



Do we need governance in health care and, if so, what kind?

What are the driving forces in health care?

September 28th 2018

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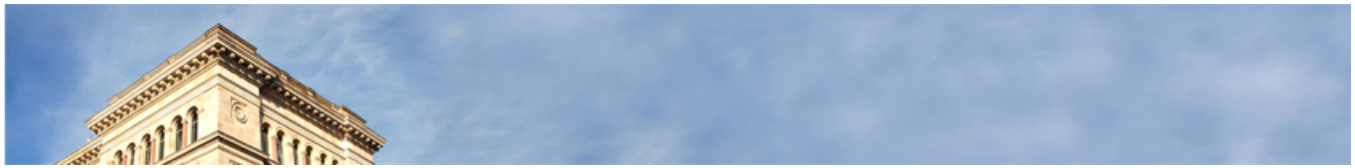
Technische Universität Berlin

Allocation of scarce resources in health care,
September 28/29th, 2018, Opatija, Croatia



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Outline

1) An enumeration: Which are the driving forces in the allocation of resources in health care? (one chart)

2) Is Governance more than a BuZZ-word? (one chart)

3) Different kinds of macro- and micro governance (three charts)

- Fiscal-Governance,
- Self-Governance (corporatism),
- Political-Governance,
- Economic Governance

4) Governance in the allocation of resources in health care (three charts):

- a) Health Governance
- b) Governance for Health
- c) Take home messages

1) An enumeration: Which are the driving forces in the allocation of resources in health care?

1. The patient and the doctor,
2. The providers of health services,
3. The parliament, federal, regional, local Government,
4. The statutory health insurance and self Government,
5. Associations, organisations, unions,
6. Lobbyism, interest groups,
7. Individuals, experts, consulting offices,
8. Competition, the market,
9. Central planning,
10. Managed Care, integrated Care,
11. Health regions,
12. More cooperation, networking and transparency,
13. Media (TV, Press. Internet),
14. Networking,
15. etc.

Several factors at the same time depending on the subject

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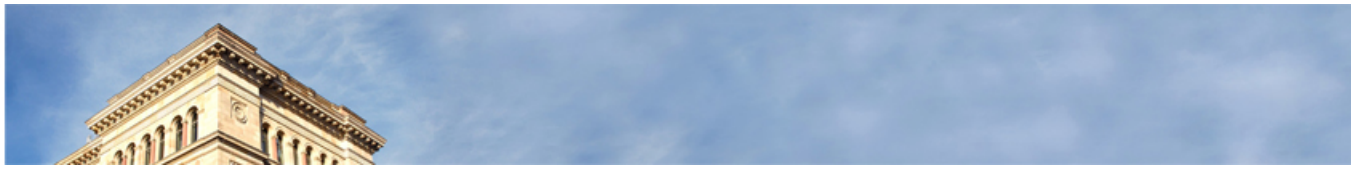
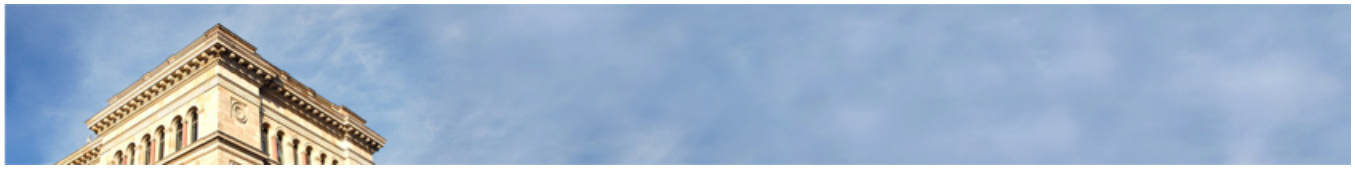


2) Governance: more than a Buzz-word?

1. The Concise Oxford English Dictionary defines a buzzword (hyphenating the term as buzz-word) as a slogan, or as a fashionable piece of jargon. Buzzwords do not simply appear, they are created by a group of people working within a business as a means to generate hype.[9]

2. Buzz-word" is a word or expression from a particular subject area that has become fashionable by being used a lot, especially on television and in the newspapers. A buzz-word is a word or phrase, new or already existing, that becomes very popular for a period of time

Is governance such a buzz-word?



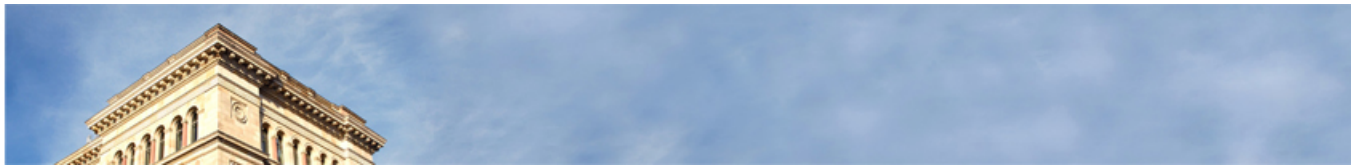
3) Different kinds of macro- and micro-governance

Fiscal Governance and allocation

- Tax systems and parafiscal systems
- Planning-programming-budgeting-system (PPBS)
- Governance through bureaucracy and central planning

Self-Governance and allocation

- Cooperatistic and self-governmental systems
- Citizens participation
- Direct and indirect democracy
- Corporate Governance through networking



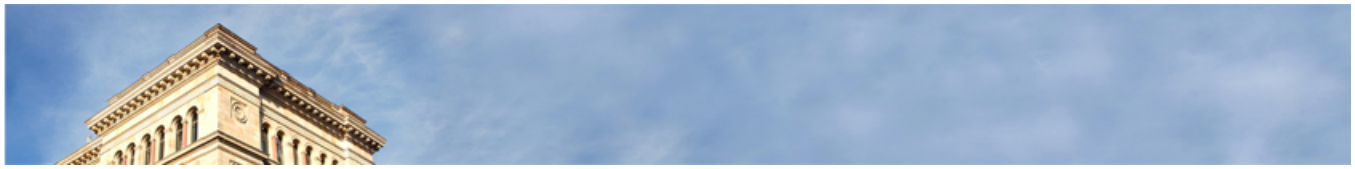
3) Different kinds of macro- and micro governance

Political governance and allocation

- Evidence-based policy
- Governance through interest groups and lobbyism
- Governance by charisma
- Stop and go interventions (Tinbergen), muddling through (Lindblom) Social piecemeal engineering (Popper)

Economic Governance and allocation

- Financial incentives
- Competition and market-based instruments
- Budget-based governance
- Governance by targets, outcome and performance
- Who, what and why?: A new approach to Governance in the health economy (next slide)?



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Economic footprint and health footprint

An new approach to Governance in the health economy?

Why?

„Health Footprint“

Better health
Longer – Improved– Self-determined („health dividend“)

„Economic Footprint“

Increased wealth
Value added – Employment – Taxes – Exports („economic dividend“)

What?

Processes

Innovations based on successful cooperation

Products

Structures

Politics and society as overall framework

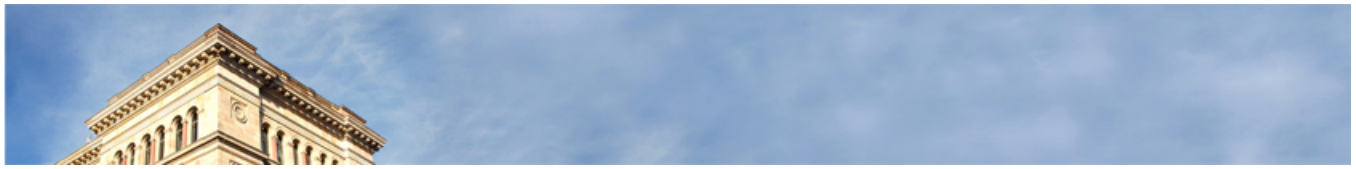
Who?

Partners in the health system, e.g. health insurance funds, hospitals, medical associations…

Health economy, e.g. Roche, Siemens, Sanofi , Philips …

Research and Dovelopment e.g. Charité, Fraunhofer, Max Planck Institutes, OECD

Source: Riederer (2015).



4) Governance in the allocation of resources in health care

a) Health Governance

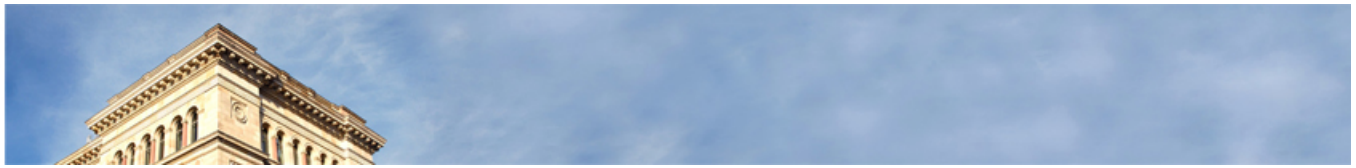
(1) A variety of terms have been assigned to precede health governance definitions. These terms commonly describe governance ideals (e.g. good, democratic) or characteristics of the organization of actors in governance arrangements (e.g. hierarchical, networked).

(2) Dimensions of governance are defined from different perspectives and in varied combinations, capturing values, sub-functions and/or outcomes of governance.

Conclusion

Despite a growing literature base, a concerted effort is needed for a more accessible understanding of health governance that is both practical at present and actionable for policy-makers.

Source:https://doi.org/10.1016/j.healthpol.2014.01.007



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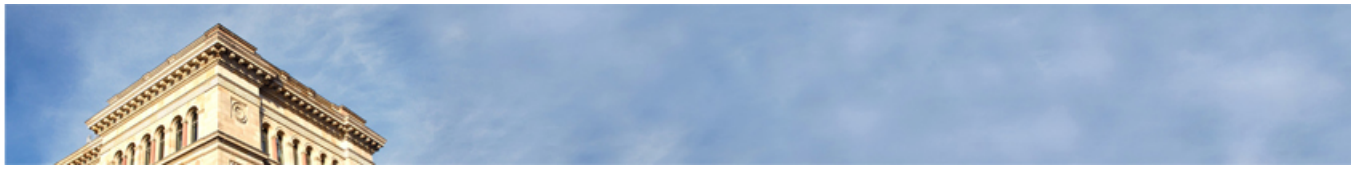
4)Governance in the allocation of resources in health care

b) Governance for Health

- describes the attempts of governments and other actors
- to steer communities, whole countries or even groups of countries
- in the pursuit of health as integral to well-being

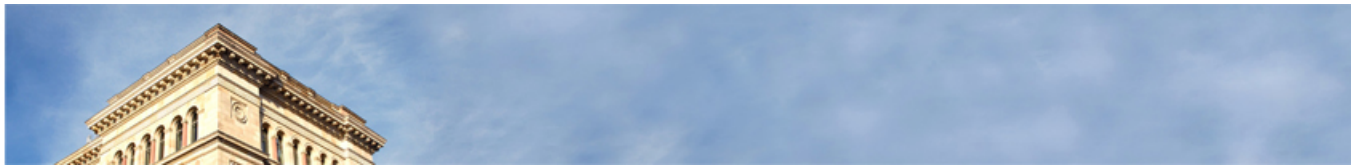
(Ilona Kickbusch,2012).



4) Governance in the allocation of resources in health care

c) Take home messages

- The term Governance is not needed because it can mean what you want it to mean.
- Within the allocation of resources the explanatory value of governance differs e.g.
  - Governance of sectors and services,
  - Governance of collective and selective contracting,
  - Governance of financing private, public and non-profit hospitals,
  - Governing of priorities, Governing the health economy etc.
- Driving forces (see chart 3) are governing (steering, ruling, administering, defining, guiding, regulating, etc.) the allocation of scarce resources in health care
- Health coaching, e.g. a region, a town (Belgrad, Ljubiljana), a population group



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In case there is time enough.

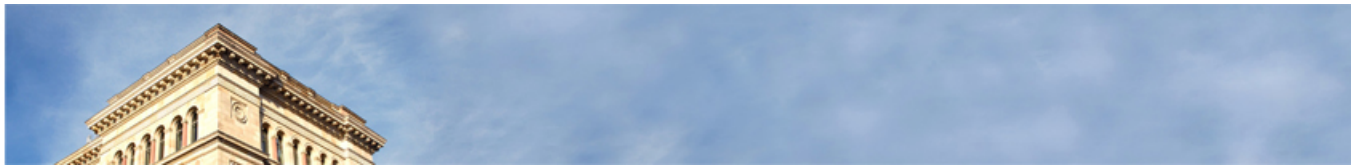
Back up charts to the allocation of scarce resources

5) How to set priorities in the allocation of health care: a different approach (three charts)

6) A new role of funds: Who is governing the funds and the providers of health care (three charts)

7) Financing hospitals as an example: How are they governed?(three charts)

- in real terms,
- in monetary terms and
- by the legal framework



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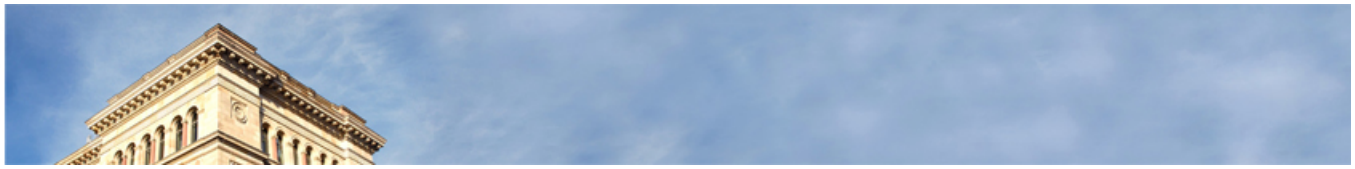
How to set priorities in allocating health care?

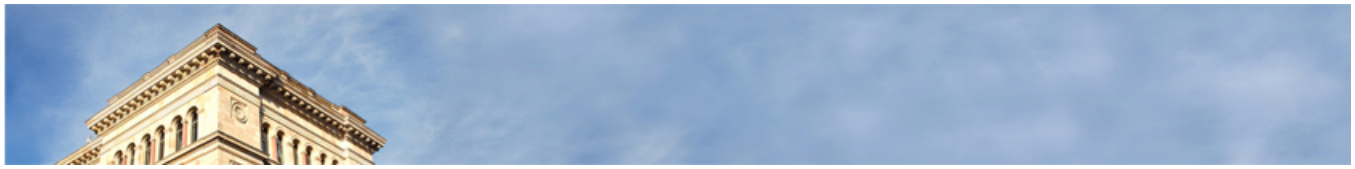
1) in real terms
2) in monetary terms
3) by the legal framework



How to define priorities in health care?

1) In real terms on a macro, regional and on a micro level by

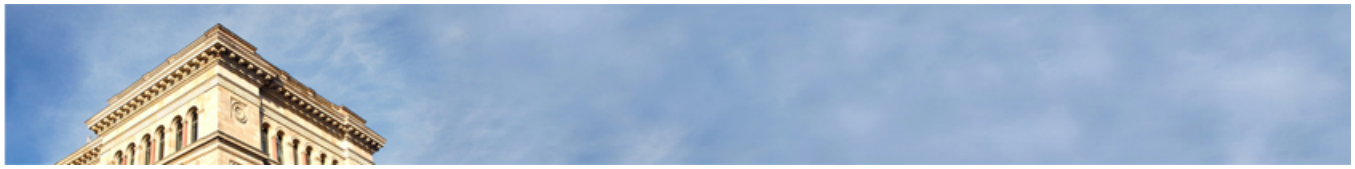
- defining avoidable mortality and morbidity (epidemiology)
- guidelines, standards, evidence-based medicine (medical treatment)
- prevention of risks (life style)



How to define priorities in health care?

2) In monetary terms through financial constraints by

- global, regional, sectoral, group-specific budgets (expenditure caps)
- a revenue oriented policy e.g. codified in social law or in tax law
- Tax-financed solutions (Beveridge)
- Through employer and employee contributions (Bismarck)
- Co-payment out of pocket expenditures



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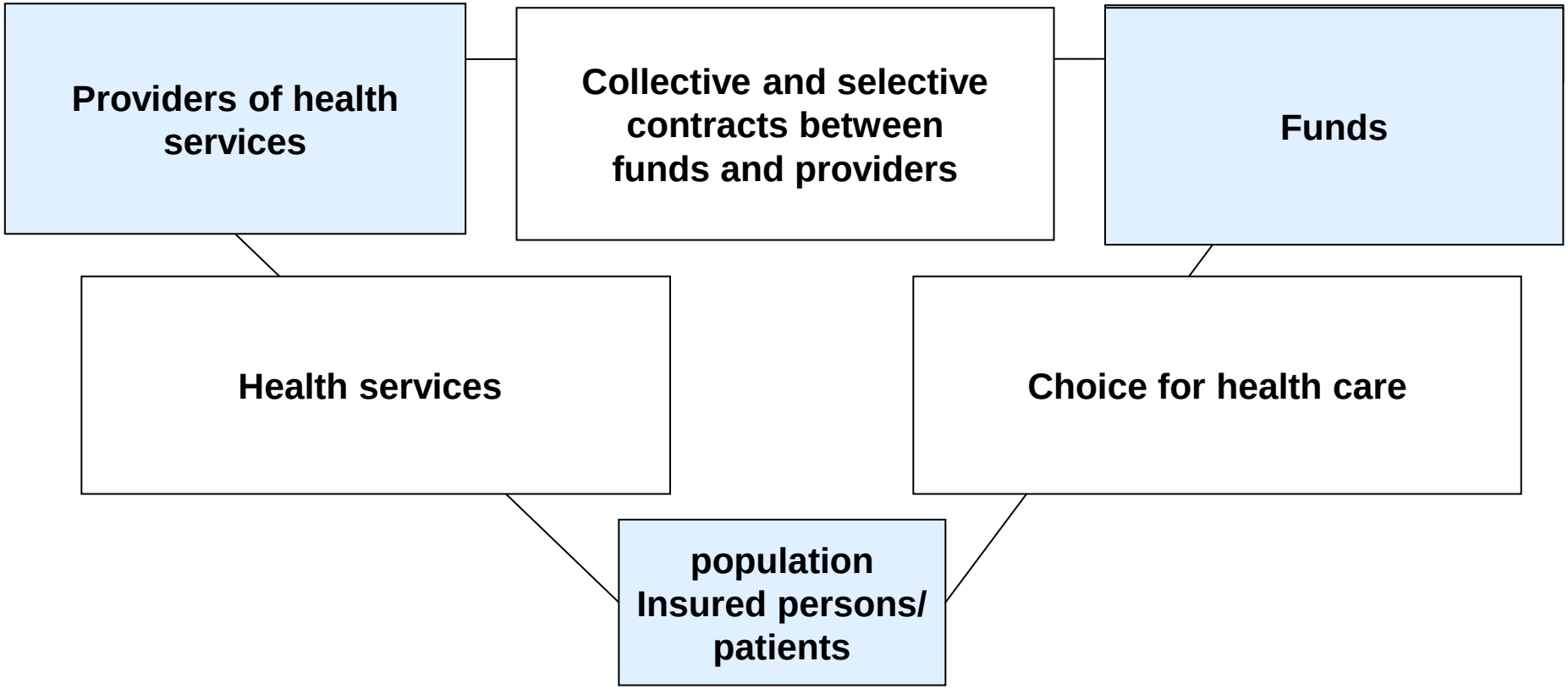
How to define priorities in health care?

3) By the legal and institutional framework

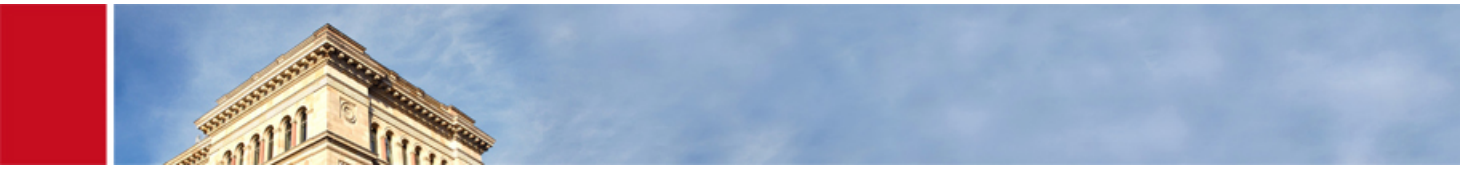
- basic mandatory coverage for all
- voluntary supplemental protection
- financing and payment of the providers is left to the funds
- a state providing benefits to a state providing guarantees

Who is governing the funds and providers?

Contracts between funds and providers



Governance of Contracts between funds and providers



providers
(Doctors, Hospitals, Rehabilitation center, pharmacies,,Wellness- and Fitness, etc.)

collective and selective contracting between funds and providers

Insurances,
funds
)

health services und health products

- Core health services
- out of pockett health care

choice of Health care

- Statutary health insurance
- Additional private insurances
- Complete private insurances

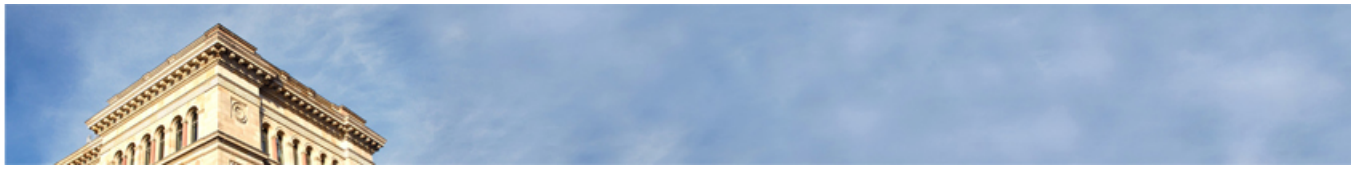
Procurement of medical equipment

population

Insured / Patients

Risk-adjusted transfers

Central Health Fund of the
Statutory health insurance
starting 1st .of January 2009)



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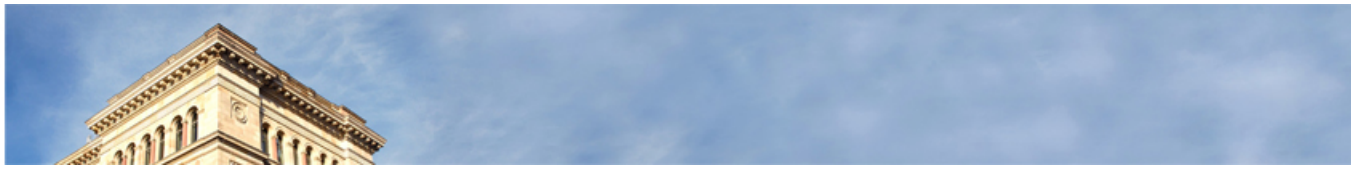
Governance in the Health Economy

	Financed through pooled public and private funds	Financed through direct private payment	
Core Health Economy	***Goods and services*** *from the Core Health Economy through* ***pooled public and private funds***	***Goods and services*** *from the Core Health Economy through* ***direct private payment***	**Health expenditure survey**
Extended Health Economy	***Goods and services*** *from the Extended Health Economy through* ***pooled public and private funds***	***Goods and services*** *from the Extended Health Economy through* ***direct private payment***	**Secondary data**



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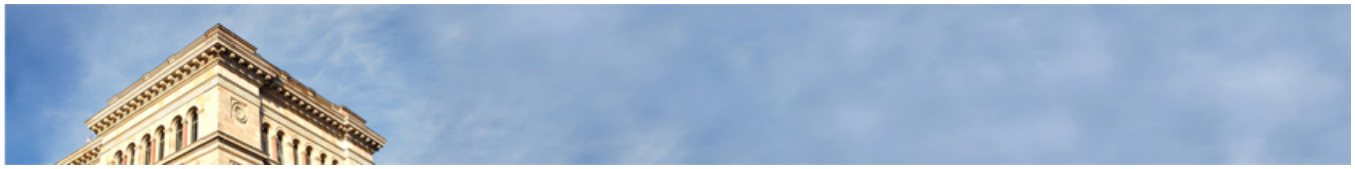
Financing hospitals as an example: How are they governed?

1) How to finance the hospitals?

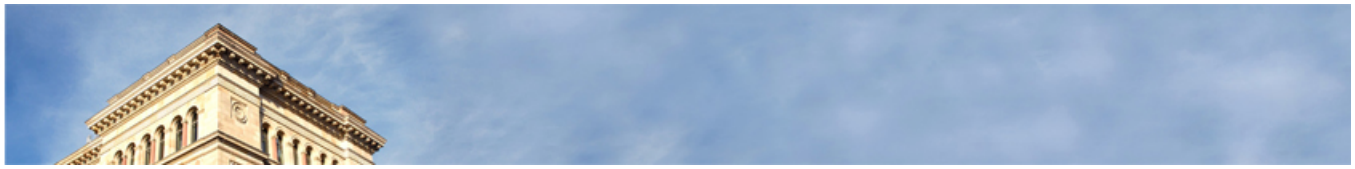
- Tax-financing on different levels within the public sector (municipalities, regions, federal, national level); no earmarked taxes
- Payroll financing with employer and employee (earmarked) contribution within a social security system with different branches (pension fund, statutory health insurance, nursing home care for the elderly, accident insurance)
- Financing investment (building, equipment etc.) and financing the current expenditures for treatment (dual financing)



Financing hospitals as an example

2) Financing expenditures for treatment

1. In-patient services in hospitals, nursing homes and rehabilitation facilities
2. Out-patient treatment in hospitals
3. At the office based doctor and the dentist
4. In pharmacies
5. For remedies (physiotherapy, speech and occupational therapy)
6. For medical appliances (eyeglasses, hearing aids etc.)
7. For accident rescue and patient transport



Financing hospitals as an example

3) Future financing

Two major perspectives

1) The establishment of an Investment fund financed by a lump sum of the states (Länder)
2) Revenue and expenditures in „one hand“ of the (sickness) funds. So-called monistic financing through the contributors of the (sickness) funds and not longer by the taxpayer
3) A new perspective: private equity

Take home message from the 3 topics in the „Back up charts“?

Transparency, cooperation and incentives

V ECPD REGIONAL CONFERENCE ON HEALTH ECONOMICS
ALLOCATION OF SCARCE RESOURCES IN HEALTH CARE

Dušan Keber

Allocation of resources in health care: setting priorities and tools from a health policy perspective

EUROPEAN CENTER FOR PEACE AND DEVELOPMENT (ECPD)
UNIVERSITY FOR PEACE EST BY THE UNITED NATIONS

Opatija, 28 - 29 September 2018

What is health care resource allocation?

- Health care resource allocation is the process through which national-level health care funds are distributed to the purchasers and/or providers of health care on behalf of patients in accordance with society's objectives.
- Funded organizations might be local government (Sweden) local administrative boards (the United Kingdom), sickness funds (Belgium, Germany, the Netherlands and Switzerland) or health providers (Slovenia).
- The resource allocation task is to distribute The process differs between countries.

Three levels of resource allocation

Level 1: Allocating resources to healthcare versus other social needs.

Level 2: Allocating resources within the healthcare sector.

Level 3: Allocating resources among individual patients.

Goals of resource allocation

Strategic health care resource allocation is being driven by at least two main goals: equity and efficiency.

Equity: In countries with public health system, the *equity* reflects the requirement to secure equal access to health care for equal health needs and equal contributions in the form of premiums or taxes for equal income or wealth.

Efficiency: resource allocation seeks to make purchasers and providers more responsive to the issues of costs and benefits, i.e. cost effectiveness.

Method for resource allocation

The prevailing method for resource allocation is **risk adjusted capitation**, which seeks to adjust per capita payments to reflect the average expenditure for individuals on the basis of their characteristics.

Strategic resource allocation based on the method of risk adjusted capitation seeks to distribute limited resources in accordance with society’s equity and efficiency objectives.

Country examples of capitation algorithms

England

hospital and community health services, prescriptions (the cost of drugs prescribed by GPs and primary medical services

Wales

reported prevalence of 17 health conditions

Netherlands

age and gender, income, region, consumption of pharmaceuticals, and some chronic conditions.

Sweden

mixture of socio-demographic, socio-economic and health-care utilization variables

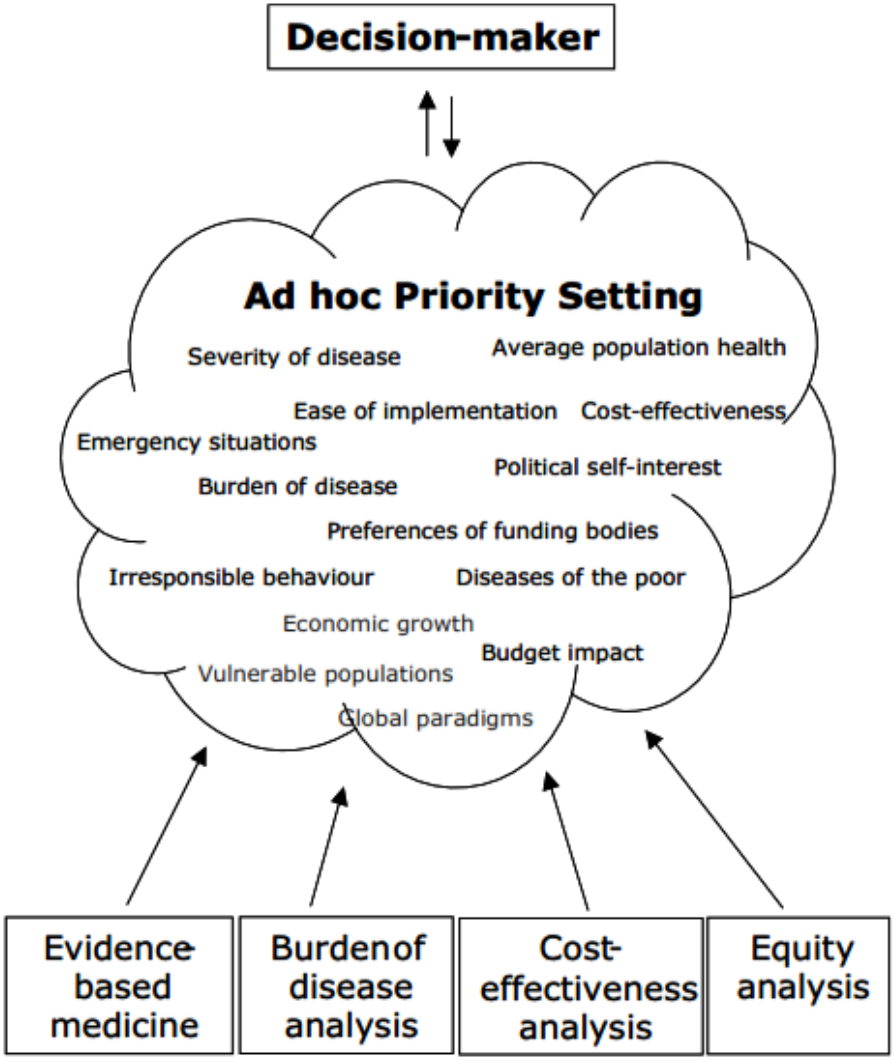
Germany

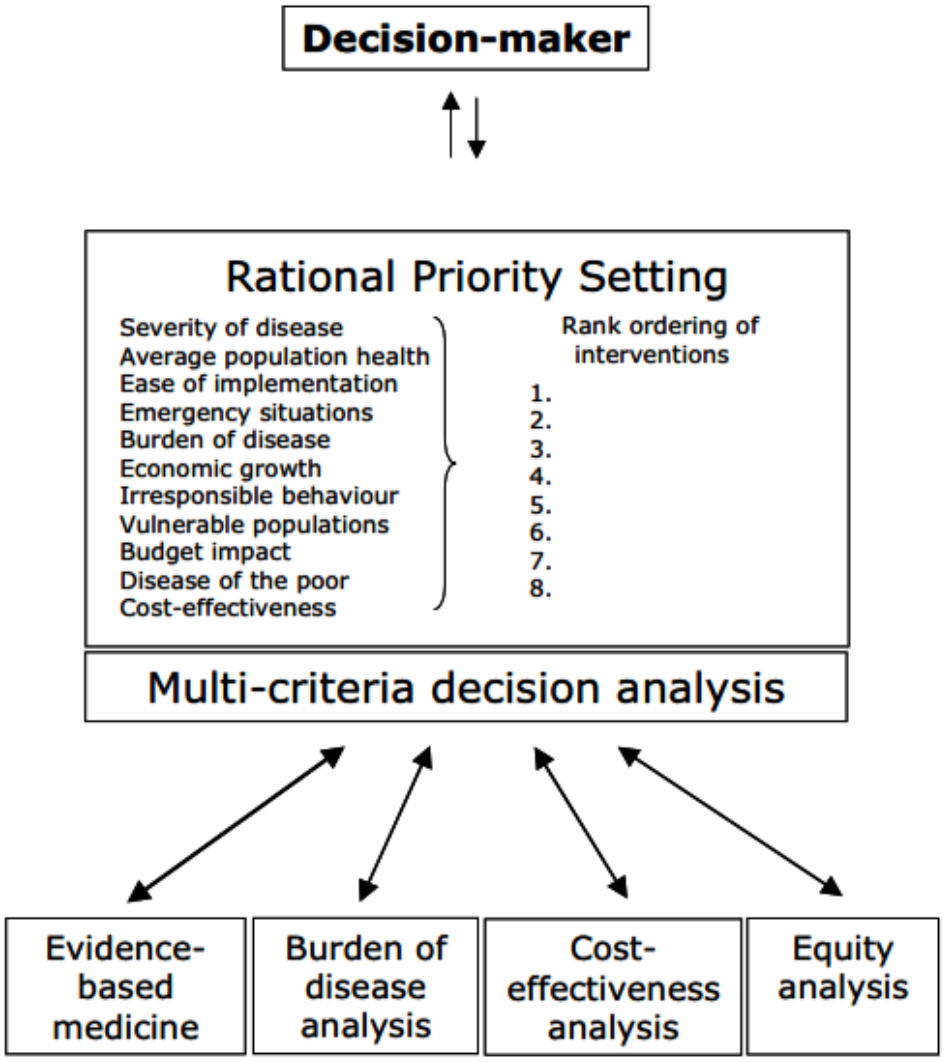
age and sex, invalidity, morbidity (50-80 pre-selected diseases) and sick pay

Challenges of risk adjustment

- ‘Utilization-based’ approaches may undermine improvements in efficiency and service quality.
- Traditional capitation payments are based on current patterns of expected utilization. They perpetuate current inequities.
- Finding independent measures unaffected by utilization or supply is the primary and most challenging task.
- Risk selection becomes a problem when organizations are not compensated for their high risk/high cost members.
- „Cherry picking“, promoting other non-desirable behaviors.
- There is a need for complementary methods, such as prospective and retrospective risk sharing.
- There is a need for a centralized information system which records all services for each individual patient.

Ad hoc and rational priority setting





Priority-setting for national health policies, strategies and plans

- The aim of the priority-setting process is to select among different options for addressing the most important health needs, given limited resources.
- The process of priority-setting is inherently political; resulting priorities reflect a compromise among stakeholders, including the population.
- Priority-setting determines the key objectives for the health sector for a given period, thus directly feeding into the content of the national health plan.
- The priority-setting exercise generally follows a situation analysis and precedes decisions on resource allocation and planning.

Goals of priority-setting

- to relate the most important citizens' health needs and demands, as identified in the situation analysis, to the best options for addressing those needs and demands;
- to ensure that programmes and interventions are evidence-based, cost-effective and fairly distributed, addressing health needs of all population groups, particulary the poorest segments of society;
- to inform national strategies and resource allocation of the public fund;
- to provide key reference information and evidence for policy-making, monitoring and evaluation.

Priority-setting in the context of universal health coverage (UHC)

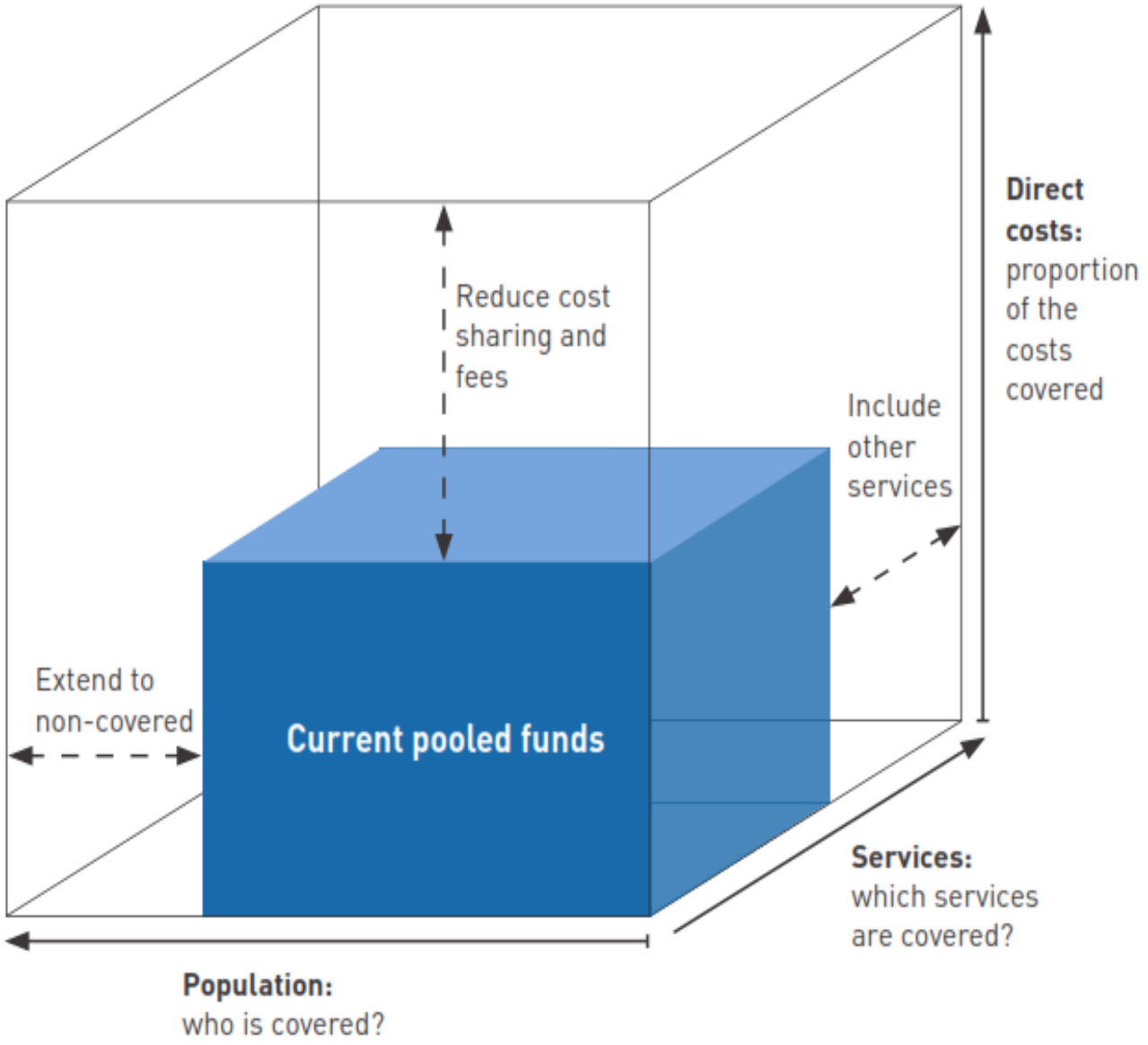
WHO definition of UHC: Universal health coverage ensures that all people can use all health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.

Achieving universal health coverage is a goal which all UN Member States subscribed to in September 2015.

WHO recommends working on three dimensions :

- extension of health coverage to the population not covered,
- improvement of the health service package provided,
- reduction of cost sharing and out-of-pocket payments.

Three dimensions to consider when moving towards UHC



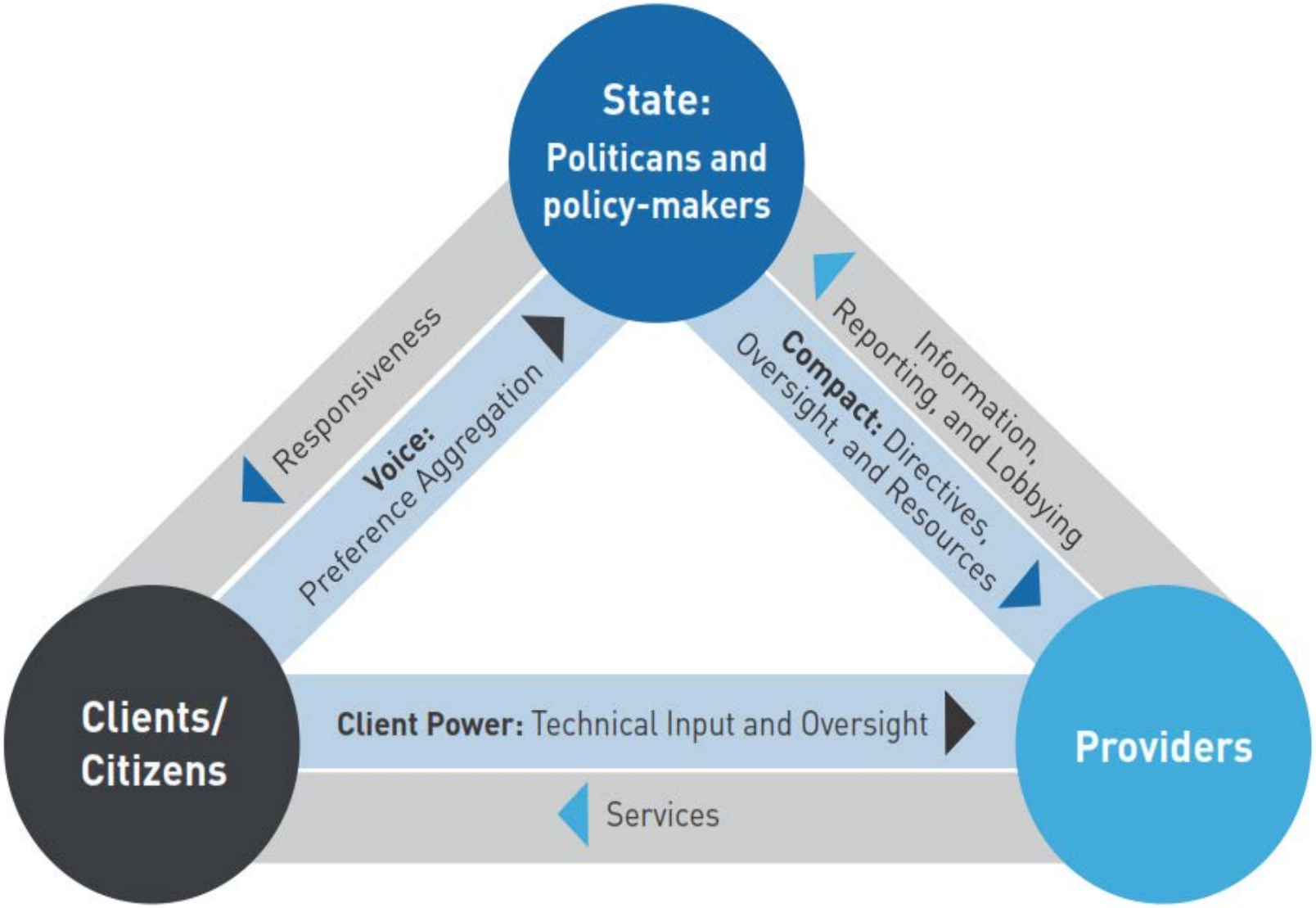
Priority-setting basics

- Priority-setting examines the degree to which an identified important need can be addressed, taking into account resource limitations.
- Priority-setting is a multifaceted process that is usually informed by the situation analysis.
- The priority setting process is based on certain criteria. There might be trade-offs between the various criteria, and the weight of each of them will be a political decision.
- Priority-setting exercise is where the principal decisions are made after the situation analysis discussions; these decisions feed directly into national health plan development.

Why is it important to prioritize?

- Priority-setting is necessary to adapt to a changing context.
- Priority-setting addresses challenges raised during the situation analysis.
- Priority-setting identifies challenges expected to be prominent in the future.
- Implicit priority-setting happens if it is not consciously made explicit.

Who should be engaged in priority-setting?



Criteria for priority-setting

1. burden of the disease (health issue)
2. effectiveness of the intervention
3. cost of the intervention
4. acceptability of the intervention
5. fairness

1. Burden of the disease

The “burden of disease” is a quantitative, timebased measure combining years of life lost due to premature mortality or due to life in states of less than full health.

- The ***magnitude*** of a health problem may be indicated, for example, by the proportion of the population at risk or affected in terms of mortality and morbidity.
- ***Severity*** can be determined by the effects of the health threat, measured in quality- adjusted life-years (QALYs) and disability-adjusted life-years (DALYs).
- The ***urgency*** of a problem may also be a reason for declaring it a priority (e.g. the threat of an epidemic outbreak)
- ***Perception*** looks at the burden of the health problem from the patient and population perspective.

2. Effectiveness of the intervention

- Two types of situations:
  - The evidence base has not yet been established at the global level and needs scientifically-sound testing.
  - The evidence base exists at global level, but the applicability and (cost) effectiveness needs to be verified locally.
- Other considerations:
  - potential of new solutions vs. current interventions
  - acceptability of the intervention by the target population
  - The availability of resources

3. Cost of the intervention

- Affordability and efficiency of the solution to address a health problem need to be carefully considered.
- The cost of the intervention must be economically feasible and economically sustainable.

4. Acceptability of the intervention

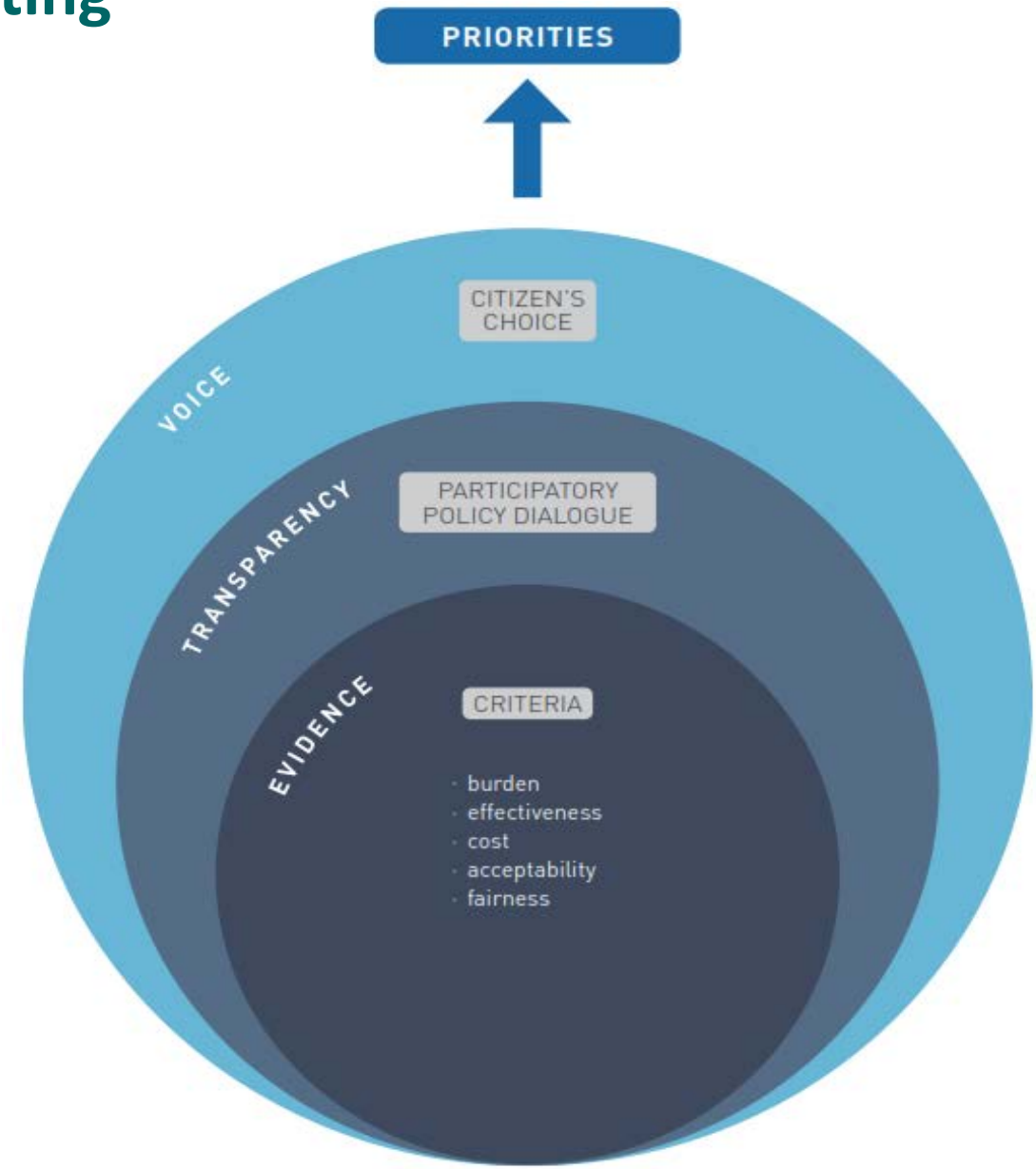
- The acceptability of a priority health intervention refers to whether a community or target population accepts the chosen health intervention that addresses a priority problem.

- It also refers to the willingness by those who will be carrying out the intervention to do so – for example, health service providers, MoH, and subnational health authorities.

5. Fairness

- Fairness is defined by treating people equally, free from bias or injustice.
- Fairness is closely linked to the judgment and trade-off on the importance of a health need and the effectiveness of an intervention.
- Duty to “rescue those with a life-threatening condition: this concept highlights the ethical dilemma between the two principles “sickest-first” and “maximizing cost benefit”.
- Giving priority to the health problems of deprivileged subgroups, even though the treatment of this health problem is not the most cost-effective.
- Treating equally subjects that may be at risk because of their unhealthy lifestyle (dietary habits, drug abuse, etc.).

Evidence, Transparency, Voice: Three steps of approach in priority-setting



Tools for assessing health needs

- **burden of disease analysis**
  quantification of the gap between the ideal of living to old age in good health, and the current situation where healthy life is shortened
- **health needs assessment**
  epidemiological, qualitative, and comparative methods to describe health problems of a population
- **2x2 grid**
  The grid organizes health problems using two dimensions, need and feasibility, to form a quadrant.
- **health technology assessment (HTA)**
  multidisciplinary form of research used to generate evidence about the performance of health technologies

Avoidable health inequalities

Three sources of health inequalities:

- the quality of health services;
- access to health services;
- factors outside the direct control of the health system, such as wealth, lifestyle, genetic and environmental factors.

Designing a funding formula to remove health inequalities:

- identification of effective health-care interventions designed to reduce the health inequality;
- identification of disadvantaged groups;
- identification of the areas where such groups live;
- allocation of resources;
- ensuring that the resources are spent appropriately.

Ethical values which influence priority setting and resource allocation

Fairness: all members of society should have guaranteed access to adequate health care.

Equity through solidarity: the community helps the disadvantaged.

Rights and societal obligation: that basic human needs (food, shelter, education, health care, justice) create an obligation on society to provide some level of common access to these fundamental goods.

Social wisdom: we must shape our health care so that we accomplish what we value.

