



More effective healthcare spending through measuring outcomes

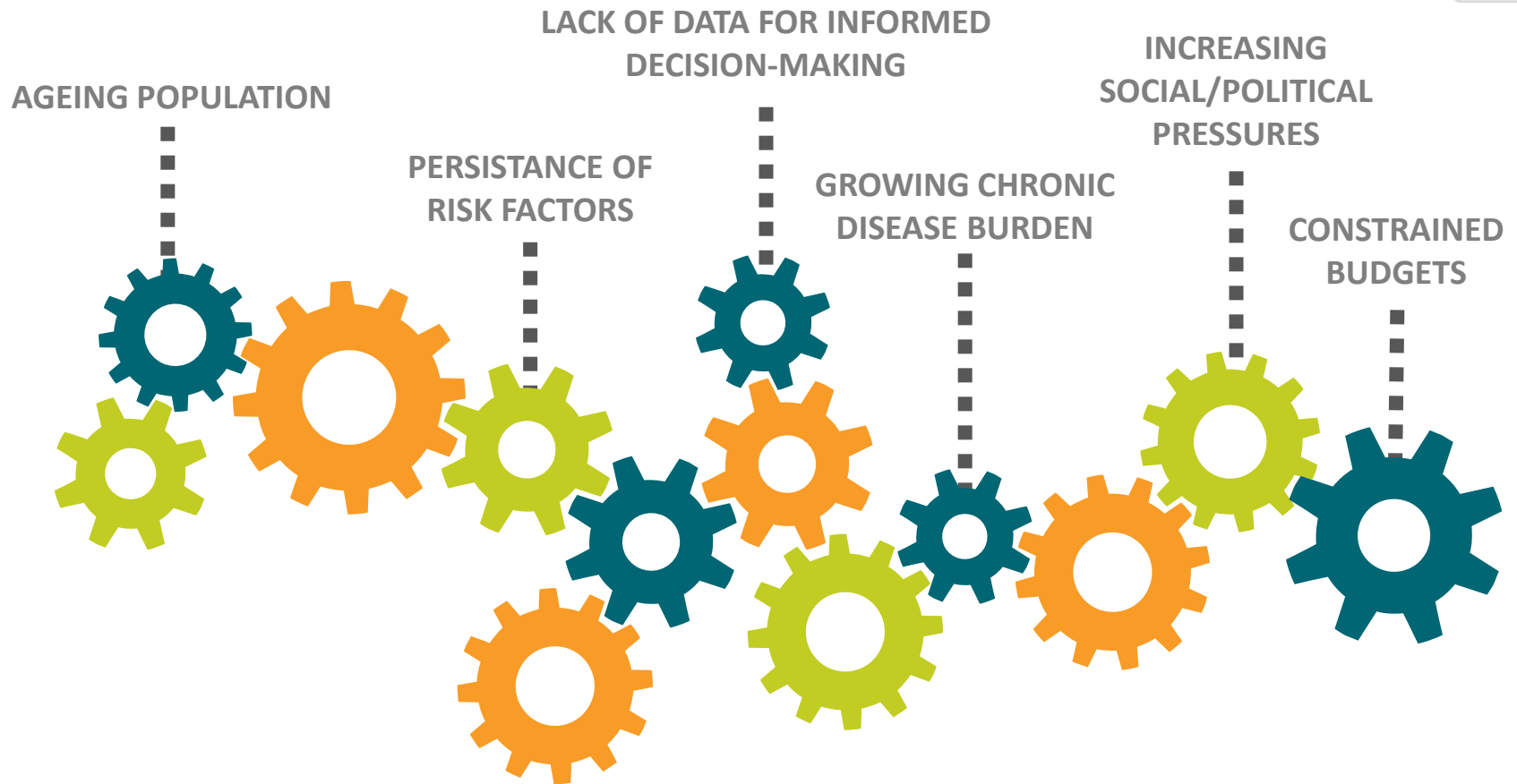
Nathalie Moll, Director General, EFPIA



UIMP
Santander, 14 September 2017



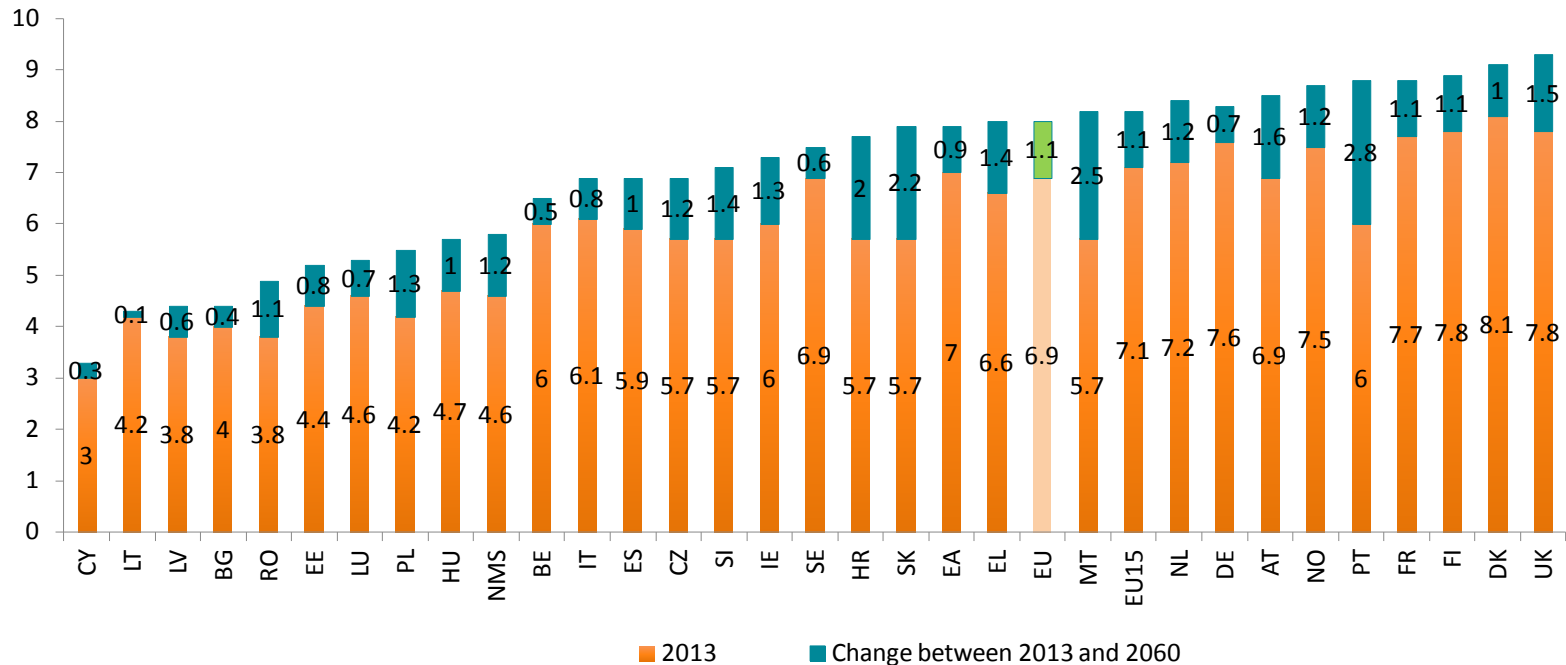
Healthcare systems across Europe are facing unprecedented challenges, driven by an ageing population and an increased prevalence of chronic disease





Projected increase in public expenditure in healthcare due to demographic change (2013-2060) (% of GDP)

Population ageing creates sustainability challenge for EU health systems



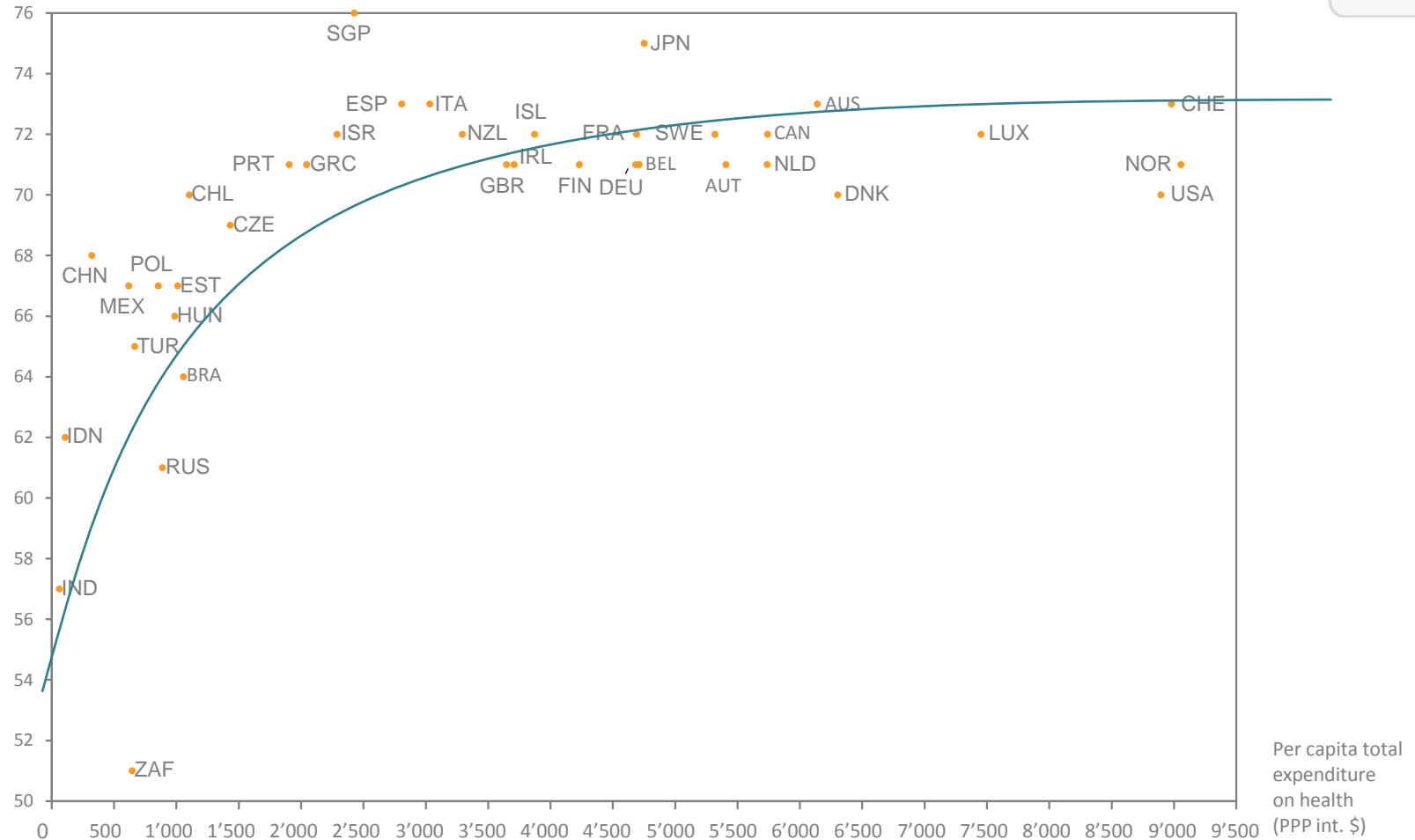
NOTE: FOR THE EU, NMS (NEW MEMBER STATES) AND THE EA (EURO AREA) THE AVERAGE ARE WEIGHTED ACCORDING TO GDP.

EUROPEAN COMMISSION (2015). THE AGING REPORT.

