barriers such as perceived lack of time, lacking tools for summarizing options and concerns about a resulting overuse of healthcare due to more active monitoring.

Furthermore, the participation of patients and high follow-up rates are sometimes difficult to achieve. Jacqueline Hartgerink from DICA, for instance, described that patients were afraid their answers would limit the treatment options they would be offered. Moreover, questionnaires were reported to be too research-focused, i.e. that what actually mattered to physicians and patients was not being measured.

3.5.5 Success factors

One example of a success strategy is the breast cancer program at Santeon, which has shown a reduction of 74% in reoperations and 30% inpatient stays (BCG, 2018). In Santeon's case, different success factors have been identified. Firstly, a shared ambition and long-term commitment to VBHC at a leadership level. Secondly, a clinic-wide rollout with set improvement cycles to leverage the lessons learned from different sites and create a trusted learning environment. Multi-disciplinary improvement teams including patients can thereby define together what value means for them. Transparency is slowly widened from internal to open discussions, over the external availability of data for detailed analysis to the use of value-based contracting and for continuous improvement. Thirdly, a central infrastructure and governance system including a VBHC support team was set up.

Further recommendations by experts in the Netherlands in the wider rollout and use of PROMs include starting small in-pilot and hospital network-wide rollouts to generate experience and lessons to be learned, to actively involve patients in the process and to start reporting back to physicians immediately to keep up motivation. Dr. Veeze further recommends that transparent data-sharing including PROMs is fostered at a national level. Additional success strategies are summarized below.



Implementation challenges	Success factors
Patient involvement	<ul style="list-style-type: none"> » To collect and share data that is actually relevant to patients and physicians, DICA creates common standards for PROMs questionnaires by involving patients and healthcare professionals in the design of questionnaires and the decision-making on how these should be used and when. In a 2-year-long adjustment period, questionnaires and integration in the care pathway are being continuously reevaluated. » On the basis of this information DICA sets a data and questionnaire standard that needs to be followed to participate in the auditing process. Moreover, DICA continuously adjusts the way in which data is reported back to hospitals based on their feedback.
Physician commitment	<ul style="list-style-type: none"> » Particular success factors for Diabeter according to its founder Dr. Veeze are <ul style="list-style-type: none"> – easy integration in the care process via visualization and digital tools which enable physician-level benchmarking and – giving healthcare professionals free autonomy to come up with new ideas for improving patient care.

3.6 Norway

PROMS APPROACH

- » **Level of implementation:** Bottom-up implementation & top-down support
- » **Disease and treatment areas:** mental health, orthopaedics, NCDs (e.g. diabetes and heart diseases)
- » **Use for:** research, quality improvement, shared decision-making, benchmarking
- » **Key challenge:** integration of PROMs in clinical practice, resource allocation, common IT solutions

The Norwegian health system provides universal health coverage and is primarily funded through general taxes and payroll contributions which are shared by employers and employees (Commonwealth Fund, 2020g). The national government of Norway is responsible for regulating, funding and overseeing care provision. Healthcare delivery is organized in a semi-decentralized fashion: While the state is responsible for specialty care including hospital services, responsibility for primary care, preventive and long-term care as well as social services rests with the municipalities. The state owns four regional health authorities (RHAs) which are entrusted with the implementation of national health policy within the regions. Hospital care is mostly provided through 20 public hospital trusts, state-owned and governed as publicly owned corporations. In 2018, Norway had 35.3 hospital beds per 10,000 inhabitants, a 7% decrease from 2000 (WHO, 2020). Referral by general practitioners is required for elective and acute specialty care exempt from specific cases such as accidents or heart attacks. Patients can choose freely between hospitals for elective services, but not for emergency care. While health coverage among Norwegian residents is universal, most outpatient care services such as specialist consultations or prescription drugs require some level of cost-sharing.

To ensure the quality and safety of care Norway has established various mechanisms: The National Board of Health Supervision audits different areas of the health system at national and provider level (Commonwealth Fund, 2020g). Hospitals have to inform the board of serious adverse events and warnings or fines can be issued by the board. The regulation for “Leadership and quality improvement in the health services” obliges hospitals to perform quality and safety improvement activities. Moreover, it requires hospitals to measure and assume accountability for performance. A national reporting and learning system for adverse events in hospitals has been introduced.

3.6.1 PROMs Implementation

At present, no national policy for PROMs has been established in Norway. However, there are some research environments and programs that have engaged in the field of PROMs. In order to pool their knowledge, two dedicated bodies have been established in Norway to provide services to registries and research environments: The Specialist Center for Patient-Reported Data was established within the national service environment for medical quality registries in 2015 (Enden, T. et al. 2018). It provides advice and guidance in the use of PROMs and PREMs, predominantly to national quality registries and research groups located in the region overseen by Helse Vest, the Western Norway Regional Health Authority. Another body, PROMiNET provides guidance in the use of PROMs in clinical research and practice in Southern and Eastern Norway Regional Health Authority (Helse Bergen, 2017). PROMiNET was established with the financial support of this Regional Health Authority (PROMiNET, n. d.) and is organized under the regional research support at Oslo University Hospital. There are network partners within all hospitals located in the region.

Both initiatives offer courses and conferences to promote the use and improve the quality of PROMs in medical quality registries and clinical research (Enden, T. et al., 2018). They aim to ensure the validity, reliability, sensitivity to change and appropriateness of Norwegian PRO-data. To this end, information about validated questionnaires and measurement methods is made easily accessible and can also be obtained by researchers and clinicians in the other Norwegian regions.

While the registry infrastructure for PROMs is relatively advanced, there are only few providers that have integrated PROMs in their clinical practice. Lovisenberg Diakonal Hospital is currently one of the most visible examples for PROMs at provider level. To further connect top-down PROMs initiatives of national registries with evolving bottom-up projects, registries are currently exploring ways of integrating PROMs tools with the Norwegian EHR system. According to Dr. Christer Mjåset, deputy CEO of Helseplattformen AS and neurosurgeon, work is ongoing in the Central Norway Regional Health Trust to implement PROMs collection in the new EPIC platform “Helseplattform” (The health platform) that is set to be launched in 2021-23.

3.6.2 Disease and treatment areas of focus

In Norway, PROMs are used predominantly for orthopedic diseases and procedures as well as for neurological and mental health conditions as reflected in the number of National Quality Registries within these areas. PROMs for patients with chronic conditions such as childhood diabetes, specific cancer types such as prostate cancer, and indications requiring acute care such as myocardial infarction and cardiac arrest are also collected for dedicated



quality registries. According to Dr. Christer Mjåset, PROMs are relatively well accepted in the orthopedic research community and utilized clinically to a certain extent in mental health. For instance, PROMs initiatives at Lovisenberg Diakonale Hospital are focusing on applications in areas of mental health, cancer treatment and the management of chronic obstructive pulmonary disease.

3.6.3 Form of data utilization

At present, PRO-data is used for various research projects and the collection of PROMs takes place predominantly through national quality registries: Currently there are 54 National Medical Quality Registries that have been approved by the Ministry of Health and Care Services for collecting structured information along the entire course of treatment for patients within defined disease groups (Nasjonalt servicemiljø for medisinske kvalitetsregistre, 2017). Indicators fall into three categories: Infrastructure, process and results data. The last category also includes PROMs in 26 of these registries. As of today, 7 of these 26 quality registries use ePROM (Nasjonalt Servicemiljø for Medisinske Kvalitetsregistre, n. d. b). Other quality registries that wish to use electronic solutions for collecting PROMs are supported by the Center for Clinical Documentation and Evaluation (SKDE), an independent unit affiliated to the Northern Regional Health Authority.

Aggregated PRO-data is used for registry-based research, for instance, to identify best practices and adapt clinical guidelines accordingly. The Norwegian Hip Fracture Register can be regarded as an example of PRO-data utilization for this purpose: Initiated in 2005 by the Norwegian Orthopaedic Association (Nasjonalt Servicemiljø for Medisinske Kvalitetsregistre, n. d. a), the register has grown to over 125 000 data sets including PRO-data which is extracted from questionnaires sent to all patients 4, 12 and 36 months after surgery. In 2010, a recommendation for the treatment of displaced femoral neck fractures in elderly patients by hemiarthroplasty rather than osteosynthesis was derived from an analysis of the registry's outcome data (Gjertsen, J. E. et al., 2010). The data analysis revealed better results including reduced pain levels, higher quality of life and better functional outcomes for hemiarthroplasty in this patient group. While in 2005, half of all patients with femoral neck fractures received treatment by osteosynthesis, the proportion of patients undergoing this procedure had decreased to about 5 % by 2017 (Nasjonalt Hoftebruddregister, 2018). 95 % of this patient population received hemiarthroplasty at this point.

While PRO-data is already integrated in almost 50 % of all National Medical Quality Registries, and aggregated PRO-data is used for research informing clinical guidelines, there are few examples of PROMs integration in clinical practice at a provider or department level: Lovisenberg Diakonale Hospital, Norway's largest nonprofit private hospital located in Oslo, launched its "Love-PROM" project and initiated systematic PROMs collection for specialized mental healthcare programs in 2013 (Lovisenberg Diakonale Sykehus, 2019): Text messages are sent to patients prior to admission or consultation at the hospital. Questionnaires can be completed at home and patients' answers downloaded in the hospitals information system within minutes. Thereby, timely access to PROMs results is granted. Moreover, answers are automatically analyzed and a report for the treating physician generated. The report visualizes results and highlights answers that might require medical attention to set a focus for subsequent patient-physician communication and treatment. Aggregated PRO-data together with cost and process measures is summarized in a dashboard accessible to clinical supervisors and management. Furthermore, all received PRO-data is transferred to the respective registries on a daily basis. An algorithm supports the automated selection and

administration of PROMs questionnaires. As part of its “LovE-PROM” initiative, Lovisenberg Hospital is building a network with other provider organizations to share insights and promote rollout of their strategy across more hospitals and disease and treatment areas.

PROMs at an individual level is also being increasingly used for remote follow-ups and monitoring of patients. For this type of PROMs utilization, reimbursement has been introduced.

3.6.4 Challenges

Challenges in the use of PROMs have been mostly identified at a patient-physician level: Experts report lacking anchorage of PROMs in clinical practice; results of PROMs collected for registries bypass physicians and patients since they are not reported back to them at an individual level. Paper-based collection of PROMs for registries is perceived as laborious and results do not reach clinicians in a timely manner. Also, aggregated PRO-data collected at the hospital level cannot be used for research by clinicians directly without the consent either of patients or the regional health office. Only few providers such as Lovisenberg Hospital have implemented digital solutions to automate the distribution of questionnaires to patients, PROMs collection, analysis and transfer to national quality registries.

Given these circumstances, both patients and clinicians remain skeptical towards the collection and use of this type of data. Especially, physicians often perceive PROMs as a time-consuming management tool and are afraid of being measured and compared. An inappropriate or lacking risk-adjustment of results is another concern mentioned during interviews. Furthermore, there are currently few prominent examples that can serve as a proof of concept and act as a driving force for encouraging PROMs utilization in clinical practice.

3.6.5 Success factors

Successful strategies for PROMs implementation in Norway were identified on a provider level as well as for top-down, registry-based approaches.

Based on experiences with PROMs in clinical settings, Per Arne Holman, Head of Analysis for patient safety and research at Lovisenberg Diakonal Hospital, proposes five key aspects for successful implementation: The administrative part of PROMs implementation should be automated where possible, questionnaires selected which are meaningful to patients and clinicians, PRO-data should be available to patients directly – not via physicians, PRO-data measurement should be performed on time for adjustments to clinical care pathways, the focus should remain on learning and development, and transparency of results implemented to this end.

Successful bottom-up initiatives were also regarded as an important driver for PROMs use at system level, in particular in Norway where a research-focused top-down approach currently prevails. A strong registry-based research infrastructure promotes the use of aggregated PRO-data to give insights into best practices and adapt national guidelines. The integration of data warehouses and PROMs tools in national EHR systems and the automated transfer of data to national quality registries are likely to increase the quality and amount of data. Since the funding of registries is limited (EUR 100.000 -150.000/registry/year) and often requires co-financing by the providers hosting the registry, the eligibility of PROMs for reimburse-



ment could decrease the financial burden. PROMs used as part of remote monitoring or telemedical follow-ups in areas such as mental health can already be reimbursed today.

Implementation challenges	Success factors
Limited anchorage of PROMs in clinical practice , PROMs directly reported to registries	» Complementing top-down approach from registries with more bottom-up initiatives (e.g. clinical champions driving PROMs implementation in their respective field)
Limited acceptance of PROMs by patients and physicians (fear of unfair comparison)	» Incentives for both physicians (research, benchmarking, best practice sharing) and patients (promote involvement, health literacy) to participate in PROMs collection and utilization » Full transparency of the purpose and utilization of PROMs (mainly for quality improvement and to promote patient-centered healthcare)
Fragmentated IT infrastructure complicating collection of PROMs across providers, National IT system for automated PROMs missing	» Connection of regional/provider-based data warehouses at national level » Integration of PROMs tools in national EHR system
Timeliness and usability of PROMs in clinical practice if paper-based collection (e.g. for quality registries)	» PROMs results primarily accessible for patients and physicians, aggregated PRO-data subsequently (preferably automatically) transferred to registries simultaneously
Limited funding for registries and financial support for PROM	» Reimbursement for PROMs (e.g. a fee per patient if PROMs is used for remote monitoring)
Few prominent examples of PROMs attracting further bottom-up initiatives	» Gradually implement different pilots and gather experience with PROMs (prove clinical relevance) » Platform for providers implementing PROMs to exchange what has been learned and best practices

3.7 Sweden

PROMS APPROACH

- » **Level of implementation:** Bottom-up with government backing
- » **Disease and treatment areas:** chronic diseases, surgical / orthopaedics, cancer, mental health / neurology
- » **Use for:** quality improvement, research, benchmarking, public reporting, P4P
- » **Key challenges:** decentralisation, legal barriers

Sweden has a decentralized universal healthcare system. At the national level, the Ministry of Health and Social Affairs sets health policies, while at the regional level, 21 county councils are responsible for financing and providing health services in their respective region. Finally, at the local level, 289 municipalities are responsible for the care of elderly and disabled persons. The National Board of Health and Welfare is a government agency that develops standards, collects and disseminates information, and maintains health data registries and official statistics (Commonwealth Fund, 2020h).

All residents are automatically covered by the public insurance and private supplementary insurance accounts for less than 1% of health expenditures (Commonwealth Fund, 2020h).

Sweden currently has approximately 70 public hospitals funded by the county councils, 6 private hospitals and 7 university hospitals. In 2018, the country had 21.4 hospital beds per 10,000 inhabitants, a 40% decrease from the year 2000 (WHO, 2020).

3.7.1 PROMs Implementation

Sweden does not specifically have a national strategy for PROMs, but it has a national framework for monitoring and improving healthcare quality based on the 6 principles of “good care”, one of which is patient-centeredness, defined by the National Board of Health and Welfare in 2006 (ACSQHC, 2018, Kandelaki, K. et al., 2016). Patient-centeredness was further cemented in the Swedish healthcare system with the Patient Act of 2014. Its objective was to strengthen the patient’s position in healthcare (Socialstyrelsen, 2020). The country also has a long tradition of national registries which benefit from favorable patient data regulations and substantial government funding (Mattsson, T., 2016).

It is important to note that, given Sweden’s decentralized system, the term “national” may refer to either a national government-administered initiative or to an initiative coordinated by the Swedish Association of Local Authorities and Regions (SALAR), an employers’ organization and an organization representing all regions and municipalities in the country. For instance, there are two types of national registries in Sweden. The mandatory government-administered national registries operated by the National Board of Health and Welfare (e.g. the National Patient Registry and the Medical Birth Registry) are not legally permitted to include PROMs at the moment. By contrast, the disease-specific National Quality Registries (NQRs), most of which were initiated by healthcare professionals and which are coordinated by SALAR, do collect patient-reported data. As a result, there are no national government-led initiatives collecting patient-reported outcomes, while there are two SALAR-coordinated initiatives that implement PROMs on a national scale: the NQRs and a regularly conducted National Patient Survey. However, the National Board of Health and Welfare publishes a regular health system performance assessment report which includes regional comparisons, as well as various thematic reports that focus on specific topics or disease areas (Hanning, M. & Schmidt, I., 2014), both of which include PROMs data from the NQRs for the reports if the data is applicable and robust.

There are currently 103 NQRs in Sweden coordinated by SALAR and co-funded by the national government and SALAR (Nationella Kvalitetsregister, 2019). The Swedish government promotes the development and broad implementation of quality registries by offering economic incentives. All NQRs receive one of four certification levels to indicate how advanced they are in terms of the inclusion of relevant indicators, data analyses, data reporting, coverage rate, etc. The certification level is an important factor for national funding. As a result, most NQRs cover a large percentage of all eligible patients. In the year 2014, approximately 60% of NQRs covered more than 80% of their target population, with several attaining near completeness (Emilsson, L. et al., 2014). However, since participation is voluntary for healthcare providers and patients, the coverage varies widely among registries. For instance, long-standing registries such as the NQRs for Knee and Hip Arthroplasty achieve coverage rates of around 98%, while the NQR for Psychosis Care covered merely 5% of its target population in the year 2014 (Emilsson, L. et al., 2014). Currently, more than 80% of NQRs collect PROMs, though the response rates and quality of PROMs also vary among registries (Nationella Kvalitetsregister, 2019). While, for instance, the NQRs for Knee and Hip Arthroplasty have been collecting PROMs data for 12 and 18 years and have postoperative response rates of 80% and 90% respectively, other



registries scarcely use PROMs (Wilson, I. et al., 2019). In addition to the NQRs, smaller registries exist that are not coordinated by SALAR.

The second SALAR-coordinated initiative, the National Patient Survey, consists of several individual national surveys on patient-perceived quality and experience of primary, inpatient and outpatient care. All county councils and regions have participated in the National Patient Survey since 2009. In 2018, the regions launched a united and coordinated effort to collect patient-reported data for the patient surveys and created the National Platform for Structured Patient-Reported Measures (patientenkat.se). The platform provides the technical infrastructure for presenting patient-reported data across regions and providers.

Finally, PROMs are also implemented in regional pilot projects for value-based healthcare and in clinical studies and research projects across the country. Karolinska Institutet is among the institutions at the forefront of PROMs research.

3.7.2 Disease and treatment areas of focus

As PROMs are used in most National Quality Registries and in several patient surveys, various disease areas are covered, including surgical/orthopedics, cancer, chronic diseases, and mental health/neurology. In the context of value-based healthcare, PROMs are used in individual regional pilot projects for hip and knee replacement surgery, spinal surgery, obstetrics, bariatric surgery, stroke, diabetes, osteoporosis and breast cancer. Hip and knee replacements were among the earliest initiatives, due to very long waiting times for specialist treatment and the pressing need for reform.

3.7.3 Form of data utilization

In Sweden, PROMs are used in different ways, predominantly, however, for quality improvement, benchmarking and research purposes.

The National Quality Registries have varying initial purposes. For instance, some are mainly used to monitor quality among providers, whereas others serve the purpose of evaluating treatment options and clinical practice. Ultimately, they are all used for quality improvement and research purposes. The National Quality Registries also allow benchmarking between regions and in some cases between hospitals. Public reporting of hospital-level outcomes is currently not mandatory, yet more and more registries are reporting them. Many registry reports, however, are mainly targeted at researchers and clinicians and are not comprehensible to patients (Pross, C. et al., 2017).

The National Patient Survey uses PROMs primarily for benchmarking between providers and regions and for public reporting purposes. All patients and providers can view the results at a regional or provider level on the platform. The aim is for the NQRs to also become consumers of the survey data in the future and no longer collect their own data from patients.

PROMs are also used in regional value-based payment projects utilizing bundled payments. In 2009, Stockholm County introduced OrthoChoice, a pilot project for hip and knee replacements. Four years later, the county expanded the model to include spinal surgery. PROMs are used to measure quality of care and in some cases to determine the qual-

ity bonus amount. For instance, in the bundled payment scheme for spinal surgery, approximately 10 % of the total payment is based on patient-reported pain reduction (IVBAR, 2014). Later, more initiatives were launched, guided by the Swedish National Collaboration for Value-Based Reimbursement and Monitoring of Healthcare (SVEUS). The SVEUS project's aim was to share knowledge and advance the development of value-based monitoring and reimbursement systems across regions. The initial phase of the project was financed by the Ministry of Health and Social Affairs, and participants included 7 county councils and SALAR, as well as several clinician and patient associations, NQRs and universities. The national SVEUS project was discontinued, as there were concerns that it was too closely tied to a private company, however some of the pilot projects and initiatives continue on a regional level.

3.7.4 Challenges

Certain challenges impede the further implementation of PROMs on a national scale. They include legal barriers. For instance, government-administered registries are not permitted to include PROMs at the moment, as all data collected are strictly regulated by law. Furthermore, it is not permitted to use data collected for one purpose for a different purpose. Therefore, registry data collected for research purposes cannot be used in routine care.

