

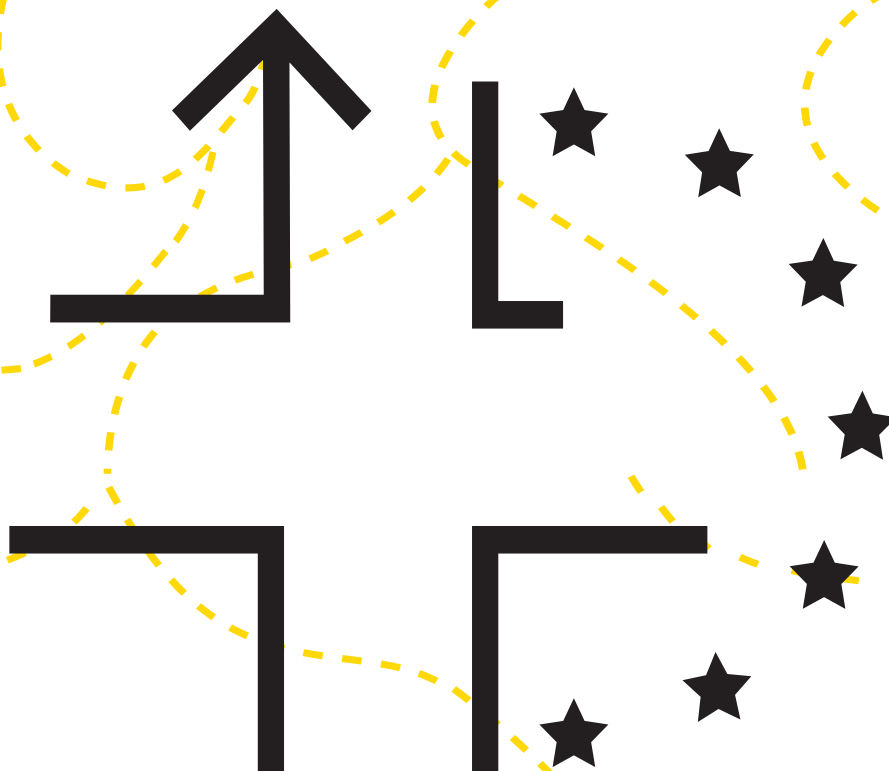


EUROPEAN
HEALTH PARLIAMENT

COMMITTEE ON OUTCOMES-BASED HEALTHCARE

Boosting Healthcare
Outcomes in Europe

2017-2018



COMMITTEE ON OUTCOMES-BASED HEALTHCARE

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The views and opinion expressed in this article reflect the perspective of the European Health Parliament Committees collectively. It does not reflect the views of the individual EHP members, nor the views of their respective employers or partner organizations supporting the project.

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How do we drive efficiency in health care? Focusing on outcomes that truly matter to patients, is a good place to start. We need to focus on solutions that have shown to improve outcomes and efficiency across the entire care pathway – from small-scale efforts to system-wide changes. As a policymakers, I am willing to join forces with patients, researchers, healthcare professionals and others to drive this paradigm shift towards outcomes-based healthcare. I also encourage my colleagues to implement the necessary infrastructure in all EU Member States.

Dr. Christina Rångemark Åkerman

President of the International Consortium for Health Outcomes Measurement (ICHOM)



Moving towards measuring what matters most to patients is crucial for the long-term sustainability of health systems globally. I am deeply encouraged to notice how the recommendations from the European Health Parliament's Committee on outcomes-based healthcare underlines the importance of harmonization of outcomes, patient involvement in defining the outcomes and the need to automate the collection of the harmonized data. Their recommendations will help today's health systems to reduce existing variations, understand the effectiveness of different treatments, support patients towards shared-decision making and, last but not least, fully focus on what matters most to a society: its citizens!

Prof. Philip Poortmans

President of the European Cancer Organisation (ECCO)



I warmly congratulate the European Health Parliament for taking on this difficult but pressing topic of data and outcomes-based healthcare. The challenges and solutions identified in this paper serve as an excellent stimulus for the decision-making that inevitably needs to be made by political and health system managers. I therefore urge all interested stakeholders to take the time to read the paper and to familiarise themselves with the terms of the debate on outcomes-based healthcare and its associated data requirements.

Andrew Bottomley, PhD

Assistant Director – Head of Quality of Life Department at European Organisation for Research and Treatment of Cancer (EORTC)



I am very pleased to see in this EHP policy report that patients' views on their quality of life can hopefully be more useful in shaping future health care treatment and services, across the EU, thus ensuring European research and services can be truly patient-focused.