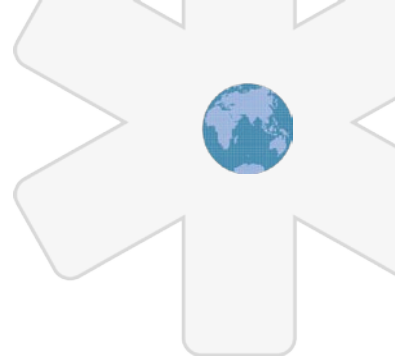
Relationship between healthcare expenditure and overall health status show potential to increase value for money



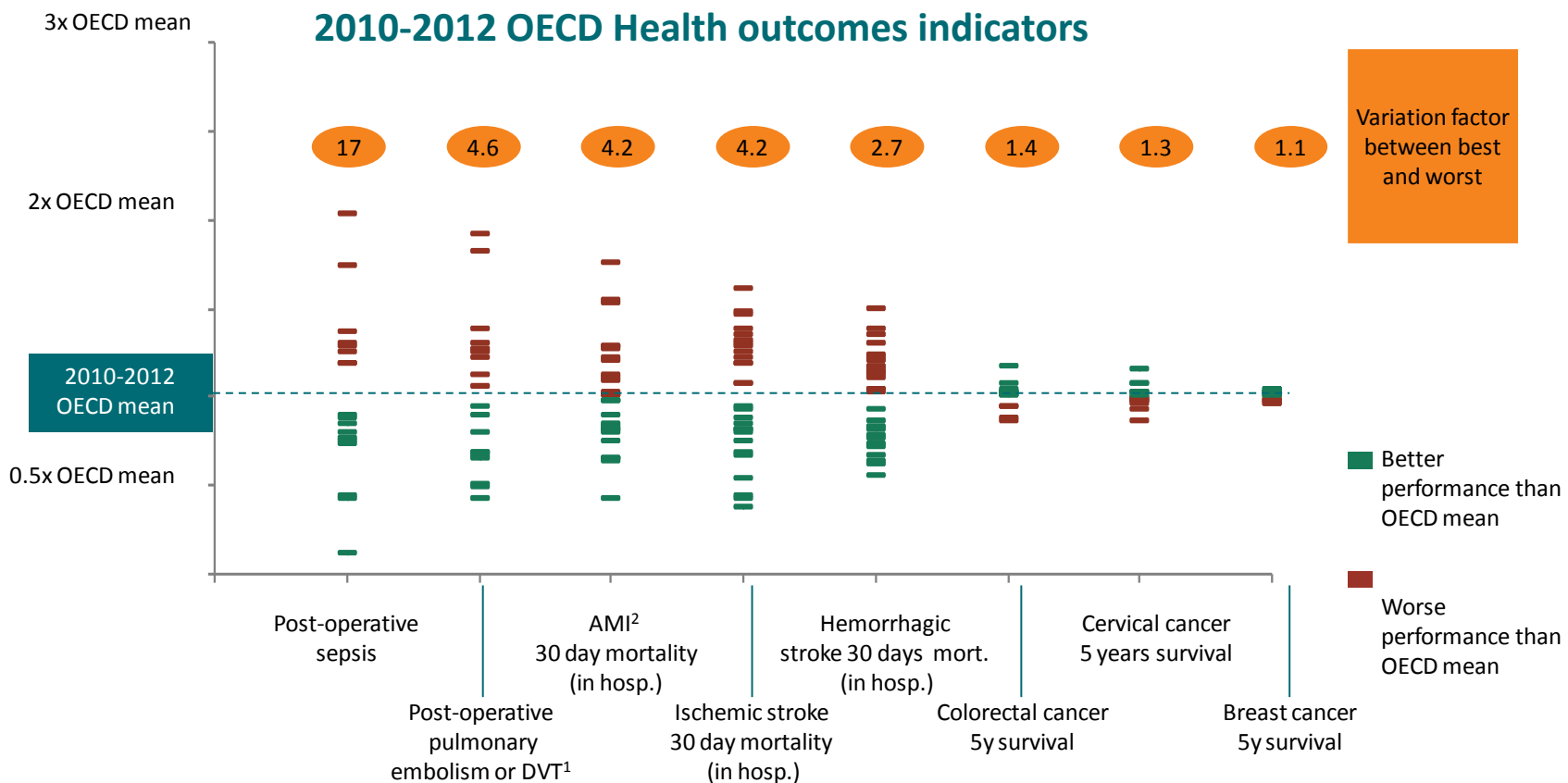
Health Life Expectancy at Birth



SOURCE: WORLD HEALTH ORGANIZATION, 2012



Outcomes vary widely across countries



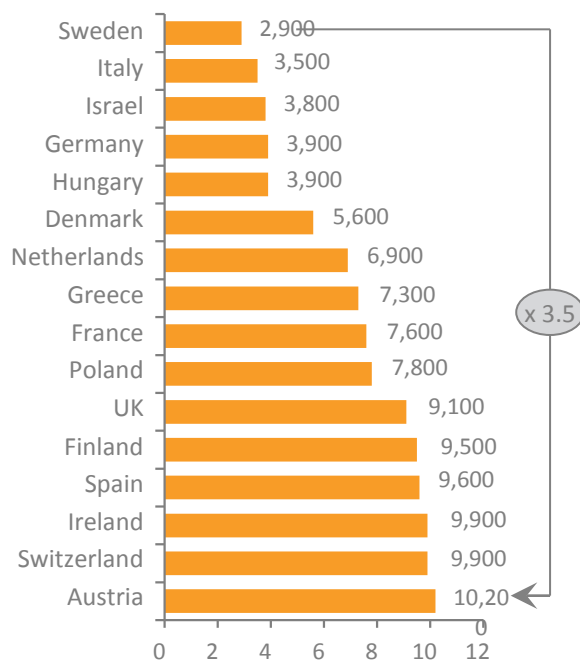
1. DEEP VEIN THROMBOSIS 2. ACUTE MYOCARDIAL INFARCTION

NOTE: LATEST AVAILABLE DATA FOR 2012, 2011 OR 2010. MEXICO NOT INCLUDED
 SOURCE: BCG ANALYSIS BASED ON OECD STAT EXTRACTS

Variation of heart failure outcomes across European countries

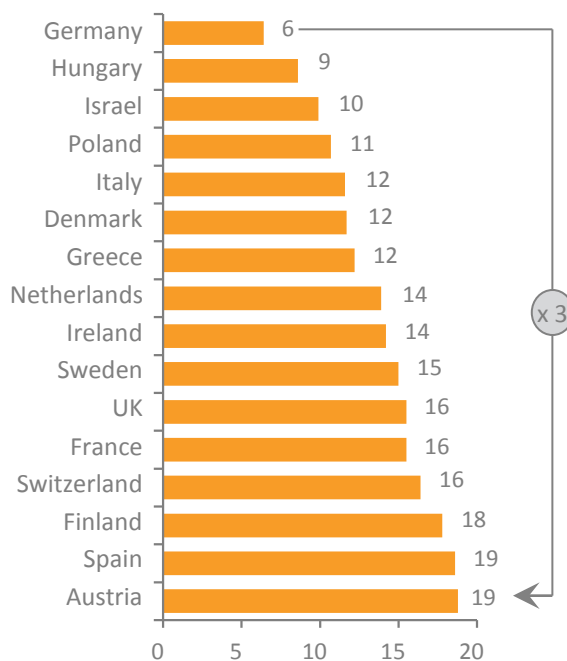


> 3x variation in death during first HF admission



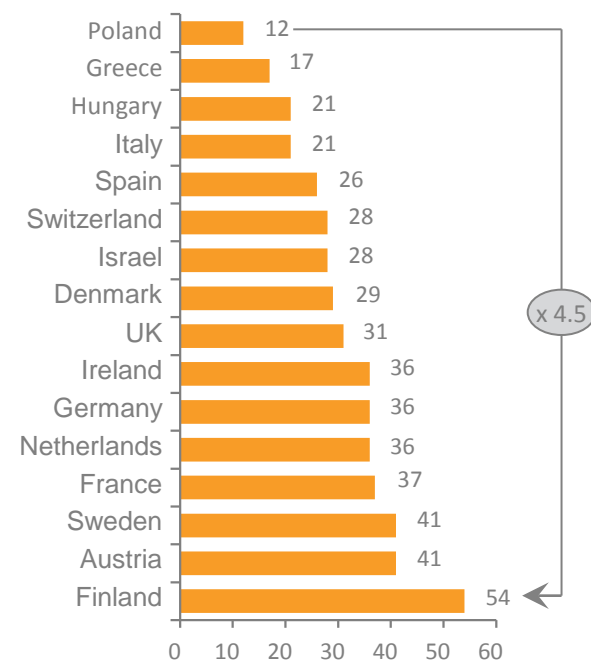
Death during first admission, %

3x variation in 12 week mortality rate for HF



12 week mortality rate, %

>4x variation in 12 week readmission rate for HF



12 week readmission rate, %

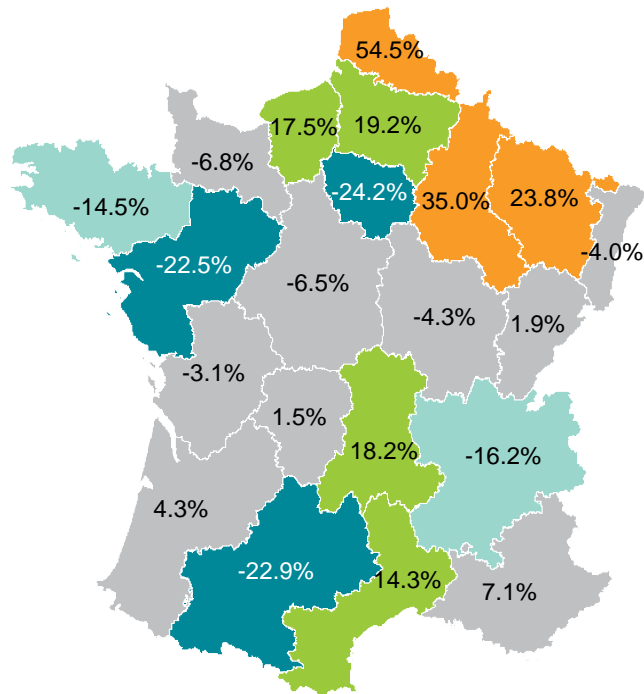
NOTE: THE SURVEY WAS CONDUCTED DURING 2000–2001 IN 115 HOSPITALS FROM 24 COUNTRIES BELONGING TO THE EUROPEAN SOCIETY OF CARDIOLOGY. A TOTAL OF 46,788 DEATHS AND DISCHARGES WERE SCREENED FROM WHICH 11,327 (24%) PATIENTS WERE ENROLLED WITH SUSPECTED OR CONFIRMED HEART FAILURE. THE STUDY ENSURED QUALITY OF DATA FOR COMPARABILITY THROUGH DIFFERENT MEASURES: CLUSTERS OF HOSPITALS WERE FORMED THAT GENERALLY INCLUDED ONE UNIVERSITY HOSPITAL AND ONE OR MORE COMMUNITY HOSPITALS IN ORDER TO OBTAIN A MORE REPRESENTATIVE SAMPLE OF HOSPITAL DEATHS AND DISCHARGES, CASES HAD TO FULFILL FOUR CRITERIA TO BE MORE COMPARABLE, LARGE SAMPLE SIZES PROVIDE SUBSTANTIAL PROTECTION FROM RANDOM ERROR

SOURCE: THE EUROHEART FAILURE SURVEY PROGRAMME, EUROPEAN HEART JOURNAL (2003) 24, 442–463



Large variations also within countries

Premature mortality¹ 2008-2010 due to HF compared to French national average



Risk factors alone can't explain the variation

Regional distribution of risk factors can explain part of the variation in mortality