In addition, using PROMs data in the clinical setting is hindered by technical barriers. Not all regions and hospitals have the same IT infrastructure in Sweden. This problem is amplified by the division of responsibilities between regional and national levels. Lastly, some healthcare professionals still need to learn about the value of PROMs in improving the quality of care. PROMs were for instance implemented as a part of the organizational change of Karolinska hospital, Sweden's second largest hospital network, in 2016 and 2017. The restructuring was met with resistance by some clinical leaders and received high media attention in Sweden. Some elements implemented as part of a transition towards VBHC suffered from a negative image in the media and further implementation initiatives were slowed down. Since then, PROMs implementation has been separated from organizational changes and largely driven by patient advocacy groups. Integration of PROMs into clinical work such as the redesign of patient care pathways has continued and supported a shift to more patient centric health care delivery in Sweden.

3.7.5 Success factors

Sweden is among the countries most advanced in implementing PROMs on a national level. The country's established quality registries provide a unique opportunity to collect PROMs for a number of different diseases and across regions. Furthermore, the National Platform for Structured Patient-Reported Measures provides the technical infrastructure for collecting and processing a large amount of data and offers full transparency to patients and medical professionals. Due to Sweden's decentralized healthcare system, the bottom-up approach has prevailed. The endorsement by healthcare professionals helped convince other providers of the benefit of using PROMs. At the same time, government funding helped to advance the implementation further.

The Swedish Rheumatology Quality Registry provides a successful example of using PROMs to monitor patient symptoms and transferring the information to clinicians in real time to improve the quality of care. The registry was founded in 1995 and currently covers approximately 90% of all rheumatoid arthritis patients in the country. Disease-specific and



generic PROMs are tracked over time and displayed on a user-friendly dashboard, which is used to inform clinical care and support shared decision-making and patient self-management. As a result, patients are more confident, involved and empowered to take charge of their condition (Oliver, B. J. et al., 2019, Nelson, E. C. et al., 2015). Furthermore, experience suggests that patient reporting improves clinical outcomes. For instance, patients in Gävle County, that routinely uses PROMs, saw a significant decrease in inflammatory activity in rheumatoid arthritis patients compared to patients in regions that do not routinely collect PROMs. In addition, national inflammation levels also reduced drastically from around 12% in 2009 to around 4% in 2014 (Oliver, B. J. et al., 2019).

OrthoChoice provides a further successful example from Sweden. While the OrthoChoice project did not begin with the intention of collecting PROMs, it paved the way for value-based payment schemes that include a quality bonus based on PROMs. Other proposed success strategies from Sweden are summarized below.

Implementation challenge	Success factors
Implementing PROMs in the provider setting: acceptance by all healthcare professionals and	<ul style="list-style-type: none"> » Launching a public discussion on how to best use the data at all levels (clinical, regional and national) » Establishing guidelines on how to assess the validity and reliability of PROMs » Demonstrating the benefits for patients and for research
Platform interoperability: Divide between national registries and registries by healthcare professionals + common data infrastructure missing for the use in research/benchmarking	<ul style="list-style-type: none"> » Healthcare professional advocacy of a common data framework and the change in law to use data in research /be able to merge it with EHR » Further expansion of the National Platform for Structured Patient-Reported Measures to include more PROMs and integration with the National Quality Registries



3.8 Switzerland

PROMS APPROACH

- » **Level of implementation:** Predominantly voluntary, bottom-up provider or regional projects; First mandatory PROMs collection in the Canton of Zurich and the Canton of Basel-City
- » **Disease and treatment areas:** elective surgery (spine surgery, hip & knee replacement) and cancer care
- » **Use for:** patient monitoring, shared decision-making, public reporting, P4P, research
- » **Key challenges:** lack of common IT solutions and common standards enabling comparisons, resource allocation

The Swiss healthcare system is organized in a decentralized fashion, with the 26 cantons exerting key functions through their federal governments (Commonwealth Fund, 2020i). This includes regulations of health system financing, quality assurance and the governance of public health initiatives as well as licensing providers and coordinating hospital services.

The Federal Office of Public Health (FOPH) oversees mandatory health insurance, pharmaceutical pricing and health technology assessment. Moreover, the agency holds responsibility for national health strategies. In 2009, all major partners in the Swiss healthcare system founded the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ), a nonprofit organization entrusted with the task of developing national standards for quality measurement and the transparent reporting of results at provider level in areas of acute somatics, rehabilitation and psychiatry (ANQ, 2020). The National Quality Agreement, signed by all hospitals and clinics in 2011, provided a legal fundament for standardized hospital quality assurance in Switzerland.

Hospitals are public or private, and hospital care accounted for about one-third of total health expenditures in 2016 (Commonwealth Fund, 2020i). The country had 46.3 hospital beds per 10.000 inhabitants in 2018, which represents a 26% reduction from 2000 (WHO, 2020). Hospital planning is performed by the cantons, yet coordination of plans with other cantons is legally required.

3.8.1 PROMs Implementation

The quality of care has been a priority for Switzerland over the last decades and has been addressed by a number of measures: For instance, Switzerland introduced a legal basis for quality assurance procedures including performance reviews and hospital comparisons with regard to quality in 1994 as part of the Swiss health insurance act. In addition, the Swiss Health2020 strategy outlines national priorities including the improvement in quality of life, ensuring and enhancing the quality of care and creating more transparency. Notably, PROMs as quality indicators have moved into focus over the last years and interest in Value-Based Healthcare has increased. Yet no national policy for PROMs has been adopted until today, and frameworks exist only on a regional level.

The cantons are starting to implement PROMs at different scales: The canton of Zürich has obliged all of its 21 listed hospitals to collect and report PROMs for patients undergoing hip and knee replacement prior to and one year after surgery (Thiel, n. d.). This project was initiated by the Canton of Zürich and Swiss Orthopedics in July 2019. PRO-data and clinical data is transferred to an existing registry (SIRIS), data are analyzed and results reported back to the participating hospitals on an annual basis (Farshad, 2019). Quality control is performed by the Swiss orthopedics quality board using a scoring system to assess indication quality and quality of care. The “Swiss orthopedics excellence” quality label is awarded to hospitals participating in the external quality assurance of Swiss Orthopedics. A step-by-step extension of this approach to other areas of orthopedics is taken into consideration. This development is in line with the strategic priorities outlined in the “Quality strategy of inpatient care in the canton of Zurich 2017-2022”: Treatments should be geared to the patient’s health-related quality of life, and PROMs are mentioned as information to be considered in a quality-based competition between providers (Zürich Gesundheitsdirektion, 2017).

Another example of a cantonal framework for PROMs has been introduced in the canton of Basel-City: As part of the agreement between the canton and its hospitals, PROMs have to be implemented at each hospitals’ own responsibility and expense, and results have to be reported back to the canton (Gesundheitsdepartment des Kanton Basel-City, n. d.). PRO measurement can only be performed by employing validated methods which have received approval from the dedicated cantonal department.



Except for regional projects such as in the Canton of Zurich and in the Cantons of Basel-City, PROMs are predominantly collected either as part of clinical research or provider-driven pilots. For instance, University Hospital Basel (USB) has implemented 15 outcome standard sets across various indication areas including orthopedics, cancer care and chronic diseases and presents one of the most prominent and comprehensive PROMs initiatives at a hospital level in Europe. Other provider and department-level initiatives include the collection of PROMs via the Kaiku Health Platform as part of care pathways in the departments of radio oncology and orthopedics affiliated to the private clinic group Hirslanden Kliniken (Kaiku Health, 2018).

Since 2018, stronger demands for a concerted political PROMs initiative are emerging. Most prominently, the FMH (Foederatio Medicorum Helveticorum), the Swiss Medical Association, published an opinion paper on PROMs postulating the integration of PROMs into routine care, involvement of medical professional societies in the choice of PROMs instruments, financial support and targeted research funding for PROMs and utilization of aggregated PRO-data to establish clinical decision support systems (FMH Zentralvorstand, 2018). Furthermore, a report commissioned by the FOPH calls for national efforts to develop a comprehensive set of quality and safety indicators to be implemented nationally at affordable costs (Vincent, Staines, & A., 2019). “These indicators should be used, on the one hand, to support health professionals in evaluating and improving their practice. On the other hand, they would serve managers, as well as political decision-makers, to organize and monitor the system such that optimal care services can be provided.” The report postulates that PROMs should be part of the national strategy and anchored in all care facilities. The cantons, however, are seen as bearing responsibility for their implementation.

Given the growing public attention and the endorsement of national bodies such as the ANQ, it might be speculated that more cantons will follow suit and implement similar frameworks for PROMs if barriers such as financial sustainability, lack of a supportive IT infrastructure and standardization of PROMs processes can be overcome with national support.

3.8.2 Disease and treatment areas of focus

Regional PROMs initiatives and pilots are predominantly focusing on orthopedics (such as hip and knee replacement) and cancer care. Currently, there is no common digital solution for PRO-data collection across different sites and sectors. Therefore, outcome measurement over the full cycle of care for patients receiving treatments in primary care settings or at various sites remains challenging.

PROMs in orthopedics and cancer are easier to perform in the absence of a cross-sector platform for outcome measurement since patients undergoing elective orthopedic surgery often receive care in an in-patient setting and cancer treatment is usually only provided at dedicated centers. Outcomes can be integrated into care pathways and be tracked by a single provider in these areas.

3.8.3 Form of data utilization

At present, PROMs are predominantly used at provider level: For instance, at University Hospital Basel (USB) the continuous collection and assessment of PROMs support shared decision-making and enhanced patient monitoring to improve outcomes and patient satisfaction.

In addition, interest in PROMs utilization as a tool for more patient-centered quality assurance as well as for national and international comparison among providers has increased. Aggregated PROMs results are also considered an important dimension in the definition of adequate care for identified patient cohorts and reduction of potential over-treatment. However, these applications require a larger amount of data that, depending on case volume, only becomes available after a certain time of PRO-data collection. USB, for instance, has started to report patient-reported outcomes for breast cancer treatment to the OECD (OECD, 2019) after two years of PRO measurement and aims to contribute PRO-data to European registries such as Eurospine for international benchmarking in the near future. Recently, the department for Quality management at USB has also established a cooperation for the international benchmarking of PROMs results and value-based payment for selected indications. In 2020, USB announced a two-year VBHC partnership with Roche Pharma AG & Roche Diagnostics AG in the field of lung cancer: PRO-data will be collected and used directly in the care pathway for lung cancer patients at USB (Medienmitteilung Universitätsspital Basel, 2020). Anonymized PROMs results will be shared with Roche to jointly derive knowledge on the possibilities of personalized treatment. In the partnership, PROMs are also correlated with corresponding cost data to develop approaches for outcome-based payment options.

3.8.4 Challenges

While interest in PROMs and the number of pilots is growing, lack of a national framework including requirements for processes, a common IT infrastructure and deployed standard sets promote the development of a fragmented landscape. This fragmentation complicates the utilization of PRO-data for national comparison and external quality assurance. Furthermore, the establishment of a digital solution supporting the collection and analysis of PRO-data is perceived as costly and required investments are often a barrier to implementation. Smaller cantons or provider organizations lack a critical mass, and hence bargaining power and financial resources for digital PROMs solutions. A common platform for nationwide PROMs collection could lower the resource burden at an individual provider level and centralize auditing and the analysis of data to ensure fair comparisons between providers. Furthermore, a national solution could promote outcome measurement across departments and sites.

While some providers such as USB have successfully integrated PROMs in clinical practice, insights into the use of aggregated PRO-data is still limited. Therefore, pilots are being launched on a department, provider or cantonal level, such as in the Canton of Wallis, where PRO-data are to be collected in different settings including hospitals, care homes and disease areas (orthopedics, pain management and cancer care) to explore the potentials of PROMs utilization beyond the individual level. A proof of concept of PROMs on a larger scale is still needed to act as a dynamo for a national PROMs strategy.



3.8.5 Success factors

PROMs initiatives in Switzerland were identified predominantly in the fields of orthopedics, elective surgery and cancer care. In the absence of a national framework or infrastructure for PROMs (including financial support or incentives, a common digital solution and a platform for PRO-data collection), some larger hospitals are collaborating with MedTech, IT providers and start-ups to establish tools for outcome collection.

Experience with PROMs collection beyond the provider level is still limited, given the relatively short timeframe of implementation. Successful strategies have been identified for provider-driven, bottom-up initiatives with regard to strong clinical leadership promoting the sustainability of initiatives and quality of data. Furthermore, implementation in disease areas with high perceived relevance and awareness of PROMs and supportive factors (such as a high degree of standardization or care being provided at a single site) predominate. Treatment areas requiring a longer inpatient stay or regular appointments were found to be more favorable for PRO-data collection than acute care settings. Strategies for the successful deployment of PROMs at national level have still to be tested. Lighthouse projects such as those at University Hospital Basel have gained international recognition – among peers and other stakeholders including payers and industrial players – and are likely to create followers. Moreover, USB is actively promoting the implementation of PROMs in Switzerland by sharing their experience with other providers including university hospitals and stakeholders during on-site visits and conferences.

Additional challenges identified in the course of conducted interviews as well as identified strategies to overcome them are summarized in the following table.

Implementation challenges	Success factors
Commitment of clinical champions: Implementation dependent on commitment of individual departments or providers	<ul style="list-style-type: none"> » Choosing departments that are proactively driving PROMs implementation for projects » An idea is to encourage health insurances to incentivize the participation of patients in PROMs through premium discounts.
Infrastructural Challenges: Cross-sector PROMs collection over full cycle of care difficult, no common IT platform for PROMs	<ul style="list-style-type: none"> » Focus on patient populations receiving care predominantly in an inpatient setting or with regular appointments at the hospital » Cantonal level or national guidance concerning recommended IT providers
Questionnaires: Choice of different questionnaires across providers (preferences changing over time further complicating comparison with other providers)	<ul style="list-style-type: none"> » Keeping generic questionnaires to compare across diseases but adding condition-specific metrics especially for more complex conditions » Integrating PROMs and PREMs in order to ensure that patients are not asked to complete numerous questionnaires or feedback forms » Integrating questionnaires for patients with multi-morbidities and chronic conditions
Patient asked too many questions	
Cultural Aspects: Cultural differences influencing the results of certain questionnaires complicating comparisons	<ul style="list-style-type: none"> » At an individual level: communication with patient about results to clarify deviations » At a system level: Adjustment (similar to risk-adjustment) for identified differences when assessing and presenting results

3.9 United States (of America)

PROMS APPROACH

- » **Level of implementation:** Voluntary, bottom-up provider / hospital networks and Medicare bundled payments
- » **Disease and treatment areas:** broad range of diseases depending on clinic
- » **Use for:** patient monitoring, shared decision-making, research and P4P
- » **Key challenges:** no common EMR system and standards, unrealistic targets for financial incentives, data infrastructure

The USA system is a mixture of public and private with half of the healthcare spending coming from public payers and care largely being delivered by private providers. Various public healthcare programs exist, e.g. for adults over 65 and some individuals with disabilities (Medicare), for the low-income group (Medicaid) and with different programs and provider groups for children and veterans (Veterans Health Administration). Healthcare coverage and health policy is regulated on a state level with additional important regulations on a national level. Private insurance is predominantly covered by employers. Private and public insurance can set their own benefit packages and cost-sharing arrangements and practice selective contracting with provider networks, but need to follow federal and state regulations. The USA is the country spending most on healthcare, with a health expenditure share of 17.7% of the total GDP (CMS, 2019).

57% of the 5,198 short-term acute care hospitals in the U.S. are nonprofit; 25% are for-profit; and 19% are public (AHA, 2020). In addition, there are 209 federal government hospitals. In 2017, there were 28.7 hospital beds per 10,000 inhabitants, an 18% reduction from 2000 (WHO, 2020). In 2017, an estimated 96% of nonfederal acute care hospitals and 86% of office-based physicians had adopted a “certified” electronic health record (EHR) system. 80% of hospitals and 54% of physician offices had adopted an EHR with advanced capabilities, such as the ability to track patient demographics, list medications, store clinician notes, and track medication orders, laboratory tests, and imaging results (Commonwealth Fund, 2020j).



3.9.1 PROMs Implementation

In the USA, no comprehensive national strategy concerning PROMs exists. However, the implementation of PROMs is widespread throughout different states and especially in various large clinic networks or integrated systems, e.g. Kaiser Permanente and the Mayo Clinic network, which have the financial and infrastructural means to set up data collection and analysis platforms. Many Accountable Care Organizations that manage care across regions use PROMs as follow-ups for their patient populations. Moreover, the National Committee for Quality Assurance (NCQA) as a national performance-reporting system for health insurance plans includes PROMs for depression monitoring (NCQA, 2020). The USA is a leading innovator regarding PROMs adoption. The International Consortium for Health Outcome Measures (ICHOM) has been established in Boston. Moreover, leading research on VBHC (Michael Porter and Elizabeth Teisberg) and PROMs as an intervention (Ethan Basch for oncology) originated in the USA health system. PROMs have already achieved widespread awareness among healthcare professionals, health policy makers and healthcare managers.

The collection of PROMs is partly incentivized through bundled payment initiatives by private and public insurances for selected procedures such as joint replacement. Following the Medicare Access and the Children’s Health Insurance Program (CHIP) Reauthorization Act of 2015, a mandatory quality incentive program was established in 2017 called the Medicare value-based healthcare program. Moreover, private insurers have implemented bundled payment contracts with separate hospitals or hospital networks. Due to the mostly private nature of the USA healthcare system, PROMs are further used to enhance competitiveness between providers in the private healthcare market. Moreover, the Food and Drug Administration (FDA) – set a guideline for the use of PROs to support claims in approved medical product labeling in 2007.

National registries which include PROMs are, for instance, the four American Academy of Orthopedic Surgeons (AAOS) registries: the American Joint Replacement Registry (AJRR), the Musculoskeletal Tumor Registry (MsTR), the Shoulder & Elbow Registry (SER) and the American Spine Registry (ASR) (AAOS, 2020). In addition, PROMs are used in routine care although differences exist on a provider level with providers that are part of larger networks being more advanced than individual clinics. PROMs pilot and implementation studies have been rolled out regularly for the past 20 years. One of the first studies was the Medical Outcomes Study in 1989, a two-year multicentered study collecting PROMs data from patients with chronic diseases, which led to the development of the now frequently used SF-36-questionnaire (RAND, 2020). More recent studies include the Pain Program for Active Coping and Training (PPACT), a clinical trial in three regions of the Kaiser Permanente clinic system which identified barriers and facilitators for the implementation of PROMs in pain management (Owen-Smith, 2018).

3.9.2 Disease and treatment areas of focus

PROMs are collected and utilized in a wide range of disease and treatment areas in the USA, from orthopedics to behavioral health, geriatric surgery, multiple sclerosis and cancer. Use in the provider setting depends on clinical champions, and hence disease areas for which PROMs are collected vary at provider level. In the Medicare and Medicaid mandatory PROMs program, the following procedures are included: lumbar discectomy/laminotomy, total knee replacement, cataracts, orthopedic impairments and varicose veins. A prominent disease area of implementation is cancer, due to leading research in this field which showed an increasing survival rate with continuous PROMs follow-ups (Basch, E. et al., 2017). Moreover, studies explore additional PROMs application areas which are less common in other countries. For instance, the PROPC-NY initiative, an 18-month research collaboration in New York City which explored the feasibility of integrating PROMs into primary care in 3 healthcare organizations (United Hospital Fund, 2018).

3.9.3 Form of data utilization

PRO-data in the USA healthcare system is used on an individual and system level. On the individual level, PROMs are used as decision support and in the interaction with patients. Different providers and provider networks are using, e.g., the Epic EHR system that provides end-to-end workflows for the deployment, collection, review, and analysis of electronic medical records and PROMs alike. This system allows for real-time PRO-data retrieval by physicians to allow for shared decision-making. Although the data transferral is not yet straightforward and requires additional backend development capacity on the

provider side, it already allows for fast data processing and the merge of medical and PROMs data. Although it is anticipated that PRO-data will soon be used in patient involvement empowerment, this is currently rarely the case. However, multiple apps have been developed for disease self-management and healthy living which ask questions similar to PRO-questionnaires and sometimes include the passive measurement of health-related data. Passive measurement in this context means the use of sensors like wearables or ambient digital devices that can collect data on functioning such as sleep, general activity, gait or emotions, without requiring the patient to respond to a questionnaire. Eric Schneider, a PROMs expert at the Commonwealth Fund, sees especially the passive measurement of patient health data and the use of Apps for PRO collection and interactive use as a trend and facilitator for wider PROMs implementation in the future.

On a provider level, PROMs are used for benchmarking, quality assurance, care pathway design and comparison, marketing and health research. For instance, over 60 practices in the ImproveCareNow network are using PROs and clinical data to improve results for children with inflammatory bowel disease by comparing PROs in different clinics and thereby improving remission rates for 17 000 patients in 30 states (Nelson, E. C. et al., 2015). Various hospitals and hospital networks use PROMs, e.g. Mass General Brigham, where PROMs are driving clinical decision-making via a cross-department dashboard including historical PROMs data (Mjåset, C. et al., 2020). Moreover, different hospitals publish PRO-data on their websites for marketing purposes, which is especially relevant in the competitive USA provider landscape. PROMs are used for public reporting via various groups and platforms such as the Wisconsin Collaborative for Healthcare Quality (WCHQ) (Franklin, P. D. et al. 2017).

