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VALUE-BASED HEALTHCARE

PERSONAL
VALUE

TECHNICAL
VALUE

ALLOCATIVE
VALUE

SOCIETAL
VALUE



DEFINING VALUE IN “VALUE-BASED HEALTHCARE”

Report of the
**Expert Panel on effective ways of
investing in Health (EXPH)**

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Print ISBN 978-92-76-08993-3 doi:10.2875/872343 EW-04-19-516-EN-C

PDF ISBN 978-92-76-08992-6 doi:10.2875/35471 EW-04-19-516-EN-N

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

(EXPH)

Opinion on
Defining value in “value-based healthcare”

The EXPH adopted this opinion at its 16th plenary on 26 June 2019
after a public hearing on 4 June 2019

About the Expert Panel on effective ways of investing in Health (EXPH)

Sound and timely scientific advice is an essential requirement for the Commission to pursue modern, responsive and sustainable health systems. To this end, the Commission has set up a multidisciplinary and independent [Expert Panel](#) which provides advice on effective ways of investing in health ([Commission Decision 2012/C 198/06](#)).

The core element of the Expert Panel's mission is to provide the Commission with sound and independent advice in the form of opinions in response to questions (mandates) submitted by the Commission on matters related to healthcare modernisation, responsiveness, and sustainability. The advice does not bind the Commission.

The areas of competence of the Expert Panel include, and are not limited to, primary care, hospital care, pharmaceuticals, research and development, prevention and promotion, links with the social protection sector, cross-border issues, system financing, information systems and patient registers, health inequalities, etc.

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The opinions of the Expert Panel present the views of the independent scientists who are members of the Expert Panel. They do not necessarily reflect the views of the European Commission nor its services. The opinions are published by the European Union in their original language only.

ACKNOWLEDGMENTS

Members of the Working Group are acknowledged for their valuable contribution to this opinion.

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The declarations of the Working Group members are available at:
https://ec.europa.eu/health/expert_panel/wg-value-based-healthcare_en

EXECUTIVE SUMMARY

Background and Mandate:

All healthcare systems today are under pressure to spend their resources wisely and efficiently. Though great improvements have been achieved by strategies to enhance cost-effectiveness and performance of healthcare services within the last 20 years, an OECD report on "Wasteful Spending in Health" (2017) presented alarming data on inappropriate care and wasted resources with estimations ranging from a conservative 10% up to 34% of expenditures. Ever more often the concept of "value-based healthcare" is discussed as idea to improve resource allocation. However, there is no single agreed definition of value-based healthcare or even of what value means (for whom) in the health context. Therefore, the Expert Panel on Effective Ways of Investing in Health (EXPH) was requested to provide an analysis on "How to define value in "value-based healthcare (VBHC)" and "How to inform healthcare decision making to become more effective, accessible and resilient".

An analysis of why a turn towards intensified strategies to increase better use of resources shows that the gap between need and demand for healthcare and actual investments (correlated to the GNP) is widening and as a result financial sustainability and access to universal health care are increasingly endangered. Persistent problems are the unwarranted variation of activities and outcomes of interventions (e.g. high levels of volume and intensity like elective surgery in some regions without reducing burden of disease in comparison to other regions), underuse of effective interventions as well as inequity by disease (e.g. different (financial) access to treatment for patients with the same functional condition e.g. hemiplegia, but with a different cause: brain tumor versus stroke, in countries with a well-funded 'Cancer Plan'), and overuse causing waste and patient harm (e.g. overdiagnosis by extensive use of laboratory and radiological tests resulting in overtreatment causing unnecessary activities and anxieties).

A **reallocation of resources** - the freeing of resources and accordingly the reinvestment - from low to high value care is perceived by the EXPH as the utmost necessity for sustainable and resilient European healthcare systems.

Guiding Values for European healthcare systems and EXPH definition of VBHC:

The concept of solidarity is deeply rooted in European history and the perceptions of European citizens on solidarity have – according to recent research results – not changed over time. The political commitment to universal healthcare is enshrined in Art 35 of the

Charter of Fundamental Rights of the European Union. The concept of solidarity can be perceived not only as a value as such but also as a structuring principle for practices, regulations and institutions: access and equity, quality and performance, as well as efficiency and productivity can be seen as indicators for achieving the goal of a fair distribution of solidarity-raised healthcare resources to those in need.

Health is considered to be an *intrinsic* value: a precondition for pursuing a “good life”, for obtaining other (vital) goals what people wish to pursue in life. Since universal healthcare intends to provide health to the population (patient populations as much as the whole population) the “equitable” achievement of health for all is the aim as precondition for social cohesive European societies.

Currently, “value” in the context of healthcare is often discussed as “health outcomes relative to monetized inputs”, aiming at increasing cost-effectiveness. This interpretation of “value” is perceived by the EXPH as too narrow and the notion of “valueS-based healthcare” seems more suitable in conveying the guiding principles underlying solidarity-based healthcare systems.

The EXPH therefore proposes to define “value-based healthcare (VBHC)” as a **comprehensive concept** built on four value-pillars: appropriate care to achieve patients’ personal goals (**personal value**), achievement of best possible outcomes with available resources (**technical value**), equitable resource distribution across all patient groups (**allocative value**) and contribution of healthcare to social participation and connectedness (**societal value**).

Propositions for implementation of VBHC (as defined by EXPH):

To ensure financial sustainability of universal healthcare a **long-term strategy** towards a reallocation of resources from low to high value care – as defined in the EXPH concept is proposed. The EXPH recommends to create greater **awareness to health as essential investment** in an equal and fair European society (“health is wealth”) and to the centrality of European values of solidarity. The development of a consistent language (of waste, in-/appropriate care, etc.) and the training of “change agents” (leaders) are as much part of this strategy as investments in piloting, monitoring and evaluating the reallocation and shifting of resources.

The EXPH recommends to support the R&D of **methodologies on appropriateness of care** (measuring and monitoring patterns of clinical practice and unwarranted variation

as well as inequity by disease as a basis for a potential to reallocate resources), to support the creation of **Learning Communities** to bring together the best expertise, experiences and practices and to measure, benchmark and to learn from each other putting in place actions in the EU (incl. the shifting of resources from budgets where there is overuse to disease groups where there is evidence of underuse and inequity), to encourage **health professionals to take responsibility and feel accountable** for increasing value in health care for populations, which may require freeing resources from low-value care to reinvest in high-value care and finally to support **patients' initiatives for engagement** in shared decision-making (SDM), recognising the importance of patients' goals, values and preferences, informed by high quality information.

To ensure the sustainability of universal health coverage the EXPH identified value improvement as the single most important means of achieving this. Increasing value in our healthcare systems will require strong collaboration and intensive liaison that encompasses evaluation of interventions (to distinguish true innovation and identify low value interventions), monitoring healthcare services delivered (healthcare services research and planning to identify unwarranted variation and care of high value) and surveys of providers (ensuring that personal value by providing person-centered information to patients).

Opinion to be cited as:

Expert Panel on effective ways of investing in Health (EXPH)
Defining value in "value-based healthcare", 26 June 2019

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1. TERMS OF REFERENCE

The landmark 2017 OECD report on “Wasteful Spending in Health” [1] presented alarming data on inappropriate care and wasted resources. The report stressed that a significant amount of health spending is “at best ineffective and at worst wasteful”. Estimations of wasted healthcare resources range from a conservative 10% [1] up to 34% in the USA [2]. On the other hand, many patients’ needs for care remain unmet: it is estimated that one in three patients is not offered the care he/she needs [3]. Without policy interventions European healthcare systems are in danger of delivering an increasing amount of low value care, while insufficient resources are left for care of high value. Many European regional or national initiatives have started to tackle the problem of wasteful spending by identifying low value care, but only a few (if any) have actually started to take action to redirect it to high value care.

All healthcare systems today are under pressure to adapt to upward pressure on costs associated with new technological developments, increasingly complex patients with multiple chronic conditions, increased public expectations, and changing clinical practice. In this context, it is becoming increasingly important for health systems to spend the resources they do have wisely and efficiently. Consequently, value-based health systems are seen by some as a system change which could improve the quality of healthcare for patients, while simultaneously making healthcare more cost-effective. However, there is no single definition of value-based healthcare or even of what value means in the health context. What a patient considers valuable may not be the same as what a physician considers valuable. Moreover, the interests and values of different stakeholders, such as payers, healthcare providers or producers of medicines and medical devices will not be aligned.

The Expert Panel on Effective Ways of Investing in Health is requested to provide its analysis on the following points:

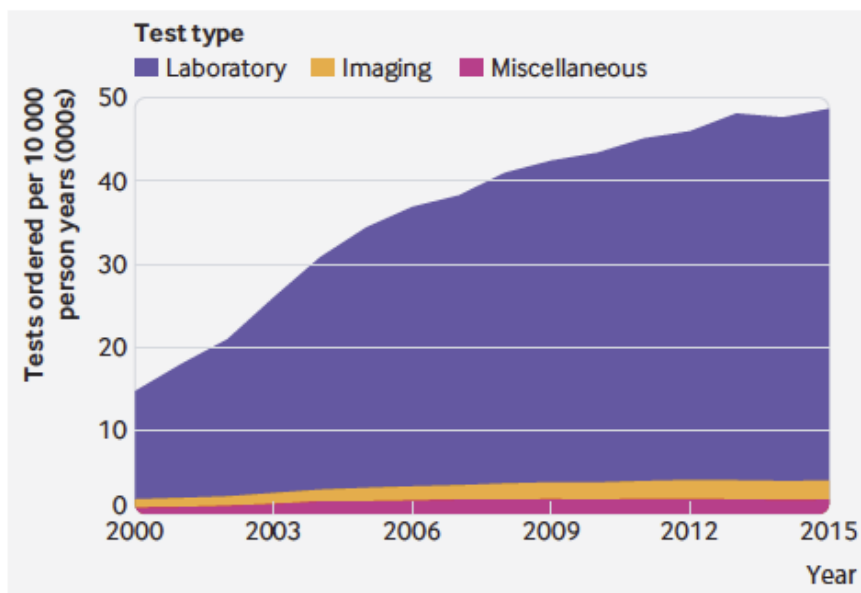
- (a) How do you define value in “value-based healthcare”? What aspects of health systems could the different definitions cover?
- (b) How can “value-based healthcare” inform decision making, contribute to health system transformation, and help health systems across the European Union become more effective, accessible and resilient?

2. BACKGROUND ON WHY THE NEW PARADIGM OF VALUE BASED HEALTHCARE IS ESSENTIAL

Medicine has made tremendous progress over the last forty years as a consequence of two trends. Firstly, there have been remarkable technological developments such as hip replacement, organ transplantation, chemotherapy, magnetic resonance imaging (MRI) and increasingly, new treatments for rare diseases based on genomic advances. Secondly, there has been a steady increase in investment in healthcare, whether through taxation or indirectly through insurance schemes so now about 10% of the EU GNP – though with striking differences across countries (4.95% of GNP in Romania and 11.15% in Germany [4]) – is invested in health and social care. All European nations are committed to universal health coverage (UHC) and this has been reinforced through the adoption of the United Nations (UN) Sustainable Development Goals (SDG), Goal 3 on health and the UHC target therein. While there is agreement on UHC, important differences exist in who is covered, which services are covered (e.g. important differences exist in coverage of long-term care), levels of financial protection and cost sharing, as well as quality of services.

Despite the widespread acceptance of UHC, now enshrined as a target in the Sustainable Development Goals, it is recognised that this commitment poses a challenge because of three trends. The first is population ageing and corresponding organizational challenges to care for patients with multi-morbid and chronic conditions. The second is the development of new interventions for the prevention and treatment of diseases which have been shown by research to be both effective and cost-effective, but which require additional resources to be invested or which are taken up in practice without stopping the lower value interventions they were meant to replace. The third has been termed a relentless increase in the volume and intensity of clinical practice. For example, a review of temporal trends of laboratory testing within UK primary care settings (see Figure 1) demonstrated a three-fold increase between 2000 and 2015, with every general practitioner (GP) now spending 70 minutes each day looking at diagnostic (laboratory, radiology, etc.) results [5, 6]. The available resources – not only financial but also in terms of time – are finite so it is essential that patients and clinicians get the greatest value from what is available.

Figure 1: Temporal trends in total (diagnostic) test use by type



Source: O'Sullivan 2018 [5]

The need and demand for healthcare arising from these trends is predicted to increase at a faster rate than investment, so it is clear that steps will have to be taken to close the gap between need and demand on the one hand and resources on the other to achieve and ensure the financial sustainability of universal health coverage. Universal healthcare coverage is meant to provide healthcare and financial protection to all residents of a particular country or region, but the challenge is that the demand to meet all perceived (individual patients') needs for healthcare must be balanced against other societal goals and needs (e.g. education).

The first arm of a strategy to increase value in healthcare is to continue with and to increase improvement processes that have been so important in the last twenty years namely

1. Prevention, not only the primary prevention of disease, but also tertiary prevention, for example the onset of dementia and frailty to reduce treatment need.
2. Improving outcomes by providing only cost-effective interventions appraised by a process of Health Technology Assessment (HTA) and cost-benefit analysis, eventually funded by discontinuing lower value interventions.
3. Improving outcomes by increasing quality and safety of processes.
4. Increasing productivity.

These healthcare initiatives have been very important, but even though they have been implemented widely, three problems have either developed or persisted or even increased in every country:

1. One of these problems is unwarranted variation, namely variation in investment or access or activity or outcome that cannot be explained by either variation in need or the explicit choice of the populations served. It is important to recognise that this is different from variation in quality and safety, in which there is clear agreement on what constitutes good or bad levels of performance for example
 - A high percentage of patients with stroke being admitted to a stroke unit is good, and
 - A low percentage of people who have had a joint replacement needing corrective surgery is good.

However, there is no agreement on the right rate in a population of, for example, antidepressants prescribing; MRI and other radiological examinations; knee replacement; cataract operation; PSA testing; palliative home care interventions or the amount of investment for people with musculoskeletal problems.

Unwarranted variation can be found in every country and this reveals the other two main challenges:

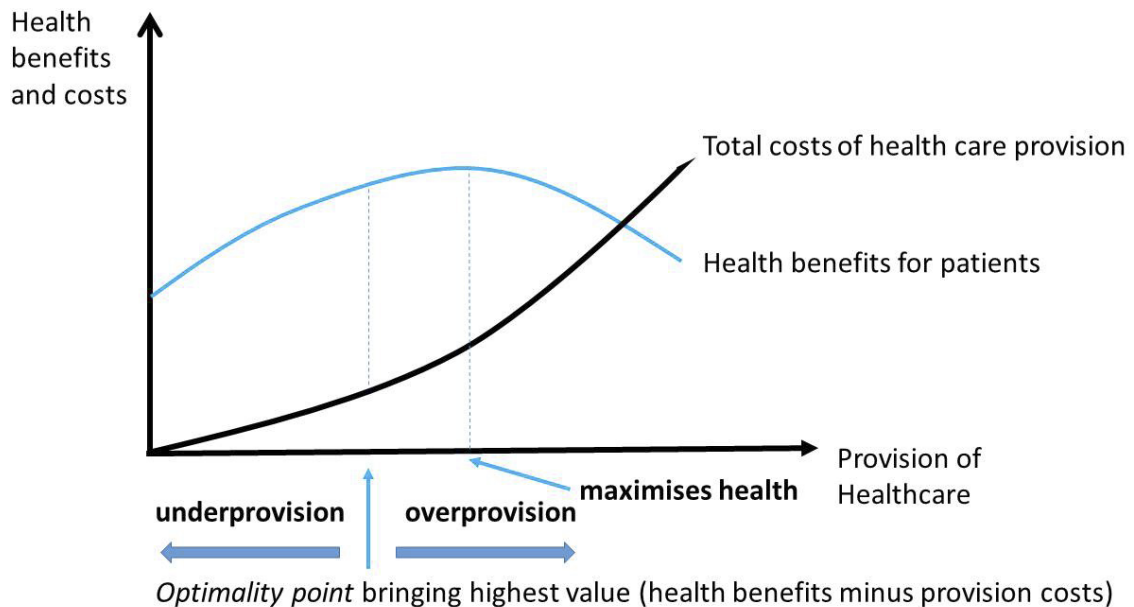
2. Underuse of effective interventions which results in
 - failure to detect, address (treat) or prevent the diseases and disability that healthcare can detect, address (treat) and which may also aggravate ...
 - inequity, e.g. "inequity by disease", in patients with the same functional status but different 'diagnosis', especially when the diagnosis is conditional to the reimbursement of interventions.
3. Overuse which always results in
 - a. waste, that is anything that does not add value to the outcome for patients or uses resources that could give greater value if used for another group of patients and may also result in ...
 - b. patient harm in terms of over-diagnosis, anxiety, overtreatment, and side effects of unnecessary care, even when the quality of care is high

To meet the challenge to ensure the financial sustainability of UHC and find resources to fund innovations of proven cost-effectiveness it becomes essential to identify overuse and waste and switch resources from lower value to higher value healthcare.

The extent of lower value care and therefore the scope for reinvestment

OECD estimates suggest that at least 10% of all the resources invested in healthcare do not give a good return on investment. This may be because investment in for example high levels of elective surgery, robot-assisted surgery, imaging equipment, laboratory testing or prescribing certain types of drugs has gone beyond the point of optimality where value (the difference between patients benefits and provider costs) is maximised. Increasing resources beyond this point still generates additional health benefits (up to a point) but these are below the additional costs.

Figure 2: (Theoretical) illustration of the relation between healthcare provision, health benefits and costs of provision



Source: own presentation based on A. Donabedian [7]

In addition, there is a drift to new lower value activity - estimated by NHS England's Rightcare Programme as accounting for about 2% of the healthcare budget annually, reflecting two trends

- New technology which may be cost-effective but is introduced without shifting resources from lower value activity to fund the innovation,
- The inexorable increase in the volume and intensity of clinical practice illustrated by the growth in laboratory testing and medical imaging.

We therefore need to get more value from the available resources, not only by continuing the four processes that have been so important in the last twenty years - prevention, evidence based decision making, quality improvement and increase of productivity but also by ...

- Identifying waste, for example by minimising unnecessary cost,
- Shifting resources from lower value to higher value activity,
- Preventing the drift into practice of low value activity,
- Ensuring that the people who are treated by clinical services are those people who would benefit most from those services, that is treating the right people at the right time in the right place,

- And finally – as a consequence of all of the above – finding a balance between healthcare that contributes to improved outcomes and achievement of goals that matter for individual patients and support the underlying value of solidarity in European societies.

This is the new paradigm of “value-based healthcare¹”, which is much broader than the increasingly widely used term “value-based pricing”. The latter is an important issue that will be discussed in more detail later but even when value-based pricing has been used to determine the price and therefore cost to the healthcare payer, those who pay for health services still have to compare the relative value of the investment needed with what could be achieved if the same resources were used to fund other innovations, to pay other interventions or even to do more of something that already exists.

¹ Value-based healthcare does not imply value-based pricing: a distinction will be discussed in the following chapters.

3. OPINION

3.1. Guiding values for European healthcare systems

The modern European welfare state that has developed since the 1950s takes different forms in different countries but, at its heart lies the concept of solidarity, where individuals contribute according to their ability and obtain benefits according to their need. This requires mechanisms that protect the individual “from cradle to grave”, based on transfers from rich to poor, from those in working ages to children and older people, and from those in good health to those who are ill [8]. This concept is enshrined in the EU Treaties, including the values and objectives of the Union, which include solidarity “between generations” and “among Member States”, while Chapter IV of the Charter of Fundamental Rights is entitled Solidarity and covers rights at work, family life, welfare provision and health [9].