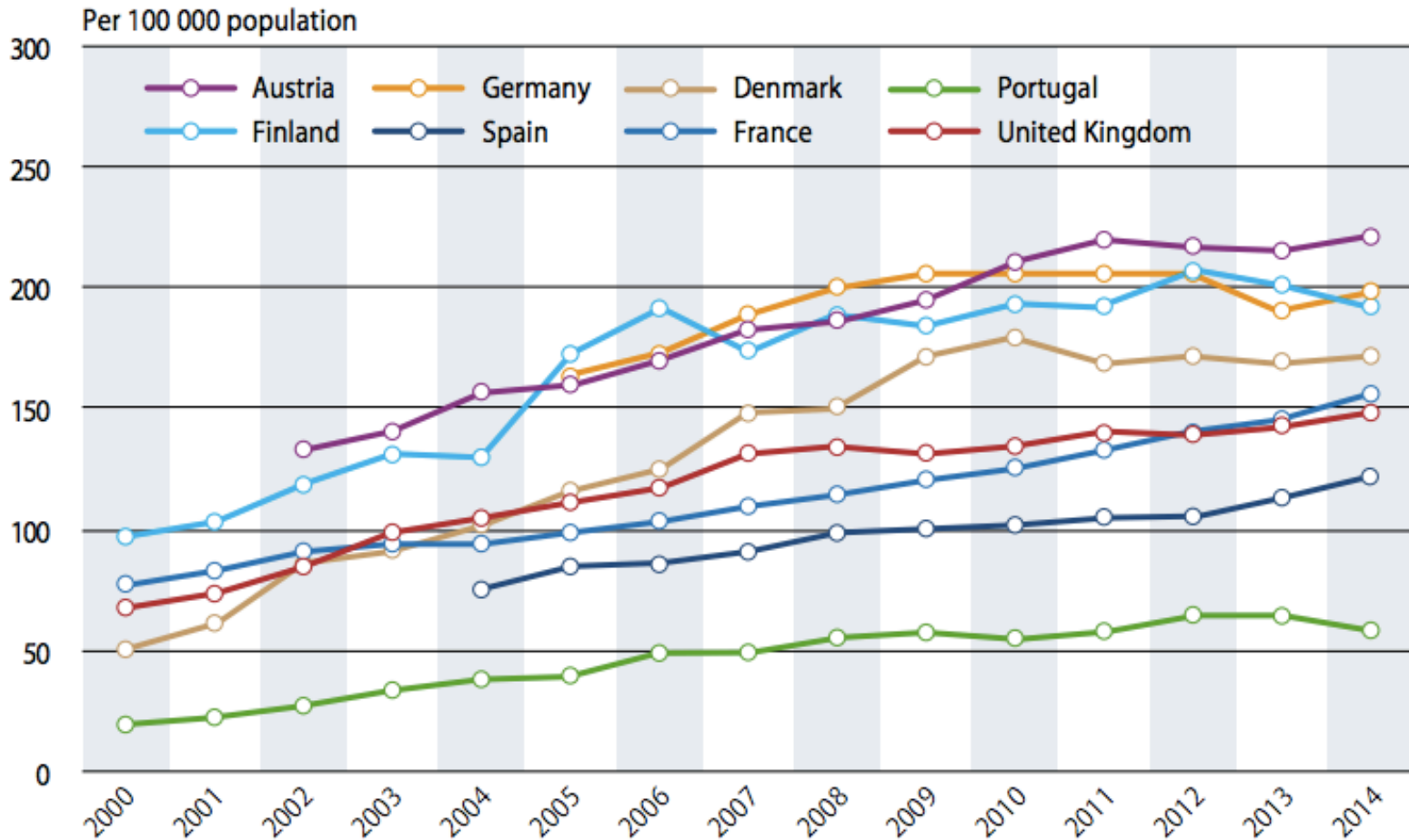
- Age, income level, diabetes, hypertension, dyslipidemia, obesity, tobacco, alcohol, etc.

The report also mentions differences in offer and quality of care as contributors to mortality variation

1. BEFORE 65

Huge practice variation between OECD countries

Rates of knee replacement vary hugely across OECD health systems. Is this justified?

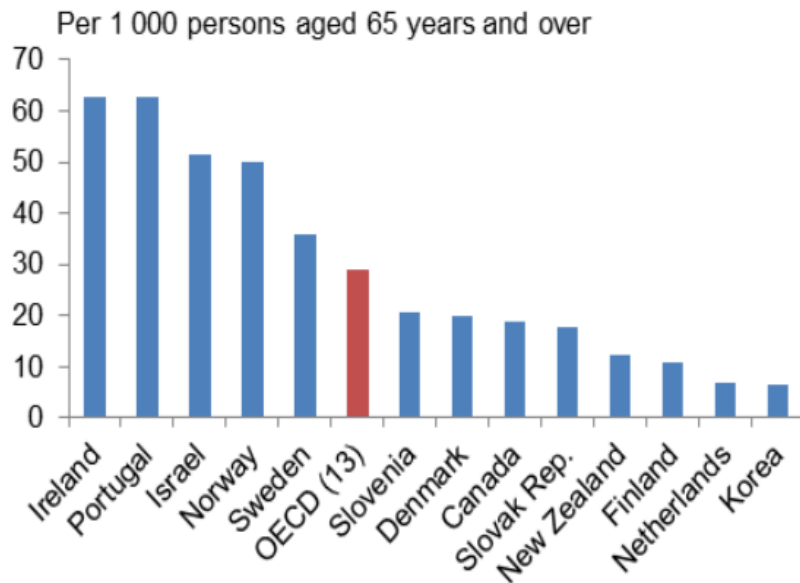


...asking the people who have had the operation is the way to find out.

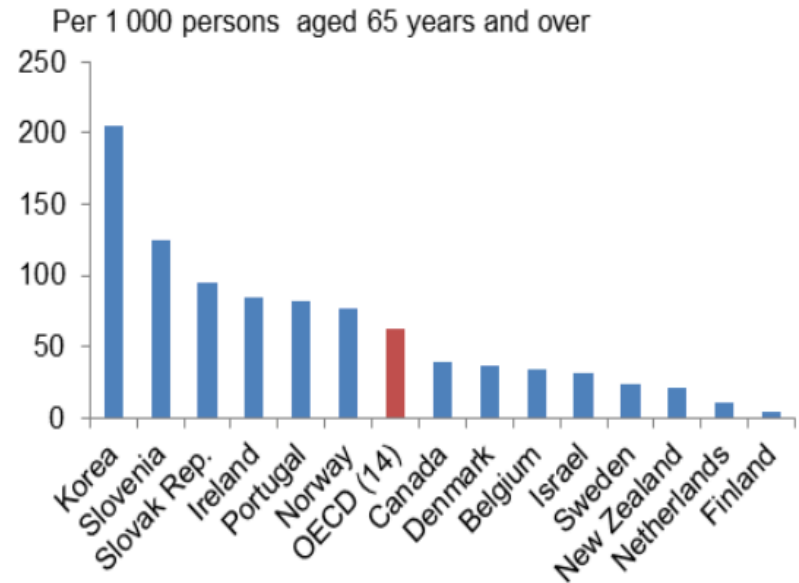
How do you identify the best clinical practice?



Elderly people prescribed long-term benzodiazepines or related drugs 2013 (or latest year)



Elderly people prescribed long-acting benzodiazepines or related drugs 2013 (or latest year)

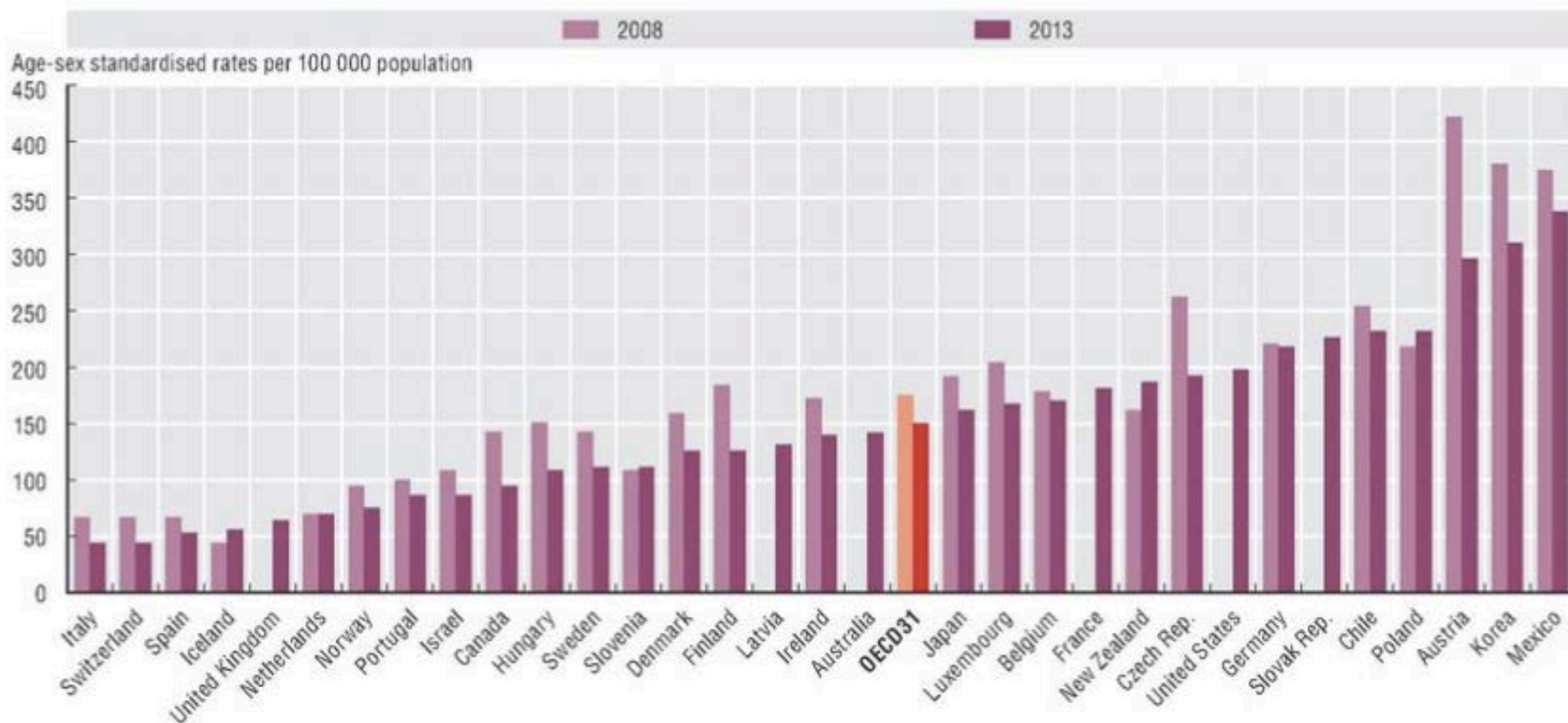


SOURCE: OECD

Most comparative data on “proxy outcomes”...




8.3. Diabetes hospital admission in adults, 2008 and 2013 (or nearest years)



Note: Three-year average for Iceland and Luxembourg.

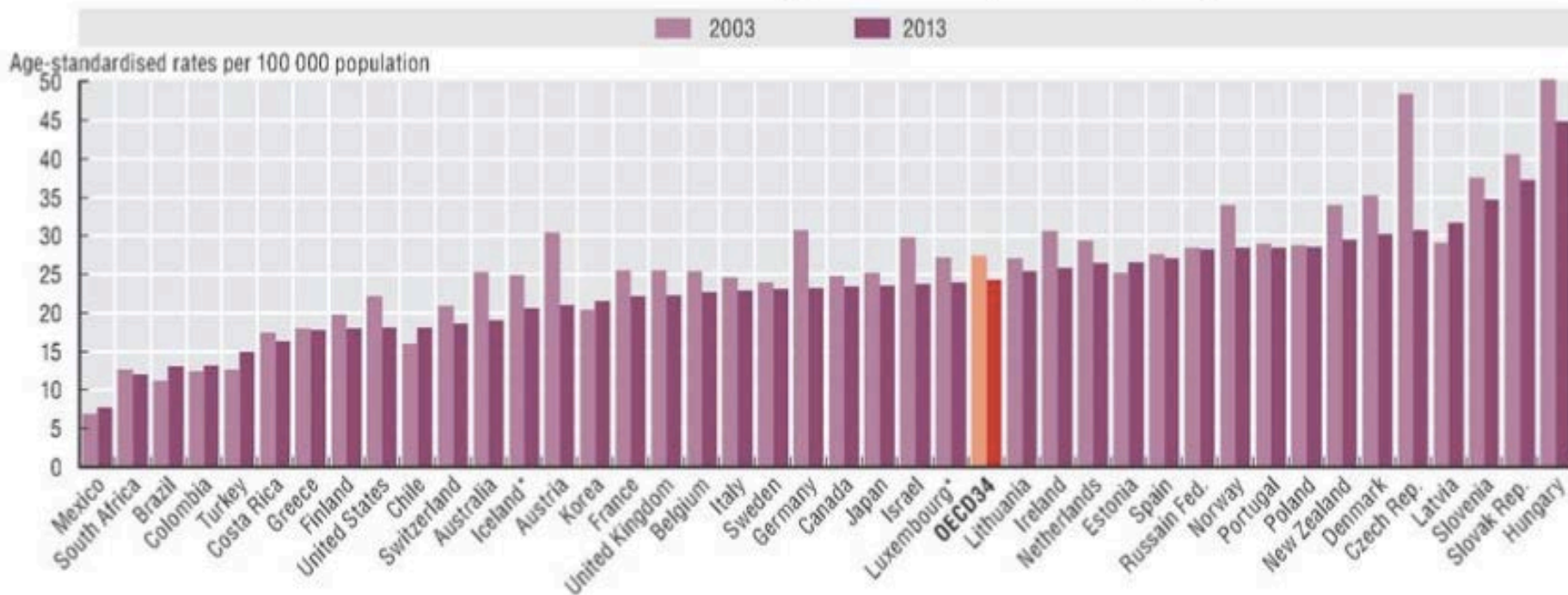
Source: OECD Health Statistics 2015, <http://dx.doi.org/10.1787/health-data-en>.