Various value-based payment systems, primarily bundled payment arrangements, already exist between private health insurances and providers. Under the Medicare value-based healthcare program, centers for Medicare and Medicaid Services can choose between two options, the Merit-based Incentive Payment System (MIPS) or the Advanced Alternative Payment Model (APM) (CMS, 2016). MIPS is made up of quality performance indicators chosen from a predetermined list by the provider, of which half are PROMs. APMs are treatment-related incentive structures that partly include PROMs. Beyond the public bundled payment system, private healthcare payers, (e.g., Blue Cross/Blue Shield of Massachusetts, the Minnesota Community Measurement network, and the Pacific Business Group on Health) require the collection of PROMs for participation in their value-based payment programs (Massachusetts Medical Society, 2018).

3.9.4 Challenges

The mostly privately organised healthcare system makes a national strategy for the collection and use of PROMs standards difficult to implement top-down. Accountability frameworks which measure PROMs are sometimes perceived as a short-term political strategy to improve healthcare without a long-term vision on how insights can be integrated in the care pathway. What is criticised is that in most cases PRO-data measurement for accountability at high levels has not been linked directly to quality improvement programs that professionals can use to improve performance. This would require setting data standards and analytical frameworks which actually facilitate the analyses that are most useful to healthcare professionals and providers. On the other hand, a more centralised approach facilitates benchmarking between providers and enhances the scope for quality improvement. The currently less centralised approach does, however, foster the innovative use of PROMs on a provider level.



PROMs utilization by providers has so far been driven by home-grown approaches, where larger hospital networks, which already have a strong data infrastructure, have integrated PROMs. Smaller providers usually cannot as yet offer the benefits of PROMs for shared decision-making and internal benchmarking or improvement strategies as they do not have an existing strong data infrastructure in place and lack the scale to allow useful comparisons. Even in the larger networks, current IT systems still do not allow for all the functionalities needed to collect and retrieve PRO-data analytics that are most relevant from the physician perspective and allow for patient access as well. This is also reflected by large hospital networks that have formed a group to advocate for more functionalities in the widely used EHR system Epic. Although Epic has some PROMs capabilities, it lacks some functionalities in comparison to “best-in-class” third party vendors. Another challenge is making the data actionable for physicians, which is a key factor that hospitals are trying to improve in their current PROMs systems.

To ensure provider participation, according to Jacob Lipka who runs the PROMs division at Providence, payers should set targets that are generally considered achievable, reflecting the difficulty of collecting these data outside the clinic or hospital setting. Motivating patients to fill out PROMs questionnaires as well as accounting for individual differences when comparing aggregated patient data were mentioned as key obstacles for the fair and successful implementation of bundled payment contracts based on PROMs.

3.9.5 Success factors

Jacob Lipka defines the following aspects as main success criteria for PROMs implementation in the USA and globally. Firstly, and most importantly, a strong and early commitment of healthcare professionals, especially those in leadership positions, is vital. In the Providence clinic network, the use of PROMs has been facilitated by creating a system that is as automated as possible with pre-selected options based on patient criteria. The second most important success criterion is the governance structure to support the implementation and analysis of data. Successful implementation requires careful planning and continuous integration into the clinical care pathway. A shared vision of healthcare professionals, management, payers and patients furthermore enables a sustainable use of PROMs. Thirdly, the IT system that is interoperable with EMRs is especially relevant for making maximum use of PROMs in conjunction with clinical data. For this purpose, different care provider networks have formed a group to advocate for more functionality and open APIs in the Epic system to allow for a more comprehensive use and collection of PROMs. Additional success strategies under development and ideas by experts are summarized below.



Implementation challenges	Success factors
Missing data processing functions Difficulties in involving HCPs and patients	<ul style="list-style-type: none"> » Influence Epic development: strength in numbers approach » Computer adaptive test to shorten questionnaires » Transparency: continuously sharing reports with staff on the latest aggregated data to show them the value of collecting PROMs » Automated systems that are easy to use for healthcare professionals » Instead of only using active patient reporting also use passive reporting (e.g. voice to identify depressive symptoms) and merge these aspects with PROMs to show a comprehensible real-time picture (holistic health) to patients themselves (using apps)

Financial incentives with realistic targets missing	<ul style="list-style-type: none"> » Strong involvement and incentives from private payers – create real financial incentives » Bundled payment systems for a full episode of care incentives and PROMs follow-ups to track success and improve care practice
Lack of common standards and consequently lack of use in small provider settings	<ul style="list-style-type: none"> » Working backwards when creating standards: First asking what should be done with the data and then designing questionnaires and collection systems accordingly » Involving patients more in the codesign

3.10 Germany

PROMS APPROACH

- » **Level of implementation:** Mainly voluntary, bottom-up provider level or cross-provider projects; Selective introduction at national scale (DeQS-RL) in 2021
- » **Disease and treatment areas:** elective surgery (mainly orthopaedics) and cancer care, rehabilitation
- » **Use for:** research, patient monitoring, shared decision-making
- » **Key challenge:** resource allocation, common IT solutions and PROMs standards

In Germany, health insurance is mandatory for all permanent residents. The statutory health insurance system (SHI) covers nearly 90 % of the population and consists of more than 100 competing, nonprofit, nongovernmental health insurance funds (“sickness funds”) (Commonwealth Fund, 2020e). The private health insurance system (PHI) is substitutive to the SHI system and covers about 10 % of the population, including civil servants, self-employed or high-income residents

Health policy decision-making powers are shared between states, federal governments and self-regulated organizations of payers and providers. Regulations concerning direct financing and delivery of healthcare in the German healthcare system are delegated to self-governing associations within sickness funds and provider associations, together representing the Federal Joint Committee (G-BA). The G-BA determines which services have to be covered by sickness funds and sets quality assurance mechanisms for providers. The G-BA is supported by the Institute for Quality and Efficiency (IQWiG), which evaluates the cost-effectiveness of drugs and medical devices with added therapeutic benefits, and the Institute for Quality and Transparency (IQTIG), which is responsible for intersectoral quality assurance.

Most of the university hospitals are state-owned, while municipalities own about 50 % of all hospital beds and play a role in public health activities. Around 1/6 of all beds are provided by private, for-profit hospitals, and their number has been growing in recent years (Commonwealth Fund, 2020e). In 2017, Germany had 80 hospital beds per 10.000 inhabitants (Statistisches Bundesamt, 2020). This represents a 12 % reduction from the year 2000 (WHO, 2020).



Quality assurance in hospitals has gradually increased and evolved from voluntary initiatives to obligatory tasks: In 2001, a statutory quality assurance system (externe Qualitätssicherung EQS) was established (Deutsches Ärzteblatt, 2014). It is based on the “Guideline on Quality Assurance Measures in Hospitals” (QSKH-RL) and the “Guideline on Cross-institutional and Cross-sectoral Quality Assurance Measures” (QESÜ-RL), which was recently replaced by the DeQS-RL. The QSKH-RL obliges all providers in the statutory health insurance system to introduce internal quality management and to participate in cross-institutional, external quality assurance (Fifth Book of the Social Code SGB V, section 135a): Annual Quality reports entailing over 200 structural, process and outcome quality indicators at hospital or department level for about 25 diagnoses or procedures (21 of these based on the QSKH-RL) are compiled by hospitals (IQTIG, 2020). Aggregated, anonymized data is analyzed centrally by the IQTIG and summarized in an annual report.

3.10.1 PROMs Implementation

The assessment and improvement of quality of care have been priorities on the national agenda since the 1990s. More recently, the patient perspective on quality of care and outcomes – and along with it PROMs – has moved into focus: Internationally renowned examples such as the Martini-Klinik Hamburg and the Schön Kliniken have spurred adoption across a number of providers and disease areas and political debates on large-scale implementation. First frameworks such as Quality contracts (Qualitätsverträge) and research funding (e. g. through the GB-A Innovation Fund) facilitating the implementation of PROMs at provider level have emerged. Yet, in the absence of a national policy explicitly mandating PROMs collection and utilization, the German PRO landscape has been dominated by a growing number of bottom-up initiatives in this field with few stakeholders creating alignment among them.

DEEP DIVE

Initiative Qualitätsmedizin (Initiative Quality Medicine – IQM), founded by public, private and university hospitals in 2008, aims at standardized outcome measurement based on routine data and the German Inpatient Quality Indicators (G-IQI), public reporting on hospital websites and continuous improvement of outcomes in hospitals through peer reviews (IQM, n. d.). Today, more than 450 German, Austrian and Swiss hospitals have become members of IQM and publish quality reports on their websites on an annual basis. Outcomes for 60 diagnoses and procedures are assessed using about 380 indicators. IQM members have to accomplish quality targets set for 40 of these indicators. Significant deviation from the average triggers peer reviews. Currently, IQM focusses on including patient-reported outcome measures in their set of quality indicators. In February 2021, IQM signed a framework agreement with Heartbeat Medical, a German IT-provider for large-scale collection of PROMs. This cooperation provides access to the providers digital platform for standardised data collection including PROMs and CROMs for close to 500 IQM member hospitals in Germany and Switzerland and enables nationwide and cross-state quality benchmarking (Heartbeat Medical, 2021).

In 2019, the Initiative Quality Medicine (IQM) assessed the level of PROMs implementation in a survey among its 490 members in Germany, Austria and Switzerland (IQM, 2019): The survey revealed that about 28 % of the 367 responding hospitals have already implemented PROMs. The percentage of PROMs users is highest in university hospitals (about 42 %) and private hospitals (36 %) according to the survey. Providers predominantly use their own questionnaires or tools to assess PROs (38 % of PROMs Users) or a combination of published

and own tools (34%), only 6% reported using ICHOM or PROMIS standard sets or tools recommended and provided by medical societies (13%).

According to Heartbeat Medical, a German IT-provider specialized on PROMs, more than 200 German providers or departments are currently collecting PROMs using their digital solution. Most of these implementation and research projects are clinician-lead pilots which received endorsement by the hospital's management and motivated by academic interest (e.g. in university hospitals) or potential gain of competitive advantages for private providers.

Some of the hospitals that have already gained experience with the collection and integration of PROMs in clinical practice and have recently engaged in large-scale pilots such as "PROMoting Quality" in the field of joint replacement (see box for description)

EXAMPLES

Examples of PROMs research projects supported by the Innovation Fund

PRO-B – Charité University Hospital Berlin, BARMER, BKK VBU, DAK-Gesundheit, Deutsche Krebsgesellschaft e.V., OnkoZert GmbH

- » Area: breast cancer treatment
- » Aim of project: Improve quality of life and potentially extend survival, reduce hospital stays for patients suffering from metastatic breast cancer
- » Methods: IT-based, intensified Patient Reported Outcomes (PRO) monitoring and intervention in case of deviating results in an intervention group compared to a control group (with PROMs, but without active monitoring and intervention) in selected centers across Germany

PROMoting Quality – TU Berlin, 9 implementing hospitals, HRTBT Medical Solutions GmbH, BARMER, BKK Dachverband e.V., aQua – Institute

- » Area: Hip and knee joint replacement
- » Aim of project: Intersectoral use of PROMs to increase the patient-reported outcome quality and evaluate effects on cost of care
- » Methods: PROMs performed prior to surgery and after discharge in intervention groups and regular feedback for treating physicians to trigger intervention if necessary; control group without PROMs triggering intervention

EPOS – Department of Neurology, University Hospital Hamburg-Eppendorf (UKE)

- » Area: Stroke
- » Aim of project: Introduce and evaluate use of PROMs in routine care of stroke patients, investigate factors influencing PRO, evaluate acceptance of PROMs by patients and medical staff.

LQ-DMP – Helmholtz Zentrum München GmbH, Institute for Health Economics and Healthcare Management

- » Area: Chronic obstructive pulmonary disease
- » Aim of project: Examine the extent to which the COPD disease management program can be improved by measuring and considering the health-related quality of life of those affected as a care goal
- » Methods: Surveying of DMP participants of a large health insurance company to investigate influence on quality of life and self-management of patients



and PRO-B in the field of breast cancer are supported by the Innovation fund (Innovationsfond – BGM, 2019), a health policy instrument introduced in 2015 to spur care practice research and innovation (see box for further examples).

Another large-scale cross-provider pilot for PROMs collection and comparison has been initiated by Qualitätskliniken.de (4QD), University Hospital Hamburg-Eppendorf (UKE) and Deutsche Rentenversicherung (DRV) in the area of rehabilitation for patients with the indications hip or knee replacement and back pain in 2018 (Preuß, F. 2019). 4QD provides an online portal for the centralized public reporting of outcomes and hospital comparisons based on five dimensions (medical quality, patient safety, patient satisfaction, satisfaction of referring physicians and ethics). A sixth dimension has been added only this year: since 2020, 4QD is the first institution in Germany to assess and publicly report indication-related quality information based on PROMs for multiple providers: Results from 24 clinics measuring PRO with instruments recommended by international experts at admission and end of rehabilitation stays for 3,048 patients were evaluated in a first pilot phase (Neudam, A. 2020). Risk-adjustment was performed and a Patient-Reported Outcome Quality Index (ProQI), a simple index value, was developed for comparison of achieved PROs among participating clinics. Results of the first pilot phase published in February 2020 revealed high positive effects of rehabilitation on PROs in the orthopedic indications hip replacement, knee replacement and chronic back pain (Schulz, D.H. 2020). The analysis also showed significant differences in outcomes between rehabilitation clinics. Participating clinics received a detailed report, and a study report summarizing the results is accessible via the qualitaetskliniken.de website.

The DeQS-RL, a new guideline on data-assisted institution-wide quality assurance can be regarded as a first attempt to move towards PROMs use at national scale: Among others the main goals of the DeQS-RL are “to strengthen patient safety and patient orientation” as well as “to gain valid and comparable insights into the quality of care of service providers and providers” (Gemeinsamer Bundesausschuss, 2019). Results from systematic patient interviews taking into account their perspective on treatment experience (PREMs) and outcomes (PROMs) should in future be included as an additional indicator in the quality assessment of medical services. According to the IQTIG, the DeQS-RL will become effective on 01.01.2021.

DEEP DIVE

The DeQS-RL – A first move towards PROMs use at national scale?

In 2016 the G-BA commissioned the IQTIG with the development of questionnaires to assess quality of care based on patient surveys for designated procedures. A data flow concept was defined by the G-BA in 2018 and a final report of the IQTIG released in 2019. The first patient survey should be introduced as part of the quality assurance procedure for percutaneous coronary intervention and coronary angiography (QS PCI) (DeQS-RL, 2019). In addition, questionnaires are currently being developed for other disease and treatment areas such as kidney replacement therapy, outpatient psychotherapy and discharge management. Questionnaires are envisaged for minimally invasive heart valve interventions (MHI-RL) as well as the prevention of nosocomial infections and postoperative wound infections (QS WI). Implementation, first only for QS PCI, is planned for 01.07.2021: Providers performing PCIs will transmit contact details of all patients who underwent this procedure. A dedicated dispatch center will select 200 patients (per year and provider) who will receive a request for participation and the questionnaires 4 weeks after discharge. In institutions with less than 200 cases annually, all

their cases will be included. The anonymized questionnaires are to be sent back to the Federal Evaluation Center of IQTIG for evaluation. Results will be transmitted to the National Labor Communities which may decide to contact providers to clarify deviations.

Even though the guideline is considered a move towards PROMs use at national scale, assessment of the delineated process reveals limitations for its applicability and potential gain. Following the guidelines' current form, PROMs would not be integrated into clinical practice and patient care pathways. Only a sample of 200 patients per provider and indication would be contacted to collect PROMs retrospectively and paper-based. Results would not be transmitted to individual providers or physicians and not be accessible to the larger public. In consequence, neither physicians nor patients would be able to use PROMs results in their interaction. Individual use of PRO-data such as for monitoring and symptom management cannot be performed since relevant data is only collected after interventions, anonymized and the results bypassing both physicians and patients. Especially patients would be subject to an additional administrative burden without receiving direct returns for their efforts. In addition, the use of aggregated data for quality improvement at provider level through identification of best practices is complicated by a lack of transparency. Given these limitations, the actual cost-benefit relationship appears questionable.

3.10.2 Disease and treatment areas of focus

Areas for first cross-provider PROMs collection and comparison as part of a large-scale pilot initiated by Qualitätskliniken.de (4QD), University Hospital Hamburg-Eppendorf (UKE) and Deutsche Rentenversicherung (DRV) include rehabilitation for orthopedic patients (knee-, hip- and spine patients), for cancer and psychosomatic patients with diagnosed depression and anxiety in 4QD member hospitals (Preuß, 2019). For PROMs collection at department or provider level, a survey conducted by Initiative Qualitätsmedizin (IQM) among its 490 members in August 2019 indicated oncology as the main area of application (IQM, 2019): 65 of the 136 member hospitals reported applying PROMs in this disease area, with PROMs in breast cancer being the most frequent within the field (24 of 65 hospitals), followed by bowel cancer (17 hospitals) and prostate cancer (15 hospitals). Orthopedics and traumatology represent the second most frequently named area of PROMs application in the IQM survey (51 of the 136 member hospitals), with joint replacement and pain being the most frequent indication areas for PROMs overall (27 hospitals each). Other disease areas included indications summarized under "visceral surgery". Results of the survey are in line with findings from a literature search conducted for this report: PROMs initiatives and research projects were most frequent in the field of oncology and orthopedics, followed by PROMs application in psychosomatic medicine and mental health. Indication areas for which patient surveys including PROMs are envisaged based on the DeQS guideline include percutaneous coronary intervention and coronary angiography, kidney replacement therapy, outpatient psychotherapy and discharge management.

3.10.3 Form of data utilization

Since PROMs are predominantly used in a pilot or research setting at present, utilization is focused on the patient-physician and provider level in this context: PROMs are currently used within certain departments, providers or provider associations to promote more



patient-oriented care through enhanced symptom screening and monitoring, improved communication, and shared decision-making and to support patient involvement. Physicians at Schön Klinik Neustadt, for instance, administered PROMs instruments such as the EQ-5D and the WOMAC questionnaire at admission, and 3 and 12 months after surgery (Kaplan, R. S., Witkowski, M. K. & Hohman, J. A., 2014). Outcome measurement is also performed during rehabilitation to evaluate and track improvement throughout the care pathway. An Orthopedic Expert group meets bi-annually to discuss outcome performance and refine measurement instruments if needed. In addition, an Orthopedic Practice Group meets twice a year and discusses recommendations such as changes in care protocols for all Schön hospitals issued by the expert group. At Neustadt, outcomes were reviewed on a monthly basis by the orthopedic department. Every three months aggregated data was posted on an online dashboard for internal benchmarking within the department. Innovation Fund projects such as PRO-B and PROMoting Quality (Kuklinski, D. et al., 2020) are exploring the use of PROMs to trigger targeted interventions for individual patients if reported outcomes deteriorate.

Beyond the innovation fund projects, aggregated PROMs data is currently being used for internal quality assurance and to screen for specific characteristics or symptoms as well as to generate evidence for best practices in clinical studies. Only few providers such as Martini-Klinik are publicly self-reporting aggregated PROMs data on their websites (Martini-Klinik Hamburg, n. d. b).

Interest in the utilization of aggregated PROMs data for assessing providers' performance, benchmarking and external quality assurance is growing: For instance, the current Qualitätskliniken.de (4QD) PROMs initiative in the area of rehabilitation aims to promote transparency within the sector and enable risk-adjusted benchmarking (Preuß, F. 2019). A first pilot phase in the area of rehabilitation for patients with the indications hip or knee replacement and back pain was finalized in February 2020. Rollout across other indication areas is planned. IQM has recently quantified interest in PROMs for benchmarking in its member survey on the current use of and demand for PROMs (IQM, 2019): Use of PROMs for benchmarking is perceived as important by about 83% of all respondents (and 51% of current PROMs Non-Users). IQM is responding to this growing interest with a framework agreement signed with the German IT provider Heartbeat Medical in 2021. Almost 500 IQM member hospitals in Germany and Switzerland will have access to a digital platform that supports standardized outcomes measurement (PROMs and CROMs) and enables nation-wide and transnational quality benchmarking (Heartbeat Medical, 2021).

Utilization of PROMs for outcome-based payment (pay for performance, P4P) such as bundled payments is being explored at provider level. For instance, Martini-Klinik, a wholly owned subsidiary of the Hamburg University Hospital and integrated practice unit (IPU) specialized in prostate cancer diagnosis and treatment, negotiated integrated care contracts with the five largest German statutory health plans in 2007–2009 (Porter, M. E. Deerberg-Wittram, J. & Feeley, T.W. 2019). Under this contract, Martini could treat publicly insured patients but was reimbursed 0.5% less than the standard DRG payment for prostate cancer treatment. Moreover, Martini committed to deliver high-quality care and meet set quality targets such as up to >95% for urinary continence and up to >97% for erectile function. Failure to accomplish these targets can trigger investigations by the health plans. For international patients, a care bundle including all outpatient and inpatient care at Martini-Klinik and surgery has been established.