Salomé Azevedo

Platform Manager and Research Assistant at Patient Innovation



Patient Innovation believes the work of the Committee on Outcomes-Based Healthcare within the European Health Parliament project is a good starting point to implement a sustainable, data-based strategy to achieve high-quality healthcare in all EU Member States.

Suzanne Wait, PhD

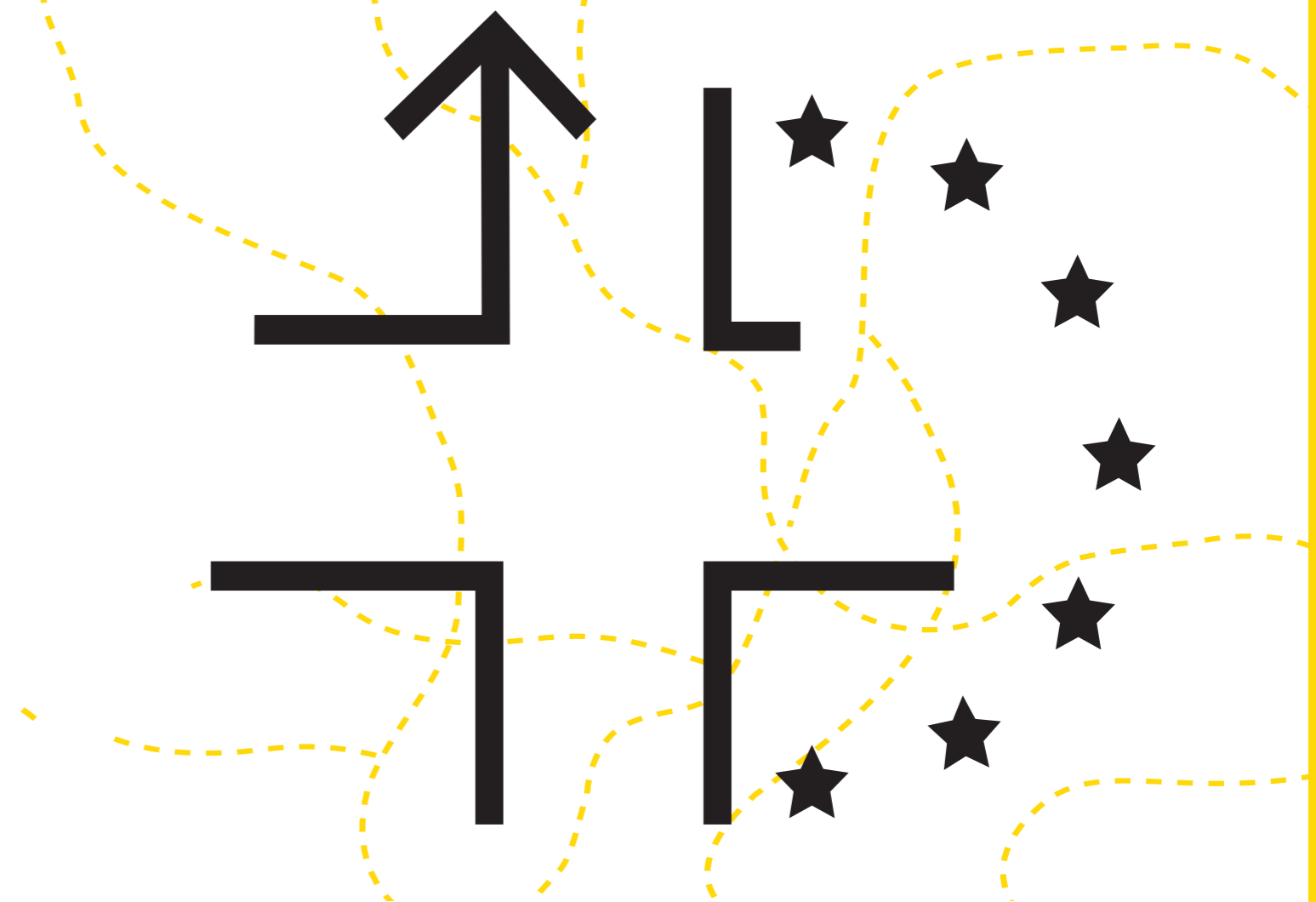
Managing Director at The Health Policy Partnership



Many have spoken about the need to move towards an outcomes-based approach to care in the past few years, but putting this in practice remains challenging. We cannot allow ourselves to collect data for data's sake – instead we need to think about which data to collect, and how this can contribute in a meaningful way to improve our systems of care, keeping the patient foremost in our minds. This report from the European Health Parliament has been drafted with that ethos and brings forward excellent recommendations that all policymakers, and indeed everyone working in health policy, should subscribe to.