StatLink  <http://dx.doi.org/10.1787/888933281111>

...or very broad (mortality, survival et.c.)




8.33. Colorectal cancer mortality, 2003 to 2013 (or nearest years)



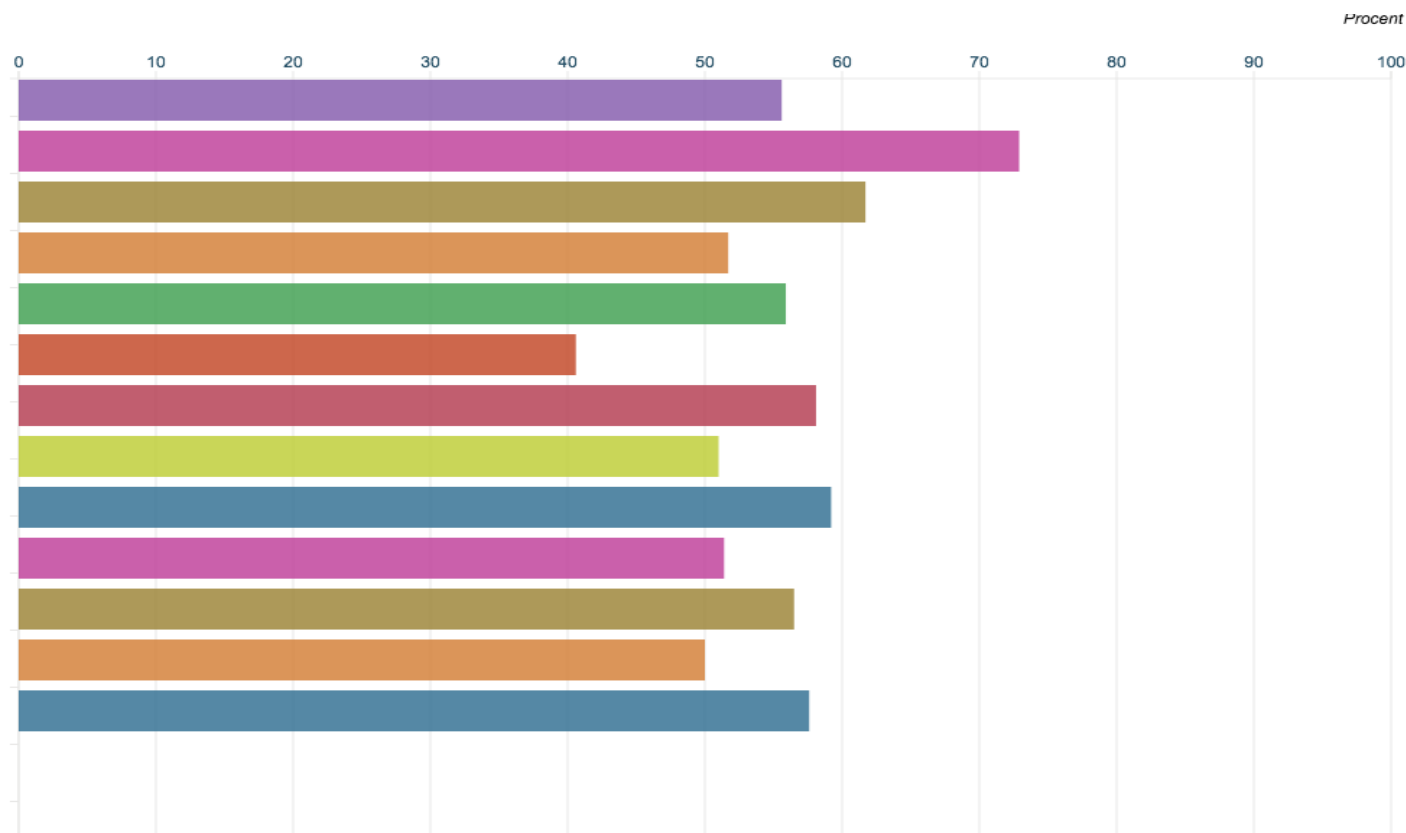
* Three-year average.

Source: OECD Health Statistics 2015, <http://dx.doi.org/10.1787/health-data-en>.

StatLink  <http://dx.doi.org/10.1787/888933281219>

Information on data for Israel: <http://oe.cd/israel-disclaimer>

Reduced pain in legs after surgery for spinal stenosis



- Riket
- Blekinge
- Gävleborg
- Kronoberg
- Västerbotten
- Örebro län
- Stockholms län
- Skåne
- Västernorrland
- Uppsala län
- Västra Götaland
- Värmland
- Kalmar län

Urval:

Kön: Totalt, Ålder: Alla, Mätperiod: År

Källor:

Svenska ryggregistret (Swespine)

Hämtat från vardenisiffror.se










Estimated 20 – 40 % waste in health systems

- According to a WHO report from 2010, on average 27% of healthcare expenditure is wasted
- There are several sources of waste, but **half** of the total waste is estimated to be due to **practice variation** and use of low-value interventions
- A recent OECD report concludes that around one fifth of healthcare expenditure could be channeled towards better use

4 key sources of waste have been characterized, 3 of which could be addressed through outcomes focus



	Description	Example
Practice variation	<p>1</p> <p>Overtreatment</p> <p>Care routed in outdated habits, ignoring scientific findings, motivated by something other than optimal care, etc.</p>	<p> Knee replacement rate ~2x OECD 29 average and large variation across regions</p> <p> ~1% of HC costs in overuse of CT and MRI scans</p>
	<p>2</p> <p>Failures of care delivery and coordination</p> <p>Poor execution or lack of best practices, e.g. effective preventive care or patient safety, fragmented and disjointed care, low volume for specific treatments per hospital, etc.</p>	<p> Lower prevention care in diabetes resulting in more complications (e.g. amputations)</p> <p> Higher cumulative revision rate for primary hip arthroplasty for surgeons with lower caseload</p> <p> >\$40B readmissions costs</p>
3	<p>Pricing, payment and incentives failures</p> <p>Payments and incentives not rewarding valuable interventions, variation in pricing of services with equivalent outcomes</p>	<p> Some payment mechanisms leading to higher complication rates</p> <p> >200% differences in CABG¹ prices for same payer and state</p>
4	<p>Administrative complexity</p> <p>Waste created by inefficient or flawed rules and overly bureaucratic procedures across stakeholders</p>	

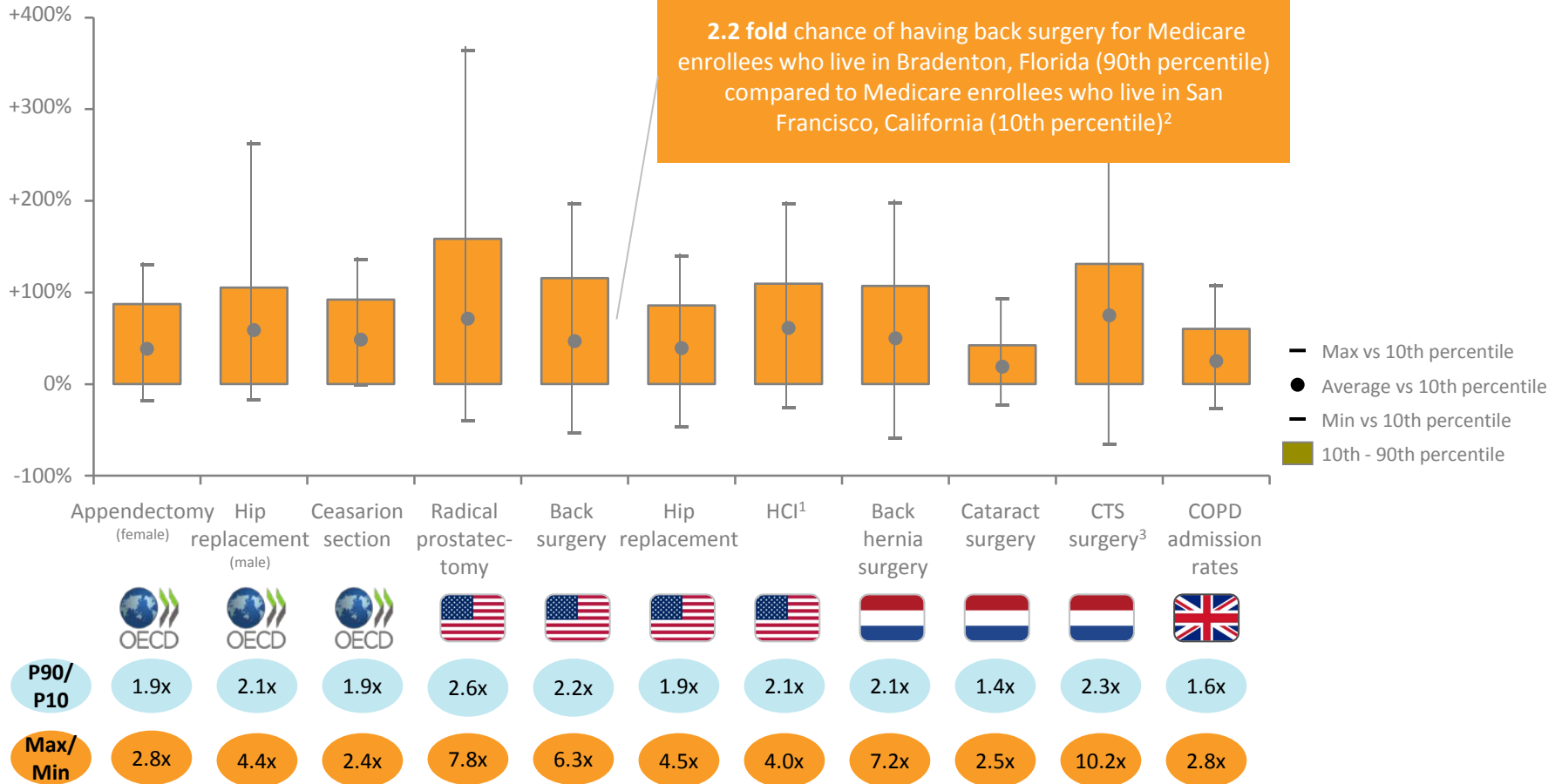
Could be addressed through outcomes focus

1. CORONARY ARTERY BYPASS GRAFTING

Practice variation found in all countries and diseases and has been extensively described in literature

Currently most publically available practice variation data are related to surgical procedures. However, available data on chronic diseases and end-of-life suggest high PV for those diseases as well.