Quality contracts (Qualitätsverträge)

A policy enacted as part of the “Hospital Care Structure Reform Act” in 2016 (Krankenhausstrukturgesetz, KHSG) has created the option of negotiating exclusive quality contracts between health insurance companies and hospitals (GKV Spitzenverband, 2018). The aim is to test how further improvements in inpatient care can be achieved, particularly by agreeing on higher quality targets and incentives. Testing of incentives and agreement on quality indicators within the framework of quality contracts will be performed between 2019 and 2023. Four focus areas for quality contracts were defined by the G-BA: Joint replacement, prevention of postoperative delirium in the care of elderly patients, respiratory weaning in long-term ventilated patients and care for people with intellectual disabilities or severe multiple disabilities in hospitals. Contractual partners can decide on the quality instruments to be used and the respective incentive model. According to § 110a SGB V §8 instruments for achieving higher quality requirements can include, among others, indicator results or results of patient surveys. The IQTIG is entrusted with the evaluation of the quality contracts success based on reports, data and final surveys provided by the contractual partners.

The law on the further development of health care (Gesundheitsversorgungsweiterentwicklungsgesetz – GVWG) passed in 2020, that aims to promote quality and transparency, better services and stronger networking in care (Bundesministerium für Gesundheit, 2021), supports an expansion of quality contracts: By the end of 2023, four additional disease or treatment areas for quality contracts are to be defined and the trial period was extended to 2028. In order to obtain a sufficient number of contracts, an annual expenditure volume per insured person was also set. For 2022, the amount to be contributed by statutory health insurances was set at 0.30 euros per insured person. With almost 72 million people with statutory health insurance in Germany, this would result in an overall budget for quality contracts of 21.7 million euros for 2022 (DEKV Presseportal, 2020). Moreover, an overview of the concluded contracts should be published regularly. The GVWG also includes regulations for further development of patient surveys. According to the new law, in the development process, national and international survey instruments should be taken into account and patient surveys should be digital and barrier-free. In order to further promote quality transparency, the GVWG also contains a regulation for the publication of institution-related, cross-sector comparisons.

On a larger scale, quality contracts (Qualitätsverträge) between payers and providers are testing the impact of agreed incentives and quality targets on the quality of inpatient care. Quality instruments can include results of patient surveys and payments can be tied to the attainment of agreed quality targets such as (patient-reported) outcomes.

The contract between Barmer, one of the largest statutory insurances with a strong interest in PROMs, and the German Center for Orthopedics at Waldkliniken Eisenberg signed in November 2019 is an example of a quality contract including PROMs (Deutsches Ärzteblatt, 2019). A patient’s quality of life is assessed at the beginning and after treatment as well as severity of pain recorded throughout the treatment. Moreover, a standardized pre-operative screening for comorbidities such as diabetes, anemia or depression increasing the risk of developing complications is performed. Individual characteristics of the patient are recorded to optimize them prior to surgery whenever possible or to inform about an alternative choice of treatments, provided that the disease status allows for conservative treatment. Hospitals receive an additional reimbursement of 150 Euros per patient for this extended screening to promote increased indication quality.



Germany's Institute for Quality and Efficiency in Healthcare (IQWiG) has also started to include PRO-data in its assessment of effectiveness or safety of new products. The importance of real-world evidence for continuous health technology assessment after market approval is increasing. These trends reinforce the interest of the pharmaceutical and medtech industry in PROMs. In registry-based trials, for instance, PROMs can be used together with clinician reported outcomes to evaluate the added benefit of new products (DIMDI, 2011). A study examining the integration of PROMs in German AMNOG assessments and their impact on the G-BA decision until 2016 found that PROMs were used in 60% of all subpopulations (Borchert, K. et al. 2016). The most frequent instruments used were the SF-36, the EORTC QLQ and the EQ-5D questionnaires. According to the study, integration of PROs in AMNOG dossiers may have positively impacted the rating for an added benefit and might support subsequent price negotiations.

3.10.4 Challenges

Despite the increasing number of pilot projects at provider level, the engagement of IQD and IQM to use PROMs as a quality indicator in a large set of member hospitals and the growing interest in patient-centered healthcare and quality, commitment to PROMs at system level is still lacking. In terms of quality assessment, the focus remains largely on process or infrastructural indicators.

In the absence of a national IT platform or appropriate tools for PROMs accessible to all providers free of charge, PROMs is perceived as costly and resource-intensive. The integration of digital solutions offered by private IT providers is particularly sumptuous: Substantial fees are charged for establishing interfaces which allow for interoperability of digital PROMs tools with the hospitals' EMR system. Concerns about data security and compliance with regulations such as the European General Data Protection Regulation (GDPR) were mentioned as another hindering factor in expert interviews.

Since the collection of PROMs is not part of reimbursement, costs of implementation and performance have to be borne by individual providers unless pilots are eligible for funding through quality contracts or the innovation fund. The effectiveness, sustainability and profitability of PROMs use at scale has not yet been successfully demonstrated. Moreover, uncertainty about tools and standard sets to be used present another challenge for implementation.

Challenges identified throughout the conducted interviews are confirmed by the results of the IQM survey of 2019 (IQM, 2019): Of 221 members who are currently not using PROMs about 37% considered them as not (yet) relevant and about 24% perceived PROMs as too laborious. Barriers to implementation put forward by the respondents included lack of staff and resources, lack of competence in this area at their institution and absence of standards or consensus on tools to be used.

3.10.5 Success factors

Given the fact that most initiative provider-level bottom-up examples are still at an early phase, successful strategies for PROMs implementation can be derived from the most advanced pioneers in this field. Lighthouse projects such as Martini-Klinik (Porter, M. E. Deerberg-Wittram, J. & Feeley, T. W. 2019), specialized in prostate cancer care, or the private hospital group Schön Kliniken (Kaplan, R. S. et al., 2014), specialized in mental

health and orthopedic conditions, have received international recognition for their results, assessed inter alia with PROMs. In both cases, physicians aimed at providing their patients with the best possible care and measuring the attainment of this goal. To this end, indicators that adequately represented the outcome of patients had to be selected, results measured and data analyzed to derive new insights. At Martini-Klinik, a substantial amount of outcome data – both clinical and patient-reported outcome measures – was collected and pooled in the Martini database over 15 years: In 2019, Martini-Klinik documented approximately 30,000 cases in its data system (Katz, G. et al., 2020). The analysis of collected outcome and clinical data allowed conclusions to be drawn for the improvement of outcomes. At Martini-Klinik as well as at Schön Klinik, outcome performance is discussed at regular meetings and informs about changes in care protocols. Internal benchmarking is performed up to the individual physician level. Martini-Klinik introduced public selfreporting on its website and international benchmarking at a later stage. Both examples illustrate that integration of PROMs into daily clinical practice, a culture of transparency and a strong emphasis on sharing best practices supported a continuous improvement in the quality of care. Furthermore, the transparency of achieved outcomes and benchmarking are likely to drive competition with a focus on quality of care and encourage followers.

Other factors for success can be derived from over 200 providers or departments using the digital solution for PROMs collection offered by Heartbeat Medical: Successful implementation of PROMs at provider level often requires the commitment of clinical leaders as well as top-down support through management. Academic interest (e.g. in university hospitals) and the gain of competitive advantages for private providers are strong drivers for adoption.

Political and multi-stakeholder interest has followed suit: Apart from providers, insurances are starting to explore PROMs as a dimension of quality of care through quality contracts or in innovation fund projects. According to the former ICHOM president and head of RoMed Hospital, Dr. Jens Deerberg-Wittram, three enabling factors for a large-scale adoption of PROMs have emerged in the last decade: digitalization and the widespread use of mobile devices give rise to new possibilities for PRO-data collection and utilization. In particular the COVID-19 pandemic has highlighted the value that digital health solutions can bring to patients. Awareness and perceived relevance of PROMs are increasing, and PROMs tools have become accepted in fields such as orthopedics and cancer care. Frameworks such as quality contracts and the innovation fund create possibilities for providers and insurers to establish the required PROMs infrastructure and gain experience with PRO-data utilization. Payers' interest in PROMs and potential benefits has been growing over the last five years. For instance, BARMER, one of Germany's largest statutory insurances, is exploring possibilities of PROMs in innovation fund projects such as PROMoting Quality and through quality contracts.

Nevertheless, a number of challenges remain to be overcome to successfully transfer PROMs from provider level to system level. Challenges mentioned during the conducted interviews and identified success factors or proposed solutions are listed in the table below. Moreover, as part of the IQM survey on PROMs (IQM, 2019), hospitals not yet using PROMs mentioned resource allocation for PROMs (additional staff, tools), IT and knowledge support, better evidence for the validity and benefit of PROMs, as well as the comparability of results and a standardized approach as important facilitating factors. Furthermore, a need for easily applicable, efficient digital solutions for PROMs, keeping administrative efforts to a minimum while generating timely and meaningful results for clinical use, was expressed. Respondents also expressed high interest in a top-down support of PROMs implementation and called for coordination with medical societies and scientific supervision.



Implementation challenges	Success factors & proposed strategies
<p>PROMs implementation in the clinical sector is fragmented, over 30% still not convinced of relevance</p>	<ul style="list-style-type: none"> » Implementation of tools that are easy to use for both physicians and patients, and directly show what is relevant for these stakeholders » Medical societies and healthcare professional associations should be more involved by implementing PROMs in registries and advocating in favor of PROMs » More governance and a system-wide approach is needed to prevent fragmentation of the PROMs field
<p>PROMs questionnaires: too many questions, replication for multimorbid patients, too general</p> <p>Uncertainty about best choice of questionnaires/standard sets</p>	<ul style="list-style-type: none"> » Top-down approach to create a 8 dimension-based framework for PROMs questionnaires which maintain specificity and relevance for patients and physicians while allowing for comparisons » Guidelines should recommend questionnaires to be used for PROMs within certain disease areas and include specific recommendations on how to integrate them into clinical care pathways.
<p>PROMs tools: Applications for mobile devices might exclude elderly people</p> <p>Low follow-up rates</p>	<ul style="list-style-type: none"> » Opting for an email-based distribution of questionnaires (with the possibility of sending questionnaires to family members) » Email with questionnaire or reminders sent from treating physician/hospital address (familiar to patient) instead of sending from IT provider address » Discussion of baseline PRO assessment at first consultation to underline the value of PROMs results increases follow-up rates
<p>PROMs collection and utilization: Lack of experience in integration of PROMs in clinical pathways and utilization of results</p>	<ul style="list-style-type: none"> » Integration into the workflow needs to be supported by a stakeholder with various skillsets who can create alignment among others (healthcare professionals, management) together » Need for training of HCPs in use of PROMs tools and results
<p>IT infrastructure: Every provider purchases platform/digital solution for PROMs individually, interfaces to EMR systems often difficult and costly</p>	<ul style="list-style-type: none"> » Introducing an obligation to establish interfaces in the healthcare system (between different EMR systems and digital PROMs tools), similar to the banking system, without additional fees » Establishing a national platform or PROMs registry to collect and share aggregated PRO-data for research/benchmarking
<p>Lack of incentives and financial support to establish PROMs infrastructure and measure outcomes in a sustainable way</p>	<ul style="list-style-type: none"> » Incentives for PROMs collection/financial support for PROMs infrastructure need to be provided » Quality contracts and Innovation fund can be a support for PROMs implementation by providing funding for infrastructures or financial incentives to achieve better outcomes with PROMs as a relevant dimension » Another incentive for PROMs could be the perceptibility of the high quality of care created through transparency of achieved outcomes (e.g. in national PROMs registry or as part of medical society certification processes)



4 Discussion

This review of PROMs adoption across countries has helped identify common themes within PROMs piloting and implementation as well as in disease and treatment areas of focus and differences in PRO-data utilization. This has allowed an abstraction of the challenges that the countries have experienced and the success factors they leverage to support PROMs adoption across different geographic, administrative and system levels, disease areas and utilization forms. Based on these lessons learned, elements of a broad PROMs roadmap for Germany can be charted. This roadmap can be used to provide information for future discussions at a medical professional, specialty, department, healthcare provider organization, society, regulatory and policy level and to lay out options to spur further PROMs adoption.











4.1 Common themes across countries

Across countries, common themes and attitudes to PROMs have emerged, such as a motivation to drive PROMs adoption, a sense of opportunity of the current moment and the disruptive power of the COVID-19 pandemic for health system change. PROMs have generally been perceived as a powerful tool to increase patient involvement, drive patient-centered care and compare therapy options from the patient perspective. Beyond these aspects, trends along the three main analytic lenses of PROMs implementation, disease and treatment areas of focus, and forms of data utilization were identified. A summary of the selected countries' PROMs approach along the three analytical lenses is presented below and overarching trends are described in the following sections (see Table 1).

4.1.1 PROMs implementation

The selected countries are at different stages of the PROMs implementation process, with one country having implemented a national PROMs approach (England), some including PROMs in national registries or having set a national PROMs standard for selected diseases (Canada, Denmark, USA, the Netherlands, Norway, Sweden) and in larger hospital networks (USA, the Netherlands). Others have implemented a regional PROMs strategy (Switzerland, Australia), or have mainly implemented PROMs in pilot and research projects (Germany). However, across all countries, there are an increasing number of PROMs pilots and frameworks for quality assurance on a national scale and pilot projects in the provider and research setting. To apply what has been learned and best practices on a broader basis, researchers and health professionals involved in these pilot projects are often pushing for a more national or state-level PROMs support structure to sustain the beneficial effects of PROMs collection and to expand the scope of implementation to more patients, more disease areas and to simplify data collection and analysis further. In Germany, growing

TABLE 1: Overview – Characteristics of selected countries' PROMs approaches

	Level of implementation	Disease and treatment areas of focus	PRO-data use
 Australia	» Mainly bottom up: Cross-clinical and pilot level, but also state-level initiative in NSW	» 25 diseases covered by NSW state program » Focus: cancer, hip and knee replacement, rheumatology	» Research, service improvement, benchmarking, shared decision-making
 Canada	» Mixture of top-down PROMs standards and bottom-up implementation; Province based implementation	» Focus on elective surgeries and chronic diseases » National standard for hip and knee replacement	» Performance monitoring, research, shared decision-making
 Denmark	» Top-down recommendations and infrastructure	» Chronic diseases, orthopedics, cancer, mental health, etc.	» P4P, outcome improvement, patient monitoring, reporting to registries
 England	» Mainly top-down implementation but also bottom-up initiatives and registries	» Nationally, hip and knee replacement focus » Pilot projects in additional areas, e.g. mental health	» Public reporting, research, quality improvement
 Netherlands	» Bottom-up implementation and top-down financial support	» Speciality care – cancer, diabetes, heart diseases, hand and wrist care etc.	» Benchmarking, research, quality improvement, shared decision-making
 Norway	» Bottom-up implementation and top-down support	» Mental health, orthopedics, NCDs (e.g. diabetes and heart diseases)	» Research, quality improvement, shared decision-making, benchmarking
 Sweden	» National health data platform and bottom-up initiatives	» Chronic diseases, surgical/orthopedics, cancer, mental health/neurology	» Quality improvement, research, benchmarking, public reporting, P4P
 Switzerland	» Predominantly voluntary, bottom-up provider or regional projects » First mandatory PROMs collection in the Cantons of Zurich and Basel-City	» Elective surgery (spine surgery, hip & knee replacement) and cancer care	» Patient monitoring, shared decision-making, public reporting, P4P, research
 USA	» Voluntary, bottom-up provider / hospital networks and Medicare bundled payments	» Broad range of diseases and treatment areas: cancer care, orthopedics, primary care, varicose veins etc.	» Patient monitoring, shared decision-making, research and P4P
 Germany	» Mainly voluntary, bottom-up provider level or cross-provider projects » Planned selective introduction at national scale (DeQS-RL) in 2021	» Elective surgery (mainly orthopedics) and cancer care, rehabilitation	» Research, patient monitoring, shared decision-making, (public reporting, P4P)

interest was observed in implementing PROMs at a hospital level, with 138 of 367 hospitals reporting to use PROMs (IQM, 2019). The framework agreement made between IQM and Heartbeat Medical in February 2021 is another sign for the increasing interest in PROMs.

The analysis shows that the underlying health system framework and the degree of centralization to a large extent determine the PROMs implementation strategy pursued so far as well as the options moving forward. Nationally organized health systems such as the NHS in England are close to nationally implementing PROMs, whereas federally organized health systems (Australia, Switzerland) either show regional or pilot projects or a move towards state-based implementation. England with its government-driven national PROMs strategy has already experienced some limitations of a quickly adapted top-down national implementation. According to an evaluation by the NHS, the actual use of publicly reported PRO-data tended to be low due to various limitations in the reporting of data. In contrast to these findings, a study by Gutacker et al. (2016), reflected a positive correlation between reported average health gain based on PROMs with the provider choice by patients. In the Netherlands, where common standards were set in collaboration with clinicians and patients, the resulting options for quality improvement led to a widescale voluntary participation of hospitals that reached national level. Bottom-up-level implementation followed by the scaling of best practices as suggested by experts from multiple countries led to more direct use of PROMs by healthcare professionals and the management level of providers. However, the pure bottom-up strategy also had its downsides and led to questions concerning the (financial) sustainability of the implementation and the comparability of measured outcomes due to the variety of questionnaires and standards being used, and hence the question of getting the most out of PROMs' potential for quality improvement, patient information and empowerment, and public reporting. Hence, as stated by Pross, C. et al. (2017), system centralization and decentralization need to be balanced to ensure both national comparability and local innovation.

Overall, in countries without a national framework, there is an increasing demand for national data collection and clearly defined reporting mechanisms supported by a common and open IT infrastructure. Moreover, paper-based collection was reported as being a clear barrier for high participation rates by patients and for its usability by providers. Across some countries, the COVID-19 pandemic has been described by experts as a digital health disruptor supporting the adoption of a remote monitoring of patients' wellbeing via PROMs as well as the integration of these PROMs into digitally enabled remote care models.

4.1.2 Disease and treatment areas of focus

Across countries, similar disease areas were covered in PROMs projects. Predominantly, orthopedics, particularly hip and knee replacements, was a common field for large-scale pilot projects (Sweden, Switzerland, England, USA), national reporting (England) and state-level projects (Denmark). Orthopedics has been identified as low-hanging fruit in terms of PROMs implementation, especially due to its clear start and end point in the care process (Elvira Häusler, Muller Healthcare Consulting) and because it falls in the area of elective surgery. Additional reasons were the high degree of standardization, the high volume and costs of procedures and the care provision in an individual setting. In comparison, acute illnesses or those which fall into end-of-life care were seen as less favorable areas for PROMs implementation because in severe cases, where patients are too sick to answer questionnaires, PROMs collection might be a burden for patients (Jaqueline Hartgerink, DICA). Nevertheless, also in palliative care the quality of care and outcomes needs to be continuously improved and should

include patient as well as family reported outcomes for this purpose, as successfully done e.g. in the Patient Care Outcome Collaborative (PCOC) in Australia (Dudgeon, D., 2018).

Beyond the field of orthopedics, most provider-level, pilot and research projects as well as existing registries appear to be in the field of oncology. Especially Australia's PromptCare project, the US Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment by Basch, E. et al (2017) and the Martini-Klinik focusing on prostate cancer in Germany are prominent examples. Furthermore, the field of elective surgery has seen a rise in PROMs activity on a national and international scale, such as a designated registry for elective surgeries in Canada or the European Eurequo project on cataract surgery. Currently, PROMs are still less often applied for chronic diseases, but numerous countries have started pilot projects in this area after implementing PROMs in first-mover disease domains. Even though this field was identified as an area in which patients would profit most from PROMs, the actual implementation has been difficult. Reasons include the fact that treatment mostly takes place in a primary care setting and patients are likely to see different providers over the course of treatment, which creates the need for efficient cross-sector collaboration and data exchange. As we have seen from PROMs experiences across countries, it is particularly difficult (see more below in common challenges section) to spur PROMs innovation and adoption in chronic diseases. As the OECD's PARIS initiative is focusing on chronic diseases, there could be more guidance in this field in the future, leading to more concrete actions globally. Overall, a common trend across countries was to add further adjacent disease areas to those already introduced for PROMs once success stories for one or some disease areas could be shared. This implementation process seems to take place starting with the easiest implementation in disease areas with a clearly defined treatment procedure and time to the more complex ones involving different providers or sectors and requiring continuous care.

4.1.3 Forms of data utilization

From the individual use of PRO-data to various forms of population-based use of PRO-data, countries cover different utilization forms. In countries without a national PROMs framework (Australia, Denmark, Germany, Switzerland, USA, Canada, Norway), PROMs are predominantly used to perform more holistic patient and physician monitoring and improve patient-physician communication in a shared decision-making process based on PROMs data, such as in the PromptCare project in Australia or the Providence care network USA. In some countries, PRO results are also used for partially automated remote monitoring (such as in the context of the AmbuFlex application in Denmark) or telemedical fields of application. Exceeding defined threshold values can trigger automatic notification of the medical specialist and inform them of a possible deterioration in the patient's state of health. In some research projects, PROMs are used to determine the need for medical interventions (e.g. in the context of the innovation fund research projects ProB and Promoting Quality or in the study by Basch et al. (2017)). Moreover, at department or provider level, PROMs are used to identify best practices and improve outcome quality like at Martini-Klinik in Germany or Lovisenberg Hospital in Norway. In addition, PROMs are used to generate evidence for patient-relevant aspects of treatment and outcomes once sufficient data has been generated, e.g. at Diabeter in the Netherlands. The lack of more standardized data collection and aggregation is currently limiting a broader utilization of PROMs, especially a population-based use of PRO-data, such as public reporting, aggregated quality improvement and research. In Germany and the Netherlands, some payers are piloting PROMs collection for selective contracting and risk-sharing between payers and larger providers, e.g. Martini-Klinik, Schön Kliniken and Waldkliniken Eisenberg in Germany and Diabeter and

Santeon in the Netherlands are on the verge of establishing or have already established selective contracting or VBHC arrangements with health insurers. Finally, pharmaceutical and medical technology companies in some countries are partly involved in PROMs collection, e.g. Medtronic bought Diabeter and in Switzerland value-based healthcare contracts are being discussed with pharmaceutical providers and generally show a rising interest in PROMs as part of Real-World-Evidence (RWE) to demonstrate their products' added benefit.