COMMITTEE ON OUTCOMES-BASED HEALTHCARE

Boosting Healthcare Outcomes in Europe




EMPOWERING PATIENTS




IMPROVING OUTCOMES




CREATING EUROPEAN SOLUTIONS

Executive summary

Despite the fact that the European Commission has successfully managed to drive the collection of 'hard' data, there remain considerable gaps and challenges in health data coverage.

EU Member States have developed significantly different approaches to monitoring and assessing healthcare system performance. Countries also record and store health data differently as wide variations are being observed in the definition of medical indicators and structure of Electronic Health Records (EHRs), while only few countries have introduced a Single Patient Identifier (SPI) systems facilitating crossborder integrated care.

Ensuring data standardisation and interoperability is just, however, one part of the solution. EU healthcare systems tend to measure inputs (e.g. healthcare spending), processes (e.g. blood pressure checks) and outputs (e.g. blood results), but do not sufficiently take into account outcomes (e.g. quality of life indicators), which matter most to patients. In addition, there is no standardised approach to collecting, analysing or interpreting Patient-Reported Outcomes (PROs) in clinical trials and evidence shows that patients' involvement in the development of PROs remains limited.

To drive the transition towards outcomes-based health care, we recommend to:

1. Boost the collection of patient outcomes data by ensuring that PROs questionnaires are co-created with patients, fostering the inclusion of PROs as primary outcomes along with traditional clinical endpoints in clinical trials, and expanding the collection and use of Real World Evidence (RWE);
2. Set up common core indicators (including patient outcomes data) for Health Systems Assessment Frameworks (HSAF) to run benchmark assessments, learn from best practices, and drive policy change;
3. Launch an EU multi-stakeholder Expert Group to drive political momentum, leverage existing outcomes-based initiatives, collect recommendations and provide country-specific guidance to Member States on how to adopt such indicators and standards;
4. Complete the implementation of Electronic Health Records (EHRs) and move towards the implementation of Single Patient Identifier (SPI) systems across the EU;
5. Incentivise and empower countries by developing an EU-wide repository of existing initiatives improving patient outcomes, sharing guidance on outcomes-based healthcare in the European Semester review, and integrating outcomes-based healthcare in education curricula.

HEALTHCARE CHALLENGES AT A GLANCE



20-40%

of healthcare spending is estimated to be wasted on ineffective interventions

(WHO 2010)



1 in 10

patients in OECD is harmed at the point of care or receives low-value care making no difference to their health outcomes

(OECD 2017)



2 years

of life gained for patients in OECD countries if inefficiency in health care is reduced

(DG ECFIN 2015)



€2,8 bn

is the minimum annual economic burden of adverse events in EU28 while 44- 50% of them are preventable

(DG SANTE 2016)

Introduction

With 20-40% of healthcare spending estimated to be wasted on ineffective interventions at a time of limited resources and increased demand for healthcare innovation and services, the efficiency of EU healthcare systems must be challenged. How? By building outcomes-based, data-driven, and patient-centred healthcare systems.

The International Consortium for Health Outcomes Measurement (ICHOM), a non-profit, multi-stakeholder organisation, has defined outcomes as “the results people care about most when seeking treatment, including functional improvement and the ability to live normal, productive lives.”¹

By collecting, mining and sharing patient-centred evidence, we believe the outcomes-based healthcare revolution will usher a new world of opportunities for policymakers and stakeholders to provide the right services to the right people at the right time. This EHP contribution sheds lights on some of the main challenges facing EU healthcare systems and sets out a series of recommendations for stakeholders (EU institutions, Member States, payers, HCPs, patients, advocates, researchers, and the industry) to consider and act upon.

Where We Are

Data fragmentation and interoperability

The European Commission has successfully managed to drive the collection of ‘hard’ data with its European Core Health Indicators (ECHI) initiative providing reliable statistics on mortality rates, survival, incidence and healthcare expenditure. However, there remain considerable gaps and challenges in health data coverage.