Regional practice variation



NOTE: WHERE POSSIBLE, APPROPRIATE CASE MIX ADJUSTMENT HAS BEEN PERFORMED. 10TH AND 90TH PERCENTILES ARE IN SOME EXAMPLES BASED ON PROXY (BY REMOVING TOP/LOWEST 10% REGIONS)

1. THE HCI INDEX COMBINES THE NUMBER OF DAYS PATIENTS SPENT IN THE HOSPITAL AND THE AVERAGE NUMBER OF INPATIENT PHYSICIAN VISITS DURING THE LAST TWO YEARS OF LIFE . 2 RATES WERE ADJUSTED FOR AGE, RACE, AND SEX USING THE U.S. MEDICARE POPULATION AS THE STANDARD 3. CTS STANDS FOR CARPAL TUNNEL SYNDROME SOURCE: DARTHMOUTHATLAS.ORG; VEKTIS REPORT "PRAKTIJKVARIATIERAPPORT 7 ELECTIEVE ZORG AANDOENINGEN APRIL 2014"; NHS CCG TOOLS; OECD HEALTH WORKING PAPERS, NO. 61

5 key elements have been identified in models that have proved successful at increasing HC value



	Description of the component	Contrib. to value
1	Identify target population (e.g. disease groups) Focus on disease groups and other relevant population sub-segments <ul style="list-style-type: none"> Identify patients based on their healthcare needs, behaviors, etc. to prevent and manage illness, rather than simply treat disease 	Identify patients with common needs and highest costs
2	Define target outcomes Define target outcomes to improve care and reduce costs <ul style="list-style-type: none"> That matter to patients and clinicians, balanced along full cycle of care - prevention and cure, comparable, linked to population 	Identify which health outcomes are needed for a healthy population
3	Measure and learn from variation Monitor outcomes and learn from variation to improve <ul style="list-style-type: none"> Establish registries, inter-operable data systems across providers, real-time measuring, transparency of outcomes, etc. 	Improve to achieve target outcomes at minimum cost
4	Define treatment pathway with coordinated delivery Define treatment pathway around the patient vs. provider, enabling coordinated delivery across all stakeholders <ul style="list-style-type: none"> New models need to be based on the patient along the care chain, vs. single procedure or single episode of care 	Whole-person focus <ul style="list-style-type: none"> also reduce waste from coordination
5	Align payments and incentives Ensure reimbursement models enable value focus including outcomes along full cycle of care <ul style="list-style-type: none"> Payments aligned to providers' collective performance against target outcomes, instead of promoting price and volume. Ensure incentive design does not promote unwanted behaviors (e.g. hiding bad results...) Gradual transfer of risk to providers 	Align stakeholders to achieve previous goals

Geisinger ProvenCare CABG¹ bundle scheme led to reduced mortality and complications at lower costs



Coronary Artery Bypass Graft (CABG) program is based on clinical guidelines and measurement

Geisinger launched ProvenCare as a collaborative approach to treat different diseases and treatments, including CABG surgery since 2006

A package price for elective CABG was developed, including

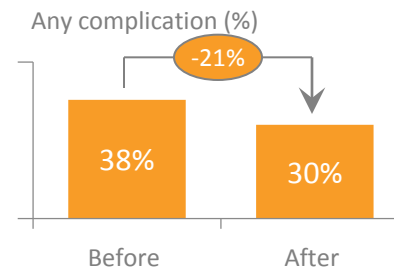
- preoperative evaluation
- all hospital and professional fees
- all routine post-discharge care (e.g. smoking cessation counseling, cardiac rehab)
- all follow-up care and rehospitalizations for any related postop. complication occurring within 90 days of surgery

Development of actionable ProvenCare processes based on clinical guidelines and close measurement of clinical outcomes through EHR

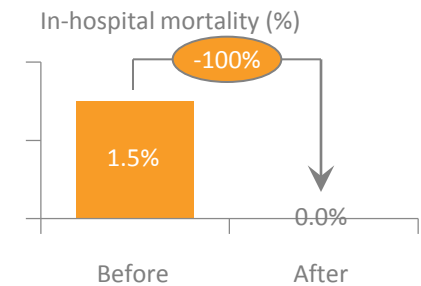
- From screening a patient for the risk of stroke before surgery, to making sure the patient has started on a daily aspirin regime upon discharge

Proven positive effect on costs, mortality and complications

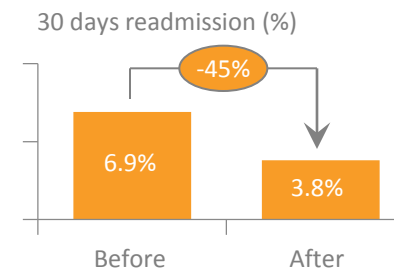
Reduced complications



Reduced mortality



Reduced readmissions



Reduced costs

- 4.8% reduction in cost per CABG case
- Health plan paid 28-36% less for CABG with Geisinger vs. other providers
- Hospital's contribution margin increased by 17.6%
- Total inpatient profit per case improved \$1,946

Gesundes Kinzigtal (GK) has reduced mortality by 53% while reducing costs



Gesundes Kinzigtal (GK) targets programs for chronic conditions

Since 2006, GK has been contractually accountable for the whole health care service budget for ~50% of the 69k inhabitants of the region

- GK cooperates with ~100 providers and has agreements with pharmacies, health clubs, etc.

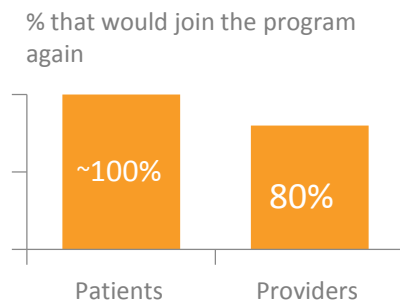
GK's care and preventive programs target common chronic diseases

- Identification of patients at risk
- Individual treatment plan and goal-settings agreements
- Patient self-management and shared decision making
- Coordinated follow-up care through jointly developed care pathways, synchronization of medications across formularies, etc.
- System-wide electronic health records, incl. access for patients
- Insurers share the savings generated vs. usual cost for people associated with GK¹

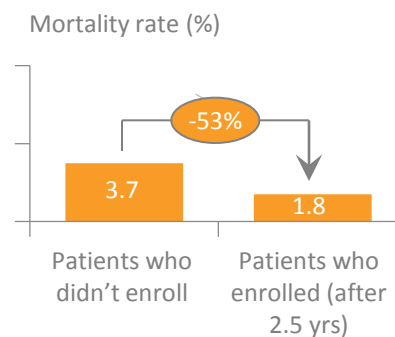
GK has conducted several evaluations with external research institutions

Proven positive effect on costs, mortality and patient experience

Positive patient and provider experience



Reduced mortality



Reduced costs

Margin per person increased by €151 for the GK population

- compared to nonenrolled

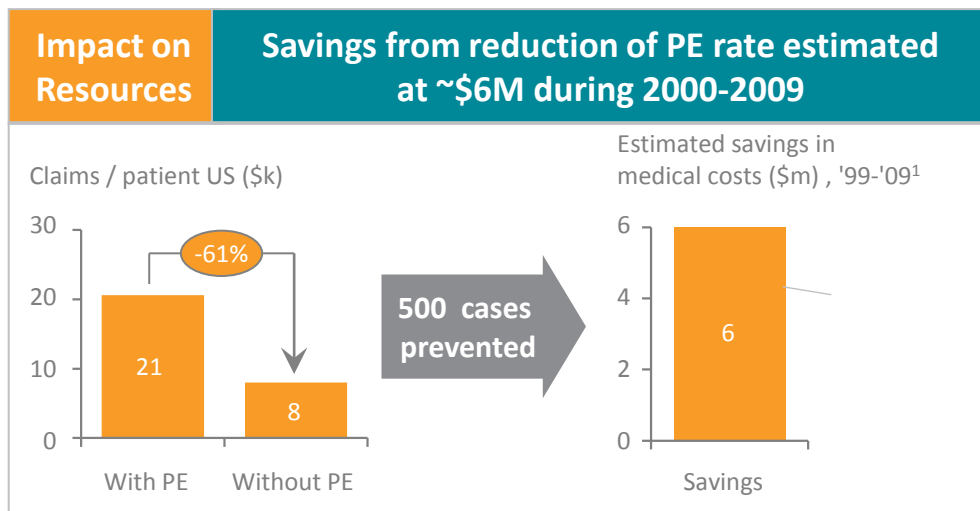
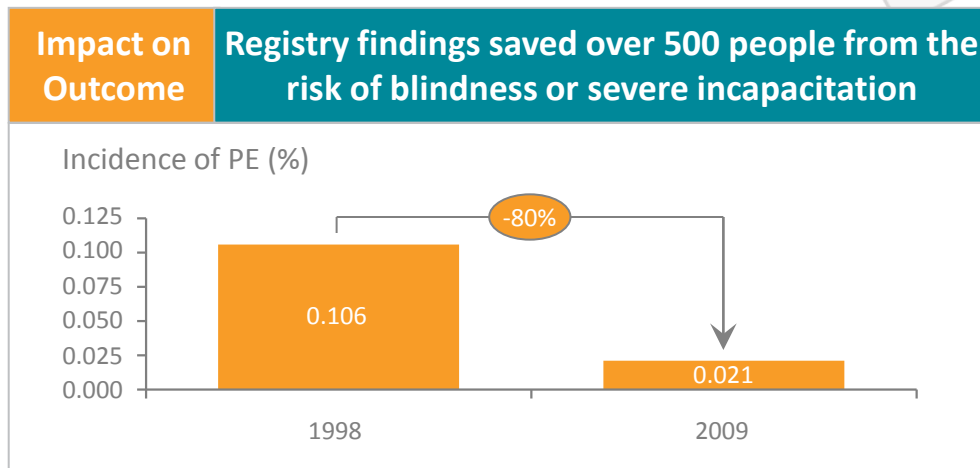
1. INSURERS GET ALLOCATED A FUND BASED ON GOVERNMENT RISK STRUCTURE COMPENSATION MECHANISMS DEPENDING ON THE PEOPLE THEY COVER

Cataract registry findings allowed Sweden to lower PE rates by 80% - avoiding blindness for 500 patients



Background

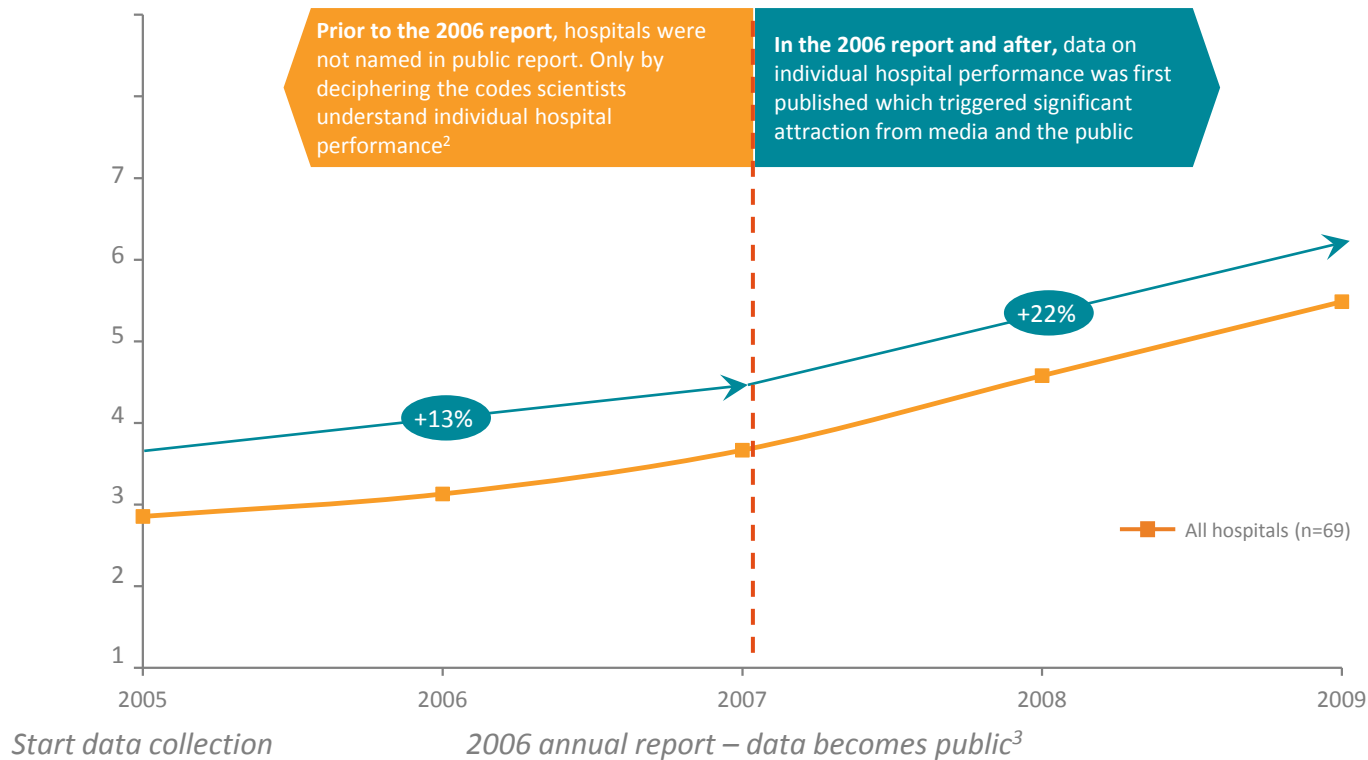
- National Cataract Registry established in 1992
- Postoperative endophthalmitis (PE) is a severe inflammation – risks leading to blindness
- Active work on identification and implementation of best practice to avoid PE done by the registry