DOM ZDRAVLJA ZAGREB
CENTAR

People-centered integrated care and digital information technology support in primary medicine

Ass. prof. Antonija Balenović, MD. PhD
Prof. Ana Stavljenić-Rukavina, MD. PhD

HEALTH CARE ZAGREB - CENTAR

European Innovation Partnership on Active and Healthy Ageing
REFERENCE SITE

INTRODUCTION

Primary health care (PC) - the fundamental principles

- **4 Principles** – availability (first contact), continuity, comprehensive and coordinated care
- **Health systems built on 4 PC** principles achieve better health and greater equity in personal and public health than systems with a specialty care orientation
- **Fragmentation** results in suboptimal care, higher cost due to duplication and poor quality of care
- PC set of principles, policies and clinical functions is considered as **the corner stone** of any health system - make an **excellent starting point** from where to improve and integrate care

PRIMARY CARE PROVIDERS

European Innovation Partnership on Active and Healthy Ageing
REFERENCE SITE

INTRODUCTION

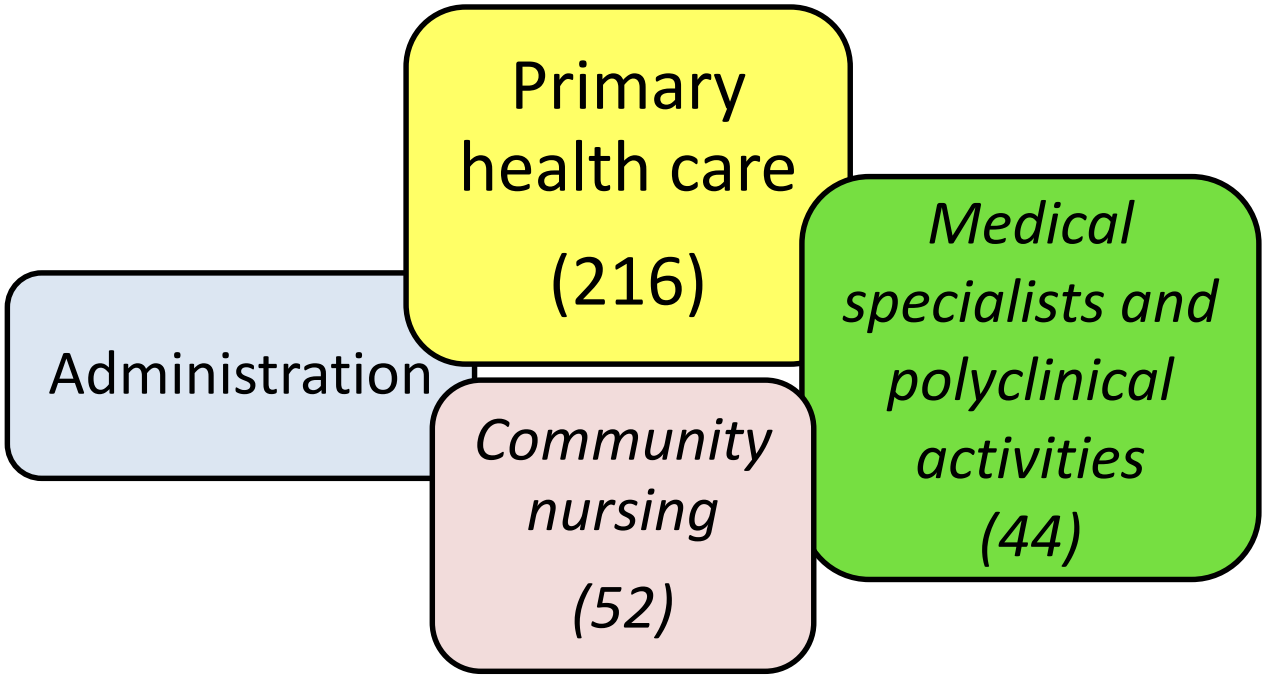
General Practice (GP) in Croatia

- **2.277 doctors** work as GPs (gate-keepers, 49 % vocational trained)
- **Free choice** (average number of **pt/GPs lists =** 1.834)
- **Contract** with the Croatian Institute for Health Insurance:
  - Private/individual contractors (concession) - integrated into the public sector
  - Primary Health Care Centers - salaried doctors (GP teams within the Health Centers)
- **92.1 %** of the population registered in general practice
- Croatia: 4.284.889 inhabitants

Croatian National Institute of Public Health. Croatian Health Service Yearbook 2014. Zagreb: Croatian National Institute of Public Health, 2015.

INTRODUCTION

Health Care Centre Zagreb-Centar (HCCZ)



The largest health center in Croatia = 63 locations; 910 employees

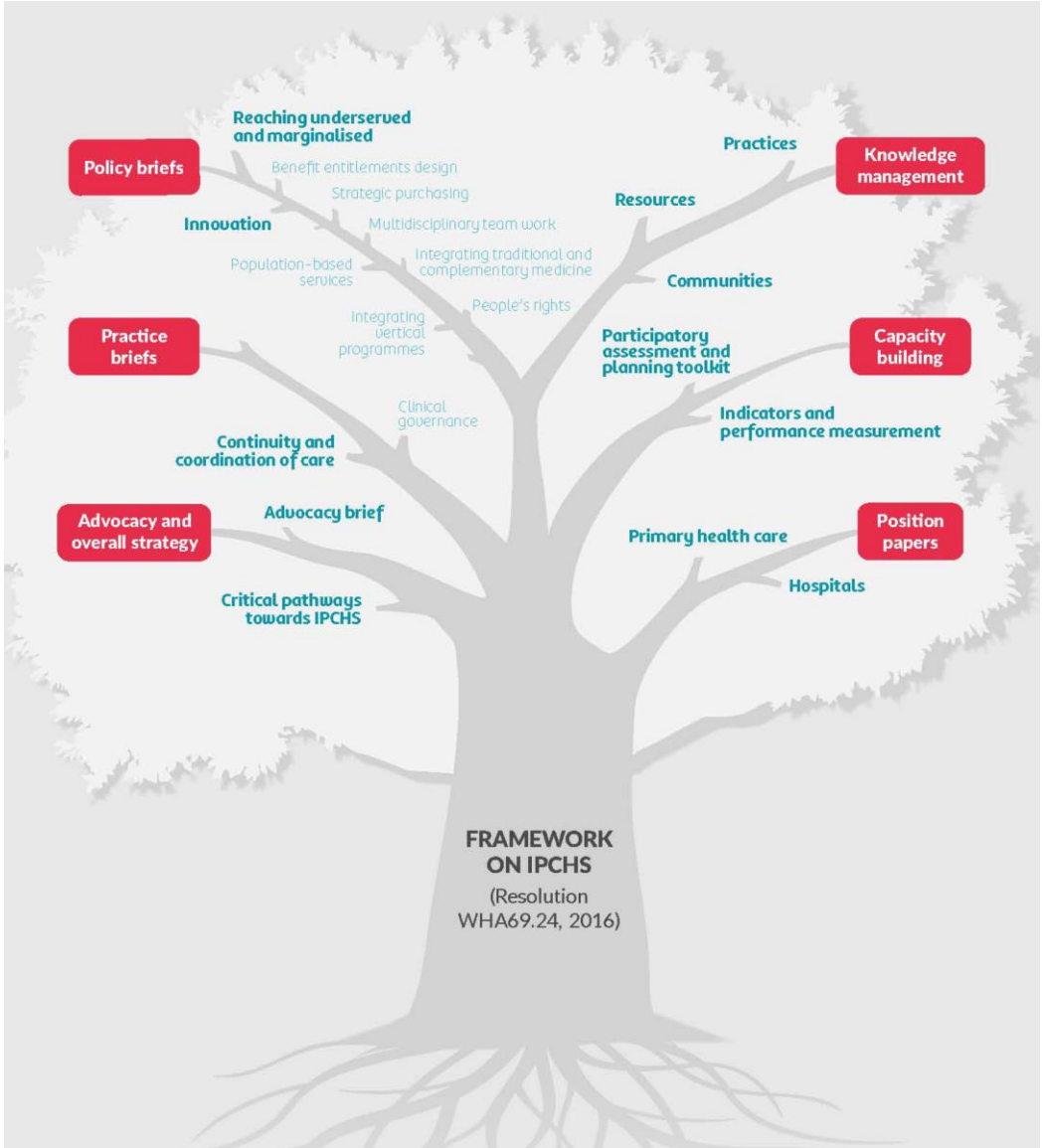
- ✓ Covering PHC needs of 350.000 inhabitants of the City of Zagreb
- ✓ Over 300.000 examinations in PHC and 200.000 polyclinical specialist examinations / year
- ✓ In addition -183 concessionaires use space and resources of the HCCZ

INTRODUCTION

The future provision of health care

- Requires a reorganization of provision of care:
  - New health care models
  - Skilled health professionals (new tools and different skills)
  - Increased empowerment and engagement of patients
  - Delivering services that are coordinated across sectors and organizations that provide health care (integrated care)

Integrated people-centered health services (IPCHS) implementation support guidance, products and tools



Dare to transform
Integrated people-centred health services
World Health Organization

- WHO „Dare to transform" IPCHS (2018)
- WHO Resolution on primary health care (2009)
- Declaration of Alma-Ata (1978)

World Health Organization

Continuity and care coordination: key messages form the literature

75%
Patients who value seeing their usual primary care provider *(5)*.

High continuity means **13%** fewer hospital admissions *(6)*.

63%
Patients who value seeing someone they know and trust *(5)*.

High continuity means **27%** fewer visits to an emergency department *(7)*.

Coordinated home-based primary care results in **17%** lower medical costs *(8)*.

Hospital at home results in **19%** lower care costs *(9)*.

Over 4 out of 5 People with mental health needs who can be managed through primary care *(10)*.

23 out of 25 studies of medical homes reported reduced use of care *(11)*.

- Primary care provider!
- Home-based primary care results!
- Continuity!

Continuity and coordination of care: a practice brief to support implementation of the WHO Framework on integrated people-centred health services

ISBN 978-92-4-151403-3

State of Health in the EU – 2017 Report

- How can we ensure that people remain as healthy as possible for as long as possible?
- How can we reduce health inequalities?

- How can we keep health care affordable and timely accessible?
- How should we organise and finance our health care models to ensure they are fit to respond to tomorrow's needs?

EC for Health and Food Safety

European Innovation Partnership on Active and Healthy Ageing
REFERENCE SITE

CONCLUSIONS

STATE OF HEALTH in the EU-companion Report 2017

- Five key conclusions drawn from the Country Health Profiles:

1. Health promotion and disease prevention require **multi-sectoral collaboration** with other policy fields and necessity to bring together lessons learned and good practices in order to up-scale them in other countries or settings

2. Strong primary care guides patients through the health system and helps avoid wasteful spending - EU is **still working on the identification** of tools and methodologies to assess the performance of primary care systems

CONCLUSIONS

STATE OF HEALTH in the EU-companion Report 2017

- Five key conclusions:

3. Integrated care models are important for the success, better effectiveness, accessibility and resilience, and of being able to share information effectively, yet **still "under construction" - what is the right skill mix** and training of medical experts

4. Proactive health workforce planning and forecasting make health system resilient to future shocks – "put the right number of professionals in the right place at the right time" - but **still unanswered questions** to work on them

5. The patient is at the centre of the next generation of better health data for policy and practice – "Patient Reported Indicators Survey" – **next generation of complementary health indicators to be defined**

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REFERENCE SITE

Combining primary care and integrated care

- **The core value of primary care is the integration of the biomedical, psychological and social dimensions** of health and well-being expresses in framework as:
  - Person-focused care
  - Population-based care

- They serve as guiding principles for achieving better coordination of services **across the entire care continuum**
  - For policy makers, managers, professionals and other stakeholders
  - To better understand the synergetic nature of integrated care

International Journal of Integrated Care
ISSN 1568-4156
Volume 13, 22 March 2013

WHO 2018 – EIGHT PRIORITY PRACTICES

Continuity and coordination of care

1. **Continuity with a primary care** professional (continuous contact)
2. **Collaborative planning** of care and shared desicion-making (coaching families and informal caregivers)
3. **Case management** for people with complex needs (care planning and coordination to integrate the services)
4. **Collocated services** or a single point of access (to the local services and community support)
5. **Transitional** or **intermediate care** (from hospital to home)
6. **Comprehensive care** along the entire pathway (anticipates crises and can provide urgent response in the evening and at the weekend)
7. **Technology to support** continuity and care coordination (tools and platforms for the exchange of information)
8. **Building workforce capability** (developing the skills, strengths and confidence of the wider workforce…)

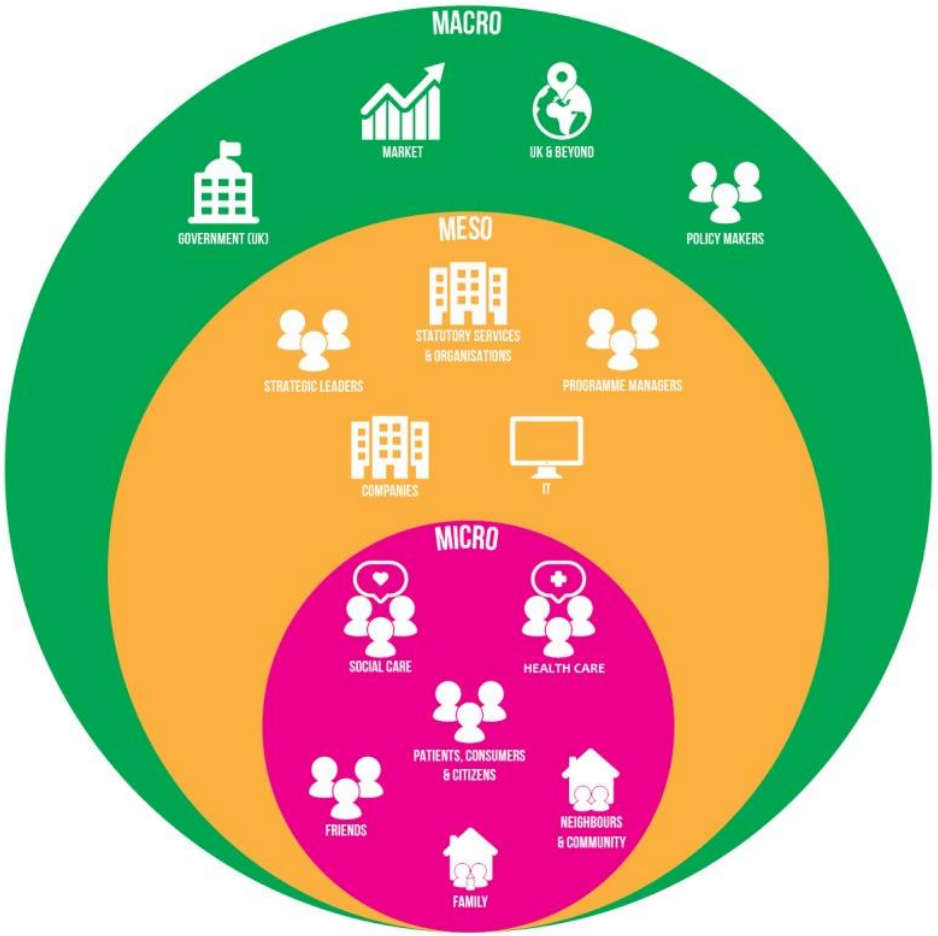
Continuity and coordination of care: a practice brief to support implementation of the WHO Framework on integrated people-centred health services

ISBN 978-92-4-151403-3

World Health Organization

Point in a health system at which continuity and care coordination exert an influence

Level	Point
Micro	Clinical integration
Meso	Professional integration Functional integration Organizational integration
Macro	System integration



International Journal of Integrated Care
ISSN 1568-4156
Volume 13, 22 March 2013

European Innovation Partnership on Active and Healthy Ageing
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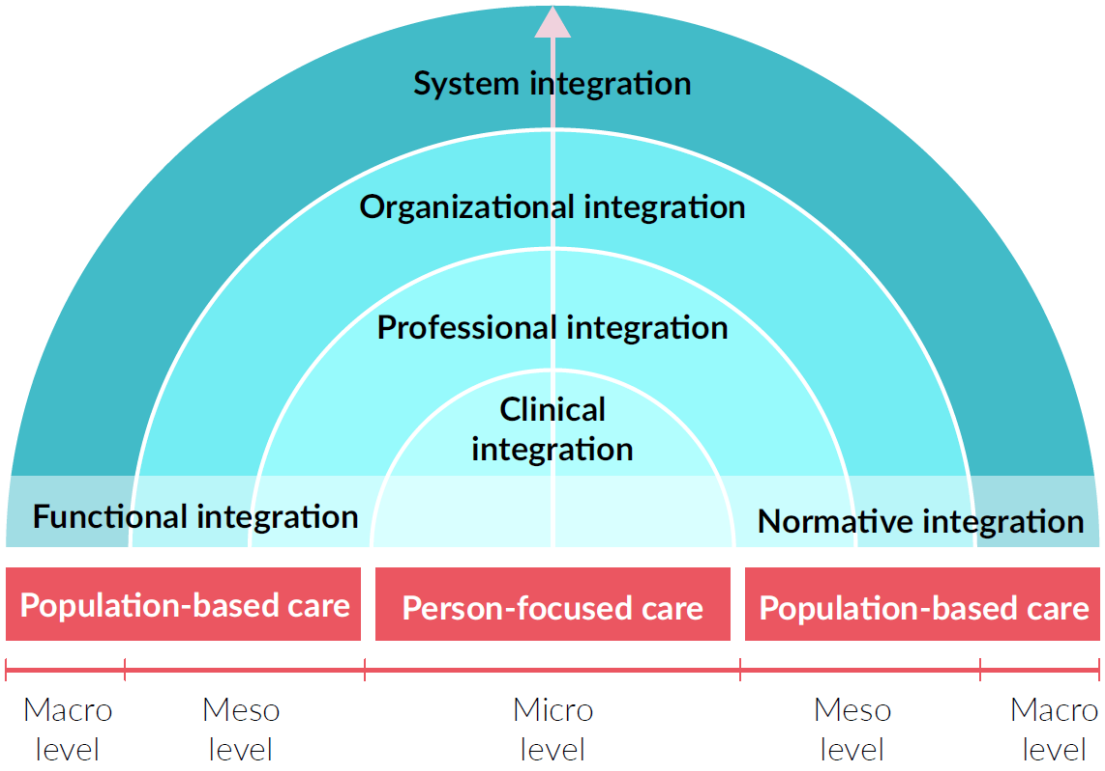
How? Where? Who?
Integrative function of primary care



Linking the micro, meso and macro level!

FUNCTIONAL integration – Important aspect is the linking of the **financial management** and **information systems (ICT)**

NORMATIVE integration – Based on **shared values, culture and goals** across individuals, professionals and organisations is essential!

International Journal of Integrated Care
ISSN 1568-4156
Volume 13. 22 March 2013

European Innovation Partnership on Active and Healthy Ageing
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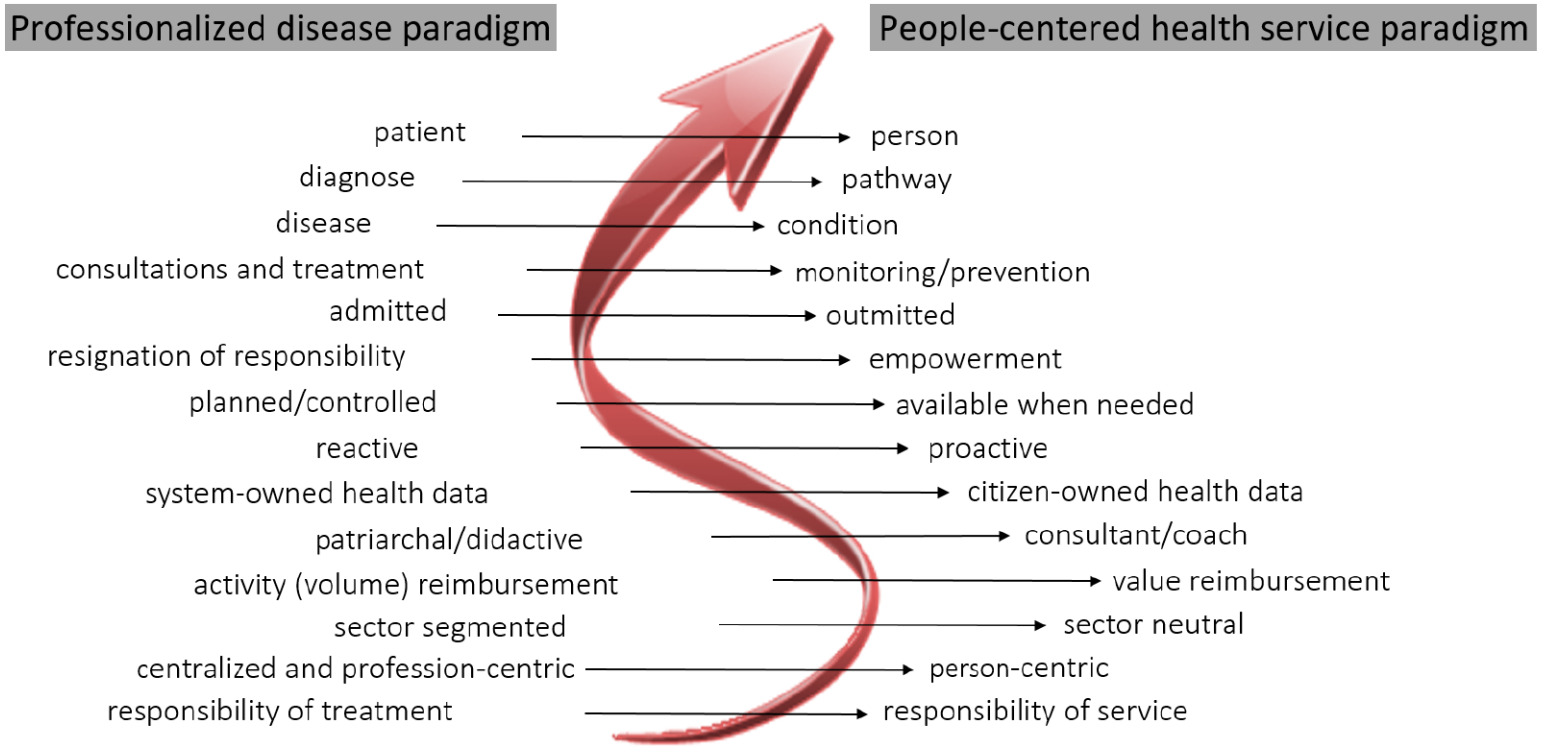
Service Transformations – Care model



- **ECM** (Epital Care Model – Denmark 2011) – eHealth driven socio-technical care system - three chronic conditions were planned digitally
- To assist both the patients and their health care providers - necassary to **develop advanced ICT system and services** for personalized care

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The importance of rapid and accurate exchange of health data!

Good communication – would you like to have a cup of tea from this field?

INTRODUCTION
EIP-AHA

European Summit on Digital Innovation for Active & Healthy Ageing
Brussels, 5-8 December 2016

The European Innovation Partnership on Active and Healthy Ageing (EIP- AHA) - an initiative launched by the European Commission (EC) to foster innovation and digital transformation **in the field of active and healthy ageing**


EIP ON AHA

CERTIFICATE OF AWARD

City of Zagreb

has been awarded "1 Star" Reference Site of the European Innovation Partnership on Active and Healthy Ageing

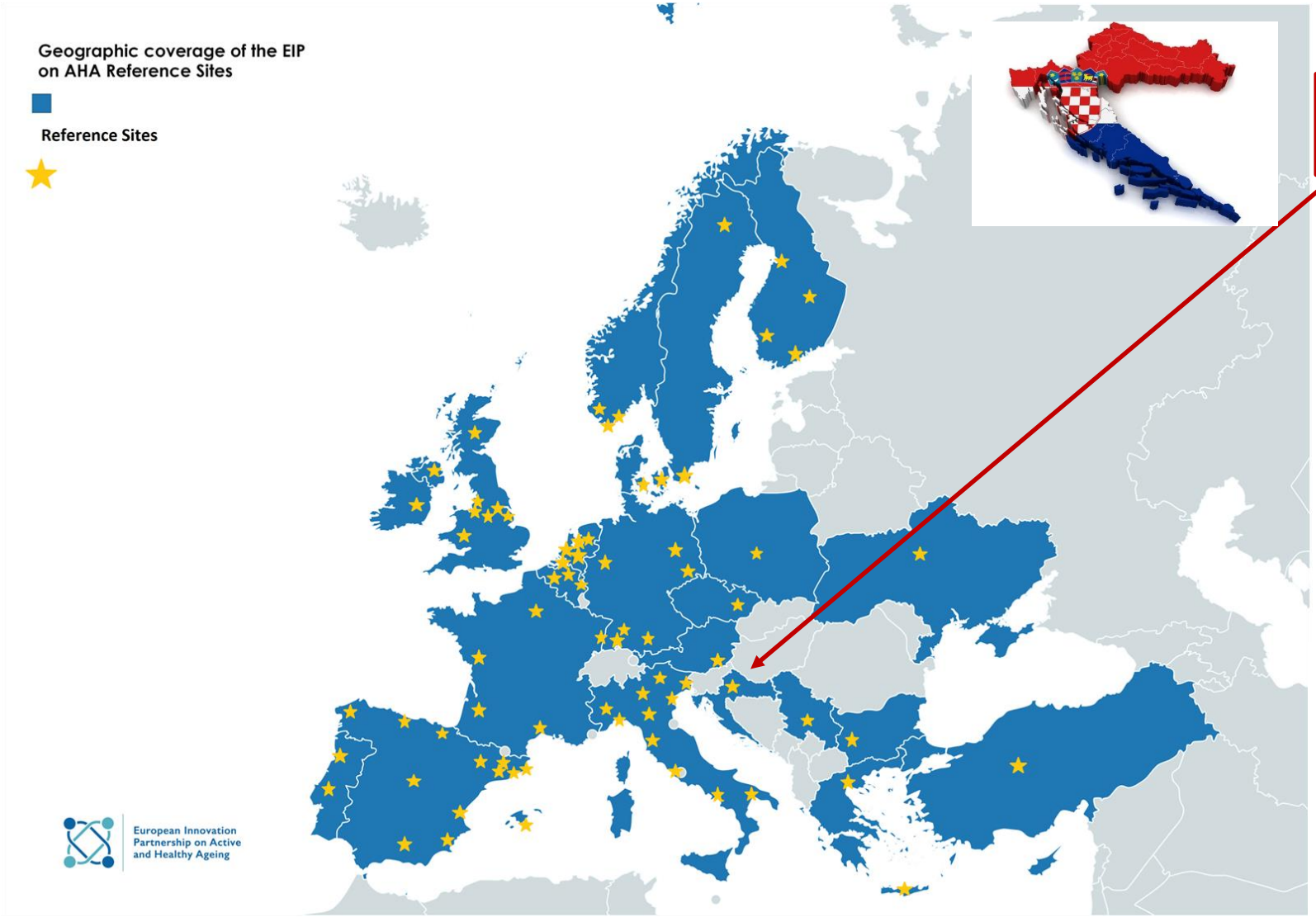
Brussels, 7th December 2016

„City of Zagreb" - Reference Site since 2016

European Innovation Partnership on Active and Healthy Ageing
REFERENCE SITE

INTRODUCTION

CITY OF ZAGREB (CROATIA)



The global ageing phenomenon…

- Challenging problem - reshaping peoples living, spending, needs…
- We live in an increasingly complex and hyper-connected world - it requires **new partnerships**
- Nobody cannot do this alone (the Commission, Governments, Cities…), neither can private companies
- It has to be a **joint effort between all stakeholders**, both in the public and the private sector

- Like other societal challenges - it calls for cooperation and investment across administrative and economic silos
- When in a crisis the best option is **to innovate** in the way
  - deliver services
  - address unmet needs
  - cooperate
  - invest in our future

RS GOALS

REFERENCE SITES COLLABORATIVE NETWORK

- The RSCN is a non-profit association, based in Brussels, that **creates synergies and shares experiences** between Reference Sites
- The Network aims to **identify evidence-based good practice** in Health and Care strategies and policies and service delivery models
  - Efficient collection, analysis and sharing of health data

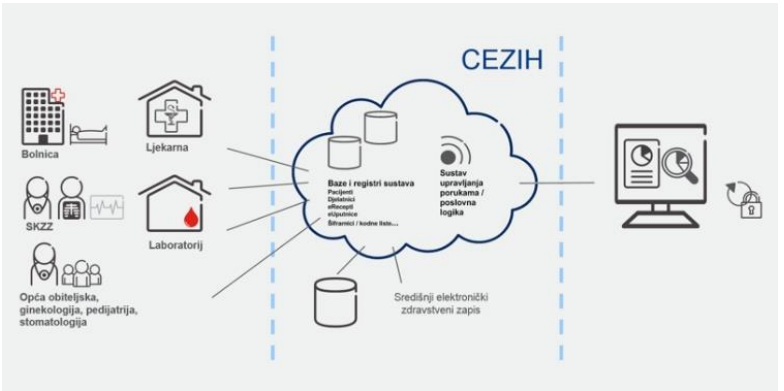
- Although in Croatia there is **single e-Health strategy** that is carried out on national level, **City of Zagreb** has important role in development and testing of e-Health solutions that are in pilot-phase before scaling-up nationwide
  - City of Zagreb can influence the quality and level of services to be implemented nationwide

e-Health solutions:
Scaling-up nationwide

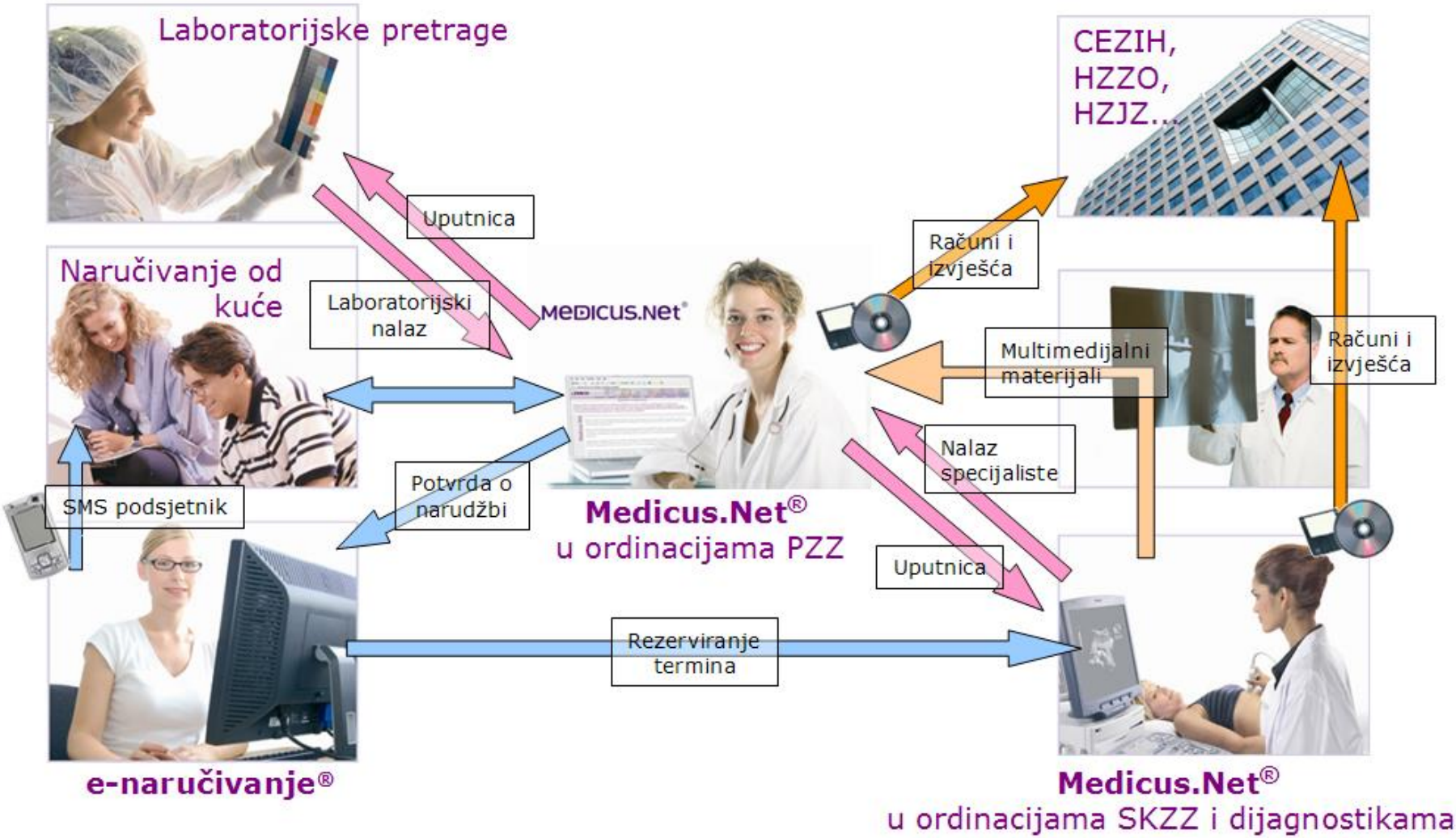
ACHIEVEMENTS

CROATIA – eHealth solutions

- Development of **eHealth solutions** is one of the regional and national priorities reflected in the well-established, **nation-wide** ePrescription system, eHealth Records system (EHR) on the level of primary health care which is currently being expanded to include some secondary health care services (eLab, eAppointment system)
- Implemented software for **preventive activities in EHR** for primary and secondary prevention of chronic diseases - diabetes mellitus, hypertension, COPD, obesity
- GP implemented - rational therapy prescribing for the elderly – named „chronic patient panels“



HCCZ – the benefits of connecting people and devices ...



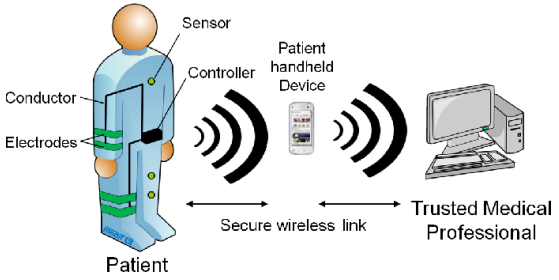
ACHIEVEMENTS

CROATIA – eHealth solutions

- The **electronic monitoring of defined parameters** through a chronic patient panel - alert physicians the importance for prevention, screening and early diagnosing
- Through the panels GP can also evaluate the elderly patients regarding their **adherence to recommended measures** and using prescribed medication in order to prevent their occurrence and progression of disease

mHealth – HCCZ another step…

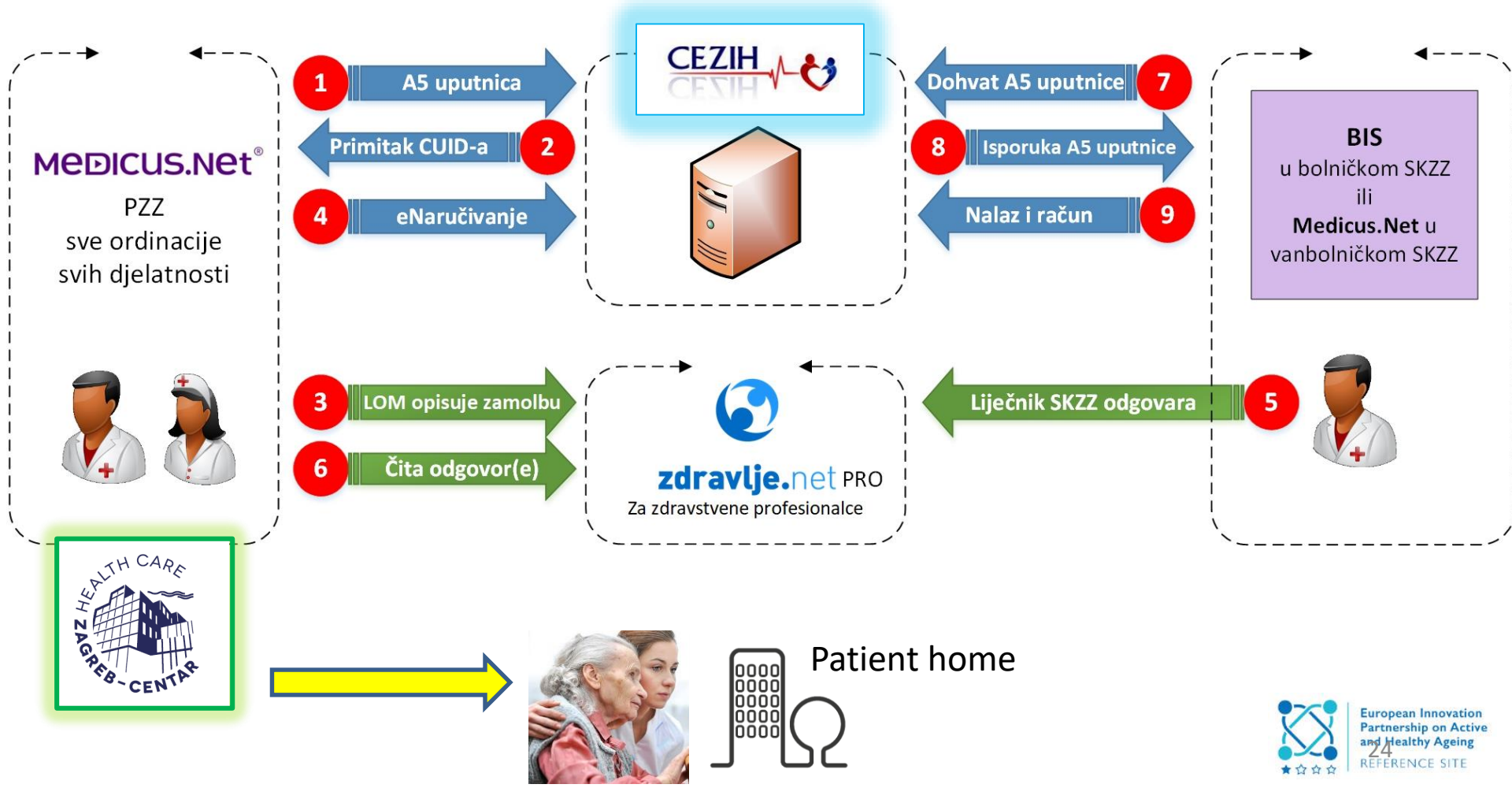
- **AIM**: To motivate elderly (patients, family members, …)
- To raise **creativity and education** among doctors (GP, specialists) and IT inventors



RS ACHIEVEMENTS

HCCZ – eHealth and mHealth solutions

- Business Process Schedule „**zdravlje.net** PRO” (Health.Net PRO)



RS ACHIEVEMENTS

ZAGREB – eHealth and mHealth solutions

- During 2017 HCCZ together with ICT Company developed several **new communication modules (mHealth platforms) built on top of existing EHR:**

1. **„Patient Health Diary“,** for input patients vital signs (blood pressure, heart rate), glucose levels (with defined intake moments – fasting, before meal, after meal…), height/weight values and waist width

   The measurement data is momentarily available in the GPs application within the patient's EHR, so GPs can track their patients' health on daily basis and react immediately if the values are concerning (call the patient in for a check-up, refer him to a specialist) and use it as a prevention tool to engage a patient to keep track of his own health and quality of life

2. **„Health.net“,** a secure web application that enables patient to GP communication in real time, prescription requests, message exchange, booking appointments and delivery of specialist's findings or lab results;

3. **„eConsultations“** for direct cross-specialty medical consultations;

Standard reference model - PC

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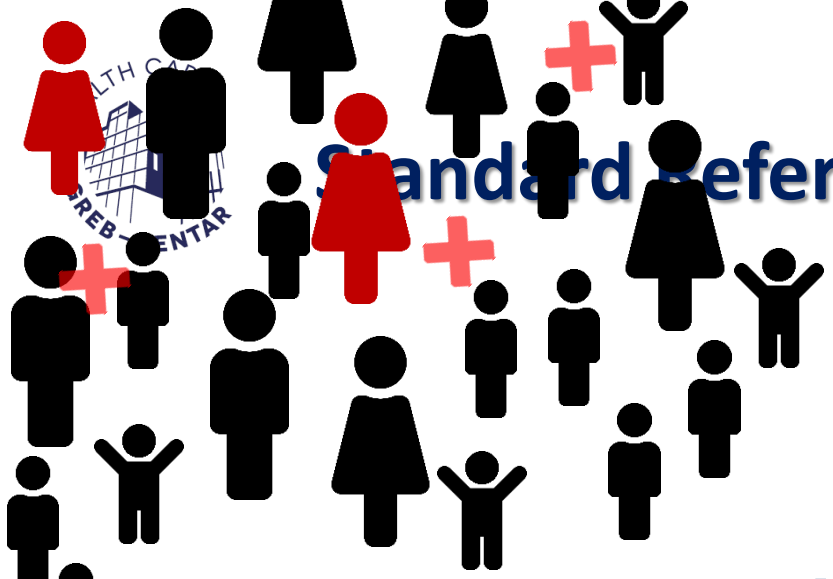
REFERENCE SITE

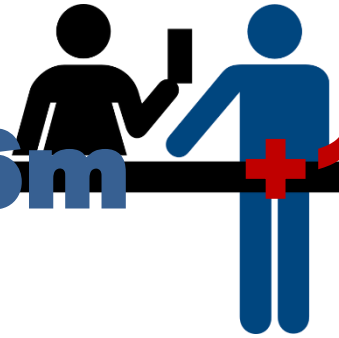
rd Reference model - PC

Standard reference model - PC



+1m

+1.5h



+6m

+12m

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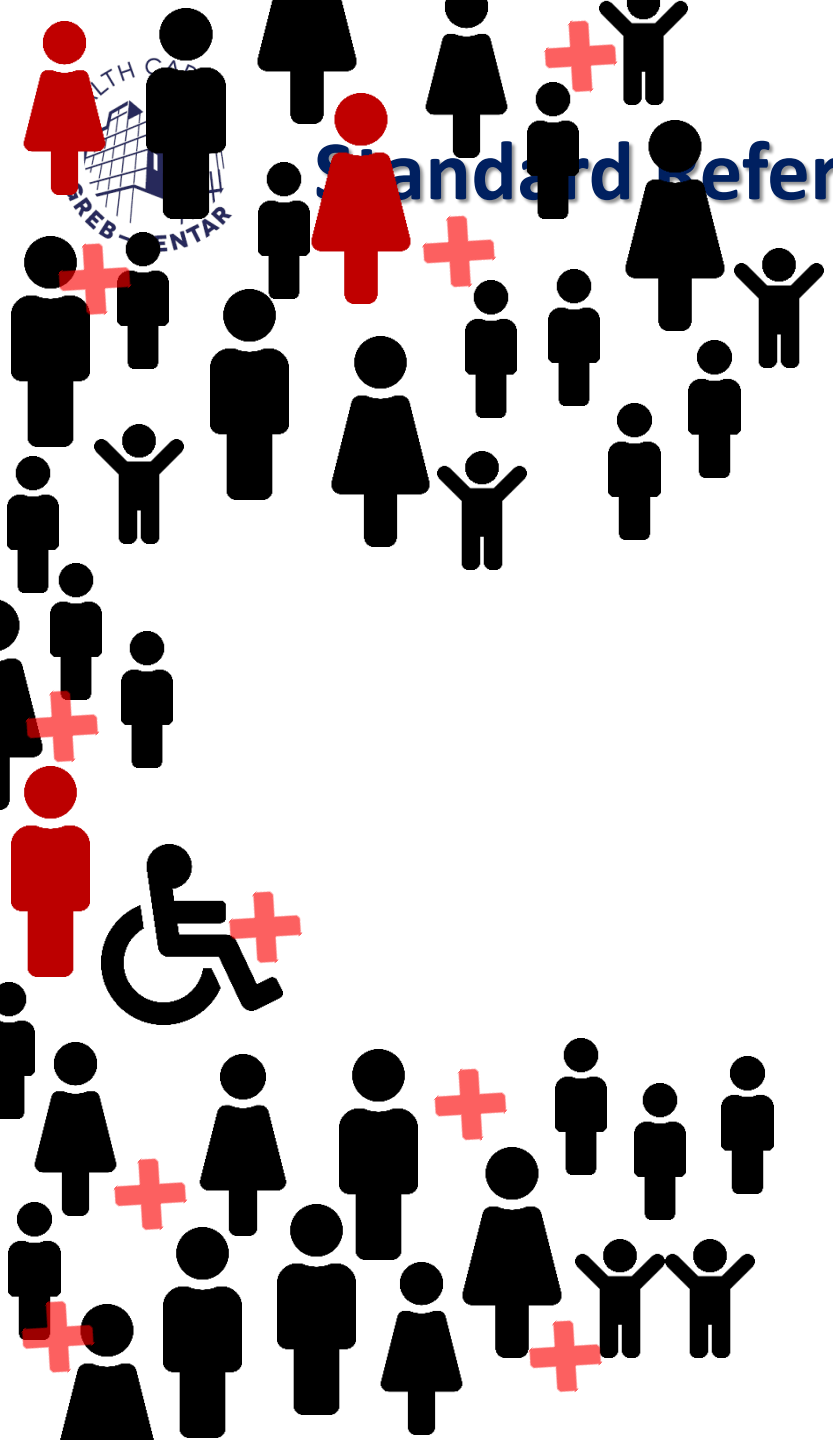
Standard Reference model - PC



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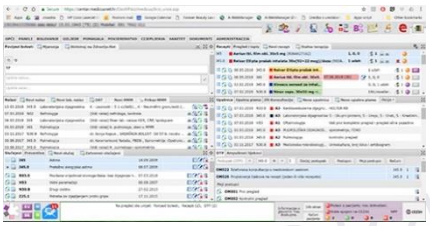
Standard Reference model –unnecessary costs

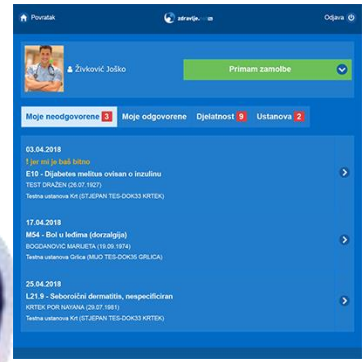
+4h

(+1,5h)

Absence from work - to perform the examination

eConsultations - principles





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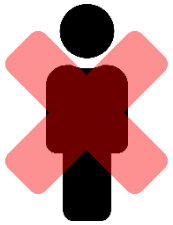
eConsultations - benefits and savings

Patients without the diagnosis



eConsultations - benefits and savings

HCZC:

- 130.000 GP patients
- 4 referrals per patient / year = 520.000 specialist consultation

Savings:

- 20% eConsultation = 104,000 eConsultation / y
- 416.000 hours to patients / y
- 17.500 hours for specialists / y

x 35 for CRO

! Waiting lists reduced !

European Innovation Partnership on Active and Healthy Ageing
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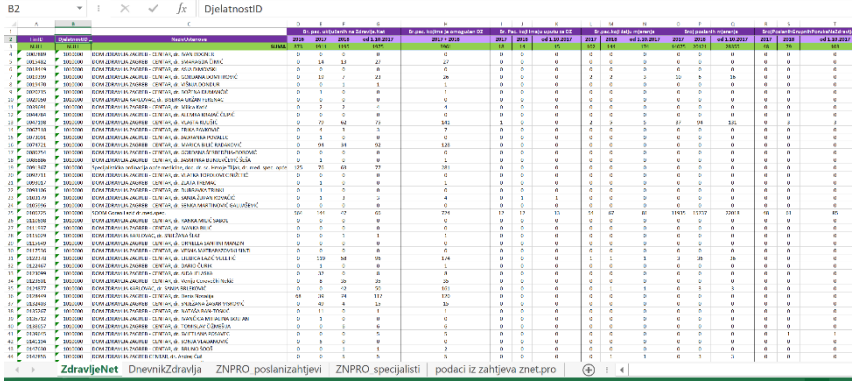
eConsultations - Obstacles



Results (literature and our experience) show that:

- **Readiness issues** have been ubiquitous across macro, meso, and micro levels and across sectoral boundaries: market, policy, organizational, professional, and patients
- These issues are not invincible challenges but their existence does need **to be acknowledged** and **addressed** if deployment at scale to the widest population is to be realized.

European Innovation Partnership on Active and Healthy Ageing
REFERENCE SITE

Mobile portal for patients „zdravlje.net PRO” (Health.Net PRO)

14/9/2018 Statistics:

- Patients enabled to participate in Health.Net PRO = 3961
- GP actively involved in HCCZ = 70/101
- Specialist actively involved = 33
- Hospitals = 4
- Medical area = 15
- Messages exchanged with patients = 174
- Measurements (blood pressure, heart rate, glucose levels, height/weight/waist) = 28.355
- eConsultations - GP to specialist = 29

eConsultations – obstacles and recommendations

Journal of Medical Internet Research ISSN 1438-8871
The leading peer-reviewed journal for health and healthcare in the Internet age
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J Med Internet Res. 2017 Feb; 19(2): e42. PMCID: PMC5334516
Published online 2017 Feb 16. doi: 10.2196/jmir.6900 PMID: 28209558

Readiness for Delivering Digital Health at Scale: Lessons From a Longitudinal Qualitative Evaluation of a National Digital Health Innovation Program in the United Kingdom

Monitoring Editor: Gunther Eysenbach

Reviewed by Carolin Auschra, Suzanne Clough, and Ilaria Montagni

Marilyn R Lennon, BSc, PGDip, PhD,[1] Matt-Mouley Bouamrane, PhD,[1] Alison M Devlin, BSc (Hons), PhD,[2] Siobhan O'Connor, RN, BSc, CIMA CBA,[3] Catherine O'Donnell, BSc (Hons), MPH, FHEA, PhD,[4] Ula Chetty, BSc, MRCGP, MBChB, MRCP,[2] Ruth Agbakoba, MSc, B Sc (Hons),[2] Annemieke Bikker, MSc,[2] Eleanor Grieve, BA (Hons), MPH,[4] Tracy Finch, BA (Hons), PhD,[5] Nicholas Watson, BSc (Hons), MSc, PhD,[6] Sally Wyke, FRSE, FRCGP, PhD, B Sc (Hons),[5] and Frances S Mair, FRCGP, DRCOG, MD[2]

Table 4

Recommendations for future implementation work in digital health.

Recommendation no.	Recommendation
Recommendation 1	Further commitment and investment in both national and local infrastructure will be required if digital health care is to become normalized.
Recommendation 2	Guidance relating to ownership and control of personal health data and data privacy regulations are required to mitigate current uncertainty in the digital health arena.
Recommendation 3	Brand trust and confidence is crucial. Accreditation and official endorsement of products and services is an important determinant of future successful deployment of digital health services as is peer recommendation for consumer wellness products. Clear systems to facilitate trust and confidence need to be put in place.
Recommendation 4	Technical and service interoperability needs to be prioritized and, if necessary, incentivized to ensure the scaling up of digital health care across systems and sectors.
Recommendation 5	Future digital health services need to be more accessible by those who are currently socially or economically excluded including those whose first language is not English, and those with sensory, physical, or cognitive impairments.
Recommendation 6	There is a need to invest in further awareness raising, upskilling of consumers and more affordable and accessible technologies if the true potential of digital health and wellbeing technologies are to be fully realized and the concept of professional and lay champions to promote technologies and services merit support.
Recommendation 7	More extensive and intensive public engagement and debate on the subject of the risks versus benefits of digital health needs to be undertaken to address concerns around security and safety of digital health and wellness products and services.
Recommendation 8	Greater emphasis needs to be placed on both upskilling and also ensuring the next generation of health professionals are more "digitally" able. Digital health care needs to be a feature of undergraduate health professional training.
Recommendation 9	Guidance is required to shape and support a market that spans consumer wellness and statutory health services. Consideration must be given to future funding models, procurement, and the potential for hybrid data, including sharing, storage, and management models that permit digital health apps and services to be taken up and used via consumer markets and/or statutory channels.
Recommendation 10	There is a need to promote health care stability and a culture of long term planning. Instability and constant change can be a deterrent to investment and hinders implementation in the digital health sphere.