Box 1: History of concepts of solidarity

The concept of solidarity long pre-dates the 20th century, with antecedents in major religions, however, the view that the state should participate in this process is more recent. Already the philosopher Thomas Hobbes (17th century) was calling for a “social contract” whereby individuals would cede their individual rights for a guarantee of protection by a sovereign authority. Also other philosophers (John Locke, Jean-Jacques Rousseau) took what would now be seen as a narrow view of the role of the state in protecting its citizens, against poverty, hunger, and disease. The limitations of this narrow approach became obvious with the onset of the industrial revolution and, with it, large scale urbanisation and industrialisation that broke existing social ties. The threat of contagion by infection, especially, the re-emergence of cholera, caused by unsanitary conditions led to reforms in different parts of Europe, and the creation of a system of social insurance by Bismarck. By the end of the nineteenth century the modern European welfare state was beginning to emerge in a number of countries, often drawing on the experience with Germany’s sickness funds.

It was, however, in the years immediately following the Second World War that the modern welfare state developed into its present form. The underlying principles are consistent with the ideas set out by John Rawls in his theory of justice [10] arguing for policies that produce the highest payoff for the least advantaged. In many respects, this is the situation that pertained in Europe after World War II: a system of social solidarity was established in almost all European countries since then.

Though rooted in European history, memories do, however, fade and it cannot be assumed that the motivations that were present in the 1950s have persisted. In particular, there have been concerns that the European model of solidarity may be challenged by increasing ethnic diversity, drawing on work comparing Europe with the USA, which provided compelling evidence that the failure to create a European style welfare in the latter reflected an unwillingness of an ethnically diverse and divided society, and in particular a dominant racial group to invest in public goods that would benefit everyone [11].

Research undertaken in Europe a decade ago suggests that this has not (yet) happened [12], although those findings predated the recent migration crisis and the rise of populist politics. Recent data from the Social Survey (2016) show that representatives of all European countries agree or agree strongly between 44.5% (Czech Republic) to 88.9% (Portugal) that the "state should redistribute income", while between 12.3% (Lithuania) and 55.5% (Czech Republic) disagree (Table 1). Figure 3 shows, for those countries participating in both waves, the change between 2002 and 2016. This shows that there have been changes, in both directions, in different countries.

Table 1: Social Survey (2016) on "agreement to redistribution of income"

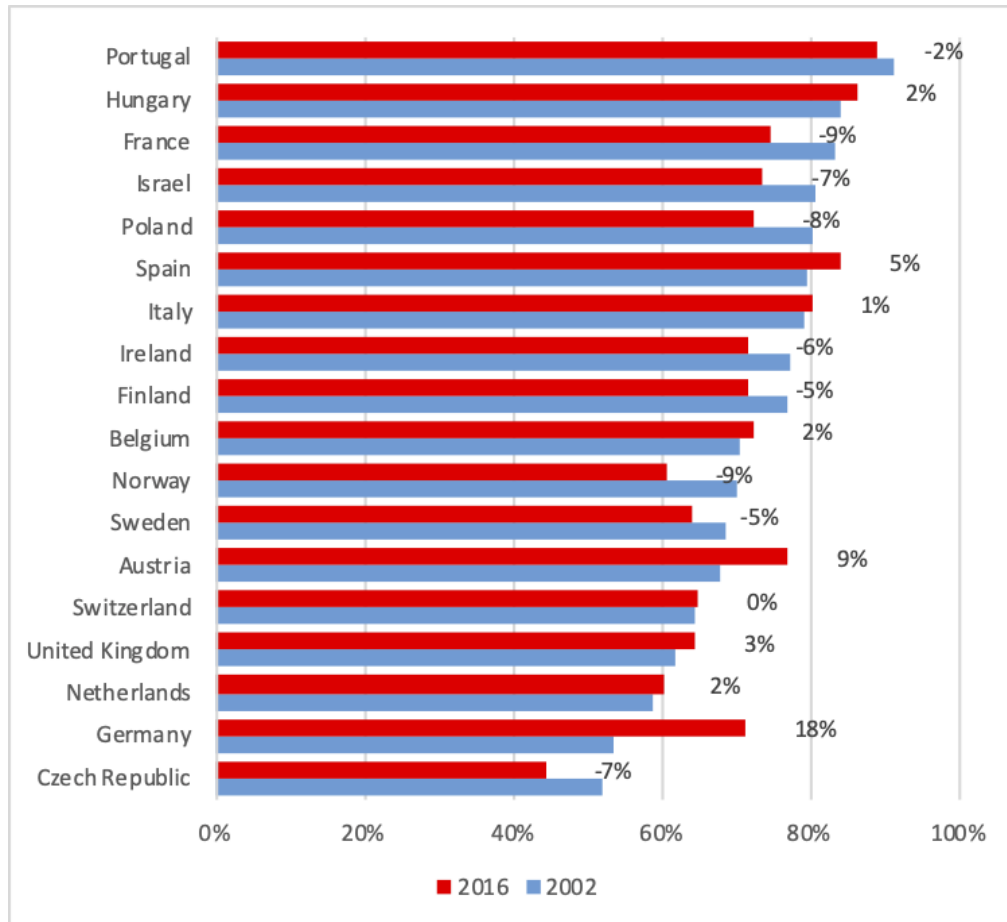
Do you agree that state should redistribute income

	Neutral or disagree/ disagree strongly			Agree/ agree strongly		
	95.0% Lower CL	%	95.0% Upper CL	95.0% Lower CL	%	95.0% Upper CL
Austria	21.1%	22.9%	24.8%	75.2%	77.1%	78.9%
Belgium	25.6%	27.6%	29.7%	70.3%	72.4%	74.4%
Czech Republic	53.4%	55.5%	57.6%	42.4%	44.5%	46.6%
Estonia	28.8%	30.8%	32.9%	67.1%	69.2%	71.2%
Finland	26.4%	28.4%	30.5%	69.5%	71.6%	73.6%
France	23.4%	25.3%	27.2%	72.8%	74.7%	76.6%
Germany	26.9%	28.6%	30.3%	69.7%	71.4%	73.0%
Hungary	12.1%	13.7%	15.4%	84.6%	86.3%	87.9%
Iceland	20.8%	23.5%	26.5%	73.5%	76.5%	79.2%
Ireland	26.7%	28.4%	30.1%	69.9%	71.6%	73.3%
Israel	24.6%	26.3%	28.1%	71.9%	73.7%	75.4%
Italy	18.2%	19.7%	21.3%	78.7%	80.3%	81.8%
Lithuania	11.0%	12.3%	13.8%	86.2%	87.7%	89.0%
Netherlands	37.5%	39.8%	42.2%	57.8%	60.2%	62.5%
Norway	36.7%	39.2%	41.6%	58.4%	60.8%	63.3%
Poland	25.4%	27.5%	29.7%	70.3%	72.5%	74.6%
Portugal	9.5%	11.1%	12.9%	87.1%	88.9%	90.5%
Russian Fed.	29.9%	31.8%	33.7%	66.3%	68.2%	70.1%
Slovenia	12.3%	14.1%	16.1%	83.9%	85.9%	87.7%
Spain	14.3%	15.8%	17.5%	82.5%	84.2%	85.8%
Sweden	33.5%	35.9%	38.4%	61.6%	64.1%	66.5%
Switzerland	32.6%	35.0%	37.4%	62.6%	65.0%	67.4%
UK	33.3%	35.4%	37.5%	62.4%	64.6%	66.7%

CL confidence limit; Figures weighted for design weight

Source: European Social Survey (<https://www.europeansocialsurvey.org/>)

Figure 3: Change in percentage in “agreement to redistribution of income” in rounds 1 (2002) and 8 (2016) of European Social Survey



Figures weighted for design weight

Source: European Social Survey

These are important figures, even though the data on support for income redistribution cannot be applied directly to support for solidarity in healthcare, but can be perceived as indication of shared values in Europe. As solidarity is the underlying concept for a redistribution of healthcare resources towards those members of society in need, the principles for reallocation of resources will be considered in the next section.

3.1.1. Solidarity in practice: the principles of access and equity, quality, efficiency

On the basis of Art 35 of the *Charter of Fundamental Rights* of the European Union [9] and the *European Pillar of Social Rights* stating that “Everyone has the right to timely access to affordable, preventive and curative healthcare of good quality”, healthcare is one of the policy priorities of the European Union to build a more inclusive and fairer European Union and to ensure social cohesion within the EU [13]. The concept of

solidarity underlying these political commitments can be perceived not only as a value as such but also as a structuring principle for practices, regulations and institutions [14, 15]: the development and policies and institutions to increase social justice and help to create the political and economic circumstances that allow societies to operationalize the concept of solidarity.

The core principles of European solidarity-financed health systems - access and equity, quality and performance, as well as efficiency - can be seen as indicators for achieving the goal of a fair distribution of healthcare resources to those in need.

Access and equity: Access and equity are principles that contribute to the goal of social justice. Equity relates to fairness: It recognises that some people are more disadvantaged than others, resulting in health differences between socio-economic and other groups. There is a responsibility to address this lack of equity by offering public services to reduce this gap. Access to high value care means the free and unrestricted access to immunization or preventive programs, equity means that clinical outcomes of e.g. acute conditions such as stroke or myocardial infarction are equal across all social groups and not - as the GINI-index² tells us - much worse for those socio-demographic groups living in worse economic conditions. But access is related to the need for healthcare *and* the ability to benefit: arguments (by industry, patient groups) on "unmet need" for particular - often high cost - interventions fail to recognise that need is defined in terms of ability to benefit and alternative interventions are considered in the context of scarce resources and the necessity to make choices [16, 17].

With increasing examples of "unsustainable prices" for the treatment of some patients, "access to medicine(s)" has become a major topic in recent political discussions. Already within the Belgian EC-presidency (2010) [18], later by the Dutch EC-presidency (2016) [19] and lately the Austrian EC-presidency (2018) the topics of "equitable access and fair pricing" have gained prominence in discussions about innovative policies, as set out in an earlier EXPH opinion [20] that examined initiatives to promote the rational and responsible use of valuable innovative medicinal products so as to obtain an optimal clinical outcome and efficient expenditure (in terms of affordability, accessibility and sustainability). Lack of (public and personal) affordability is a major barrier to access and equal access to high value care.

Quality and performance: The principle of high quality, and well performing health systems relate to the question of whether the healthcare provided is fit for purpose, and therefore contributes to the goal to provide optimal (and safe) care to all who need it.

² GINI index or coefficient: its value ranges from 0 (or 0%) to 1 (or 100%), with the former representing perfect equality (wealth distributed evenly within a country's wealthiest and poorest citizens) and the latter representing perfect inequality (wealth held in few hands).

Health systems vary widely in performance, and countries with similar levels of income and health expenditure differ in their ability to attain key health goals. Performance is centred around three fundamental goals: improving health, enhancing responsiveness to the needs of the population, and assuring fairness of financial contribution. Health systems performance assessment (HSPA) measures the achievement of high-level health system goals, benchmarking against indicators and targets. Such quality or performance indicators encompass clinical outcomes (e.g. stroke mortality), avoidability of death or morbidity (e.g. diabetes-related burden of disease), avoidability of hospitalizations (e.g. asthma hospitalizations) and ever more often indicators what matters to patients (Patient Reported Outcome Measures [PROMs] and Patient Reported Experience Measures [PREMs]) etc. It is however important to appreciate that although low quality care is of low value; high quality care is not necessarily of high value, if the care is given to the wrong individuals, whose preferences have not been ascertained and/or the intervention does not address the problem that is bothering them most. Additionally, more value could be derived by investing those resources in another intervention in other patients.

Efficiency and productivity: The principle of efficiency - weighing the outcomes against the resources used - contributes to the goal of producing as much value with available resources as possible. It should also take into consideration the fairness of distribution of resources to those in need. In contrast, productivity relates the outputs to the resources used. Productivity can be captured in different ways, for instance the number of knee replacement procedures per physician in a given time period. In contrast, efficiency measures the value produced from the resources spent, for instance how successful knee replacements are in achieving pain reduction.

3.1.2. Ethics of resource allocation in favour of population health

Medical research is expected to continue to improve or increase the number of possibilities for the prevention, detection, and treatment of diseases. However, in all countries (worldwide), healthcare budgets are under considerable pressure, leading to urgent reflections on how to gain the greatest health benefit for the population within the available resources. Decisions have to be made about how to achieve the greatest health benefit for the population while ensuring a fair distribution of resources.

Regardless of the funds available for healthcare, the concept of opportunity costs, both within the health sector and across the whole of government investments is key. Opportunity costs are based on the reality that by investing resources in one way, some opportunity for benefit through investing those resources elsewhere will be lost. Opportunity costs of spending more on a particular health intervention occur both outside the healthcare sector (less spending on other valued goods, like education or transport infrastructure) or within (less spending on care for other people). Within limited budgets

this concept is the underlying driving force for “ethical resource allocation” to gain the most health benefit for the population, though “most health” does not address distribution as such. Wasting healthcare resources on interventions with small effects (low-value care) is considered undesirable, when the same resources could be invested in healthcare services with greater effects, all else being equal. But even if it is the general public’s will to put more societal resources into healthcare services, and not only the will of the providers, the allocation or reallocation/shift must be reasonable and based on arguments of benefits [21]. Equally, pursuing some measures that create less health than others can be justified if the health gain achieved is of higher societal value (e.g. in vulnerable groups or more severely ill).

The prioritisation of public resources determined by a democratic participatory process with the aim of an objective benefit is always necessary even though this prioritisation often takes place implicitly or intuitively. Prioritisation decisions under difficult conditions, such as under economic pressure, are often referred to as *rationing* because interventions with little (sometimes even of no proven) benefit or too high price compared to the benefits are not prioritised. In democratic societies, these decisions require not only fundamental trust in the legitimacy of the decision-making institutions (ministries, social insurance funds, health funds, parliaments), but also the legitimacy of the decisions themselves through disclosure of the rationalities (principles and criteria) employed in these prioritization decisions. Many countries have explicitly stated principles that underpin priority setting, such as solidarity, severity, human worth/dignity, cost-effectiveness etc. [22], while many have (also) implemented procedural criteria, such as Accountability for Reasonableness (A4R). A4R provides a procedure for just priority setting with four characteristics for enhancing fairness and legitimacy of decisions [23-25]:

1. Publicity (decisions are fully transparent),
2. Relevance (decisions are based on rationalities that are considered to be relevant and accepted by those concerned),
3. Revisability (decisions can be revised in the event of new evidence or arguments),
4. Enforceability (process that ensures 1 to 3).

Additionally, the process must also be – according to A4R - empirically feasible [26]. Appraisal processes are often referred to as “deliberative” (careful consideration of arguments, weighing of advantages and disadvantages, and the neglect of particular interests), to achieve fair healthcare with equal access to medical services for all. Factual evidence requires interpretation and different stakeholders can interpret the value of an intervention differently [27].

The guiding principles underpinning solidarity– as described above – are defined by "access and equity", "quality and performance", "efficiency and productivity". The rationale that investing resources in one way means that some opportunity for benefit through investing those resources elsewhere is being lost is the underlying driving force for "ethical resource allocation", defined as the most health benefit as perceived by that population [21].

3.2. Intrinsic and extrinsic Value

The concept of value is defined in many ways. Common to most of them is that value is related to what is considered to be good. Persons, things, and institutions can be good in many ways, and they can be good in themselves or good for something. Philosophers also frequently differentiate between intrinsic and extrinsic values. While intrinsic values are good in and for themselves, extrinsic values are good because they contribute to obtain something else that is good. Life, happiness, friendship, and love are examples of what are considered to be intrinsic value ([28], pp. 87–88). Extrinsic values can come in many forms. For instance, the concept of instrumental values relates to valuing something because it is instrumental in obtaining something else that is valuable. Contributory values contribute to the value of a whole. Relational values are good because they are related to something good. There are also other types of extrinsic values.

In value-based healthcare, a variety of values are at play. First, health itself is considered to be an intrinsic value. While some argue that health is an enigmatic precondition for pursuing or having values in the first place [29] others argue that health is a value in itself ([28], pp. 87–88). Health appears to be a universal good for all people, a prerequisite for a flourishing and good life, and something that we all should pursue and help people to obtain.

Correspondingly, one can argue that health is both a precondition for pursuing values (in general), it is an intrinsic value (in itself), and it is an extrinsic value for obtaining specific other goals. Hence, health is a concept with a complex value-relationship. Healthcare, on the other hand, is most often considered to be an extrinsic value in order to obtain health. Accordingly, "value-based healthcare" appears somewhat complex in terms of values: "value-based services promoting health" where health is of (intrinsic and extrinsic) value. While "value-based promotion of value" may seem somewhat tautological, the meaning of value-based healthcare is much more specific. In a way it brings healthcare back to its extrinsic purpose: to promote health.

However, if health itself is a(n intrinsic and extrinsic) value, and the goal of "value-based healthcare" is to promote health, it becomes crucial to have a meaningful concept of

health. Despite the great merits of WHO's definition of health, it has turned out to be challenging to operationalize the provision of "a state of complete physical, mental, and social wellbeing and not merely the absence of disease or infirmity" (WHO 1947). An alternative definition of health, that may be more easily applicable, is that "[h]ealth is the bodily or mental state of a person which is such that he or she has an ability to realize vital goals, given standard or otherwise accepted circumstances" [30].

"Vital goals" are here defined as what people wish to pursue in life ("minimal happiness"). Hence, it is clear that health (as a value) is related to the subjective experience of the individual, but not necessarily to the fancies of each individual. Accordingly, value-based healthcare in terms of a health-oriented healthcare will focus on the experience of individuals. However, as individuals' health is related to other individuals, value-based healthcare must take into account the health of other individuals, of groups, and the health of the population as a whole. Given the interests of all individuals, the aim is not "optimal happiness," but rather "minimal happiness," as the philosopher Nordenfelt [30] put or "equitable happiness" in a more amenable language.

To conclude, the meaning of the value of health depends on the perspective and the goals of the beholder, but the meaning of the value of healthcare is "equitable" achievement of health of groups of people or the whole population as a precondition for pursuing a good life.

3.2.1. Concepts of Value(s)-based healthcare

Ever more often, the concept of "value-based healthcare (VBHC)" is discussed as an idea to improve our health care systems, but there is no single agreed definition of VBHC. Currently, "value" in the context of healthcare is often discussed as "health outcomes relative to monetized inputs" [31] and focuses on a solely provider-centered healthcare management approach aiming at increasing cost-effectiveness. These discussions are also linked to considerations concerning performance-based payment systems. Thus, it is a definition that may suit and guide management interventions at the provider level, to increase value delivered to the payer and manage the health system as a whole. However, on closer inspection, the current use of "value" does not (entirely) abide by the principle of health being a precondition for pursuing a good life, as described in the previous chapter. On the contrary, the notion of "valueS-based healthcare" is more suitable in conveying guiding principles underlying solidarity-based healthcare systems.

From the earliest days of the evidence-based medicine (EbM) there has been a focus on value. Despite having been accused of cookbook medicine, because the evidence was based on a study of patient groups with one common characteristic, the definition of EbM emphasised the need for "the more thoughtful identification and compassionate use

of individual patient's predicaments, rights, and preferences in making clinical decisions about their care" [32]. Evidence based healthcare (EbHC) was launched at the same time as EbM and as long ago as 2001 the term value based healthcare (VBHC) was used for the first time [33] describing how in " the era of value based healthcare ... the situation that is set to become the prevailing system of resource allocation in which those who pay for healthcare will require that interventions are provided only when their outcomes give greater benefits than any of the alternative uses of equivalent resources". The NHS in England explicitly adopted the concept of value in 2004 and published the first Annual Population Value Review in 2006, publicizing the scale of variation in the allocation of resources to different sub-groups defined by need, for example people with cancer or people with mental health problems. This was followed by the publication of the book *How To Get Better Value Healthcare* in 2007 [34]. In addition to the work in Oxford on EbM, a group developed the concept of "Values-Based Medicine (VbM)" as "the theory and practice of effective healthcare decision-making for situations in which legitimately different (and hence potentially conflicting) value perspectives are in play" [35] and take the different perspective on "value(s)" into consideration.