In countries with national registries using PROMs (Norway, Denmark, the Netherlands, Sweden, England), in addition to the previously mentioned utilization forms, PROMs are also used for external quality assurance and for generating evidence to identify best practices. In the form of external quality assurance, PROMs are used for the benchmarking of providers, peer reviews and PDCA-cycles for continuous improvement – e.g. certain Danish National Quality Registries including PROMs data, and DICA in the Netherlands reporting back benchmarked data to all hospitals on a daily basis. At national and international levels PROMs are also used to generate evidence for identifying best practices, such as in the orthopedics field in Norway. In these countries, public reporting is, however, not the main goal of PROMs collection, but rather the support of clinics for care improvement and research. Some experts interviewed from the medical field also perceive that the data should mainly inform healthcare professionals and benchmarking, rather than be openly accessible to patients. This was also reflected in the DICA consultation of patients and physicians, in which patients stated that they would prefer to discuss PRO-results directly with their physician (Jacqueline Hartgerink, DICA). Other experts underline the importance of using digital tools not only for data retrieval and analysis but also for empowering patients by making data directly accessible for them (Dr. Ilona Köster-Steinebach, APS).







In countries with a regional or national framework or supporting infrastructure for PROMs (England, Denmark, Australia, Switzerland), standard question sets and a PROMs data collection infrastructure are established, yet the translation into clinical settings is sometimes difficult. The integration into the care pathway requires more than standards, especially medical champions pioneering PROMs collection and a supportive leadership. Whereas England focused on public reporting on the NHS Digital platform, the establishment of a designated PROMs agency in Denmark was aimed at creating common PROMs standard sets and aiding implementation. Experts recommended that next to the consultation of patients and physicians, the questionnaire development should take place in closer collaboration with academic research. In New South Wales (Australia), an IT platform was created, in partnership with a private provider, as a previously governmentally driven IT solution did not provide the capabilities needed to enable successful utilization by healthcare professionals. In the Cantons of Zurich and Basel-City (Switzerland), the regional measurement of PRO-data in selected disease and treatment areas, such as for hip and knee surgery, has recently commenced. In some hospitals, this mandate has yet to be translated into the utilization of PRO-data on the provider level, whereas others have already gained first experiences with PROMs.

There are discussions on the inclusion of PROMs for cost-effectiveness evaluations, e.g. by the NICE in the UK, and Germany's IQWiG has started to include PRO-data in its assessment of effectiveness or safety of new products. Moreover, multiple apps have been developed for disease self-management and healthy living which ask questions similar to PRO-questionnaires and sometimes combine this with the passive measurement of health-related data. Although there is currently often a missing link to clinical care, self-management apps and other health apps hold a large potential in facilitating the collection and use of patient data. Similarly, however, there is a risk of data privatization which could hinder its use for benchmarking, public reporting and quality of care improvement.

4.2 Challenges and success factors

Across countries, common challenges were identified as well as various success strategies that either helped to overcome these challenges or were recommended by experts as alternative, more promising approaches. The success factors broadly fall into the six categories of standardization, clinical champions, patient focus, IT platform and digital data collection, incentives and political will, and can positively impact the implementation and utilization of PROMs both at the micro level (patients and healthcare professionals) as well as the meso and macro level (department, provider, regional and national) (see Table 2).

TABLE 2: Common implementation challenges and success factors for PROMs implementation

Implementation challenges	Success factors
Micro Level – Individual patient & healthcare professionals	
<p>Barriers to filling out questionnaires</p> <ul style="list-style-type: none"> » Health literacy & cultural aspects – Patients’ understanding of questionnaires (health literacy, cultural differences, language barriers) » Amount of questions – Patients overwhelmed by too many questions per visit and session or by the accumulation of questionnaires in different clinics, especially in the case of multimorbid patients or patients with chronic diseases 	<div style="display: flex; align-items: center; margin-bottom: 10px;">  <div> <p>Standardization</p> <ul style="list-style-type: none"> » Aggregated, integrated questionnaires for multimorbid individuals » Provide adequate setting for PROMs, e.g. quiet space, sufficient time and assistance » Use online and digital tools in which language and font size can be easily adjusted </div> </div> <hr/> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div> <p>Patient focus</p> <ul style="list-style-type: none"> » Allow patients to share data with different providers to prevent duplication » Establish and continuously reinforce the role of patient societies in identifying what matters to patients: format and number of questions; reminders and support tools » Physician and nurse explain and emphasize the value and mechanics of PROMs </div> </div> <hr/>
<p>Value of PROMs perceived as low</p> <ul style="list-style-type: none"> » Adherence – Patients not encouraged to adhere to PROMs follow-up, PRO-data not utilized or emphasized by physicians » PROMs vs PREMs – Negative view on PREMs – PROMs perceived as not scientifically sound, too subjective » Inpatient vs. primary care setting – GPs not or insufficiently involved, patients switching providers in an outpatient and acute care setting, data does not carry over » Prioritization of clinical outcomes or process measures in medical societies and current clinical management 	<div style="display: flex; align-items: center; margin-bottom: 10px;">  <div> <p>Clinical champions</p> <ul style="list-style-type: none"> » Support research on PROMs » PROMs trainings to support interpretation and shared decision-making » Educate and train GPs on PROMs benefits » Raise awareness for PROMs as patient empowerment and management tool » Clinical leaders advocating for use of PROMs </div> </div> <hr/> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div> <p>Standardization</p> <ul style="list-style-type: none"> » Accountability framework which clarifies who reacts to PRO-data results and how </div> </div> <hr/> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div> <p>Patient focus</p> <ul style="list-style-type: none"> » Accessible data: Enable patient access to, selfmanagement of and sharing of PRO-data </div> </div> <hr/> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div> <p>IT tools</p> <ul style="list-style-type: none"> » Digital solutions not only gather, but also provide actionable insights and remote care options for HCPs </div> </div>

Implementation challenges

Success factors

Meso and Macro Level – National, regional, provider & department

Barriers to data collection and analysis

- » Insufficient use in care practice – Unclear how to use data, low quality of data and insights generated, no guidance on how to use in care practice
- » High administrative burden – Paper collection or additional program not interoperable with hospital information system
- » Delayed and outdated data – data not collected, analyzed or shared back in real time, without actionable insights
- » Missing data interoperability between departments, providers, registries and regions
- » Lack of care integration – lack of follow-up by hospitals, no care integration, no interest in systematic follow-up
- » Financing disparities and limitations

**IT platform & digital data collection**

- » Cross-sector digital platform or standards for the interoperability of different PROMs collection tools, also interoperable with different hospital information systems
- » Common database from which healthcare professionals can retrieve data in real time
- » Public – private partnerships to benefit from latest innovation
- » Open standards, APIs and data-sharing between IT systems for full interoperability

**Clinical champions**

- » Training program for HCPs on how to integrate PROMs and insights into care practice
- » Adjust care pathways according to results of the aggregated data analysis

**Incentives**

- » Financial incentives and /or public funding to support PROMs adoption and investment in digital tools and infrastructure, e. g. via value-based contracts or lump sums for collecting PRO-data

Missing guidance and best practices

- » Lack of digital and PROMs tool standards: No minimum standards and APIs, intransparent PROMs tool supplier landscape, insufficient digital integration of healthcare IT, existing registries do not include PROMs and lack interoperability
- » Generic PROMs vs. disease-specific PROMs – Common PROMs measures do not cover enough detail to systematically identify problems in care practices or are too specific for comparability
- » Standardization difficulties – need to present data for subgroups (treatment area, age group etc.) but also overall averages
- » Insufficient risk adjustment – Clinicians worried about patient selection and the comparability of patient groups

**Standardization**

- » Supporting PRO agency or recommendations that help providers implement PROMs in the clinical workflow
- » Minimum standards for digital health PROMs collection tools, interoperability standards and recommendations on PROMs use for digital care enablement (alerts, remote monitoring, education)
- » Create common framework along comparable dimensions which cover physical, mental and social health aspects
- » Mixture of disease specific and general questions, combine systematic, standardized PROMs sets with deep dives where relevant for contextual insights
- » Common framework for risk adjustment (national or regional level)

Missing political support and cooperation

- » Lacking cooperation between regional / state level and national level if there is a divided responsibility concerning healthcare
- » Missing quality assurance processes, regulation and financing to create a common framework and IT solution for PROMs collection

**Political will**

- » Health professionals: advocacy for the benefit of PROMs collection for research /for physician-patient interaction and for patient empowerment
- » Policymakers: support national efforts for a common framework and incentives in this field

4.3 Lessons learned for Germany

Looking at Germany and its current level of PROMs adoption, the absence of a national policy explicitly mandating PROMs collection and utilization coincides with a growing number of bottom-up initiatives with few, yet influential stakeholders creating alignment among them. Some organizations are exploring ways of introducing PROMs for national quality assessment and public reporting for specific treatments, providers are testing the use of PROMs for clinical decision-making and the “Hospital Care Structure Reform Act” has created the option of negotiating exclusive quality contracts between insurers and hospitals, in part based on PROMs.

Going forward, a balance needs to be achieved on the one hand between a top-level support structure that prevents fragmentation and over time enables benchmarking benefiting patients nationwide and on the other hand innovative bottom-up solutions that best serve and are driven by healthcare professionals and patients. Piloting PROMs rollouts beyond singular providers on a regional level can generate additional lessons to be learned prior to a national scale-up.

The interest among stakeholders to implement PROMs for various utilization forms was perceived as high, but especially if PRO-data was directly used in the clinical care pathway, in shared or clinical decision-making and for quality of care improvement. I.e. this individual use of PRO data should be a primary utilization form to generate an immediate benefit for patients and clinicians. However, to draw insights that can improve the quality of care over time, it is important that PRO-data facilitates benchmarking and research as well. If sufficient experience, research and trust is generated, further utilization forms such as public reporting, wider selective contracting, or pay-for-performance can follow.

Established PROMs programs internationally and in Germany today predominantly focus on orthopedics and oncology. These fields can consequently be leading fields in Germany, also for a wider-scale PROMs rollout, while other treatment areas can closely follow suit and utilize what has been learned from the first mover domains. In this respect, chronic care was mentioned as a particularly relevant area for patients to enable continuous quality of life and quality of care improvements.

Based on the comparative, cross-country analysis and expert interviews, this report identifies improvement areas and success factors that can drive an increased adoption of PROMs in Germany. A potential PROMs roadmap for Germany is outlined along the previously identified 6 main determinants of successful PROMs adoption at a micro patient and medical professional level and a macro provider and health system level.



Patient focus

Whereas other countries have successfully included patients in the design and application of PROMs, such an approach is currently lacking in Germany.

Engaging patients in the development of PROMs frameworks and questionnaires and enhancing patient access to and use of their own PRO-data should be a core aim of a German PROMs strategy. Moreover, patient organizations need to advocate for their perspective to be included and regarded more in the care process.

- » Hence, stakeholders responsible for the standardization of PRO measurement, collection and reporting should involve patient representatives and engage with patient societies to keep the goal of patient-centered care at the forefront of any future PROMs implementation steps. Patients should be particularly involved in:
 - Defining priority areas for PROMs implementation.
 - Setting up a PROMs questionnaire framework for a potential national rollout.
 - Establishing questionnaires for specific disease or treatment areas.
 - Evaluating the results of pilot programs before national rollout.
- » Patient involvement should take place via focus groups of patients as well as through the inclusion of “expert patient representatives”, who are provided with and underwent training to represent the patient perspective in the political and clinical spheres
- » Moreover, patients should have access to their own PROMs results to promote involvement and self-management, and strategies should aim at enhancing health literacy in this respect
- » To overcome data privacy restrictions, patients should be allowed to share their own PRO-data with different and new physicians who are part of their care network. This could be a core feature of the ePA that is being introduced in 2021. PROMs results are an option for public reporting, but only at a later phase of PROMs implementation.
- » Public reporting of PROMs is important for achieving transparency in the health sector and thereby publishing easily accessible and comprehensible information for patients. However, for public reporting to support care improvement processes and patient empowerment, solid research, trust and experience needs to be established beforehand

BEST PRACTICE

PRO Secretariat: Patient involvement in PROMs development in Denmark

The PRO Secretariat at the Danish Health Data Authority works with patients and healthcare professionals to define areas for PROMs adoption and create standards for PRO questionnaires. **Patients are involved in brainstorming workshops separately from healthcare professionals.** According to Sanne Jensen from the PRO Secretariat, patients have an opportunity to express their opinions fully. The continuous involvement further emphasizes that questionnaires address what matters most to patients and are understandable to them. New questionnaires are tested on two levels: Patients test for comprehensibility and meaningfulness, whereas health professionals test whether the questionnaire and its associated algorithms support their clinical practice as intended. Furthermore, a continuous revision after implementation in the hospital setting ensures that problems identified as part of the implementation can be used as lessons to be learned for the further rollout in other provider settings.

BEST PRACTICE

Providence Hospital Network: Shared decision-making based on real-time data in the USA

At Providence, a hospital network which consists of healthcare providers in 7 USA states, PROMs are integrated into the care pathway in a way that enhances shared decision-making with patients. A dedicated team of Epic analysts, who are trained to build and modify components of EMRs, have created a data infrastructure that merges PROMs with EMR data. The

data architecture includes visualization components to easily identify the core aspects of a patient's report directly in the patient's chart. **A preselection of visualized data is shown to the physician on the screen, which facilitates the use of patients' answers within the consultation.**

Data shown in the analysis dashboard is real time to enhance timely decision-making. Although patients cannot currently access their results by themselves, they are encouraged to look at and discuss the data together with the physician at the consultation. In this way, physicians can contextualize the results for patients and patients can directly ask and discuss the results with the physician. An Epic component called "Smart Phrases" moreover enables quickly and easily populating clinical notes with PRO-data. Making the use of data as easy as possible via automation and visualization is reported to lead to a more common use among healthcare professionals and a more frequent discussion with patients for purposes of shared decision-making.



Clinical champions

In terms of the most successful forms of application, experts and pilot project results have reflected the most positive experiences to be related to PROMs integration in daily clinical practice. When PROMs results were used by physicians in a consultation with patients, targeted and more meaningful conversations were reported (e.g. Denmark). This integration into daily practice enabled shared decision-making and increased the awareness and acceptance of PRO measurement on both sides. Furthermore, the digital PRO-data collection and reporting enabled earlier interventions and targeted follow-ups for patients in need of medical attention. For Germany, this means that while other forms of application such as public reporting can be of interest long-term, in the first instance the widespread integration into clinical practice driven by clinical champions should be the primary aim. To enable valuable research and benchmarking, PROMs from the provider setting should be shared in a common data platform as well.

Although PROMs have continuously gained more presence, the awareness for the relevance and benefits of PROMs among clinical staff is still limited in Germany, with 36.65% perceiving PROMs as not relevant (IQM, 2019). Multiple experts emphasized that without clinical champions and clinical leadership support, PROMs implementation is impossible. Patients are becoming more informed, but also need to be educated by healthcare professionals about the value of PROMs for their care quality and wellbeing.

Possible strategies for spreading awareness for the value of PROMs among healthcare professionals and establishing more champions are training programs for the active use of PROMs results in clinical practice or a platform to celebrate successes and share best practices. Meetings for internal quality assurance and conferences can be used for this purpose as well. Experts reiterated that continuously sharing information with clinical staff can be the main motivating factor, as it addresses the clinician's intrinsic motivation to improve care for patients. Hence, once PROMs collection has been implemented, actionable results should be shared in real time and in regular reports to continuously motivate healthcare professionals. Making PROMs systems easy to use and actionable could further motivate health professionals. Another motivating factor to aid the collection of PROMs according to various experts could be the availability of data for scientific publications.

- » **Commitment of clinical champions is a key driver for successful implementation of PROMs. Nationwide support and incentives for clinicians can increase uptake across providers.**
 - Academic interest in PROMs has been identified as a strong facilitating factor for PROMs uptake. Therefore, a **PROMs scholarship or dedicated research fund** eligible for clinicians and other healthcare research professions committing themselves to promoting PROMs research and implementation within their specialty should be established to create further dynamics.
 - **A national roundtable of PROMs scholars** should be set up to facilitate a cross-sector and specialty exchange of insights and build a **curriculum for PROMs training of medical staff**. This national roundtable could also develop recommendations for health care policy concerning a stronger promotion and integration of PROMs in the German health care system.
 - **Additional platforms (such as dedicated conferences and online portals)** within and across medical specialties should be established to create visibility for accomplished successes in terms of quality of care assessed with PROMs and the sharing of best practices.

BEST PRACTICE

Martini-Klinik VBHC model: Clinical leadership and vision for patient feedback and continuous improvement

The Martini-Klinik in Hamburg, founded by Prof. Hartwig Huland, has solely focused on prostate cancer care since its inception in 2005 and is the leading example of successful PROMs implementation in Germany. **It was one of the first to voluntarily commit to long-term health outcomes measurement and to initiate public self-reporting in Germany driven by clinical champions in this field.** Following a stepwise approach, which started with the clinician-driven collection of data in an excel sheet, the Martini-Klinik slowly grew to become a leading provider for prostate cancer care, collecting PROMs along the full cycle of care and integrating them with EMRs. The Martini-Klinik accomplishes complication rates ranking far below those of the German hospitals' average (Martini-Klinik Hamburg, n. d. a) and has had selective care contracts with the five largest German statutory health funds since 2009.

Today, the Martini-Klinik is not only known for quality treatment but also for its prolific scientific output, an additional motivator for PROMS collection and use: The data of 30,000 patients stored in the Martini Data System combined with data from biomaterial samples contributes to 50-80 scientific papers being published on annual basis (Huland, H., 2018).

Members of the faculty have chaired the development of the ICHOM standard set for prostate-cancer (Martin, N. E. et al., 2015), fully implemented the standard set and promoted international benchmarking in the "Prostate Cancer Outcomes" Study (Martini-Klinik Hamburg, n. d. c).

One example of PROMs utilization in clinical practice at the Martini-Klinik is the linkage between PROs and other types of data such as genetic profiles to help prognose oncological outcomes as well as to plan the individual therapeutic approach. Moreover, PRO data facilitates shared decision-making with patients and informs quality improvement strategies.

The collected outcomes data also serves as a direct feedback instrument for each surgeon:

Every 6 months, surgeons receive a detailed report on their own results and those of their peers, and training is offered to surgeons ranking below average. This process promotes continuous improvement of the skills of each surgeon, and thus of the outcomes achieved.

Clinical leadership and an overarching support structure enable real-time data use at University Hospital Basel

In 2016, Prof. Christoph A. Meier became the new CMO of University Hospital Basel (USB) to drive change in healthcare delivery following the principles of Value-Based Healthcare.

He perceived measurement as the key for generating evidence to define adequate care that matters to patients. The aim of implementing the collection of standardized patient outcomes as well as cost measurement received endorsement. Hence, the required infrastructure was provided, a VBHC team recruited and a contract for a 5-year development partnership with Heartbeat Medical signed to develop a user-friendly IT solution.

By 2017, the first ICHOM standard set for breast cancer was implemented at USB, followed by 12 more standard sets within three years. The implementation followed a clear strategy and implementation road map: **First projects were initiated in departments with medical leaders who were convinced of PROMs and supported implementation in daily clinical practice.**

Implementation of ICHOM standard sets in some of the departments, such as oncology, with multiple treatment options was another strategic move: It supported shared decision-making and allows for benchmarking at a later stage to identify best practices and to improve outcomes. **In the first few months of each PRO pilot, the project manager was in close contact with the clinical team to provide daily support,** supervised data completeness and reported inclusion rates back to the clinic. Review meetings were held regularly prior to handover of the complete PROMs ownership to the department.

Today, patients enter PROMs on iPads at the clinic or via automated e-mail prompts. The IT tool established together with Heartbeat Medical also provides a graphical display of PROMs results and their development over time. **Results are already immediately accessible to physicians and can be discussed with the patient during consultations.**

Two years after the inception of the VBHC initiatives at USB, outcomes evaluations are showing first achievements, especially in the breast cancer unit: Patients reported high satisfaction with post-operative results 6-12 months after surgery and USB ranks among the best in an international comparison (OECD, 2019).



Standardization

A common German questionnaire framework is currently lacking that is defined for or adjustable to different disease areas, languages and health literacy levels.

According to Prof Rose, PROMIS leader and director of the psychosomatic department at Charité Berlin, this could follow an 8-level framework that makes results comparable on an aggregated level but still leaves room for disease-specific questions and adjustments to the setting it is used in, along the dimensions of physical (physical functioning, pain, sleep disturbance, fatigue), mental (depression, anxiety, cognitive functioning) and social (social participation) health. A questionnaire framework defining a core set of questions needs to be harmonized with medical societies but implemented top-down to support research into quality of care improvement. Based on the lessons learned from other countries, the framework should be codesigned with patients to make questions relevant for

them and enhance response rates; it should include disease-specific and general questions and include a maximum of 30 questions per patient and response interval. A way of keeping questionnaires relevant for patients and as short as possible can be in the form of computer adaptive tests (CATs) which dynamically select questions based on the respondent's previous answers, considering a minimum viable question and data set.