Key words:

Commitment

Investment

Guidance

Brand trust

Confidence

Interoperability

Accessible

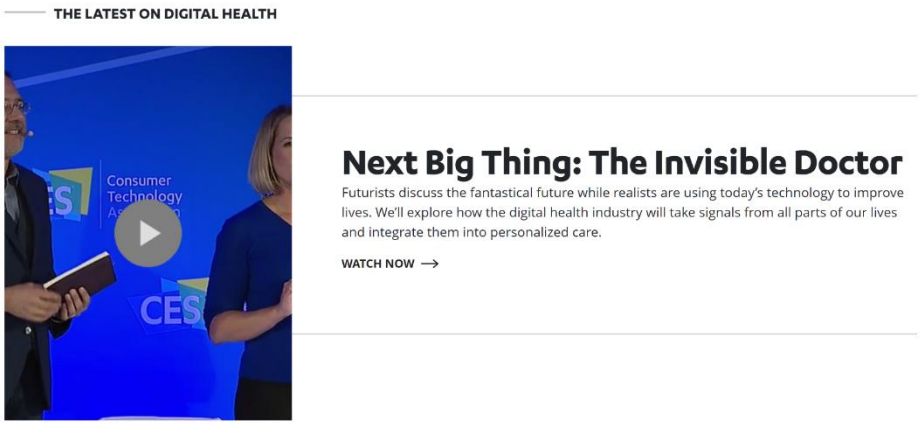
Awareness

Public engagement

Health care stability - culture of a long term planning

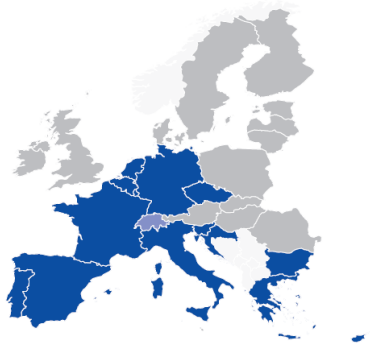
E-HEALTH

OPPROTUNITIES OR THREATS TO QUALITY?



INVESTING IN SUPERCOMPUTING – THE EUROHPC JOINT UNDERTAKING

The Commission will invest jointly with the Member States in **building a world-class European supercomputers infrastructure**. Joining forces at European level for **processing big data** is critical to meet the growing demands of our economy and society. Supercomputers will help to improve our citizens' lives significantly, be it for better healthcare, higher car safety, optimised energy consumption, or fight against climate change.



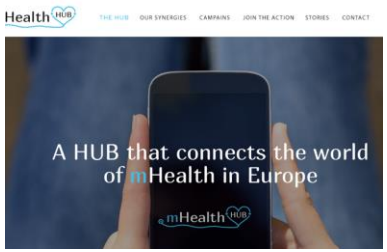
14 Member States

Belgium, Bulgaria, Czech Republic, Germany, Greece, Spain, France, Croatia, Italy, Cyprus, Luxembourg, the Netherlands, Portugal, Slovenia and Switzerland*

EU mHEALTH HUB

Horizon2020: WHO - ITU joint initiative

- **mHealth HUB - to support services for EU countries and regions for deploying and scaling up mHealth programs:**
  - Exploring mHealth program opportunities;
  - Support to establishing with key stakeholders
  - Planning mHealth program implementation;
  - Integrating mHealth solutions with eHR
  - Building Open Data models
  - Monitoring and evaluating mHealth programs
  - Data security control and legal framework for the mHealth use



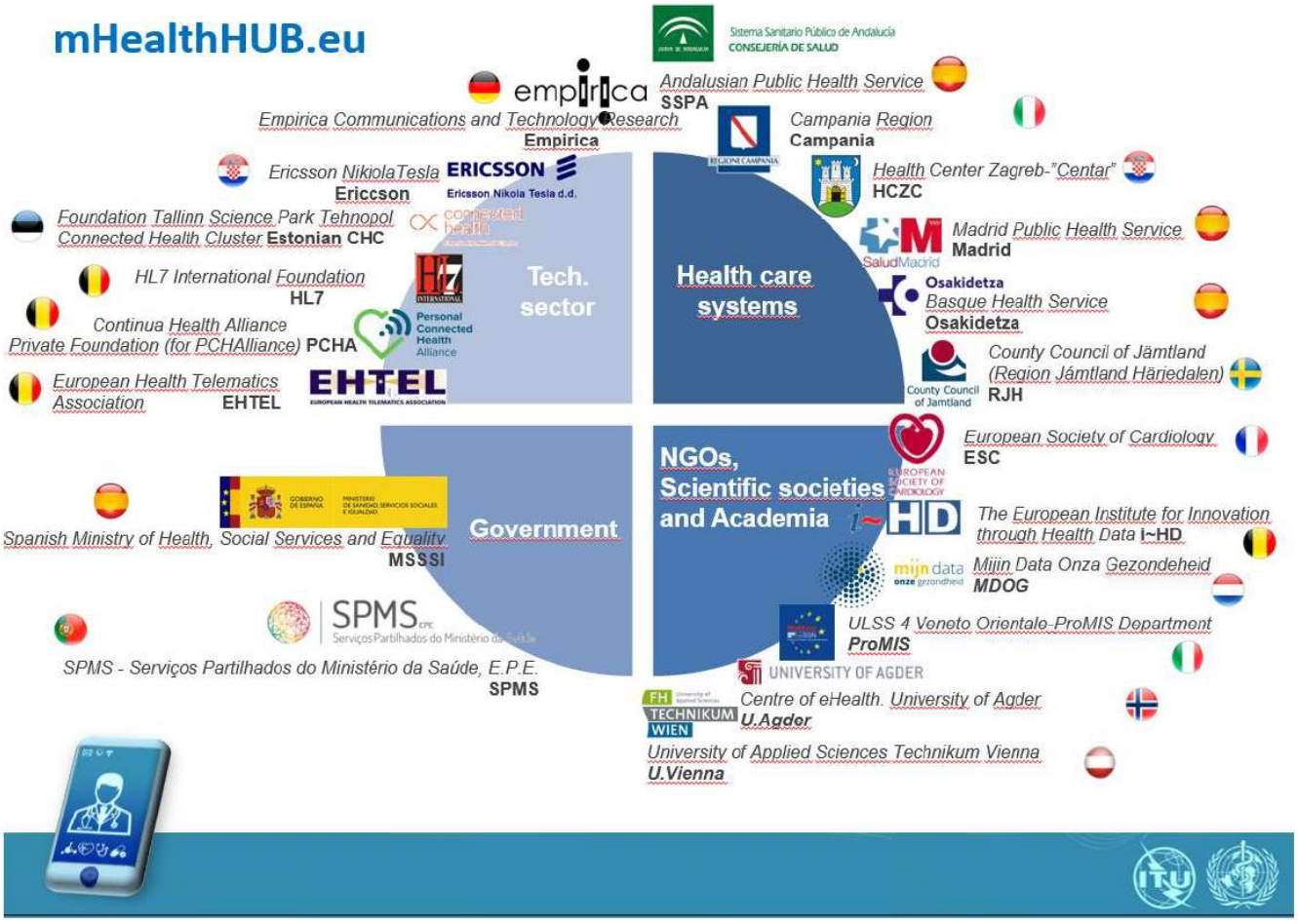
11/2017 We successfully passed the pre-qualification stage

10/2018 Waiting for the official public announcement ☺ **WINNERS!**

European Innovation Partnership on Active and Healthy Ageing
REFERENCE SITE

mHealth Hub – EU 2018

- The Consortium holder – Spain (Sevilla) – Andalusian Public Health Service



CONCLUSION

ICT support in primary medicine

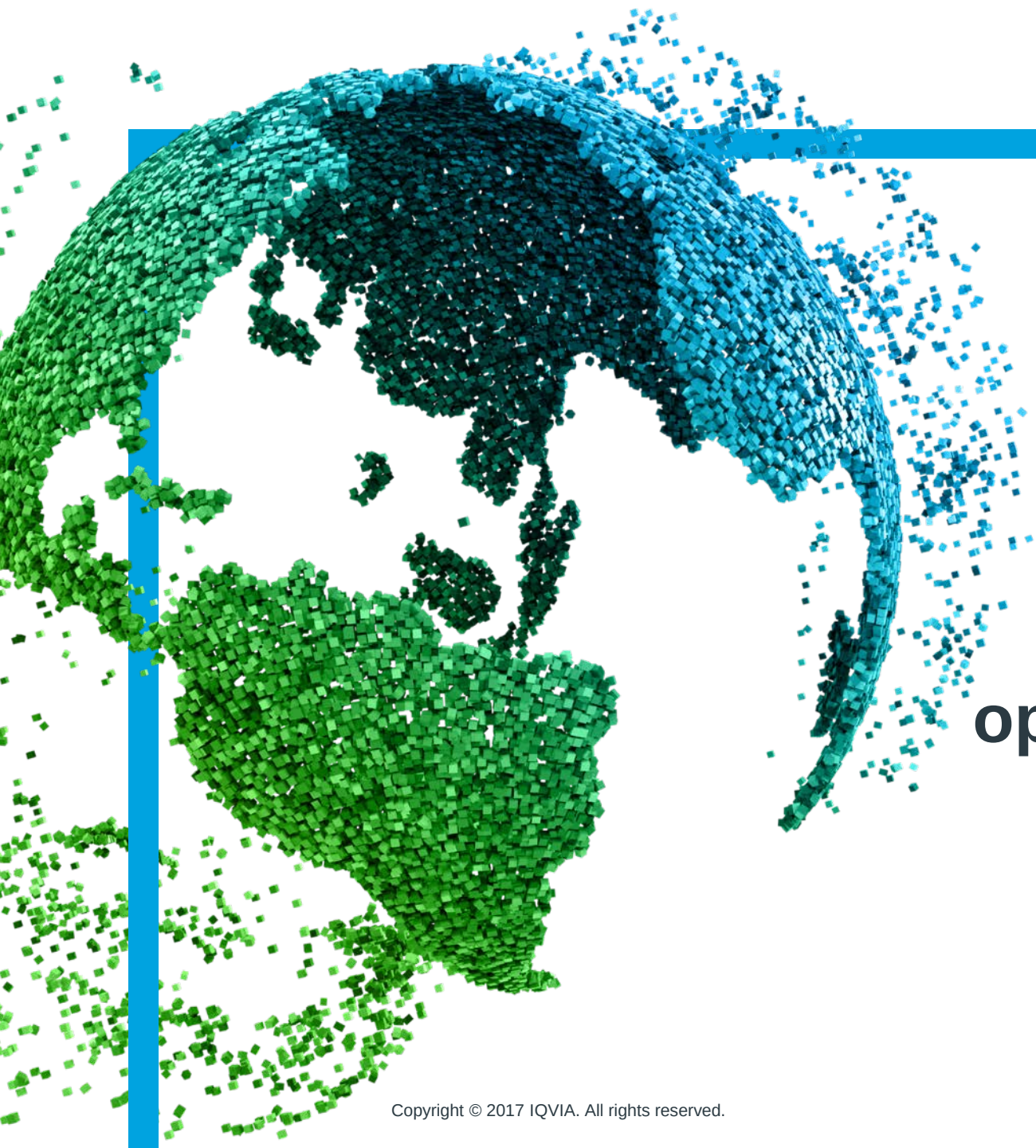
Although there is receptiveness to digital health, barriers to mainstreaming remain:

- Greater investment in national and local infrastructure
- Implementation of guidelines for the safe and transparent use and assessment of digital health
- Incentivization of interoperability
- Investment in upskilling of professionals and the public would help support the normalization of digital health
- Prepare the market and accelerate use of digital health and wellness services in proper context and at scale

Researchers, health care practitioners, patients and policy makers – all have to understand the current landscape and the actions required - in order to benefit from ICT in healthcare

Thank you!

European Innovation Partnership on Active and Healthy Ageing
REFERENCE SITE



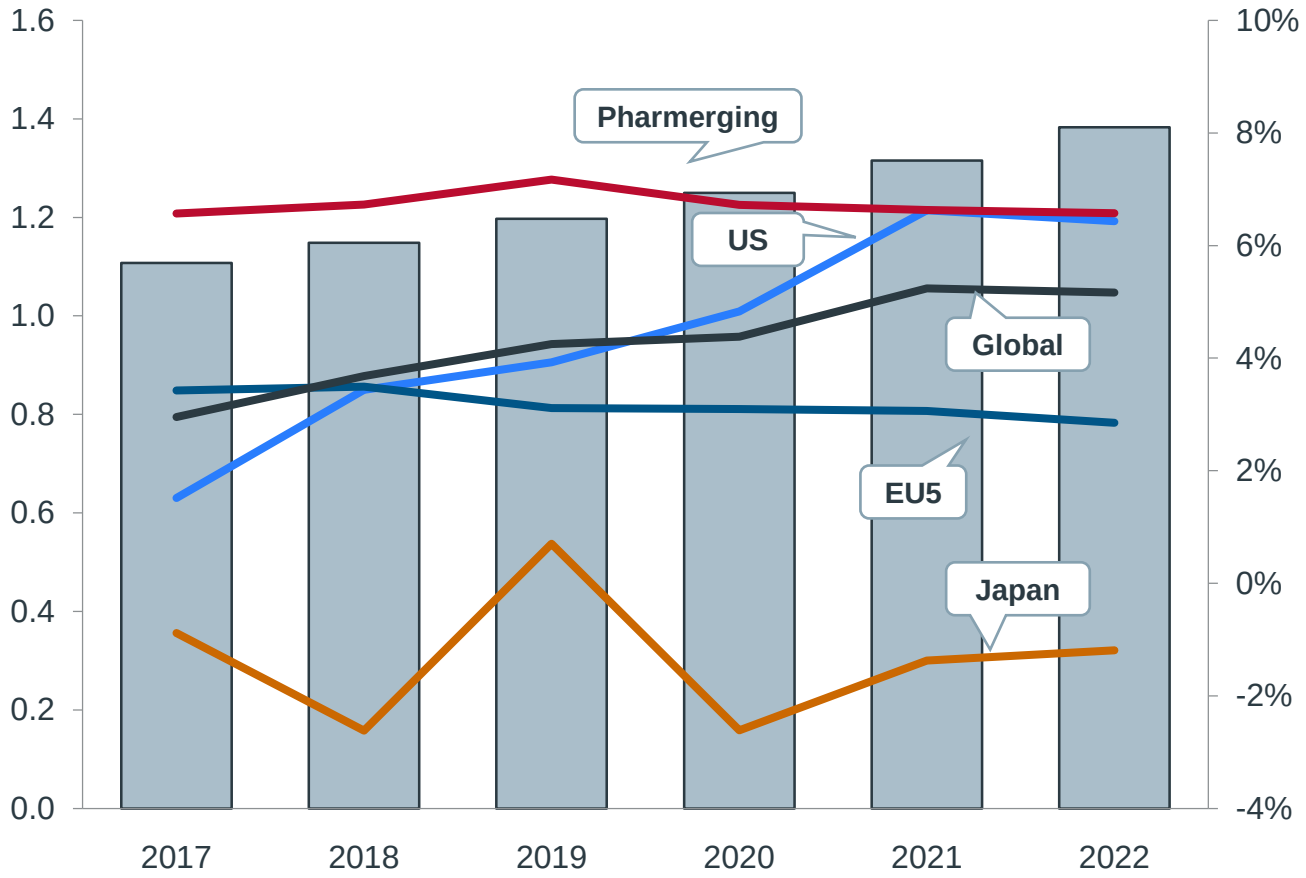
IMS Health & Quintiles are now IQVIA™

The increased biosimilare competition – is it an opportunity for the Region?

Per Troein, VP Strategic Partners, IQVIA

Global pharma to grow at 3-6% CAGR to 2022: 2-5% at net prices

Global sales (2017-22) Tn US$



Notes: *Subject to PPRS rebate; Ex-manufacturer price levels, not including rebates and discounts. Contains Audited + Unaudited data; Growth considered on par if the there is overlap between country and region CAGR ranges
Source: IQVIA Thought Leadership Analysis; Market Prognosis March 2018

The key drivers of growth

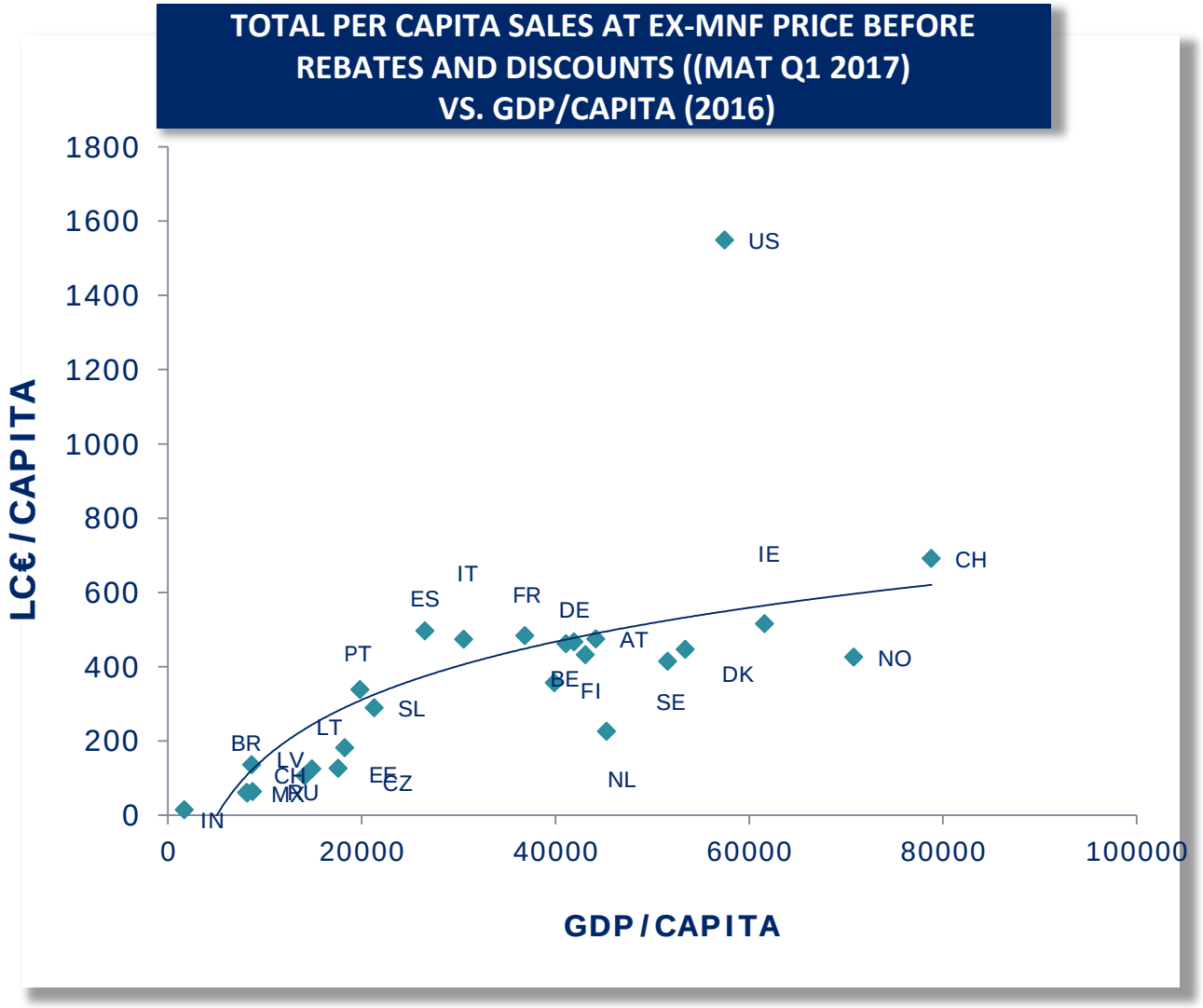
- **Under-served markets;** still, only about 10% of the Global population (largely North America, Europe, Japan, and Australia) have good access to drugs. Other markets tend to have pockets of populations with limited access.

- **Population growth, aging and more chronic diseases;** the Global population continues to grow, the population is growing older especially in certain regions and the older population have more treatment needs. In addition, today we have more chronic diseases (through a combination of lifestyle issues and better management of diseases, e.g. HIV).

- **New treatments for unmet needs;** research continues to bring treatments to areas that previously lacked treatment options. Many of the medicines that have recently come to the market have been focused on more severe conditions, for very small population groups.

- **Price development;** the price development for a given drug has significant impact on the overall growth. Competition after patent expiration has significantly lowered value growth in most markets. However, some markets, most notably the US, have also seen price increases on existing drugs.

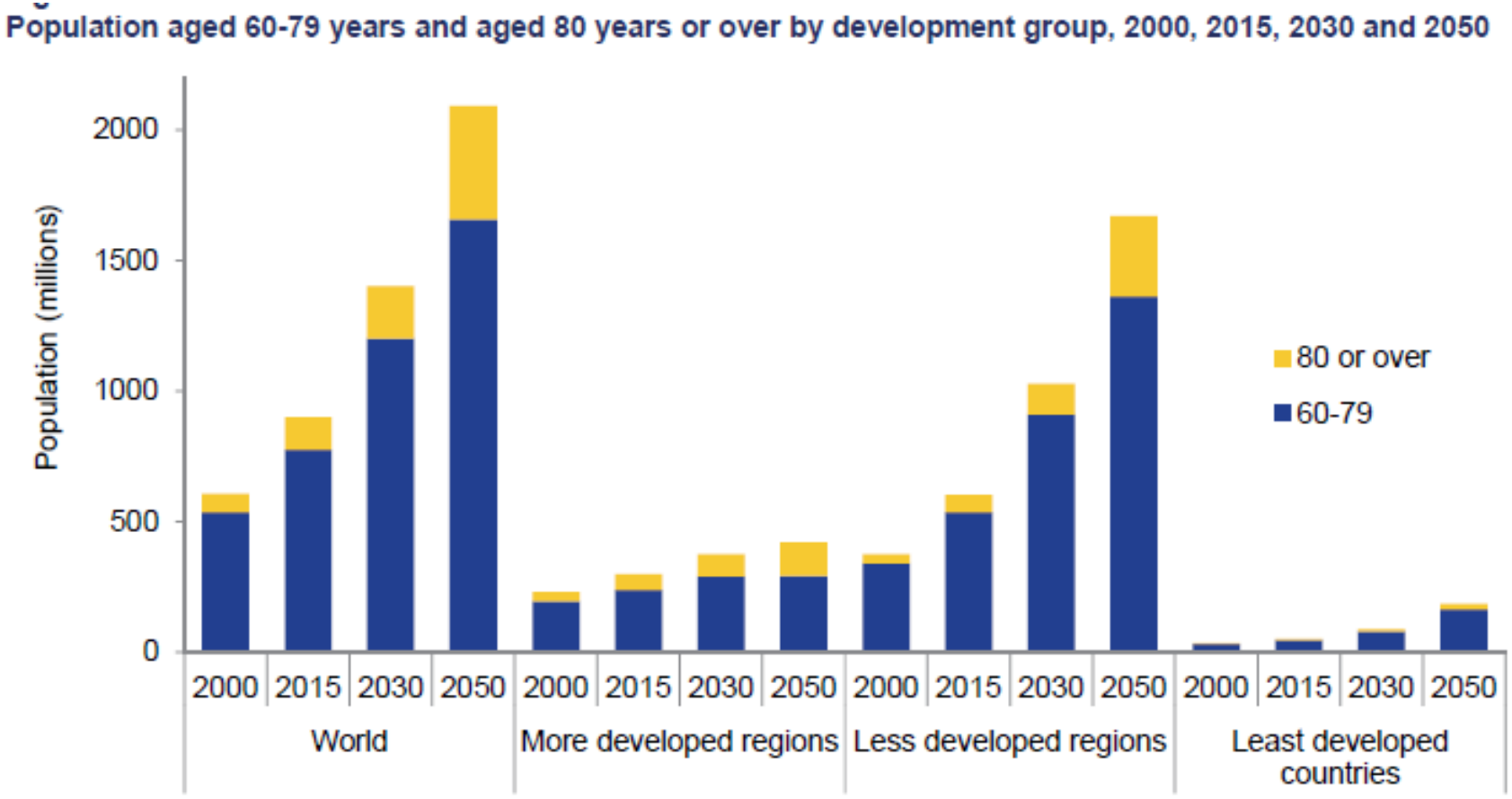
Pharmaceutical spend closely linked to GDP



- The amount spent on pharmaceuticals is linked to the GDP per capita
- As GDP/capita grows, pharmaceutical spend also grows
- Very low GDP countries spend a very low share on pharmaceuticals
- At a certain level, the increase needs to decline

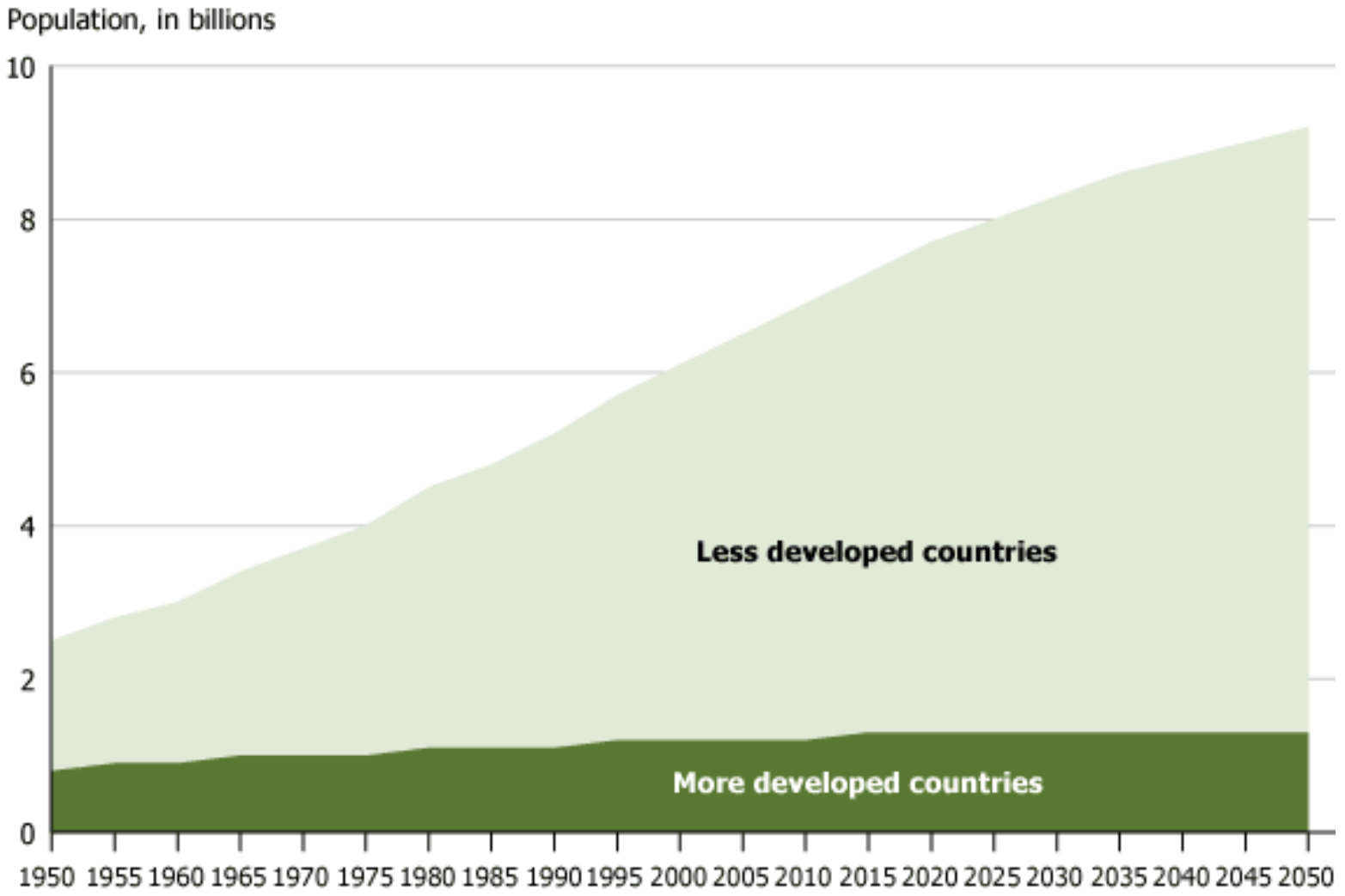
Source: IQVIA MIDAS MAT Mar 2017; Total audited market, Rx only; Population and GDP/Capita numbers from World Bank

The number of older people grow significantly



Data source: United Nations (2015). *World Population Prospects: The 2015 Revision.*

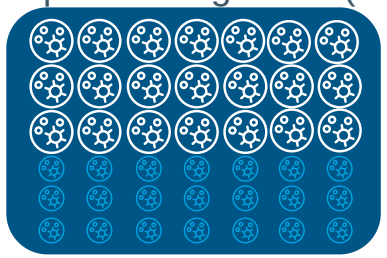
Significant population growth in less developed countries



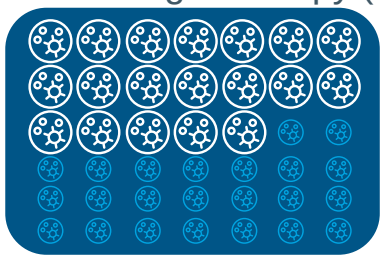
Last Year's Therapeutic Innovation Characteristics

Characteristics of 2017 New Active Substances

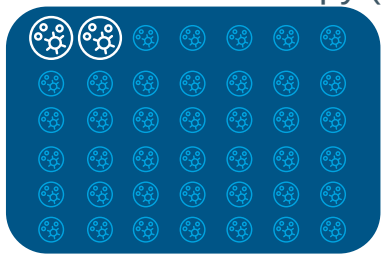
Orphan Designation (21)



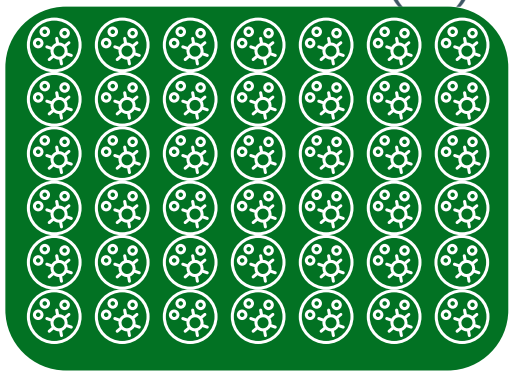
Breakthrough Therapy (19)



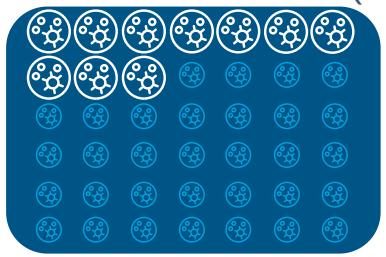
Cell or Gene Therapy (2)



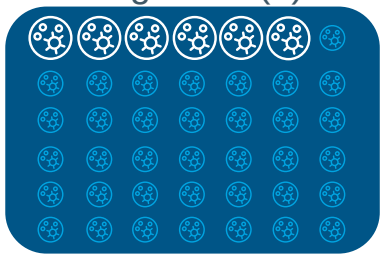
NAS Launches (42)



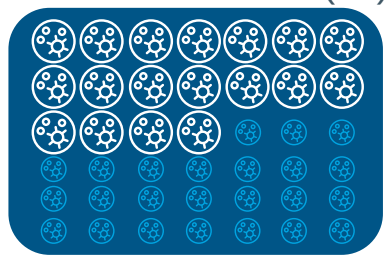
Predictive Biomarker (10)



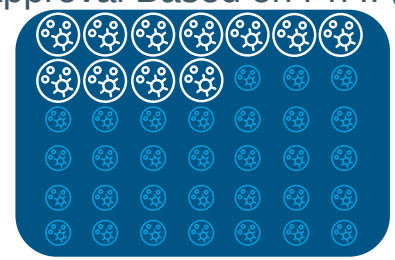
Companion Diagnostic (6)



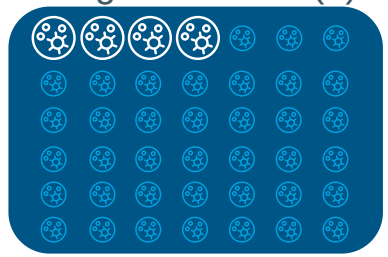
PRO Data on Label (18)



Approval Based on Ph II (11)



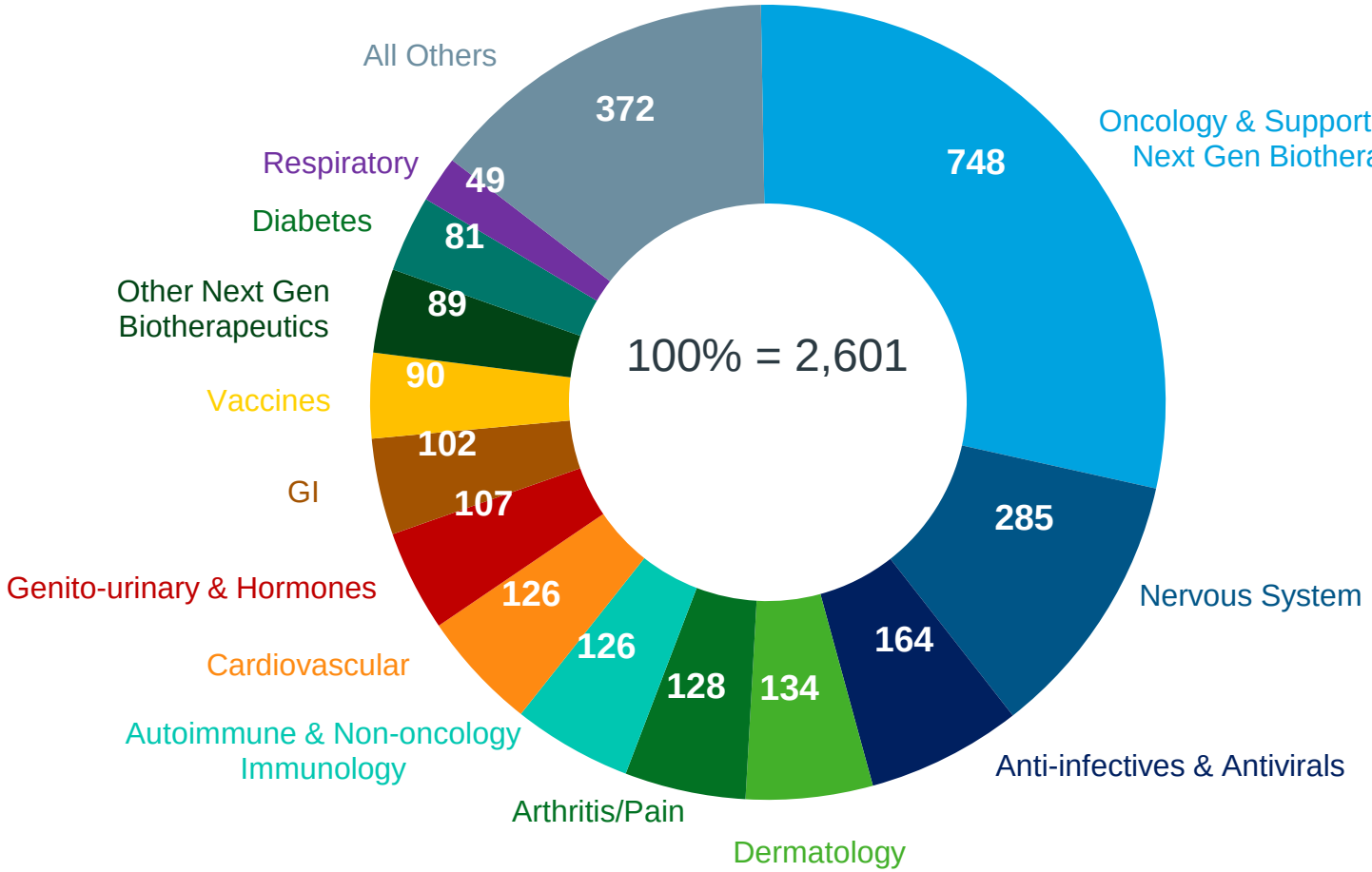
Single Arm Trial (4)



Source: IQVIA Institute, Mar 2018

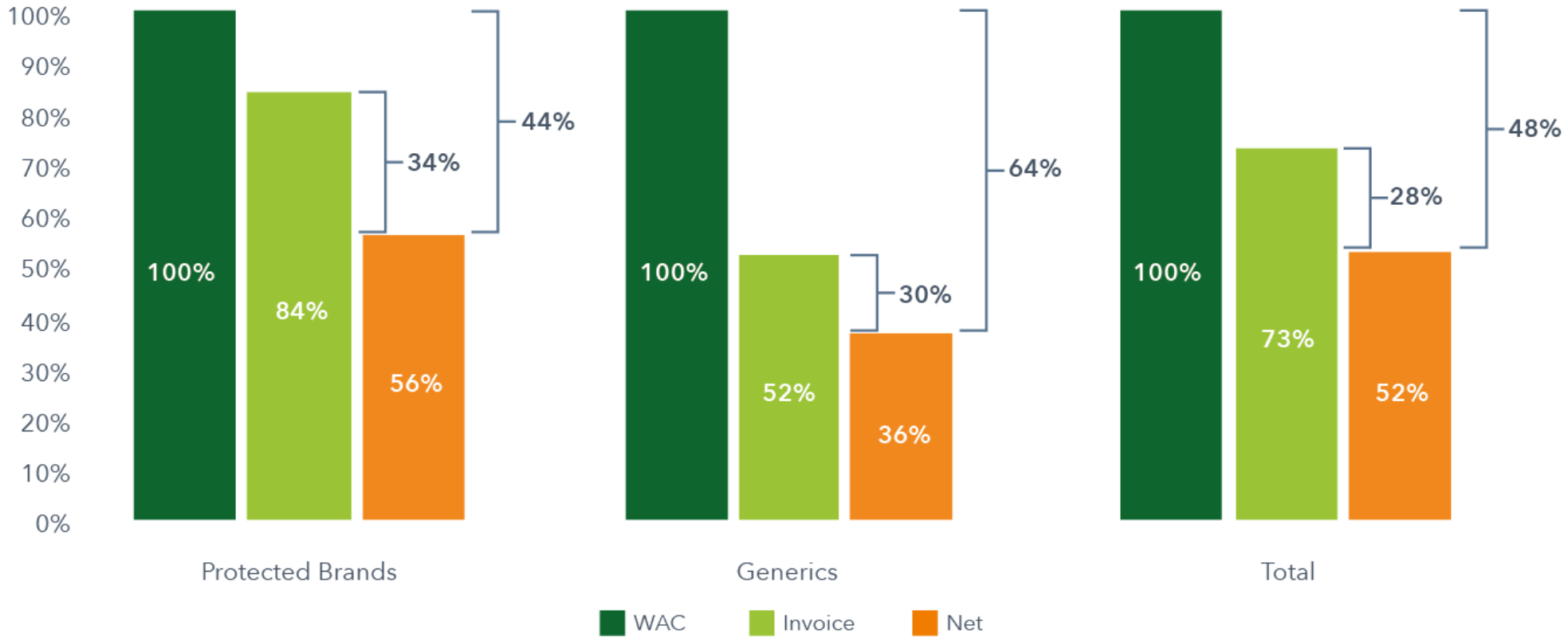
The Late Phase R&D Pipeline Composition

Late Phase R&D Pipeline by Top Therapy Areas



Source: IQVIA Institute Global Oncology Trends 2018: Innovation, Expansion and Disruption, May 2018

For all medicines, average payer rebates were 48% of Gross Sales in 2017



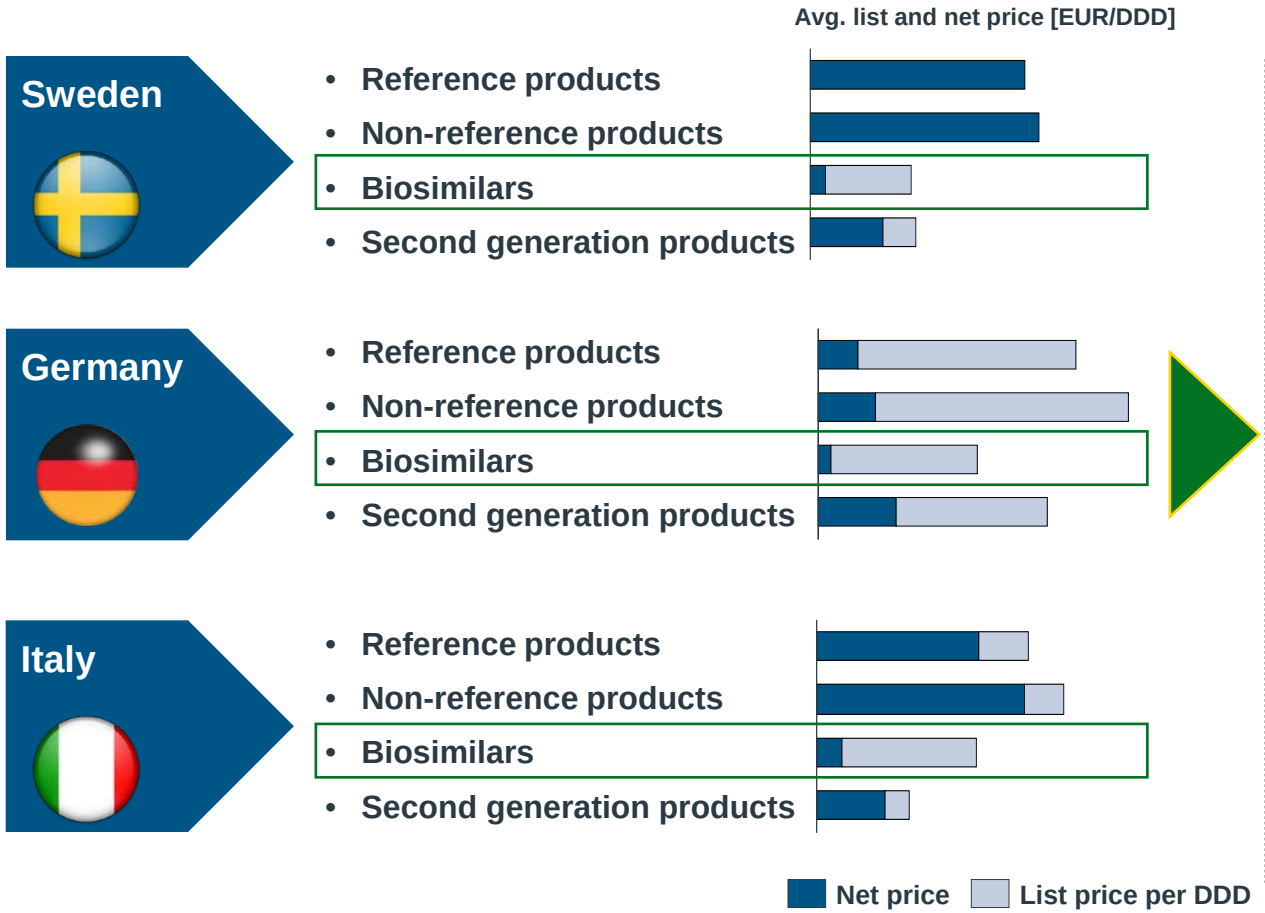
Source: IQVIA Institute; IMS MIDAS; National Sales Perspectives; Public Company SEC filings, Dec 2017
Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018

…. also rebates in Europe can be high

- IQVIA's assessment of total level of rebates benefitting the payer in selected countries (total market/all products)
  - Italy – 36%
  - Germany – 24%
  - Netherlands – 9%
  - Belgium – 11%
  - Sverige – 5%
  - Denmark – 18%
  - Norway – 16%

Price development

Biosimilars are sold to highly rebated prices in all markets – but 2nd generation products are also rebated

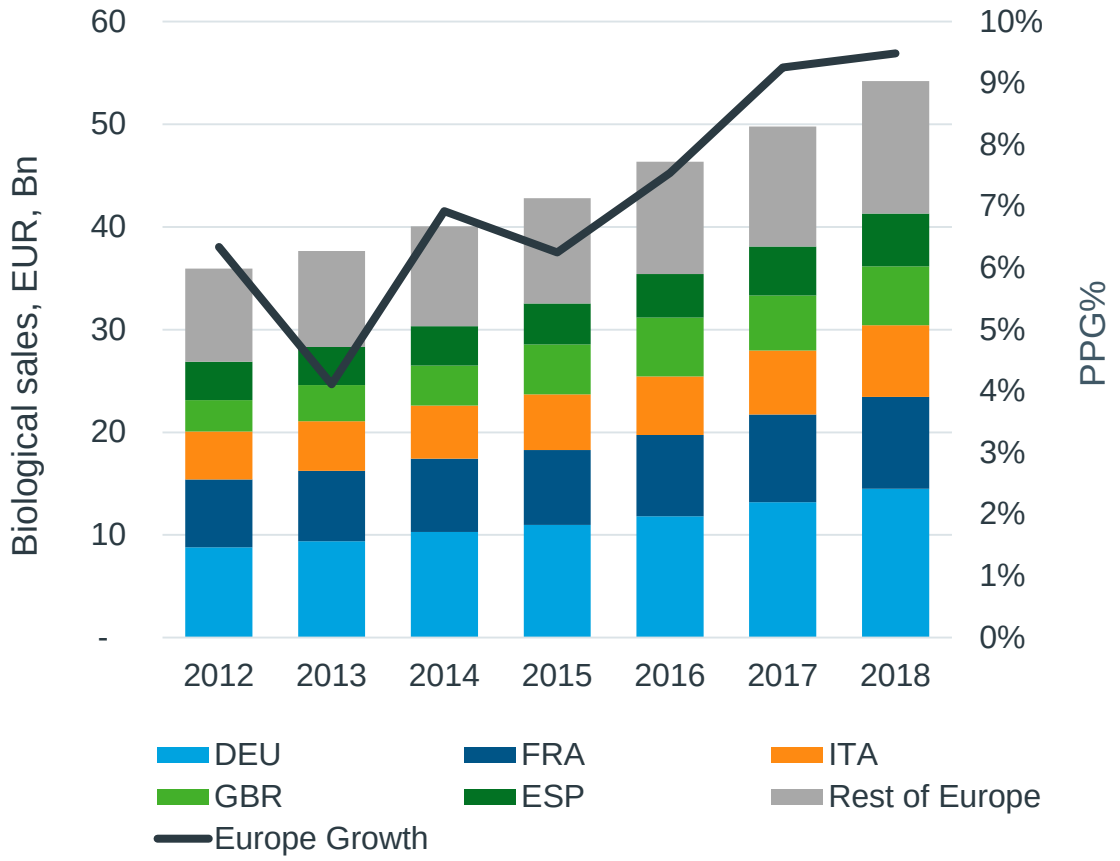


- The originator has focused the defence on switching users to second generation and it is also where the rebates has been given
- The competion has been fierce and Biosimilar discounts can be 80-90%
- The net prices are actually fairly similar
- Markets illustrate that even if high rebates are available in a market, this doesn't always determine the highest sales market share

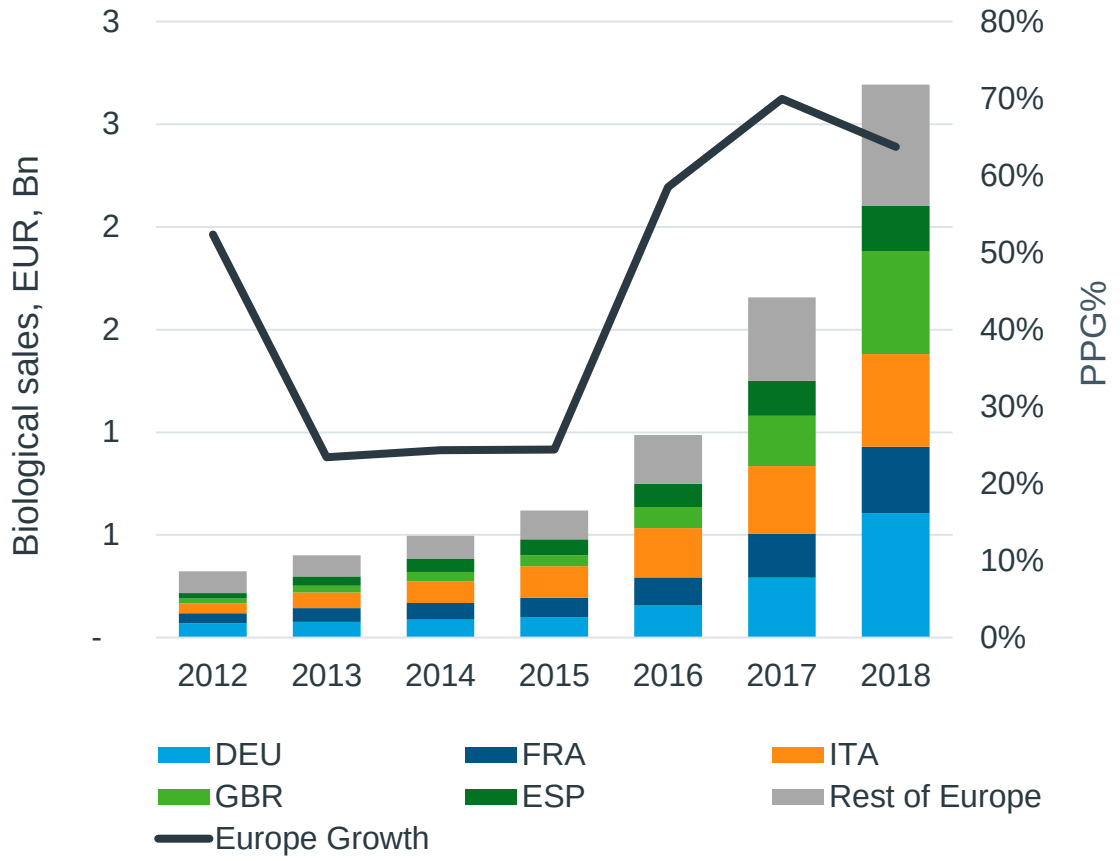
Source: QuintilesIMS Consulting: Q1 2017

Biologics account for ~30 % of European sales. Biosimilars only account for 5.0% of biologics in Europe

Europe biologic market dynamics, €54Bn



Europe biosimilar market dynamics, €2.7Bn

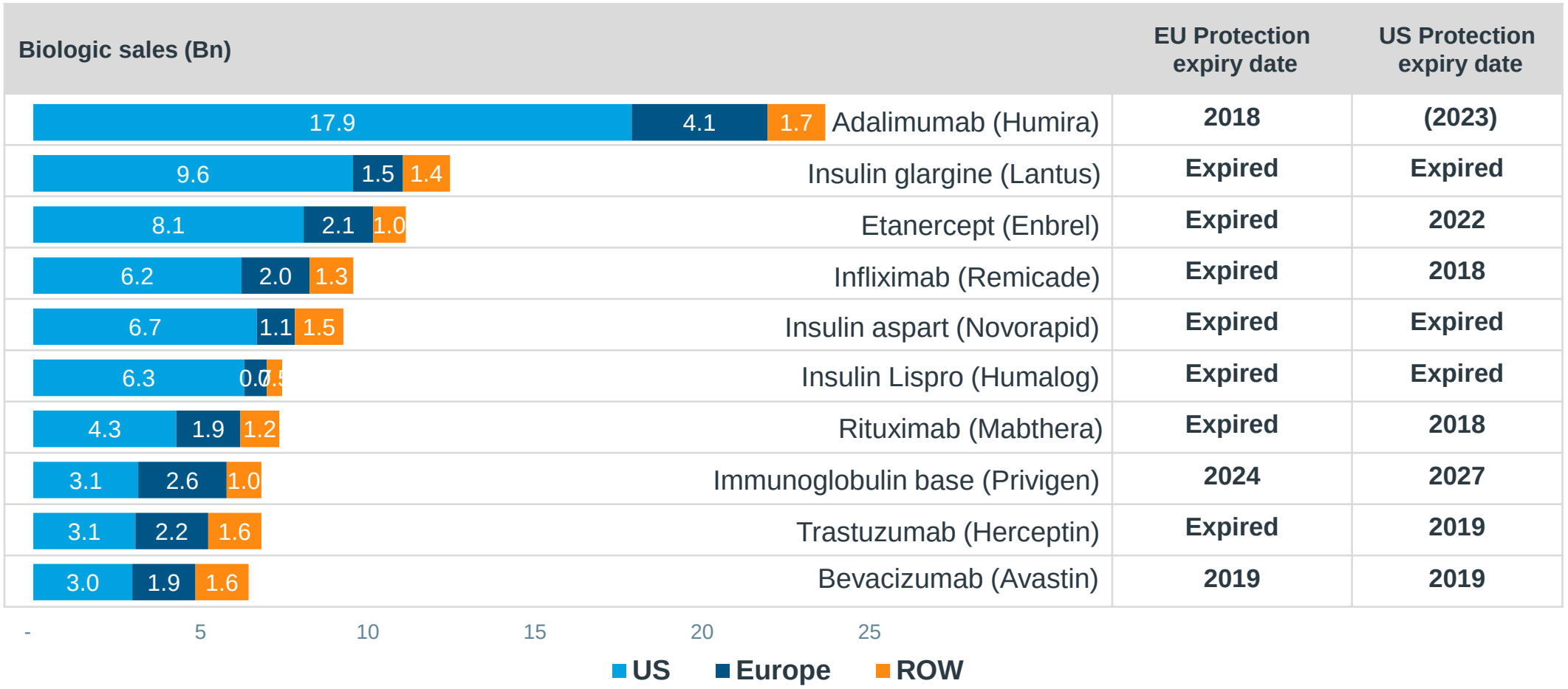


Source: IQVIA MIDAS MAT Q1 2018. Europe = European Economic Area (excludes Turkey, Russia etc.)