Broader public discussions about the value of healthcare services were stimulated by the IOM-Report [36], followed by Michael Porter's proposition that value-based healthcare is assessed by "health outcomes achieved per dollar spent" [31]. Although this may make it difficult to call VBHC "holistic", it is claimed to be more individually focused (patient-centered) than the broader concept of cost-effectiveness analyses. *"VBHC is intended to adopt the patient perspective. Value-based healthcare is chiefly focused on individual outcomes and implemented at the level of patient- clinician interactions"* [37].

The expert panel (EXPH) considers that the use of the term "value" in this narrow (Porter's) perspective has become a buzzword for provider-centered management practices and cannot be taken as full health system, patient-centered, approach, especially since aspects of equity are missing. Of course, improvement in healthcare delivery is beneficial to the health system, though it does not exhaust the value provided by the health system. Naturally, some elements coming from the provider-centered approach are useful (as the emphasis on patient's experience and the role of improving patient's treatment path). As detailed below, a value-based healthcare view based on the goals and values of society requires further elements to be considered.

accepted by prestigious institutions such as the Royal College of Physicians of the United Kingdom [44] the Berlin Chamber of Physicians [45] and the Istituto Superiore Sanita in Italy. The Academy of Medical Royal Colleges in the UK(AoMRC) very explicitly connect the discussion of value with considerations about waste and fair distribution by stating “...avoiding waste and promoting value are about the quality of care provided to patients – which is a doctor’s central concern. One doctors’ waste is another patient’s delay. Potentially, it could be that other patient’s lack of treatment” [46]. There is a clinical cost to wasted resources and also, as the report shows, a cost to the environment.

3.2.2. Value(s)-based healthcare for universal health coverage

To summarize, the term value in the healthcare setting, as used in much of the literature from the United States would be classified as (technical) efficiency in countries committed to universal health coverage (UHC). In such countries value includes efficiency but also includes the need to ensure that the resources have been allocated and used to treat those people who would benefit most and to reduce inequality. It is often people from the most deprived subsections of the population who are not referred or are receiving inappropriate care (see above on access, equity, quality and efficiency). Within this broader context the Harvard Business School concept of VBHC and value-based pricing (VBP) falls short, since it is only based on assessment of individuals, not populations of patients and does not address values such as equity and affordability. It should be noted that the focus on outcomes by the Harvard Business School epitomised by the launch of the International Consortium of Health Outcomes (ICHOM) has been very helpful [39, 47].

The approach adopted in the UK and Italy [43] has three distinctive aspects of value in what is called the “Triple Value” Model....

- **Personal value**, meaning that an individual receives appropriate care and is determined by how well the outcome relates to the value and goals of individual patients, considering both good and bad outcomes. This requires shared decision-making [SDM] based on full information on relative benefits and risks/harms of different options, including option of doing nothing – communication and elicitation of preferences. For example, knee replacement may provide increased flexibility in the joint but unless it has resolved the problem that was bothering the patient most it is of little or no value.
- **Allocative value**, determined by how equitably the resources are distributed to different subgroups in the population, for example to people with different conditions, such as cancer or mental illness, or to groups defined by socio-

demographic characteristics. When there are large differences in allocation of resources to one group of patients, “inequity by disease” may occur [48].

- **Technical value or utilisation value**, relating to achieving the best outcomes with the available resources and determined by how well the resources allocated for investment for a particular subgroup of the population, defined by their condition, are used for all the people in need in the population. This aspect of triple value includes the need to identify and minimise inequity for example under referral and treatment of people from the most deprived sub groups of that population.

The Expert Panel on effective ways of investing in Health (EXPH) suggests to add a fourth dimension to create a “Quadruple Value” Model (see Box 3 on interrelations)

- **Societal Value**, relating to whether the impact of the intervention in healthcare contributes to social cohesion, based on participation, solidarity, mutual respect, equity and recognition of diversity. The societal value is rather a perspective than a toolkit to enhance outcomes.

The EXPH therefore proposes to define “value-based healthcare (VBHC)” as a comprehensive concept built on four value-pillars: appropriate care to achieve patients’ personal goals (personal value), achievement of best possible outcomes with available resources (technical value), equitable resource distribution across all patient groups (allocative value) and contribution of healthcare to social participation and connectedness (societal value).

Tensions between “personal value” and “allocative value” might emerge. A prioritisation will be based on the context of “societal value”, e.g., societies with a ‘utilitarian values’ (Europe and USA) may prioritise investments that predominantly enhance efficiency and effectiveness; those with ‘liberal’ values’ (USA) may prioritise responsiveness and individual choice, while those with ‘communitarian values’ may prioritise investments that emphasise solidarity and equity” (Europe) [47, 49].

Box 3: Interrelation of quadruple values: the example of the Community Health Centre (CHC) Botermarkt – Ledeborg in Ghent (Belgium; www.wgcbotermarkt.be/eng/)

- The CHC Botermarkt is a not-for-profit organization, operating since 1978 in Ledeborg, at the time a deprived area of the city of Ghent. The inter-professional team is composed of family physicians, nurses and assistant-nurses, social workers, dentists, oral hygienists, nutritionists, tabacologists, psychologists, receptionists and health promoters. The comprehensive person-centred approach by a team, taking care of very vulnerable people, required in-service training of a

lot of disciplines, in order to respond to the professional challenges. A new discipline of health promoters was introduced, that put the preventative role of Community Health Workers in practice. The Centre takes care of 6200 patients, representing 95 nationalities, and of 250 “undocumented” people. Further, it is responsible for health promotion activities for a community of 10,000 people (**Allocative value**: *distribution of the resources*) (**Societal value**: *access for vulnerable people*).

- The Centre delivers integrated Primary Health Care-approach through promotion, prevention, curative care, rehabilitation, palliative care and social care [50]. Accessibility (no financial, geographical or cultural threshold, but “proportionate” efforts e.g. through interpreters, video-translation) and quality are central and an inter-professional comprehensive person-centred eco-bio-psycho-social frame of reference is used. Special focus is on strengthening health literacy and empowerment (**Personal value**: *appropriate care is delivered*).
- An inter-professional electronic goal-oriented health record [51], accessible for the patient and for all involved health care providers, documents the episodes of care (**Personal value**: *orientation towards achievement of patient’s goals*).
- All patients are registered on a patient-list, open to all people living in the defined geographical area. Payment is through a monthly integrated needs-based capitation (taking into account socio-demographical, epidemiological, contextual and income variables). This financing method stimulates task-shifting and competency sharing and strengthens prevention (**Allocative value**: *cost-effective distribution of resources according to needs*).
- Participation of the population and the community is of utmost importance. CHC Botermarkt implements Community-Oriented Primary Care, and regularly, local stakeholders meet in a Network on “Society, Welfare, Health”. Based on epidemiological, sociological and practice-based information, they perform a ‘Community Diagnosis’ and develop programs that tackle the upstream causes of ill-health (e.g. poverty, traffic unsafety, lack of playgrounds, bad housing conditions, epidemics, oral health). This strategy increases social cohesion (**Societal value**: *contribution to connectedness and social participation*).
- An analysis of the performance of CHCs (compared to usual practices in fee-for-service) in Belgium concluded that the Centers score excellently in access, especially for vulnerable groups, demonstrate good quality of preventive services, rational antibiotic prescription and other indicators and patients in CHCs cost less than usual practices in utilisation of secondary care services [52] (**Allocative value**: *cost-effective and evidence-based use of resources*).
- There are clear indications that this PHC-approach contributes to social cohesion and connectedness in a very diverse population, increasing the resilience of the community and facilitates development of innovative policy-projects (e.g. integration of public health and primary care) (**Societal value**: *social participation and innovation*).

It is important to note that the value attached to health gains by patients and by society can conflict (given collective financing and the need to trade-off interventions and patients): small increases in health/lifetime can be seen as highly valuable by patients, but as less valuable by society. Both values should, - in theory - be captured and, where

necessary, trade-offs be balanced to achieve allocative efficiency. Also, distributing resources by need assumes equal (marginal) effectiveness of interventions anticipating that by redistribution no additional value would be produced, called the point of indifference by Vilfredo Pareto. Societal value goes one step further than allocative value by explicitly encompassing the broader aspects of health as enabler for wellbeing, productivity and social cohesion and that for eventually equally effective interventions those socially deprived might need to be prioritized.

Those pillars of value underpin solidarity-based healthcare systems: Personal value assures the health and autonomy of each member of the society. Allocative value relates to justice. Technical value is directed at system efficiency. Societal value supports basic social (inter-subjective and interactively reinforced) values underlying the other values. The principle of **equity** may be ensured by an equitably allocation of resources, a **fair distribution** may be ensured by the contribution of healthcare to social cohesion, **efficiency** may be ensured by an optimally allocation of resources, **patient-centred** and **quality** of care may be ensured by goal-oriented interaction on benefits and harms between physicians and patients.

Given the different aspects of value, many of which are dependent on different stakeholder interests, it is important to define different conceptions of value and develop a more comprehensive view of value in a wider health system context, encompassing the aspects mentioned above and taking into account **societal values such as solidarity** in European welfare states. Such definitions will be a prerequisite for assessing how the concept of value can help achieve the Commission's goal of supporting effective, accessible and resilient health systems.

When seeking to deliver value-based healthcare, it is important to take into account the diverse values that come into play in healthcare and health policy. Health professionals have a range of values, such as the value of diagnostic and therapeutic strategies [53]. Health economists, Health Technology Assessment agencies and health policy makers have their own heuristic and moral goals [54]. Moreover, a wide range of biases can distort rational priority setting [55, 56]. This seems to be crucial as it has been documented that there is little evidence that the establishment of a values framework for priority setting has had any effect on health policy, nor that priority setting exercises have led to the envisaged ideal of an open and participatory public involvement in decision making [57].

3.2.3. A Framework for Implementation of Value(s)-Based Healthcare

Though no generally agreed definition exists, the concept of "value-based healthcare (VHBC)" is used in an inflationary manner or – as one author calls it "the dilution of value

in healthcare” [58]. Some proclaim VHBC as “the strategy that will fix healthcare” [59], others warn of a reduced (efficiency) approach to “value” [60] and stress the relevance of the relationship between VBHC and EbM. The question of who is to benefit from VBHC (individual patients or the total diseased patient population) and the role of values, especially the value of solidarity with the severely ill and the socially deprived, has been the focus of recent debates.

Discourses about value in healthcare tend to focus on reducing costs, increasing efficiency [31] and, more recently, minimizing unwarranted variation in healthcare utilization [61]. But to really understand value, we also need to develop a deeper understanding of what patients (and clinicians), citizens and societies value most from their healthcare.

Value of healthcare for an individual can be interpreted as directly relating to the *health* benefit, the difference in health with and without healthcare (benefit from recovering health). But value for individuals can also include non-clinical components of benefit that relate to patient experience and responsiveness [62, 63]: timeliness of the treatment, whether the patient was involved in the decision, treated with respect, and amenities etc. Moreover, it can include indirect benefits, such as increased productivity and income due to better health. Health and non-health benefits translate into higher (subjective) well-being (or utility in economics jargon) which can also be thought of as the value of healthcare for the individual. Several metrics have been developed to measure the health of individuals; some are disease specific and others are generic (e.g. Quality-adjusted life year – QALY, and Disability-adjusted life year - DALY), which in turn can be used to measure the benefits from healthcare. More recently, capability measures for adults like the ICECAP have been developed to capture the broader impact of health and social care on wellbeing of patients (beyond health).

Value of healthcare for an individual may differ from the perspective of an individual who already has an illness (ex-post perspective) as opposed to that of individuals who have not yet experienced a specific illness (ex ante perspective). Most countries use ex ante valuations in the context of HTA and economic evaluations, although this may be debated [64]. A further consideration beyond the source of valuation of health gains (patients or general public), as health benefits do not reflect ability to pay health benefits are valued equally across otherwise similar people even with different income levels. This is an important deviation from normal market based distributions of goods and value [65]. It is an expression of the solidarity within healthcare systems and views of equality of people within healthcare.

At the individual level, the benefits of healthcare, including the value of increased health, need to be traded off against the (individually relevant) costs of receiving the care. This

could include aspects like travel and time costs, out of pocket payments, the (un)pleasantness of the process of receiving care, etc. In principle, people will only demand healthcare if the benefits exceed the costs for them. One could view this as a *net* value of healthcare (i.e., benefits minus costs). Note that in the literature value and net value are not always distinguished.

Similarly, at higher levels of decision making, the benefits of healthcare also need to be traded off against the associated costs. The value of health and wellbeing produced is a central element in those decisions as well. The elements considered may be broader than at the individual level, including all relevant impacts on society, ranging from health benefits and increased productivity, to solidarity and social cohesion. For a final trade-off, policy makers taking a system, population and societal perspective need to consider both health benefits and costs of healthcare. There are different approaches to taking benefits and costs into account. One way of trading off benefits and costs is through cost-effectiveness or cost-utility analysis, a method of comparing the costs (or opportunity costs) and benefits of alternative healthcare treatments. In such evaluations health effects (expressed in non-monetary terms) are compared to costs in monetary terms. Note that cost-savings or broader benefits, like the monetary value of productivity gains, are captured on the cost-side of these evaluations. Effects are expressed in terms of natural units, like life years saved or hip fractures avoided in cost-effectiveness analysis. In cost-utility analysis health effects are expressed in terms of Quality-Adjusted Life-Years (or – though rarely - Disability Adjusted Life Years). Such outcome measures combine length and quality of life, and are based on preferences of people for different health states. Like indicated, most *ex ante* preferences are used for this [64]. They measure health benefits in a generic way, so that outcomes for different programs and diseases can be compared. When incremental costs of a new intervention versus a relevant comparator have been calculated (net of savings) they can be divided by the incremental gain in health effects, resulting in an incremental cost-effectiveness ratio (ICER).

This ICER should then be compared to a cost-effectiveness threshold decided by a policymaker. In general, two approaches are taken in setting these thresholds, one is to base it on a (societal) willingness to pay, while the other one calculates the opportunity costs of healthcare spending (how cost-effective is current care). Both can be seen as a kind of approximation of an appropriate societal monetary valuation of health gains, that is subsequently used regardless of, for instance, income levels of patients treated. Without further adjustments, these methods can be used to help policymakers maximise the health of their population, and arguably increase the value of healthcare provided. In some countries, thresholds are varied to take account of equity considerations, for instance allowing higher ICERs for interventions that benefit people who are younger at

the end of life, or disadvantaged on grounds of characteristics such as disability or ethnicity. Importantly, this variation is not directly based on individual willingness or ability to pay, but on notions of equity, justice and solidarity. It allows maximising societally valued health, recognising that some gains may be more valuable than others.

Besides the traditional clinical outputs or (cost-) benefit measures, patient-reported outcome measurements (PROMs), patient reported experience measurements (PREMs) and – as proposed later – patient-defined outcomes can and should be taken into consideration. A framework for the implementation of the four pillars of a value(s)-based healthcare the goals and the means (instruments) to achieve the goals is proposed as follows.

3.2.4. Goals and values of people concerned: patients, physicians, planning, and policy

While values are the fundamental driving forces of individuals and institutions, goals define the direction of concrete activities; those goals are the specific ways we intend to execute the values. Those concerned in healthcare (patients, clinicians, payers, etc.) are led by different goals and - also - those goals might change over time. The following chapter intends to shed some light on the goals of the different actors and their methods to achieve their goals.

Relationship between values, principles and goals

Values are the underlying and fundamental basic goals and are closely associated with our principles. Preferences are expressions of values.

Principles are the operational rules that guide persons and/or institutions.

Goals are specific aims and objectives that define a direction of activities of persons and/or institutions.

In the second half of the 20th century, the concept of patient-centeredness became important in healthcare. In medicine, a lot of attention was paid to training physicians in “communication-skills”, promoting the patient’s role in the consultation. Increased “health”-literacy, fueled by access to the internet, demanded new approaches to communication to put “patient-centeredness” in practice. In 1991, Mold [66] proposed a “goal-oriented approach” that is well-suited to a large variety of healthcare issues, that is more compatible with a team approach, and places a greater emphasis on physician-patient collaboration. As described earlier, value based healthcare encompasses personal value and “goal-oriented care” by determining “what matters” to patients.

Goals and values of patients: Each individual will pursue to live a good life, as defined by the individual. Living a healthy life is a prerequisite and a key part for most people. Characterized by a greater emphasis on individual strengths and resources, this approach represents a more positive concept for healthcare. The measure of success in “goal-oriented care” is the patient, not the physician/professional. This innovative approach, however, was not adopted at large scale. One of the reasons was probably that “evidence-based medicine” [67], was sometimes interpreted and implemented in a reductionist way, even though EbM always intended to incorporate the patient’s preferences. Healthcare outcomes are decided by how the patient and the doctor perceive health and disease, and this perception needs to shift from problem-orientation to goal-orientation. Moreover, it is important to complement “medical evidence” with “contextual evidence” and “policy evidence” [68]. Since 2010, the challenge of multi-morbidity has led to further interest in “goal-oriented care”: in each consultation, a clear exploration of what really matters for the patient is required. Very often, the patients’ goals are related to being able to function and to social participation, for instance a patient with Parkinson’s may have the goal to achieve independence when for using the bathroom or when walking to church. [69].

Goals and values of Clinicians: Physicians and clinicians may have many different goals. At the forefront of physicians’ goals is the individual patient’s wellbeing, balancing potential benefits and, taking account of the patients’ preferences and their individual goals. This is for example expressed in the principle of beneficence. Gaining reputation as an “innovative” practitioner, trying new interventions lacking evidence, might be a goal for some physicians and clinicians. To act and to help, e.g., to “give something” even when no treatment is indicated, can influence the goals and values. Additional, increasing the physicians’ and clinicians’ income by maximizing fees, status and prestige can also be considerations [70, 71].

Goals and values of Provider/ institution: The goals of organizations include providing beneficial interventions to many patients at “reasonable” cost and enhancing the profile of one’s institution as one providing high value care (low re-admission or low recurrence rates). To achieve these goals, cost-effectiveness analyses and budget impact analyses are conducted to inform priorities for investments. Of course, many payment systems simply pay for activity and even if the payer requires certain quality levels to be met, the provider institution is not incentivized to optimize value for the population as a whole because of the focus on ensuring quality only for those patients who obtain that specialist service.

Goals and values of payers and planning (tax and insurance): The goal of payers is to maximize health from a given budget in the whole population, and not only a few

patients. To achieve these goals, priorities have to be set (expressed implicitly or explicitly) in order to define the inclusion or the exclusion of services in benefit catalogues and policies incentivizing the utilization of high value, but low cost interventions may still be introduced or perpetuated. On the one hand, prevention programs are launched and on the other hand increasingly risk-sharing financial arrangements for costly interventions are initiated. The issue is more complicated in insurance based health services where the budget for a defined population is not so clearly visible but there is increasing interest in value as costs and co-payments increase faster than income levels or pension levels.

Goals and values of Industry: The goals of industry may involve maximizing profits (increasing the value to the shareholders or to the owners of companies) in the case of for-profit organizations or other objectives, in the case of not-for-profit entities. Not-for-profit organizations may include access to care and/or progress in knowledge of their goals. To achieve their objectives, health care providers have to offer products and services that are purchased or reimbursed by payers. Providers of health care will make different decisions regarding products and services offered and related investment also according to their perspective. Providers that face pressure to produce short-term financial results are likely to conduct business differently from those that take a long-term perspective. Forms of ownership and management that lead to a focus on short-run profit maximizing will have different goals from those that take a long-term view. The decisions that matter, in addition to prices of services and products, relate to R&D efforts, range of services and/or products provided and their pricing and procurement strategies [72].