- » **A nationwide recommendation for a common PROMs questionnaire framework is needed.** This framework should entail:
 - A questionnaire to assess health-related quality of life (e.g. following EQ5D standards) to ensure comparability across disease areas
 - Common disease-specific questionnaires (building upon standards such as KOOS, HOOS or WOMAC and FJS in the field of hip and knee replacement) which are considered relevant by patients and are endorsed by clinical key opinion leaders (e.g. the respective medical society)
 - A limited set of PREMs to avoid over-questioning of patients.
- » **The questionnaire framework should be developed using a Delphi approach to involve all relevant stakeholders:** patients, clinical opinion leaders, medical societies. Its applicability to clinical settings should be evaluated in an initial pilot phase prior to national rollout.
- » **Where possible, the questionnaire framework should follow international standards such as ICHOM standard sets to allow for international comparisons.** Comparability of PROMs results will enable research to create an evidence base for improving the quality of care and enable overall public health improvement in a variety of countries
- » **The questionnaire framework should also address the aspect of licensing fees for certain PROMs questionnaires and offer solutions to help minimize this kind of costs for implementing providers, e.g. by supporting joint negotiations and collective purchasing for multiple providers.**

Moreover, the need for a clear guideline and a multi-stakeholder expert body was identified that would help determine how to embed PROMs in clinical practice, and to collect, analyze and use data in a safe and actionable way that benefits patients and supports health-care professionals and researchers in their work. A common methodology for the collection and analysis of PROMs data including risk adjustment to allow the fair comparison of results is required. An agreement on relevant disease groups for PROMs collection has to be found on a national level, which should be continuously revised as new evidence emerges. Data interoperability and access is another core aspect in Germany: Integration of PROMs questionnaires and results in electronic health records (ePA) needs to be facilitated to keep administrative efforts to a minimum. Access to aggregated PRO-data to promote best practice sharing across providers and regions could be enhanced by integrating PROMs in registries such as the German Endoprosthesis Registry.

- » **A nationwide guideline for PROMs collection is needed.** This guideline should entail:
 - Information of when and how often to distribute PROMs questionnaires for a given disease or indication (e.g. continuous measurement at regular intervals for chronic diseases).
 - Specifications of the requirements PROMs tools need to fulfil, e.g., digital data collection, interoperability with existing electronic health record systems, data safety standards
 - Details on how to integrate PRO-data with other types of data (such as clinician-reported outcome data, process or infrastructure indicators and PREM data)
- » **A multi-stakeholder, national expert body can support guideline development and guide implementation and best practice identification to facilitate a timely rollout of PROMs at national scale.**

Standardization and continuous Improvement at the Dutch Institute for Clinical Auditing (DICA)

The Dutch Institute for Clinical Auditing (DICA) is a nonprofit organization that collects, analyzes and reports hospital data including clinical indicators, PROMs and PREMs. DICA was founded in 2010 by surgeons and covers 23 diseases, of which 10 also include PROMs and PREMs measurement (Beck, N. et al., 2020).

DICA creates common standards for PROMs questionnaires by including patients and healthcare professionals in the continuous adjustment of questionnaires in relevant disease areas. In brainstorming sessions during a 2-year period after the launch of a questionnaire, the questionnaire and its integration in the care pathway is continuously adjusted. Standardized questionnaires are then sent out to participating hospitals. Hospitals can add additional questions to the standard set if they wish to do so. DICA has continuously expanded its reach and now covers all hospitals, some for more treatment categories than others. Participation is voluntary, but hospitals participate to advance the quality of health-care in their unique provider setting. This is made possible as the data collected by DICA can be accessed on a daily basis via the *Codman Dashboard*. In addition, the medical community is informed about quality improvement options via a yearly report, conferences and scientific articles.

DICA further enables benchmarked feedback to be given to clinicians, and short-cycled improvement initiatives are implemented to continuously adjust the quality of the collection, analysis and reporting of clinical, PROMs and PREMs data. As transparency is a core element of the DICA strategy to enhance quality improvement, providers thus cannot deny data being published publicly once they participate in the program.

DICA is continuously evolving and establishing additional standard sets and utilization forms for the retrieved data. It is planned to enable access to real-time data to inform patient treatment decisions in the near future. This will enable shared decision-making and a common framework for integrating PROMs in clinical care.



IT infrastructure

An IT infrastructure across clinics and sectors that addresses data security concerns and can be integrated into existing registries and electronic health records (ePA) is currently lacking in the German health system. Many providers are hesitant about implementing PROMs due to required up-front investments for digital solutions to collect PRO-data and interfaces with existing electronic health records at their institution. A diversity of hospital data systems exists on the provider and even department level in Germany. Hospital data systems currently do not have open interfaces, which makes the interoperability with PROMs solutions especially difficult to achieve. As suggested by Prof. Rose, a national common IT infrastructure should coincide with the designation of a stakeholder responsible for quality assurance, such as the IQWiG. By providing a common IT platform in which PROMs can be integrated, a holistic picture of PROMs, PROMs and PREMs can guide the decision-making and continuous quality improvement in clinical practice. Main private IT suppliers such as Microsoft, Google, IBM and Oracle have also committed themselves to removing hurdles to interoperability for healthcare solu-

tions. Furthermore, the health innovation hub, a think tank, sparring partner, and implementation supporter for the German Federal Ministry of Health, is putting strong emphasis on the important aspect of interoperability of software and hardware solutions for application in health care. Engagement with the private sector to enable a common infrastructure is of paramount importance.

To keep the innovation power going, providers should have a free choice of suppliers for the collection and reporting of PROMs, following common standards so that outcomes can be integrated into the common IT platform/the ePA. Quality as well as security standards should be set to guide the decision among private providers. PROMs initiatives should leverage the possibilities of digital health tools for the collection, data integration, automatic analyses and use by patients and providers, in a more reliable and efficient manner relative to paper-based PROMs collection. Paper-based collection of PROMs should only be used where absolutely necessary, e.g. for elderly patients without digital access to PRO questionnaires. To make results actionable the IT tools should include visualized results on computers/tablets in the provider setting. Financial means should not only support the IT tools but also the staff needed to implement and sustain it in the provider setting. Moreover, an investigation into how far PROMs collected in self-management apps and other health apps can be integrated or used for healthcare quality improvement, benchmarking and public reporting should follow in the future. Following an investigation, clear rules are needed to prevent the privatization of patients' data by private companies and enabling its use for public and individual health improvement.

- » An open common and basic national IT system for PROMs collection should be established to provide access to PROMs and other outcome-relevant measures for all providers regardless of their financial endowment. This system should:
 - Be interoperable with existing and future electronic health records (ePA) and PROMs tools and compliant with national standards for data security.
 - Be supported by a regulation requiring IT providers to offer interfaces to PROMs solutions free of charge. This could help reduce resource use, improve the timeliness of PROMs collection and enable real-time automatic assessment.
 - Be compliant with international data- and IT-standards for application in health care
- » The national IT system should be supported by standards for interoperability, data governance and clinical use as well as guidance for the scaling and implementation of digital health and apps for PROMs collection and use in clinical practice

The Swedish National Platform for Structured Patient-Reported Measures

In June 2018, the regions of Sweden launched a united and coordinated effort to collect patient-reported data and created the National Platform for Structured Patient-Reported Measures. The effort is funded by the regions and coordinated by SALAR – an organization representing all regions and municipalities in the country. The platform collects patient-reported data for two initiatives: the Healthcare Barometer – a national population survey that monitors attitudes toward healthcare – and the National Patient Survey – a comprehensive term for several national surveys on the patient-perceived quality and experience of primary, inpatient and outpatient care. The Swedish experience provides a best practice example for a national IT platform with the following features:

- » **The capacity to collect and process a large amount of data each year:** the platform collects and displays information on every Swedish healthcare provider
- » **The integration with the Swedish patient health portal:** patients receive notifications on the portal when they are asked to participate in a survey and can access the data
- » **The automation of many processes:** the system recognizes whether a patient has already answered a given question in a different survey and applies the answer and automatically sends out paper questionnaires in case individuals do not answer using the online portal
- » **A high degree of transparency:** all patients and providers can view the results at regional or provider level

In the current version, each region distributes the surveys. In the future, the regions plan to create an infrastructure that allows every caregiver to distribute the surveys themselves: this would allow them to decide which measures they want to include and would create a more participatory environment.



Incentives

Using PROMs means additional cost and time efforts for providers in Germany if it is not financed in a research project. Hence, financial incentives need to be established to compensate for the time effort of collecting PROMs as well as to establish an infrastructure for the collection and use of PROMs in clinical practice. Pay-for-performance measures were reported to be rather counterproductive by various experts, especially from a medical perspective. Whereas in the USA, financial incentives were mentioned as favorable, in Germany these were sometimes described as toxic for the motivation of healthcare professionals. According to various interviewed experts, payment should at first not be based on the achieved level of PROMs, but rather as an incentive to collect PROMs. It was argued that outcome-based payment can initially lead to reduced motivation and trust among clinical professionals if systems are not set up in a fair way and driven by clinicians.

In Germany, a policy enacted as part of the “Hospital Care Structure Reform Act” in 2016 has created the option of negotiating exclusive quality contracts between health insurance companies and hospitals. As this was in a trial phase from 2019 to 2023, some providers, such as the Eisenberg clinic, have utilized PROMs as a quality measure in these contracts. However, quality contracts were described as posing too many bureaucratic hurdles to create a real financial incentive for hospitals. Moreover, the option for third-party suppliers who collect PROMs to apply for funding is not given under the current regulation. Thus, there is a need for adjustment of the current set-up of quality contracts to make their utilization easier and more valuable to providers.

Expanding the integration of PROMs in HTA processes is a lever to support market access for products which actually improve quality of life from a patient perspective. Beyond the incentives for the provider, pharmaceutical and medical technology company level, incentives need to be set for patients to answer PROMs questionnaires and utilize the information provided to them. Incentives for this purpose include instant feedback for patients and gamifications such as progress bars and benchmarking options in apps, making information easily understandable, in an interesting way.

- » **PROMs collection should be incentivized. However, initially financial incentives should not be tied to outcomes achieved**
 - **In the first stage, financial incentives should not be tied to outcomes achieved.** An incentive structure which makes **payment dependent on the actual collection and use of PROMs rather than PROMs results** was perceived as positive by various experts to achieve buy-in from clinicians and providers.
 - **In a second step, additional incentives could be created through certificates or excellence labels for providers participating in PROMs collection and reporting results** (e.g. to clinical quality registries or medical societies). This should be accompanied by incentives for patients to fill out and track their PROMs information continuously.
 - **In a third step, selective contracts and payment systems connected to outcome quality should be adjusted and expanded based on new insights.** Selective contracting between hospitals and insurers in the form of quality contracts for endoprosthetics being established in Germany are a first positive step. However, these need further adjustments to reduce bureaucratic hurdles, enable the application by private providers supporting hospitals and expand into other treatment areas. Emerging research, practical insights into the utility of first selective contracts and the involvement of a variety of stakeholders should create a foundation to expand risk-adjusted PRO-based payment and best practice development.

BEST PRACTICE

FIAT – „Financement Incitatif a la Transparence“

France has recently started a **regional pilot to explore a PROMs framework in the field of cataract** in the region of Limoges and Nantes (“Arrêté du 23 juillet”, 2020). This pilot is supported by the “Article 51” which was introduced by the Social Security Financing Act for 2018 in order to promote innovation in health (ARS Ile-de-France, 2019). Experimentation of new models addressing inefficiencies and inadequate care in the French health system, improving access to care and the relevance of treatments for patients is eligible for funding by the French Ministry of Health under this paragraph. The project “Valorisation of transparency and relevance for cataract surgery in the territories of Limoges and Nantes” introduces PROMs (Catquest-9SF) in the routine care of patients undergoing cataract surgery in participating ophthalmology centers. It was initiated in July 2020 and aims at:

- » Increased involvement of patients in the evaluation of quality of care
- » Risk-adjusted, transparent comparison of the surgical performance and care delivered by individual providers
- » Measuring the impact of transparency (public reporting) on quality of care and outcomes

Collection and public reporting of PROMs via a platform provided by “PromTime”, a trusted third party analyzing and publishing final results, is incentivized through a dedicated funding system (FIAT, “Financement Incitatif a la Transparence”): Each practitioner or health-care professional receives 30 Euro for a complete set of patient outcomes (pre- and post-surgical PROMs and CROMs) entered into the platform. Public reporting of outcomes will be introduced in a three-phase process. The pilot is designed in analogy to a two-arm randomized trial to demonstrate the potential effects of outcomes collection and transparency.

The project required derogations to the French law to authorize nominative benchmarks at practitioner level and allocation of the FIAT fee. It might enable the emergence of similar models for other indication areas. The pilot will be evaluated after a period of 4 years.

Certification to incentivize PROMs reporting: The “Swiss orthopedics excellence” label

The canton of Zürich has obliged all of its 21 listed hospitals to collect and report PROMs for patients undergoing hip and knee replacement prior to and one year after surgery. This project was initiated by the Canton of Zürich and Swiss Orthopedics, the Swiss society of orthopedics and traumatology, in July 2019. PRO-data and clinical data are transferred to an existing registry (SIRIS), the data are analyzed, and results reported back to the participating hospitals on an annual basis. A scoring system has been developed to enable the assessment of the indication quality and quality of care. Quality control will be performed by the Swiss orthopedics quality board. **A quality label named “Swiss orthopedics excellence” has been established and will be awarded to hospitals participating in the external quality assurance of Swiss Orthopedics.** A step-by-step extension of this approach to other areas of orthopedics is taken into consideration.



Political will







Although there is political momentum for PROMs and for the digitalization of healthcare in general, which is even accelerated by the COVID 19 pandemic, more top-level support is needed to make a wide-scale implementation of PROMs possible. Medical and patient societies could advocate for PROMs and pronounce the need for political support for large-scale pilots to provide the required proof of concept. This support could be linked with the government’s digitalization strategy and the DeQS-RL. As the DeQS-RL is currently limited in its focus on integrating data (PRO-data with ePA) and providing results to clinicians and patients for care improvement and shared decision-making, an adjustment would be favorable for it to play a relevant role in a successful PROMs implementation in Germany. The country comparison reflects that **neither a top-down nor a pure bottom-up strategy led to the full spectrum of PROMs utilization.**

- » Thus, in Germany a combined approach is required. This entails:
 - A **supportive top-down framework** in terms of questionnaire standardization, a clear common methodology for PROMs collection, allocation of financial resources and the establishment of additional incentives as well as an independent body auditing the results.
 - **Bottom-up commitment of clinical champions** to support an integration into daily clinical practice and deliver best practice examples to create followers.
- » **Large-scale pilots for a proof of concept in the German context are needed to create political dynamics.** Potential areas for such large-scale pilots include, among others, cancer care and orthopedics due to a favorable infrastructure and characteristics of care processes in these areas. Agreements such as the one between IQM and Heartbeat Medical in 2021, which enables outcome measurement across a large number of providers, can provide a fundament for such large-scale projects.

In conclusion, 6 success factors should be considered for a potential German PROMs strategy to unlock the full potential of PROMs for improving quality of care and promoting patient empowerment. The focus on what really matters to patients has to remain at the core of all actions taken. This can be achieved by involving patient organizations

and continuously reevaluating the use and value of PROMs from a patient perspective. A combination of top-down implementation through political, financial, standardization and IT support, leaving room for provider-level commitment and adjustments as well as bottom-up initiatives led by clinical champions, is of particular relevance. Finally, Germany faces the need for a stakeholder that transgresses the different levels and stakeholders involved – political stakeholders and agencies, healthcare professionals, patients and private IT suppliers to address the 6 core success factors of a PROMs implementation. The following table summarizes this:

TABLE 3: **Success factors for PROMs implementation in Germany**

	Micro – Individual, patient, physician	Macro – National, regional, hospital and department
 Patient focus	Shared decision-making, self-management based on PRO-data	Patient organization advocacy for PROMs, inclusion in the design and implementation of PROMs
 Champions	HCPs in the provider setting advocate for the value of PROMs	Roundtables, scholarships, platforms
 Standardization	Step by step rollout of common standards (PDSA cycles)	Framework for questionnaire, Guideline for data collection & analysis (risk adjustment), a responsible body for quality assurance
 IT	Training for HCPs and hiring analysts	Common IT infrastructure and financing, link with EHR and a quality assurance institute
 Incentives	Peer reviews based on aggregate analysis in the provider setting	Financial incentives (not tied to outcomes achieved)
 Political will	Pilot project demonstrating the value of PROMs in provider settings, bottom-up commitment of clinical champions	A supportive top-down framework

References

-
- AAOS (2020). *About the AAOS Registry Program*. Retrieved October 1, 2020, from <https://www.aaos.org/registries/registry-program/about-the-aaos-registry-program/>
- ACORN (2014). *Arthroplasty Clinical Outcomes Registry*. Retrieved September 30, 2020, from <http://www.acornregistry.org/>
- Adam, R., Burton, C.D. Bond, C.M., Bruin, M. & Murchi, P. (2017). Can patient-reported measurements of pain be used to improve cancer pain management? A systematic review and meta-analysis. *BMJ Supportive & Palliative Care*. <https://doi.org/10.1136/bmjspcare-2016-001137>
- Agence Régionale de Santé (ARS) Ile-de-France (2019). *Article 51 : un dispositif pour l'innovation en santé*. Retrieved October 7, 2020, from <https://www.iledefrance.ars.sante.fr/article-51-un-dispositif-pour-linnovation-en-sante>
- Alberta Government (2020). *Alberta Community Health Survey (ACHS)*. Retrieved September 2020, from <https://open.alberta.ca/opendata/alberta-community-health-survey-achs-telephone-conducted#summary>
- American Hospital Association (AHA) (2020). *Fast Facts on US Hospitals*. Retrieved September 22, 2020, from <https://www.aha.org/statistics/fast-facts-us-hospitals>
- Anell, A., Glenngård, Anna H., & Merkur, Sherry (2012). Sweden: Health System Review. *Health Systems in Transition*, 14(5), 1–159.
- ANQ (2020). *Association – ANQ*. Retrieved September 29, 2020, from <https://www.anq.ch/en/anq/association/>
- AOANJRR (2020). *Welcome to the AOANJRR*. Retrieved October 1, 2020, from <https://aoanjrr.sahmri.com/>
- Arrêté du 23 juillet 2020 relatif à l'expérimentation de valorisation de la transparence et de la pertinence pour la chirurgie de la cataracte dans les territoires de Nantes et Limoges (2020). <https://www.legifrance.gouv.fr/download/pdf?id=IhV8YBj8ff6F2ICX931-zY1CdwXMTfXME5rVOvDFceo=>
- Australian Commission on Safety and Quality in Healthcare (ACSQHC) (2016a). *Patient-reported outcome measures: An environmental scan of the Australian healthcare sector*. <https://www.safetyandquality.gov.au/sites/default/files/migrated/PROMs-Environmental-Scan-December-2016.pdf>
- Australian Commission on Safety and Quality in Healthcare (ACSQHC) (2016b). *Patient-reported outcome measures: Literature Review*. <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/patient-reported-outcome-measures-literature-review>
- Australian Commission on Safety and Quality in Healthcare (ACSQHC) (2018). *Patient-reported outcome measures: Stakeholder interviews*. <https://www.safetyandquality.gov.au/sites/default/files/migrated/PROMs-stakeholder-interviews-report-2018.pdf>