Important Biologics have already lost or are about to lose exclusivity

Global Top 10 Biologics Sales

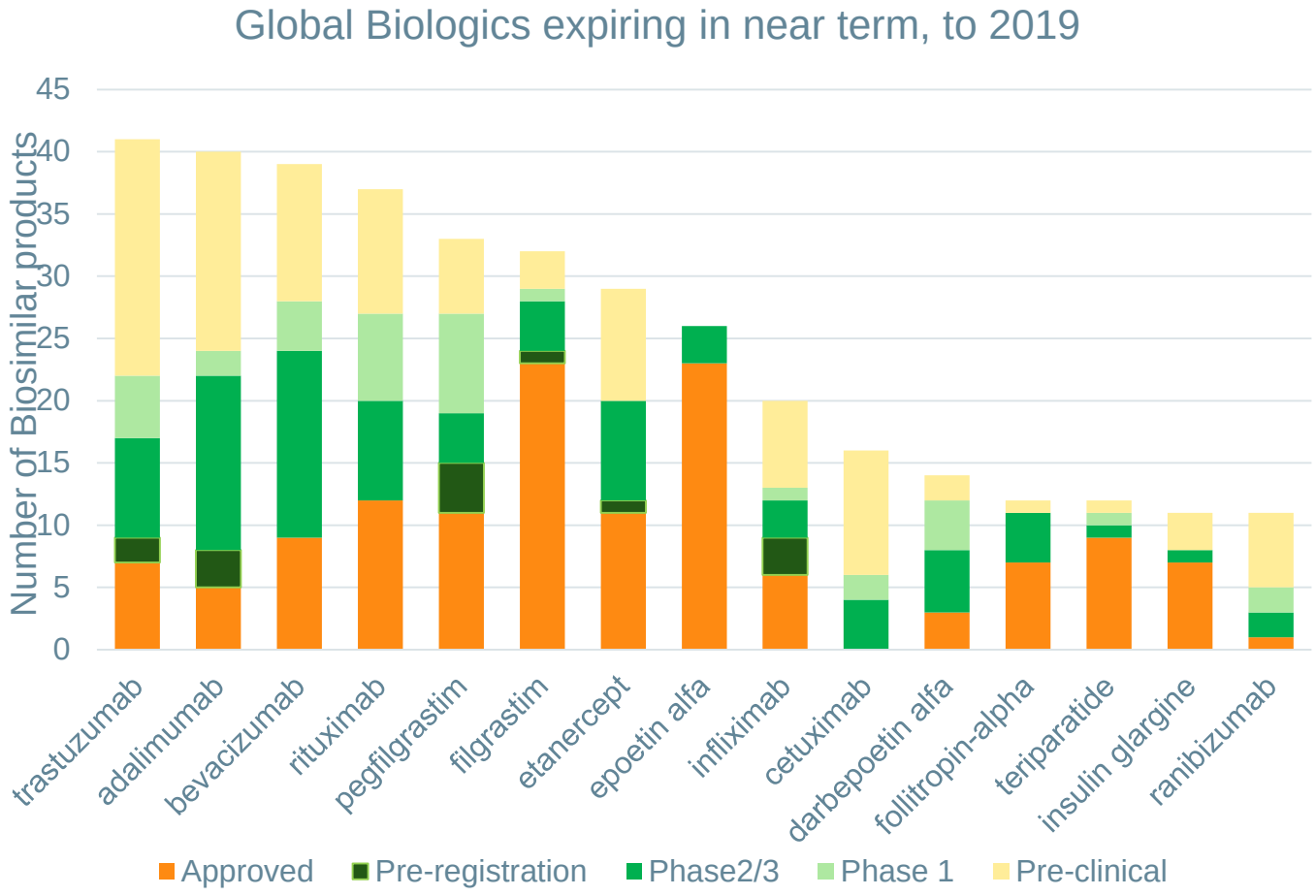
US$ MAT Q1 2018

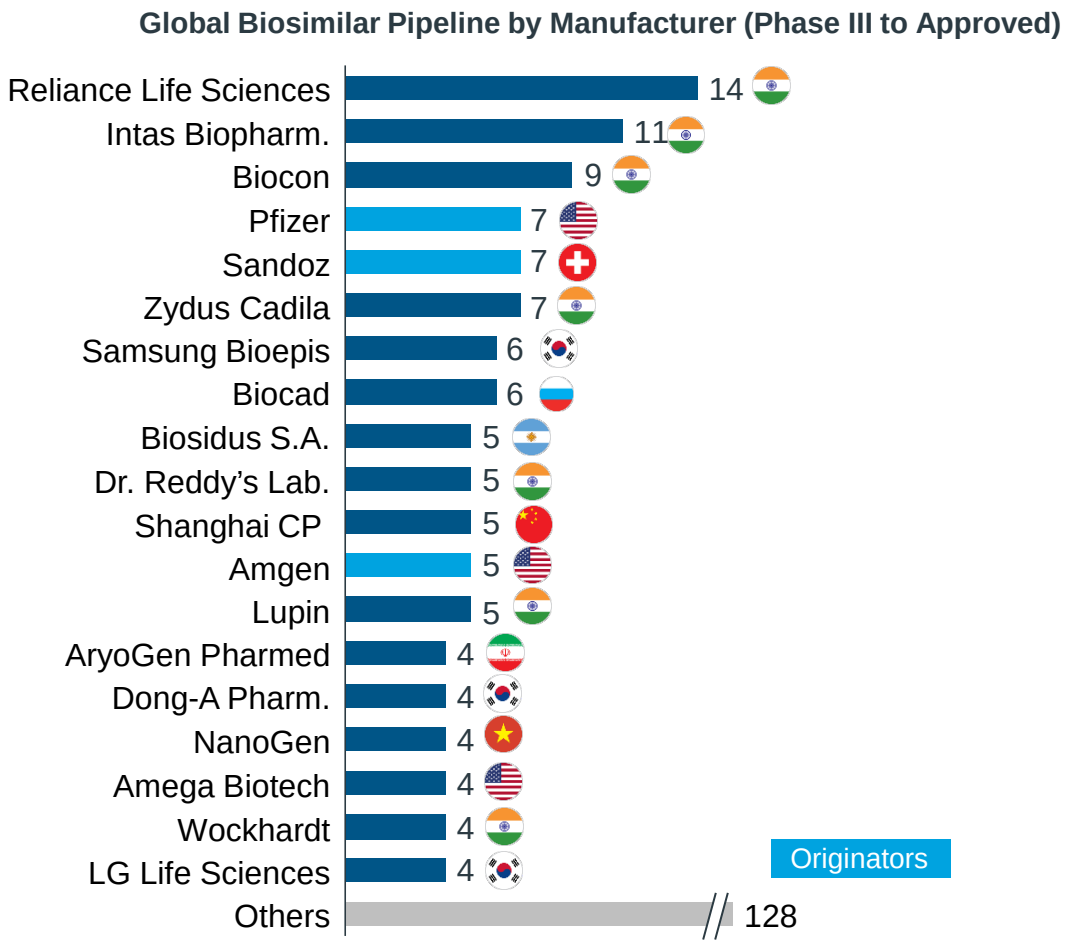


Biologic sales (Bn)	EU Protection expiry date	US Protection expiry date
Adalimumab (Humira)	2018	(2023)
Insulin glargine (Lantus)	Expired	Expired
Etanercept (Enbrel)	Expired	2022
Infliximab (Remicade)	Expired	2018
Insulin aspart (Novorapid)	Expired	Expired
Insulin Lispro (Humalog)	Expired	Expired
Rituximab (Mabthera)	Expired	2018
Immunoglobulin base (Privigen)	2024	2027
Trastuzumab (Herceptin)	Expired	2019
Bevacizumab (Avastin)	2019	2019

Source: IQVIA MIDAS MAT Q1 2018; IQVIA Institute Jan 2018; *Approved by EMA / FDA and on market

Biosimilar development is being actively pursued by a large number of companies for the leading molecules



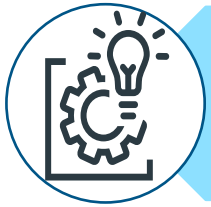


Source: IQVIA MIDAS MAT Q3 2017; IQVIA Institute Jan 2018

The promise – savings and increased access

Price reduction through competition

Increased access driven by a lower price



Savings can finance new innovation

IQVIA report for EU Commission DG GROW 2018

The Impact of Biosimilar Competition

- IQVIA has prepared as a set of indicators to monitor the impact of biosimilars in the European markets at the request of the European Commission services with initial contributions from EFPIA, Medicines for Europe, and EuropaBio.
- The report sets out to describe the effects on price, volume and market share following the arrival and presence of biosimilar competition in the EEA.

Observations by IQVIA

- In this document IQVIA suggests a number of key observations based on the data from the report.

Reading guide

- IQVIA has developed a simplified guide to read the report that has a broad set of KPIs for multiple countries.
- EPO and Austria are used as the example.

Eastern European countries had the lowest TD/capita before, and the highest increase in volume TD since biosimilar entry

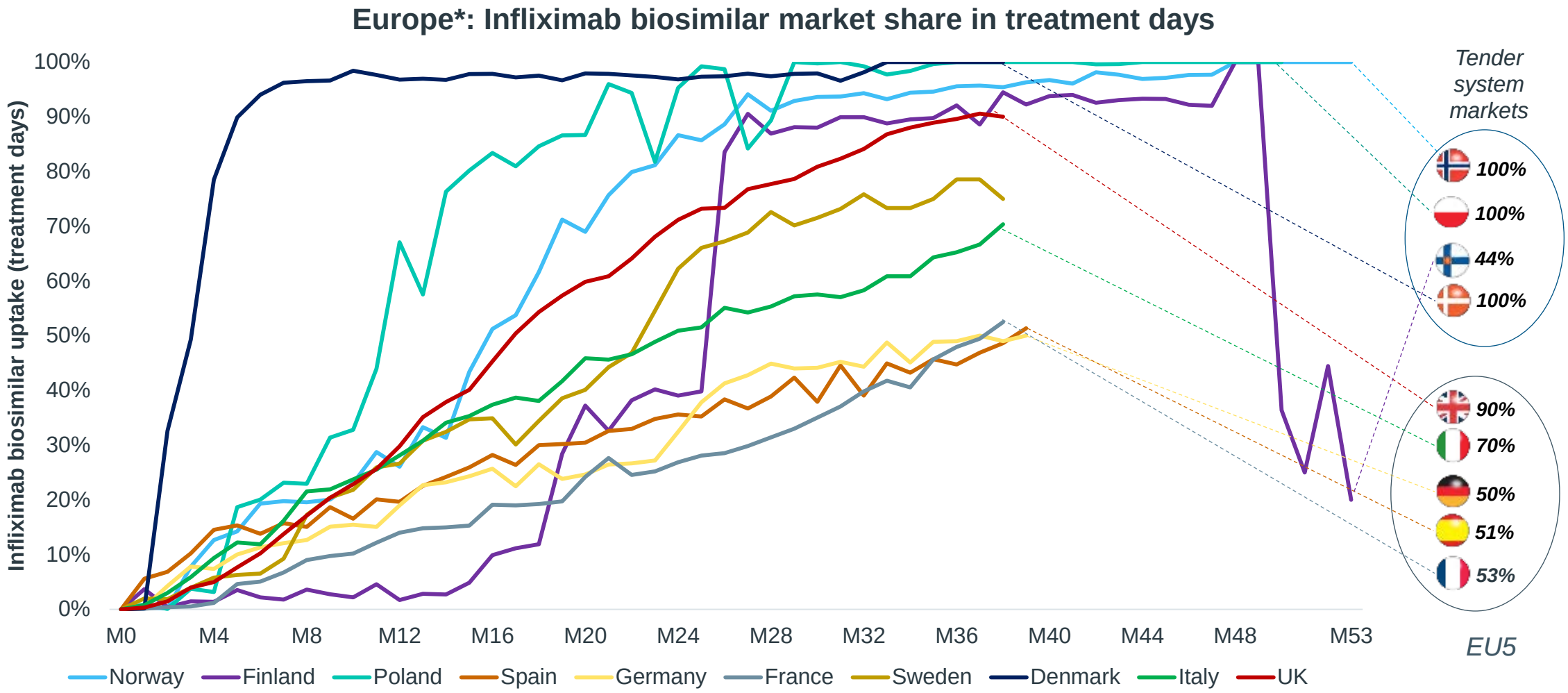
GCSF KPI's

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded sales of Biosimilars
BU	100%	100%	14%	-77%	-77%	-60%	354%	354%	1893%	0.002	0.035	2009
RO	100%	100%	71%	-70%	-70%	-63%	339%	339%	489%	0.003	0.019	2009
CZ	100%	100%	66%	-34%	-34%	-22%	290%	290%	122%	0.005	0.010	2010
SK	100%	100%	35%	-83%	-83%	-65%	477%	477%	426%	0.009	0.045	2009
UK	99%	99%	68%	8%	8%	15%	247%	247%	66%	0.014	0.024	2008
PL	97%	97%	51%	-64%	-64%	-49%	173%	173%	118%	0.017	0.036	2009
SL	61%	61%	10%	-69%	-69%	-56%	95%	95%	249%	0.018	0.063	2009
GR	100%	100%	90%	-64%	-64%	-42%	1190%	1190%	-80%	0.020	0.004	2009
SE	95%	95%	67%	-55%	-55%	-31%	270%	270%	33%	0.022	0.030	2009
DE	81%	81%	14%	-31%	-31%	-31%	57%	57%	108%	0.025	0.052	2008
CH	62%	62%	16%	-38%	-38%	-29%	39%	39%	54%	0.026	0.041	2009
NO	82%	82%	4%	-37%	-37%	-12%	28%	28%	152%	0.028	0.069	2009
EU	91%	91%	30%	-39%	-39%	-25%	134%	134%	43%	0.029	0.041	
IT	94%	94%	39%	-26%	-26%	-17%	128%	128%	9%	0.032	0.034	2009
NL	46%	46%	5%	-34%	-34%	-27%	24%	24%	-14%	0.033	0.028	2009
HU	100%	100%	80%	-67%	-67%	-49%	300%	300%	16%	0.035	0.041	2009
ES	91%	91%	74%	-39%	-39%	-24%	62%	62%	-33%	0.036	0.024	2009
PT	89%	89%	56%	-90%	-90%	-60%	98%	98%	-44%	0.038	0.021	2010
DK	95%	95%	13%	-50%	-50%	-21%	-2%	-2%	17%	0.042	0.049	2009
BE	17%	17%	2%	-30%	-30%	-12%	8%	8%	18%	0.044	0.052	2011
FR	90%	90%	18%	-38%	-38%	-23%	225%	225%	40%	0.053	0.074	2009
AU	98%	98%	22%	-51%	-51%	-40%	90%	90%	77%	0.054	0.095	2009
FI	98%	98%	16%	-44%	-44%	-27%	70%	70%	51%	0.054	0.081	2009
IE	25%	25%	3%	-29%	-29%	-16%	-1%	-1%	46%	0.055	0.080	2009

Eastern European countries

Source: IQVIA MIDAS MAT December 2017; Table ranked by TD/Capita (Yr before BS entrance)

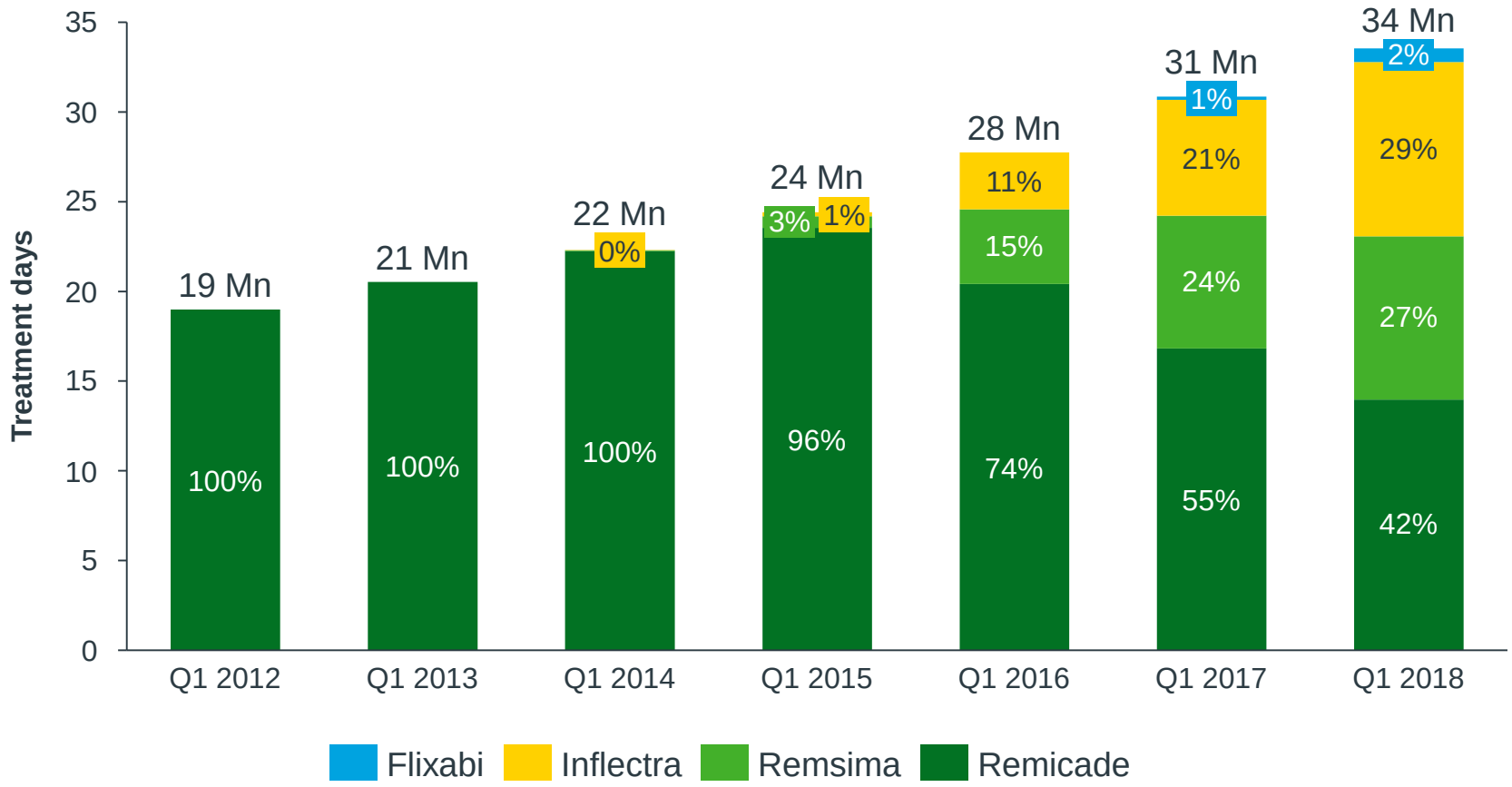
Tender markets sustain complete cannibalisation of originator shares, UK and Italy among top penetrated markets in EU5



Notes: *High uptake countries and EU5, Latvia and Bulgaria excluded because only biosimilar manufacturers present in market; Source: IQVIA MIDAS Restricted MTH April 2018

Infliximab – overall volume growth and a shift to biosimilars

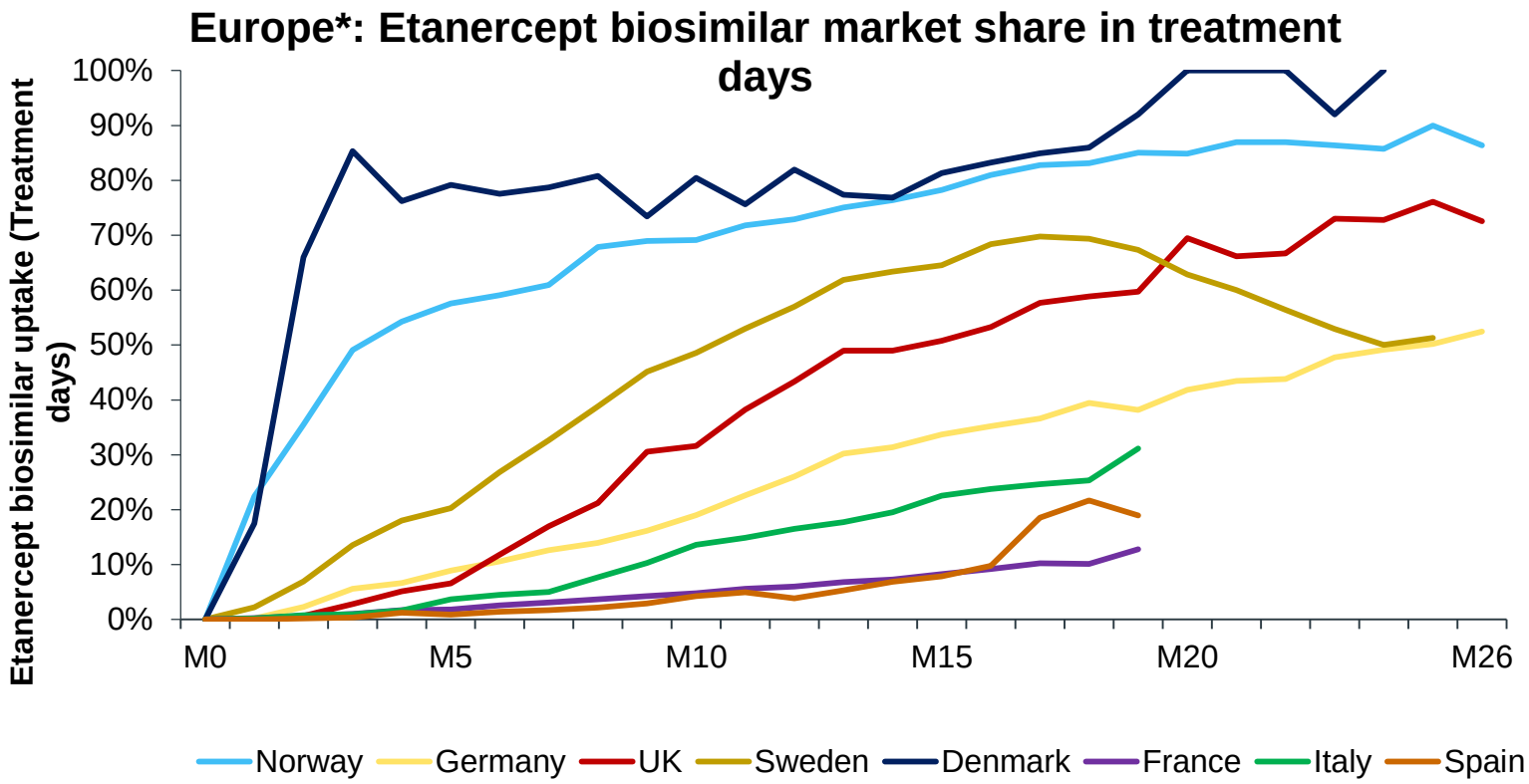
Europe: Treatment increase as a result of biosimilar usage



Country	Infliximab TD % growth increase	
	Q1 2014-Q1 2016	Q1 2016-Q1 2018
France	41%	55%
Germany	27%	34%
Italy	4%	37%
Spain	31%	51%
UK	28%	33%
Finland	62%	43%
Poland	-5%	52%
Canada	61%	60%
Japan	50%	-2%
US	28%	54%
Europe	33%	44%

Notes: Infliximab unknown has been excluded, refer to notes for details on methodology; Source: IQVIA MIDAS Restricted QTR Q1 2018

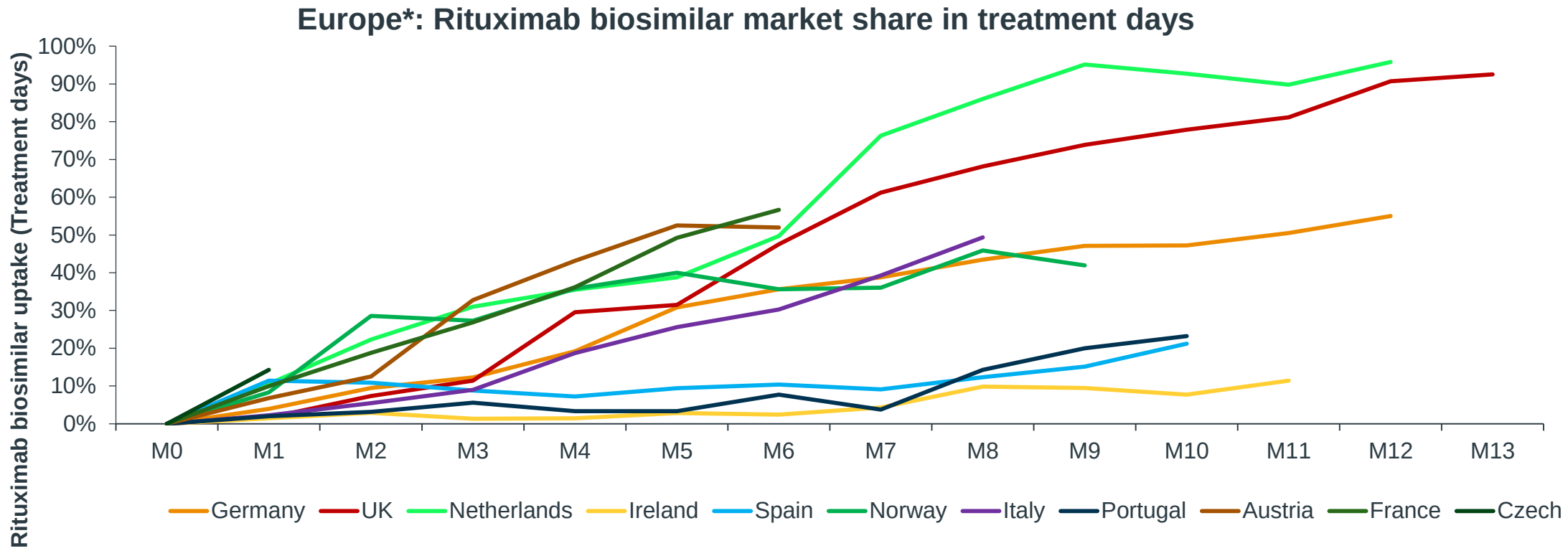
Etanercept biosimilars show rapid uptake in most countries, faster than infliximab biosimilars



Biosimilar share as of Mar 2018#	Norway	Germany	UK	Sweden	Denmark	France	Italy	Spain
	86.4%	52.4%	72.6%	51.3%	100.0%	12.8%	31.2%	19.0%

Notes: *Europe- EU5 and high uptake countries, #Arranged in order of launch, FPB (VIAL DRY), FNA (PRE-FILL SYRNG), FMB (DRY AMPS.INJ), FRP (U-D CARTRIDGE NFC coded molecules have been excluded;
Source: IQVIA MIDAS Restricted MTH Apr 2018

Within a year of launch, UK and Netherlands have more than 90% penetration by rituximab biosimilars



Biosimilar share as of Apr 2018#	Germany	UK	Netherlands	Ireland	Spain	Norway	Italy	Portugal	Austria	France	Czech
	55.0%	92.6%	95.8%	11.4%	21.2%	41.9%	49.4%	23.2%	52.0%	56.7%	14.3%

Notes: : *EU5 countries and countries with high biosimilar uptake , DDD for Rituximab has been considered as 1, #Arranged in order of launch , FPE (VIAL SC) coded molecules have been excluded, Data for US and Canada not available; Source: IQVIA MIDAS Restricted MTH Apr 2018

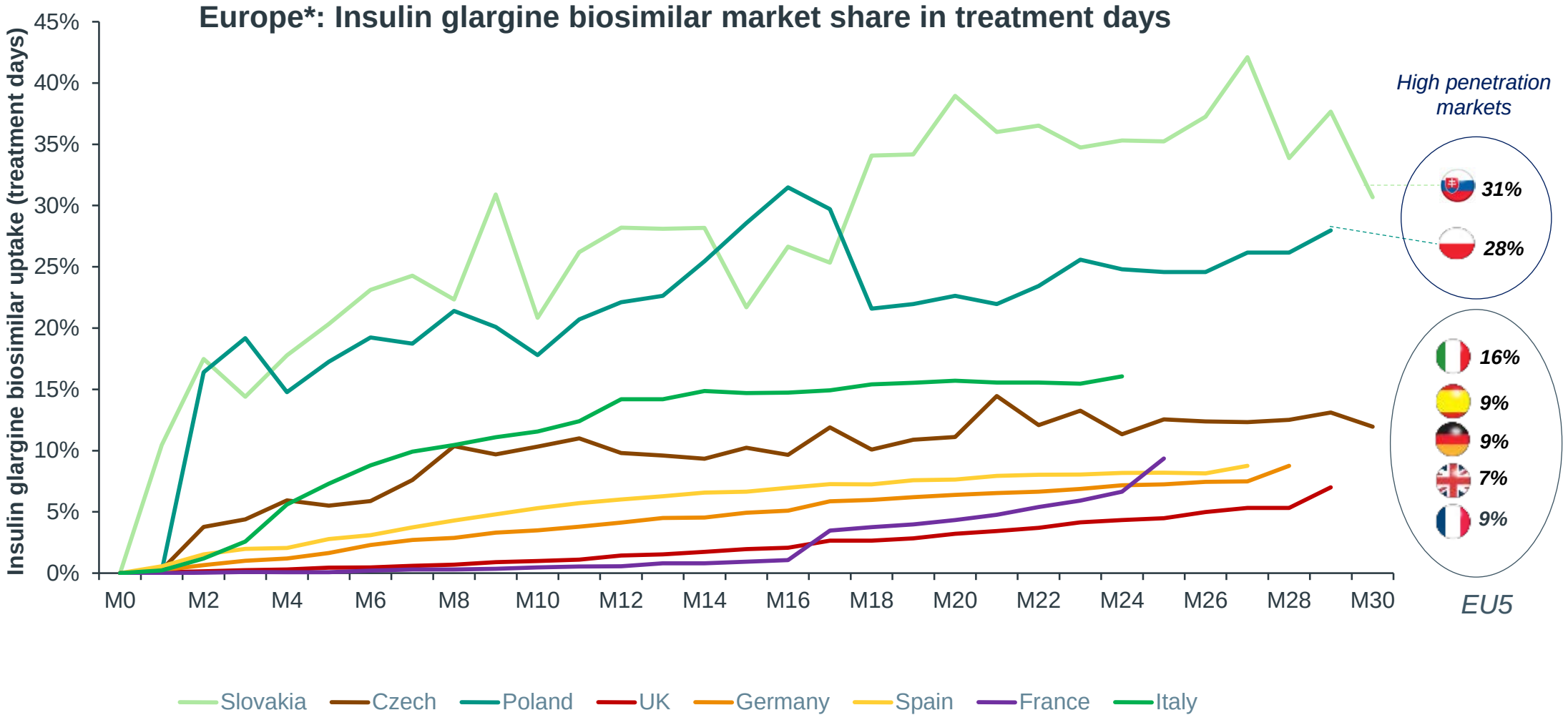
Oncology KPI's shows that not all countries still have access of the biosimilar

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded sales of Biosimilars
PT	2%	1%	1%	-4%	-3%	-3%	9%	10%	10%	0.04	0.05	2017
ES	5%	3%	3%	-1%	-11%	-9%	-16%	12%	13%	0.04	0.05	2017
IT	3%	2%	2%	-1%	-5%	-5%	-5%	7%	8%	0.04	0.05	2017
NL	38%	33%	33%	-16%	-15%	-15%	16%	17%	17%	0.05	0.06	2017
IE	2%	2%	1%	-7%	-7%	-7%	2%	3%	3%	0.06	0.06	2017
UK	29%	18%	18%	-2%	-6%	-6%	-16%	6%	6%	0.06	0.06	2017
FR	2%	2%	2%	-10%	-15%	-15%	2%	15%	14%	0.06	0.07	2017
DE	16%	15%	14%	-5%	-5%	-5%	4%	4%	5%	0.06	0.06	2017
DK	0%	0%	0%	-3%	-7%	-7%	-11%	2%	1%	0.08	0.08	2017
NO	12%	7%	7%	13%	14%	14%	1%	2%	2%	0.08	0.08	2017
AU	1%	1%	1%	6%	5%	7%	-1%	-4%	-2%	0.09	0.08	2017
FI	0%	0%	0%	0%	0%	0%				0.09	0.09	
PL											0.02	
BE											0.05	
BU											0.03	
CZ											0.01	
GR											0.00	
HU											0.04	
RO											0.01	
SK											0.03	
SL											0.06	
SE											0.09	
CH											0.07	
EU	11%	8%	7%	-3%	-7%	-6%	-2%	7%	7%	0.049	0.052	

Eastern European countries

Source: IQVIA MIDAS MAT December 2017; Table ranked by TD/Capita (Yr before BS entrance)

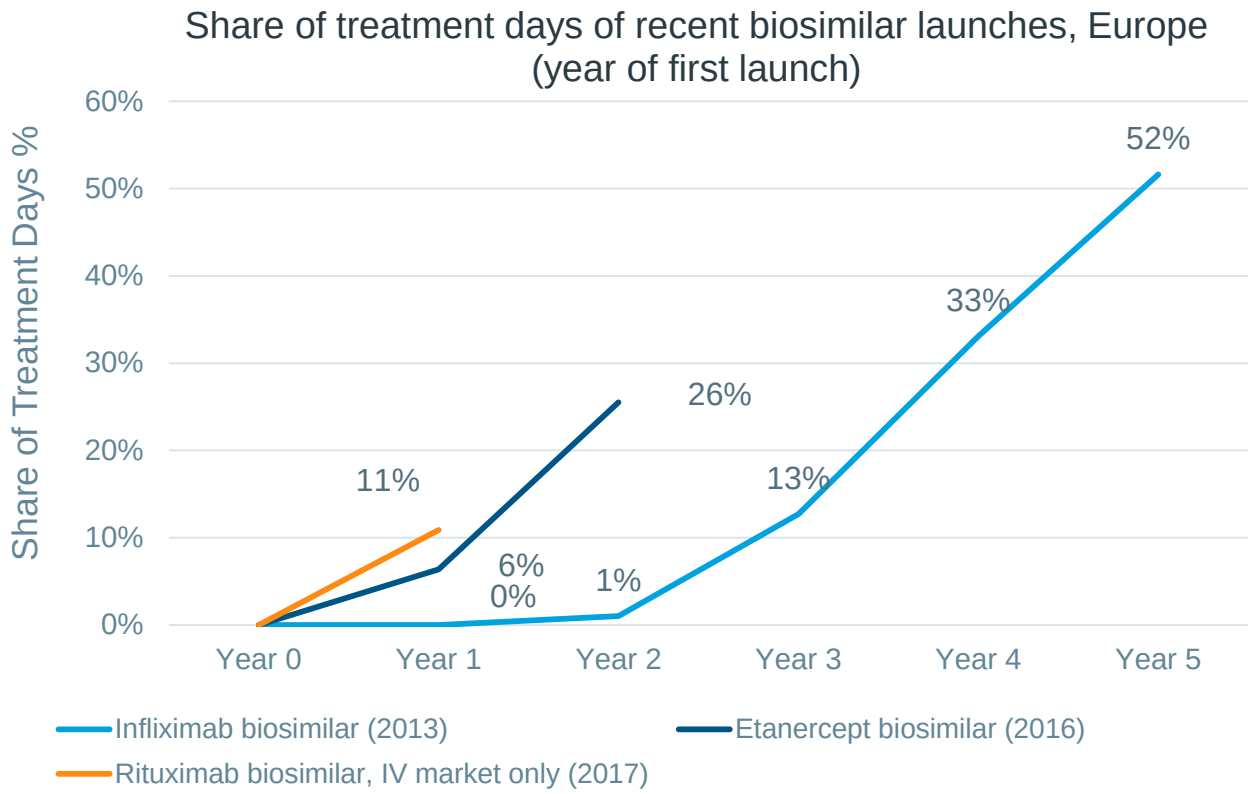
Insulin glargine biosimilars struggle in the European market, weakest performance in EU5



Notes: *EU5 countries and countries with high biosimilar uptake, GPE (VIAL SC RET), GPE (VIAL SC RET), FME (AMPOULES S.C.) coded molecules have been excluded ;
Source: IQVIA MIDAS Restricted MTH Apr 2018

The speed of uptake has increased for some of the more recent biosimilar launches

- The speed of uptake has increased for some of the more recent biosimilar launches, including those where there are multiple biosimilars in the same class.
- For example, in the anti-TNF class, the uptake of etanercept biosimilars has been faster than infliximab biosimilars across Europe.
- Whilst there will be product specific differences partially driving this variation, it is also the case that over the years, stakeholders have gained more experience and familiarity with biosimilars. As prescribers become more receptive and willing to use biosimilars, this will continue to be an important lever in driving their uptake.
- The faster implementation of demand-side policies will also contribute to the faster uptake of newer biosimilars.

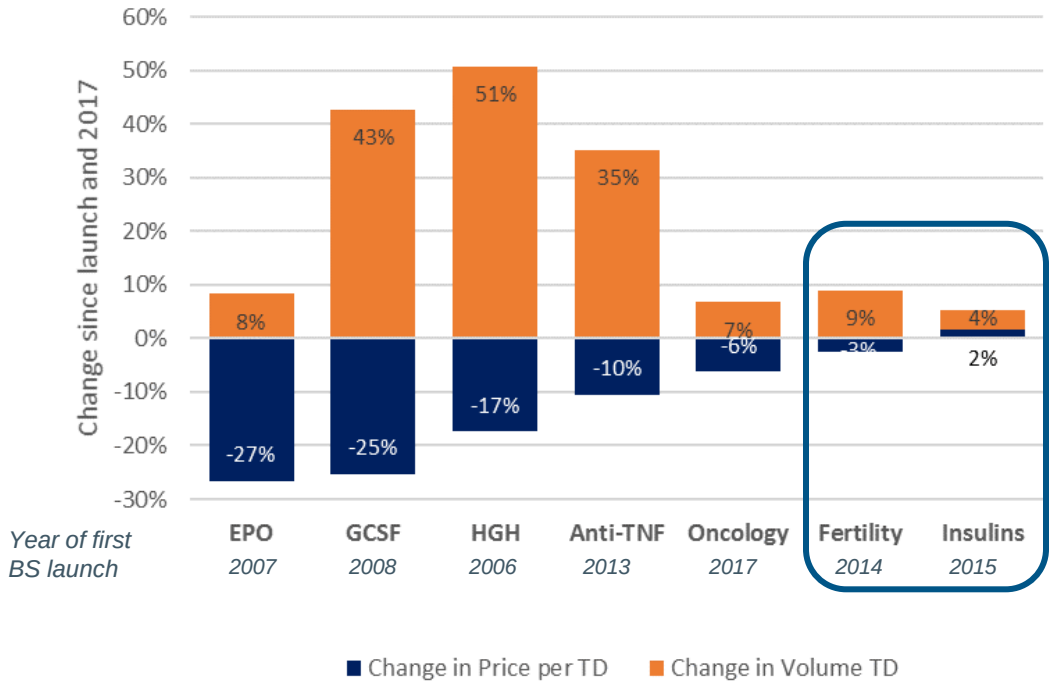


Source: IQVIA MIDAS MAT December 2017; Each product treatment day share calculated with respect to the individual market

Not all classes have achieved high biosimilar uptake

- There is a wide variation in the uptake of biosimilars across classes in Europe, and time on the market does not always determine success.
- In some classes (e.g. Insulins and Fertility), prior to biosimilar entrance there was already a highly competitive market situation for established products.
- There are also market specific characteristics which can influence uptake. For example, in most European markets, Insulin is a retail product, prescribed by primary care physicians, reimbursed from the retail budget. There are different barriers to launching retail biosimilars vs hospital biosimilars, such as the substantial company investment required to promote to a large population of primary care physicians, and fewer incentives offered compared with hospital biosimilars.

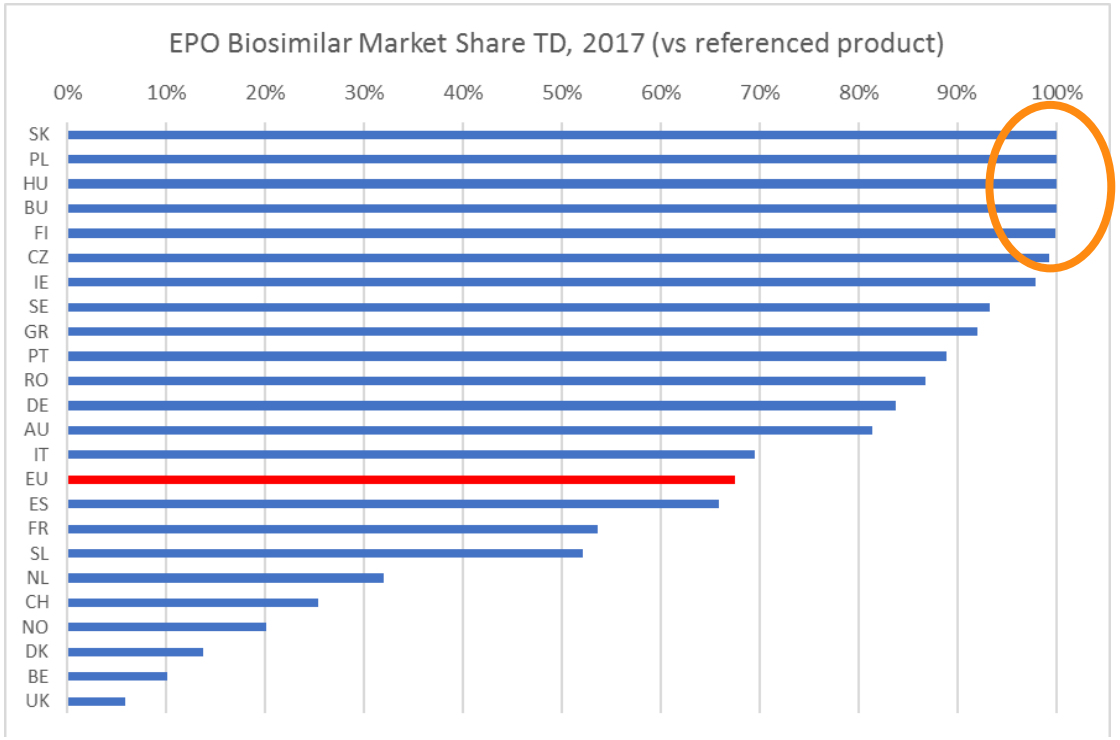
Change in price and volume treatment days of total market between launch and 2017

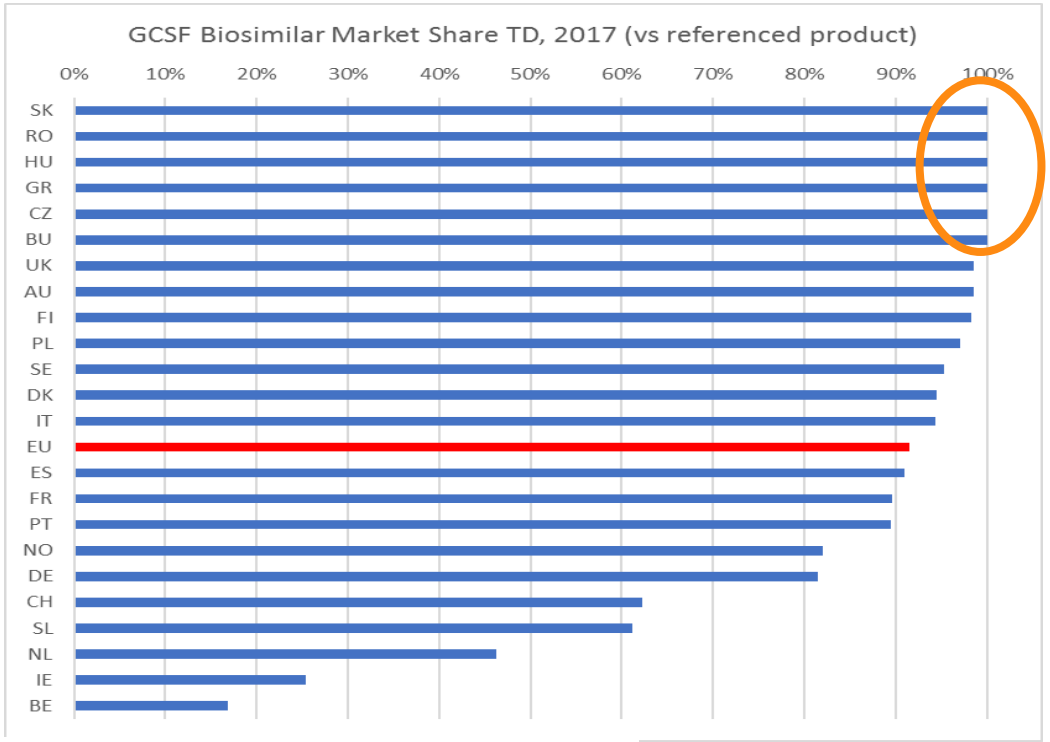


Source: IQVIA MIDAS MAT December 2017

In some countries, biosimilars have completely taken over the market (vs referenced product)

- In classes where biosimilars have been on the European market for several years, there are now many examples of countries where the referenced product is no longer available, and biosimilars have 100% volume market share (BS vs ref products only – not vs total market)
- These are often countries with low GDP/capita in Europe where the incentive to switch to biosimilars may be high
- Some of the countries analysed had very low use of the reference product before the launch of the biosimilar, meaning access to the biologic product was granted by biosimilars entering the market





Source: IQVIA MIDAS MAT December 2017

Infliximab biosmilars have achieved 100% penetration in tender markets while etanercept biosimilars in Denmark only

Europe, Japan, US & Canada- Biosimilar share of molecule treatment days

		Biosimilar treatment day share (Apr 2018)			
	Country	**infliximab**	**insulin glargine**	**etanercept**	**rituximab**
EU5	UK	90.0%	7.0%	72.6%	92.6%
EU5	France	52.5%	9.3%	12.8%	56.7%
EU5	Germany	50.0%	8.7%	52.4%	55.0%
EU5	Italy	70.4%	16.1%	31.2%	49.4%
EU5	Spain	51.4%	8.8%	19.0%	21.2%
High penetration EU	Finland	20.0%	4.5%	0.0%	0.0%
High penetration EU	Norway	100.0%	3.3%	86.4%	41.9%
High penetration EU	Poland	100.0%	28.0%	33.3%	-
High penetration EU	Denmark	100.0%	6.1%	100.0%	33.3%
	Ireland	25.0%	0.0%	0.0%	11.4%
	Australia	14.3%	-	6.3%	-
	Japan	6.8%	37.4%	-	10.2%
	Canada	4.9%	4.7%	6.3%	-
	US	4.5%	25.8%	-	-

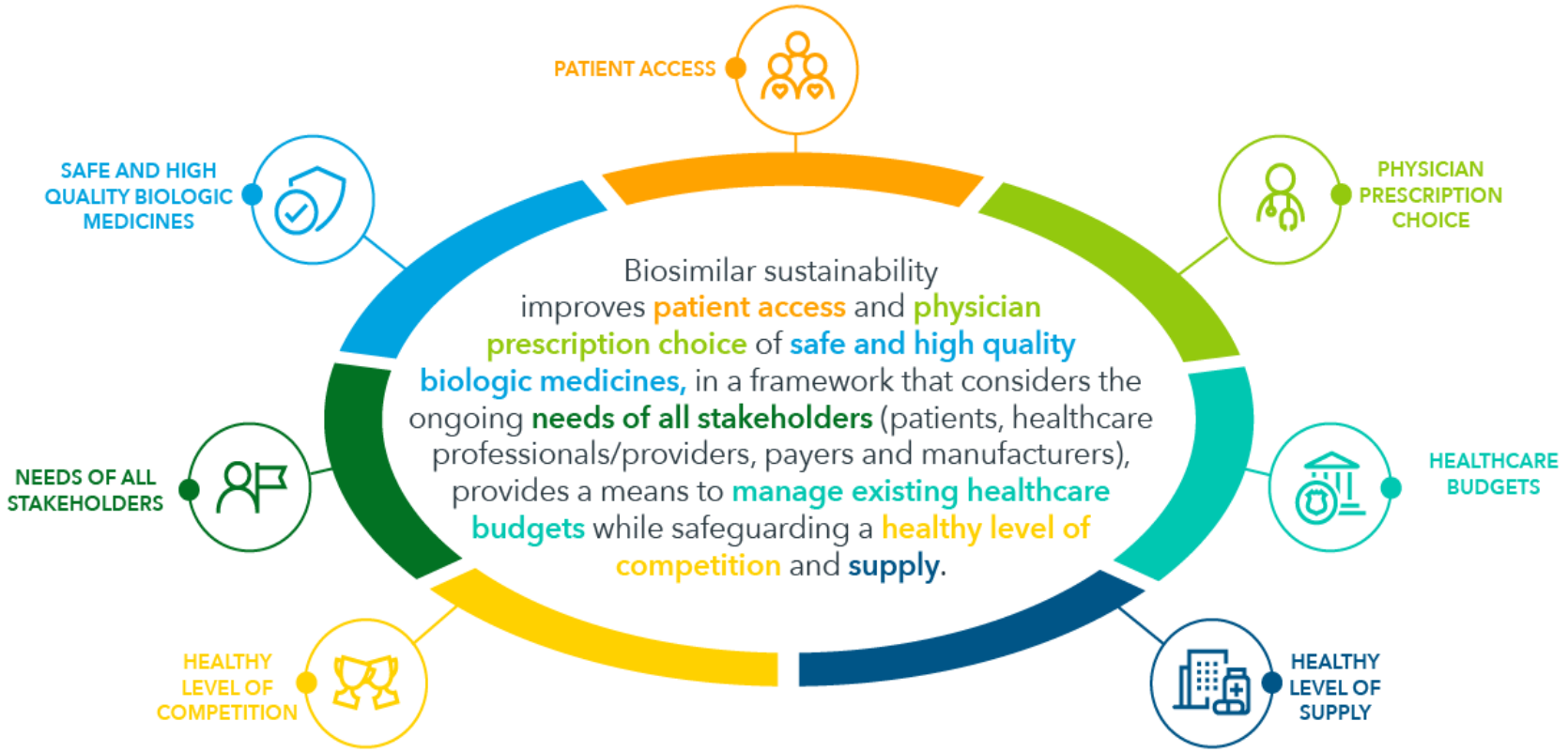
High uptake

Low uptake

Note: *Uptake represented within 6 months of launch; NFC exclusions have been mentioned in notes section; Source: IQVIA MIDAS Restricted MTH April 2018

Sustainability requires accommodation and balancing of all stakeholders' need

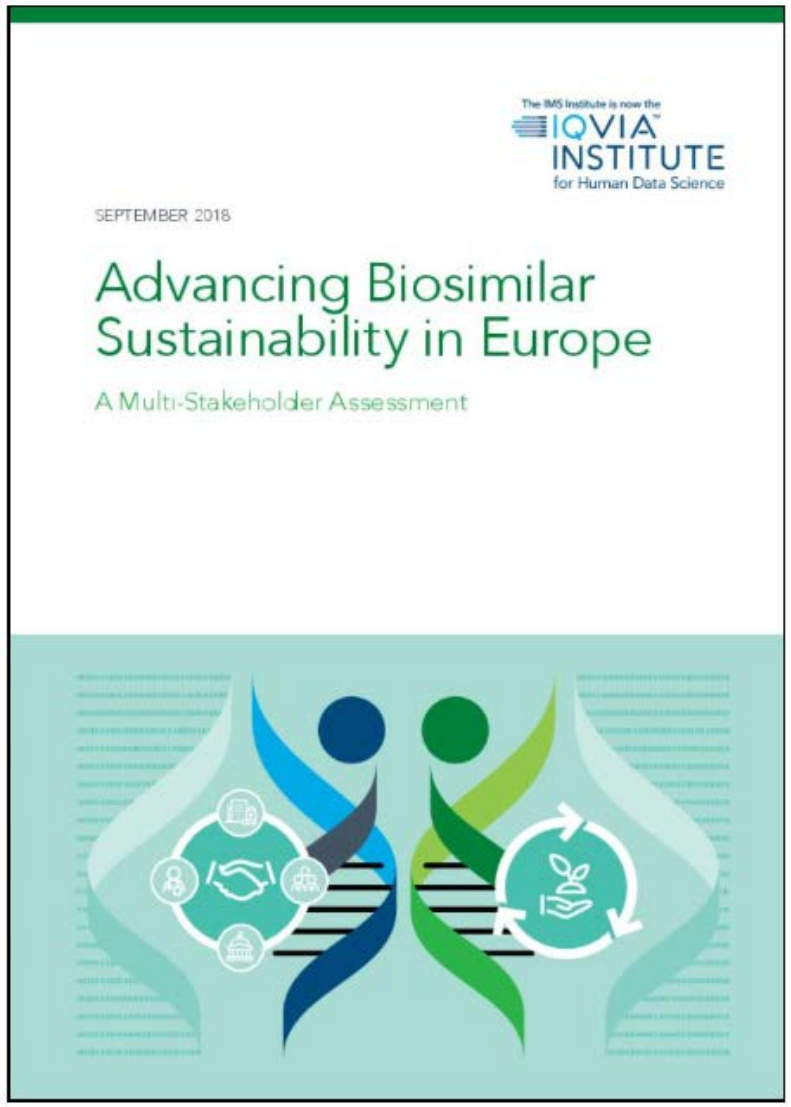
Multi-stakeholder definition of biosimilar market sustainability



Source: IQVIA Global Consulting Services, Jul 2018

Report: Advancing Biosimilar Sustainability in Europe: A Multi-Stakeholder Assessment. IQVIA Institute for Human Data Science, Sep 2018.