The world is awash in health data, with information being generated at an ever-increasing pace: 153 exabytes (exabyte = 1e+12 megabytes)

were produced in 2013 and 2,314 exabytes are estimated to be produced in 2020.² Health wearables, genomic analytics, and the digitalisation of hospital databases are a few examples contributing to the big data revolution. However, data remains for the larger part in silos, as countries mostly operate with fragmented databases (e.g. public and private patient registries, national and regional databases, etc.). Besides ECHI, EU Member States do not necessarily monitor, collect, and measure the same data, making it complex to run benchmark assessments, compare data sets, and learn from best practices.

i. Fragmented assessments of healthcare systems

Following the adoption of the 2008 Tallinn Charter,³ Health System Performance Assessment (HSPA) frameworks have been developed across the EU to monitor and evaluate the performance of healthcare systems and units (such as hospitals) against a number of criteria such as quality, access, equity, and efficiency. On paper, these frameworks were developed to support performance-driven health policies, while increasing the value for money in a context of economic downturn. However, the Expert Group on HSPA, representing national ministries of health, pointed out in its 2014 report that EU countries have developed significantly different approaches to monitoring and assessing healthcare system performance. Not only are HSPA goals defined by each country but the number of indicators vary from less than 30 in Austria to more than 1,000 in Finland.⁴

ii. Significant discrepancies in electronic health records

The lack of data interoperability is also apparent in the way Member States record and store health data. Not all general practitioners currently record health data electronically, which makes it difficult to perform nation-wide analysis. Furthermore, wide variations have been observed in the definition of medical indicators and structure of Electronic Health Records (EHRs) used to keep track of the patient’s pathway (e.g. prescription, consultations and hospitalisation, etc.). In this regard, a 2014 report of DG Connect comparing national legislation on EHRs revealed that less than half of EU Member States implemented specific rules and standards on EHR interoperability.⁵ Similarly, while the 2011 EU cross-border healthcare directive set the foundations for safeguarding patients’ rights to seek treatment outside their home country, only few countries such as Denmark, Estonia, Ireland and the UK have introduced single patient identifier (SPI) systems facilitating cross-border, integrated care.⁶

iii. Insufficient integration of socio-economic data

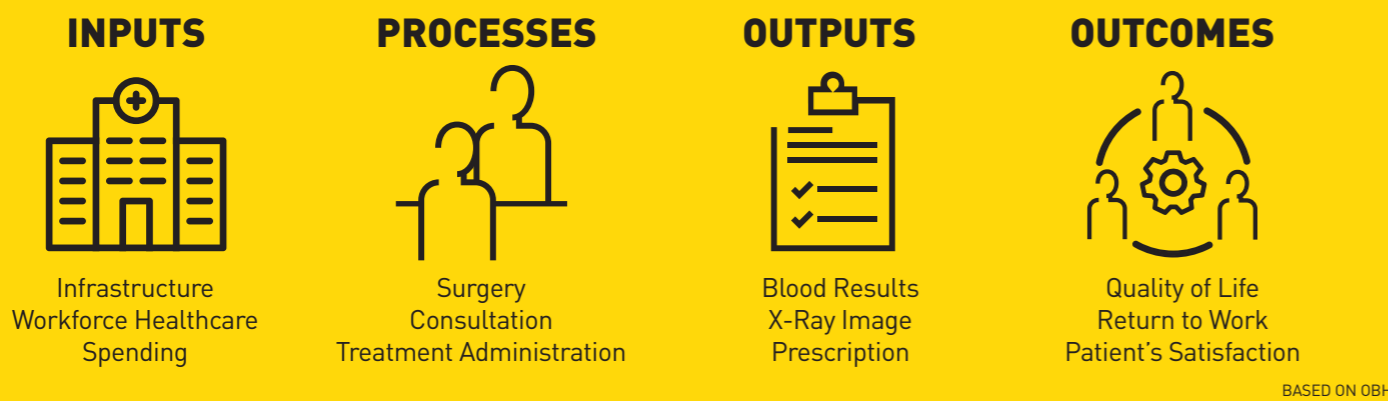
Health policy decisions are essentially based on health-specific data such as medical records, medical resources utilisation, care consumption, morbidity, and mortality data but too often fail to integrate data on social determinants of health generated by National Statistical Offices (e.g. unemployment, education, health literacy, etc.). Social

determinants of health are mostly responsible for health inequities and play a leading role in the development of chronic conditions such as diabetes, cancer, and chronic obstructive pulmonary disease. As a result, health systems tend to focus more on ad-hoc disease treatments rather than long-term prevention programs. Lifestyles and the socio-economic dimension of health are not taken into account in the patient pathway adequately enough.