Goals and values of HealthCare Planning and Health Policy: Health policy seeks to create a regulatory environment and governance structure to maximize health from a given budget for the whole population. To achieve the goals of equity of access, high quality performance as well as efficiency, an appropriate legal and regulatory framework is required. There is a need for long-term strategies based on data-collection for need assessment in and across disease-groups, innovation strategies based on Technology Foresight & Horizon Scanning to facilitate reallocation of resources based on program budgeting.

Policy/ Government Goals: Finally, the goals of governments include social cohesion and equity across generations. This requires finding a balance between the many policy areas competing for the national budget. The concept of "Health in All Policies" calls on governments to consider the impact of new policies (regulation, budgets, strategies) on health as one major contributor to the progress of nations.

Table 2 gives a (non-comprehensive) overview of the many methodologies and instruments applied to achieve one's specific goals. In the toolbox of potential instruments "value based pricing" is one among many approaches to achieve prices based on actual benefits accrued in individual patients and has its place as management tool. In the context of a broader discourse on value-based healthcare the EXPH proposes not to use the wording "value-based pricing", but rather a broader view of pricing strategy. Note that prices do not create value per se, they divide value generated among the different agents. Prices may influence value indirectly by the reactions and adjustments that different pricing systems induce. Different pricing strategies will, therefore, have distinct implications for the several goals of a health system.

Table 2: Typology of means (instruments) to achieve the goals of different stakeholder in healthcare

Whose s Values	Values and goals	Means to achieve the goals
Patients	Benefit/ outcome, adverse events + complications, achievement of individual patient 's goals	Added benefit assessment shared-decision-making (SDM)
Clinicians	Benefit + harm, Progress in goal achievement of many patients	Relative Effectiveness Assessment (REA) Clinical guidelines
Provider/ institution	Net benefit + costs/budget impact	Budget Impact Assessment Cost-effectiveness Analyses (CEA) Utilities Risk-sharing/managed-entry agreements
Payers + planning	Population health within given budget Net benefit + opportunity costs + quality + equity	Priority setting Programme Budgeting
Industry	Market share and sales	Marketing "Value-based" pricing strategies "Value-based" procurement strategies
Health Policy	Net benefit + opportunity costs + equity + appropriateness (balance innovation and net benefit)	Need Assessment Aggregated (weighted) utilities Technology Foresight & Horizon Scanning Program Budgeting,
Policy/ Government	Social impact (cohesion), impact on generations	Health Impact Assessment (HIA) Societal Impact

Source: own presentation

3.3. Initiatives to increase value in healthcare

As described in the introduction, over- and underuse of healthcare interventions are increasingly perceived as major contributors to the waste of public resources. Overuse is defined as the provision of medical services that are more likely to cause harm than good [73]. The harm might be physical, psychological, financial or societal (e.g. inequity). Overdiagnosis is perceived to be the driver of "too much medicine", the subject of major campaigns by the BMJ, the Dartmouth Institute and many other organisations against the harm and cost implications of overtesting and overtreatment [74]. Overdiagnosis turns people into patients unnecessarily. Incidental findings due to overuse of diagnostics have become a serious problem: there is a large variability across different imaging techniques, but "incidentalomas" occur in 5% - 42% of imaging procedures, many of them of uncertain potential seriousness [75].

Underuse is defined as the failure to use effective and cost-effective medical interventions that are likely to avoid morbidity and mortality [76]. Causes of underuse of effective and affordable interventions might be lack of access (lack of coverage, financial barriers, administrative barriers, remoteness, immigration-status), lack of availability (limited resources or regulatory control), clinical uptake of evidence-based interventions (inconsistent use of interventions, inappropriateness) and patient adherence (non-acceptance or non-compliance due to culture, stigma, language, socio-economic status). Underuse is generally more a problem of low and middle income countries (LMIC), but the underuse of effective non-pharmacological or non-clinical interventions (in prevention, in rehabilitation, but also in treatment of chronic diseases etc.) is common in high-income countries, often creating inequity and reinforcing inequalities.

There is a need for reallocation of resources away from low value care towards high value care. However – under resources constraints –, the acceptance of the need for reallocation will require a culture that prioritizes what matters to patients, taking account of their preferences and their goals.

3.3.1. Patient-centered definitions to increase value in healthcare

From a patient's perspective, if it is to deliver high value the healthcare system needs to shift from a "disease-centered" to a "person-centered" approach, where patients are equal and active partners in their care. Care at all levels needs to be driven by patients' needs, goals, priorities and preferences – starting from ensuring that not only patients' needs drive research and development (R&D) of new therapies, but also by embedding patient-centered practices at the clinical and organizational levels and in governance. There is accumulating evidence [77] on the key role of patients in defining what value actually means in value-based healthcare, contributing their own experiential knowledge and expertise acquired through living with a disease or condition. This is reflected in both the policy discourse and in practice, albeit to date in a somewhat piecemeal fashion. For a patient, innovation in healthcare is not only about new treatments, but better treatments and quality of life – from medicines, non-pharmaceutical options, self-management support, or change in the way care is delivered and organized.

Much of the resource invested in research may be classified as waste [78]: an important factor, besides weak methodology and design, unnecessary duplication, and failure to publish, is that research is too rarely driven by patients' identified priorities, nor does it routinely include measures of outcomes and quality of life that are meaningful for patients [79]. Partnering with patients in research to deliver value is a promising area that is being prominently driven by organizations such as INVOLVE in the UK, promoted by the BMJ [80], which requires submissions to document how they involved patients in

the study (e.g. in setting research questions, outcome measures, design, implementation and dissemination).

There is acknowledgement by many stakeholders involved in the life cycle of medicines (industry, regulators, the HTA community, payers, healthcare professionals), that the end points that matter to patients should be central to decision-making processes, and even more fundamentally, patients should be involved in identifying unmet medical needs and research prioritization. There are sterling examples of where this is happening throughout Europe, but generally it remains ad hoc and fragmented.

The Patient and Consumer Working Party at the European Medicines Agency (EMA) is drafting a reflection paper on enhancing the patient perspective in the regulatory process – this paper, which should be submitted to a public consultation in early 2019, aims to bring greater clarity on how to increase both the quantity and quality of the patient contribution. Of course, this is not only a responsibility of the Regulator –the industry needs to integrate patients’ perspectives much earlier in the process.

There is a need for a structured and systematic approach to addressing this and several IMI (Innovative Medicines Initiative) projects – including PARADIGM (Patients Active in Research and Dialogues for an Improved Generation of Medicines: <https://imi-paradigm.eu/>) on patient engagement – are helping to close this gap, also exploring the ‘return on engagement’. This more robust approach to meaningful patient involvement could and should go beyond medicines to research on technology, systems, and social innovation.

Unfortunately, patients’ preferences can be influenced by a wide range of stakeholders (e.g. industry, media), hopes and expectations, as well as cognitive/ emotional biases.

Potential impact of greater patient involvement/empowerment on reducing waste/increasing value

Empowered, active patients are not necessarily “cost-drivers”: in fact, when patients are given full information and a range of choices, they often prefer the less invasive, less intensive option [81]. The 2017 OECD report also cites substantial, largely unwarranted geographic variations in rates of certain procedures. A study from Denmark that focused on elective surgery showed that, when patients were involved in shared decision-making, they were less likely to choose surgery [82]. The results were echoed in a Cochrane review on the topic [83].

Another example is patient safety. According to the OECD’s 2017 report on waste in healthcare, adverse events happen in 1 out of 10 hospitalizations and they add 13-17% to hospital costs. Up to 70% could be avoided. Little attention has been paid so far to the

contribution that patients' and families' involvement and empowerment can make to improve patient safety in different healthcare environments [84].

So far, patient-targeted interventions – primarily self-management and improving information or health literacy for the patient – have received most attention both in the academic literature [85]; shared decision-making is relatively neglected, though it is arguably fundamental to driving change in clinical practice (the UK seems to be a front runner in this regard).

Arguably, there is still too little evidence on the economic benefits at micro or macro level of patient involvement. However, a 2018 review of patient involvement in clinical research estimated that the return in terms of value of involving patients can significantly exceed the initial investment [86].

Measuring what matters

“What can be counted, counts,” and “what gets measured, gets done”, so it is vital to identify the right outcome measures for assessing healthcare performance, reflecting on what outcomes patients find most important. The problem is that many, if not most, of the commonly used outcome measures were never co-designed with patients in the first place, so they often reflect the priorities of professionals or what well-meaning professionals assumed would matter to patients.

The role of patients in defining outcomes that matter to them is integral to the OECD's PaRIS initiative [87], which will conduct a cross-country survey on assessing health system performance from the perspective of the patient, focusing both on outcomes that matter to patients and on patient experiences of care. Whilst the purpose of PaRIS is to provide comparative information for high level policymakers, it is hoped that it will also help drive change in healthcare practice on the ground.

While a focus on outcomes is welcome, process also matters. The experience of care is often equally important to patients [88]. Improving process can also contribute to improved outcomes; the much-cited example of the Martini Klinik in Germany shows that it was a change in process and a transformation in the culture of the organization that made improved outcomes possible [89].

Patient experience cannot be fully captured in indicators and requires in-depth exploration using interactive tools, based on real engagement with the patients. Patient narratives can be a very useful tool: National Voices in the UK has developed a “narrative on person-centered, integrated care”, and a similar effort is underway in Ireland. These narratives describe what “good” looks like through a patient's eyes and can help in the development of appropriate measures [90].

Some ground-breaking work has examined the role of patients and their representative organizations in health system transformation, contributing to the shift towards patient value-based healthcare. This requires a step beyond „patient-centered“ care which tends to be defined by other stakeholders than patients, towards an unequivocal commitment to patient empowerment, as a move toward value based healthcare and sustainable, quality health systems of the future.

The Empathie Study [91] highlighted the role of patient empowerment, at both individual and collective levels, in understanding and incorporating the patient’s perspective and the patient’s voice. Three tenets of patient empowerment were defined in the study: health literacy and access to quality information; meaningful dialogue with medical professionals and shared decision-making; and self-management, with a focus on behavior, attitudes and the potential of new technology and digital health in enhancing patient empowerment. Further examples [92] [93] provide compelling evidence.

Education and communication are moving forward – both the education of patients to be able to contribute as effectively as possible their expertise and know-how, and the education of all other health professionals involved in delivering value-based healthcare, to enable them to work with patients in an optimal and ethical way. The EUPATI project (<https://www.eupati.eu/>) provides an example in the sphere of patient education on therapeutic innovation. A fundamental challenge is to effect change in clinical practice so that healthcare becomes “in reality” a dialogue, a conversation focusing on “what matters to you” rather than “what is the matter with you”. Patients’ involvement in health professionals’ education is a relevant and very under-explored area.

Ultimately, to achieve value (for patients, and for society), patient perspectives need to be embedded at every level in the health system, from therapeutic R&D and research across the whole medicines and medical devices lifecycle, but also in clinical practice, service design and evaluation, and the design of infrastructures. Many indicators, preconditions, and precursors of disease perceived as important to health professionals, may not be of value to the individual patient, but leading to overdiagnosis [94]. The discourse now needs to move beyond „patient-reported“ outcomes and start prioritizing „patient-defined“ outcomes. Digital technologies will eventually play an important role in measuring what matters to patients [95]: The potential of digitalization in value-based healthcare will only be realized if both health care professionals and patients trust that this will lead to better outcomes, and have confidence in the processes and the tools. This requires leadership, effective cultural change management, and ehealth literacy skills building.

Last, but not least, the “value” discussion must also consider affordability of healthcare – to patients and to society. The patient community in Europe sees value, and indeed

values, embedded, for example, in the target on Universal Health Coverage for all in the framework of the Sustainable Development Goals. It could be argued that a pre-requisite for value-based healthcare is Universal Health Coverage, based on values such as solidarity, fairness and equity [96]. Last but not least there is the "invisible" value of financial protection.

Box 4: Case study "Social Prescribing": a way to integrate medical and social services, England

Under the motto "there is more than medicine", "Social Prescribing (SP)" - practised in England since the 1990s - attempts to support people with physical or mental health problems, for whom medical treatment did not lead to any improvement in the conditions and social isolation additionally aggravates the condition (possibly causes them), by means of "referral" to local, non-clinical centres. In general, a distinction is made between different models of "social prescribing", which differ mainly in the degree of cooperation between general practitioners' practices and SP centres. The ultimate goal of SP is to promote well-being and health by helping patients to gain more control over their own health and also to satisfy social needs. Consequently, SP can lead to the relief in the outpatient sector and in primary care, according to evidence from accompanying research.

Over the years, more than 100 such SP centres have been established in England, which together offer a wide range of different therapies in the areas of volunteering, creative activities, joint learning, gardening, sports, etc. [97]. In the programme "Green Dreams East Lancashire", for example, patients are brought into regular contact with nature (walking together, gardening): this showed a positive effect on physical and psychological well-being and significantly reduced their stress level. At the same time, this offered a good opportunity for socially isolated patients to make new contacts. Another example, the "Creative Alternatives Selfton" programme, showed that active creative activity not only improved the well-being, health and quality of life of patients, but also their social capital. In "The Workers' Educational Association" programme, joint learning for adults is promoted, which has a positive effect on smoking and sports behaviour, as well as on the life satisfaction of the participants. But it is not only the patients who report the SP's successes; informal carers (family members and relatives) also play a role in these programmes. An example is the "Carer Resilience Service", through which relatives of dementia patients are offered support in the area of care, which has had a positive effect on health and safety, as well as on the relationship between caregiver and patient.

A number of qualitative studies on effects and outcomes show that SP generally has a positive effect on the mental health, well-being and social capital of many patients. According to the evidence from accompanying studies, fewer doctors are consulted, less medication is prescribed and fewer emergency services are used, which is accompanied by a reduction in health expenditure [98]. However, robust and systematic evidence on the effectiveness of SP is limited and proof of cost-effectiveness has not yet been provided [99] [100].

All in all, however, the concept of SP comes close to the goal of personalized healthcare, where services are tailored to an individual whose aspirations, needs and capital are aligned, and thus points to an alternative path of healthcare for everyone.

3.3.2. Quantifying and categorising loss of value

A 2017 OECD report found that up to a fifth of health spending could be channeled to better use [1]. Three main categories of wasteful spending:

- Wasteful clinical care covers instances when patients do not receive the right care. This includes duplicate services, preventable adverse events – for instance, wrong-site surgery and many infections acquired during treatment – and low-value care – for instance, medically unnecessary caesarean sections or imaging, or patient’s psychological suffering due to inappropriate communication and/or low quality provider/patient relationships.
- Operational waste occurs when care could be provided using fewer resources within the system while maintaining the benefits. Examples include situations where pharmaceuticals or medical devices are discarded unused or where lower prices could be obtained for the inputs purchased (for instance, by using generic drugs instead of originators). In other instances, costly inputs are used instead of less expensive ones, with no additional benefit to the patient. In practical terms, this is often the case when patients seek care in emergency departments or are admitted to hospital with preventable exacerbations of chronic diseases that could have been treated at the primary care level, or cannot be released from a hospital in the absence of adequate follow-on care.
- Governance-related waste pertains to resources that do not directly contribute to patient care. This category comprises unneeded administrative procedures, as well as fraud, abuse and corruption, all of which divert resources from the pursuit of healthcare systems’ goals.

To tackle waste and loss of precious resources many national and supranational activities have been initiated as follows, and will be described in more details below:

- Health Policy Planning analyzing unwarranted variation, to identify over- and underuse
- Health Policy initiatives investigating disinvestment for re-investment
- Policy and provider institutions analyzing corruption, fraud, misuse of public resources
- Research Policy to reduce waste and increase public value in biomedical and health research
- Clinician led initiatives to “choose wisely” as basis for communication with patients to reduce overuse
- Health and regulatory policies for better access to high-value (but costly) medicines

- Health, finance and regulatory policies for better incentives in favour of fair distribution and optimal use of resources

3.3.3. Health Policy and Planning: Unwarranted variation, over- and underuse

Unwarranted variation has been defined by the originator of health atlases, John Wennberg, as:

“Variation in the utilization of healthcare services that cannot be explained by variation in patient illness or patient preferences.”³

Unwarranted variation is unacceptable: it wastes resources, and it is the hallmark of poor-quality and lower-value healthcare. The prime importance of investigating the causes of variation is that it offers the opportunity of identifying and eliminating lower value activity.

It could be argued that health services have adapted to, and learnt to tolerate, unwarranted variation rather than explore and address the problem. Professionals – clinicians and managers alike – frequently dispute the existence of unwarranted variation, often alleging fault with the data which could be seen as justification for maintaining current practice. Such responses are understandable but, in the context of increasing need and increasing demand for healthcare, together with calls for increased efficiency, those responses can no longer be supported. Indeed, a paradigm shift is required if health services are to face the challenges of identifying, classifying and reducing unwarranted variation in order to increase value for individuals and populations.

Unwarranted or warranted variation should be managed in different ways, as set out in Table 3 [101] adapted from Wennberg et al. [102]. There are some services, such as clinically proven effective services, for which evidence-based medicine (EbM) provides reference standards, making it possible to agree what constitutes good and bad performance. Persistent and significant deviations from the standard is to be considered as negative and is therefore to be avoided since it might impact negatively on patient health, and patient safety (letter A of Table 3). Another category of services comprises those where low-cost care settings can produce the same outcome (letter B of Table 3). Performance evaluation systems (PES) especially focus on monitoring results for the above mentioned typologies of services (letters A and B) and urge health systems to constantly improve in order to achieve the reference standards. There are instead other services (letters C and D of Table 3), which have no reference standard; however, they have rates unevenly geographically distributed for the same need [103-105].

³ <http://www.dartmouthatlas.org/>

Table 3 Variation in different health services categories

Category of health services		Impact on variation
A	Clinically proven effective services (e.g. volumes of specific surgical procedures)	In this case variation is unwarranted. It means that the health system failed to properly and equitably answer to citizens health needs
B	Services delivered according to care settings	Variation determined by the organisational choices of the health provider whose services and treatments may be delivered in long-term care settings with the same health outcomes
C	“Elective services” to be delivered according to patient needs, choices and risk propensity (e.g. hip replacement)	Refer to treatment for which usually different options with different trade-offs exist. Variation ought to reflect patients’ different needs and preferences.
D	Supply-sensitive services: services whose intensity of use might increase when the number of services (e.g. beds, physicians) increases	Variation might be unwarranted: the health provider faces problems to ensure equity and appropriateness. Overuse or underuse of specific procedures can occur

Source: [101]

Interventions for reducing unwarranted variation differ according to health service categories. For services belonging to categories A and B, where standards and EBM protocols are available, measurement and dissemination of information can help to reduce geographic variation, but if knowledge is to lead to change, measuring and disseminating results must be supported by other policy and managerial mechanisms. For services belonging to categories C and D, as demonstrated in numerous studies, geographic variation in the provision of care cannot be completely explained by patient characteristics and preferences but instead is mainly influenced by differences in clinicians’ behaviour and judgment. Clinicians, in turn, often do not realize that their treatment decisions vary greatly across geographic areas and have relevant impact on healthcare costs [101].

Variations in quality are inevitable. Healthcare is delivered by human beings, and even if they use the same equipment, the quality of care, that is, the degree to which it meets pre-set standards, will vary [106]. Variations in expenditure, activity and outcome rates are more difficult to understand than variations in quality (see Box 5 on Quality Registries as one tool for disclosing unwarranted variation). In measuring quality there is clear agreement on what constitutes good and bad, for example a high rate of admissions to stroke units is good and a low level of screening coverage is bad but for many services and interventions the issue is not clear cut and

- A high level of intervention may be good, or may represent overuse, which always wastes resources and may do harm whereas

- A low level of intervention may be good or may represent underuse of high value healthcare, perhaps compounded by inequity if rates are particularly low in deprived sections of the population.