We have published a report on sustainability of biosimilars



https://www.iqvia.com/institute/reports/advancing-biosimilar-sustainability-in-europe

This report was produced independently by the IQVIA Institute for Human Data Science based on research and analysis undertaken by the IQVIA Consulting Services group and commissioned and funded by Pfizer. Pfizer employees were among those interviewed by the IQVIA Consulting Services group.

Extrapolation of Indications is strictly regulated, allowing for extrapolation to target groups w/o study extension

Safe & high quality biologic medicines:
Extrapolation of Indications has to be requested and granted by Regulatory Authority

Totality of evidence: biosimilarity in analytical, non-clinical, clinical studies

Historical studies, extensive evaluation of reference product

Supporting evidence for extrapolation of indications

MOA in each condition of use

PK and biodistribution

Immunogenicity

Toxicity

Other factors affecting safety or efficacy

Extrapolation of Indication Example 1: Sandoz's Erelzi™ biosimilar of Enbrel® (etanercept) - EU

Studied Indication
moderate to severe, chronic plaque-type psoriasis (PsO)

Non-studied ("extrapolated") Indications
rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS)

Extrapolation of Indication Example 2: Sandoz's Rixmyo™ biosimilar of MabThera® (rituximab) - EU

Studied Indication
rheumatoid arthritis (RA) and
oncology (AFL - advanced stage follicular lymphoma)

Non-studied ("extrapolated") Indications
Non-Hodgkin's lymphoma (NHL), granulomatosis with polyangiitis and microscopic polyangiitis

FDA Guidance on Biosimilarity, 2015

While agreeing that biosimilars are equivalent in therapy, KOL are concerned about forced change and tender impact on choice

KOL interview outcomes

	PROs	CONs
Patient access	- Guidelines may be changed and **move therapy to preceding treatment lines** - Savings perceived as **potential source to finance access to other innovative therapies**	- **Quotas have not limited specialist choice** in prescription, access will not increase in given therapy/indication in short term - In oncology, price benefit on filgrastim **moved pegilated form to second line despite medical benefits**
Physician prescription choice	- Physicians **see biosimilars as equivalent choice** in therapies for new initiations - **Payer allows for maintaining original therapy** and leaves switch in most cases to doctor's decision (e.g. split of quotas to new and switch patients in infliximab tender) - **Participation in clinical trials** provides useful hands-on experience, which is perceived as strongest ‚argument' for use	- Potential **number of switches raises concerns about immunogenicity** - **Minor price difference should not justify push for switch** / another tender winner and

Although biocomparability studies are not directly challenged, short term experience in therapy and production raise concerns

KOL interview outcomes

Safe & high quality biologic medicines

PROs

- **Biocomparability studies are accepted by most KOL**, EMA makes careful and educated decision on accepting extrapolations
- EMA quality **control procedures are trusted**
- Some perceive **later established manufacturing** plants as **source of purer product quality** and **„bio better" products**

CONs

- Especially **non-KOL prescribers need to be educated** about both extrapolation and EMA's quality investigations
- For new drugs, **short term experience and limited duration of biocomparability studies discourage prescriptions**
- Some mentioned **‚exotic' location and lack of „error-free" manufacturing track record** as concern for production quality

While considering other factors, payer decision in tenders is largely driven by price and volume

Healthcare budgets: payer's key points in decision making

Factors for consideration | **Assessment measures**

1 Complexity

- High complexity of both the molecules and production process
- Biological source (typically mouse / Chinese hamster ovary) bear different manufacturing risks vs. traditional chemical procedures

2 Similarity

- Molecules are not identical but only similar
- Level of similarity was harder to measure, now EMA /FDA worked out processes
- Originators focusing on extension of protection period by patenting specific indications (rituximab, infliximab) or route of administration (rituximab, trastuzumab)

3 Attitude

- Concerns of typical non-KOL prescribers still outweigh economic benefits
- Strong education needed for acceptance
  - Safety
  - Efficacy
  - Increased access
  - Ease of switching
  - Manufacturers, sites
  - Legal situation, NEAK position
  - EU's attitude and uptake

4 Price

- Tenders focus on unit prices and rebates
- Complementary services not yet assessed

5 Volumen

- Considerations ranging from hard measures (forced switch, suggesting and monitoring) to soft measures (education and prescription incentives)
- Separate tendering for new and switch patients

… there are mainly too areas were we have concerns in some countries

Best practices to achieve sustainability for all stakeholders in the biosimilars market (3/3)

Healthcare Budgets

- **Continue to incentivise** the uptake of biosimilars to facilitate budget release in the short term, while considering the long-term sustainability of the market
- **Design incentives** considering the needs of target physicians and care-institutions

Healthy Level of Competition

- Sustain healthier levels of competition with **multiple-winner tenders** as compared with single-winner tenders
- Incentivise biosimilar manufacturers to innovate in areas to support patients and providers by **making purchasing decisions based on additional criteria beyond price**

Source: IQVIA Global Consulting Services, Jul 2018

Report: Advancing Biosimilar Sustainability in Europe: A Multi-Stakeholder Assessment. IQVIA Institute for Human Data Science, Sep 2018.

The observations for Eastern Europe

Hungary is a hybrid between switch potential and new sales

- The TD per capita usage prior to biosimilar competition is significantly lower in Eastern Europe compared to Western European countries
- Whilst the priority in western European countries is to switch patients to the biosimilars for cost-effective purposes, the priority in Eastern European countries is **expanded usage at a more attractive price**
- Given that the result of the entrance of lower cost biosimilars in Eastern European countries is often expanded patient usage, overall this may **increase budgetary requirements** which have to be managed
- In these countries, the critical factor is **medical marketing** of the benefits of biosimilars and ensuring stakeholders gain an **understanding and familiarity with biosimilars**.
- Companies with a local presence in these countries may benefit by being more **locally connected** to the key stakeholders.

Key take home messages

1. Significant innovation provided by biological drugs
2. Biosimilars are equally safe and efficient
3. Lower cost makes the treatment affordable for more patients
4. Suitable strategy for leveraging competition necessary
5. Need to manage the implementation of agreements

Thank you

Per Troein, VP Strategic Partners
per.troein@quintilesims.com

Disclaimer:

- The analyses, their interpretation, and related information contained herein are made and provided subject to the assumptions, methodologies, caveats, and variables described in this report and are based on third party sources and data reasonably believed to be reliable. No warranty is made as to the completeness or accuracy of such third party sources or data.
- As with any attempt to estimate future events, the forecasts, projections, conclusions, and other information included herein are subject to certain risks and uncertainties, and are not to be considered guarantees of any particular outcome.
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Digital Revolution or Evolution: The future digital hospital

V ECPD REGIONAL CONFERENCE

Prof. Dr. Thomas Lux

Head of Competence Center eHealth (CCeHealth)

Chair of Process Management in Healthcare

ECPD | Opatija (HR) | September , 2018 |

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University of Applied Sciences

Germany, Krefeld

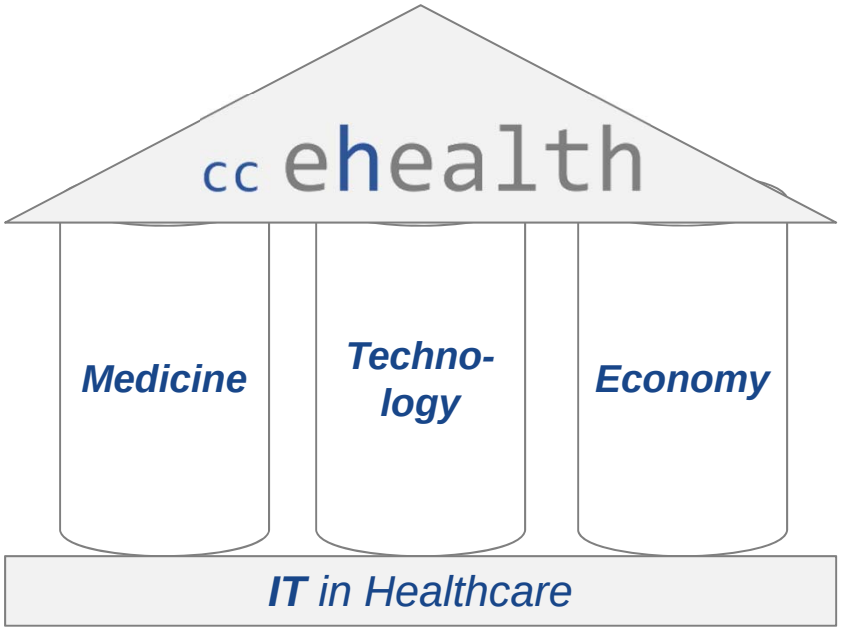
Hochschule Niederrhein
University of Applied Sciences

University of Applied Science Niederrhein (Germany)

- ~15.000 Students, 10 Faculties
  Located: Germany / Northrhine Westfalia
- Faculty of Healthcare
  - Health Care Management
    (Bachelor and Master-Studies)
  - eHealth – IT in Healthcare
  - **Application-Oriented:**
    E-Health-Lab, Showroom, etc.
  - Different research Projects

Competence Center eHealth

- Founded 2009 University Bochum and 2014 University Krefeld



Executive Board
Prof. Dr. Thomas Lux (founder)
Prof. Dr. Hubert Otten
Prof. Dr. Syliia Thun
Prof. Dr. Bernhard Breil

Research areas

- *Hospital Engineering*
- *Medical ICT*
- *(ICT-)Standards in Healthcare*
- *(Medical) Business Process (Engineering)*
- *Networks in the public health sector*
- *ICT-security in health care*
- *Patient safety*

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Overview

- Digital Revolution and Process Management
- Digitization, Digitalization, and Digital Transformation
- Measurement of Digitalization
- “Digital Trends” in Healthcare

„I think there may be a world market for maybe five computers.“

(Thomas Watson, IBM CEO 1943)

„There is no reason why anyone wanted to have a computer in his house .“

(Ken Olson, Präsident, CEO and Founder, Digital Equipment Corp. (DEC), 1977)

„We build trucks and not bicycles “

(Heinz Nixdorf, Founder, Nixdorf Computer AG)

„Who actually needs this silver disc?“

(Jan Timmer, CEO, Philipps AG, 1982)

The first rule of any technology used in a business is that automation applied to an efficient operation will magnify the efficiency. **The second** is that automation applied to an inefficient operation will magnify the inefficiency.

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Business Process Reengineering (BPR)

„ the **fundamental** rethinking and **radical** **redesign** of *business processes* to achieve dramatic **improvements** in critical contemporary modern measures of performance, such as cost, quality, service, and speed.“

(Hammer/Champy)

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Process revolution vs. evolution

Process-Revolution

Re-design of Core Business Processes

Process-Evolution

Step-by-step, permanent improvement

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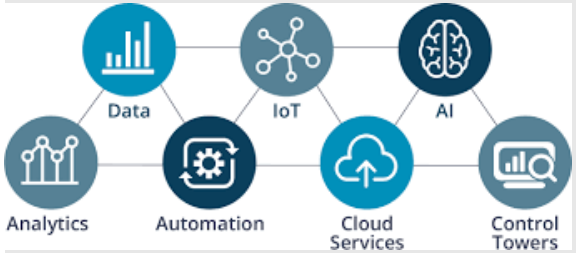
Digitization, Digitalization and Digital Transformation

3 Steps from Analog to Digital

- **Digitization**
  Change from Analog to Digital

- **Digitalization**
  Making (digitized) information work for you

- **Digital Transformation**
  Creating complete new business concepts



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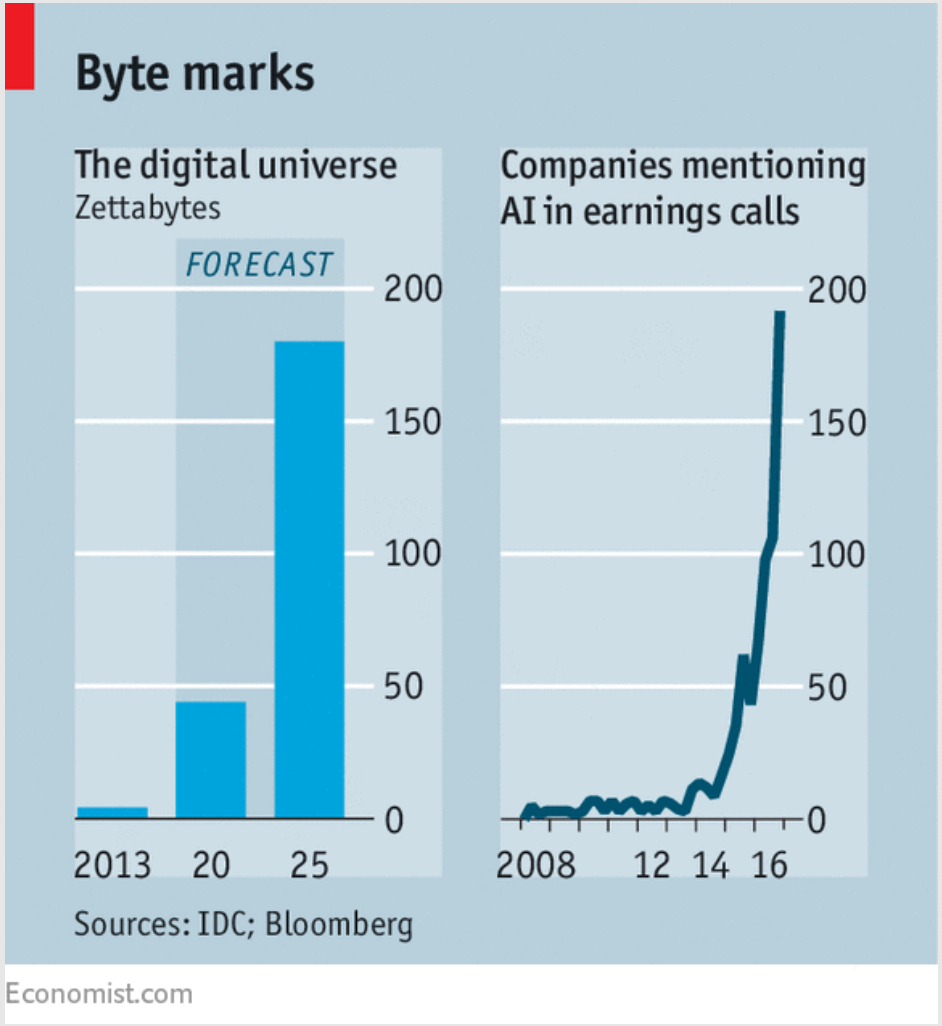
The ‚Digital Universe', …



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…the Power of the digital Giant….

Quelle: Die Zeit, 06.06.2018

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…Digitization of the industries

The MGI Industry Digitization Index

2015 or latest available data

Relatively low digitization — Relatively high digitization

● Digital leaders within relatively undigitized sectors

Sector	Over-all digiti-zation[1]	Assets: Digital spending	Assets: Digital asset stock	Usage: Transactions	Usage: Interactions	Usage: Business processes	Usage: Market making	Labor: Digital spending on workers	Labor: Digital capital deepening	Labor: Digitization of work	GDP share %	Em-ploy-ment share %	Produc-tivity growth, 2005–14[2] %
ICT											5	3	4.6
Media		1									2	1	3.6
Professional services											9	6	0.3
Finance and insurance											8	4	1.6
Wholesale trade					4						5	4	0.2
Advanced manufacturing											3	2	2.6
Oil and gas		2									2	0.1	2.9
Utilities											2	0.4	1.3
Chemicals and pharmaceuticals											2	1	1.8
Basic goods manufacturing											5	5	1.2
Mining											1	0.4	0.5
Real estate	●										5	1	2.3
Transportation and warehousing	●								5		3	3	1.4
Education	●			3							2	2	-0.5
Retail trade	●										5	11	-1.1
Entertainment and recreation											1	1	0.9
Personal and local services											6	11	0.5
Government	●										16	15	0.2
Health care											10	13	-0.1
Hospitality	●	6									4	8	-0.9
Construction											3	5	-1.4
Agriculture and hunting											1	1	-0.9

Quelle: McKinsey Internationale

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E-leadership in Europe

Source: Digital Transformation Scoreboard 2017

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Efficient and effective use of resources?!

- *Effectiveness*

  Consideration of the range of services

  - Specialized medicine
  - High-tech medicine
  - Highly qualified specialist staff

- *Efficiency*

  Organization of the service creation process

  - Efficient (process) organization within the organization
  - Connecting the actors (processes networking)

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HIMSS - the EMR Adoption Model (EMRAM)

STAGE	HIMSS Analytics EMRAM EMR Adoption Model Cumulative Capabilities
7	Complete EMR; External HIE; Data Analytics, Governance, Disaster Recovery, Privacy and Security
6	Technology Enabled Medication, Blood Products, and Human Milk Administration; Risk Reporting; Full CDS
5	Physician documentation using structured templates; Intrusion/Device Protection
4	CPOE with CDS; Nursing and Allied Health Documentation; Basic Business Continuity
3	Nursing and Allied Health Documentation; eMAR; Role-Based Security
2	CDR; Internal Interoperability; Basic Security
1	Ancillaries - Laboratory, Pharmacy, and Radiology/Cardiology information systems; PACS; Digital non-DICOM image management
0	All three ancillaries not installed

Quelle: https://www.himss.eu/healthcare-providers/emram

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HIMSS- Stages of the Model

Stage 0: The organization has not installed all of the three key ancillary department systems (laboratory, pharmacy, and radiology).

Stage 1: All three major ancillary clinical systems are installed (i.e., pharmacy, laboratory, and radiology). A full complement of radiology and cardiology PACS systems provides medical images to physicians via an intranet and displaces all film-based images. Patient-centric storage of non-DICOM images is also available.

Stage 2: Major ancillary clinical systems are enabled with internal interoperability feeding data to a single clinical data repository (CDR) or fully integrated data stores that provide seamless clinician access from a single user interface for reviewing all orders, results, and radiology and cardiology images. The CDR/data stores contain a controlled medical vocabulary and order verification is supported by a clinical decision support (CDS) rules engine for rudimentary conflict checking. Information from document imaging systems may be linked to the CDR at this stage. Basic security policies and capabilities addressing physical access, acceptable use, mobile security, encryption, antivirus/anti-malware, and data destruction.

Stage 3: 50 percent of nursing/allied health professional documentation (e.g., vital signs, flowsheets, nursing notes, nursing tasks, care plans) is implemented and integrated with the CDR (hospital defines formula). Capability must be in use in the ED, but ED is excluded from 50% rule. The Electronic Medication Administration Record application (eMAR) is implemented. Role-based access control (RBAC) is implemented.

Stage 4: 50 percent of all medical orders are placed using Computerized Practitioner Order Entry (CPOE) by any clinician licensed to create orders. CPOE is supported by a clinical decision support (CDS) rules engine for rudimentary conflict checking, and orders are added to the nursing and CDR environment. CPOE is in use in the Emergency Department, but not counted in the 50% rule. Nursing/allied health professional documentation has reached 90% (excluding the ED). Where publicly available, clinicians have access to a national or regional patient database to support decision making (e.g., medications, images, immunizations, lab results, etc.). During EMR downtimes, clinicians have access to patient allergies, problem/diagnosis list, medications, and lab results. Network intrusion detection system in place to detect possible network intrusions. Nurses are supported by a second level of CDS capabilities related to evidence-based medicine protocols (e.g., risk assessment scores trigger recommended nursing tasks).

Quelle: https://www.himssanalytics.org/emram

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HIMSS- Stages of the Model

Stage 5: Full physician documentation (e.g., progress notes, consult notes, discharge summaries, problem/diagnosis list, etc.) with structured templates and discrete data is implemented for at least 50 percent of the hospital. Capability must be in use in the ED, but ED is excluded from 50% rule. Hospital can track and report on the timeliness of nurse order/task completion. Intrusion prevention system is in use to not only detect possible intrusions, but also prevent intrusions. Hospital-owned portable devices are recognized and properly authorized to operate on the network, and can be wiped remotely if lost or stolen.

Stage 6: Technology is used to achieve a closed-loop process for administering medications, blood products, and human milk, and for blood specimen collection and tracking. These closed-loop processes are fully implemented in 50 percent of the hospital. Capability must be in use in the ED, but ED is excluded from 50% rule. The eMAR and technology in use are implemented and integrated with CPOE, pharmacy, and laboratory systems to maximize safe point-of-care processes and results. A more advanced level of CDS provides for the "five rights" of medication administration and other 'rights' for blood product, and human milk administrations and blood specimen processing. At least one example of a more advanced level of CDS provides guidance triggered by physician documentation related to protocols and outcomes in the form of variance and compliance alerts (e.g., VTE risk assessment triggers the appropriate VTE protocol recommendation). Mobile/portable device security policy and practices are applied to user-owned devices. Hospital conducts annual security risk assessments and report is provided to a governing authority for action.

Stage 7: The hospital no longer uses paper charts to deliver and manage patient care and has a mixture of discrete data, document images, and medical images within its EMR environment. Data warehousing is being used to analyze patterns of clinical data to improve quality of care, patient safety, and care delivery efficiency. Clinical information can be readily shared via standardized electronic transactions (i.e., CCD) with all entities that are authorized to treat the patient, or a health information exchange (i.e., other non-associated hospitals, outpatient clinics, sub-acute environments, employers, payers and patients in a data sharing environment). The hospital demonstrates summary data continuity for all hospital services (e.g., inpatient, outpatient, ED, and with any owned or managed outpatient clinics). Physician documentation and CPOE has reached 90% (excluding the ED), and the closed-loop processes have reached 95% (excluding the ED).

Quelle: https://www.himssanalytics.org/emram

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EMR in Europe

Stage	Denmark	Germany	Italy	Netherlands	Spain	Turkey	Europe*
Stage 7**	0.0%	0.7%	0.0%	2.9%	0.0%	0.2%	0.3%
Stage 6**	0.0%	0.0%	2.2%	8.6%	6.3%	2.1%	2.5%
Stage 5	100.0%	16.9%	34.8%	62.9%	47.9%	16.7%	29.5%
Stage 4	0.0%	4.9%	2.2%	0.0%	4.9%	10.4%	6.7%
Stage 3	0.0%	9.2%	1.5%	0.0%	2.8%	7.7%	5.3%
Stage 2	0.0%	29.6%	34.1%	22.9%	26.4%	44.3%	34.5%
Stage 1	0.0%	1.4%	18.5%	2.9%	2.1%	8.4%	7.9%
Stage 0	0.0%	37.3%	6.7%	0.0%	9.7%	10.4%	13.3%
N	24	142	135	35	144	666	1,462

EMRAM Scores Krankenhäuser Q4/2016
Quelle: www.himss.eu

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What is E-Health?

- eHealth is the use of information and communication technologies (ICT) for health. Examples include treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health.
  (WHO, 2015)

- **Networking** of the actors in the healthcare sector; Provision of suitable technology and technical concepts, methods and tools.
- **Integration** of the processes in the enterprise and cross-actor integration of the processes, in particular the treatment paths of the patients, supported by the use of integrated IT systems
- **Interoperability** of the processes and IT systems at syntactic and semantic level
- **E-Health**: **Enabler** of new, innovative, networked, cross-actor process organizations in the healthcare sector.

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Trend or Buzzword?

- Digital Medicine
- Personalized health, healthcare and care Individualized medicine
- Clinical Data Warehouse Systems
- Big Data and Smart Data
- mHealth / Smart Health / HealthApps / xHealth
- Telemedicine - new care models
- Intelligent systems
- "Digital break-up" of sectoral structures

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Digital Medicine

- Digital acquisition of medical data
- Biomedical research - sequencing of genomes, electronic storage, processing and use
- "Intelligent" linking of data, driven forward e.g. by Funding Concept Medical Informatics
- Big Data Centers
- Further funding priorities of the BMBF:
  - Interactive ICT technologies for a patient-friendly medical technology,
  - Electronic systems for smart medical systems,
  - ICT for safe and reliable medical technology,
  - Photonic system solutions for medicine,
  - Networked production of medical technology systems economically and in the highest quality

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mHealth / Smart Health / HealthApps / xHealth

- ✓ Mobile Health
  - ✓ increasingly relevant, especially in structurally weak countries
  - ✓ Sales in 2013 approx. 4.5 billion, 2016 approx. 15.4 billion
- ✓ Smart Health
  - ✓ Advanced sensors, discreet (permanent) "monitoring", VR technologies
    → permanent collection and analysis of health data
- ✓ HealthApps
  - ✓ Approximately 160-200TSD HealthApps
  - ✓ 3 Mrd. Downloads (2016)
- ✓ xHealth
  - ✓ Patient centered - patient is master of his data
  - ✓ Patient releases data (self-determined)

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Intelligent Systems

PWC Study: 5 Trends why Artificial Intelligence and Robotics have no Alternative:

1. Increase in chronic, complex, longer-term illnesses
2. Explosion of (structured and unstructured) health data
3. IT in healthcare: from product to service and solution
4. Democratization of access to health care
5. Blurring of the boundaries of public health, in particular through the "Internet of Things"

Quelle Frost & Sullivan, 'Transforming healthcare through artificial intelligence systems', 2016;
PWC-Studie What doctor? Why AI and robotics will de ne New Health (2016)

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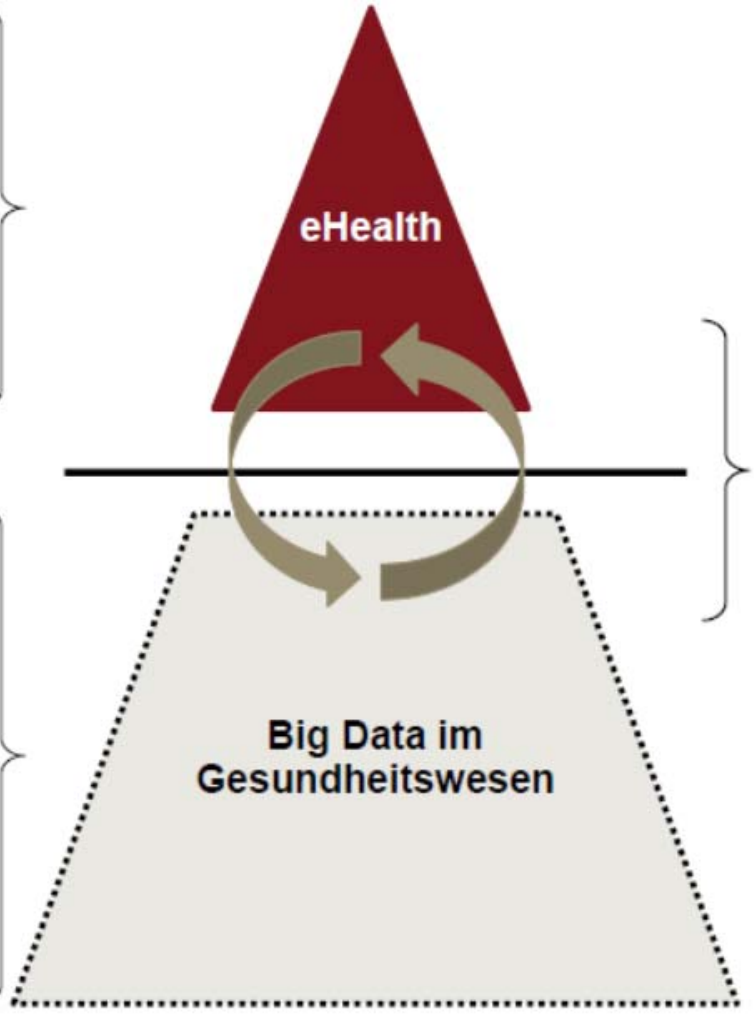
„Big Data“ - Analytics

eHealth
Gesundheitsbezogener Einsatz von IKT im Gesundheitswesen

Big Data
(Echtzeit-)Gewinnung von neuen Erkenntnissen und Zusammenhängen aus großen, weitgehend unstrukturierten Daten

- Epidemiologie und Gesundheitsmonitoring
- Epidemieprognose
- Entscheidungsunterstützung
- Gesundheitsprävention
- Forschungsunterstützung
- Leistungs- und Qualitätsbeurteilung
- Betrugsbekämpfung
- (Interne) Prozessverbesserung



Hohe Interdependenz

eHealth-Anwendungen sind **häufig Basis** für **Big Data**, da diese die Datenerhebung vereinfachen

Aggregierte Ergebnisse aus **Big Data-Analysen** bilden wiederum **relevante Grundlagen** für **eHealth-Anwendungen**

Quelle: BMG (2016)

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„Digital“ challenges for the actors

- ✓ Inpatient care: hospitals
- ✓ Outpatient care: (specialist) medical practices
- ✓ Nursing care: facilities, services, ...
- ✓ Service providers: health insurance
- ✓ Beneficiary: patients

- ✓ Required conditions? in the healthcare system

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Inpatient Care

- ✓ Healthcare research: using your own data for better quality or outcome
- ✓ Revenue security through digital, structured documentation
- ✓ Efficiency improvement of the processes
- ✓ Standardized, IT-supported processes
- ✓ Integration of e-health into the service offering

☹ Challenge:

- „DRG“ brings money
- Investment funds limited / financial situation rather bad
- Investing in "direct" service areas
- Comparatively poor staffing in IT

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Mega-Trend IoT (1)

Ärzte Zeitung 08.06.2017

- ✓ collaborative robotic:
  Human and robotic working together
  - ✓ division of labor between human and robot
  - ✓ Support in nursing
  - ✓ Surgical robot
  - ✓ (Partial) automated transport systems

com.Magazin 11.11.2015

- ✓ 3D-Print – new supply chains:
  digital spare part, medical products, medicines, food?!
  - ✓ Implants, organs and stem cells (bioprinting)
  - ✓ Individual medication, production of polypillen
  - ✓ 3D printer Pizza

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Mega-Trend IoT (2)

Wirtschaftsbrief Gesundheit

- ✓ Predictive Maintenance:

  Predictive maintenance based on sensors, algorithms and empirical values

  - ✓ Medical
  - ✓ Facility technology
  - ✓ Logistics

- ✓ What comes next?!

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Conlusion - Mega-Trend IoT

Internet of Things (IoT

achine Learning

Artificial Intelligence

ive Analytics

We are just at the beginning of these changes!

How the (data) world really will look in ~~10 to 20~~ 3-5 years ???

cc ehealth

Thank you!

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Empowering Health Professionals in Digital Health: Developing integrated Health Informatics Curricula - Results from the HiCure Project.

V ECPD REGIONAL CONFERENCE

Prof. Dr. Thomas Lux

Head of Competence Center eHealth (CCeHealth)

Chair of Process Management in Healthcare

ECPD | Opatija (HR) | September , 2018 |

Co-funded by the Erasmus+ Programme of the European Union

Erasmus+

HiCure
Excellence in Health Informatics Integrated Curricula

HiCure

Development of Health Informatics integrated curricula in Computing and Health-oriented undergraduate degrees

Co-funded by the Erasmus+ Programme of the European Union

Excellence in Health Informatics Integrated Curricula

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Niederrhein University of Applied Sciences

Partner

- Partner Countries:
  - Birzeit University (Palestine)
  - Hebron University (Palestine)
  - Jordan University of Science and Technology (Jordan)
  - Hashemite University Jordanien
- Programme Countries:
  - EAI-Atlantica University (Portugal)
  - HOCHSCHULE NIEDERRHEIN (Germany)
  - ATILIM UNIVERSITESI FOUNDATION (Turkey)
  - CUFR Jean-François Champollion-Albi University (France)

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Aims of the HiCure Project

- To improve the **level of competences** and **skills** of the four partner universities in Palestine and Jordan (Birzeit Uni, Hebron Uni JUST, Hashmite Uni).
- To enable the four partner universities to develop **sustainable integrated curricula** in Health Informatics, across the domains of health and information technology

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Objectives (I)

1. To implement an innovative undergraduate health informatics (HI) pathways within the undergraduate health and IT programmes in partner country universities.
2. To develop, validate and implement 12 courses and 4 case studies in health informatics using student- centred adaptive e-learning contemporary education methodology.
3. To develop capacities in educational integrated curricula development (aligned to QA procedures and informal education approaches)

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Objectives (II)

4. To improve the level of competencies and skills of staff in partner country universities by
    1. training visits for staff to EU partners to develop health-informatics expertise (in both HI and curriculum development and innovative learning)
    2. providing research collaboration opportunities with EU staff through joint- supervision of students' projects.
5. To create opportunities of collaboration between academia and industry in the areas of health-informatics and health-oriented information technologies.

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Working Pages (I)

- **Preparation**
  - WP1 : Health Informatics Pathway Structures [Lead: HSNR]
- **Development**
  - WP2 : Developing Capacity Building and Teaching platform and Resources [Lead: HaU]
  - WP3 : Development of Teaching Courses for Health Informatics [Lead: UALTA]*
  - WP4 : Development of Health Informatics-focused Case studies [Lead: HU]

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Working Pages (II)

- Quality Assurance
  - WP5: Quality Control and monitoring [Lead: AUF]
- Dissemination and Exploitation
  - WP6 : Implementation of the Health Informatics Pathways [Lead: BZU (+JUST)]
  - WP7 : Dissemination and Sustainability [Lead: JUST (+BZU+HU)]
- Management
  - WP8 : Management of the project [Lead: BZU]

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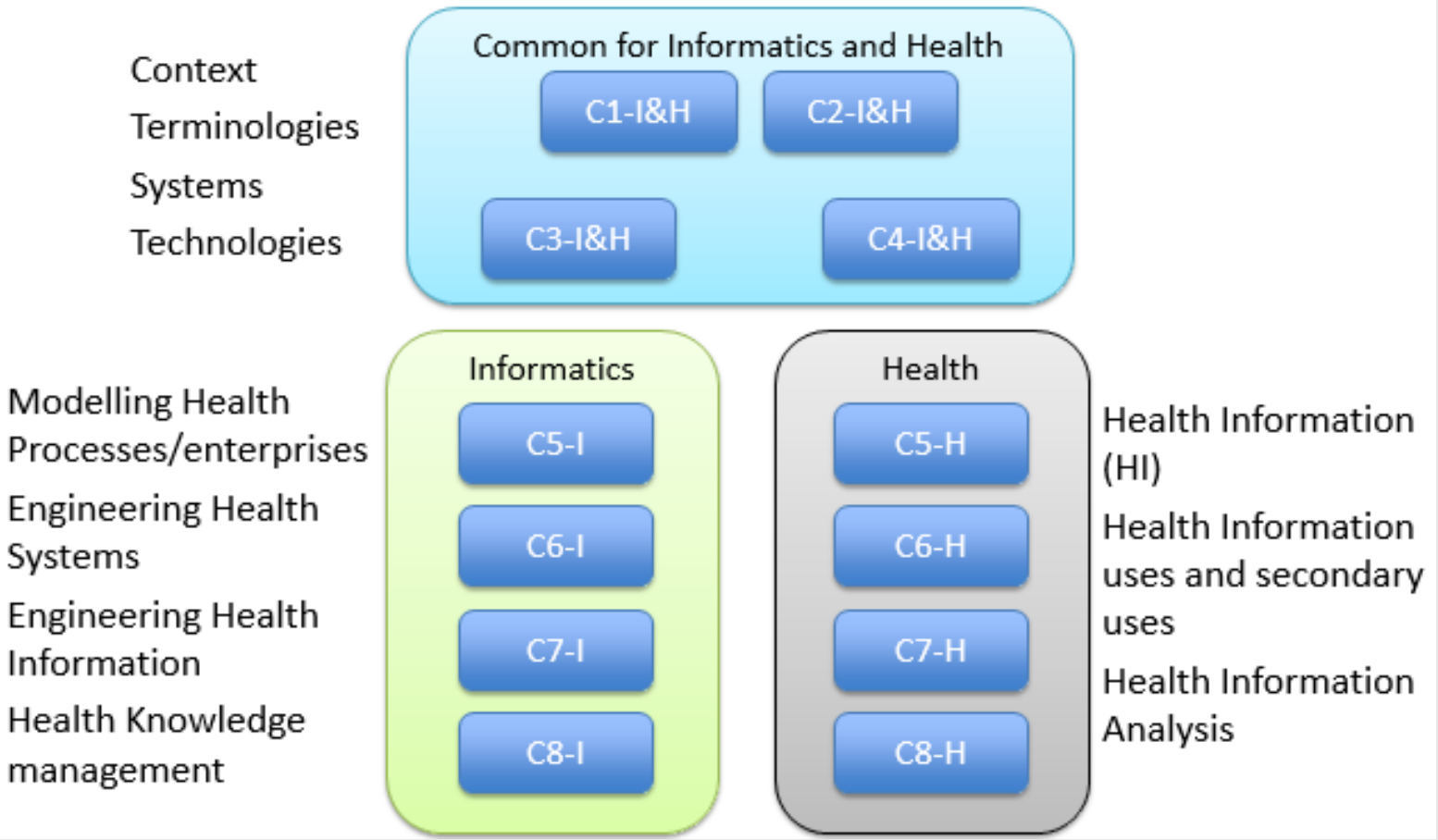
Integrated Pathways in Health Informatics



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Objectives

- Reviewing current health informatics curricula and existing programs in EU partners
- Revise existing program structures in both IT and health-oriented courses in partner countries
- Define structures and ways of creating an integrated curricula part of the existing programs

Co-funded by the
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Methods

- Literature Review
  - Recommendation of the IMIA on Education in Health Informatics
- Review Bologna Process
- Review Health Informatics curricula of partner countries
  - Germany, Portugal, France, Turkey

Co-funded by the
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Results

- Curriculum must be based on Competencies
  - Mapped to skills and subskills
  - Mapped to topics and courses

- Use of Topics instead of concrete courses
  - Allows each partner country to define an appropriate course

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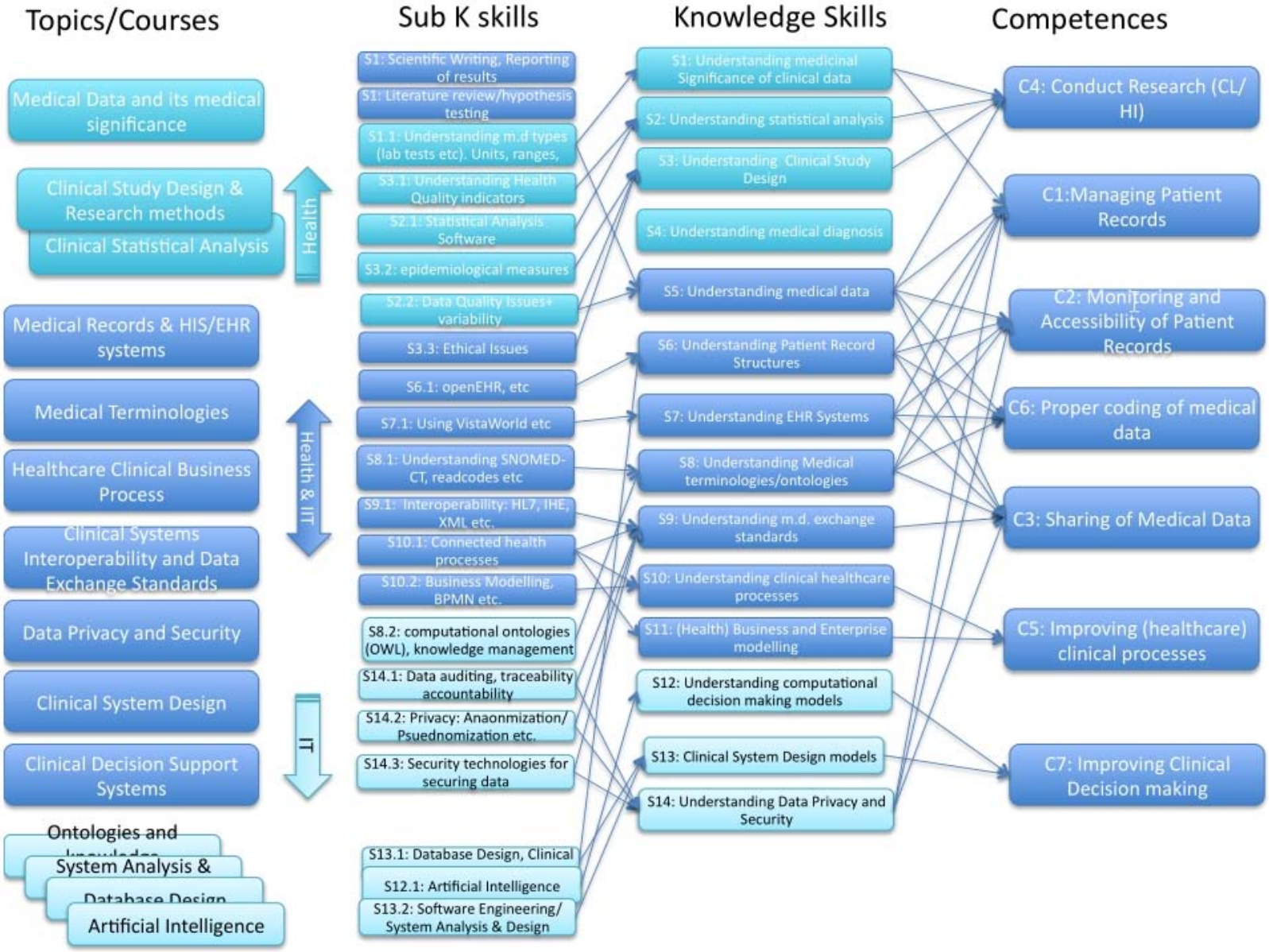
Analyze: HI-Courses and content in Germany

Course	Bachelor	Master	Total
Medical Informatics	10	10	20
Bioinformatics	6	5	11
Informatics (with minor course in Medical Inf./Bio-Inf.)	6	5	11

Module	Bachelor	Master	Total
Biomedical signal and image processing	25	19	44
E-Health (IT in Health-Care)	8	9	17
ICT in Health Care	13	4	17


Topics/Courses
Sub K skills
Knowledge Skills
Competences
Medical Data and its medical significance
Clinical Study Design & Research methods
Clinical Statistical Analysis
Health
Medical Records & HIS/EHR systems
Medical Terminologies
Healthcare Clinical Business Process
Clinical Systems Interoperability and Data Exchange Standards
Health & IIT
Data Privacy and Security
Clinical System Design
Clinical Decision Support Systems
IT
Ontologies and
System Analysis &
Database Design
Artificial Intelligence
S1: Scientific Writing, Reporting of results
S1: Literature review/hypothesis testing
S1.1: Understanding m.d types (lab tests etc). Units, ranges,
S3.1: Understanding Health Quality indicators
S2.1: Statistical Analysis Software
S3.2: epidemiological measures
S2.2: Data Quality issues+ variability
S3.3: Ethical Issues
S6.1: openEHR, etc
S7.1: Using VistaWorld etc
S8.1: Understanding SNOMED-CT, readcodes etc
S9.1: Interoperability: HL7, IHE, XML etc.
S10.1: Connected health processes
S10.2: Business Modelling, BPMN etc.
S8.2: computational ontologies (OWL), knowledge management
S14.1: Data auditing, traceability accountability
S14.2: Privacy: Anaonmization/ Psuednomization etc.
S14.3: Security technologies for securing data
S13.1: Database Design, Clinical
S12.1: Artificial Intelligence
S13.2: Software Engineering/ System Analysis & Design
S1: Understanding medicinal Significance of clinical data
S2: Understanding statistical analysis
S3: Understanding Clinical Study Design
S4: Understanding medical diagnosis
S5: Understanding medical data
S6: Understanding Patient Record Structures
S7: Understanding EHR Systems
S8: Understanding Medical terminologies/ontologies
S9: Understanding m.d. exchange standards
S10: Understanding clinical healthcare processes
S11: (Health) Business and Enterprise modelling
S12: Understanding computational decision making models
S13: Clinical System Design models
S14: Understanding Data Privacy and Security
C4: Conduct Research (CL/ HI)
C1:Managing Patient Records
C2: Monitoring and Accessibility of Patient Records
C6: Proper coding of medical data
C3: Sharing of Medical Data
C5: Improving (healthcare) clinical processes
C7: Improving Clinical Decision making

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Competences-Topics

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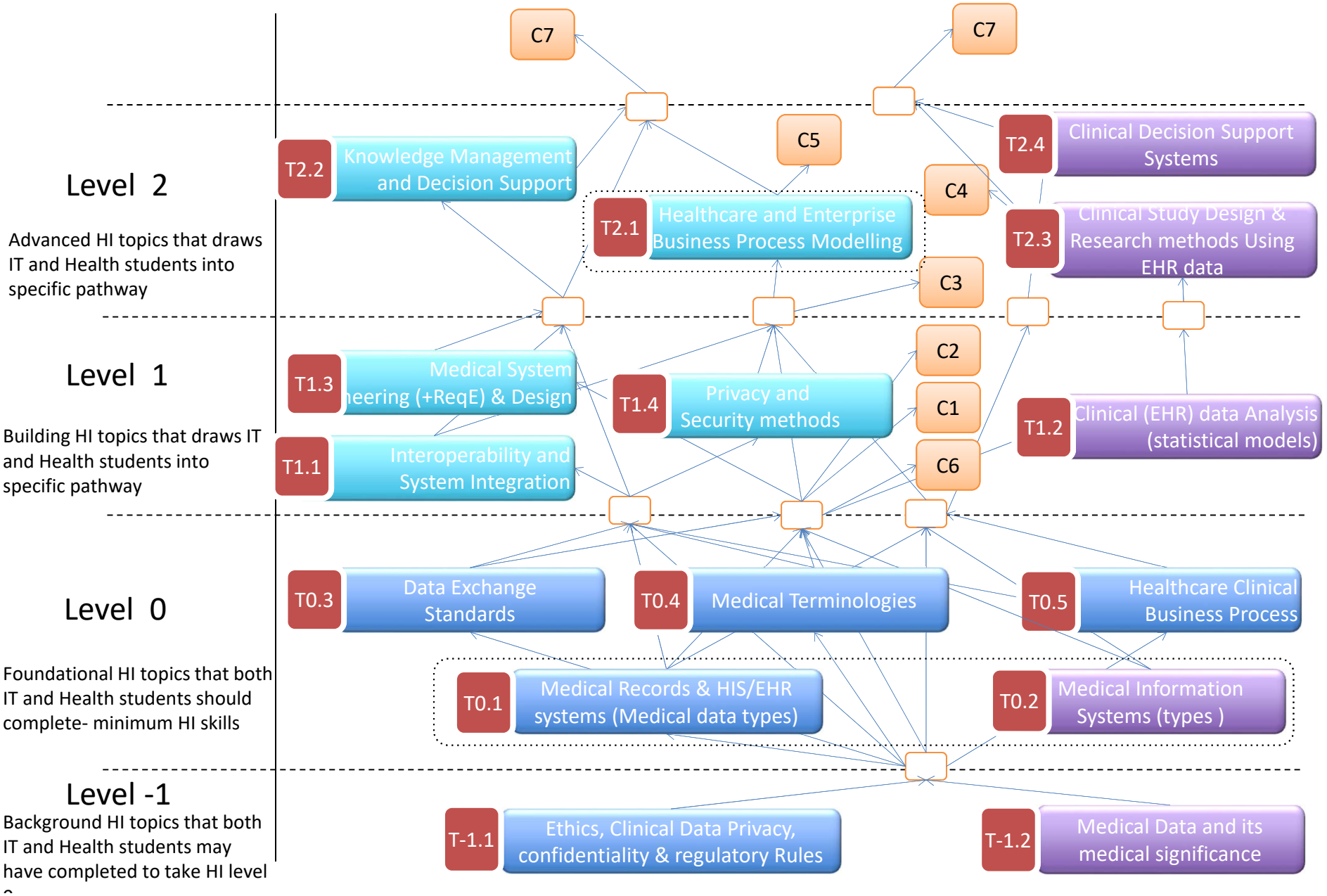

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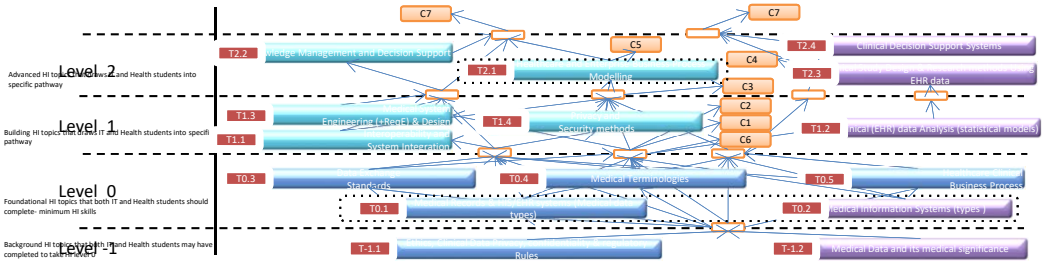
Sustainability -1

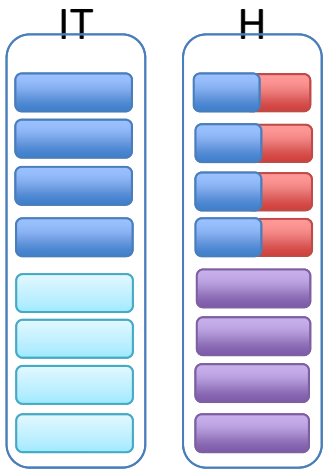
HiCure Overall Pathway



HiCure Implementation-1

BZU

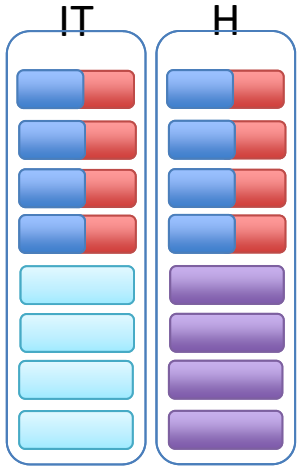
IT H



HiCure Implementation-2

Hebron

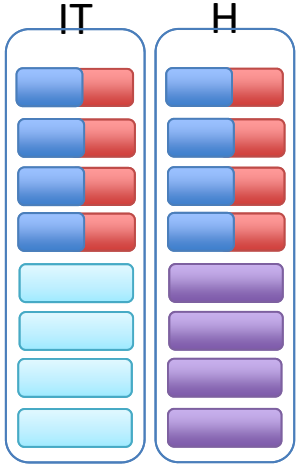
IT H



HiCure Implementation-3

JUST

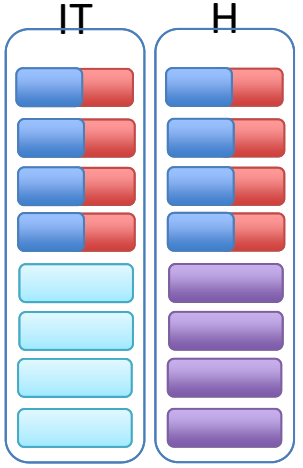
IT H



HiCure Implementation-4

Hashemite

IT H



Thank you!