Insufficient collection and use of patient outcomes data

i. Outcomes vs. inputs, outputs and processes

Health systems collect vast amounts of data (e.g. number of patients being treated, quantity of services delivered, healthcare spending, guidelines, etc.) and typically focus on rates of recurrence, survival, and treatment as markers of success. We tend to measure inputs (e.g. healthcare spending), processes (e.g. blood pressure check), and outputs (e.g. blood results) more than true outcomes (e.g. preserved quality of life, reduced pain) which matter most to patients.



ii. Insufficient integration of patient outcomes in clinical trials

A growing number of clinical trials are going beyond conventional Randomised Controlled Trials (RCTs) and collect Patient-Reported Outcomes (PROs) to include the patient's perspective in the drug development process. The number of trials collecting PROs grew from 6.1% (2005-2007) to 16.3% (2011-2013).⁷

The European Medicines Agency (EMA)'s 2016 guidance document reinforced the need for the development and application of PROs in the oncology setting. EMA advises that, where relevant, the integration of PROs should be pursued as an objective in clinical trial protocols. Despite growing interest among sponsors, clinicians, payers, regulators, and patients in developing and applying PROs across the drug lifecycle, progress has been slow. The EMA recognises that there is no standard approach to collecting, analysing or interpreting PRO data in clinical trials and that PRO measures are used often as secondary or exploratory outcomes, but rarely as primary outcomes in regulatory submissions.⁸

iii. Unsatisfactory involvement of patients in outcomes definition

A number of studies investigating the quality and acceptability of PROs found no clear evidence of patient involvement in the development of PRO questionnaires⁹ which are, in practice, primarily developed by healthcare professionals, hence not always accurately reflecting patient views.