Box 5: Quality Registries as one tool for disclosing unwarranted variation

Registries are systems for the collection of logically coherent, related data with some inherent meaning, typically reflecting events that have occurred. Quality registries, in particular, seek to use systematic data collection to improve quality of care. They contain data (diagnosis, events, treatments, outcomes) on individual patients within the health care system, including individualised data concerning patient problems, medical interventions, and outcomes after treatment. National Quality Registers are used e.g. in the Nordic countries to improve outcomes of medical care and enhance patient participation.

In Sweden, an agreement between the Swedish state and the Swedish Association of Local Authorities and Regions states that Quality Registries aim to support clinical improvement and research in order to provide patients with the best possible healthcare. Sweden has a legal framework for Quality Registries and a national organisation with a clear remit to support such registries. The Swedish Quality Registries include data at individual level, collected within the healthcare system. The data responsibility for Quality Registries lies with the respective regional and local authorities ("CPUA"-central personuppgiftsansvarig)

(https://www.nordforsk.org/en/programmes-and-projects/projects/project.2017-11-06.6533047689?set_language=en).

Norway and Denmark have systems and definitions that are similar to Sweden's. In Norway, the main purpose of the Quality Registries is to improve quality in medical practice. From a legal perspective, the systems in Sweden, Norway and Denmark resemble each other but are not identical. For example, in Denmark it is mandatory for hospitals, other health care institutions and practicing professionals to collect data on patients for the Quality Registries. In Finland, university hospitals have voluntarily set up clinical quality registries and the National Institute of Health is now setting up national quality registries resembling those in Sweden.

National Quality Registries are used in an integrated and active way for continuous learning, improvement, research and management to create the best possible health and care together with the individual. National Quality Registries are also very important for disclosing unwarranted variation in the use and outcomes of healthcare services.

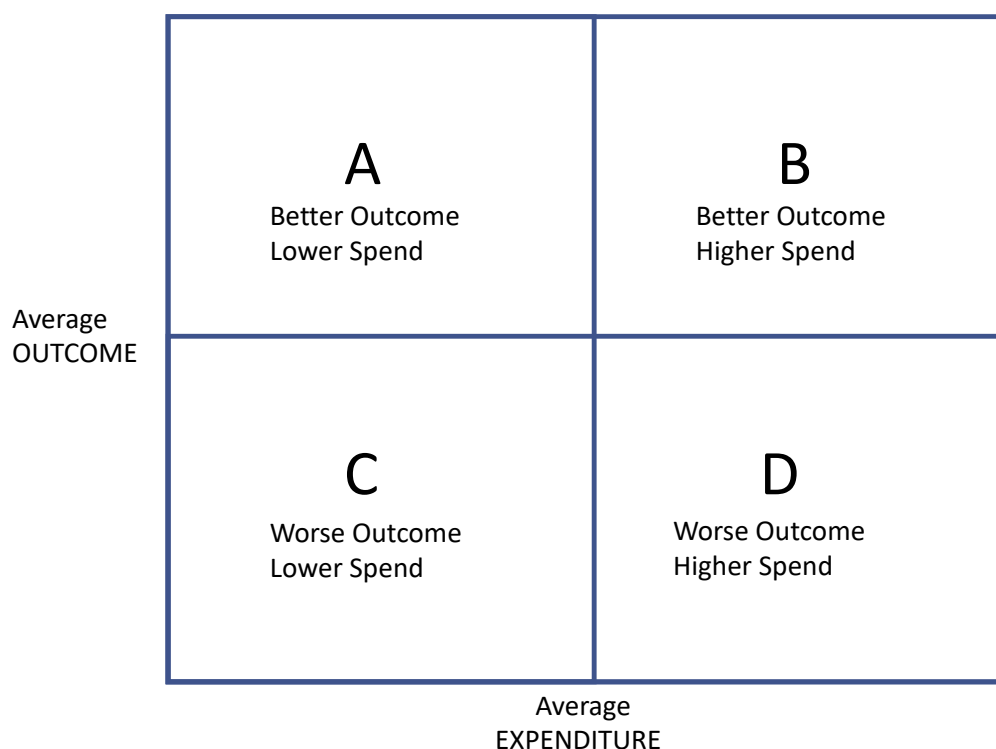
Differences in expenditure - or investment to use another term - on a disease or a group of diseases is a function of three variables:

1. The amount of resource allocated to spend on that particular group of diseases, or programme;
2. The cost of each unit of treatment;
3. The number of people receiving the intervention (esp. when the indications for treatment or diagnostic testing or referral to specialist investigation are dependent on clinical judgement, e.g. hip pain as opposed to hip fracture).

Measures to reduce cost can increase productivity but a much greater issue is the variation in investment in different subgroups of the population, sometimes called programme budgeting. In countries where the budgeting systems allow this type of comparison the expenditure by different jurisdictions on different subgroups, such as people with cancer or people with mental health problems varies from 1.5 to 2 fold, implying the risk of 'inequity by disease' [48].

Increasingly variations in outcome are being measured. These are, of course, in some way the result of variations in quality, but they are also influenced by variations in the severity of the disease in the patients treated. For example, where there are high levels of investment, people with lower levels of need will be treated. For the population, value is measured by the relationship between outcome and investment, and when spend and outcome are plotted the performance of different population based services can be classified using the framework shown below:

Figure 4: Value as relationship between outcome and expenditure



Source: NHS England Rightcare Programme (<https://www.england.nhs.uk/rightcare/>)

For each of these four types of service a different strategy is needed.

- Services in group A should be praised and encouraged to write up their methods and processes for sharing with others
- Services in group B should be praised but should be encouraged to review their investment and see if there are ways in which costs could be reduced without

affecting outcome or if increased need, for example from population ageing could be met without additional resources

- Services in group C should be encouraged to learn from group A before simply asking for more resources
- Services in Group D need a major review

The investigation of variation in healthcare between populations as distinct from between systems is not a new undertaking, but is based on decades of research, particularly in the USA and the UK. It is also important to bear in mind that variation for certain reasons is positive (e.g. variations in the context of patient-centred and goal-oriented care implementation); if all reasons for variation were negative, it would be easier to take action to remedy it [107]. Some variation is inevitable, some is random, and perhaps some is an outcome of differing rates of innovation and improvement, both essential pillars of a modern healthcare system.

Box 6: Case study on the diabetic foot pathway in Tuscany, Italy

This section presents the experience conducted in Tuscany Region on the diabetic foot care pathway. This experience started in 2012 with the aim to explore the determinants of regional variation in the population outcomes results and improve value for patients [108]. The outcome measure that was taken into account to evaluate the pathway performance is the hospitalization rate for diabetes-related amputations. Considering 2012 data, Arezzo LHA was the best performer with no more than 18.78 diabetes-related amputation rate per million residents, while Pisa LHA had the highest recourse to this surgical intervention delivering 100,43 amputations per million residents.

This outcome result was analyzed also in terms of resources allocated to the services related to the diabetes-foot pathway. Figure 1 shows the two different cost items related to the clinical pathway examined: i) severe amputations and ii) preventative treatments (i.e. revascularization).

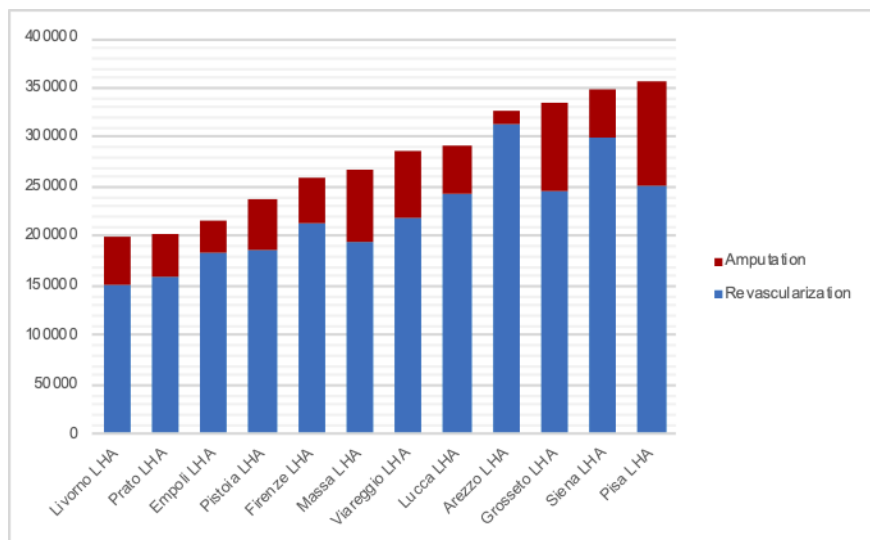


Figure B 1: Estimated LHA expenditure of hospitalizations for diabetes-related revascularizations and lower limb amputation per 100,000 residents – Average of the four-year period between 2009 and 2012.

As one may notice in figure 1, when comparing the total amount of resources consumed by the diabetic-foot pathway in the different LHAs, the best performer in terms of outcome (i.e. Arezzo LHA) have the same level of expenditure of the worst performer (i.e. Pisa LHA). However, even though Arezzo LHA does not account for the overall lower cost per 100,000 residents, it accounts for a cost mix mostly oriented toward preventative services, thus being able to achieve more value for patients with the same amount of resources of other LHAs with poorer outcomes.

Based on this experience, the Pisa LHA, working together with the Pisa Teaching Hospital, implemented strategies for reallocating resources towards a service-mix that increase population value. As such, from 2012 to 2016, the services-mix of amputations and revascularizations in the Pisa area sharply changed towards the preventative interventions (i.e. revascularizations). In fact, even though the resources consumed for these two cost-items remain equal, the percentage of resources linked to amputations decreased from the 30% to the 19% (see figure B2).

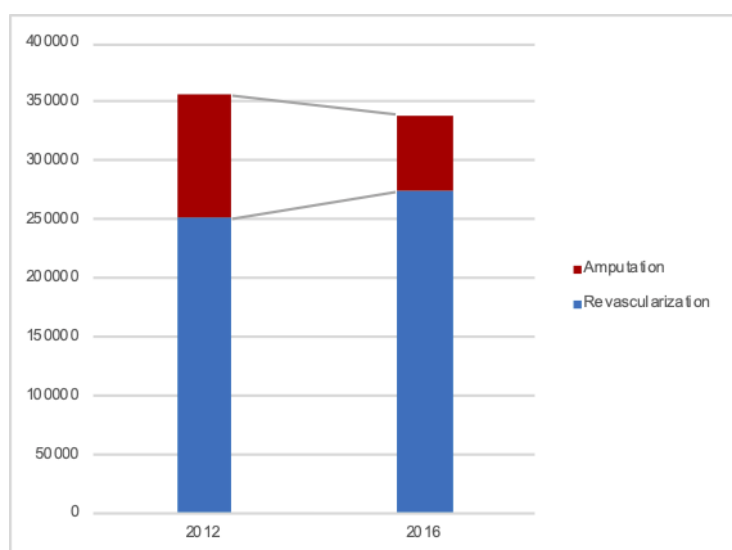


Figure B 2: Estimated LHA expenditure of hospitalizations for diabetes-related revascularizations and lower limb amputation per 100,000 residents in Pisa – Average of the four-year period between 2013 and 2016.

Finally, thanks to a large sharing process among all the clinicians involve in the diabetic foot care pathway and the different resource allocation the Pisa LHA amputation rate decreased from 100,43 in 2012 to 51,98 in 2016.

Source: [109]

The importance of national and local clinical cultures

Sometimes variation is warranted by differences in need, but much of the variation is unwarranted. Wennberg attributed this not to poor quality care but to differences in clinical culture [104]. When it is clear that everyone needs an intervention – to have their blood pressure measured, for example – then everyone knows what to do. As soon as judgement is required, however – about which people with moderately raised blood pressure should be treated – then culture becomes important. Obviously one doctor's interpretation of the evidence can vary from another's which explains variation between clinicians, but what Wennberg found was that a different culture could be identified in different clinical communities. In some communities of practice, surgery for back pain was viewed as something to offer early. In others it was regarded as a last resort. He demonstrated that there was a certain way of working that he described as a surgical signature that described the pattern of intervention in a population.

'Surgical signatures reflect the practice patterns of individual physicians and local medical culture, rather than differences in need – or even differences in the local supply of surgeons.'

The development of this culture takes time, and the culture endures because the community of practice often relates to one medical school that plays an important role in the development of the culture by ensuring new entrants to the specialist training programmes develop the signature of that programme. Then, when one community needs to recruit a new specialist, they choose the applicant from a shortlist, all of whom have been trained and inculcated in the style of practice promoted by the medical school, because they are closest to the preferred local variant of the style of practice.

Most clinicians are unaware of how they compare with other clinicians, not in terms of quality but in terms of value. This requires performance to be related to the population served and not to the number of patients treated, which measures quality not value. It is important to emphasise that, although some variation results from financial incentives in health services which have fee-for-service payment of doctors, unwarranted variation is found in services which have doctors paid by capitation or salary with no financial

incentive to do more. The wish to do good and the belief that more is better leads to a drift in the threshold at which an intervention is offered.

Box 7: Case Study on Reduction of unwarranted variation of IZZI/ Zinnige Zorg ("Sensible Care"), The Netherlands

In 2013, the "Zinige Zorg" program - based at the Dutch Zorginstituut (ZIN) - was established: it has the task of systematically determining the appropriateness of interventions with large variances in practice - despite age and morbidity standardization - and consequently to reduce inappropriate medical services. This is being attempted in a multi-stage process: Through this program the Dutch healthcare system is systematically analyzed, per ICD-10 domain, to identify and remove inappropriate care. Interventions with large differences in specific indication areas (hip and knee surgery, aftercare for primary breast cancer or skin cancer, care for lung and terminal colon cancer) are identified via data analyses of Dutch social security funds. The data analyses and the corresponding scientific evidence from guidelines will be handed over to the respective medical societies for a period of about 12 months in order to develop criteria for appropriate indications and ultimately to implement them in conjunction with a further process step of development of patient information for shared decision-making.

Methodology

Purpose: promoting appropriate care in the consultation room



Additionally, an IZZI reference network of European Healthcare Institutes has been established aiming to discuss, support and develop similar initiatives that stimulate appropriate care.

See more details in Appendix

The impact of unwarranted variation on individuals

To regard the values of an individual and the values of a population as separate issues is misguided. As the intensity of healthcare interventions changes, so the relationship between the benefit and the harm for a population changes, and the balance between the probability of benefit and the probability of harm for an individual patient also changes.

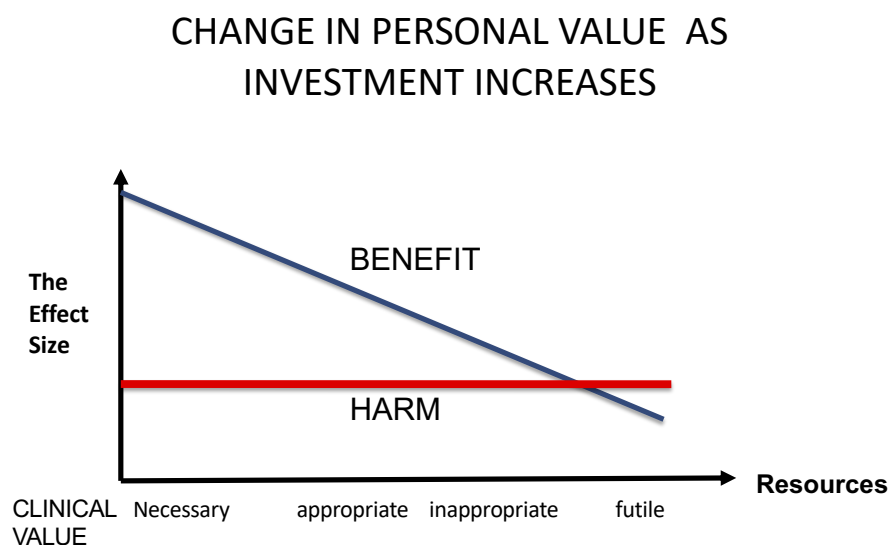
What has emerged is a recognition that changes in value at a population level are accompanied by changes in clinical practice and decision making

- As more resources are invested in a system of care
- Treatment is offered to people who are less severely affected

- Such people will receive less benefit because their problem is less but
- The probability and magnitude of harm they might experience , for example form an operative complication, is the same as for people who are more severely affected

A new language has emerged with concepts of appropriateness and futility. The changing relationship can be expressed diagrammatically

Figure 5: Concepts and terminologies in defining clinical value



Source: own presentation M. Gray

Al Mulley and his colleagues, at Dartmouth University, have coined the term 'the silent misdiagnosis' [110] to describe the common situation in which clinicians have accurately diagnosed a disease but have failed to identify the patient's preferences, goals and values. They argue that not only do decisions need to be based on the best current evidence but also that decision-making needs to be sensitive to the preferences of individual patients. When seeking to explain the causes of unwarranted variation, Wennberg noted that patients' preferences were often either not elicited or, if they were, their preferences were ignored.

"...elective, or "preference-sensitive" care, interventions for which there is more than one option and where the outcomes will differ according to the option used because patients delegate decision making to doctors, physician opinion, rather than patient preference, often determines which treatment patients receive. I argue that this can result in a serious but commonly overlooked medical error:

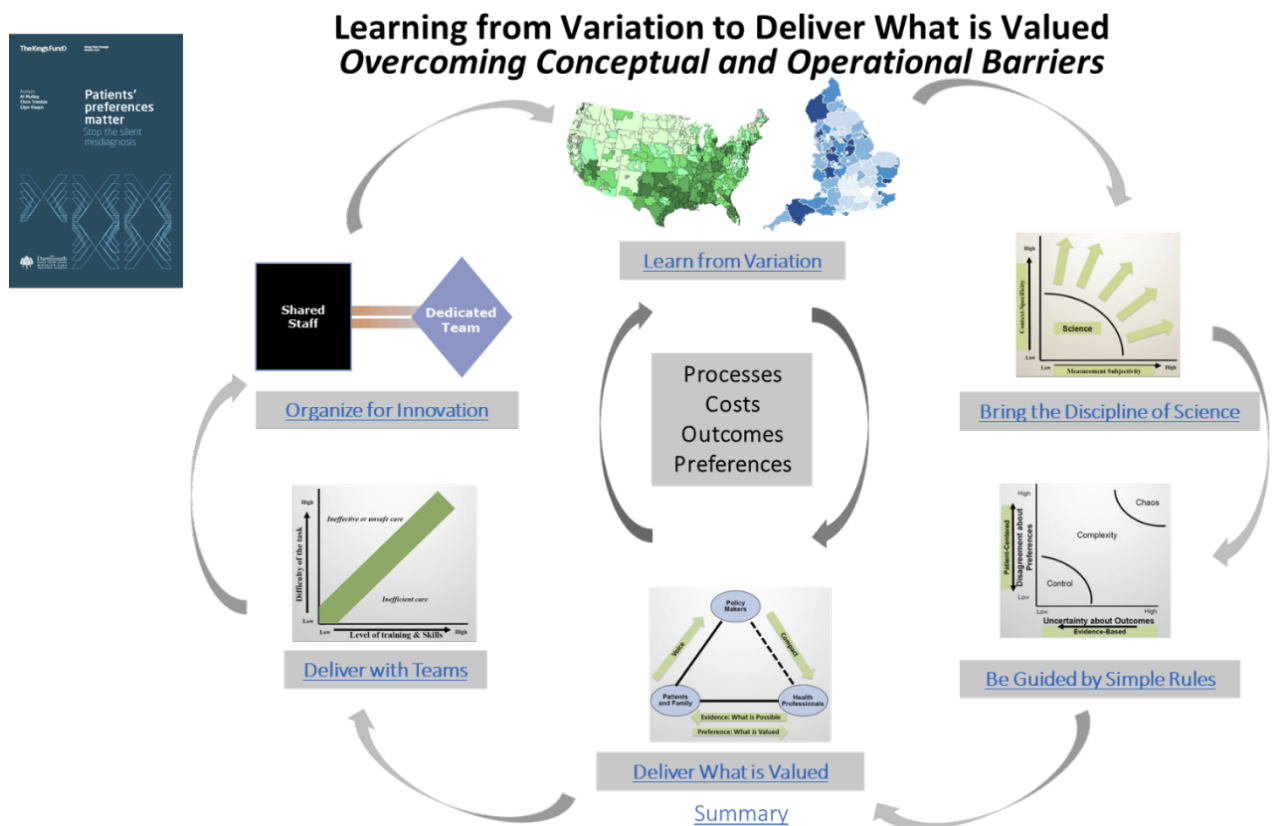
operating on the wrong patients – on those who, were they fully informed, would not have wanted the operation they received” [111].