- Australian Commission on Safety and Quality in Healthcare (ACSQHC) (2020c). Case studies of PROMs implementation. Retrieved 9 November 2020, from: <https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/patient-reported-outcomes/case-studies-proms-implementation>
- Australian Government Department of Health (2011). *The national health reform agenda – implications for CVD*. Retrieved October 1, 2020, from <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/cardio-pubs-revresp-toc~cardio-pubs-revresp-nat>
- Australian Government Department of Health (2020). The Australian health system. Retrieved October 1, 2020, from <https://www.health.gov.au/about-us/the-australian-health-system>
- Barmer schließt Qualitätsvertrag zur Endoprothetik (2019). *Ärzteblatt*. <https://www.aerzteblatt.de/nachrichten/107525/Barmer-schliesst-Qualitaetsvertrag-zur-Endoprothetik>
- Basch, E., Deal, A.M., Dueck, A.C., Scher, H.I., Kris, M.G., Hudis, C., Schrag, D. (2017). Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *JAMA – J. Am. Med. Assoc.* <https://doi.org/10.1001/jama.2017.7156>
- Beck, N., van Bommel, A.C., Eddes, E.H., van Leersum, N.J., Tollenaar, R.A. & Wouters, M.W. (2020). The Dutch Institute for Clinical Auditing: Achieving Codman’s Dream on a Nationwide Basis. *Annals of Surgery*, 271, 627–631. <https://doi.org/10.1097/SLA.0000000000003665>
- Borchert, K., Altevers, J., Braun, S. & Mittendorf, T. (2016). The Value Of Patient Reported Outcomes In German Amnog Dossiers. *Value in Health*, 19(7), A483. <https://doi.org/10.1016/j.jval.2016.09.787>
- Boston Consulting Group (BCG) (2018). *How Dutch Hospitals make value-based health care work*. Retrieved September 22, 2020, from <https://www.bcg.com/de-de/publications/2018/how-dutch-hospitals-make-value-based-health-care-work>
- Bundesministerium für Gesundheit (n. d.) *Glossar: Innovationsfonds*. Retrieved September 28, 2020, from <https://www.bundesgesundheitsministerium.de/service/begriffe-von-a-z/i/innovationsfonds.html>
- Bundesministerium für Gesundheit (2021). *Gesundheitsversorgungsweiterentwicklungsgesetz (GVWG)*. Last retrieved February 18, 2021, from <https://www.bundesgesundheitsministerium.de/gesundheitsversorgungsweiterentwicklungsgesetz.html>
- Canadian Multicentre Osteoporosis Study (CAMOS) (2020). Information about the study. Retrieved 22 September, 2020 from: <http://www.camos.org/index.php>
- Canadian Institute for Health Information (CIHI) (2015). PROMs Background Document. https://www.cihi.ca/sites/default/files/proms_background_may21_en-web_0.pdf
- Canadian Institute for Health Information (CIHI) (2017). Patient-Centred Measurement and Reporting in Canada: Launching the Discussion Toward a Future State. <https://www.cihi.ca/sites/default/files/document/visioning-day-paper-en-web.pdf>
- Canadian Institute for Health Information (CIHI) (2018). Patient-Reported Outcome Measures – Information Sheet. Retrieved September 20, 2020 from: <https://www.cihi.ca/sites/default/files/document/proms-infosheet-2018-en.pdf>
- Canadian Institute for Health Information (CIHI) (2019a). Hospital Beds Staffed and in Operation, 2017–2018: Excel File for download. Retrieved September 24, 2020, from <https://www.cihi.ca/sites/default/files/document/beds-staffed-and-in-operation-2017-2018-en-web-revmay3.xlsx>
- Canadian Institute for Health Information (CIHI) (2019b). Patient-Reported Outcome Measures Data Collection Manual Hip and Knee Arthroplasty. <https://www.cihi.ca/sites/default/files/document/proms-data-collections-manual-2019-en-web.pdf>

- Centre for Healthcare Innovation. *Manitoba's PRM Strategy (Patient-Reported Measurement)* (2020). Retrieved September 24, 2020 from <https://www.chimb.ca/prm>
- Centers for Medicare and Medicaid Services (CMS) (2016). *CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)*. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf>
- Centers for Medicare and Medicaid Services (2019). *NHE Fact Sheet*. Retrieved 5 November, 2020 from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet>
- Commonwealth Fund (2020a). *International Healthcare System Profiles: Australia*. <https://www.commonwealthfund.org/international-health-policy-center/countries/australia>
- Commonwealth Fund (2020b). *International Healthcare System Profiles: Canada*. <https://www.commonwealthfund.org/international-health-policy-center/countries/canada>
- Commonwealth Fund (2020c). *International Healthcare System Profiles: Denmark*. <https://www.commonwealthfund.org/international-health-policy-center/countries/denmark>
- Commonwealth Fund (2020d). *International Healthcare System Profiles: England*. <https://www.commonwealthfund.org/international-health-policy-center/countries/england>
- Commonwealth Fund (2020e). *International Healthcare System Profiles: Germany*. <https://www.commonwealthfund.org/international-health-policy-center/countries/germany>
- Commonwealth Fund (2020f). *International Healthcare System Profiles: Netherlands*. <https://www.commonwealthfund.org/international-health-policy-center/countries/netherlands>
- Commonwealth Fund. (2020g). *International Healthcare System Profiles: Norway*. <https://www.commonwealthfund.org/international-health-policy-center/countries/norway>
- Commonwealth Fund (2020h). *International Health Care System Profiles: Sweden*. <https://www.commonwealthfund.org/international-health-policy-center/countries/sweden>
- Commonwealth Fund. (2020i). *International Health Care System Profiles: Switzerland*. <https://www.commonwealthfund.org/international-health-policy-center/countries/switzerland>
- Commonwealth Fund (2020j). *International Healthcare System Profiles: United States*. <https://www.commonwealthfund.org/international-health-policy-center/countries/united-states>
- Damman, O. C., Jani, A., Jong, B. A., Becker, A., Metz, M. J., Bruijne, M. C., Timmermans, D. R., Cornel, M. C., Ubbink, D. T., Steen, M., Gray, M. & El, C. (2019). The use of PROMs and shared decision-making in medical encounters with patients: An opportunity to deliver value-based health care to patients. *Journal of Evaluation in Clinical Practice*, 26, 524–540. <https://doi.org/10.1111/jep.13321>
- Danske Regioner (2016). *Danske Regioner – Værdibaseret styring tager form i regionerne*. Retrieved September 30, 2020, from <https://www.regioner.dk/services/nyheder/2016/juni/vaerdibaseret-styring-tager-form-i-regionerne>
- Deutsches Ärzteblatt (2014). *Externe Qualitätssicherung: Follow-up in die weite Welt*. Retrieved September 28, 2020, from <https://www.aerzteblatt.de/archiv/158364/Externe-Qualitaetssicherung-Follow-up-in-die-weite-Welt>

- Deutsches Ärzteblatt (2019). Spahn kündigt Krankenhäusern Konsequenzen bei Qualitätsproblemen an. Retrieved September 28, 2020, from <https://www.aerzteblatt.de/nachrichten/103826/Spahn-kuendigt-Krankenhaeusern-Konsequenzen-bei-Qualitaetsproblemen-an>
- DEKV Presseportal (2020). Starkes Signal für Patientenversorgung: Jährlich 22 Millionen Euro für Qualitätsverträge bis 2028. Retrieved February 22, 2021, from <https://www.presseportal.de/pm/126495/4768099>
- DIMDI (2011). *Kurzfassung HTA: Der Stellenwert von Patient-Reported Out-comes (PRO) im Kontext von Health Technology Assessment (HTA)*. https://portal.dimdi.de/de/hta/hta_berichte/hta220_kurzfassung_de.pdf
- Dudgeon, D. (2018). The Impact of Measuring Patient-Reported Outcome Measures on Quality of and Access to Palliative Care. *J Palliat Med*;21:S76–80. <https://doi.org/10.1089/jpm.2017.0447>.
- Dutch Institute for Clinical Auditing (2020). Retrieved September 28, 2020, from <https://dica.nl/>
- Easpai, B. N. G., Tran, Y., Bierbaum, M., Arnolda, G., Delaney, G. P., Liauw, W., Ward, R. L., Olver, I., Currow, D., Girgis, A., Durcinoska, I. & Braithwaite, J. (2020). What are the attitudes of health professionals regarding patient reported outcome measures (PROMs) in oncology practice? A mixed-method synthesis of the qualitative evidence. *BMC Health Services Research*. <https://doi.org/10.1186/s12913-020-4939-7>
- Emilsson, L., Lindahl, B., Köster, M., Lambe, M., & Ludvigsson, J. F. (2015). Review of 103 Swedish Healthcare Quality Registries. *Journal of Internal Medicine*, 277(1), 94–136. <https://doi.org/10.1111/joim.12303>
- Enden, T., Bernklev, T., Jelsness-Jørgensen, L. P., & Amdal, C. D. (2018). Pasientene kjenner best egen helse. *Tidsskrift for Den Norske Laegeforening*, 138(8). <https://doi.org/10.4045/tidsskr.17.1054>
- Management im Gesundheitswesen (MiG), TU Berlin (2020). *PROMoting Quality*. Retrieved September 28, 2020, from https://www.mig.tu-berlin.de/menue/research/aktuelle_projekte/promoting_quality/
- Farshad, M. (2019). Qualitätsstrategie swiss orthopaedics. https://live.fmh.ch/files/pdf23/qualitaetsstrategie_swiss_orthopaedics_20_2_2019.pdf
- FMH Zentralvorstand / Comité central de la FMH (2018). PROMs fördern die patienten-orientierte Behandlung. *Schweizerische Ärztezeitung*, 99(40), 1352–1353. <https://doi.org/10.4414/saez.2018.17188>
- Franklin, P. D., Chenok, K.E., Lavalee, D., Love, R., Paxton, L., Segal, C., & Holve, E. (2017). Framework To Guide The Collection And Use Of Patient-Reported Outcome Measures In The Learning Healthcare System. *eGEMs (Generating Evidence & Methods to improve patient outcomes)*, 5, 17. <https://doi.org/10.5334/egems.227>
- Fraser, N., Lavers-Sailly, M. (n. d.). *Patient Reported Outcome Measures: Canada's opportunity to be a leader – Hospital News* Retrieved October 1, 2020 from <https://hospitalnews.com/patient-reported-outcome-measures-canadas-opportunity-leader/>
- Fredriksson, M., Halford, C., Eldh, A. C., Dahlström, T., Vengberg, S., Wallin, L., & Winblad, U. (2017). Are data from national quality registries used in quality improvement at Swedish hospital clinics? *International Journal for Quality in Health Care*, 29(7), 909–915. <https://doi.org/10.1093/intqhc/mzx132>
- Gemeinsamer Bundesausschuss (G-BA) Innovationsfonds (2020) *Förderprojekte – Neue Versorgungsformen*. Retrieved September 28, 2020, from <https://innovationsfonds.g-ba.de/projekte/neue-versorgungsformen/>
- Gesundheitsdepartement des Kanton Basel-City. (n. d.). *20200812_Leistungsvereinbarung_GD_PROMs*.

- Girgis, A., Durcinoska, I., Arnold, A., Delaney, G.P. (2019). Interpreting and Acting on the PRO Scores from the Patient-reported Outcomes for Personalized Treatment and Care (PROMPT-Care) eHealth System. *Medical Care*. Lippincott Williams and Wilkins, pp. S85–S91. <https://doi.org/10.1097/MLR.0000000000001094>
- Girgis A., Durcinoska I., Arnold A., Descallar J., Kaadan N., Koh E.S., Miller A., Ng W., Carolan M., Della-Fiorentina S.A., Avery S., Delaney G.P. (2020). Web-Based Patient-Reported Outcome Measures for Personalized Treatment and Care (PROMPT-Care): Multicenter Pragmatic Nonrandomized Trial. *J Med Internet Res* 2020;22(10):e19685. DOI: 10.2196/19685
- Gjertsen, J. E., Vinje, T., Engesæter, L. B., Lie, S. A., Havelin, L. I., Furnes, O., & Fevang, J. M. (2010). Internal Screw Fixation Compared with Bipolar Hemiarthroplasty for Treatment of Displaced Femoral Neck Fractures in Elderly Patients. *The Journal of Bone and Joint Surgery–American Volume*, 92(3), 619–628. <https://doi.org/10.2106/JBJS.H.01750>
- GKV Spitzenverband. (2018). *Qualitätsverträge – GKV-Spitzenverband*. Retrieved September 29, 2020, from https://gkv-spitzenverband.de/krankenversicherung/krankenhaeuser/qualitaet_1/qualitaetsvertraege/qualitaetsvertraege.jsp
- Govaert J. A., Fiocco M., van Dijk W. A., Scheffer A. C., de Graaf E. J., Tollenaar R. A., Wouters M. W.; Dutch Value Based Healthcare Study Group (2015). Costs of complications after colorectal cancer surgery in the Netherlands: Building the business case for hospitals. *Eur J Surg Oncol*. 41(8):1059–67. doi: 10.1016/j.ejso.2015.03.236. Epub 2015 Apr 17. PMID: 25960291.
- Government of the Netherlands (2018a). Outcome-based healthcare 2018 – 2022. Retrieved November 10, 2020 from: <https://www.government.nl/documents/reports/2018/07/02/outcome-based-healthcare-2018-2022>
- Government of the Netherlands (2018b). Bestuurlijk akkoord medisch-specialistische zorg 2019 t/m 2022 [Administrative agreement on specialist medical care 2019 to 2022]. Retrieved November 10, 2020 from: <https://www.rijksoverheid.nl/documenten/brieven/2018/06/04/bestuurlijk-akkoord-medisch-specialistische-zorg-2019-t-m-2022>
- Gutacker N, Siciliani L, Moscelli G, Gravelle H (2016). Choice of hospital: Which type of quality matters? *J Health Econ*;50:230–46. <https://doi.org/10.1016/j.jhealeco.2016.08.001>.
- Hanning, M. & Schmidt, I. (2014). Peer Review Health System Performance Assessment (Brussels, 19–20 May 2014): Sweden [Questionnaire]. <https://ec.europa.eu/social/BlobServlet?docId=11870&langId=en>
- Health Improvement Scotland (n.d.) PROMs Knowledge Transfer Partnership Project. Retrieved February 18 2021, from http://www.healthcareimprovementscotland.org/our-work/person-centred_care/proms_questionnaire_project.aspx
- Heartbeat Medical (2021). Initiative Qualitätsmedizin and heartbeat medical sign framework agreement on Patient Reported Outcomes. Retrieved February 17, 2021, from: https://heartbeat-med.com/wp-content/uploads/2021/02/Press-release_IQM-and-heartbeat-medical-sign-framework-agreement.pdf
- Helse Bergen (2017). *In English: Centre on patient-reported outcomes data*. Retrieved September 30, 2020, from <https://helse-bergen.no/fag-og-forsking/forsking/fagsenter-for-pasientrapporterte-data/in-english-centre-on-patient-reported-outcomes-data>
- Helsedirektoratet. (n. d.). *Innsatsstyrt finansiering 2020 Regelverk*. Retrieved October 7, 2020, from www.helsedirektoratet.no
- Hjollund, N. H. I. (2019). Fifteen years' use of patient-reported outcome measures at the group and patient levels: Trend analysis. *Journal of Medical Internet Research*, 21(9). <https://doi.org/10.2196/15856>

- Huland, H. (2018). Systematic, standardized outcome measurement for clinical science and quality control [PowerPoint slides]. <https://www.regioner.dk/media/6838/systematic-standardized-outcome-measurement-for-clinical-science-and-quality-control-v-prof-dr-hartwig-huland.pdf>
- ICHOM (2017). Collaborating for Value: the Santeon Hospitals in the Netherlands. https://ichom.org/files/case-studies/Santeon_Case_Study_Final.pdf
- ICHOM (2019). *International Consortium for Health Outcomes Measurement-Conference 2019*. Retrieved September 29, 2020, from https://www.executiveinsight.ch/application/files/7515/7001/8693/ExIn_ICHOM_report_final.pdf
- Independent Healthcare Providers Network (IHPN) NHS Confederation (2019). Independent sector providers caring for NHS patients. Retrieved September 29, 2020, from: <https://www.ihpn.org.uk/wp-content/uploads/2019/01/IHPN-headline-indicators-Feb-2019-with-data-up-to-Dec-2018.pdf>
- IQM (n. d.). Über IQM. Retrieved September 29, 2020, from <https://www.initiative-qualitaetsmedizin.de/ueber-uns>
- IQM (2019). *Initiative Qualitätsmedizin Pilotprojekt Patient Reported Outcome Measures (PROMs)*.
- IQTIG (n. d.). *Qualitätsverträge*. Retrieved September 29, 2020, from <https://iqtig.org/qs-instrumente/qualitaetsvertraege/>
- IQTIG (2020). *Tätigkeitsbericht 2019*. https://iqtig.org/dateien/berichte/2020/IQTIG_Taetigkeitsbericht_2019_barrierefrei.pdf
- IVBAR (2014). *SVEUS – National collaboration for value-based reimbursement and monitoring of health care in Sweden: OECD Expert group meeting on payment systems* [PowerPoint slides]. http://www.oecd.org/els/health-systems/Item7a_SVEUS-National-collaboration-for-value-based-reimbursement-and-monitoring-of-health-care-in-Sweden_Wohlin.pdf
- Kaiku Health (2018). *Kaiku helps clinical staff provide better care for patients at Hirslanden*. Retrieved September 29, 2020, from <https://kaikuhealth.com/kaiku-helps-clinical-staff-provide-better-care-for-patients-at-hirslanden/>
- Kandelaki, K., Marrone, G., Lundbor, C.S., Schmidt, I. & Björkman, I. (2016). Patient-centredness as a quality domain in Swedish healthcare: results from the first national surveys in different Swedish healthcare settings. *BMJ Open*, 2016(6):e009056. <https://doi.org/10.1136/bmjopen-2015-009056>
- Kaplan, R. S., Witkowski, M. K., & Hohman, J. A. (2014). Schön Klinik: Measuring Cost and Value. *Harvard Business School Case 112-085*. <https://www.hbs.edu/faculty/Pages/item.aspx?num=41579>
- Katz, G. (2020). Value-based Healthcare – EIT Health. Retrieved September 28, 2020, from <https://eithealth.eu/think-tank-topic/value-based-healthcare/>
- Kuklinski D, Oschmann L, Pross C, Busse R, Geissler A (2020). The use of digitally collected patient-reported outcome measures for newly operated patients with total knee and hip replacements to improve post-treatment recovery: study protocol for a randomized controlled trial. *Trials*. 21(1):322. doi: 10.1186/s13063-020-04252-y. PMID: 32272962; PMCID: PMC7147006.
- Lauritsen, A. (2017). Quality goals in Health care National goals in Denmark [PowerPoint slides]. https://na.eventscloud.com/file_uploads/3cf9991e5855a149435fe0224ee9105c_HIMMS_Nationale_ml_PDF.pdf
- Lovisenberg Diakonale Sykehus (2019). *Kvalitetsregister psykisk helsevern voksne og TSB “LOVEPROM”* [PowerPoint slides]. Retrieved October 1, 2020, from <https://lovisenbergpsykehus.no/loveprom>
- Lunney, M., Samimi, A., Osman, M.A., Jindal, K., Wiebe, N., Ye, F., Johnson, D.W., Levin, A., Bello, A.K. (2019). Capacity of Kidney Care in Canada: Identifying Barriers and Opportunities. *Can. J. Kidney Heal. Dis.* 6. <https://doi.org/10.1177/2054358119870540>

- Management im Gesundheitswesen (MiG), TU Berlin (2020). PROMoting Quality. Retrieved September 28, 2020, from https://www.mig.tu-berlin.de/menue/research/aktuelle_projekte/promoting_quality/
- Martin, N.E., Massey, L., Stowell, C., Bangma, C., Briganti, A., Bill-Axelson, A., Blute, M., Catto, J., Chen, R.C., D'Amico, A.V., Feick, G., Fitzpatrick, J.M., Frank, S.J., Froehner, M., Frydenberg, M., Glaser, A., Graefen, M., Hamstra, D., Kibel, A., Mendenhall, N., Moretti, K., Ramon, J., Roos, I., Sandler, H., Sullivan, F.J., Swanson, D., Tewari, A., Vickers, A., Wiegel, T., & Huland, H. (2015). Defining a Standard Set of Patient-centered Outcomes for Men with Localized Prostate Cancer. *European Urology*, 67(3). <https://doi.org/10.1016/j.eururo.2014.08.075>
- Martini-Klinik Hamburg (n.d. a) *Fakten zählen*. Retrieved October 7, 2020, from <https://www.martini-klinik.de/fuer-aerzte/martini-klinik/onkologisches-outcome/>
- Martini-Klinik Hamburg (n.d. b). *Kontinenz*. Retrieved September 28, 2020, from <https://www.martini-klinik.de/resultate/kontinenz/>
- Martini-Klinik Hamburg (n.d. c). *Prostate Cancer Outcomes Study (PCO Studie)*. Retrieved October 7, 2020, from <https://www.martini-klinik.de/fuer-aerzte/studien/studienuebersicht/pco-studie/>
- Massachusetts Medical Society (2018). *Patient-Reported Outcome Measures: Current State and MMS Principles*. Retrieved October 5, 2020, from www.massmed.org/proms
- Mattsson, T. (2016). Quality Registries in Sweden, Healthcare Improvements and Elderly Persons with Cognitive Impairments. *European Journal of Health Law*, 23, 453–469.
- Medienmitteilung Universitätsspital Basel (2020). *Universitätsspital Basel und Roche arbeiten zusammen, um in der Schweiz den Wert von Krebsbehandlungen aus Patientensicht zu messen*. Retrieved October 6, 2020, from <https://www.unispital-basel.ch/medien/medienmitteilungen/details/>
- Mejdahl, C.T., Schougaard, L.M.V., Hjollund, N.H., Riiskjær, E., Thorne, S., Lomborg, K., 2018. PRO-based follow-up as a means of self-management support – an interpretive description of the patient perspective. *J. Patient-Reported Outcomes* 2, 38. <https://doi.org/10.1186/s41687-018-0067-0>
- Mcgrail, K., Bryan, S. & Davis, J.C. (2011). Let's All Go to the PROM: The Case for Routine Patient-Reported Outcome Measurement in Canadian Healthcare. *HealthcarePapers* 11(4):8-18. <https://doi.org/10.12927/hcpap.2012.22697>
- Ministeriet for Sundhed og Forebyggelse (2013). *Mere borger, mindre patient: Et staerkt faelles sundhedsvaesen*. https://sum.dk/Aktuelt/Publikationer/Publikationer/~media/Filer%20-%20Publikationer_i_pdf/2013/Sundhedsudspil/Sundhedspolitisk-udspil-13052013.ashx
- Mjåset, C., Nagra, N.S., Feeley, T.W., 2020. Value-Based Health Care in Four Different Health Care Systems. <https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0530>.
- Nasjonalt Hoftebruddregister (2018). *Årsrapport for 2017 med plan for forbedringstiltak*. Retrieved September 30, 2020, from <https://docplayer.me/105526428-Nasjonalt-hoftebruddregister-arsrapport-for-2017-med-plan-for-forbedringstiltak.html>
- Nasjonalt servicemiljø for medisinske kvalitetsregistre (2017). *About Centre on patient-reported outcomes data*. Retrieved October 1, 2020, from <https://www.kvalitetsregistre.no/artikkel/information-english>
- Nasjonalt Servicemiljø for Medisinske Kvalitetsregistre. (n.d. a). *Nasjonalt hoftebruddregister*. Retrieved October 1, 2020, from <https://www.kvalitetsregistre.no/registers/nasjonalt-hoftebruddregister>
- Nasjonalt Servicemiljø for Medisinske Kvalitetsregistre. (n.d. b). *Pasientrapporterte data*. Retrieved September 30, 2020, from <https://www.kvalitetsregistre.no/pasientrapporterte-data>