Where We Want To Be

I. Data collection and standardisation

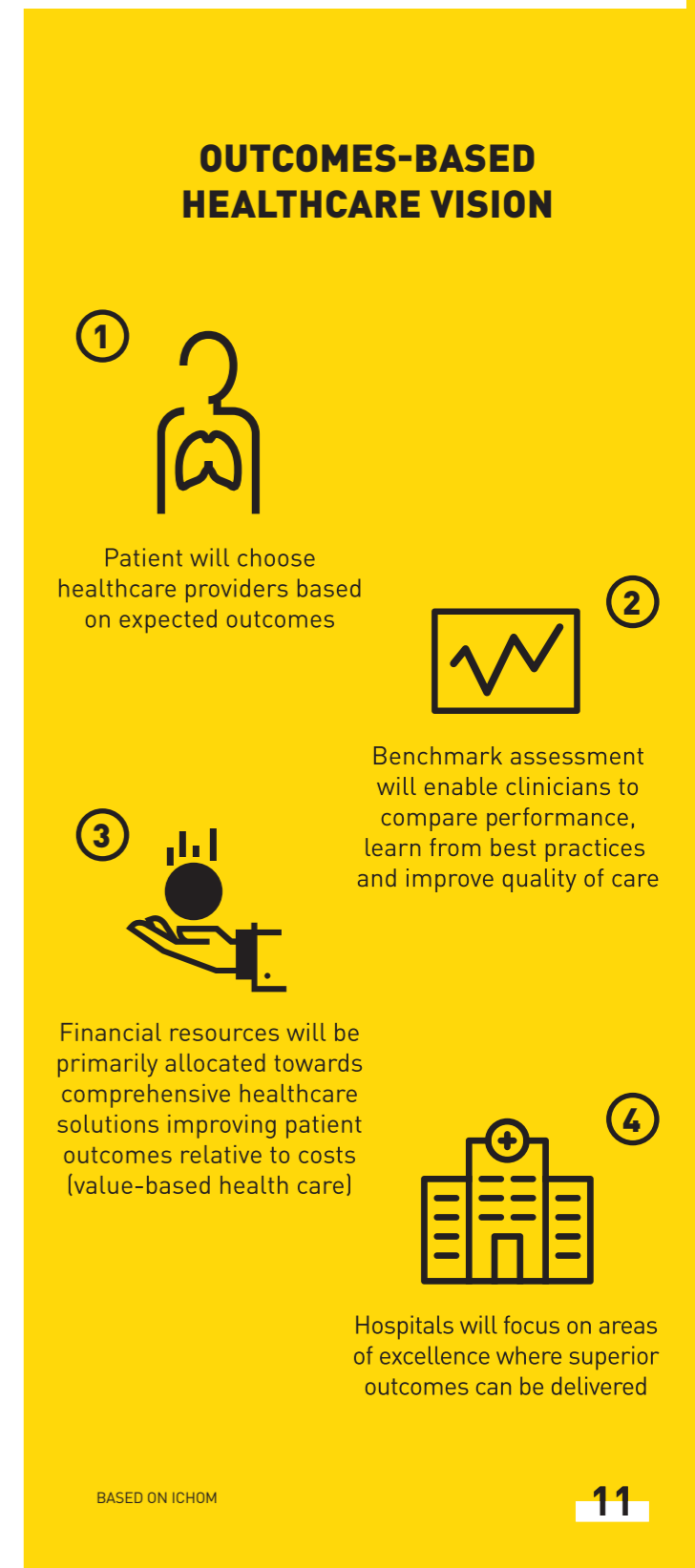
RECOMMENDATION #1

Boost the collection of patient outcomes data

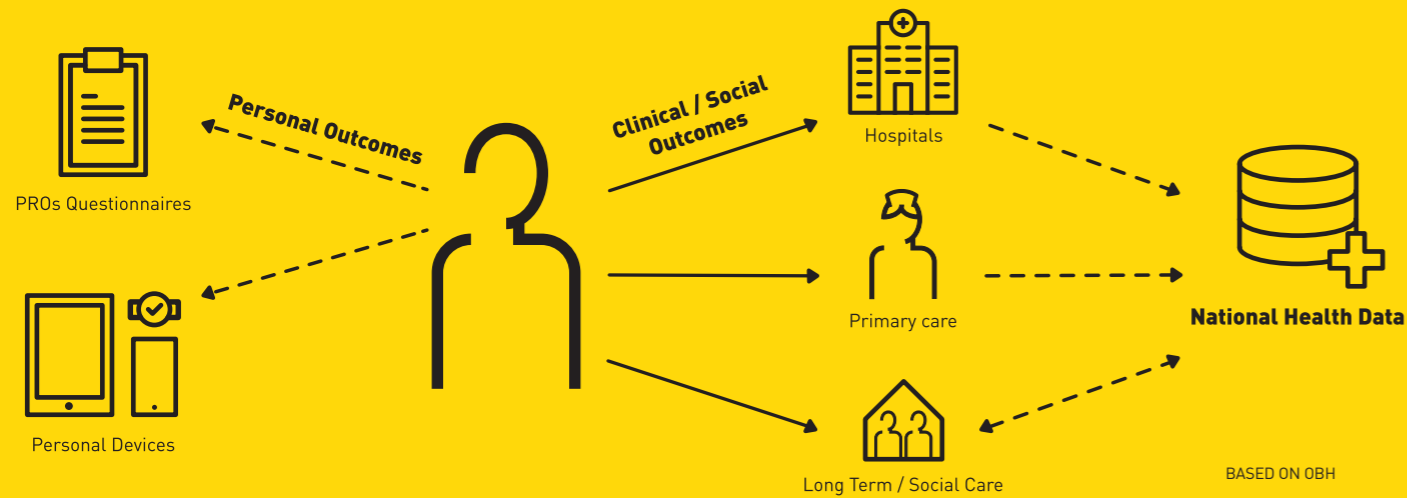
While the majority of data collected tracks processes, administrative tasks and captures clinical outcomes, there is a gap when it comes to the collection of patient outcomes data.

We recommend that:

- Patient reported outcomes and experience measures (PROMs/PREMs) questionnaires should be co-created with patients to ensure they reflect what matters most to them. More generally, it is paramount to make sure that outcomes-based healthcare is driven via an inclusive, multi-stakeholder approach, including healthcare professionals, patients, carers, industry representatives, policy-makers payers, etc.;
- Unless there is a legitimate scientific rationale, clinical trials should collect and measure PROs and quality-of-life indicators as primary outcomes along with traditional clinical endpoints such as overall survival (OS) and progression-free survival (PFS);
- Every day patients are older, less healthy and more diverse than patients involved in randomised clinical trials,¹⁰ it is paramount to further expand and systematise the collection and use of real-world evidence (RWE).



MEASURING REAL WORLD EVIDENCE



RECOMMENDATION #2

Create high-quality HSPA frameworks

Development and use of well-functioning national health systems assessment frameworks (HSPA) is an absolute necessity in order to reach a high quality of care. Although the design of HSPA is in the hands of EU Member States, common core indicators (including patient outcomes data) should be established to enable comparison of results. Furthermore, guidance on implementation of common indicators and high-quality HSPA networks should be included in the country-specific recommendations of the European Semester.