Transparency of outcomes variations also driver of quality improvement through competition

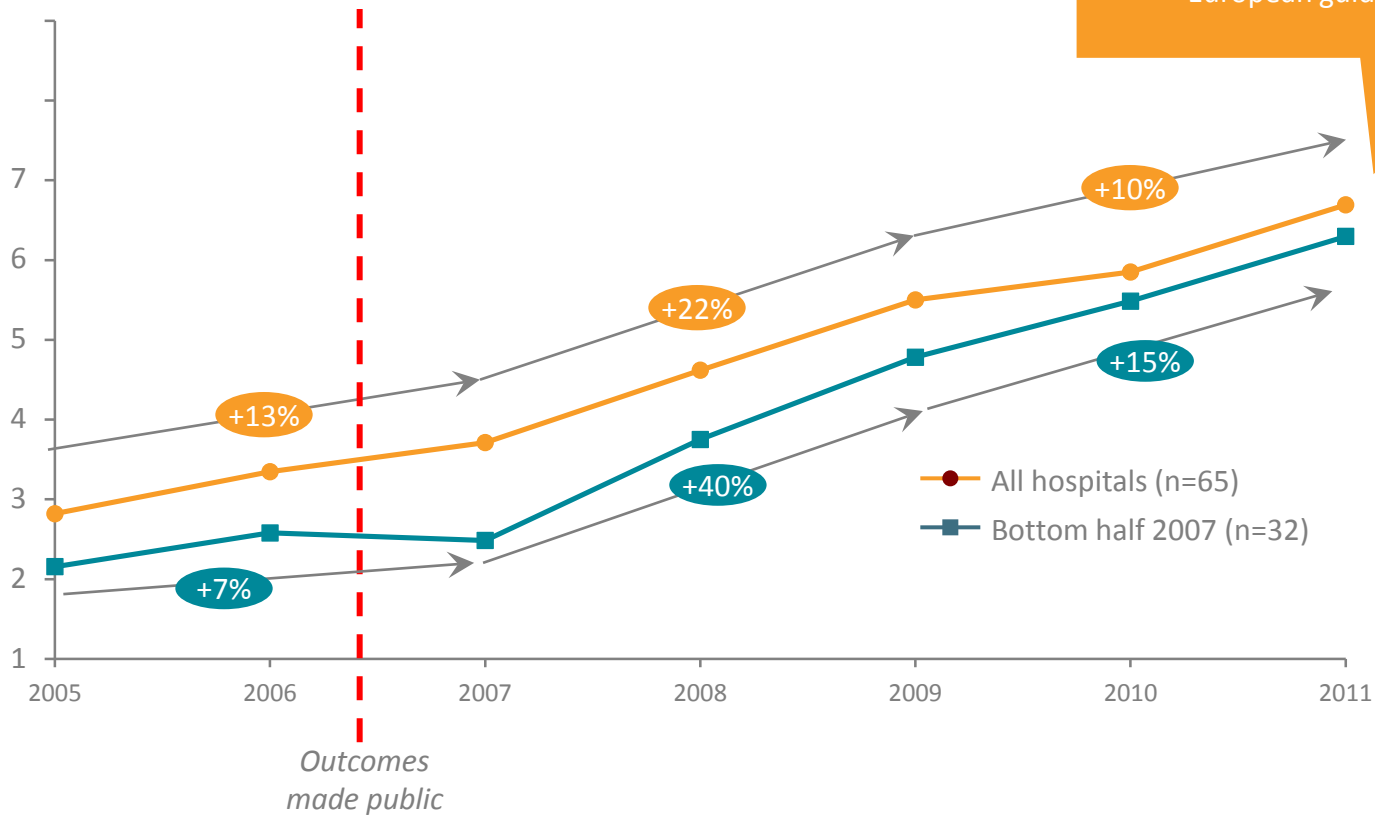
RIKS-HIA Quality Index¹ – a measurement of best practice adoption in ACS treatment



...and leads to decreased variation when low performers catch up with high performers



RIKS-HIA Quality Index¹ – a measurement of best practice adoption in ACS treatment



None of the Swedish hospitals deviates significantly from the European guidelines

1. THE QUALITY INDEX FROM RIKS-HIA MEASURES SWEDISH HOSPITALS ADHERENCE TO NATIONAL GUIDELINES (BEST PRACTICE) REGARDING ACUTE CORONARY SYNDROME (ACS). THE INDEX IS BASED ON NINE DIFFERENT PROCESS METRICS WHICH ARE DESCRIBED IN THE APPENDIX. 2. DATA ON INDIVIDUAL HOSPITAL PERFORMANCE WAS FIRST PUBLISHED IN THE 2006 RIKS-HIA ANNUAL REPORT. FROM 2006 ONWARDS THE PUBLIC AND THE MEDIA COULD EASILY ACCESS THE DATA AND COMPARE INDIVIDUAL HOSPITAL PERFORMANCE. SOURCE: RIKS - HIA ANNUAL REPORTS 2005 - 2009, BCG ANALYSIS



Paying for Outcomes – a way to ensure value for money

- More flexible, value and outcomes-focused models would offer a greater reward for those technologies that deliver most value.
- Rewards would be tied to specific results achieved, not merely the amount of treatments (e.g. pills) sold.
- Tying incentives and payment to outcomes is not just appropriate for some medicines and therapy areas but for healthcare systems as a whole.

Industry vision on payment for outcomes

A Roadmap for change

1. Alignment on a **sustainable framework of value** that reflects the opportunity for outcomes based payment models
2. Resolution of disincentives created by price referencing through the evolution of outcomes-based pricing models on a European wide basis
3. Develop and implement **national scale outcomes data** capture mechanisms that can support outcomes based pricing models, with proof of concept pilots already underway
4. Agreed approach to **horizon scanning** systematically implemented at country level providing health planners with 5-year forward visibility of emerging technologies and implications for pricing and budgeting
5. Robust **case studies of outcomes based pricing models**, operating at scale across European markets, showing how prices can change over time depending on the value delivered



Outcomes-based payments for medicines are already in place, but is still the exception

- Both in Europe and the US, there are “Managed Entry Agreements” for introducing innovative medicines where the pricing & reimbursement is related to health outcomes
- In Italy, registries run by the national agency AIFA monitor the introduction of many new medicines, and rebates are triggered for non-responders
- In Germany, Novartis concluded an agreement on Aclasta, a treatment for osteoporosis, where there is a refund if the patient suffers from a fracture within 1 year from treatment
- However, the total number of outcomes-based agreements is still small compared to pure financial deals

And we could not have positive outcomes if we didn't have the therapies in the first place.



Since 1990s, +1,100 new medicines for European patients, radically improving their lives^[EVA]

Overview of recent, life-changing medicines

HIV

85%

drop in the number of HIV deaths since its peak in 1995 in Europe and the US^[WHO]



Multiple sclerosis

Before



After

“The whole week leading up to my infusion is very rough: a lot of my regular symptoms are slightly increased: intense burning pain in my legs, leg weakness, spasms, very bad fatigue, etc.”^[GAR]

“A day or two after that, I feel the best I ever feel. My head becomes clear, I remember more, I can walk and stand longer too. I still have issues, but overall I feel considerably better.”^[GAR]

Cancer

21%

decline in cancer mortality rate since its peak in 1991 in Europe^[WHO]

83%

of cancer survival gains are attributable to new treatments^[SUN]



Hepatitis C

90%

cure rate for treated patients with 8-12 weeks of treatment^{[PHR][HEP]}

+133%

increase in cure rate for European patients^{[PHR][HEP]}

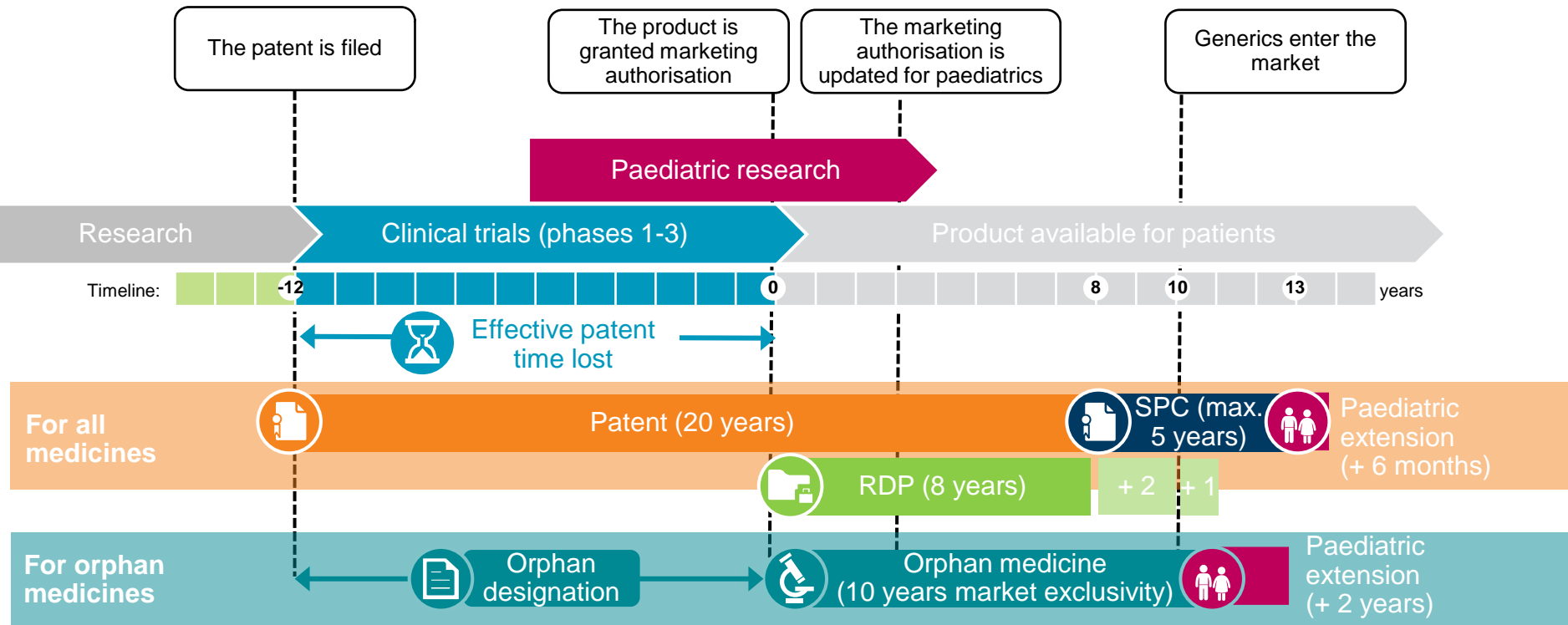


RA patients receiving new biologics have the ability to remain in employment 31 weeks longer and earn €26,000 more than patients on conventional therapy^[HAL]

QoL=quality of life; HIV=human immunodeficiency virus; Source: [EVA] Evaluate Pharma database (accessed 2017); [WHO] WHO Mortality Database; [GAR] Garlit. 'The Before and After of a Tysabri Infusion' (2016); [SUN] Sun et al. (2008); [HEP] PhRMA. '25 years of progress against hepatitis C' (2014); [PHR] PhRMA. 'Biopharmaceutical research industry profile' (2015); [HAL] Halpern et al. (2009)