- National Committee for Quality Assurance (NCQA) (2020). Utilization of the PHQ-9 to Monitor Depression Symptoms for Adolescents and Adults (DMS). Retrieved 5 November, 2020 from <https://www.ncqa.org/hedis/measures/utilization-of-the-phq-9-to-monitor-depression-symptoms-for-adolescents-and-adults/>
- National Joint Registry (2020). *Highlights: PROMs*. Retrieved September 24, 2020, from <https://reports.njrcentre.org.uk/NJR-Patient-Reported-Outcomes-Measures>
- Nationella Kvalitetsregister (2019). *About the National Quality Registries*. Retrieved October 6, 2020, from <http://kvalitetsregister.se/englishpages/aboutqualityregistries.2422.html>
- Nelson, E. C., Eftimovska, E., Lind, C., Hager, A., Wasson, J. H., & Lindblad, S. (2015). Patient reported outcome measures in practice. *BMJ*, 350(g7818). <https://doi.org/10.1136/bmj.g7818>
- Neudam, A. (2020). Positive Veränderungen im Verlauf der Reha in der Orthopädie. Qualitätskliniken. Retrieved February 18, 2021, from <https://www.qualitaetskliniken.de/pressemitteilungen/positive-veraenderungen-im-verlauf-der-reha-in-der-orthopaedie/>
- New South Wales (NSW) Government (2019). Leading Better value care booklet. Retrieved 9 November 2020 from <https://www.health.nsw.gov.au/Value/Publications/lbvc-booklet.pdf>
- New South Wales (NSW) Government (2020a). Leading Better Value Care. Retrieved 9 November 2020 from <https://www.health.nsw.gov.au/Value/lbvc/Pages/default.aspx>
- New South Wales (NSW) Government (2020b). Integrated care key initiatives. Retrieved 9 November 2020 from <https://www.health.nsw.gov.au/integratedcare/Pages/key-initiatives.aspx>
- NHS England (2017). National Patient Reported Outcome Measures (PROMs) Programme Consultation Report. <https://www.england.nhs.uk/wp-content/uploads/2017/10/proms-consultation-report.pdf>
- OECD (2019). Health at a Glance 2019: OECD Indicators (Summary in English). <https://doi.org/10.1787/e88a7402-en>
- Oliver, B. J., Nelson, E. C., & Kerrigan, C. L. (2019). Turning Feed-forward and Feedback Processes on Patient-reported Data into Intelligent Action and Informed Decision-making: Case Studies and Principles. *Medical Care*, 57, S31-S37. <https://doi.org/10.1097/MLR.0000000000001088>
- Partridge, T., Carluke, I., Emmerson, K., Partington, P., Reed, M., 2016. Improving patient reported outcome measures (PROMs) in total knee replacement by changing implant and preserving the infrapatella fatpad: a quality improvement project. *BMJ Qual. Improv. Reports* 5, u204088.w3767. <https://doi.org/10.1136/bmjquality.u204088.w3767>
- Pappot, H., & Taarnhøj, G. A. (2020). Expectations to Patient-Reported Outcome (PRO) in Oncology—PRO for a purpose, when and how? *Acta Oncologica*, Vol. 59, pp. 611–612. <https://doi.org/10.1080/0284186X.2020.1749880>
- Porter, M. E., Deerberg-Wittram, J., & Feeley, T. W. (2019). Martini-Klinik: Prostate Cancer Care 2019. *Harvard Business School Case 720-359*. 1–23. Retrieved from <https://www.hbs.edu/faculty/Pages/item.aspx?num=56450>
- Porter, M. E., Marks, Clifford M., Landman, & Zachary C. (2015). OrthoChoice: Bundled Payments in the County of Stockholm (A). *Harvard Business School Case 714-514*. <https://www.hbs.edu/faculty/pages/item.aspx?num=47439>
- Porter, M. E., Marks, Clifford M., Landman, & Zachary C. (2014). OrthoChoice: Bundled Payments in the County of Stockholm (B). *Harvard Business School Supplement 714-515*. <https://www.hbs.edu/faculty/Pages/item.aspx?num=47450>
- Preuß, F. (2019). PROMS in der Reha—Update. Qualitätskliniken. Retrieved February 18, 2021, from <https://www.qualitaetskliniken.de/news/proms-in-der-reha-update/>

- PRO Secretariat. (2019). *The Danish National Work on Patient Reported Outcomes*. Retrieved from <https://pro-danmark.dk/da/pro-english>
- Pross, C., Geissler, A., & Busse, R. (2017). Measuring, Reporting, and Rewarding Quality of Care in 5 Nations: 5 Policy Levers to Enhance Hospital Quality Accountability. *The Milbank Quarterly*, 95(1), 136–183. <https://doi.org/10.1111/1468-0009.12248>
- RAND (2020). *RAND Medical Outcomes Study: Measures of Quality of Life Core Survey from RAND Health Care*. Retrieved October 1, 2020, from https://www.rand.org/health-care/surveys_tools/mos.html
- Richtlinie zur datengestützten einrichtungsübergreifenden Qualitätssicherung (DeQS-RL) (2019). https://www.g-ba.de/downloads/62-492-2217/DeQS-RL_2019-12-19_iK-2020-07-29_AT-28-07-2020-B2.pdf
- RKKP (n. d.). In English – RKKP. Retrieved September 29, 2020, from <https://www.rkkp.dk/in-english/>
- Schougaard, L. M. V., Larsen, L. P., Jessen, A., Sidenius, P., Dorflinger, L., de Thurah, A., & Hjollund, N. H. (2016). AmbuFlex: tele-patient-reported outcomes (telePRO) as the basis for follow-up in chronic and malignant diseases. *Quality of Life Research*, 25(3), 525–534. <https://doi.org/10.1007/s11136-015-1207-0>
- Schulz, D. H. (2020). Ergebnismessung in der orthopädischen Rehabilitation – Ergebnisbericht 31. Januar 2020. Retrieved Februar 21, 2021, from https://www.qualitaetskliniken.de/fileadmin/user_upload/Ergebnismessung_in_der_orthopaedischen_Rehabilitation_Gesamtbericht_20200131_4qd.pdf
- Skovlund, S. & Ejskjær, N. (n. d.). National Project for Value Based Care & Patient Reported Outcomes in Diabetes. Aalborg University's Research Portal. Retrieved September 30, 2020, from <https://vbn.aau.dk/en/projects/national-project-for-value-based-care-patient-reported-outcomes-i>
- Socialstyrelsen (2020). Patientlagen. *About the National Board of Health and Welfare*. Retrieved October 6, 2020, from <https://www.socialstyrelsen.se/en/about-us/>
- Statistisches Bundesamt (2020). *Einrichtungen, Betten und Patientenbewegung*. Retrieved September 24, 2020, from <https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Gesundheit/Krankenhaeuser/Tabellen/gd-krankenhaeuser-jahre.html>
- Stoye, G. (2019). *Recent trends in independent sector provision of NHS-funded elective hospital care in England* IFS Briefing Note BN268. Retrieved September 24, 2020, from <https://www.ifs.org.uk/uploads/BN268-Recent-trends-in-independent-sector-provision-of-NHS-funded-elective-hospital-care-in-England1.pdf>
- Thiel, L. (n. d.). *PROMs werden Pflicht in Zürich*. Retrieved September 29, 2020, from <https://heartbeat-med.com/de/blog/proms-werden-pflicht-in-zuerich/#xthcjtye939k5emdavdweb>
- University Hospital Foundation (2020). *Northern Alberta Renal Program: Providing complete renal care*. Retrieved October 6, 2020, from <https://www.universityhospitalfoundation.ab.ca/Northern-Alberta-Renal-Program>
- PROMiNET. (n. d.). *Velkommen til PROMiNET*. Retrieved September 30, 2020, from <https://www.prominet.no/>
- Vincent, C., Staines, A., & A., S. (2019). Verbesserung der Qualität und Patientensicherheit des Schweizerischen Gesundheitswesens: Nationaler Bericht zur Qualität und Patientensicherheit im schweizerischen Gesundheitswesen, im Auftrag des Bundesamtes für Gesundheit. <https://www.news.admin.ch/newsd/message/attachments/59013.pdf>
- Volksgezondheidszorg (2020). *Aantal instellingen voor medisch specialistische zorg*. Retrieved September 24, 2020, from <https://www.volksgezondheidszorg.info/onderwerp/ziekenhuiszorg/cijfers-context/aanbod#node-aantal-instellingen-voor-medisch-specialistische-zorg>

- Wells, G.A., Russell, A.S., Haraoui, B., Bissonnette, R., Ware C.F. (2011). Validity of quality of life measurement tools – from generic to disease-specific. *J Rheumatol Suppl. Nov*; 88:2-6. doi: 10.3899/jrheum.110906. PMID: 22045972.
- Wilson, I., Bohm, E., Lübbecke, A., Lyman, S., Overgaard, S., Rolfson, O., Dahl, A.W., Wilkinson, M. & Dunbar, M. (2019). Orthopaedic registries with patient-reported outcome measures. *EFFORT Open Reviews*, 4(6):357-367. <https://doi.org/10.1302/2058-5241.4.180080>
- World Health Organization (WHO) (2020). *The Global Health Observatory: Hospital beds (per 10000 population)*. Retrieved October 1, 2020, from [https://www.who.int/data/gho/data/indicators/indicator-details/GHO/hospital-beds-\(per-10-000-population\)](https://www.who.int/data/gho/data/indicators/indicator-details/GHO/hospital-beds-(per-10-000-population))
- Wohlin, J., Stalberg, H., Ström, O., Rolfson, O., Willers, C., & Brommels, M. (2017). Effects of introducing bundled payment and patients' choice of provider for elective hip and knee replacements in Stockholm county. Stockholm. Karolinska Institutet. <https://ki.se/media/95244/download>
- Yang, L.Y., Manhas, D.S., Howard, A.F. & Olson, R.A. (2017). Patient-reported outcome use in oncology: a systematic review of the impact on patient-clinician communication. *Supportive Care in Cancer*. <https://doi.org/10.1007/s00520-017-3865-7>
- Zürich Gesundheitsdirektion, K. (2017). Qualitätsstrategie der stationären Versorgung im Kanton Zürich 2017-2022. https://www.vzk.ch/downloadcenter/dokumente-vzk/2017-qualitaetsstrategie_kanton_zuerich.pdf

Appendix

Question guide

Introduction

- » We would like to audio-record the interview. Would you give your consent to that?
 - » What is your role in relation to PROMs? (In what way do you work with PROMs?)
-

Level of implementation

- » What is the current level of PROMs implementation in your country?
 - National (e.g. registries)
 - (State)
 - Regional
 - Provider
 - » Are PROMs used more as part of clinical studies, larger-scale pilots or in routine care in your country?
 - » Are there plans to widen the level of implementation?
 - » Are any regulations / directives / political developments on PROMs currently observable or planned?
 - » In which disease area(s) are PROMs being applied in your country at the moment and why?
 - » Which disease areas do you perceive as promising areas for PROMs implementation? (easy application versus relevance to patients and others)
-

Form of utilisation

- » Which of the following areas do you perceive as the main area(s) of PROMs utilisation in your country and why?
 - Measurement and comparison as part of research or HTA
 - PROMs to improve outcome quality (internal versus external quality assurance)
 - PROMs to generate evidence for patient relevant aspects of treatment and outcomes (to promote better informed decision-making)
 - Public reporting and benchmarking
 - Value-based payment / P4P
 - » Which positive or negative results do you perceive as a consequence of this implementation?
 - » Which do you perceive as the main barriers for widescale implementation of PROMs in these three areas in your country?
 - » How do you perceive the opportunity to use PROMs as a quality indicator to facilitate the choice of patients for a healthcare provider? How do you perceive the opportunity of using PROMs as a source for evidence-based health information for clinical decision-making and patient information?
-

4 Stakeholders & Driving Forces

- » Which stakeholders should be involved in a successful implementation of PROMs on a national / state level and how?
 - » Do you see barriers concerning the support of PROMs from the stakeholder community?
-

Strategies & Political Framework

- » Which overall prerequisites need to be met for a successful implementation of PROMs on a national level?
 - » Which political framework would facilitate PROMs implementation at system level in your country?
 - » Which next steps would you recommend to widen the implementation of PROMs?
-



Trends

- » Where do you see the utilization of PROMs in your country in the coming 5 years / in 10 years?
 - » What promising trends do you observe in other countries?
-

Interviewee List

Country	Experts Name	Experts function
 Australia	Prof. Geoffrey Delaney	South Western Sydney Clinical School, Director of Cancer Services, PROMs Researcher
 Australia	Melissa Tinsley	New South Wales Agency for Clinical Innovation, Manager Clinical Information and Decision Support
 Canada	Nicole de Guia	Canadian Institute for Health Information (CIHI), Manager Organ Donation and Transplantation (ODT) project and CORR
 Canada	Kirsta Louie	Canadian Institute for Health Information (CIHI), Program Lead, PROMs
 Denmark	Sanne Jensen	PRO Sekretariatet, Team Coordinator
 Denmark	Kenneth Forsstrøm Jensen	Roche, Strategic Market Access Manager
 England	Tom Foley	NHS Digital, Senior Clinical Lead
 England	Joseph Casey	King's Health Partners London, Director Partnerships and Programmes
 England	Prof. Mike Reed	Northumbria Healthcare NHS Foundation Trust, Consultant, Trauma and orthopedic surgeon
 Germany	Dr. Jens Deerberg-Wittram	RoMed Kliniken, CEO; ICHOM President 2012-2014
 Germany	Prof. Matthias Rose	Charité, PROMIS Germany, Clinic director Department of Psychosomatic Medicine
 Germany	Yannik Schreckenberger	Hearbeat Medical, CEO and founder
 Germany	Claudia Hartmann	Charité, Implementation and Research Project Manager for VBHC
 Germany	Dr. Ilona Köster-Steinebach	German Alliance for Patient Safety – Aktionsbündnis Patientensicherheit (APS), Managing Director
 Netherlands	Dr. Henk Veeze	Diabeter, Co-Founder and Medical Director
 Netherlands	Jacqueline Hartgerink	Dutch Institute for Clinical Auditing (DICA), Head of Registrations
 Norway	Dr. Christer Mjåset	Helseplattformen AS, Deputy CEO, Neurosurgeon
 Norway	Per Arne Holmann	Lovisenberg Hospital, Head of Data Analysis
 Norway	Heidi Blegslie Aabel	Checkware; Norway Health Tech, CEO
 Sweden	Birgitta Lindelius	National Board of Health and Welfare, Program Officer
 Sweden	Hanna Emami	Swedish Association of Local Authorities and Regions (SALAR)
 Switzerland	Dr. Florian Rüter	University Hospital Basel, Director Quality Management
 Switzerland	Elvira Häusler	Muller Healthcare Consulting, Senior Consultant; Member of Scientific Advisory Board AQC Qualitätssicherung
 Switzerland	Anthony Staines	Fédération des hôpitaux vaudois, Patient Safety Program Director
 USA	Dr. Eric Schneider	Commonwealth Fund, Senior Vice President for Policy and Research
 USA	Jacob Lippa	Providence St. Joseph Health, Manager, Clinical Analytics, Value Analytics & Patient Reported Outcomes

Supplementary interviews in additional countries

 Wales	Dr. Sally Lewis	National Clinical Lead for Value-Based and Prudent Healthcare / Honorary Professor at Swansea School of Medicine
 Israel	Dr. Eyal Zimlichman	Sheba Medical Centre, Deputy Director General, Chief Medical Officer and Chief Innovation Officer

Authors



Viktoria Steinbeck

Viktoria is a Research Fellow at the Health Care Management Department at the Technical University (TU) Berlin. Her background is in Public Health and Health Economics, having obtained a Bachelor and a Double Master of Science at University Maastricht and Cologne University. As part of the Promoting Quality team at TU Berlin, she especially focuses her research on enabling patient-centered care via PROMs utilization. Previous research and work commitments led her to the European Commission, Columbia University (New York), Allianz and a consulting role in EU health politics in Brussels.



Sophie-Christin Ernst

Sophie-Christin joined the Department of Health Care Management as a Research Assistant in March 2020. She has studied Medicine at the Westfälische Wilhelms-Universität Münster and Université Paris Descartes (France). Prior to her position at TU Berlin, she worked as part of the research team at the Chair of Innovation Management and Value in Health at Université Paris Descartes – primarily contributing to a report commissioned by EIT Health drawing practical lessons from leading European medical centers involved in value-based health care, aiming to share tools and best practices. Her research so far has focused on elements of value-based healthcare, such as outcome-based pricing and risk-sharing agreements, outcome measurement and the transparency of quality of care.



Dr. Christoph Pross

Christoph is a Senior Research Fellow at the Health Care Management Department at TU Berlin. He co-leads the PROMoting Quality project as well as the DFG Quality of Care Transparency research project. His research is focused on outcome transparency, the determinants of quality of care, value-based healthcare and PROMs. Next to his part-time research position at TU Berlin, he leads the Market Access, Health Economics and Governmental Affairs team for the medical technology company Stryker GmbH & Co KG for the DACH region and Poland. Previously, Christoph worked for the Boston Consulting Group with a focus on VBHC, strategy and digital projects for medical technology, payer and hospital clients. Christoph holds a M. Sc. in Management and Strategy from the London School of Economics in the United Kingdom and a B.A. with a double major in Economics and Political Science from Davidson College in the United States.

Acknowledgements

We would like to thank all interviewed experts for sharing their valuable insights with us during the interviews and in the consequent feedback provided on the manuscript. For Australia: Prof Geoffrey Delaney and Melissa Tinsley; for Canada: Nicole de Guia and Kirsta Louie; for Denmark: Sanne Jensen and Kenneth Forsstrøm Jensen; for England: Tom Foley, Joseph Casey and Prof. Mike Reed; for Germany: Dr. Jens Deerberg-Wittram, Prof. Matthias Rose, Yannik Schreckenberger, Dr. Ilona Köster-Steinebach and Claudia Hartmann; for the Netherlands: Dr. Henk Veeze and Jacqueline Hartgerink; for Norway: Dr. Christer Mjåset, Per Arne Holmann and Heidi Blegli Aabel; for Sweden: Birgitta Lindelius and Hanna Emami; for Switzerland: Dr. Florian Rüter, Elvira Häusler and Anthony Staines for the USA: Dr. Eric Schneider and Jacob Lippa; for Wales: Dr. Sally Lewis; for Israel Dr. Eyal Zimlichman. Special thanks go to Chrissa Tsatsaronis, research assistant and the Health Care Management Department, who continuously helped with the background research for this report and assisted with interviews. The authors would also like to thank the following colleagues at the Health Care Management Department for providing their valuable feedback on the manuscript: Prof. Reinhard Busse, Prof. Alexander Geissler, David Kuklinski, Katherine Polin and Laura Oschmann.

Disclaimer

The research for this report was partly financed by the Bertelsmann Stiftung. In the project “Promoting Quality”, the Health Care Management Department at TU Berlin is the leading research party and works together with the IT provider Heartbeat Medical for the digital PRO-data collection as part of this research project. Next to his role at TU Berlin Dr. Christoph Pross works as Director Market Access, Health Economics and Government Affairs at the Medical Technology company Styker GmbH & Co KG. In this function, he works with different IT providers such as Oncare GmbH.

Imprint

© May 2021
Bertelsmann Stiftung
(Publisher)

DOI 10.11586/2021048

Bertelsmann Stiftung
Carl-Bertelsmannstraße 256
33311 Gütersloh
Phone +49 5241 81-0
www.bertelsmannstiftung.de

Managing editor
Uwe Schwenk

Proofreading
Medax Medizinischer
Sprachendienst GmbH

Design
Dietlind Ehlers

Photos
© xyz+ - stock.adobe.com

Adress | Contact

Bertelsmann Stiftung
Carl-Bertelsmann-Straße 256
33311 Gütersloh
Phone +49 5241 81-0

Marion Grote-Westrick
Senior Project Manager
Improving Healthcare – Informing Patients
Phone +49 5241 81-81271
marion.grotewestrick@bertelsmann-stiftung.de

www.bertelsmann-stiftung.de