HiCure

Co-funded by the Erasmus+ Programme of the European Union

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V ECPD REGIONAL CONFERENCE ON HEALTH ECONOMICS

ALLOCATION OF SCARCE RESOURCES IN HEALTH CARE

Dušan Keber

Ethical issues in individual, regional and national allocation of health resources

EUROPEAN CENTER FOR PEACE AND DEVELOPMENT (ECPD)
UNIVERSITY FOR PEACE EST BY THE UNITED NATIONS

Opatija, 28 - 29 September 2018

Definition of scarce resources

Resources or the use of resources that, because of naturally limited supply or economic constraints, are not readily available to all who need them.

Individual and social goods

The goal of saving an individual has to be balanced against concern for the social good and the wish to preserve such basic values as:

- justice
- fairness
- human dignity
- bodily integrity

Central ethical values in health care

Traditional medical practice has its foundation in the principles of doing no harm, acting for the good of patients and caring for all of those who come in need.

The ethical practice of allocation of scarce resources may require the thoughtful practitioner to violate these central moral tenets.

Acceptable criteria for resource allocation

1. The likelihood of benefit to the patient
2. Improving the quality of the patient's life
3. The duration of benefit
4. The urgency of the patient's condition
   (i.e.: how close is the patient to death)
5. The amount of resources required for successful treatment

Each of these five criteria serve to maximize the following three goals of medical treatment:

1. Number of lives saved
2. Number of years of life saved
3. Improvement in quality of life

Likelihood of benefit

Giving priority to patients with a greater likelihood of benefiting from treatment is necessary for any efficient use of medical resources.

- It maximizes number of lives saved as well as length and quality of life.
- Care that has a low likelihood of benefit must be distinguished from care that is truly futile (care that cannot be expected to have any physiologic benefit).

Change in quality of life

- Benefit to patient will be maximized if treatment is provided to those who will have the greatest improvement in quality of life.
- Deciding on a standard definition is dependent on patient individual values.
- Focus on functional status allows for objective measure of QOL.

Duration of benefit

The length of time a patient benefits from treatment can, in certain situations, be an appropriate consideration in maximizing overall benefit:

- limited to life expectancy but not an absolute consideration

  based on patient's own medical history and prognosis, not aggregate statistics or membership in a group

Urgency of need

Prioritizing patients according to how long they can survive without treatment can help achieve the goal of maximizing the number of lives saved.

- Important consideration but must be tempered with other criterion
- Preventing death (by treating urgency first) should generally be given priority in allocation decisions
- But not if the life saved would be of extremely poor quality or extremely short duration

Amount of resources requested

On occasion - assigning higher priority to patients who will need less of a scarce resource maximizes the number of lives saved.

Inappropriate criteria for resource allocation

Often used, but considered ethically unacceptable

1. Ability to pay
2. Contribution of the patient to society (social worth)
3. Perceived obstacles to treatment
4. Contribution of the patient to his or her own medical condition
5. Past use of resources

Three basic ethical concepts in the allocation of scarce resources

1. Utility
2. Justice
3. Autonomy

Utility

Utility holds that an action or practice tends to be right if it results in as much or more aggregate good than any alternative action or practice

It requires calculating the net benefit of the use of a resource for each person affected and summing the benefit over the number of total persons affected

In rationing scarce medical resources, it is morally imperative to consider medical utility, understood as maximization of the welfare of patients in need of treatment

Utility Must Consider

- Patient survival
- Survival of the resource
- Psychological state of the patient
- Quality of life
- Age
- Availability of alternative treatments

Justice

Justice is a primary concept for the allocation of scarce resources.

Being just is consistent with the principles of

- moral right
- equality
- fairness

A concept of fairness, proportionate to needs, ensure that all are treated equally

- It refers to fairness in the distribution of benefits and burdens of an allocation program
- But - What is fair?

Equal access to care

Equal access to care is based on the concepts of equality and justice, wherein all persons must be able to compete on an equal footing for the opportunities that society offers, however, no rights are absolute.

Autonomy

- Autonomy is seen as both a moral principle and a psychological state.
- Persons want to make their own decisions and are, thus, autonomous.
- If a resource, such as an organ, becomes available and the person is best-qualified by the principles of utility and justice to receive the organ, and they decide to turn the opportunity down for whatever reason, they shall have exercised the principle of autonomy.

Fairness and justice must consider

- Medical urgency of the patient
- Likelihood of finding or accessing the resource in the future
- Waiting times
- First versus repeat resource utilization
- Efficacy of the use of the resource

Autonomy must consider

- The issue of the right of the individual to refuse the resource
- Free exchanges among autonomous individuals
- Allocation of the resource - such as through directed donation
- The voluntary behaviors of potential recipients

Limits on the right to health care

- If each citizen has a right to healthcare, what happens when they conflict?
  - » *Can I rightfully claim an organ from a healthy person?*
  - » *What if two people need a donated kidney?*
- Even where our rights don't conflict, there will always be limits in the form of available resources

Limited resources

- Resources are always limited
- Scarcity of resources can be radical or comparative
  - Radical: not enough for everyone
  - Comparative: not enough to treat everyone now

What limits resources…?

- **Financial constraints**
  - No money to spend
  - Unfair distribution of what money there is
- **Increased supply and demand**
  - Improved treatments and technology allows medicine to treat more disease.
  - Innovations are frequently brought ‘to the market’ by companies who need to generate profit from their investment
  - People live longer and *expect* to live longer
  - With longer lives the nature of the treatment to be delivered changes over time.

Types of distribution problems

Macro-allocation

- Department of health
- Health, safety and environment
- Hospitals F

(Fighting for and then apportioning its budget)

Micro-allocation

- Deciding between patients

Macro-allocation of resources

Global problems in terms of equity:

- Insufficient resources for essential medicines e.g. anti-retrovirals
- Doctors often have to train abroad
- Staff are often lured abroad

Responses

- Individual – is there a moral duty to a country?
- Suppliers (Do drug companies have any moral obligation?)

National problems in terms of equity

- Are some regions favoured over others?
- Does socio-economic status affect access to health care?

How to macro-allocate…

Need based analysis

- How is need defined?
- How are different needs evaluated / compared?
  - Does kidney dialysis count for more or less than a ruptured appendix?
  - Does a fractured hip in an elderly person count for more or less than a young adult?
  - How to assess value of life?

Lobbying

- A range of people have input into the decisions that are made:
  - Medical professionals
  - Managers
  - Economists
  - Politicians
  - Public opinion
  - Lobby groups
  - Media
- Each group will have its own priorities and bias.

Some countries' approaches

Oregon

- People were polled for their opinion on an adaptable, prioritised list of available treatments
- Problems:
  - list inflation
  - list can fluctuate depending on the state of the budget

New Zealand

- Guidelines on how public resources are to be allocated
  - e.g. end-stage renal dialysis is not for over-75s
  - serious disease or disability likely to affect survival are grounds for exclusion.

Some countries' approaches

United Kingdom

- National Institute for Clinical Excellence (NICE)
  Decisions are made on the basis of pure clinical need and clinical efficiency.
- Treatment A has a better side-effect profile, but is (a) no more efficacious and (b) ten times more expensive than B. What to do?
  - NICE uses QALYs
  - The cost per QALY is an important determining factor: a drug costing >£25-35K/QALY would require stronger reasons to be recommended than one costing £5K/QALY
  - When NICE makes a recommendation, it is binding on purchasers, but not on practitioners.

Micro-allocation

deciding between individuals

- Decisions to treat individuals may not only be dependent on resources factors:
  - Patient autonomy
  - Availability of non-resource materials, such as organs

- Some decisions may seem instinctive
  - Treat the person who is in the greatest pain?
  - Treat the person who can realistically be saved?

Assessment of need as a quantity

- One definition of need is “when an individual has an illness or disability for which there is an effective and acceptable treatment”.
- But need may be qualified further by asking who ‘needs’ a treatment more:
  - The urgency, intensity and importance of the need
  - The amount of what is needed
  - The capacity of the person to benefit from what is needed

Treatment outcomes

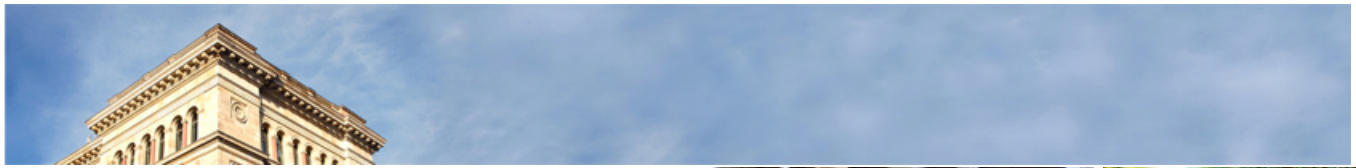
- Who will live longest with treatment?
  - Will discriminate against the older person.
  - May discriminate against those who have underlying conditions that are nothing to do with the condition being considered for treatment –double jeopardy.
  - Does the fact that both patients stand to lose the same thing (*i.e.* their lives mean that in fact they should be treated equally).
  - We each have the ‘rest of lives’ before us.
- Who will respond best to treatment?
- What about resource allocation where there is no real ‘treatment’ being proposed?

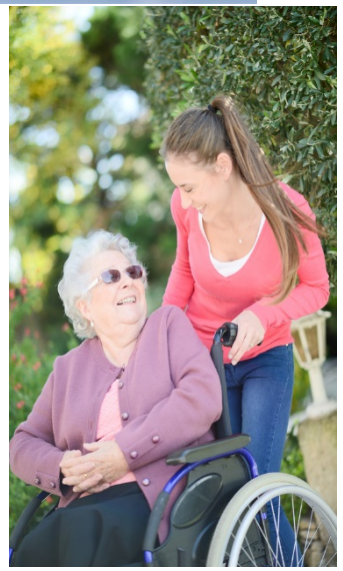
QALYs - Quality Adjusted Life Years

- A common mechanism for working out who to treat
  - Term comes from Health Economics, rather than Ethics
- Based on the idea of questioning people about how they see certain disorders.
- Asked to rank living with certain conditions/disabilites/ symptoms
  - 1 = Completely normal life
  - 0 = Death
  - Multiplied by the number of years that the person is expected to live
- The more QALYs a given treatment will produce - having regard to the cost of that treatment - the clearer the indication as to whether that treatment should be given to that particular person.

Problems with QALYs

- Assessment might not take enough consideration of how a person who actually *has* the condition etc... might feel
- May therefore involve value judgment about how people are likely to think rather than how they actually *will* think
- Numerical bias: two years of life for one person is ‘better’ than one year of life for two people (because cost of treating them is higher).
- May discriminate:
  - Elderly
  - People with conditions that are cheaper to treat
  - Those with pre-existing conditions





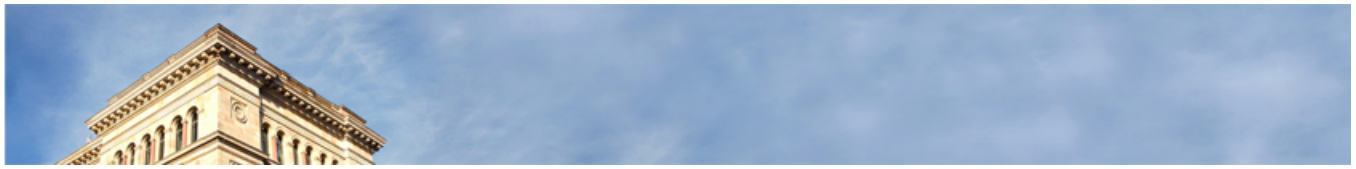
Macro, meso, micro allocation of resources in health care:

Setting priorities and tools from an economist´s perspective

September 28th 2018

Prof. Dr. Klaus-Dirk Henke,
Technische Universität Berlin

Allocation of scarce resources in health care, 28/29th September 2018, Opatija, Croatia



Allocation of scarce resources
a short introduction from a health economist

- A summary as starting point (one chart)

- Functional approach to allocation

top-down (two charts**)**

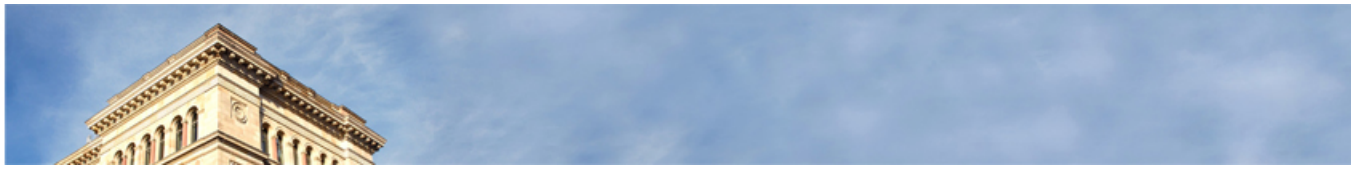
bottom-up (two charts**)**

- Institutional approach to allocation

  Fiscal agents (one chart**)**

  Sources of funds (one chart**)**

- **Take home messages**: Measuring performance in health care **(**one chart**)**



Technische Universität Berlin

A summary as starting point: There is no gold standard

Perspective 1:
There is no optimal health expenditure quota

Perspective 2:

There is no optimal structure for health expenditures

Perspective 3:
There is no optimal number of fiscal agents

Perspective 4:

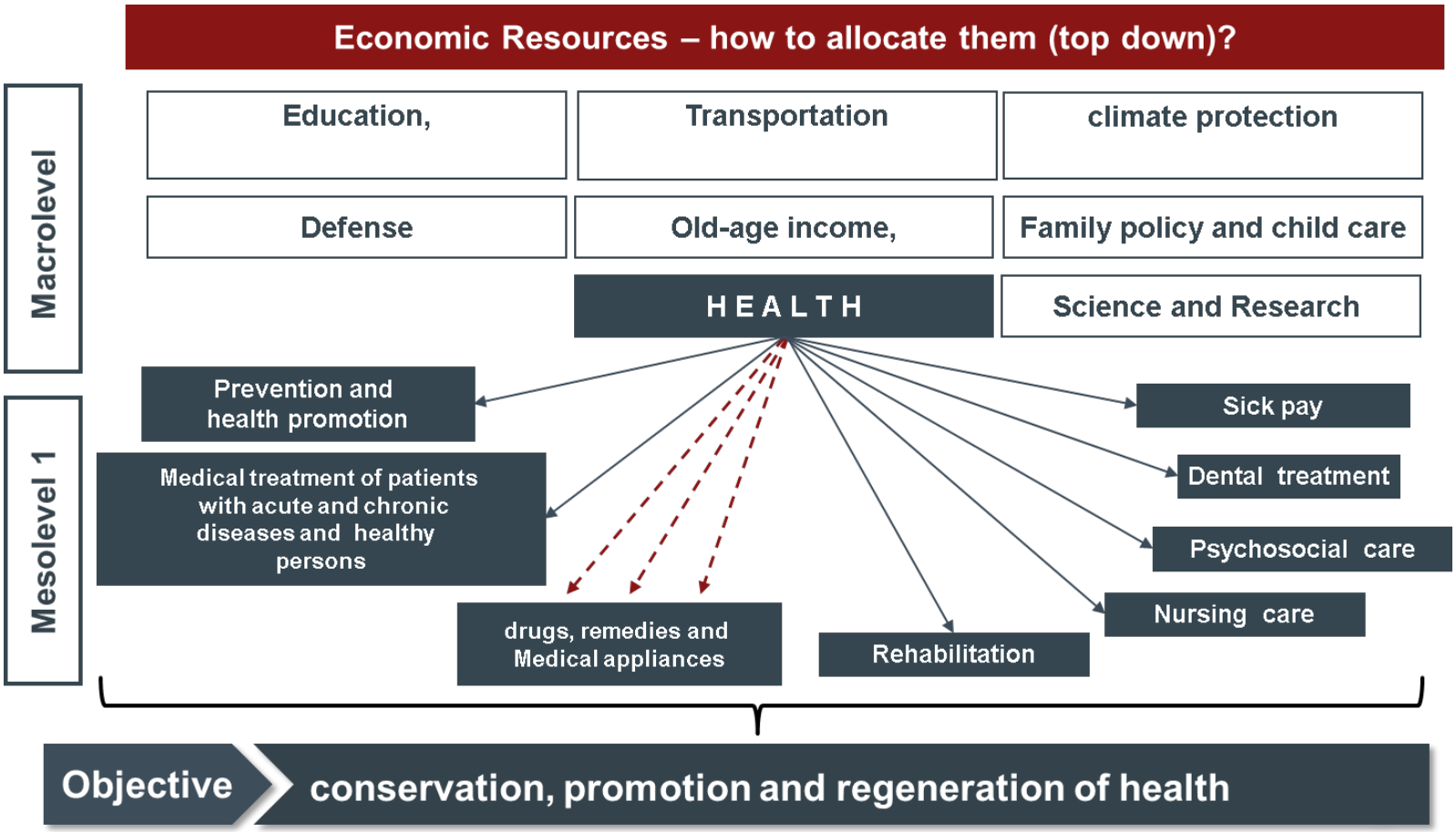
There is no optimal form of financing

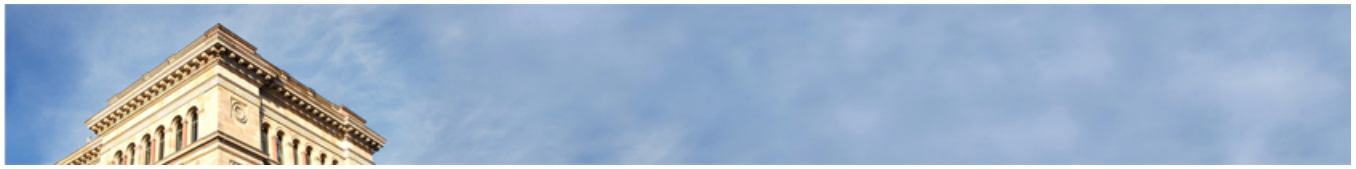
Perspective 5:
Health care is a major contributor to better health and more wealth

Perspective 6:
Healthy life years and everyday suitability are major objectives; add more life to years than years to life

A functional approach to allocation

A macro- and mesoeconomic (1) point of view





A functional approach from the point of view of a health economist

Macrolevel: There is no optimal Health Expenditures Quota

Mesolevel 1: There is no optimal structure within health care

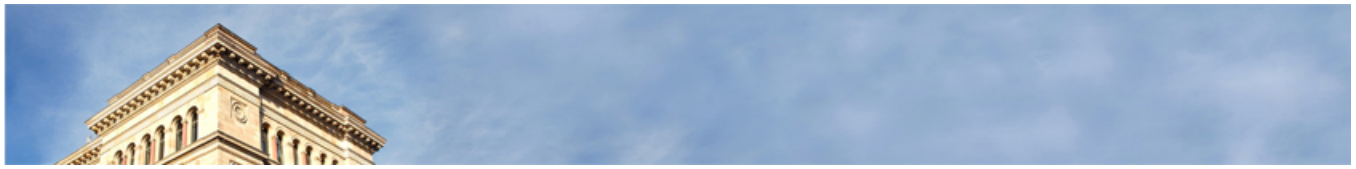
» Resources should be invested, where the health benefit is the highest

» „Value defined as the health outcomes achieved per dollar spent“ (M. E. Porter)?

» On the basis of evidence-based-medicine (EBM), health technology assessment (HTA) and health assessment (HA)

Ex-ante-Macro-Allocation of resources are indispensable; you cannot leave the allocation to the market

But: Which mechanisms and through which institutions? NICE (National Institute for Health and Care Excellence) in England, G-BA (Gemeinsamer Bundes-ausschuss, joint federal committee in Germany) and similar institutions in the balkan states.



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A functional approach to allocation

A mesolevel (2) and micro – point of view (bottom up)

Objective → **Avoidable Mortality, Morbidity and Invalidity**

Mesolevel 2

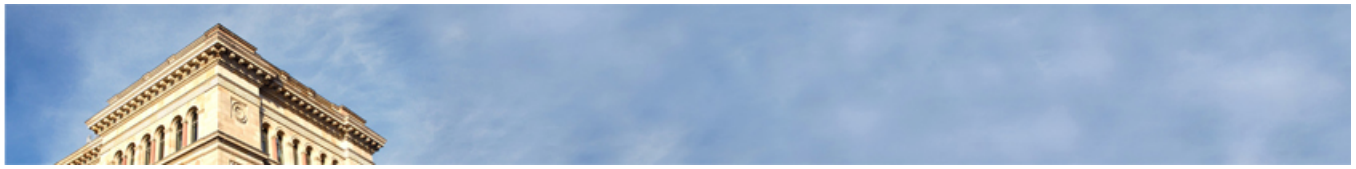
- Diseases of the respiratory organs
- Diseases of the skeleton, muscles, and of connective tissue
- Traumas
- Infectious diseases
- Psychiatric diseases and diseases of the nervous system
- Malignant growth
- Allergies
- Heart and circulatory diseases
- Diseases of the digestive organs

Disease management on the basis of multimorbidity

Microlevel

Individual demand for healthcare and protection;

funded by health budgets, fonds and and additional private expenditures



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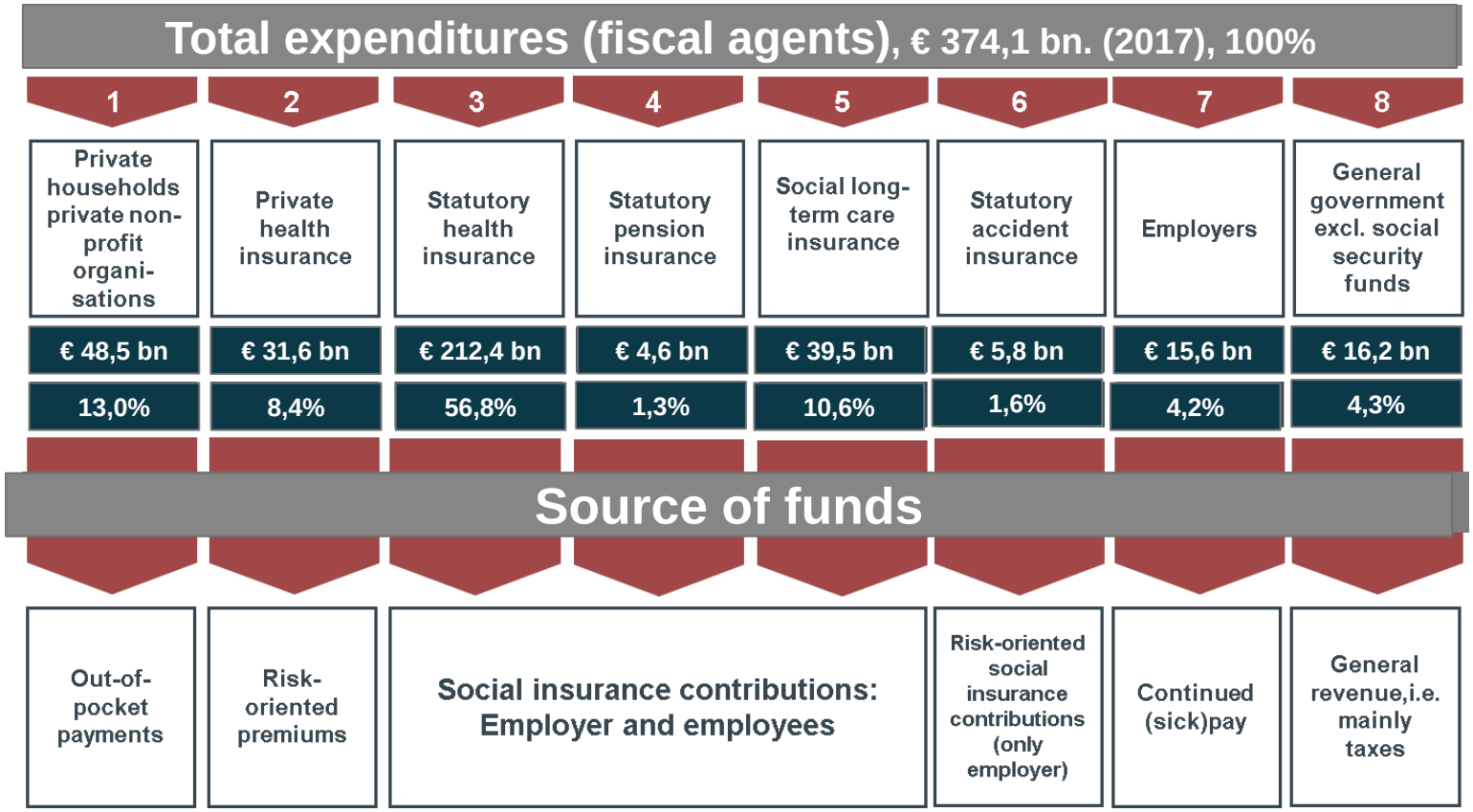
A functional approach from the point of view of a health economist

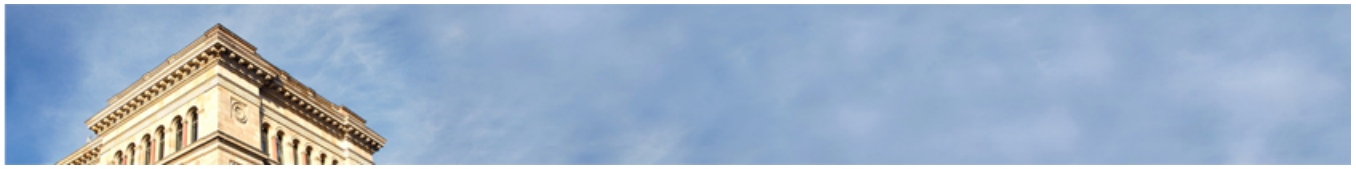
- **Mesolevel 2:** Cost-of-illness studies show us the most expensive diseases according to expenditures and to life years lost and are a basis for priority setting,
- Foundations, press/media, population group (e.g. children)
- **Microlevel:** Need for better Orientation and Empowerment of the patient, enabling the population to live a healthy lifestyle
- Freedom to choose health care coverage, the doctor, the hospital as far as possible in a given legal framework

Institutional approach – fiscal agents and sources of funds

Expenditures (fiscal agents) and Source of Funds



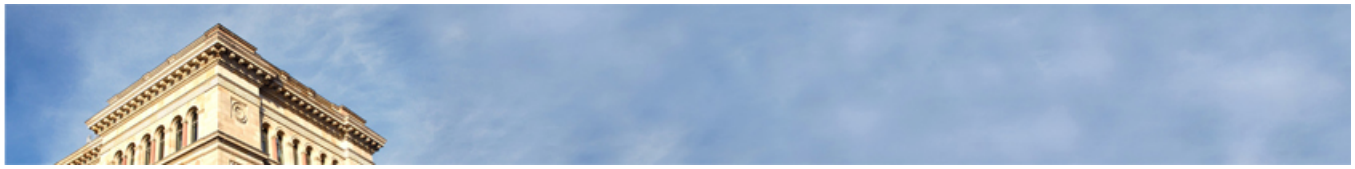
Source: www.gbe-bund.de



More questions than answers

1. Are single-payer systems better (Scandinavia, UK)?
2. How many fiscal agents are necessary?
3. Should hospital financing (current outlays and investment expenditures) be in one hand?
4. Should statutory health insurance (funds), rehabilitation and nursing home care for the elderly in one hand?
5. Should the private household be the health location Nr. one?

   YES as long as possible.



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Take home messages: Measuring performance in health care

Improving value for money

1. by paying for performance
2. through more selective contracting instead of collective contracting
3. by involving patients more in their own care
4. through a more entrepreneurial and innovative behaviour of the provider
5. through evidence-based health policy
6. through a consistent basic legal framework and binding guidelines
7. through more cooperation and transparency in the health care sector

And last but not least: Health in all policies

Thus health assessment is a major scientific challenge

(see macrolevel in chart 4)

Multi-Criteria Decision Analysis (MCDA):

Methodology for resource allocation

ÁLVARO HIDALGO VEGA
UCLM, WEBER Foundation

September 29, 2018

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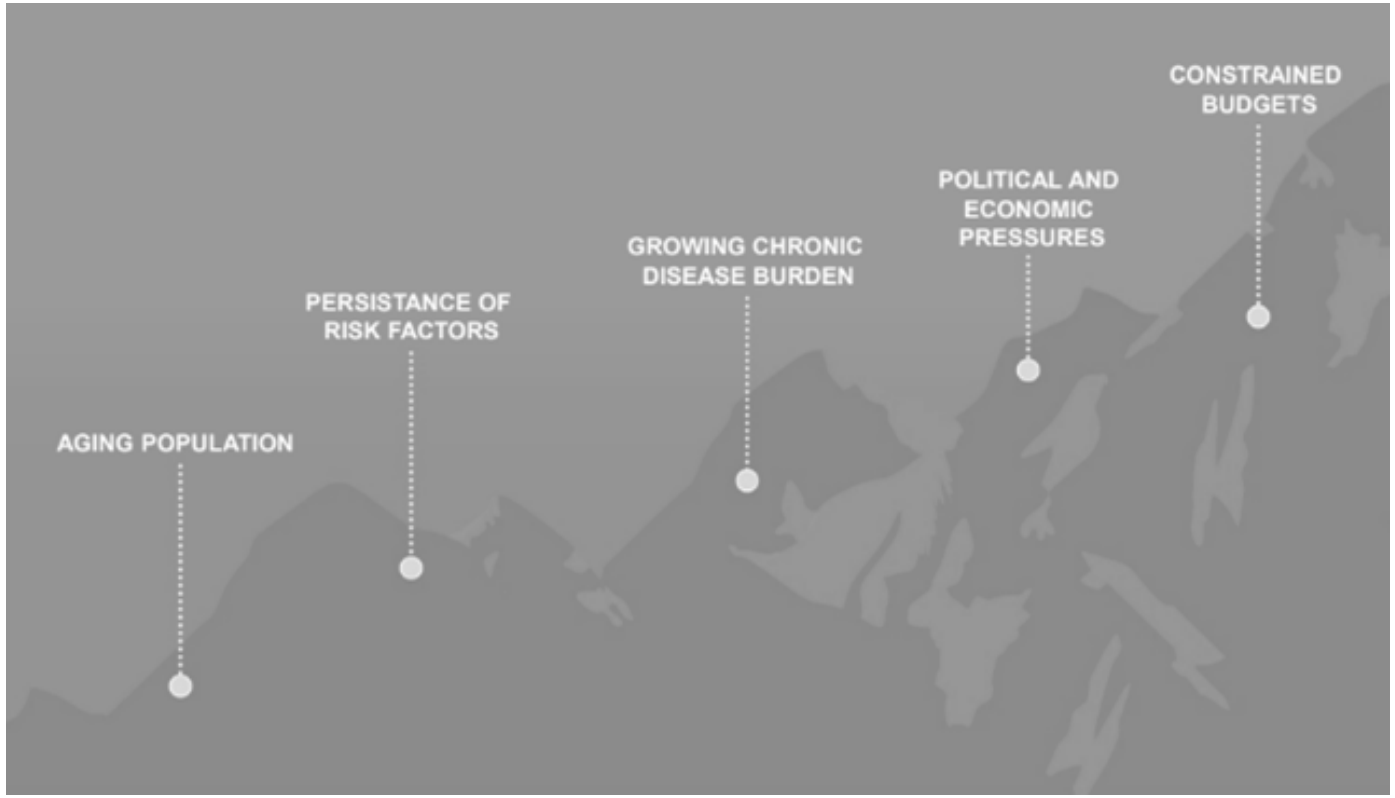
Current challenges for health systems



Increasing elderly population

- Relative decrease in resources (fewer taxpayers), chronic patients, increased life expectancy

Financial sustainability of care

- Technologies, informed/demanding patients; chronic diseases

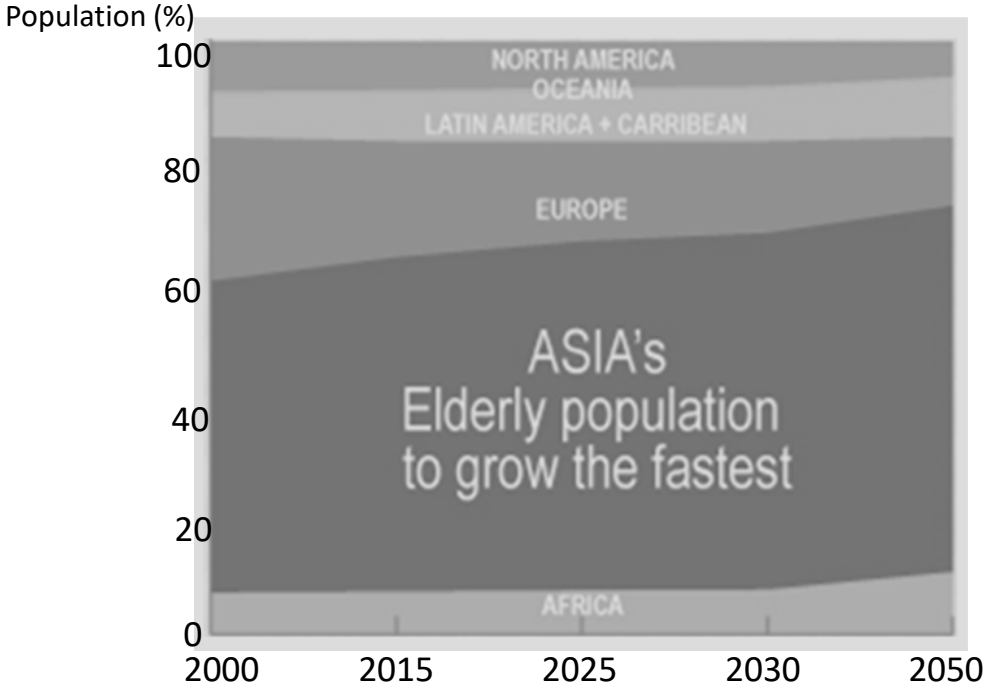
Healthcare expenditure growing faster than the economy

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Current challenges for health systems

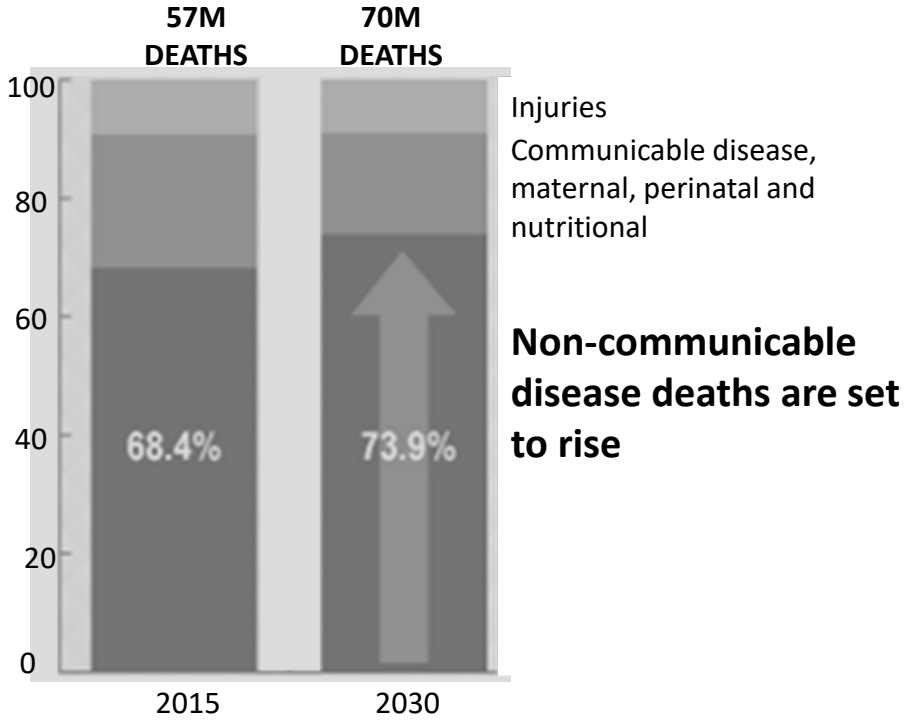
DEMOGRAPHIC SHIFTS

DISTRIBUTION OF OLDER POPULATION (60+), GLOBAL, 2000-2050.
Increasing life spans will result in a larger elderly population based, mostly concentrated in Asia; however, a growing working adult population will support them until 2025



DISEASE SHIFTS

DISTRIBUTION OF DEATH BY CAUSE, GLOBAL, 2015-2030.
With rising incidence of chronic diseases and cancers, the global mortality profile will shift towards non-communicable diseases by 2030



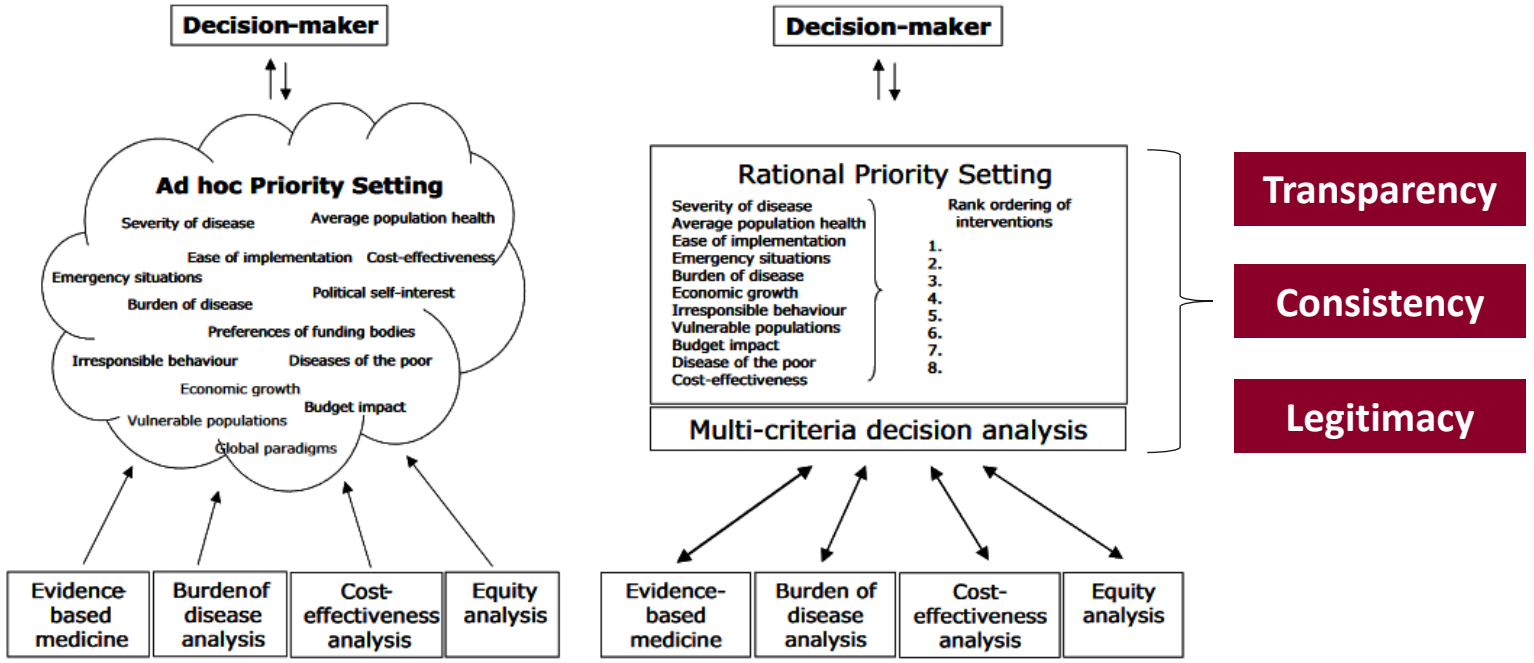
Non-communicable disease deaths are set to rise

Source: World Population Ageing Report (WHO) Frost & Suvillan, Vision 2025

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Challenges with current decision-making processes

Ad hoc priority setting and rational priority setting



Source: Baltussen 2006

Health needs and innovations put an ever-increasing demand on limited health budgets.

Policy makers need to make important decisions on the use of public resourses, any decision involves forgoing the benefits of the others (opportunity cost).

Decisions on the choice of health interventions are complex and multifaceted.

Many criteria, or factors, play an important role in the decisions. If more than one criteria is in play, approaches don't inform how to integrate these.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Main criteria and "other" considerations used internationally for prioritizing new health technologies.

Principles of allocative justice	Criteria	Australia	Canada	Denmark	Finland	France	Israel	New Zealand	Norway	Oregon	Sweden	The Netherlands	UK
• Need	General	✓	✓					✓		✓			✓
	Severity of the condition			✓		✓	✓		✓		✓	✓	
	Availability of alternatives		✓			✓	✓	✓					
• Appropriateness	Efficacy and safety					✓	✓	✓				✓	✓
	Effectiveness			✓	✓			✓		✓			
• Clinical benefits	General	✓	✓	✓			✓	✓			✓		
	Effect on mortality (life saving)						✓		✓	✓	✓		
	Effect on longevity						✓			✓			
	Effect on health-related quality-of-life	✓	✓				✓			✓			
• Efficiency	Cost-effectiveness/benefit	✓		✓		✓		✓	✓	✓	✓	✓	✓
	Budgetary impact		✓		✓		✓	✓					
	Cost		✓				✓						
• Equality	General	✓		✓				✓	✓	✓	✓	✓	✓
	Accessibility to the service	✓	✓	✓									
	Affordability to the individual						✓	✓				✓	
• Solidarity			✓	✓			✓		✓		✓	✓	
• Other ethical or social values	Autonomy	✓		✓							✓		✓
	Public health value					✓							
	Impact on future generations	✓											
'Other' considerations													
• Quality of the clinical and economic evidence			✓		✓				✓				✓
• Other considerations not elsewhere classified	Strategic issues consistency with previous decisions and precedents		✓					✓					✓

Sourcee: Golan 2011

Health Technology Appraisal (HTA) processes require the consideration of multiple criteria which go beyond improvements in patient and population health.

Decision-making, whatever the level of resource allocation, requieres the prioritising and weighting of these criteria in such a way that implicit interchange relationships are established between them.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

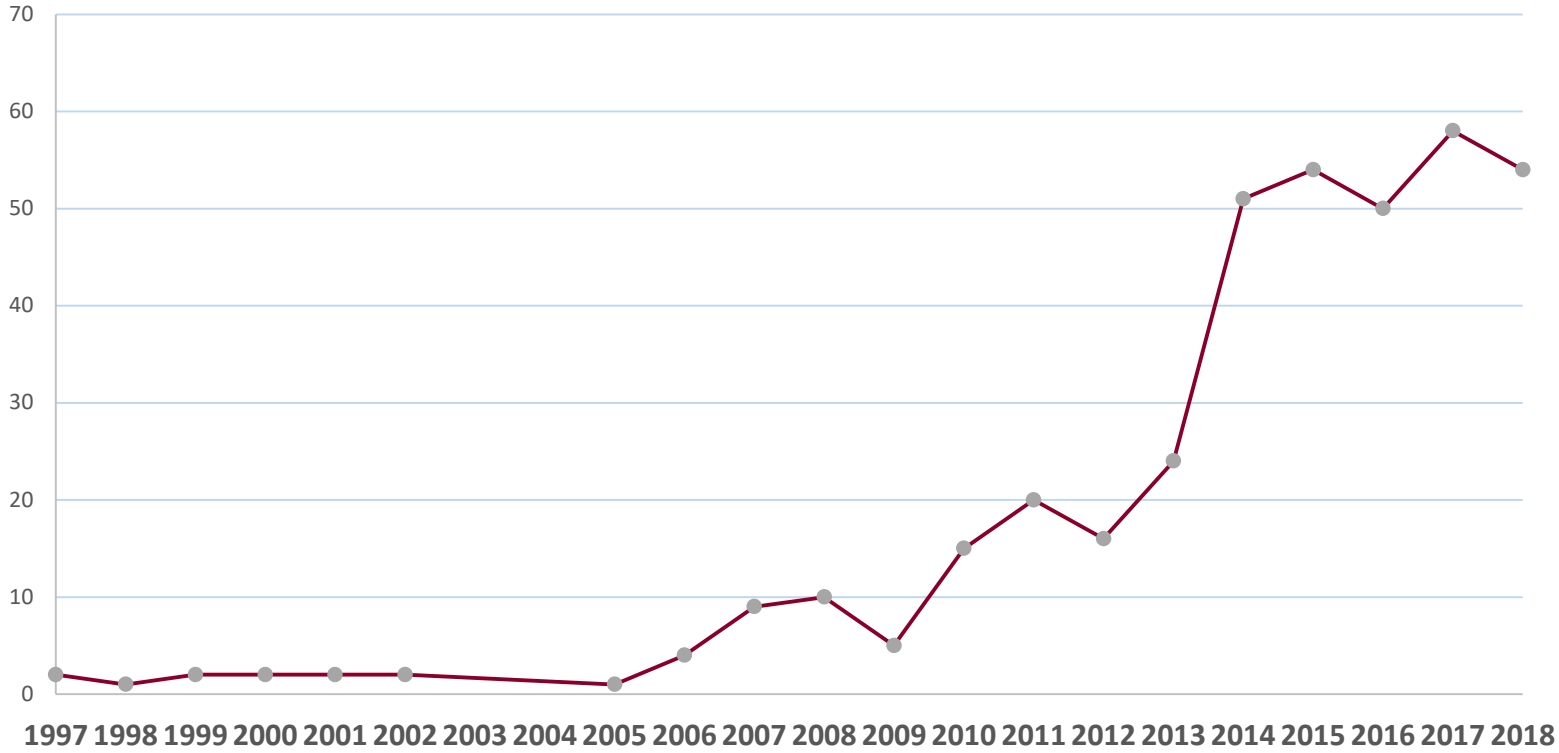
In this context, for planning, priorisation and allocation of resources, decision-makers use a series of **tools**. Among the most used instruments are the **econonomic evaluation** and the **budget impact analysis.**

But there are **other criteria** that decision-makers also often take into account, such a severity of thedisease, the population group affected, the availability of therapeutic altervatives, to name a few (Golan 2011, Baltussen 2006)

Multiple	**Criteria**	**Decision**	**Analysis**
Variety	Attributes or elements that can influence	Help with complex decision making	Methodological tool

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Number of studies published annually on MCDA in the area of healthcare*



* Searched PubMed: [(MCDA OR multi-criteria decision analysis) AND (health OR drug)

Source: Prepared from PUBMED

The number of applications of MCDA in healthcare has continuously increased in recent years.