IP provisions work side-by-side to enable pharmaceutical and biotech companies to continue innovating

Application of IP incentives^[EFP]



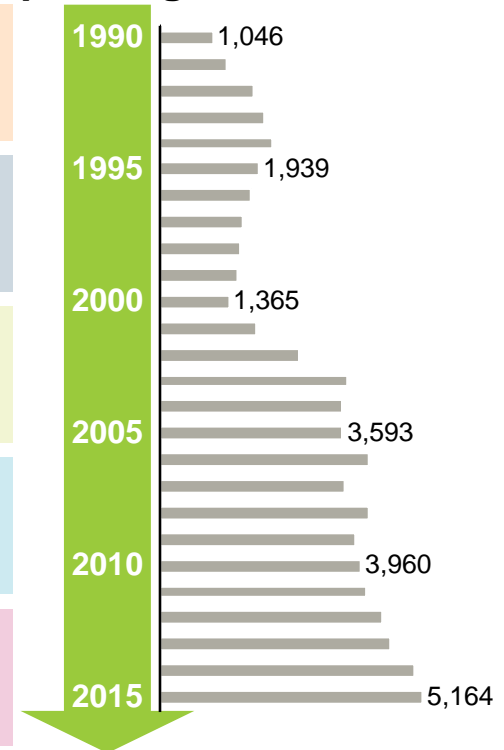
IP have been designed to ensure the competitiveness of European countries for innovation

EU IP incentives and rewards encourage ongoing research into areas of unmet need

Overview of European IP incentives^[EFP]

Patent^[REU] (1474)	Encourage companies to invest in R&D by protecting any invention from copies for a limited period of time during which the patent holder can ensure return on his investments
Supplementary Protection Certificate (1992)	Extend exclusivity for a pharmaceutical product that is protected by a patent to compensate for part of the time lost during the lengthy development period before a medicine can be made available on the market and ensure sustainable funding for such research
Regulatory Data Protection	Protect product developers' investment to generate the pre-clinical and clinical data required to obtain a marketing authorisation from unfair commercial use
Orphan Designation (2000)	Incentivise companies to research and develop medicines for rare diseases by providing specific development support and protecting them once marketing authorisation is obtained from market competition with similar medicines for the same rare ('orphan') indications
Paediatric Extension (2007)	Reward companies for undertaking the significant additional testing needed to ensure the safety and efficacy of the medicine for children, as required under Paediatric Regulation

Euro. pharma. & biotech patent grants^[WIP]



“[SPC] aims to guarantee laboratories working to develop new medicinal products a level of protection equal to that enjoyed by R&D in other sectors.”^[EUR]

Orphan incentives & paediatric rewards key to foster successful innovation in previously underserved areas

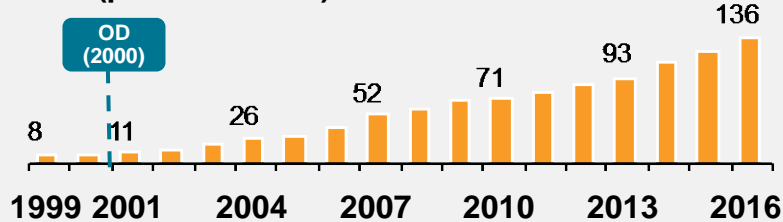


Case study: orphan medicines

Biopharmaceutical orphan medicine R&D expenditure in the EU (€ millions)^[OHE]

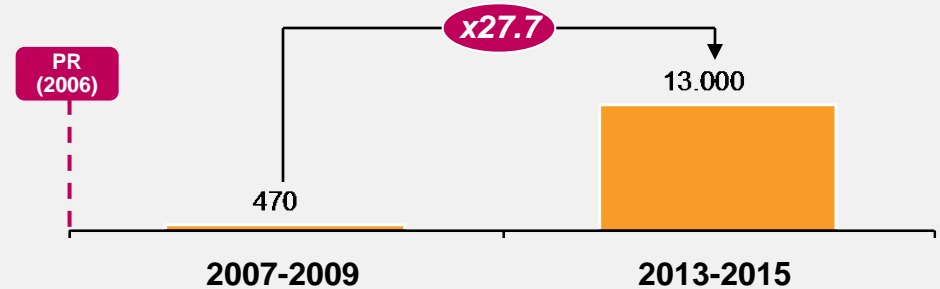


Cumulative orphan designations granted by the EMA (pre-1997-2017)^[CRA]

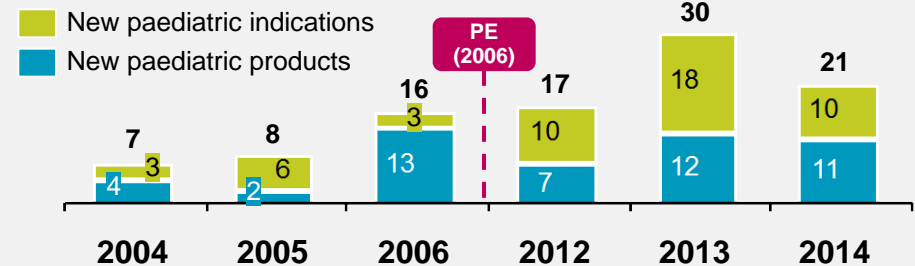


Case study: paediatric medicines

Number of neonates enrolled in trials^[EMA]



Paediatric indications/products granted by the EMA (2004-2006 and 2012-2014)^[EMA]



Since the creation of relevant IP provisions, 220 new orphan-related SMEs were created (from 32 initially), and 68 paediatric-related SMEs (from 21 initially)^[SME]



Lack of incentives and/or access to data could be key barriers to outcomes-based models

POLITICAL AND ORGANIZATIONAL REQUIREMENTS



Leadership and governance

- Leadership at national level
- Commitment from all stakeholders, specially from providers



Legislative and regulatory


- Measures that are supportive of innovation
- Regulation on outcomes usage, data ownership and privacy concerns



People and organizations

- Multidisciplinary teams and coordination of efforts
- Cultural thinking focused on outcomes
- Incentives to collect data

DESIGN REQUIREMENTS



Bases for contract's model

- Contractual models and requirements

DATA REQUIREMENTS



Metrics definition

- Alignment on standardized outcomes metrics
- Alignment on value derived from the contribution of outcomes improvement of therapies




Data collection

- Collection and tracking of relevant outcomes data (and relevant indicators)
- Access to data (may be in some level of aggregation) to relevant stakeholders



Data analytics

- Analyses of outcomes data to distill valuable insights



Data and methodologies verification

- Reliable quality data and solid methodologies (e.g. risk adjustment data)

Focus on data requirements



Muchas gracias y preguntas?



UIMP
Santander, 14 September 2017



Lack of access to data is key barrier to outcomes-based models

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Focus on data requirements

Multiple data sources in the healthcare system necessary to get full information on practice variation, costs and health outcomes



DATA SOURCES

TYPICAL 'OWNERS' AND EXAMPLES

<p>Clinical trials</p>	<p>Randomized studies to determine efficacy and safety</p>	<p>Trials run by Academic Medical Centers, Biopharma companies</p>	
<p>Disease registry</p>	<p>Repositories of data around explicitly-defined disease-specific measures</p>	<p>Maintained by academic research centers, specialty societies, regional and national database owners</p>	
<p>EMR</p>	<p>IT systems capturing data at point of care</p>	<p>Operated by providers and systems vendors</p>	
<p>Claims</p>	<p>Aggregated claims/ administrative datasets</p>	<p>Collected by private and government payers</p>	
<p>Modalities + service providers</p>	<p>Laboratory, pharmacy, and imaging datasets</p>	<p>Owned by providers or diagnostics companies</p>	
<p>Patient sources</p>	<p>Patient communities / Patient-generated data</p>	<p>Collected by providers, start-up companies, and IT vendors</p>	

EFPIA is working through IMI to develop tools to utilise data better in different disease areas

"BD4BO"

Goal: Support the evolution towards outcomes-focused and sustainable healthcare systems, exploiting the opportunities offered by big and deep data sources

COORDINATION AND SUPPORT ACTION (CSA)

EUROPEAN HEALTH DATA NETWORK (EHDN)