RECOMMENDATION #3

Leverage existing outcomes-based initiatives and drive political momentum

To implement outcomes-based healthcare systems, we need to establish common language on outcomes to ensure that every institution measures and collects data serving the same purpose. Since 2012, ICHOM has been driving this ambition forward and has successfully managed to complete the development of 23 standardised datasets covering over 54% of the global disease burden. Building on ICHOM's pioneering research activities, OECD announced in 2017 that it will accelerate and expand the standardisation of patient-centred, outcomes-based datasets as part of its Patient-Reported Indicators Survey (PaRIS). While the EU is co-funding this joint initiative, we believe it is important for the Commission to go one step further.

The Commission should set up a multi-stakeholder Expert Group to collect recommendations and provide country-specific guidance

to Member States on how to adopt such indicators and standards.¹¹ Such EU leadership is important to bridge the gap between Member States (as 6 countries – Bulgaria, Croatia, Cyprus, Lithuania, Malta, and Romania – are not part of the OECD) and to drive political momentum across the EU.

RECOMMENDATION #4

Be digital

Policy and practice need to catch up with science. The use of technology does not only allow data to be analysed and compared efficiently, but it also facilitates patients' (i.e. end-users) experience and tackles the issue of overburdened healthcare professionals, enabling faster reporting and filing systems. Hence, there is an urgent need to complete the implementation of electronic health reports (EHRs) across the EU. All EU Member States should progressively move towards the implementation of Single Patient Identifier (SPI) systems to ensure that patient files are transferable throughout the EU and to fully facilitate the implementation of cross-border healthcare, allowing swift patient movement and avoiding the duplication of health exams. Moreover, the Eurobarometer survey published in May 2017 showed that 52% of respondents would like online access to their medical data.¹²

II. Incentivise and Empower EU Member States to adopt Outcomes Based Health Care

Although a few organisations are driving the outcomes-based healthcare revolution, the concept remains in its infancy. EU institutions have a leading role to play in demonstrating its holistic value for healthcare systems and should incentivise and equip Member States to facilitate this paradigm shift. As the Director General of DG SANTE, Xavier Prats Monné, puts it: '[...] we have a mandate to develop, particularly within the Directorate General for Health and Food Safety, the necessary expertise on the performance of health systems, to build up solid country-specific and cross-country knowledge which can inform policies at national and European level.¹³

RECOMMENDATION #5

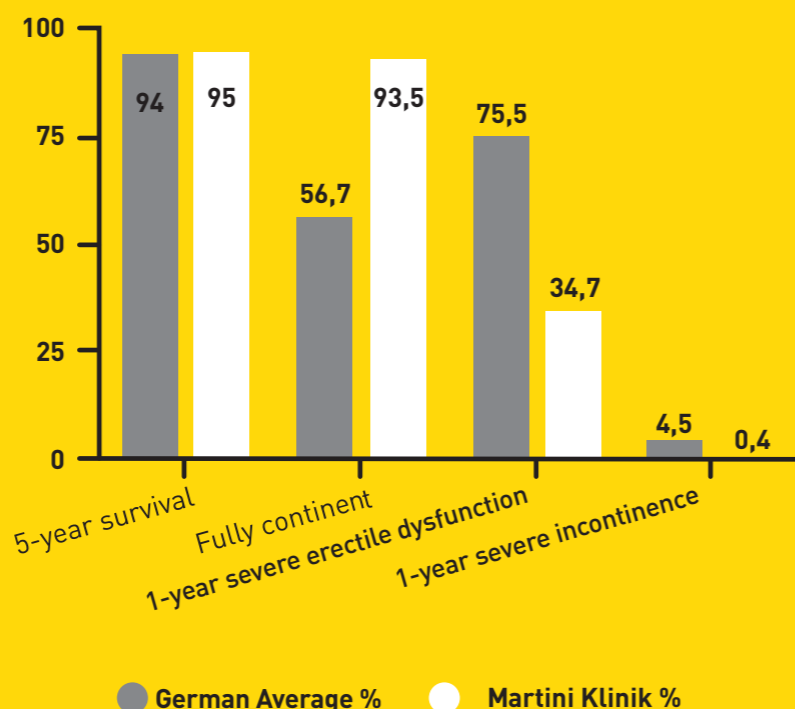
Learn from best practices

To ensure stakeholders learn from best practices, the Commission should develop an EU-wide repository of existing initiatives improving patient outcomes. Such business cases would not only shed light on the value of outcomes-based healthcare, but also promote cutting-edge science and service excellence across the EU. A prime example of such an initiative is the treatment of prostate cancer by the German Martini Klinik. This centre of excellence has developed a unique patient-centred approach which has significantly outperformed standards of care across the country (see Martini Klinik case study).¹⁴

CASE STUDY: PROSTATE CANCER AT THE MARTINI KLINIK

Since its inception in 2005, Hamburg's Martini Klinik has single-mindedly focused on prostate cancer care with a commitment to measure long-term health outcomes for every patient. In particular, this center of excellence has built an unprecedented, multi-layer data set, collecting clinical outcomes (e.g., positive surgical), mortality rates and administrative processes (e.g., urinary function, quality of life).