382 since 1997

58 in 2017

54 so far this year

Most MCDA support 4 types of health care decisions:

1. Prioritisation of interventions for coverage or reimbursement.
2. Selection of intervention.
3. Assessment for licensing.
4. Allocation of research funds

[Multi-criteria Decision Analysis: Methodology for resource allocation]

MCDA is a 'tool' designed to help decision-makers to make such complex choices

MCDA: A set of methods and approaches to aid decision-making, where decisions are based on more than one criterion, which make explicit the impact on the decision of all the criteria applied and the relative importance attached to them.

This definition of MCDA encompasses a wide range of different approaches, both "technical" and "non-technical" in nature. Some types of MCDA involve sophisticated algorithms to suggest optimal choices; others simply aim to provide some structure to the deliberative process. All aim to facilitate replicability and transparency in decision-making.

Source: Devlin and Sussex 2011

[Multi-criteria Decision Analysis: Methodology for resource allocation]

MCDA is a ‘tool’ designed to help decision-makers to make such complex choices

- Primary aim of MCDA: to develop models of decision-maker objectives and their value trade-offs so that alternatives under consideration can be compared with each other in a consistent and transparent manner
- Value focused thinking and values clarification
- MCDA practice suggests preferences are constructed as part of the decision-making process
- Consistent with deliberative-analytic methods

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Ultimately, no technical formula can make complex decisions: it can only inform them. Therefore judgement is required: the benefit of this approach is that it forces decision makers to consider why it is they feel a project should be accepted or rejected, and provides a starting point for discussions upon which to make final funding decisions.

Source: Wilson 2006

This study has documented the feasibility of MCDA for prioritising HIV/AIDS interventions in Thailand, and has shown the usefulness of a deliberative process as an integrated component of MCDA. MCDA holds potential to contribute to a more transparent and accountable priority setting process, and further application of this approach in the prioritisation of health interventions is warranted.

Source: Youngkong 2012

What is it for?

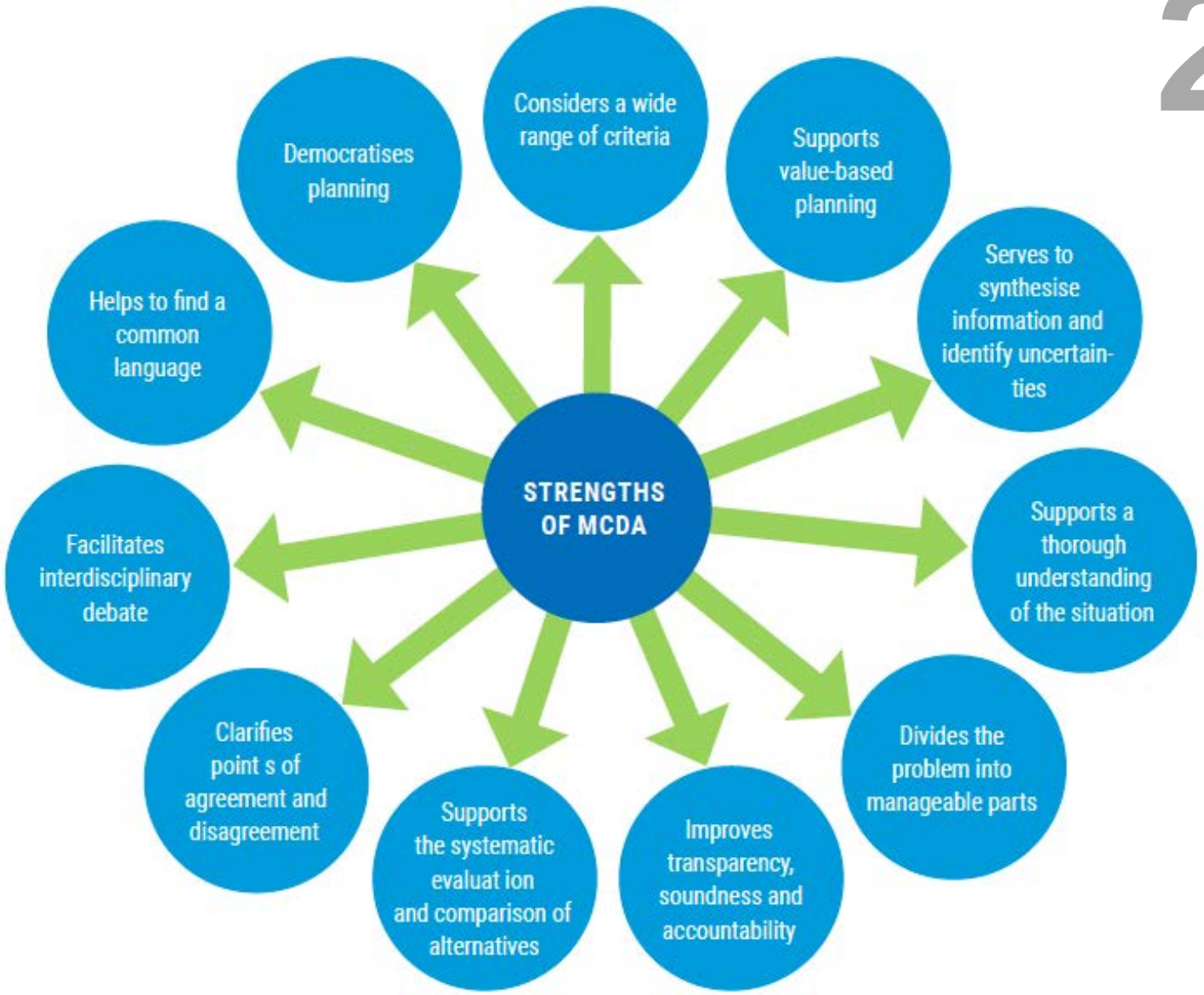
The MCDA allows decision-makers to analyse the interventions from an expanded perspective, explicitly considering different value attributes, and determining to what extent each of them affects the final value. Thus, it can **serve as a complementary tool for economic evaluation** in healthcare decision-making.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

STRENGTHS OF MCDA

MCDA would provide an explicit planning framework which can contribute to increasing the transparency, soundness and consistency of decisions, thus improving the quality of decision-making.

(Baltussen and Niessen 2006; Angelis and Kanavos, 2016).



Source: Zozaya et al. 2018

[Multi-criteria Decision Analysis: Methodology for resource allocation]

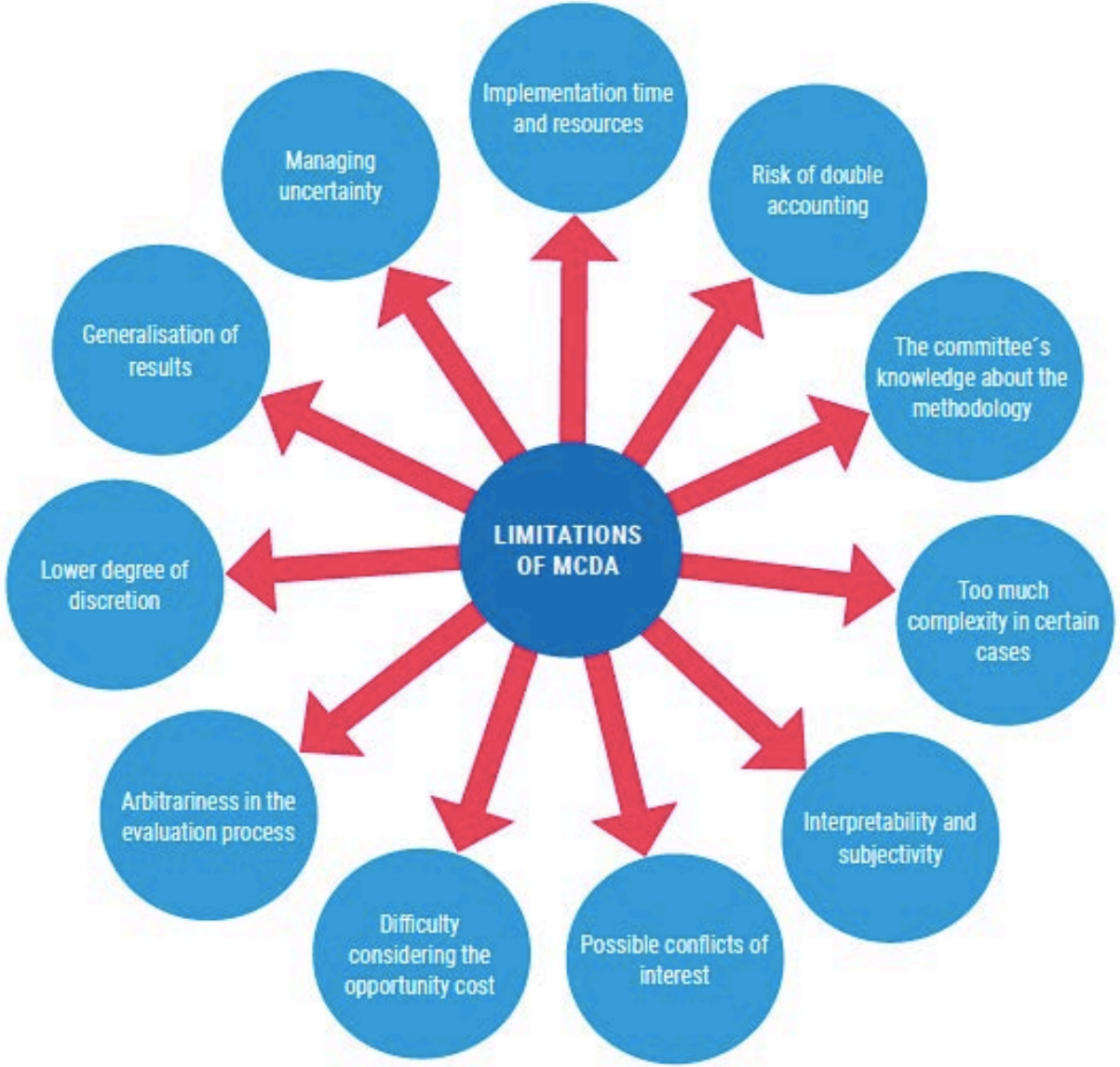
LIMITATIONS OF MCDA

MCDA also has limitations. One of its main limitations is that it does not solve the problem of subjectivity, inherent in all decision-making.

The four main barriers and challenges of using MCDA to inform decision making in HTA:

1. Double-counting
2. Challenges with scoring
3. Appropriateness
4. Quantifying the impact of uncertainty

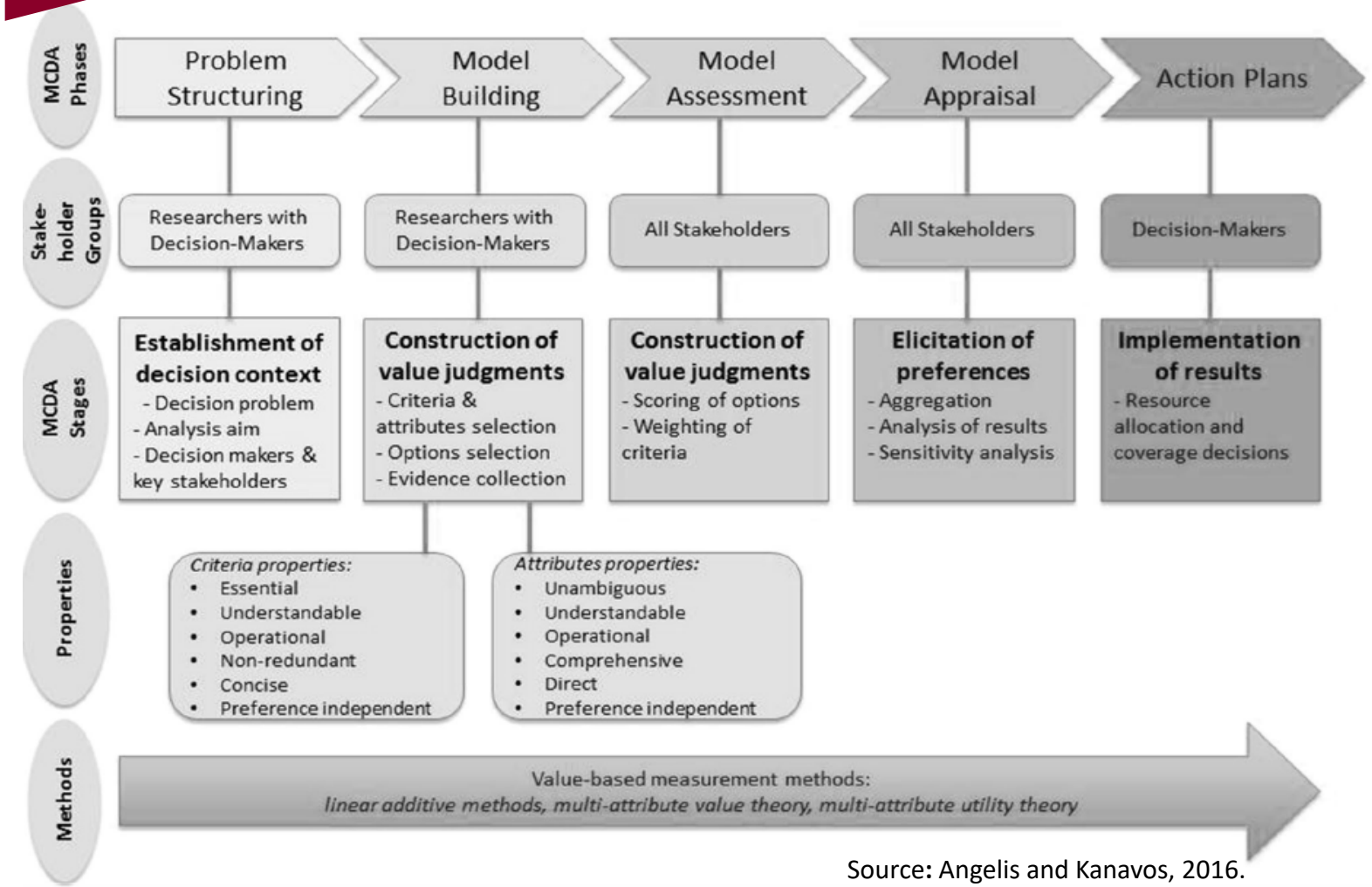
(Marsh et al. 2016; Tokala et al. 2016).



Source: Zozaya et al. 2018

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Multiple criteria decision analysis (MCDA) methodological process in the context of health technology assessment



Source: Angelis and Kanavos, 2016.

An MCDA-based methodological framework in the context of HTA could be divided into the phases **of problem structuring**, **model building**, **model assessment**, **model appraisal**, and **action plans**. For the analysis to be robust and for decision recommendations to be ultimately meaningful, criteria and attributes should adhere to a number of properties.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Specific user needs and decision problems determine which MCDA approach is most appropriate to use.

In general, some considerations should be taken into account to select the most appropriate type of MCDA:

- Consistency and internal logic
- Transparency
- Easy to use
- Requirements of the data consistent with the importance of the objective considered
- Staff trained for analysis
- Realistic times
- Capacity for reproducibility
- The software license

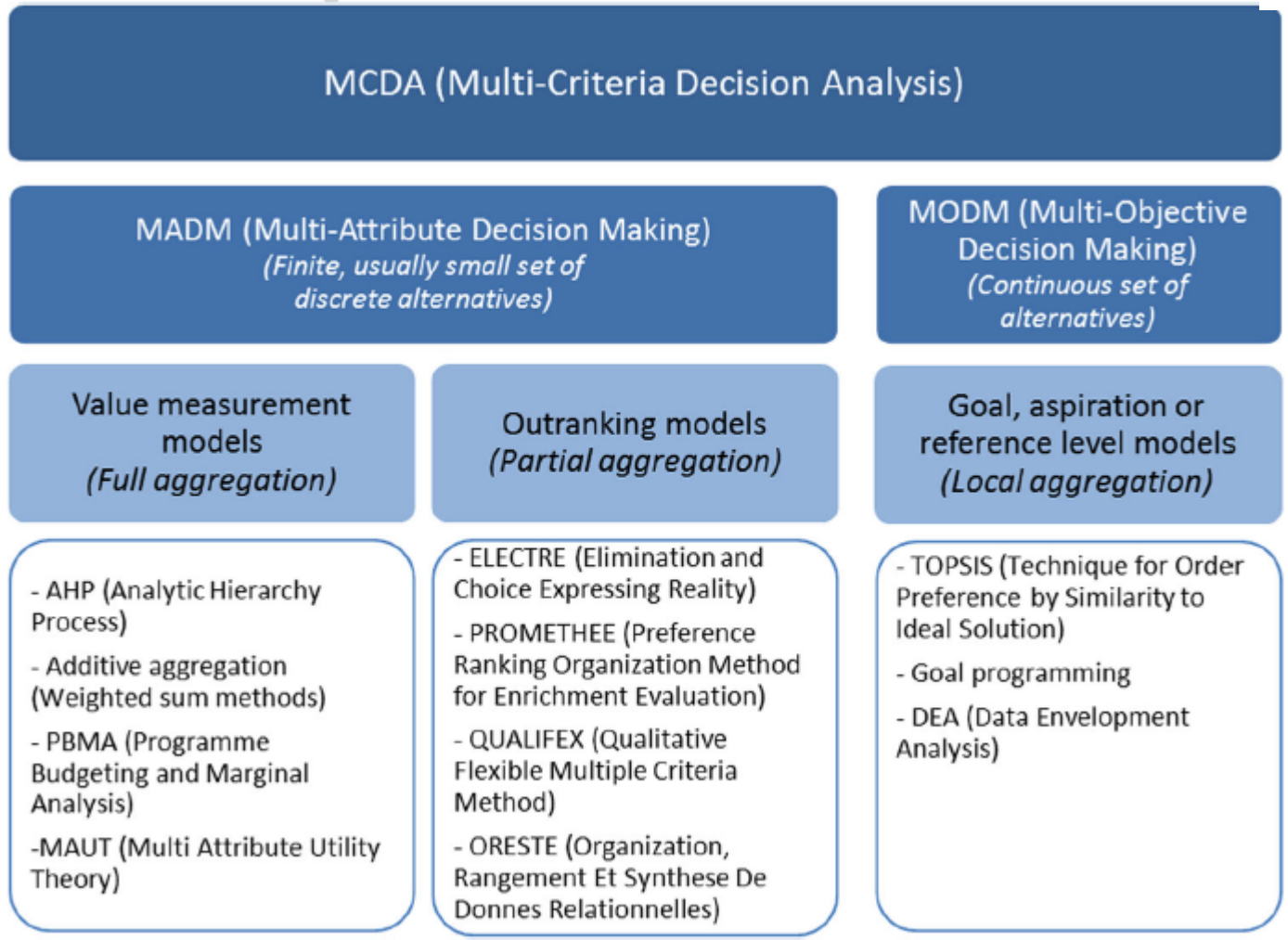
[Multi-criteria Decision Analysis: Methodology for resource allocation]

Overview of the various MCDA approaches

MCDA methods are generally differentiated between multi-objective decision making (MODM) and multi-attribute decision making (MADM) models.

Three forms of MCDA are used in practice for decision support: Value measurement, outranking, and goal programming.

The multi-criteria method most used for medical and non-medical applications is the **analytic hierarchy process (AHP)** (Liberatore and Nydick, 2008)



Source: Mühlbacher 2016

[Multi-criteria Decision Analysis: Methodology for resource allocation]

GOOD PRACTICE GUIDELINES IN MCDA

ISPOR TASK FORCE REPORT

Multiple Criteria Decision Analysis for Health Care Decision Making—An Introduction: Report 1 of the ISPOR MCDA Emerging Good Practices Task Force

Praveen Thokala, MASc, PhD[1,], Nancy Devlin, PhD[2], Kevin Marsh, PhD[3], Rob Baltussen, PhD[4], Meindert Boysen, MSc[5], Zoltan Kalo, PhD[6,7], Thomas Longrenn, MSc[8], Filip Mussen, PhD[9], Stuart Peacock, PhD[10,11], John Watkins, PharmD[12,13], Maarten Ijzerman, PhD[14]*

ISPOR TASK FORCE REPORT

Multiple Criteria Decision Analysis for Health Care Decision Making—Emerging Good Practices: Report 2 of the ISPOR MCDA Emerging Good Practices Task Force

Kevin Marsh, PhD[1,], Maarten IJzerman, PhD[2], Praveen Thokala, MASc, PhD[3], Rob Baltussen, PhD[4], Meindert Boysen, MSc[5], Zoltán Kaló, MSc, MD, PhD[6,7], Thomas Lönngren, MSc (Pharm)[8], Filip Mussen, MSc, PhD[9], Stuart Peacock, MSc, DPhil[10,11], John Watkins, PharmD, MPH, BCPS[12,13], Nancy Devlin, PhD[14]*

Table 1 – ISPOR MCDA Good Practice Guidelines Checklist.

MCDA step	Recommendation
1. Defining the decision problem	a. Develop a clear description of the decision problem b. Validate and report the decision problem
2. Selecting and structuring criteria	a. Report and justify the methods used to identify criteria b. Report and justify the criteria definitions c. Validate and report the criteria and the value tree
3. Measuring performance	a. Report and justify the sources used to measure performance b. Validate and report the performance matrix
4. Scoring alternatives	a. Report and justify the methods used for scoring b. Validate and report scores
5. Weighting criteria	a. Report and justify the methods used for weighting b. Validate and report weights
6. Calculating aggregate scores	a. Report and justify the aggregation function used b. Validate and report results of the aggregation
7. Dealing with uncertainty	a. Report sources of uncertainty b. Report and justify the uncertainty analysis
8. Reporting and examining of findings	a. Report the MCDA method and findings b. Examine the MCDA findings

Source: Marsh et al. 2016

The most commonly applied aggregation formula in healthcare MCDAs is the additive model.

Additive model

$$V_j = \sum_{i=1}^{n} S_{ij} \cdot W_i$$

where V_j is the overall value of intervention j, s_{ij} is the score for intervention j on criterion i, and w_i is the weight attached to criterion i.

Multiplicative model

$$U = U_h[1 + W_1 D_1 \ldots W_n D_n]$$

where U is the estimate of overall value, U_h is the score for impact on individual health, $D_1 - D_n$ are scores on other criteria, and $W_1 - W_n$ are weights on other criteria. This model has the property that if individual health gain is zero, U is also zero.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Types of Health Care Decisions Supported by MCDA

Table 1 – Examples of health care decisions to which MCDA might be applied.

Type of health care decision	Examples of who makes these decisions	Examples of criteria relevant to the decision	Examples of stakeholders providing preferences	Examples of the type of decisions	Repeated vs "one-off" decisions
Benefit-risk assessment (BRA)	Regulators [18]. See below for detail of EMA's assessment of MCDA as a method for BRA [12,19,20]	Criteria are the different aspects of benefits and risks that are relevant to each new medicine under consideration	Regulatory committees and/or patients	Categorical	The relevant risks and benefits will differ from case to case. The criteria and their importance therefore differ between decisions
Health technology assessment (HTA)	HTA bodies, such as G-BA in Germany, NICE in England and Wales, and PBAC in Australia. See below for details of IQWiG's pilot of MCDA for HTA [21], Thailand's use of MCDA for universal coverage [22], and the HTA framework in Lombardy Region [23]	The criteria used differ between HTA systems, but might include effectiveness, patient need/burden of disease/severity. (Note: the role of cost, cost- effectiveness, and budget impact as criteria in MCDA is contentious [24,25])	HTA committees or general public	Categorical, ranking or understanding "value"	HTA aims to apply an agreed set of principles to make judgments about reimbursement of new technologies. Arguably, the same principles and criteria should be used across repeated decisions, to ensure consistency and accountability
Portfolio decision analysis (PDA)	Decisions made by life sciences companies, choosing where best to direct R&D efforts. See below for a pharmaceutical company's experience [26]	The likelihood of success and projected profitability (or consistency with other company objectives) of alternative investment decisions	Board of directors, or a committee appointed by the board	Ranking or understanding "value"	Can be "one-off" or "repeated" based on the decision problem
Commissioning decisions/ priority setting frameworks (PSFs)	Resource allocation decisions made by local budget holders in the English NHS. Decisions made by private insurers about the bundle of services to reimburse. See below for details on English local budget holders' experience with MCDA [27]. Other examples include the use of PBMA [28–30], DCE [31,32], and EVIDEM [33,34] to set priorities	The criteria used vary considerably, but might include effectiveness, meeting unmet need/equity objectives, meeting government targets, etc.	Committee in charge of making the funding decisions	Ranking	These are "repeated" decisions, inasmuch as there is a single fixed budget, and the criteria used to prioritize any one service should also apply to decisions about other potential services, to ensure consistency and the achievement of allocative efficiency

continued on next page

Source: Tokala et al. 2016

MCDA can be useful in many decision contexts: **Benefit-risk assessment** (BRA), **Health technology assessment** (HTA), **Portfolio decisión analysis** (PDA), **Commissioning decisions/priority setting frameworks** (PSFs), **Shared decisión making** (SDM); and **Prioritising patientes'access to haealth care**. In addition to those mentioned in the list, MCDA has been used to **develop disease classifications** and for **hospital purchasing.**

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Types of Health Care Decisions Supported by MCDA

Shared decision making (SDM)	Decisions made by patients, in discussion with their doctors, about choice of treatments. See below for an example of MCDA being used to assess cancer screening alternatives [35]	For example, effect on life expectancy, quality of life, side effects from treatment, and the process of care	Patients and clinicians	Ranking	One-off decisions as the relevant risks and benefits will differ from case to case and the patients will have different preferences. The criteria and their importance will therefore differ between decisions
Prioritizing patients' access to health care	Prioritization of patients for health care services. See below for the use of "points systems" to prioritize patients awaiting elective surgery in New Zealand [36]. These can also be used for transparent, equitable, and accountable allocation of scarce resources, such as solid organs among patients waitlisted for transplantation [37]	Various measures of patient "need" and ability to benefit from treatment	Clinical leaders, patient groups, and other health professionals. Organ procurement organization at international, national, or regional level	Ranking	These often use "points systems"—algorithmic approaches that apply identical criteria and rules across all cases to ensure fairness. These are repeated decisions coordinated by a central office with no direct relationship with patients or their physicians

DCE, discrete choice experiment; EMA, European Medicines Agency; EVIDEM, Evidence and Value: Impact on Decision Making; G-BA, Der Gemeinsame Bundesausschuss; IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; MCDA, multiattribute decision analysis; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; PBAC, Pharmaceutical Benefits Advisory Committee; PBMA, Programme Budgeting and Marginal Analysis; R&D, research and development.

Source: Tokala et al. 2016

Recent publications demonstrate that MCDA methods can be an appropriate approach to inform diverse healthcare decision problems. The examples demonstrate the diverse range of decision problems and decision makers/organisations that MCDA can support.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Real-world examples of MCDA utilisation to support healthcare decision-making

Increasing use of MCDA in real practice internationally

For benefits coverage: Orphan drugs, high impact medicines

To prioritize practices under public coverage

Country	Example(s) of utilization	Source
England/UK	i. Orphan drugs, AGNSS/NICE	Devlin & Sussex [13]
	ii. Respiratory, mental, children's health, cardiovascular, and cancer interventions, NHS/Primary Care Trusts	Adams et al. [14] Airoldi et al. [15]
	iii. Major capital expenditures, NHS	
USA	i. Diagnosis and treatment decisions	Adunlin et al. [16]
	ii. Clinical trial design	Guest et al. [17]
Canada	i. Healthcare priority-setting	Diaby et al. [18]
	ii. Budgeting	Tony et al. [19]
	iii. Interventions for chronic non-cancer pain	
Germany	Incorporation of patient involvement with MCDA quantitative approaches, IQWIG	Danner et al. [20]
Sweden	i. Orphan drug coverage, TLV	World Health Organization [21]
	ii. High-cost biologics, TLV	Deans et al. [22]
Denmark	Orphan drug coverage	Deans et al. [22]
Finland	Obesity research and prevention	Borg & Fogelhol [23]
The Netherlands	i. Orphan drug coverage	Van Til [24]
	ii. Publicly funded healthcare priority-setting	Devlin & Sussex [13]
	iii. Ankle-foot repair in stroke	Baeten et al. [25]
Italy	EVIDEM framework used with medical devices, diagnostic assessments, and pharmaceuticals	Radaelli et al. [26]
France	Screenings	World Health Organization [21]
Norway	Healthcare priority-setting	Defechereux et al. [27]
Hungary	Hospital medical technologies, OEP	Devlin et al. [4]
Scotland	Orphan drug coverage, NHS	Kanters et al. [28]
New Zealand	Algorithmic approach using 1000Minds software used to analyze coronary artery bypass graft surgery, MoH	Devlin & Sussex [13] Hansen et al. [29]
South Africa	Private health plan used for liquid-based cytology for cervical cancer screening	Miot et al. [30]
Ghana	Healthcare priority-setting	Jehu-Appiah [31]
Thailand	Health interventions in the universal health coverage benefit package, NHS	Youngkong et al. [32]
Israel	New healthcare technologies, Health Basket Committee	Devlin & Sussex [13]

Source: Drake 2017

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Many decision makers in healthcare systems have been looking into the use of MCDA to support decision making in HTA

UK

Cost Effectiveness and Resource Allocation

BioMed Central

Research

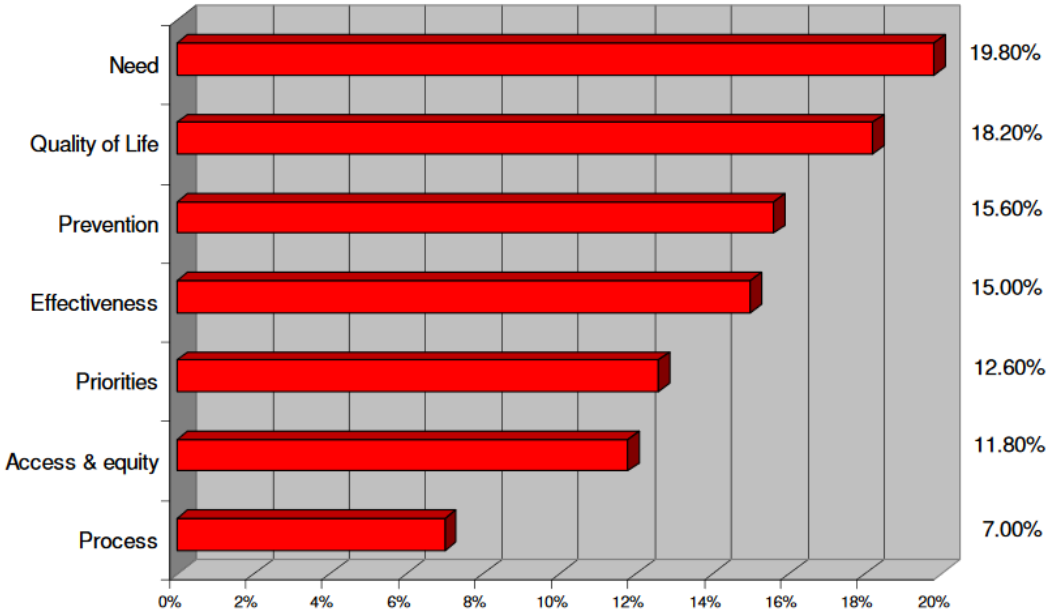
Open Access

Developing a prioritisation framework in an English Primary Care Trust

Edward CF Wilson*[1], John Rees[2] and Richard J Fordham[1]

The tool is now in use across the PCT and will be evaluated and refined after its first year of operation. By involving a wide constituency in decision making, and explicitly taking into account 'equity' as one of the criteria, we aim to make decision making within the PCT, if not 'fair and equitable' then at least 'fairer' and 'more equitable'.

Criteria and weights. Mean weightings of the criteria relative to one another



Source: Wilson 2006

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Many decision makers in healthcare systems have been looking into the use of MCDA to support decision making in HTA

Poland

RESEARCH Open Access

Potential impact of the implementation of multiple-criteria decision analysis (MCDA) on the Polish pricing and reimbursement process of orphan drugs

Katarzyna Kolasa[1*], Krzysztof M. Zwolinski[2], Zoltan Kalo[3] and Tomasz Hermanowski[2]

Table 6 A comparison of HTA and MCDA outcomes (economic criteria included) for 50 % threshold, multiple HTA restrictions imposed

		HTA					
		Positive				Negative	
		Unrestricted	Time restrictions	Limits to specific subpopulation	Finanacial restrictions	Clinical reasons	Economic reasons
MCDA	Positive	Cystadane, Volibris, Torisel	Kuvan, Increlex	Nexavar (HCC), Nplate, Tasigna, Glivec (MM), Yondelis	Tasigna, Yondelis	Elaprase, Fabrazyme, Somavert, Torisel	Fabrazyme, Somavert, Torisel
	Negative	Vidaza, Glivec (ALL Ph+), Glivec (MDS/MPD), Revatio, Glivec (DFSP), Glivec (GIST)	Zavesca	Tracleer, Ventavis, Sprycel, Atriance, Revlimid (MM/S)	Zavesca, Atriance, Revlimid (MM/S)	None	Nexavar (RCC)

Conclusions

As our study revealed, an MCDA approach may lead to different P&R outcomes compared to a standard HTA process. On the one hand, enrichment of the list of decision making criteria leads to further scrutiny of the given health technology and as such may increase the odds of a negative P&R outcome. On the other hand, it uncovers additional values and as such may increase the odds of positive P&R outcomes.

In competition with common disease, where the incremental gains are more significant, the pricing and reimbursement decision making process for the treatment of rare diseases will remain challenging. There is a growing understanding that the allocation criteria currently adopted, such as the cost effectiveness threshold, does not allow the value of orphan drugs to be fully captured [34]. It is therefore hoped that our study could contribute to the discussion on the overall appropriateness of the adaptation of an MCDA approach in CEE settings and its usefulness in the search for more transparent and equitable resource allocation in the healthcare sector.

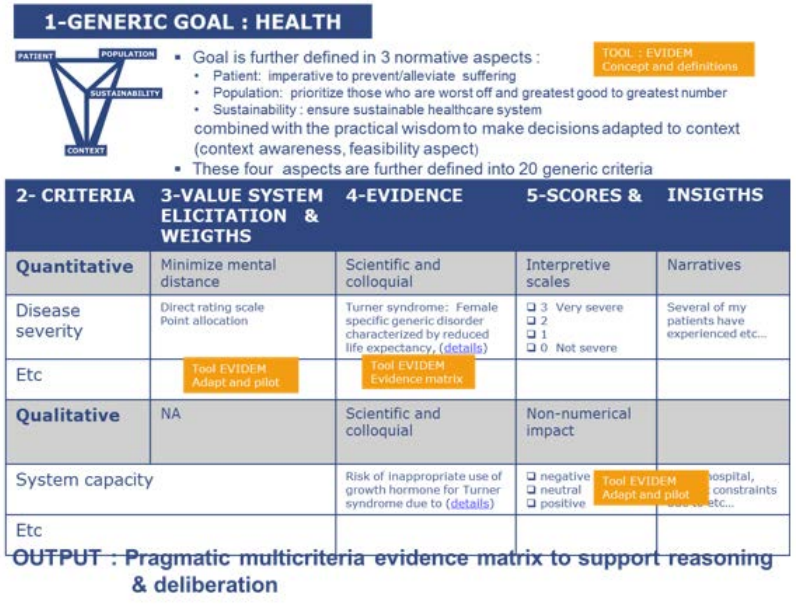
Source: Kolasa 2016

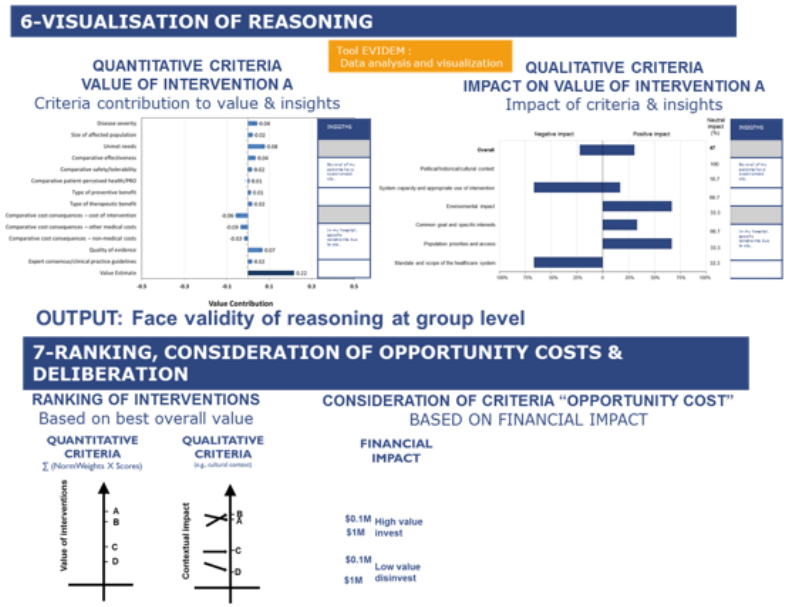
[Multi-criteria Decision Analysis: Methodology for resource allocation]

Methodological frameworks applied in healthcare

One of the best known and most used MCDA frameworks is EVIDEM (Evidence and Value: Impact on Decision-Making). In its lastest update (versión 4,0), of 2017. The EVIDEM framework groups the 13 quantitativa criteria into five domains (**need for intervention, results of the intervention, type of beneficit of the intervention, economic consecuences and knowledge of the intervention**). 7 contextual criteria are divided into two groups or domains (**normative or of viabilitiy**).

EVIDEM





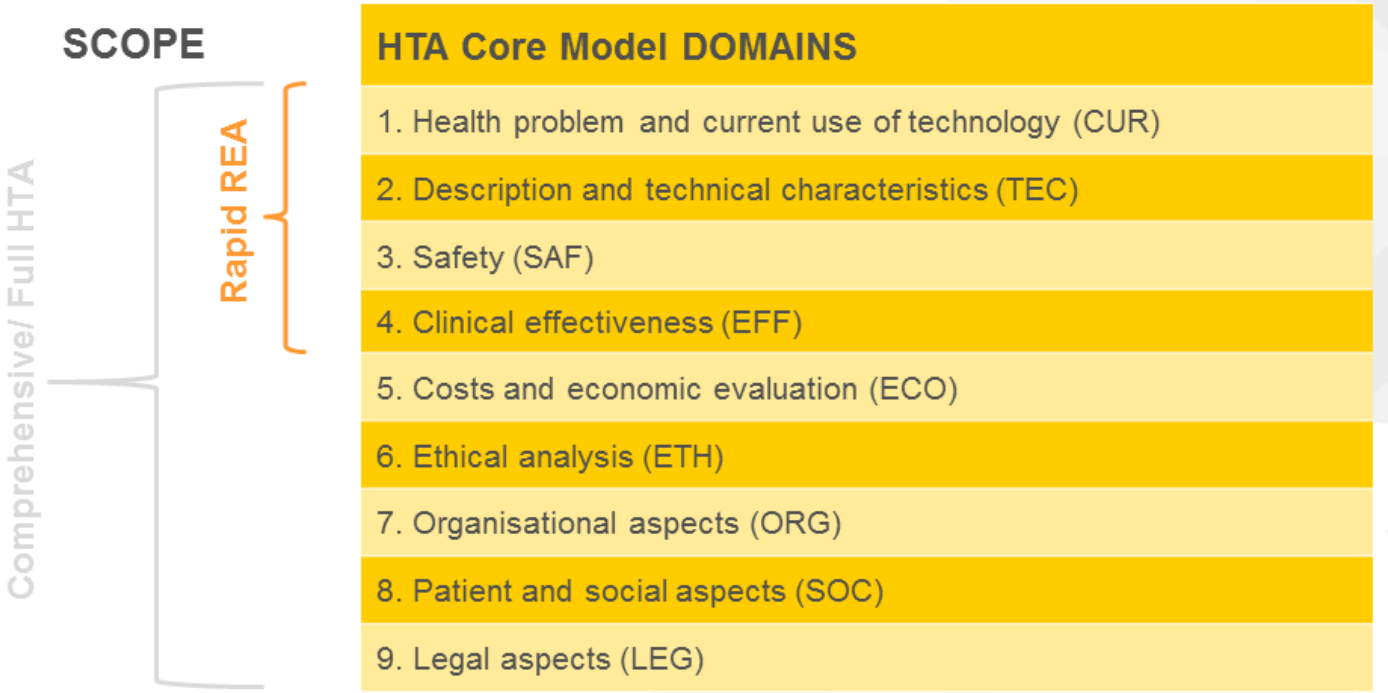
[Multi-criteria Decision Analysis: Methodology for resource allocation]

Source: EVIDEM Collaboration 2017

Methodological frameworks applied in healthcare

Another methodological framework for joint production and Exchange of HTA information is the European network for Health Technology Assessment **(EUnetHTA) Core model**

EUnetHTA HTA Core Model®



Source: European network for Health Technology Assessment JA3 2016-2020, www.eunethta.eu

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Spain

BioDrugs (2018) 32:281–291
https://doi.org/10.1007/s40259-018-0284-3

ORIGINAL RESEARCH ARTICLE

Determining the Value of Two Biologic Drugs for Chronic Inflammatory Skin Diseases: Results of a Multi-Criteria Decision Analysis

Néboa Zozaya[1] · Lucía Martínez-Galdeano[1] · Bleric Alcalá[1] · Jose Carlos Armario-Hita[2] · Concepción Carmona[3] · Jose Manuel Carrascosa[4] · Pedro Herranz[5] · María Jesús Lamas[6] · Marta Trapero-Bertran[7] · Álvaro Hidalgo-Vega[8,9]

Published online: 29 May 2018

Key Points

Multi-criteria decision analysis (MCDA) can improve the healthcare decision-making process by considering an explicit set of criteria and their relative importance under a fully transparent process.

This study approximated the overall estimated value of two innovative drugs for chronic inflammatory skin diseases (atopic dermatitis and psoriasis) from a broad and systematic view, while incorporating local multi-disciplinary views to express a societal perspective.

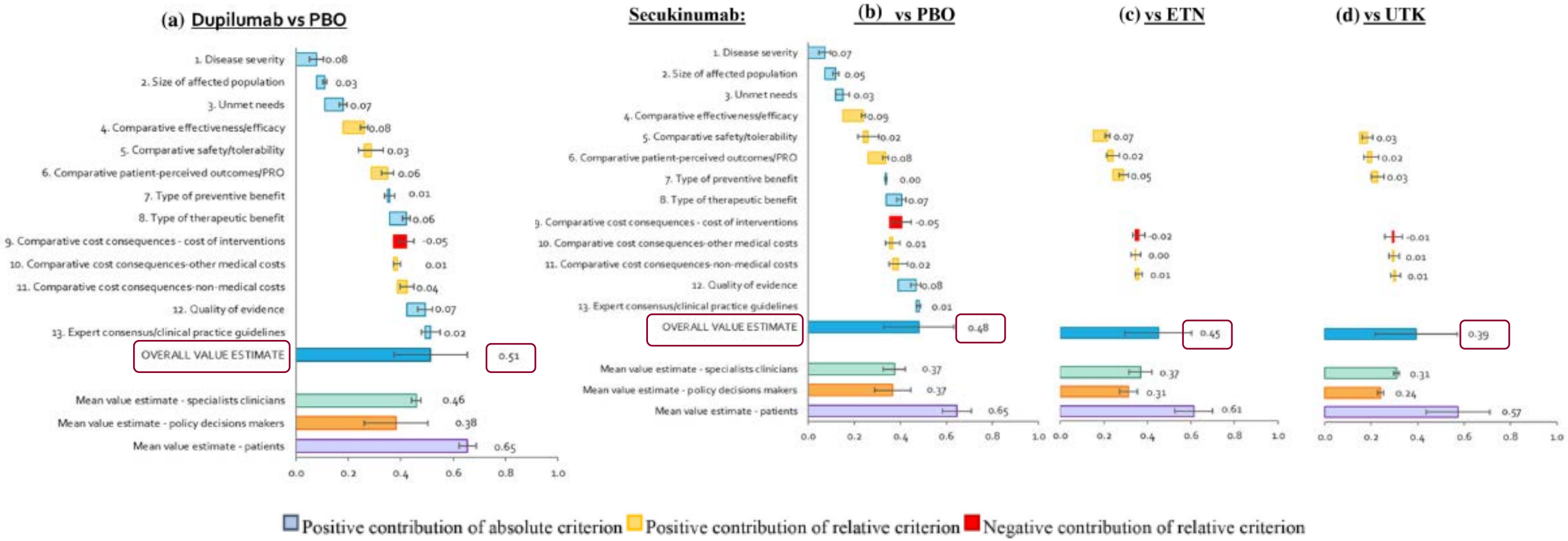
This exercise allows us to better understand where the value of dupilumab and secukinimab lies for the different stakeholders, providing useful information that could help to make better decisions on the assessment, pricing and public reimbursement of these interventions.

This study is the first MCDA performed in the field of dermatology in Spain and the first internationally that estimates the value of a treatment for atopic dermatitis

Results The overall MCDA value estimate for dupilumab versus placebo was 0.51 ± 0.14. This value was higher than those obtained for secukinumab: 0.48 ± 0.15 versus placebo, 0.45 ± 0.15 versus etanercept and 0.39 ± 0.18 versus ustekinumab. The highest-value contribution was reported by the patients' group, followed by the clinical professionals and the decision makers. A fundamental element that explained the difference in the scoring between pathologies was the availability of therapeutic alternatives. The retest confirmed the consistency and replicability of the analysis.

Conclusions Under this methodology, and assuming similar economic costs per patient for both treatments, the results indicated that the overall value estimated of dupilumab for severe atopic dermatitis was similar to, or slightly higher than, that of secukinumab for moderate to severe plaque psoriasis.

Source: Zozaya et al. 2018



Source: Zozaya et al. 2018

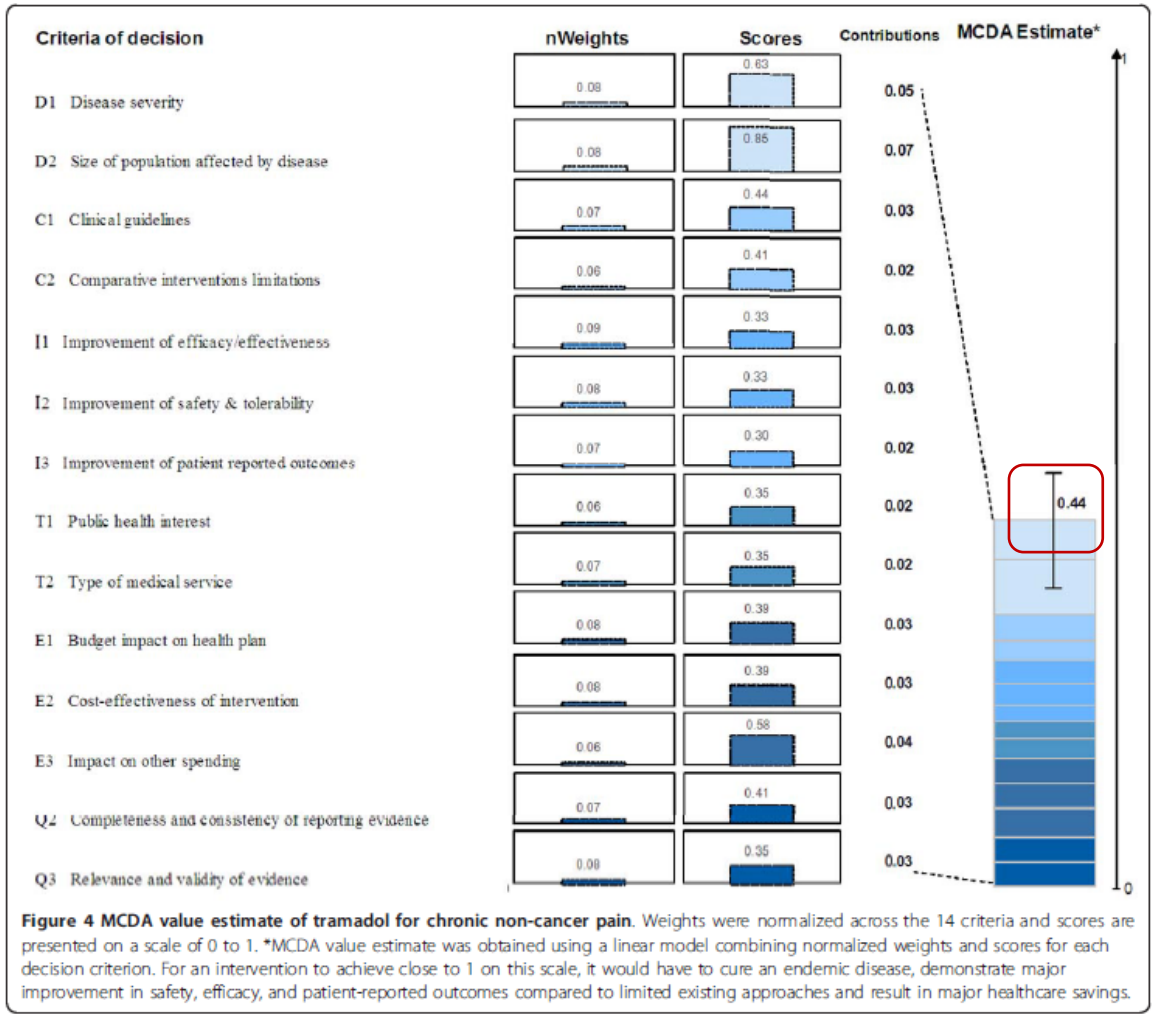


Figure 4 MCDA value estimate of tramadol for chronic non-cancer pain. Weights were normalized across the 14 criteria and scores are presented on a scale of 0 to 1. *MCDA value estimate was obtained using a linear model combining normalized weights and scores for each decision criterion. For an intervention to achieve close to 1 on this scale, it would have to cure an endemic disease, demonstrate major improvement in safety, efficacy, and patient-reported outcomes compared to limited existing approaches and result in major healthcare savings.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Bridging health technology assessment (HTA) with multicriteria decision analyses (MCDA): field testing of the EVIDEM framework for coverage decisions by a public payer in Canada

Michèle Tony[1], Monika Wagner[1], Hanane Khoury[1], Donna Rindress[1], Tina Papastavros[2], Paul Oh[3] and Mireille M Goetghebeur[1,4*]

Discussion

The framework was found useful by the drug advisory committee in supporting systematic consideration of a broad range of criteria to promote a consistent approach to appraising healthcare interventions. Directly integrated in the framework as a "by-criterion " HTA report, synthesized evidence for each criterion facilitated its consideration, although this was sometimes limited by lack of relevant data. This is in agreement with pre-

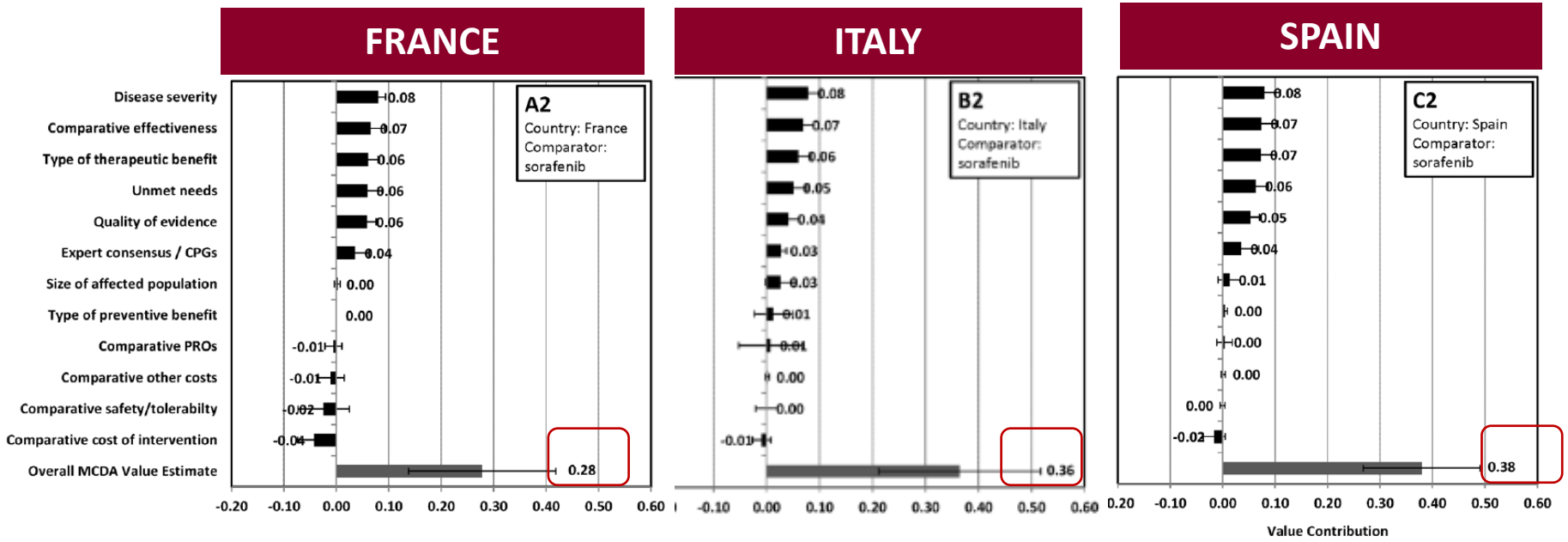
Interpretation and utility of the MCDA value estimate (i.e., the figure 0.44) was found challenging by committee members. Indeed, the MCDA value estimates are meant to be used in a comparative manner for ranking healthcare interventions, which was beyond the scope of this case study. An MCDA model adapted from the

medicines [23]. However, it should be kept in mind that MCDA value estimates are not meant to be used in a prescriptive fashion, but rather as "a framework conducive for focused discussion."[73] MCDA value estimates can serve as a basis for establishing a ranking scheme, [9] which can be modulated by ethical and context related considerations. This is often done implicitly in healthcare decisionmaking and is meant to be facilitated by the Contextual Tool. It should also be noted that

Source: Tony 2011

Appraising the holistic value of Lenvatinib for radio-iodine refractory differentiated thyroid cancer: A multi-country study applying pragmatic MCDA

Monika Wagner[1*], Hanane Khoury[1], Liga Bennetts[1], Patrizia Berto[2], Jenifer Ehreth[3], Xavier Badia[4] and Mireille Goetghebeur[1,5]



Source: Wagner 2017

Conclusions: The value of lenvatinib was consistently positive across diverse therapeutic contexts. MCDA identified the aspects contributing most to value, revealed rich contextual insights, and helped participants express and explicitly tackle ethical trade-offs inherent to balanced appraisal and decisionmaking.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Norway

Health care priority setting in Norway a multicriteria decision analysis

Thierry Defechereux[1*], Francesco Paolucci[3], Andrew Mirelman[1], Sitaporn Youngkong[4], Grete Botten[2], Terje P Hagen[2] and Louis W Niessen[1]

This study compares the values of the decision makers with the principles formulated in the law of patients' rights.