From the perspective of the patient, the value of the care received is measured not only by its outcome but also by the way it is delivered. The value that patients are prepared to place on the care received will be reduced if they feel that:

- their time has been wasted waiting in a clinic for a consultation at which laboratory results were unavailable;
- they were treated rudely and impersonally;
- they did not receive as much information as they wished.

In all health systems, patients’ perceptions of the value of services are of central importance. Good outcomes are necessary but not sufficient; good patient experience is of central importance to the 21st century patient, and therefore to those who provide and pay for their care.

Figure 6: Unwarranted variation: Learning cycle for better understanding and increase of high value care



Source: [110]

3.3.4. Less might be more: Disinvestment for reallocation

In 2004, Johnston affirmed that "increasing value requires experimentation and careful performance measurement using actionable and specific indicators. Benchmarking within and across countries, and sharing information can help" [112]. Indeed, benchmarking can play an important role in disinvestment decisions because it helps to identify where resources can be freed. This means that disinvestment includes both service reductions due to inappropriateness and savings achieved through better efficiency identified through benchmarking (e.g. lower cost for the same output) [113]. In this sense, the overlap between disinvestment and rationing could be avoided. Although freeing resources does not necessarily mean savings, it allows governments to reallocate healthcare workers. A 2007 study estimated that the amount of resources, which could be disinvested and then reallocated within the Tuscany Region varied between 2–7% of the total regional healthcare budget. A similar approach was applied to care provided to patients with chronic heart failure pathway, seeking to reduce differences between patients of high and low socio-economic status. Reducing inequity frees financial resources for reallocation [114]. This approach stresses a specific aspect of

disinvestment: improving performance on indicators that have a positive return on efficiency. Disinvestment has numerous synonymous terms such as "withdrawing from a service and redeploying resources", "decommissioning", "delisting", "resource release", and "defunding", while the term "disinvestment" is not used consistently. Elshaug [115] defines "disinvestment [as] the process of (partially or completely) withdrawing health resources from any existing healthcare practices, procedures, technologies, or pharmaceuticals that are deemed to deliver little or no health gain for their cost and thus are not efficient health resource allocation".

Box 8: Initiatives on Polypharmacy and De-Prescribing

Polypharmacy is commonly defined when a patient is simultaneously taking five or more medicines. Widely recognized polypharmacy-related concerns, particularly in elderly, are addressed by deprescribing. It focuses on withdrawing non-beneficial or even harmful medications. For instance, in Canada, an approach to include deprescribing into all treatment guidelines had been suggested. As an example, deprescribing recommendations enriched dementia care guidelines.

In the structured medication management perspective a wide range of guidelines and screening tools are available for deprescribing like BEERS criteria, STOP/START criteria, Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE), STRIP, NO TEARS, STOMP, Appropriate Medications for Older people (AMO)-Tool, Prescribing Optimizing Method (POM), ARMOR, etc.

In addition, a variety of computerized prescription tools brought into practice in many countries have shown their positive effects at least in reducing prescription errors. Some of the above-mentioned tools are categorized as explicit or criteria-based in contrast to implicit ones. The latter include the patient preferences to judge the choice. To facilitate practical applications, Ottawa innovation program introduced credible and relatively simple guidelines to support medical professionals in reducing or stopping medications in five particular drug classes. Moreover, the guidelines are accompanied with decision support tools and those for communication with patients.

Due to recognizing a value of shared-decision making in reducing unnecessary medications various approaches, particularly more active ones, to improve communication with patients are tried. Furthermore, innovations in education for health professionals as well as providers' networking in the field of deprescribing should be considered [116, 117].

Activities which can all be summarized under the umbrella term "Dis-Investment" or omission and withdrawal of inappropriate technology have been subject to increased research since 2006 [118]. In particular, Health Technology Assessment (HTA) which was initially used to support "investment" decisions, recently started to be used for "dis-investment". A crucial issue in disinvestment is the need to involve health-care providers and commissioners in decision-making processes [119]. The inclusion of health professionals and patients in disinvestment decision making is proposed as one strategy to overcome these diverging interests, while facilitating transparent identification of candidates for disinvestment. However, previous studies show that health professionals are reluctant to disinvest, as this can be perceived as a rationing instrument, which will

restrict clinical autonomy and reduce patient choice [118]. In this context, socio-technical approaches may help to engage stakeholders with conflicting objectives in confronting tightening budgets. Airoldi (2013) argued that well designed socio-technical approaches can overcome stakeholder resistance because of (1) the collective character of the deliberations; (2) the analysis of the whole pathway; (3) the involvement of patients; and (4) the development of a model based on cost-effectiveness analysis principles, which provided a credible rationale for difficult decisions [120].

Since disinvestment requires, at least initially, an increase in resources and capacities, additional funding should be assigned to institutions conducting disinvestment activities, as powerful interest groups can make disinvestment challenging.

Box 9: Research findings on aggressive vs. palliative end-of-life care

Care for cancer patients near the end of life has two major goals: extending life and managing symptoms to maintain quality of life. The potential survival benefit of anticancer therapy (including conventional chemotherapy, hormone therapy, and targeted therapy—collectively referred to as “systemic therapy” hereafter) for patients with advanced disease is modest, especially in later lines of therapy toward the end of life, and statistically significant improvements observed in clinical trials are not necessarily clinically significant. Recently approved drugs for advanced cancer have demonstrated increased toxicity independent of clinical effectiveness, suggesting that the balance of harms to benefits might be worsening. The use of systemic therapy near the end of life can expose cancer patients to severe toxicity for minimal survival gain and comes with a high cost. Early palliative care is recommended, but there is evidence that aggressive care remains common [121].

The well acknowledged landmark study by Temel et al. could demonstrate that patients assigned to early palliative care had a better quality of life than did patients assigned to standard care. In addition, fewer patients in the palliative care group than in the standard care group had depressive symptoms. Additionally, despite the fact that fewer patients in the early palliative care group than in the standard care group received aggressive end-of-life care, median survival was longer among patients receiving early palliative care [122]. Several later randomized studies involving patients with advanced cancer show that integrating specialty palliative care with standard oncology care leads to significant improvements in quality of life and care and possibly survival [123, 124].

Ever more international quality initiatives develop indicators that measure the quality of cancer care. The most commonly used generic quality indicator relates to end-of-life care: Death in a bed in acute care, intensive care and systemic therapies in the last few weeks of life is associated with negative quality of care [125]. Recent analyses of routine data from Switzerland or seven Western countries show that in Belgium, Canada, England, Germany and Norway (38.3–52.1%) the proportion of those who died in hospitals was significantly higher than in the Netherlands and the USA (29.4% and 22.2%, respectively) [126].

Box 10: Case study on second medical opinions before elective surgery, Germany

Each year more than 13 million operations are carried out in Germany (Federal Statistical Office 2010). From 2005 to 2008 their number increased by about 1.5 million. Operations on the musculoskeletal system are the most common [127]. The leading interventions are arthroscopic interventions (approximately 600,000): on articular cartilage, menisci, synovialis and in the form of arthroscopic joint revision. Critical assessments and data available do not support some of the therapies in specific indications. A randomized study in 2002 showed that arthroscopic lavage or debridement was not more effective than sham surgery in patients with knee pain and joint arthrosis [128]. A subsequent randomized study confirmed that the efficacy of arthroscopic intervention combined with conservative therapy was no greater in knee osteoarthritis after six and 24 months than in conservative therapy alone [129]. Also, the effectiveness of vertebroplasties is controversial. Two randomized studies published in 2009 could not find a significant effect on pain and spinal function by injection of bone cement in osteoporotic vertebral fractures. Germany has eight times as many vertebroplasties per million inhabitants as France.

The increasing amount of some elective surgeries, some of them prone to frequent suspicion to questionable indications, has resulted in the explicit offer of second opinions of many German health insurances to their patients. These second medical examinations and consultations have a considerable influence on the treatment: According to Barmer-GEK, three quarters (72%) of those affected will make a new therapy decision. Operations in which a second opinion is often helpful: Knee (meniscus, cruciate ligament, etc.), back / spine, hip and disc, shoulder and neck as well as dental prosthesis [130].

Patient-driven second opinions are also increasingly sought in oncology, the reported disagreement between the first and second opinion (2%-51%) range widely. The primary motivations of patients are a need for certainty, lack of trust, dissatisfaction with communication, and/or a need for more (personalized) information [131].

3.3.5. Corruption, Fraud, misuse

Another area of waste arises from corruption, fraud and misuse. In recent years, the fight against corruption in the healthcare sector has intensified due to the growing recognition that corruption in its various forms heavily distorts national healthcare programs, undermines the aims of health policy, and obstructs reforms, leading to a tremendous waste of resources. Recent reports estimate the cost of fraud in healthcare as between 3% and 8% of national health expenditures [132]. Estimates from the European Healthcare Fraud and Corruption Network (EHFCN, <http://www.ehfcn.org/>) calculate an approximate €56 billion annual loss to Europe as a result of corruption. To promote understanding of the complexity and the interconnection of corrupt activities, we present healthcare related corruption typologies of the European Union and EHFCN [133, 134]: along a spectrum in which waste (loss of value) is distinguished from corruption, fraud, misuse and error (see Table 4 for main categories and definitions of corrupt activities according to the European Union (EU) typology).

Table 4: The main categories and definitions of corrupt activities according to the European Union (EU) typology [114]

Categories	Definitions
Bribery in medical service delivery	A bribe is a financial or other advantage offered, given, solicited or accepted in exchange for privileges or treatments
Procurement corruption	Corruption of 'the complete process of acquiring goods, services and works from suppliers'
Improper marketing relations	'Improper marketing relations cover all interactions between the industry and healthcare providers and/or regulators that are not directly linked to the procurement process.'
Misuse of (high level) positions and networks	'Undue high-level interactions', such as 'trading in influence, revolving door corruption, regulatory state capture, conflict of interest, or favouritism and nepotism'
Undue reimbursement claims	Covers creative billing and reimbursement of unnecessary and non-delivered services
Fraud and embezzlement (of medicines, medical devices and services)	Fraud is the 'offence of intentionally deceiving someone in order to gain an unfair or illegal advantage' Embezzlement prevails 'When a person holding office ... dishonestly and illegally appropriates, uses or traffics the funds and goods they have been entrusted with for personal enrichment or other activities'

Evidence of the connections between corruption, scientific fraud, and lack of transparency (undisclosed conflicts of interest, paid guidelines, selective publication, etc.) is abundant [135, 136] and provided the rationale for regulations to disclose payments made to healthcare professionals, such as sponsorship to attend meetings, speaker fees, consultancy and advisory boards. The demand for transparency arose from the perception that a lack of transparency creates a "culture of opportunity". In addition to frank corruption there are numerous examples of scientific fraud: While clearly counterfeit studies are considered wrong, tendentious and / or selective reporting and the publication of the work of ghostwriters under their own name is still seen by some as a minor offence.

3.3.6. Clinician ´s initiatives to "choose wisely" as basis for communication with patients

A growing number of international initiatives are rising to the challenge to reduce low value medical care and overuse. What is completely new, however, are initiatives that are not motivated by health administration and policy, but are supported by the providers of medical services, i.e. by clinicians themselves. These activities aim to identify and avoid inappropriate health interventions. The "Choosing Wisely" initiative, launched in 2012 by the American Board of Internal Medicine (ABIM) under Christine Cassel, has received a great deal of attention since its inception and has already attracted a number of imitations in North America (Canada) and Europe (Switzerland, Germany, The Netherlands). None of the initiatives is about reducing health services on a

large scale or even removing them from the service catalogues. In most cases, only a targeted and needs-based provision of services (today often referred to as patient-centered) is to be achieved. The fact that costs are saved is a welcome side effect. The intention of all initiatives is to reduce wasteful overprovision and overtreatment; some want to achieve this with the help of joint decision-making between patients and doctors. It is also about improving the quality of care, patient satisfaction through education and co-determination and, last but not least, increased safety for patients.

At first glance, the various initiatives follow a fundamentally similar path [137]. First, ineffective services are identified and supported by literature reviews and communication with service providers (physicians and other interest groups). The result is a list of services that need to be questioned. However, the main differences lie in the details, for example in the addressees (only doctors, or also patients and consumers), in the breadth and depth of the underlying sources of information for identification (evidence analyses for identification with subsequent involvement of "stakeholders" or identification by service providers with subsequent evidence analyses), in methods of prioritization (use of prioritization instruments with criteria vs. instruments for consensus finding) and not least in dissemination and implementation strategies (dissemination in conferences and specialist committees vs. linking to guidelines, data analyses with formulation of target application values) [137].

Analyses of the impact of the initiatives and of implementation barriers are not yet available. For some initiatives, this would still be too early. Criticism is mainly levelled at the fact that most of the services identified as ineffective or inappropriate have been known for a long time and that initiatives for implementation, rather than identification, are needed (See Appendix for Initiatives by clinicians to identify low value interventions).

3.3.7. R&D: Initiatives to create public value in healthcare research

The concept of value has risen in importance in discourse on research for innovation, primarily because of concerns about the very large sums reported by pharmaceutical companies as necessary to develop new medicines, which must then be recouped from sales that are, in many countries, largely paid for from the public purse. These concerns are coupled with questions about the extent to which the resulting products represent added value, given the lack of pipelines for certain products where there is a clear need, such as new antibiotics, while some manufacturers concentrate on what are termed "me too" products, adding little, if anything, to what already exists. This issue has attracted even greater prominence following proposals for new ways to pay for innovative medicines and, in particular, what has been termed "value-based pricing", where the price of a medicine is linked to the "value" that it provides. The basic reason to have such

a link is to provide a higher reward for a better, higher-value, innovation. The economic principle behind it is that profit-maximizing companies will naturally invest more if a higher price is allowed, meaning that prices based on value would provide a strong signal for higher-value innovation to be pursued.

A quite distinct argument is that prices should be set equal, or close, to value of products. Such a rule naturally respects that prices should be different according to value to serve as a guide for innovation. However, it brings in another issue, the extraction of economic rents (also termed sometimes excess profits) by companies providing these innovations. That is, the same prices that guide innovation also have the role of dividing the value created between healthcare payers (representing the population covered) and innovative companies. The two effects, providing correct signals for R&D efforts and economic rents extraction (value split across economic agents), should be clearly separated.

The role of value in discussions regarding innovation has been extremely controversial and has led to a reassessment of the meaning of value in this concept, most notably in the work of Mazzucato. In her earlier work she challenged the widely held view that most innovation was a result of entrepreneurial activity by highly competitive private companies, instead showing, for example with reference to the iPhone, that while Apple developed the final product, this was only possible because many of the technological developments that go into it were developed in universities and government institutions, and largely with public funding [138]. More recently, she has turned her attention to pharmaceutical innovation and pricing and, in particular, the concept of value-based pricing.

Her most recent study on the concept of value traces how this has changed markedly over time [139], from the writings of classical economists such as Smith, Ricardo, Marx and others, whereby the value added was a function of the inputs used to produce something, in labour and, originally, the land from which agriculture came or minerals extracted, to the relatively recent neo-classical idea that equates value with the price that someone is willing to pay. What they will pay is, however, determined by a process of negotiation in which the manufacturer maintains property rights, in the form of patents, over the product in question. This system, it is argued, is necessary for innovation to occur (otherwise, absent any significant reward, including the possibility to recoup the cost of R&D investment, innovators would not produce the innovation in the first place). Yet, as she argues, it is questionable whether this system promotes innovation as widely as is claimed, citing examples where patents block future advances. However, she takes particular aim at value-based pricing.

Noting how an Executive Vice President of Gilead sought to justify the extremely high, and also controversial [140] price of Sovaldi, contending that “pricing is the wrong discussion... value should be the subject”, while a former vice president of Pfizer argued that “in the mind of patients, physicians, and payers, the pricing of drugs should have little to do with the expense of biomedical R&D, nor should be associated with recouping R&D investment. Pricing should be based on only one thing – the value that the drug brings to healthcare...”.

She notes how the application of the existing model can, in certain settings, limit prices, as in England where NICE will not support payment if a medicine exceeds a certain cost-utility threshold, but at the cost of excluding individuals from coverage. Where such institutional arrangements do not exist, however, as in the USA, this model can allow manufacturers to charge astronomic prices that bear no relationship to their costs. Noting how, if the logic was followed through, basic therapies such as vaccines would be incredibly expensive, she argues for a fundamental reassessment of the concept of value that recalls its original meaning in classical economics.

The institutional mechanisms using cost-utility thresholds often allow prices to go up until they meet this threshold. At a more general level, this calls for a reassessment of the mechanisms that set prices, breaking the implicit idea of price being defined as the maximum monetary value society is willing to pay. This point was discussed in EXPH (2018) [20] in more detail. The issue is not the definition of value, but rather accepting as adequate and reasonable the transfer of full surplus through prices to the producer. Using the right notion of value is important, but insufficient to deal with the issues associated with price determination (as a tool to divide value between relevant economic agents).

Besides criticism of research priorities by pharmaceutical companies, the “waste in research” has become a widely recognized and discussed issue. The lack of clear research priorities, failure to publish negative results, and the inaccessibility of some clinical research, duplication of studies that have already been done, and finally the lack of research providing worthwhile achievements were discussed at length in a Lancet series on “Research: increasing value, reduce waste” in 2014 that was preceded or accompanied by initiatives such as Research Reporting Guidelines, EQUATOR or the AllTrials” Campaign. It has been estimated that 85% of research is wasted, usually because it asks the wrong questions, is badly designed, not published or poorly reported [78]. While this primarily diminishes the value of research, it also represents a significant financial loss (See Appendix for Initiatives by researchers against waste and for increasing value research).

Further activities resulted in scientific papers on overdiagnosis and –treatment (BMJ, JAMA) and the launch of an annual conference providing space for research results on the impact on patients’ harm due to “accelerated” (diagnostic creep: widening disease definitions) medicine.

3.3.8. Initiatives to increase policies for better value

Several policies (or groups of policies) aimed at obtaining better value per unit of health spending had unexpected results in the medium and long-run, as providers, being economic agents, adjust their decisions to the context of these policies. This has resulted, over time, in perverse effects (that is, contrary to those intended when the policies were initiated and adopted). Three relevant examples are pay-for-performance, cost-effectiveness thresholds and value-based healthcare.

Pay-for-performance (P4P): Paying according to results has been introduced over the years as a guiding principle in the acquisition of health services in some settings. Payment systems have to be grounded in observable and verifiable elements. Thus, pay-for-performance often uses activity measures that are readily available instead of outcome measures (difficult to define and to observe precisely). This leads to incentives to greater activity, without necessarily corresponding to better outcomes. This may lead to unintended effects such as more activity, and more healthcare costs, without matching benefits (e.g. offering musculoskeletal operations without effectively improving mobility/pain levels).

Box 11: Perverse incentives

Sometimes the incentives to increase the value of healthcare may lead to adverse effects. In such cases, the incentives might be described as “perverse”.