This comprehensive patient-centred approach has enabled the clinic's multidisciplinary HCP team to identify the need for patients facing better complication rates to be assisted by more experienced surgeons. The results proved to be significantly higher than other institutions, and by 2013, Martini Klinik had become the largest prostate cancer treatment program in the world with 5,000 outpatient cases and more than 2,200 surgical cases annually, with patients coming from all over Germany and from other countries.



BASED ON THE CONSENSUS DOCUMENT THE VALUE OF HEALTH, IMPROVING OUTCOMES

To facilitate best-practices sharing, the European Commission could integrate further guidance on OBHC into its European Semester review, along with its existing country-specific recommendations on access, affordability, efficiency, and integrated care.

RECOMMENDATION #6

Integrate outcomes-based healthcare in education

Training plays an important part in modernising healthcare services and improving care quality. In this regard, the Commission should collaborate with leading service providers and centres of excellence (e.g. Barcelona Campus, Spain and IRCAD, France) to develop and assist Member States in running a series of workshops for healthcare providers and clinicians to understand how outcomes-based healthcare could be implemented (especially on the collection, mining, and use of electronic health data). Similarly, the Commission should encourage Member States to integrate outcomes-based healthcare in medical and nursing training programmes and education curriculum.

Conclusions

OUR MESSAGE TO EUROPEAN POLITICAL LEADERS

A wide range of pioneering initiatives are currently emerging to pave the way for an outcomes-based healthcare approach in a context of limited resources and increased demand for healthcare innovation and services. But this burgeoning field has a long way to go before being widely adopted by EU Member States as countries still face considerable challenges in the collection and implementation of health data and do not sufficiently take into account patient outcomes. Driving this ambitious paradigm shift will require the cooperation and contribution of all healthcare stakeholders.

Though healthcare remains the remit of Member States, EU institutions, and more particularly the European Commission, have a significant role to play in providing guidance to EU Member States to facilitate the implementation of best practices and improve the efficiency of national healthcare systems.

OUTCOMES-BASED HEALTHCARE

STAKEHOLDERS	WHAT'S IN IT FOR ME?	HOW CAN I CONTRIBUTE?
Patients	<ul style="list-style-type: none"> • Patients are at the centre of healthcare • Patients have the ability to choose healthcare providers based on expected outcomes 	<ul style="list-style-type: none"> • Patients should share their health data • Patients should contribute to outcomes definition, collection, and assessment
HCPs/ Researchers	<ul style="list-style-type: none"> • HCPs can develop expertise in core therapeutic areas and build centres of excellence across the EU • HCPs can deliver significantly superior outcomes for patients • HCPs can learn from best practices 	<ul style="list-style-type: none"> • HCPs should share best practices • HCPs should integrate outcomes-based, data-driven analysis in their decision-making processes • HCPs should participate in training and education programmes on OBHC
Payers	<ul style="list-style-type: none"> • Payers could better allocate resources by financing innovations and interventions delivering superior outcomes and/or reducing waste and inefficiencies 	<ul style="list-style-type: none"> • Payers should develop and implement value-based assessments • Payers should reward patient-centred approaches by prioritising quality of life indicators
Policy makers	<ul style="list-style-type: none"> • Policymakers could significantly improve the efficiency and sustainability of healthcare systems • Policymakers would collect better evidence to support health prevention programs 	<ul style="list-style-type: none"> • Policymakers should gather political will and concentrate on long-term health policies and paradigm shift toward more sustainable healthcare • Policymakers should drive the standardisation and interoperability of data sets • Policymakers should incentivise best practices in outcomes-based healthcare and integrate this approach in education curriculum
Industry	<ul style="list-style-type: none"> • Innovations could be rewarded based on patient outcomes and their added-value for healthcare systems 	<ul style="list-style-type: none"> • The industry should improve the collection of RWE and measure PROs as primary outcomes in clinical trials

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