34 decision makers

6 criteria

21 interventions in 5 groups of prevalent diseases

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Table 3 Composite League Table (COPD: Chronic obstructive pulmonary disease, K/cancer)

		Norway Coefficients	1,08	1,2638	-0,2004	-1,117	1,5045	0,3714	0,3566			
Intent N°	CLINICAL	Intervention	CRITERIA							Comp	*Select*	*Rank*
	CONDITION									Index	*Prob*	
			Dis Sev	Ind Ben	Age Mid	Age High	CER	Tot benef	WTSub			
CVD1	Angina pectoris	as per Guidelines[apG] : invest, treat (med-stent surg)	1	1	0	1	1	1	1	3,4593	0,9695 07279	1
CVD2	Atrial fibrilation	diag, trat anticoag,	0	1	0	1	1	0	1	2,0079	0,8816 24035	13
CVD3	Heart failure	Diagn, eval, Med treat	1	1	0	1	1	1	1	3,4593	0,9695 07279	1
CVD4	High Cholesterol	Preventive screening /statin treatment	1	0	1	1	1	1	1	1,9951	0,0880 28164 9	14
CVD5	Hypertension	Screening, lifestyle (exerc, diet),ACE treat	1	0	1	1	1	1	1	1,9951	0,0880 28164 9	14
Resp 6	COPD Stade 1-2	spiro diag, X-ray, gaz anal, treat adapt, rehab	1	1	1	1	1	1	1	2,1789	0,8983 38657	8
Resp 7	COPD Stade 3-4	spiro diag, X-ray, gaz anal, Br dilat, rehab-O2-Hospi	1	1	1	1	1	1	1	3,2589	0,9629 91608	3
Resp 8	Asthma no control	diag, stress test..	1	1	1	1	1	1	1	3,2589	0,9629 91608	3
Resp9	Asthma control	treat adjust: inhal cortic, Beta agonist-leukot inhibit	1	1	1	1	1	1	1	3,2589	0,9629 91608	3
Resp 10	Tabacco Use	Prevention (tax-advert ban..)	1	0	1	1	1	1	1	1,9951	0,8802 81649	14
Neo 11	Colon/rectum K	Surgery with/ without adiuvant treat	1	1	1	1	1	1	1	3,2589	0,9629 91608	3
Neo 12	Breast K	Surgery with adjuvant treat	1	1	1	1	1	1	1	3,2589	0,9629 91608	3
Neo 13	Lung K	Surgery with/without abjuvat treat	1	0	1	1	1	1	1	1,9951	0,8802 81649	14
Neo 14	colon polyps	Screening blood test/colonoscopy	0	1	1	1	1	1	1	2,1789	0,8983 38657	8
Psy 15	Unipolar depressive Disorder 1	Med treat outpatient setting/ Gen Pract	0	1	1	1	1	1	1	2,1789	0,8983 38657	8
Psy16	Unipolar depressive disorder 2	Med treat/ psycho In Hospital setting	0	1	1	1	0	1	1	0,6744	0,6624 87692	20
psy17	Alcohol use disorders	Tx on beverage/legal age/advert ban	0	0	1	1	1	1	1	0,9151	0,7140 42646	18
psy 18	Alzheimer & other dementials	comprehensive in-home care	0	0	1	1	1	1	1	0,9151	0,7140 42646	18
Psy 19	Alzheimer & other dementials	Nursing home/hospital care	0	0	1	1	0	1	1	-0,5894	0,3567 72534	21
Sen org20	Hearing loss	hearing aid	0	1	1	1	1	1	1	2,1789	0,8983 38657	8
Sen org21	refractive errors	optical correction	0	1	1	1	1	1	1	2,1789	0,8983 38657	8

Source: Defechereux 2012

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Multicriteria Decision Analysis for Including Health Interventions in the Universal Health Coverage Benefit Package in Thailand

Sitaporn Youngkong, MSc[1,2,], Rob Baltussen, PhD[2], Sripen Tantivess, MPH, PhD[1], Adun Mohara, MSc[1], Yot Teerawattananon, MD, PhD[1]*

Conclusion: This project was carried out in a real-world context and has considerably contributed to the rational, transparent, and fair priority-setting process through the application of MCDA. Although the present project has applied MCDA in the Thai context, MCDA is adaptable to other settings.

Appendix 1 Scores of the proposed health interventions against the selection criteria

Health interventions	Selection criteria						
	Size of population affected by disease	Severity of disease*	Effectiveness of health intervention	Variation in practice	Economic impact on household expenditure	Equity/ethical and social implication	Total
1. Anti-immunoglobulin E for severe asthma	4	—	3	5	5	1	18
2. Treatment for people with chronic hepatitis B	5	—	4	2	3	3	17
3. System for screening, treatment, and rehabilitation of alcoholism	5	—	5	4	1	1	16
4. Implant dentures for people who have problem with conventional complete dentures	5	—	2	2	5	1	15
5. Screening for risk factors for leukemia in people living in the industrial areas	4	—	3	5	1	2	15
6. Treatment for severe lupus nephritis	2	—	4	2	5	1	14
7. Smoking cessation program	5	—	3	2	1	3	14
ıment for people with chronic titis C	3	—	5	2	3	1	14
rbent products for urinary ecal incontinence among led and elderly people	4	—	2	2	4	1	13
ıment for unfertilized women	5	—	0	2	5	1	13
l replacement by dialysis for final stage renal failure nts	2	—	1	5	4	1	13
12. Screening and treatment for liver cancer	2	—	3	2	5	1	13
13. Physical examination package (following the Civil Servant Medical Benefit Scheme)	5	—	0	5	1	1	12
14. *Cissus quadrangularis* L. for hemorrhoid	5	—	1	4	1	1	12
15. Biological agents for psoriasis	1	—	1	2	5	2	11
16. Screening for gall bladder cancer	2	—	2	2	1	3	10
17. Orbital implant and plastic surgery of orbit and facial bones	1	—	2	1	1	2	7

* Severity of disease was omitted from the criteria list in the first year of the project (2010).

[Multi-criteria Decision Analysis: Methodology for resource allocation]

Source: Youngkong 2012

Multi-Criteria Decision Analysis for Assessment and Appraisal of Orphan Drugs

Georgi Iskrov[1,2], Tsonka Miteva-Katrandzhieva[1,2] and Rumen Stefanov[1,2]*

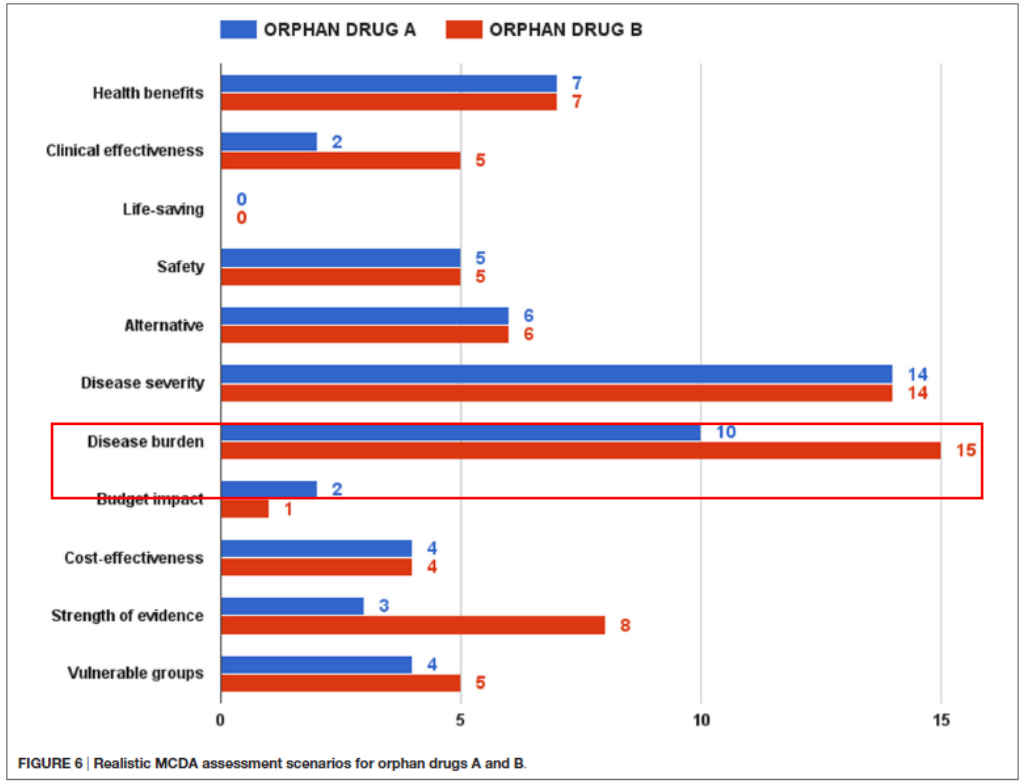


FIGURE 6 | Realistic MCDA assessment scenarios for orphan drugs A and B.

Source: Iskrov 2016

[Multi-criteria Decision Analysis: Methodology for resource allocation]

19 criteria grouped into 3 categories.
Hierarchical Point Allocation method.
Survey of 143 stakeholders: 4 groups ((medical professionals, health authorities, patient representatives, industry representatives)

TABLE 1 | Case studies for the pilot model testing.

Rare disorder's characteristics	Orphan drug A	Orphan drug B
Prevalence	<1 in 10,000 (ultra rare disorder)	1–5 in 10,000 (rare disorder)
Onset	Onset in childhood	Mixed onset
Need for carer	Strong need for carer (severe physical and/or mental impairment)	Mild need for carer (mild physical impairment, no mental impairment)

TABLE 3 | Appraisal of the MCDA results.

Result	Recommendation	Support tools
≥70 points (≥70%)	Unconditional reimbursement with public funds	Epidemiological registries
≥50 points (≥50%)	Conditional reimbursement with public funds	Epidemiological registries, risk-sharing agreements
<50 points (<50%)	No reimbursement with public funds	Individual access schemes

DRUG A: 57
DRUG B: 70

score range on which the reimbursement recommendations are based

Multi-criteria decision analysis (MCDA): testing a proposed MCDA framework fc orphan drugs

C. Schey[1,2*], P. F. M. Krabbe[3], M. J. Postma[1,3,4] and M. P. Connolly[1,2]

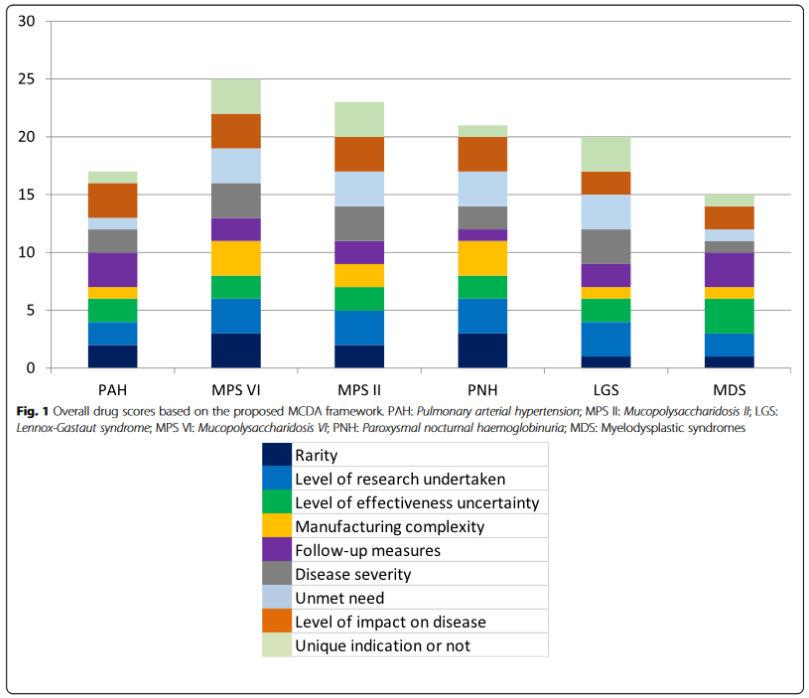


Fig. 1 Overall drug scores based on the proposed MCDA framework. PAH: *Pulmonary arterial hypertension*; MPS II: *Mucopolysaccharidosis II*; LGS: *Lennox-Gastaut syndrome*; MPS VI: *Mucopolysaccharidosis VI*; PNH: *Paroxysmal nocturnal haemoglobinuria*; MDS: Myelodysplastic syndromes

Source: Schey 2017

Abstract

Background: Since the introduction of the orphan drugs legislation in Europe, it has been suggested that the general method of assessing drugs for reimbursement is not necessarily suitable for orphan drugs. The National Institute for Health and Clinical Excellence indicated that several criteria other than cost and efficacy could be considered in reimbursement decisions for orphan drugs. This study sought to explore the multi-criteria decision analysis (MCDA) framework proposed by (Orphanet J Rare Dis 7:74, 2012) to a range of orphan drugs, with a view to comparing the aggregate scores to the average annual cost per patient for each product, and thus establishing the merit of MCDA as a tool for assessing the value of orphan drugs in relation to their pricings.

Methods: An MCDA framework was developed using the nine criteria proposed by (Orphanet J Rare Dis 7:74, 2012) for the evaluation of orphan drugs, using the suggested numerical scoring system on a scale of 1 to 3 for each criterion. Correlations between the average annual cost of the drugs and aggregate MCDA scores were tested and plotted graphically. Different weightings for each of the attributes were also tested. A further analysis was conducted to test the impact of including the drug cost as an attribute in the aggregate index scores.

Results: In the drugs studied, the R^2, that statistically measures how close the data are to the fitted regression line was 0.79 suggesting a strong correlation between the drug scores and the average annual cost per patient.

Conclusion: Despite several limitations of the proposed model, this quantitative study provided insight into using MCDA and its relationship to the average annual costs of the products.

Keywords: Multi-criteria decision analysis, MCDA, Orphan drugs, Reimbursement, Mucopolysaccharidosis II, Paroxysmal nocturnal haemoglobinuria, Pulmonary arterial hypertension, Myelodysplastic syndromes, Lennox-Gastaut syndrome

The strength of MCDAs in reimbursement decisions for orphan drugs is that they provide transparency and robustness, and unlike traditional HTA methods, assess more than merely cost-effectiveness. Defining the criteria at the outset is crucial to ensure that overlap between criteria is avoided. Furthermore, it is essential that the criteria are not selected merely to favour a preferred outcome. Weighting the criteria may be complicated, and dependent on the perspective of the assessment [41]. Future work will include research to understand the weights of different criteria and how they affect the outcomes; and to compare HTA decisions with MCDA outcomes.

[Multi-criteria Decision Analysis: Methodology for resource allocation]

SUMMARY

5

- The ADMC is a tool to help decision making. It does not substitute decision making
- Recent surge in the health field.
- Different ways of approaching an ADMC, but common stages and good practices recommended.
- It presents strengths and limitations.
- It has defenders and detractors.

CALL TO ACTION

With so many challenges in health systems, policy makers need to make important decisions on the use of public resourses. Decisions on the choice of health interventions are complex and multifaceted. Many criteria, or factors, play an important role in the decisions, whatever the level of resource allocation, requieres the prioritising and weighting of these criteria in such a way that implicit interchange relationships are established between them.

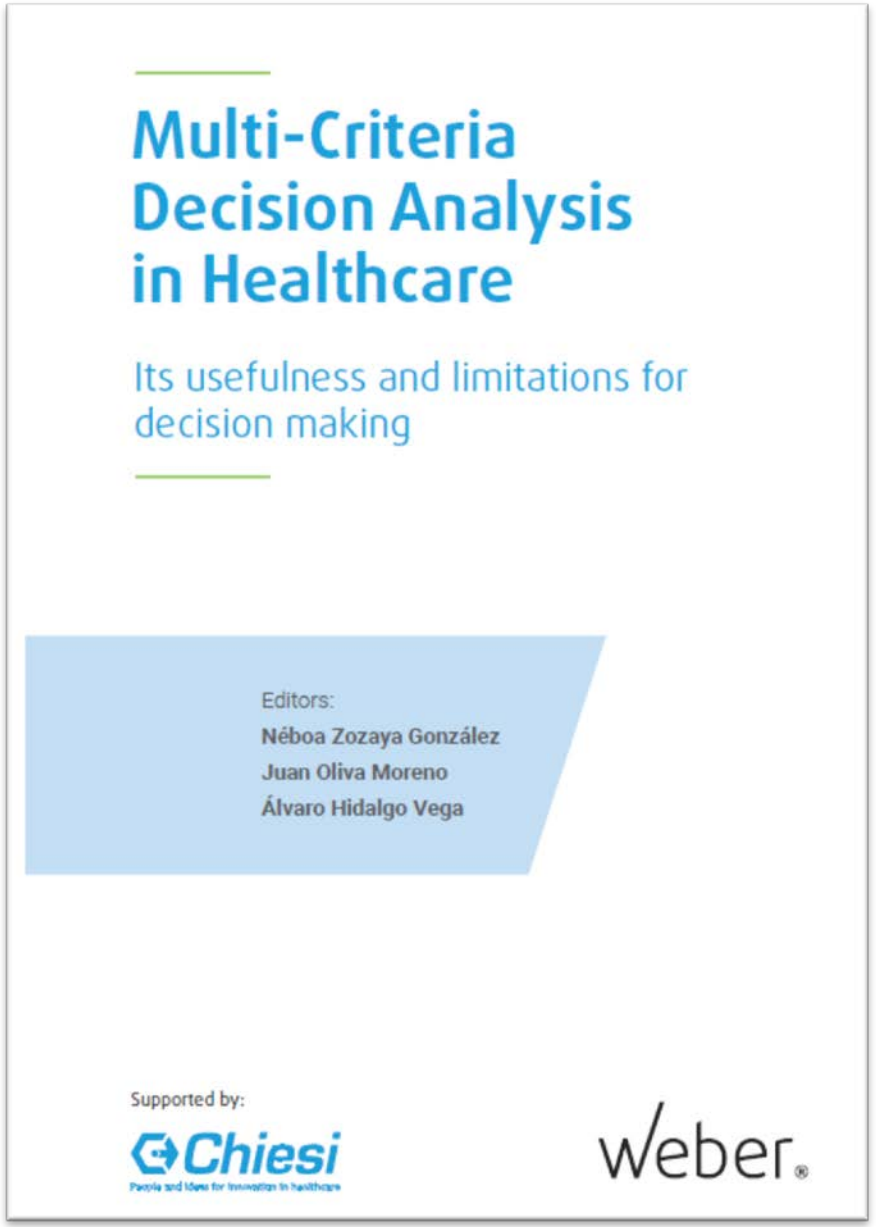
No one approach works best always, therefore decision-makers must routinely explore models and methodologies to help them tackle challenges to planning, priorisation and allocation of resources which go beyond improvements in patient and population health.

A "White Paper" which objective is to provide an exhaustive framework that condenses the existing knowledge about MCDA in the field of healthcare

COMING SOON…

Will be available next november 2018 at www.weber.org.es

[Multi-criteria Decision Analysis: Methodology for resource allocation]



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UCLM, WEBER Foundation

ECPD Regional Conference on Health Economics

Pay-for-Performance: The future of allocation?

Opatija, September 28/29, 2018

Sophia Schlette, MPH
Health Systems Knowledge Management

Framing

Concepts, Expectations

Pay-for-Performance

Why pay for performance?

Pay for what?

Pay whom?

Pay how?

Pay-for-Performance

Why pay for performance?

Quality?

Efficiency?

Bonus / malus payments

Additional income generation?

Testing new vs. old payment models

Pay for what?

- Care coordination
- Checklists
- Quality improvement
- Quality objectives
- Use of technology
- Population management
- Patient experience
- Prevention

Pay-for-Performance

Pay Whom?

- Physicians
- Physician Networks
- Single Practitioners
- Other Providers?
- Best-in-class
- Black sheep

Pay how?

- How often?
- How long?
- Benchmarking
- Anonymous or not?
- What about NPfNP? Sanctions?

PfP ≠ Income generating activities !!

Pay-for-Performance

Unintended consequences of monetary incentives

- Neglect
- Cherry-picking
- Gaming
- Greed
- Crowd-out of motivation

Bruno S. Frey: Not Just for the Money: An Economic Theory of Personal Motivation (1997)

Alternative ways of incentivizing quality care

- Why do people
  - go into medicine?
  - volunteer?
  - donate blood?

- Appealing to intrinsic motivation / empathy

Alternative ways of incentivizing quality care

- A shared vision
- Teams & trust
- Communication
- Continuing professional development
- Feedback systems
- Design thinking and improvement tools
- Championship
- Quality
- Technology, workplace & equipment

Framing

Context, Politics

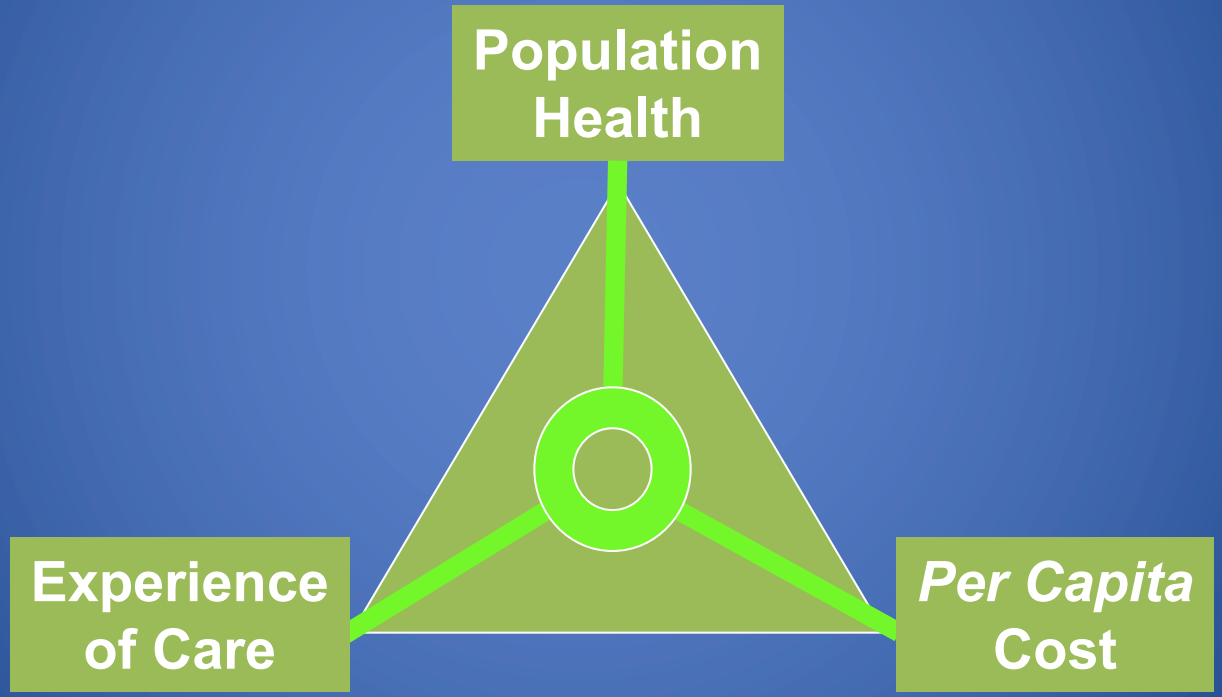
Context

- Notorious challenges in U.S. Health Care (and elsewhere)
  - Coverage
  - Quality
  - Cost
- Political Polarization
- Economic Pressure
- Leadership Gap

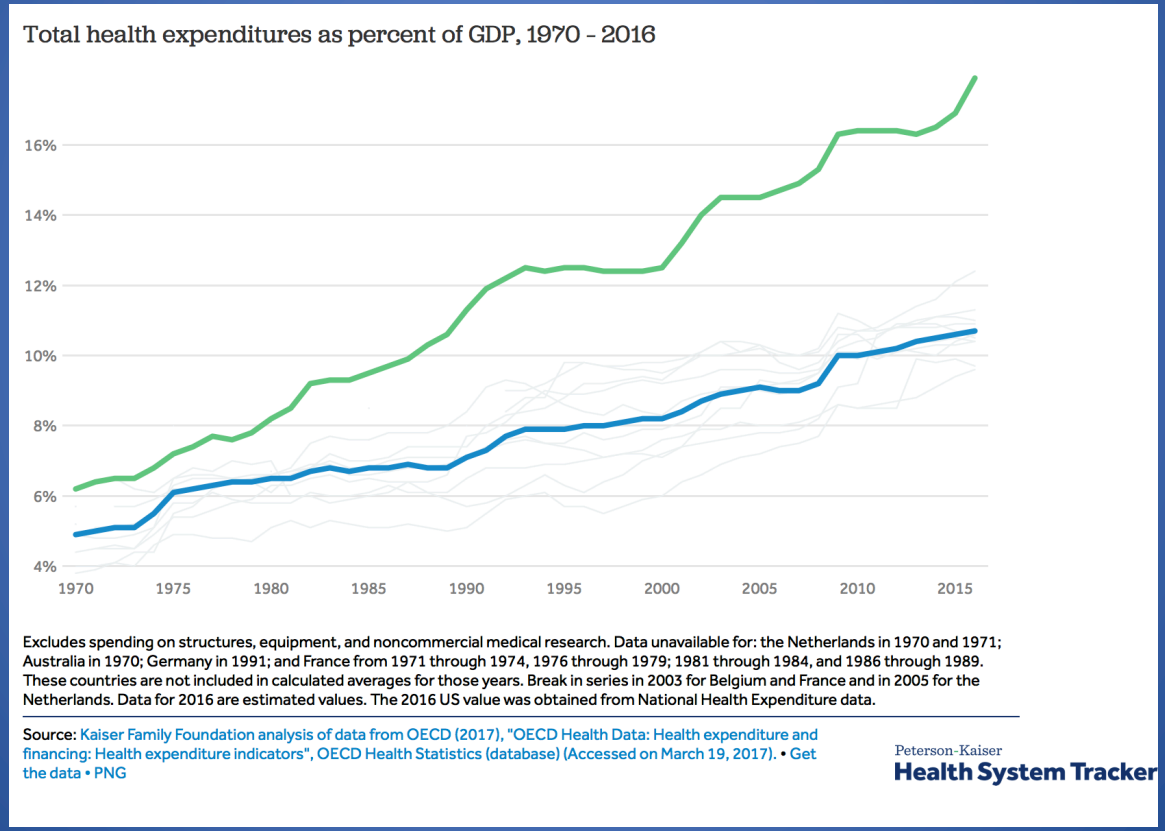
Quality Pain Points

- 2001 IOM-Report: Crossing the Quality Quasm
- 2007 ff Financial and economic crisis
- 2009 American Recovery and Reconstruction Act – Meaningful Use of Health IT
- 2010 Affordable Care Act – Triple Aim (2008)

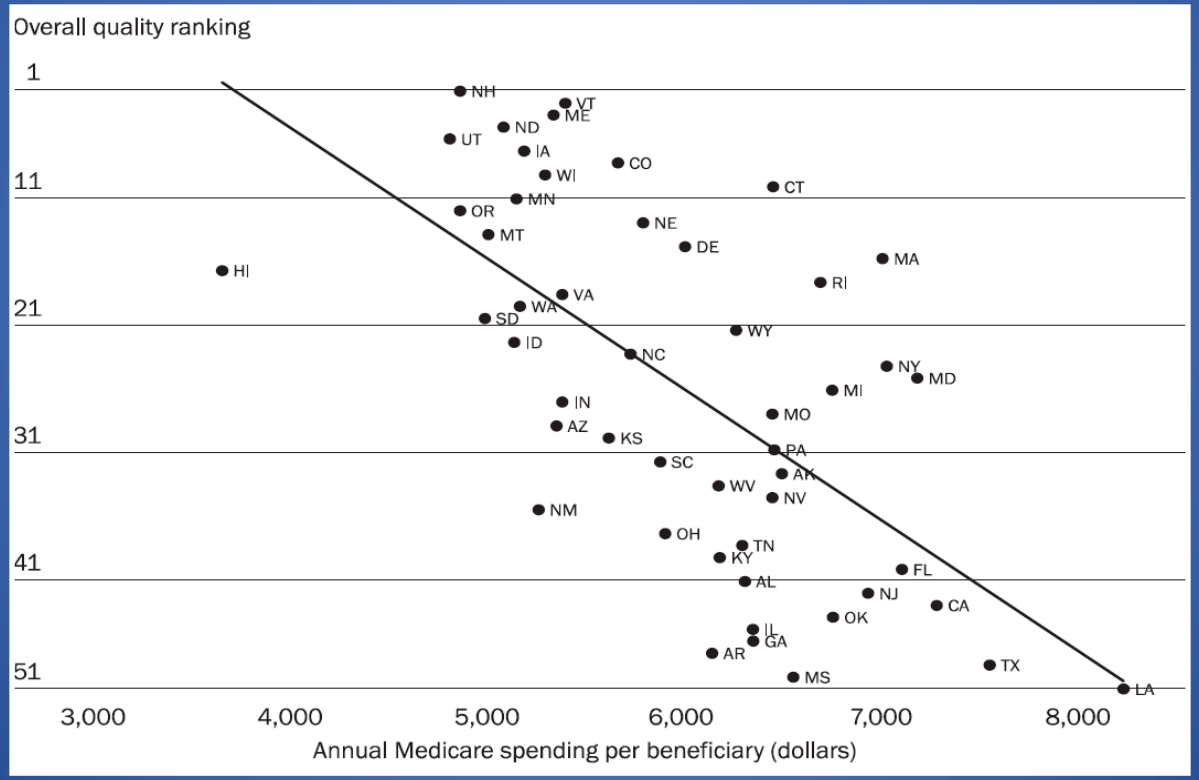
The Triple Aim



THE share of GDP, U.S. vs. rest of OECD



High Spending Regions Have Worse Quality



Baicker and Chandra, Health Affairs, 2004

Hubert H. Humphrey

"The moral test of government is how it treats those who are in the dawn of life, the children; those who are in the twilight of life, the aged; and those in the shadows of life, the sick, the needy, and the handicapped."

November 4, 1977

Many unhappy players

- Health insurers
- Companies
- Individuals
- Ethical considerations
- Total health expenditure as % of GDP projected to grow from 17,9% (2016) to 30% by 2030

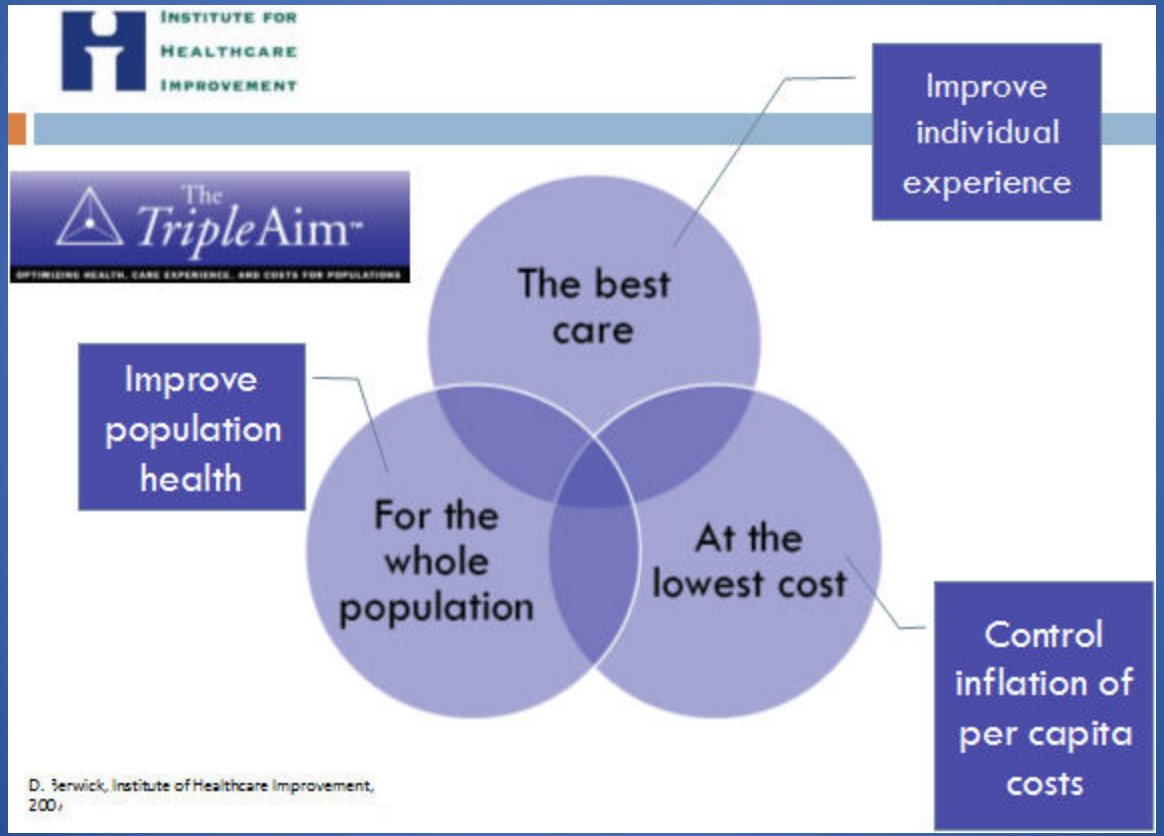
--> backdrop of Affordable Care Act

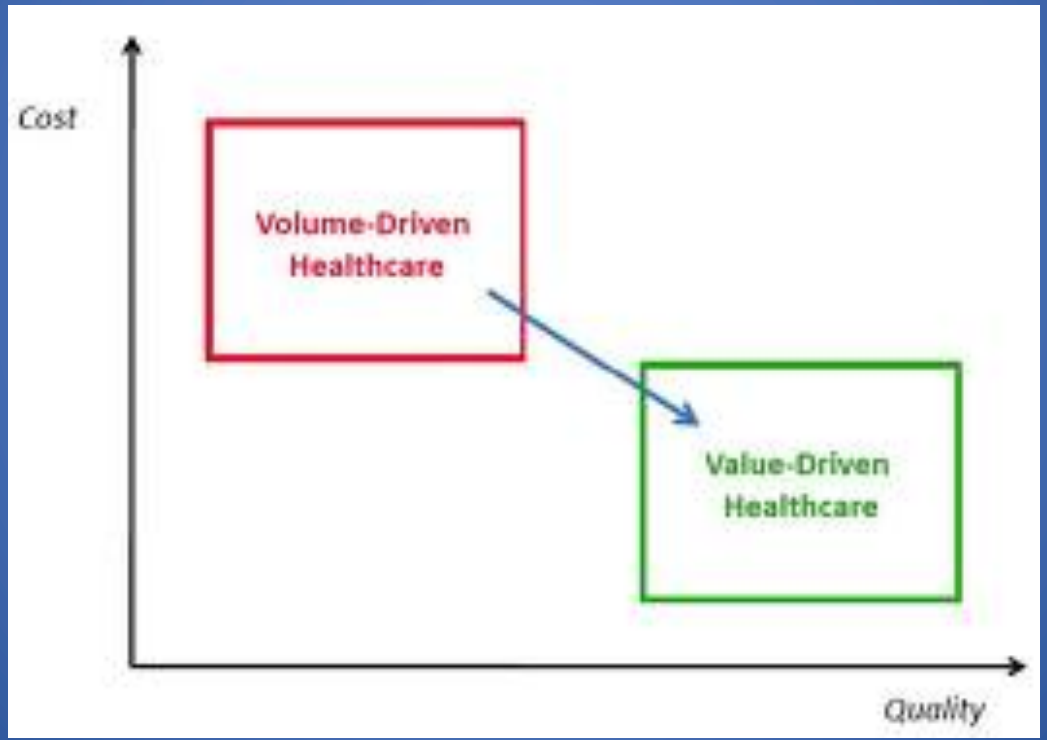
Why?

- Provider monopolies / large provider groups dictate prices
- Intransparent prices
- Health care cost going through the roof
- Cost hikes passed onto employers onto employees
- Higher co-pays, co-insurance
- Companies challenging insurance packages
- Health insurers losing business
- Rising health care costs create lose-lose-situation

Quality = Integration + Accountability

Triple Aim


INSTITUTE FOR HEALTHCARE IMPROVEMENT
The TripleAim
Improve individual experience
The best care
Improve population health
For the whole population
At the lowest cost
Control inflation of per capita costs
D. Berwick, Institute of Healthcare Improvement, 200


Cost
Volume-Driven Healthcare
Value-Driven Healthcare
Quality

From Volume to Value: How

- Involve and work well with other Agencies and Departments
- Take risks – Aim high – Failure is a necessary precondition to learning
- Get the user‘s voice in the room
- Engage the private sector
- Bias always toward cooperation
- Unlikely bed-fellows: Everyone can help

Accountable Care Organizations and Value-Based Contracting

Alternative Quality Contract

What are ACOs?

"ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to the Medicare patients they serve."

Center for Medicare and Medicaid Innovation (CMMI), 2012

Why ACOs?

„What we have now is killing us financially, and in some cases medically“.

John McDonough, Harvard School of Public Health, 2008

Why ACOs?

„We're not looking to spend less than we do today, but we want spending to grow at a rate that's affordable. And we want to empower physicians and hospitals to provide the right care".

Andrew Dreyfus, Executive Vice President for Healthcare Services at BCBSMA, 2008

Example: Alternative Quality Contract

- Boston-based ACO where BCBSMA contracts with major provider groups in the state
- Heavily overdoctored region
- Many tertiary and research oriented institutions
- Cost pressure and projections force players to act
- MA health care reform blueprint for Affordable Care Act (Romneycare → Obamacare)

AQC Measure Set for Performance Incentives

MASSACHUSETTS

	AMBULATORY	HOSPITAL

PROCESS	• Preventive screenings
	• Acute care management
	• Chronic care management
	  • Depression
	  • Diabetes
	  • Cardiovascular disease
		• Evidence-based care elements for:
		  • Heart attack (AMI)
		  • Heart failure (CHF)
		  • Pneumonia
		  • Surgical infection prevention

OUTCOME	• Control of chronic conditions
	  • Diabetes
	  • Cardiovascular disease
	  • Hypertension
	  • ******Triple weighted******
		• Post-operative complications
		• Hospital-acquired infections
		• Obstetrical injury
		• Mortality (condition –specific)

PATIENT EXPERIENCE	• Access, Integration • Communication, Whole-person care	• Discharge quality, Staff responsiveness • Communication (MDs, RNs)
DEVELOPMENTAL	Up to 3 measures on priority topics for which measures lacking	

Year-One Results: Formal Academic Evaluation

MASSACHUSETTS

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Health Care Spending and Quality in Year 1 of the Alternative Quality Contract

Zirui Song, B.A., Dana Gelb Safran, Sc.D., Bruce E. Landon, M.D., M.A.,
Yulei He, Ph.D., Randall P. Ellis, Ph.D., Robert S. Mechanic, M.D., M.B.A.,
Matthew P. Day, F.S.A., Mary Beth Landrum, Ph.D., and Michael E. Chernew, Ph.D.

"The AQC system was associated with modestly lower medical spending in the first year after implementation…a 1.9% savings relative to the control group (non-AQC)."

Remember:
The perfect is
the enemy of the good

On quality

President Obama

“….if we could actually get our health-care system across the board to hit the efficiency levels of a Kaiser Permanente or a Cleveland Clinic or a Mayo or a Geisinger, we actually would have solved our problems."

TIME Magazine, July 2009

Kaiser Permanente‘s Total Health Model

Teams –Templates – Tools

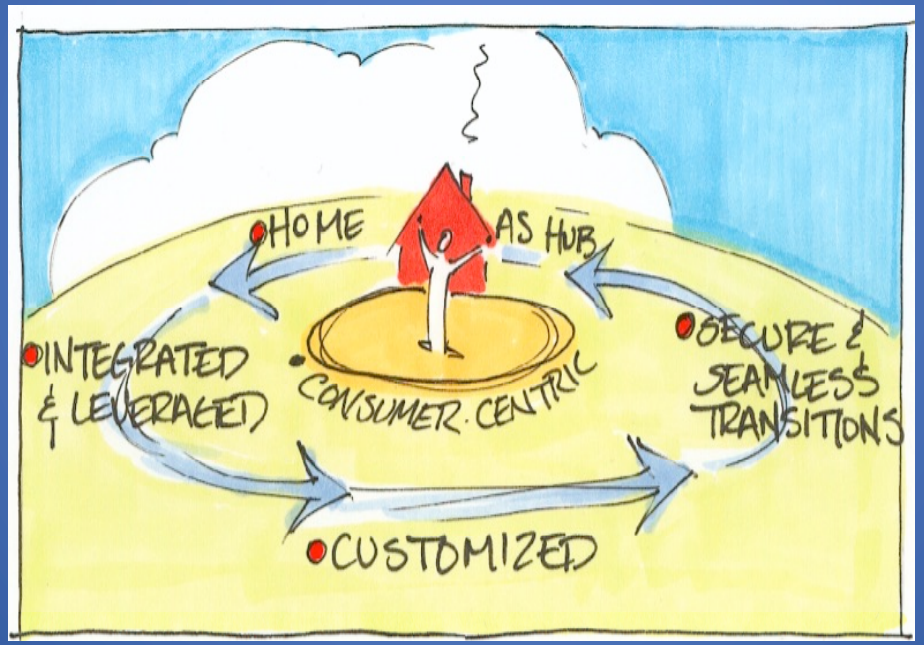
- Clinician Leadership
- Design Thinking (Garfield Innovation Center)
- HP/Prevention – chronic care management – palliative care
- Care anywhere, 24/7: KP Health Connect
- Connectivity networks: CCC, ILN

- Research, registries, training, rapid role-out

Blue Sky Vision (2003) for Health Care Delivery 2015

Home as hub

Integrated & leveraged



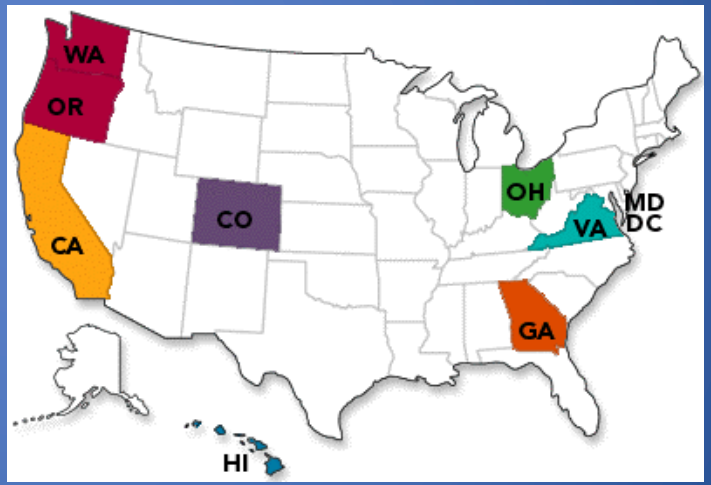
Secure, seamless care

Customized and personalized

Kaiser Permanente

= largest civilian HIT/data-driven integrated delivery system

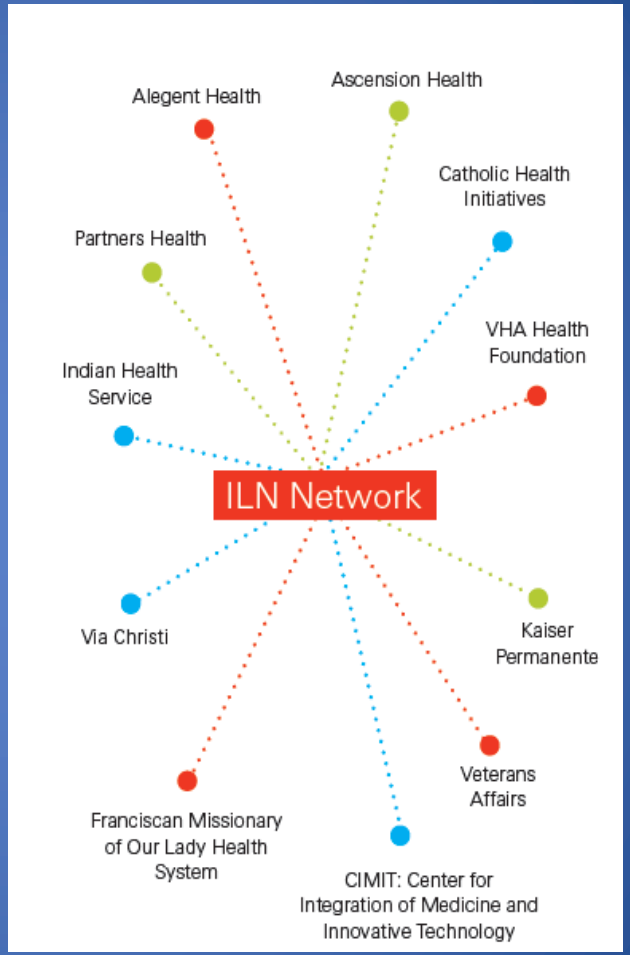
- 11.6M lives (up 10% since 2011, of 314M US pop)
- in 8 states + Washington, D.C.
- 17.4K (15K) physicians
- 174K employees
- 48K nurses
- 38 (34) hospitals
- 608 (454) medical office buildings
- $53B revenue
- $2,7B net income
- 22 NIH-Grants (2010)
- 5.2 M enrollees in PHR
- 27% transactions on mobile

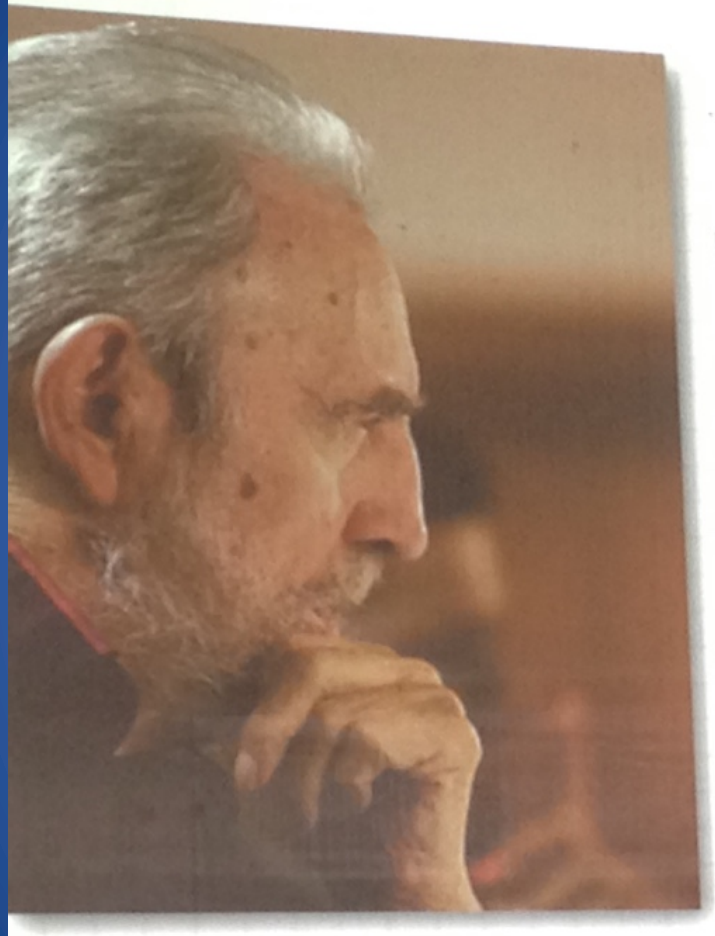


What is your vision?

The Innovation Learning Network

The purpose of the Innovation Learning Network is to foster discussion on the methods and application of innovation/diffusion, ignite the transfer of ideas, and provide opportunities for inter-organizational collaboration.





.... Somos un país pequeño, pero este país pequeño ha podido demostrar cuanto se puede cuando se quiere, cuanto se puede si los recursos humanos de cualquier país pueden ser bien utilizados...