The high efficacy of the health system is a desirable feature. Efficacy, however, is measured as units produced in relation of resource use. If for example GP:s are evaluated of the basis of the number of patient visits, their way to maximize the efficacy might be to see the same patient many times (instead of more time requiring new cases) or have many uncomplicated patients visiting instead of one complicated one, who would require a lot of time and effort. In this type of performance assessment, the most “efficient” activity would actually lead to waste of resources, while the health demands of some patients would not be satisfied at all.

The quality of surgical operations requires that one doctor performs an adequate number of operations annually. If, however, the activities of a hospital are made dependent on the number of certain surgical procedures, the indications for those operations are easily diluted. I.e. instead of following the accepted standards, the surgeons start to operate milder cases than usual to have adequate numbers of operations for the hospital license. Sometimes there are incentives that try to cover the whole care path. Emergency room visits often correlate to the poor quality of care of chronic diseases. However, if the payment for a healthcare provider is diminished on the basis of the number of emergency room visits, he might try to prevent doctors to send patients to hospital even

when they desperately need acute care. This might lead to excess mortality instead of better care of chronic diseases.

The use of cost-effectiveness thresholds by health authorities, where cost from the perspective of the healthcare payer is determined to a considerable extent by the prices set by providers of care, creates an incentive for privately determined prices to rise up to the point of meeting the threshold. This is an unintended consequence. In the absence of price competition on the provision of the product or service, a common situation in the case of new products or services, this constitutes an undesirable side effect from the payer's perspective.

The discussion of value-based healthcare has centred mostly on the valuation of benefits. Although quite important, solely focusing on benefits neglects the role of underlying (opportunity) costs in the decision-making process of choice of where to allocate funds in healthcare. This "distraction" introduces the potential for bias in decisions regarding both prices and access conditions of new products and services. Reacting to this "distraction" on the micro-level of decision-making (e.g. investments in hospitals) programme budgeting has been introduced in some tax based National Health Systems (NHS) supporting decisions on the macro-level (e.g. allocation of resources to patient populations).

Box 12: Programme budgeting

In the last few decades, the focus on strategies in healthcare has been placed on the improvement of quality, safety, effectiveness and efficiency: the targets of interest being the organisations that pay for and supervise healthcare and the institutions (hospitals, primary care health centres) that provide primary, secondary and tertiary prevention and care. However, progress has been made: a re-organisation of structures has been a feature of many services, together with managerial changes in funding designed to stimulate greater efficiency.

Nonetheless, this is not perceived as sufficient and a shift in focus on population health is now needed [141, 142]: Programme budgeting puts the focus on (patient) population funding. A program budget is a framework by which the health system administration allocates the available resources to different patient populations and activities. In the context of intense budget expenditure invested in very small patient populations (e.g. in oncology 30-40% of in-hospital drug expenses for 5% of the hospital patient population), which generates only small clinical benefits, programme budgeting facilitates a re-focusing and reallocation of resources.

The populations are defined by need, ranging from people with asthma or people with back pain to people with frailty in the last year of life. This additional population-based dimension facilitates the development of value-based healthcare. This requires a change in prioritisation from institutional budgeting to programme budgeting, by identifying all the resources invested in services for all the people in need, be it cardiovascular disease or cancer. This allows not only the estimation of value but also the involvement of

clinicians, since clinical behaviour determines much of how resources are employed and therefore the investment pattern. Hence, the responsibility for the stewardship and for the freeing of resources for reinvestment lies with the clinicians, instead of being based on explicit decisions made by payers [143].

3.3.9. Initiatives for fair access to value-based products and innovative payment methods

Health systems have the goals of providing access to affordable necessary care to people and ensuring financial risk protection. In this context, if there were no concerns regarding promotion of R&D of new products and services, prices should approximate to opportunity costs of production, irrespective of how benefits from its use are distributed. In particular, two products or services with the same production costs should have similar prices, even though patients (and/or society) may value them differently. Otherwise, if prices are significantly above the opportunity costs of production, the result is either lower access or redistribution of value from people (either patients, taxpayers or contributors to health insurance protection systems) to companies (providers). It is the need for adequate incentives for R&D of new products and services that leads to a departure from this view.

Under decentralized models of R&D, intellectual property rights (IPR), mainly patents, has two important roles to perform. First, prices that are set under patent protection provide a way for companies to recover and have a return on the R&D costs they incurred. It provides the financial incentive to firms to invest in R&D. Second, the relative prices accruing to new discoveries will guide the efforts toward one type or another of innovation. Prices have also the role of guiding the type of innovation pursued. For equal amount of R&D costs, companies (or profit-oriented research units) will be guided by the higher price (or prospective price) of a particular innovation. Pricing according to the value of the innovation then guides R&D efforts to higher value innovations.

This role only requires that a higher price is positively correlated with a higher value of the innovation. It does not require that price equals value, which would mean total value extraction by which entity owns the innovation.

This simplified view highlights the fundamental trade-off to be addressed: prices both distribute value and provide signals for R&D efforts. The pricing mechanisms need to explicitly address both concerns. One needs to recognize that value-based pricing, in the sense of prices reflecting value, is to be understood as a relative statement: different prices for different innovations, according to the difference in value they bring.

As detailed in EXPH (2018) [20], there is a role for price negotiation, on top and above HTA methodologies to screen the contribution of each innovation, and a role for more

transparency in R&D costs, as this will reveal the distribution of monetary value that is generated. Cost transparency does not mean that prices should be set against R&D costs directly. Cost-plus pricing of innovation would just stimulate higher-cost R&D efforts, irrespective of contribution to society. A broad knowledge of the R&D costs would, nonetheless, provide information on margins earned, and disclosure of this information would allow for affordable access to new products.

Focusing the discussion only on value and measuring it, however accurately, does not ensure fair access. High prices of new products and services lead payers to limit patient access. Patients tend to identify value with satisfaction with health outcomes, irrespective of the underlying costs and of whether, or not, paying for their care displaces healthcare provided elsewhere in the health system. In addition, as pointed out in Mazzucato and Roy (2017) [144], value-based pricing as a result of a (particular) value-based healthcare approach does not recognize the role of public funds (the “entrepreneurial state”) in value creation.

As argued in EXPH (2018) [20], pricing mechanisms need to address several concerns, and value-based pricing does not follow automatically from value-based healthcare considerations as the pricing mechanism that best achieves health systems’ goals.

Several initiatives have emerged in recent years to meet the concern with high prices and patient access to innovation. These initiatives can be divided into two broad groups.

1. On the one hand, international organizations have promoted discussions on the issue (OECD 2017, EXPH 2018, WHO 2015, the Fair and Affordable Pricing initiative, the WHO collaborative procedure, among others).
2. The second group is constituted by the initiatives of countries creating joint actions: the BeneluxA initiative, the Visegrad group, the La Valletta group, the FINOSE group, and the Baltic partnership.

Box 13: Initiatives to increase Access to Medicines

BeNeLuxA (<http://www.beneluxa.org>): Belgium, Netherlands, Luxembourg, Austria and Ireland. While recognizing that price and reimbursement decisions are retained at the country level, the group jointly negotiates prices of innovative drugs, aiming for a lower value (more affordable access to innovation). Cooperation extends to horizon scanning, health technology assessment (aiming for joint analysis) and information sharing. According to the information publicly available, joint negotiation in the context of the Beneluxa group of a price for a new product was done successfully by Belgium and the Netherlands.

FINOSE (<https://www.tlv.se/in-english/international-collaboration/finose---a-nordic-cooperation.html>): Finland, Norway and Sweden. The initiative from countries’ authorities aims to harmonize and share health economic analyses of new products, providing a joint assessment by the three agencies. It started in March 2018 and it will run as a pilot project for two years.

Valletta: Croatia, Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Slovenia and Spain. The objectives of the initiative include joint clinical assessment and economic evaluation. Joint work already started (at late 2018) on several pharmaceutical products.

EUnetHTA (<https://www.eunetha.eu/>): Another initiative worth mentioning is the health technology assessment regulation proposal at the European Union level, building on the EUnetHTA experience of coordination of collaboration that will enforce the harmonization of methodologies, reporting and finally uptake of the collaborative assessments.

Fair And Affordable Pricing (FAAP): Hungary, Lithuania, Poland, Slovakia, Czech Republic (observer status) and Latvia (invited guest). The initiative also aims at cooperation across countries in pricing of new (pharmaceutical) products. As in other initiatives, cooperation in technical aspects is the first step. The pricing decisions are kept at the national level, with no joint negotiation (at least for the moment).

Nordic Pharmaceuticals Forum (NLF): Norway, Iceland and Denmark, Sweden (observer). The initiative started as an informal space for cooperation among the Nordic countries, concerned initially with security of supply. The Nordic Pharmaceuticals Forum (NLF – Nordisk Legemiddel Forum) started in 2015 (<http://www.amgros.dk/en/areas/nordic-collaboration>). It has the goal of analysing the possibilities of joint tendering procedures for pharmaceuticals, as the concern on security of supply is related to older drugs, at the end of their life cycle. It is driven by Amgros, the pharmaceutical procurement office for the five regional health authorities in Denmark.

On **joint health technology assessments**, the **BeNeLuxA** initiative is already active, while the **FINOSE** and **NLF** initiatives are progressing in that direction.

On **joint price negotiations**, the **BeNeLuxA** initiative has concluded successfully one case, while the **NLF**, **Valletta** and **Visegrad** initiatives are still progressing towards it. The last two groups also announced the intention of moving to joint procurement (implying common prices for the group of countries involved).

The Baltic partnership is already active in **joint procurement** but collaboration did not extend to more areas, explored by other initiatives.

On **horizon scanning** (a forecast to highlight important pharmaceutical innovations before they reach the market), the BeNeLuxA, NLS, Valletta and Visegrad initiatives have an interest in pursuing it, while this aspect is left out by the FINOSE and the Baltic partnership.

4. CONCLUSIONS and RECOMMENDATIONS

The European Commission (EC) aims to support its Member States in achieving effective, accessible and resilient health systems. Effectiveness refers to the health system's ability to produce positive health outcomes, i.e. to improve the health of the population. Access is the ease with which individuals in need can obtain health care and is a function of provision of services, availability (including travel time and opening hours), and affordability. Resilience is the ability of the health system to adapt effectively to changing environments and apply innovative solutions to tackle significant challenges with limited resources. This last section of the opinion will conclude and provide answers to the questions of the mandate.

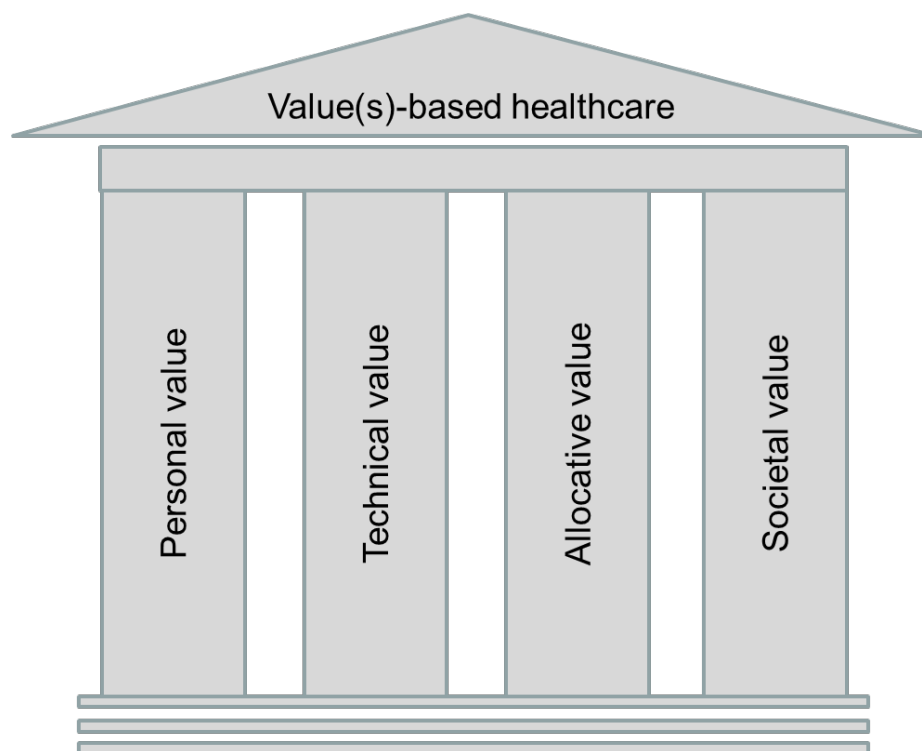
In 2017, the OECD report on "Wasteful Spending in Health" [1] brought the topic of waste of enormous amounts of public resources (estimation of 10% to 30%) to the agenda of a broader public, emphasising the need for health systems to focus on spending their resources wisely and efficiently. But awareness of how the scale of low value care, coinciding with inadequate resources for care of high value, poses a threat to universal health coverage has been well known for many years by experts in the field. In this context, the concept of value-based healthcare (VBHC) has developed over time (since 2001) and many regional and national initiatives started to tackle the problem of overdiagnosis and -treatment, inequity and unwarranted variation, etc. Few of those small scale initiatives have gone one step further to actually reallocate resources from low value to high value care.

In the meantime, the notion of "Value based healthcare (VBHC)" is increasingly used in public discourse, although – at least in the European understanding – in a distorted manner; some would even call it a "hijacking" of the notion of value. For that reason the EXPH has been asked to clearly define "value" in value-based healthcare.

- (a) How do you define value in "value-based healthcare"? What aspects of health systems could the different definitions cover?

The EXPH emphasizes the value that underlies European healthcare systems, the concept of solidarity and the commitment to universal health coverage, laid down in the Charter of Fundamental Rights (2000 [9]) and in the European Pillar of Social Rights (2017 [13]). As such the European definition of VBHC encompasses the four aspects of value: personal value (meaning that an individual receives appropriate care), allocative value (referring to the optimal distribution among patient populations), technical value (relating to the best outcomes with available resources for all the people in need to mitigate inequity) and societal value (referring to the intrinsic value of good health as enabler to participate in society and solidarity as contributor to social cohesion of equal individuals).

Figure 7: the four value pillars for a values(s)-based healthcare in Europe



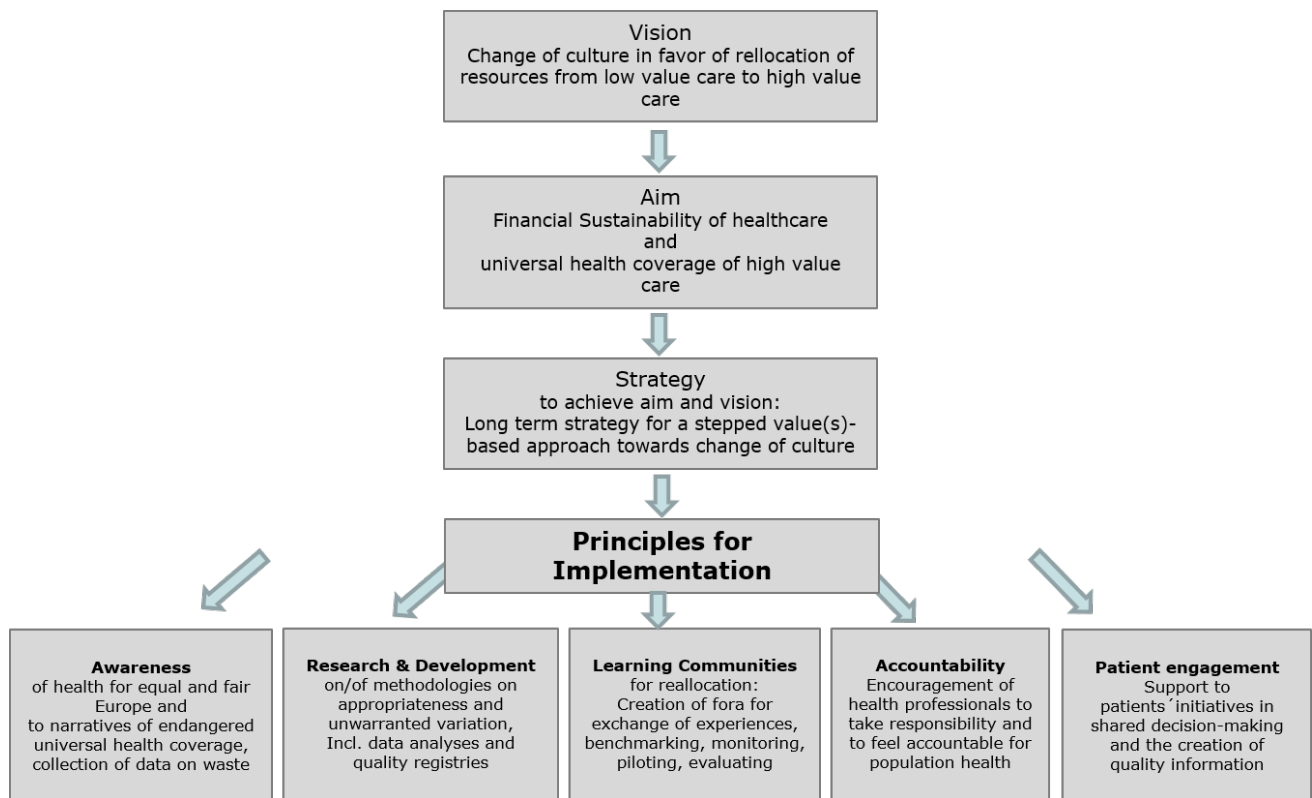
This comprehensive European concept of value(s)-based healthcare combines the narrow definition of VBHC, which only focuses on a particular economic value (whereby an intervention generates a benefit for an individual which has a value that can be monetarised), with the European societal values of solidarity (access and equity, quality and performance, efficiency and productivity). In order to avoid the further distortion and inappropriate utilisation of the notion "value", "value(s)-based healthcare" should preferably be used in its comprehensive meaning, as laid down in this opinion, when used in European public debate, in particular in discussions on strategies for sustainability of universal health coverage.

- (b) How can "value-based healthcare" inform decision making, contribute to health system transformation, and help health systems across the European Union become more effective, accessible and resilient?

Strategies to support effective and resilient healthcare for all citizens in the European Union have so far focused on the principles of access and equity, quality and performance, efficiency and productivity. A recent addition to those guiding principles is an increasing focus on reallocation from low value to high value care. Concerns have been raised that many high-risk, high-cost healthcare services and products are

overused while basic needs stay unmet: there is considerable evidence of inequity by disease (e.g. it is easy to raise (R&D, treatment-related) funds for lung cancer, but not for COPD) leading to a lack of allocative and societal value from the utilisation of resources. A cultural shift is required to make it possible to ask not whether a treatment or procedure is possible, but whether it provides real value to the patient and genuinely improves the quality of their life or their prospects for recovery [46]. The EXPH argues for a strong system of governance to support this new paradigm of shifting resources from low to high “value” in VBHC by steering (methodological and disease-based) public research on high value healthcare, by stimulating the implementation of regulatory instruments that favour accountability for improving the health of entire populations, by supporting targeted actions by member states and finally by giving clear warnings to industry about unsustainable pricing policies.

Figure 8: From vision to implementation: a multistep strategy



The EXPH recommends a strategic long-term plan to facilitate a culture that enables the freeing of resources for reinvestment in high-value care and for effective reallocation towards a value(s)-based healthcare.

Recommendation 1 (to ensure societal value): Creating greater **awareness of health as an essential investment** in an equal and fair European society (“health is wealth”), of the centrality of it as a European value, and of the commitment, in the Sustainable Development Goals, to achieving universal health coverage (UHC).