1 Design sets of standard outcomes and demonstrate value

2 Increase access to high quality outcomes data

3 Use data to improve value of HC delivery

4 Increase patient engagement through digital solutions

Coordination and operational topics

Themes / Enablers

Disease-specific topics



ROADS: ALZHEIMER'S DISEASE



HEMATOLOGIC MALIGNANCIES

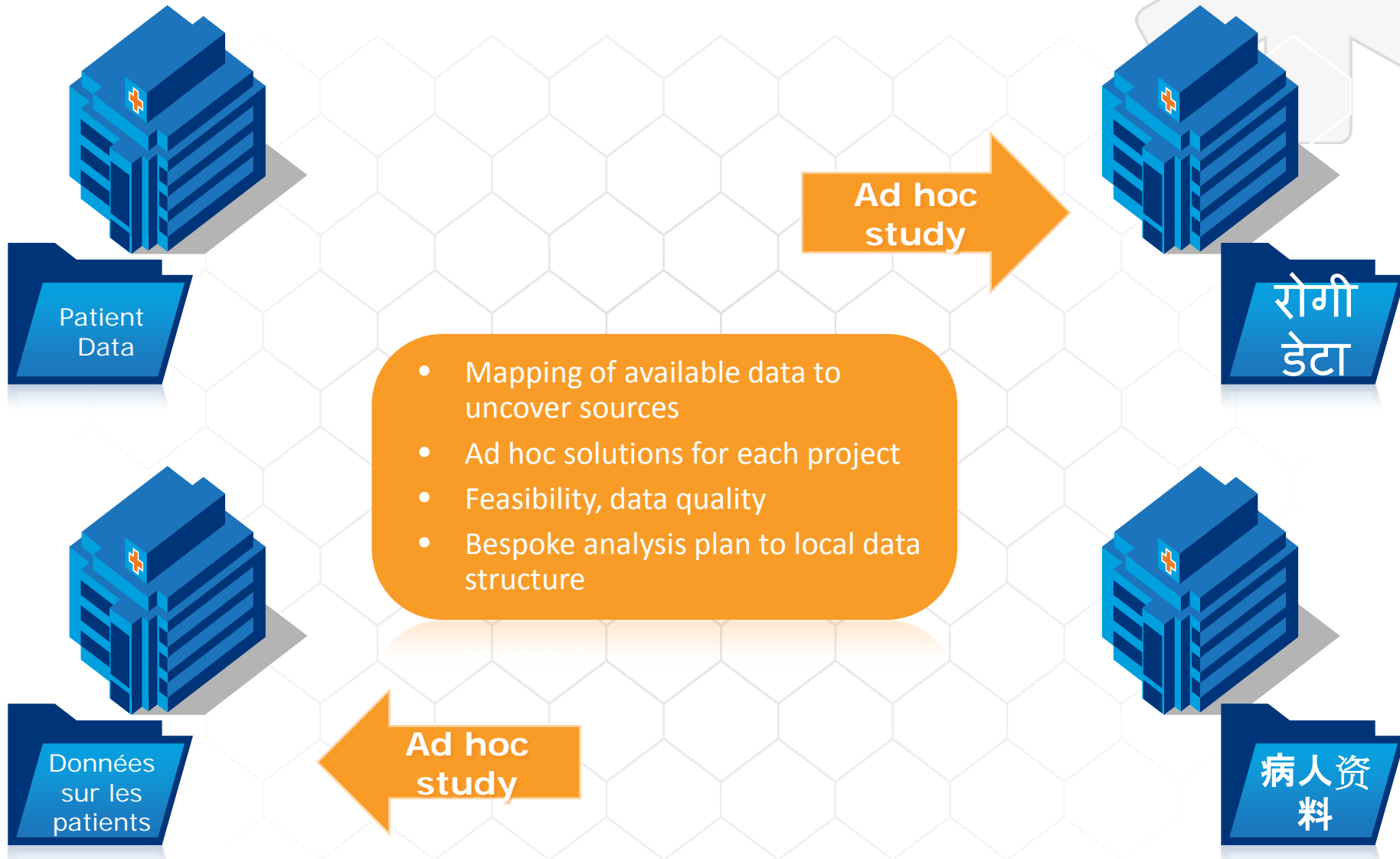


CARDIOVASCULAR

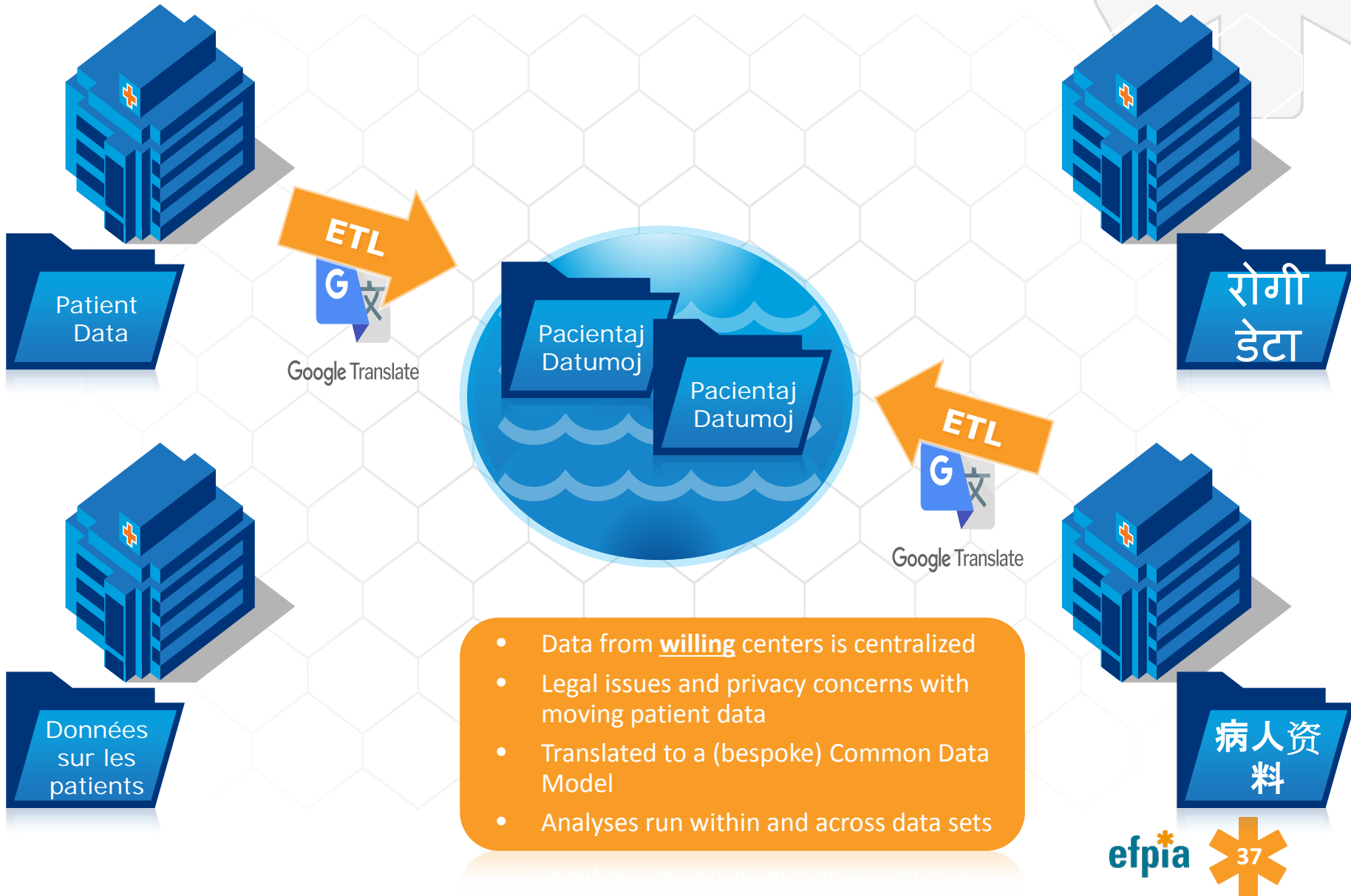


PROSTATE CANCER

Current model for utilising data



Pooled model



European Health Data Network



Patient Data

Pacientaj Datumoj



Google Translate

Pacientaj Datumoj

रोगी डेटा



Google Translate



Données sur les patients

Pacientaj Datumoj



Google Translate

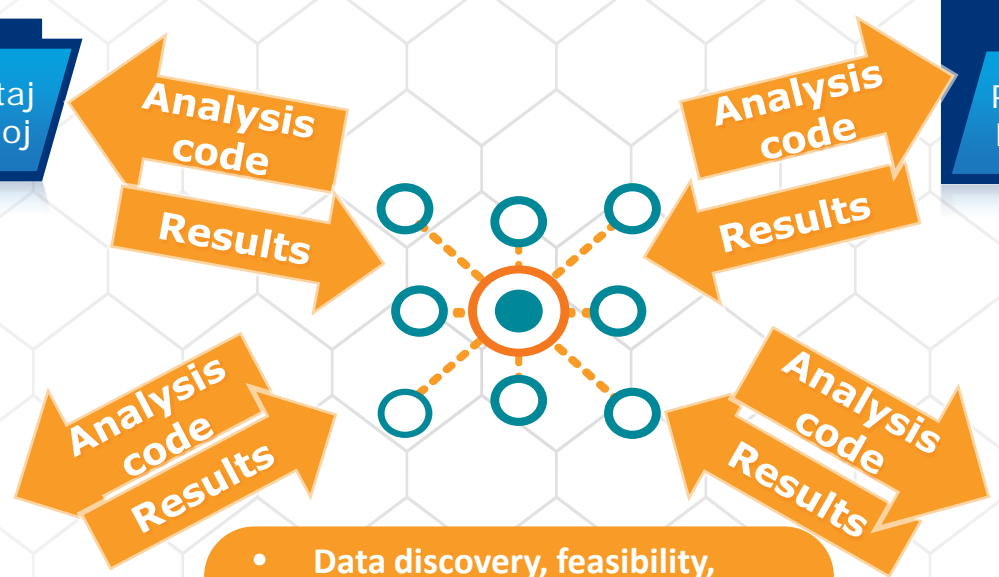


Pacientaj Datumoj

病人资料



Google Translate



- Data discovery, feasibility, quality over the network
- Single analysis code
- Data does not need to move => reduced GDPR risk, increased owner willingness

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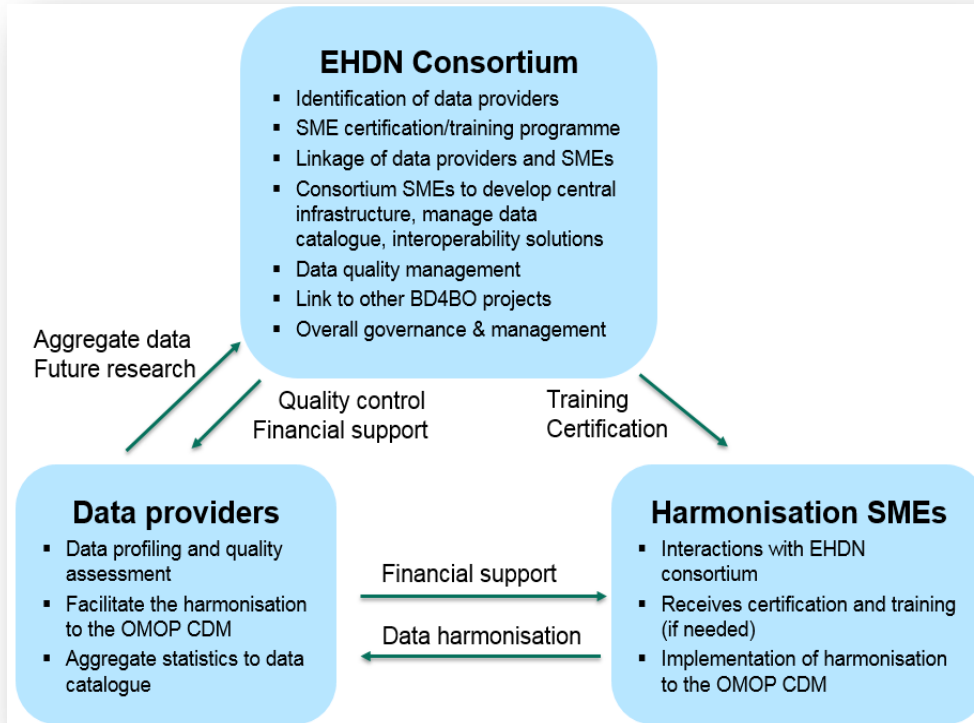
efpia



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EHDN: €28m, 12 Pharmas, EU partners, 5 years, 100m Patients' Data

OBJECTIVES OF THE FULL PROJECT



Healthcare data are very fragmented. Even data within one healthcare centre are typically spread across different repositories. Across entities, different standards are used to code diagnosis, lab results, drugs or procedures. In most healthcare systems, a majority of the core clinical data is buried in unstructured (text) notes, making data analysis even more challenging.

The EHDN will provide a harmonised model to address the structural heterogeneity and the use of different coding standards, expediting efficiencies in the research process

Besides the technical heterogeneity amongst data sources, a similar diversity in governance processes to perform studies using data collected by healthcare providers, can be seen.

The EHDN will specifically seek to provide a pragmatic governance framework that can be used to accommodate cross-centre studies, within the confines of societal parameters that manage data use in the EU.

Scope:

The first goal of the EHDN is to 'reduce to practice' the approaches pioneered in these earlier research projects and develop a standard methodology.

The second goal of EHDN is to help mature both the supply side and the demand side of this 'health data eco-system' in compliance with robust privacy and ethics governance.

The third goal of EHDN is to stimulate development of new and augmented health services through available and expanded technologies, in the interest of health outcomes.

Expected Impact:

The EHDN project aims to improve Europe's (technical) capabilities to undertake systematic health outcomes research at an unprecedented scale across the entire region..

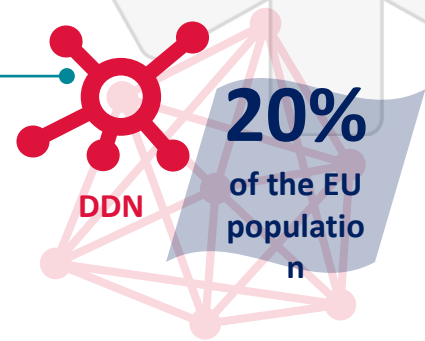
The aim of the EHDN is to not just create a network of data providers that are making data available, but also to facilitate further research that will allow these data providers to gain additional value while working towards a value based outcome mandate.

Data providers should find it easier to also participate in other future research studies.

This project should therefore also result in an increased use of outcomes based models in actual healthcare delivery and regulatory/HTA decision making

What will the data network deliver?

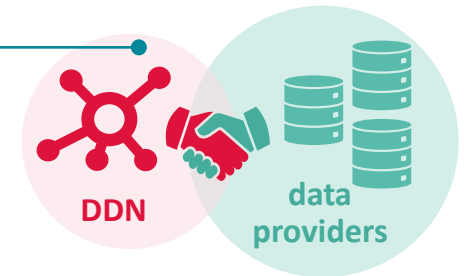
An operational network of hospital and other quality data sets covering up to 20% of the EU population or approx. 100 million persons in support of existing and new BD4BO and other health outcome related initiatives;



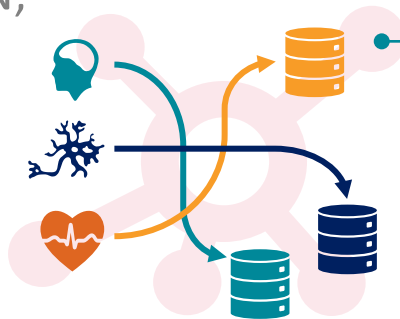
Enable inclusion of novel data types and use of the data by new stakeholder groups;



Define and clarify value proposition for data providers including an agreed strategy that will maximise the number of data providers that are willing to put data into the EHDN;



Disease specific BD4BO projects will have resource and capability to enable access to the multiple data repositories that these projects identify, including guidance on mapping to the common data model.





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