This process will provide **clear narratives** setting out how the financial sustainability of existing progress towards UHC is endangered by

- Overdiagnosis leading to overtreatment
- Inequity by disease and “voiceless” patient groups
- Unwarranted variation in healthcare interventions
- Unreasonable prices of treatments
- Waste arising from inefficiencies, fraud and corruption

Recommendation 2 (to ensure all four pillars of values: personal, technical, allocative and societal value): Develop a **long-term strategy** for a step-by step value(s)-based approach towards change of culture.

Already by 2020 first activities should have started and created a movement that

- Develops a consistent language to capture the drive towards sustainability of universal health coverage,
- Train “change agents” (leaders), who assess the risks and opportunities that exist and contextualize the change process in the EU member states,
- Define a series of goals that support the long-term objective of change, moving forward in small steps (work plans), for example using analyses of regional variation of, say, the 20 most frequent Diagnostic Related Disease Groups (DRGs),
- Invest in research and development of methodologies, in appropriateness and implementation research (H2020 and Horizon Europe),
- Pilot need-based public R&D for true innovative technologies and consider as innovations social and organisational interventions and policies (see box 4 on social prescribing) as much as technology-based interventions,
- Orientate digital interventions in ways that genuinely support high value care [95],
- Monitor the effects of large scale implementation by use of existing data sources (e.g. quality registries in Finland, Sweden etc.) and existing methodologies (e.g. indicators [3]) and
- Create mechanisms to further guide the direction of change.

Recommendation 3 (to ensure all four pillars of values: personal, technical, allocative and societal value): Support Research & Development on/of **methodologies on appropriateness** and unwarranted variation.

Examples of actions are

- Creating fora for exchange on robust methodologies for measuring and monitoring patterns of clinical practice, regional variation, appropriateness research (specifically in multi-morbidities) and inequity by disease as a basis for a potential to reallocate resources,
- Stimulating data collections (incl. real world evidence and big data) and analyses and the use of quality registries supported by health informatics for identification of regional variation and outcomes,
- Defining and aligning standard outcomes that matter to patients,
- Promoting the production of Atlases of Unwarranted Variation,

- Agreeing on developing single specifications with agreed objectives, outcomes and criteria for measuring progress for the 100 most common population subgroups which would be relevant to every member state.

Recommendation 4 (to ensure allocative and societal value): Encourage **health professionals to take responsibility and feel accountable** for increasing value in health care, which may require freeing resources from low-value care to reinvest in high-value care. Health professionals hold a key role in advocating a change of culture.

Examples of action are

- Stimulating a reflection process on the accountability for resources as a core aspect of professionalism by medical, nursing, and other societies
- Developing training in stewardship, emphasising the importance of health professionals becoming accountable for the health of the population, including equitable distribution of resources for those with different diseases,
- Steering clinician leadership to ensure acceptance of responsibility for allocative efficiency and for the social (i.e. not only the individual patient but wider society) impact of their decisions, encompassing positive and negative freedom in clinical decision-making (see Box 9: End-Of-Life Care),
- Developing skills for leadership and management of networks as well as the skills for leadership and management of institutions and services,
- Strengthen professional integrity.

Recommendation 5 (to ensure allocative and societal value): Support the **creation of Learning Communities**, including communities of health professionals, to bring together the best expertise, experiences and practices and to learn from each other by measuring, benchmarking and implementing actions across the EU. Member States should take the lead in identifying and pinpointing the most important tasks, the EC should create a supportive and facilitating environment for the establishment of those Learning Communities that will contribute to a change of behaviour and a change in legislation.

This can be done by

- Identifying, sharing and celebrating examples of good practice,
- Rewarding (co-funding, awareness and publicity, ...) countries taking systematic approaches to developing and disseminating good practice (such as the Dutch prototype known as "Zinnige Zorg", see Box 7 and A2/Appendix on IZZI) and that are drivers for transparency of outcomes,

- Stimulating exchange on managerial techniques (financial incentives, regulatory mechanisms and managerial instruments) for shifting resources from low to high value care and on measuring the effects, including positive incentives (e.g. cash) and negative ones (restriction on certain interventions),
- Creating a learning community on the piloting of programme budgeting (see Box 12: Programme budgeting) within and across diseases and accordingly for the shifting of resources from budgets where there is overuse to disease groups where there is evidence of underuse and inequity, finally
- Exchanging on strategies for changing attitudes and rethinking value [144] in our medical culture.

Recommendation 6 (to ensure personal value): Support **initiatives for patients' engagement** in shared decision-making (SDM), recognising the importance of patients' goals, values and preferences, informed by high quality information.

Action points include

- Co-creating models of care with the patient community (including families and informal carers) , and adopting a framework for meaningful patient and public involvement in health systems and services design (in evidence requirements, M&E, policy discussions and decision-making), leading to value-based healthcare in its wider sense.
- Developing, together with patients' organisations, authorities in Member States, and other stakeholders, a comprehensive strategy to implement empowering practices and goal-oriented person-centred care.
- Ensuring appropriate involvement of patients and their communities in the creation and implementation of patient-defined outcome measures and experience measures (PROMs and PREMs)
- Exploring alternative ways of encouraging research and innovation that meets patients and societies' needs and goals, while ensuring solidarity and equity, including partnerships that fully involve patients.
- Involving patients in the training and continuous professional development of all stakeholders involved in value-based health care, resource allocation and disinvestment
- Promoting effective patient and public dialogue about societal goals and priorities.

Increasing value in our healthcare systems will require strong collaboration and intensive liaison that encompasses evaluation of interventions (to distinguish true innovation and

identify low value interventions), monitoring healthcare services delivered (healthcare services research and planning to identify unwarranted variation and care of high value) and surveys of providers (ensuring personal value by providing person-centred information to patients).

LIST OF ABBREVIATIONS

COPD	Chronic obstructive pulmonary disease
DALY	Disability-adjusted life year
DRG	Diagnostic related groups
EbHC	Evidence based healthcare
EbM	Evidence-based medicine
EU	European Union
GNP	Gross National Product
HTA	Health Technology Assessment
ICHOM	International Consortium of Health Outcomes
ICECAP	Capability measure for Adults
IPR	Intellectual property rights
MRI	Magnetic resonance imaging
OECD	Organization Organisation for Economic Co-operation and Development
P4P	Pay-for-performance
PREM	Patient Reported Experience Measures
PROM	Patient Reported Outcome Measures
QALY	Quality adjusted life years
PSA	Prostate specific antigen
R&D	Research and development
SDG	Sustainable Development Goals
UHC	Universal health coverage
UN	United Nations
VBHC	Value based healthcare
VbM	Values based Medicine
WHO	World Health Organisation

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GLOSSARY

Appropriate/inappropriate

A procedure is termed appropriate if its benefits sufficiently outweigh its risks to make it worth performing, and it does at least as well as the next best available procedure. A procedure is termed inappropriate if the risks outweigh the benefits.

Cost-effectiveness

Cost-effectiveness relates the outcomes of a service to the costs. When measuring cost-effectiveness both beneficial and harmful outcomes need to be included.

Effectiveness

The effectiveness of an intervention, from single treatments through to services including the professionals within them, is the degree to which the desired outcomes are achieved in clinical practice.

Efficacy

The magnitude of the benefit demonstrated in the research setting is sometimes referred to as the efficacy of an intervention.

Equality

It is important to distinguish between two similar-sounding, but quite different, concepts: "equality" and "equity". The former implies equal shares of something; the latter, a "fair" or "just" distribution, which may or may not result in equal shares.

Equity in health

Equity in health can be defined as the absence of systematic disparities in health (or in the major social determinants of health) between social groups who have different levels of underlying social advantage/disadvantage—that is, different positions in a social hierarchy.

Healthcare opportunity cost

The concept of opportunity cost is fundamental to the economist's view of costs. Since resources are scarce relative to needs, the use of resources in one way prevents their use in other ways. The opportunity cost of investing in a healthcare intervention is best measured by the health benefits (life years saved, quality adjusted life years (QALYs) gained) that could have been achieved had the money been spent on the next best alternative intervention or healthcare programme.

Integrated care

Integrated care is an organising principle for care delivery with the aim of achieving improved patient care through better coordination of services provided. Integration is the combined set of methods, processes and models that seek to bring about this improved coordination of care.

Overuse

Overuse is the provision of medical services for no benefit or for which harms outweigh benefits.

Personal value

Improving the outcomes that matter to an individual for a given amount of resources (money, leadership, time, assets and carbon) used not only by the health and social care system but also by the individual and their family, recognising that the experience of care is a critical element.

Population value

Investing resources (money, leadership, time, assets and carbon) reasonably within a health and social care system to optimise the outcomes for the population for which the health and social care system is responsible.

Programme budgeting

Programme budgeting is a technique that enables personnel in a health service, and those who use the health service, to identify how much money has been invested in major health programmes, with a view to influencing future investment.

Quality

The quality of a service is the degree to which it conforms to pre-set standards of care.

Reasonableness

Accountability for reasonableness is the idea that the reasons or rationales for important limit-setting decisions should be publicly available. In addition, these reasons must be ones that 'fair-minded' people can agree are relevant to pursuing appropriate patient care under necessary resource constraints

Safety

Patient **safety** can, at its simplest, be defined as: The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare. ... the reduction of harm should be the primary aim of patient **safety**, not the elimination of error.

Shared decision-making

In a shared decision, a healthcare provider communicates to the patient personalized information about the options, outcomes, probabilities, and scientific uncertainties of available treatment options, and the patient communicates his or her values and the relative importance he or she places on benefits and harms.

Stewardship

Stewardship is to hold something in trust for another.

Sustainability in healthcare

Quality services and systems include sustainability as a fundamental principle. This means minimising environmental impacts, enhancing health and building resilience with individuals and their communities.

Technical value

Net benefit derived in return for a given resource use.

Underuse

Underuse is the lack of provision of necessary care (eg no aspirin prescribed after myocardial infarction),.

Unwarranted variation

Variation in the utilization of healthcare services that cannot be explained by variation in patient illness or patient preferences.

Waste

"wasteful" are: i) services and processes that are either harmful or do not deliver benefits; and ii) costs that could be avoided by substituting cheaper alternatives with identical or better benefits. Linking actors – patients, clinicians, managers and regulators – to key drivers of waste – errors and suboptimal decisions, poor organisation and co-ordination, incentives misaligned with healthcare system goals, and intentional deception

...

APPENDIX 1:

Links for further reading on initiatives

Table A 1: Examples of initiatives for evidence-based patient-information and patient initiatives in R&D

Cochrane (plain language summaries):

<https://community.cochrane.org/review-production/production-resources/plain-language-summaries>

Germany: <http://gesundheits-fuchs.com/>, <https://www.gesundheitsinformation.de/>
<http://www.patientenleitlinien.de/>; <https://www.awmf.org/index.php?id=70>

England: <https://www.nice.org.uk/about/nice-communities/nice-and-the-public>
Etc.

Table A 2: Initiatives by clinicians to identify low value interventions

2012 Choosing Wisely (AIMB), USA: <http://www.choosingwisely.org/>
2012 Choosing Wisely (OMS+ ZONMW), NL: <https://www.demedischspecialist.nl>
2012 NPS MedicineWise/ AU: <http://www.nps.org.au/>
2013 Slow Medicine, IT: <http://www.slowmedicine.it/>
2013 Too Much Medicine, GB (BMJ): <http://www.bmj.com/specialties/too-much-medicine>
2013 Preventing Overdiagnosis: Winding back the harms of too much medicine, GB + USA: <http://www.preventingoverdiagnosis.net/>
2013 Lown Institute: Right Care Movement, USA: <http://lowninstitute.org/take-action/join-the-right-care-alliance/>
2014 Choosing WiselyCA, CA: <http://www.choosingwiselycanada.org/>
2014 Smarter Medicine, CH: <http://www.smartermedicine.ch/>
2015 Klug entscheiden (DGIM, AWMF), DE: <http://www.dgim.de>, <https://www.awmf.org/medizin-versorgung/gemeinsam-klug-entscheiden.html>
2015 Choosing Wisely, UK (AoMRC): <http://www.aomrc.org.uk/>
2016 Prudent Healthcare/ Wales-UK: <http://www.prudenthealthcare.org.uk/>
2017 Gemeinsam gut entscheiden, AT (DUK/IAVEM), <https://www.gemeinsam-gut-entscheiden.at/>

Sources: [137, 145, 146], own searches

Table A 3: Initiatives by researchers against waste and for increasing value research

2004	James Lind Alliance for Priority Setting Partnerships: http://www.jla.nihr.ac.uk/about-the-james-lind-alliance/
2006	EQUATOR-Network: Enhancing the QUALity and Transparency Of health Research: https://www.equator-network.org/
2013	AllTrialsCampaign: http://www.alltrials.net and TrialsTracker: https://trialstracker.net/
2013	Conferences "Overdiagnosis: Winding back the harms of too much medicine": https://www.preventingoverdiagnosis.net/
2014	Lancet Series "Research: increasing value, reduce waste and the REWARD Alliance: http://rewardalliance.net/
2014	BMJ series: Too much medicine; JAMA series: overdiagnosis
2018	Public Return on public Investment (Mazzucato)

Sources: [147], own searches

Table A 4: Initiatives by Health Policy to identify low value interventions

2001	Over-, under- and inappropriate care (SVR), G: http://www.svr-gesundheit.de
2006	NICE „DoNotDo“ Database, UK: http://www.nice.org.uk/ (Savings and Productivity) NICE "DUETs" Datenbank, UK: http://www.library.nhs.uk/duets/
2007	GuNFT(Guideline for Not Funding existing health Technologies) and PriTec Tool, SP
2008	SBU "Uncertainties" and Disinvestment-project, S
2010	PBAC: Disinvestment of drugs and vaccinations; Framework for reviewing existing MBS items: PBMA (PBMA – Program Budgeting and Marginal Analysis
2013	Zinige Zorg Initiative (ZIN), NL: https://www.vgz.nl/zinnige-zorg

Sources: [118, 137]

APPENDIX 2:

**Good Practice Casebook
on specific regional projects or research results - focus reallocation in favour of
Value-based HC**

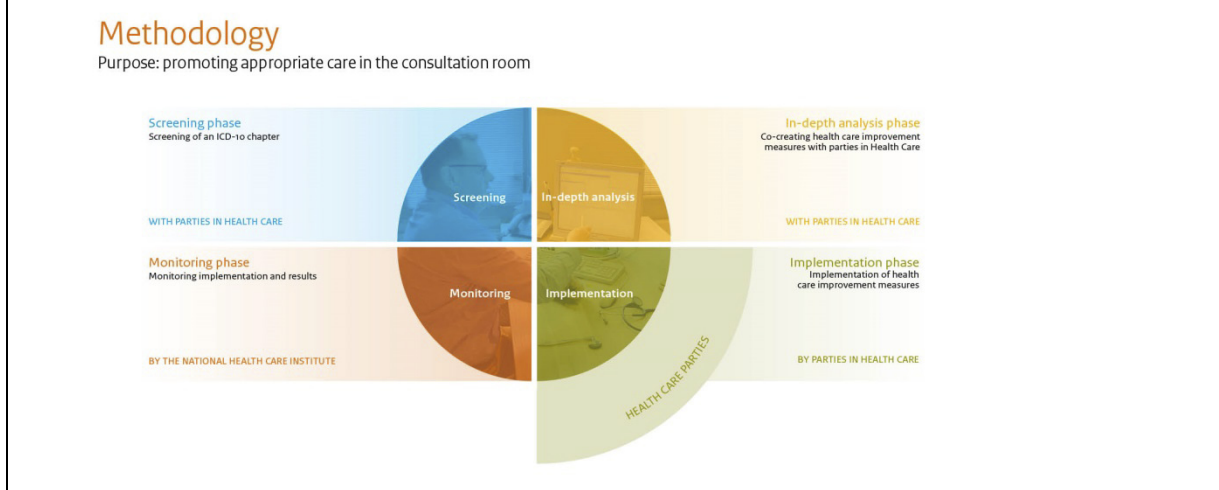
Box A 1: Case Study on Reduction of unwarranted variation, The Netherlands

The *Dutch Healthcare Institute (Zorginstituut)* designed a systematic working method for the *Zinnige Zorg* ("Sensible Care") Programme that analyses the way in which the insured care package is deployed. The key to this systematic screening is to identify and reduce ineffective and/or unnecessary care in order to improve the quality of care for patients, increase health gains and avoid unnecessary costs. We carry out systematic screenings for all ICD-10 domains. These take place based on a number of principles:

The patient's perspective: The entire healthcare pathway from the perspective of a patient is analyzed and studied. *Package management:* The focus is primarily on care that is covered by the Health Insurance Act [*Zorgverzekeringswet*] or the Long-term Care Act [*Wet langdurige zorg*]. *Good care in practice:* The basis is built on professionals' opinions about good care, as reflected in guidelines or proven by scientific research. Next, it is looked at how care is implemented in practice. This enables to identify under-diagnosing/over-diagnosing, under-treatment/over-treatment, and discover where lacunas in knowledge exist. *Involvement of the parties:* In all phases of the systematic screening the parties who are involved and who bear responsibility are involved: patients, care professionals, institutions and healthcare insurers. They are invited to attend meetings and are asked for advice on research. Before publishing reports the parties are invited to participate in a written administrative consultation.

PDCA Quality Circle: In order to promote good care, a systematic screening according to a PDCA quality circle, or improvement circle is carried out, as illustrated in the following figure. There are four sequential phases to this circle: screening, in-depth analysis, implementation and evaluation.

Figure A1: PDCA Zinnige Zorg circle



Screening phase: The objective of the screening phase is to select, for the in-depth analysis phase, one or more care pathway(s) for patients with a disorder in a designated ICD-10 field. The key to this is that care pathways are selected based on the following criteria: large number of patients, high care costs, high individual burden of disease, availability of guidelines (opinions on good care) and possibilities for research into implementation in daily practice (availability of claim data or other data). The choice of care pathways is recorded, together with the underlying analysis, in a report ('Systematic analysis') that is sent to the parties in healthcare and to the Minister of Public Health, Welfare and Sport.

In-Depth Analysis Phase: The objective of the in-depth analysis phase is, for the selected care pathway, to realise transparency about where care is not carried out in practice as might be expected based on (scientifically proven) recommendations in guidelines or according to established scientific knowledge. In other words: where could there be instances of inappropriate care? We are looking for: under-diagnosing/over-diagnosing, under-treatment/over-treatment and lacunas in knowledge. Based on this research, we make agreements with the parties involved on improvement measures. The research and the agreements on improvements (including a budget impact analysis) are recorded in a report that is sent to the parties in healthcare and to the Minister of Health, Welfare and Sport.

Implementation phase: The objective of the implementation phase is to realise agreements on improvements. Responsibility is borne by the parties in healthcare. In the implementation phase the *Zorginstituut* can play a supportive and facilitating role, for instance, by organising meetings, providing data and feedback, and by carrying out additional research. Periodically, the *Zorginstituut* reports on progress booked to the accountable parties and to the Minister of Health, Welfare and Sport.

Evaluation phase: The objective of the evaluation phase is to shed light on whether the agreed improvement measures have been realised and to determine whether other activities or measures are needed. The outcomes of the evaluation are recorded in a report that is sent to the parties in healthcare and to the Minister of Health, Welfare and Sport.

Past and current projects within this programme are:

<p>Screening phase (selecting the topics for in depth) Blood and Immunity system musculoskeletal system and connective tissue Skin and subcutaneous tissue infectious and parasitic diseases Eye and Adnexa Ear and mastoid process digestive system</p>	<p>In depth phase Cervical abnormalities Pelvic floor complaints Venous thrombosis and pulmonary embolism Lower respiratory tract infection and pneumonia Urinary tract infection? Asthma COPD Implementable cardioverter defibrillator Lower back complaints LVB Sleep Apnea Osteoporosis Psychosis Posttraumatic Stress disorder (PTSD)</p>
<p>Implementation PAOD Chest pain (instable Angina Pectoris) End of Life (bowel cancer, lung cancer) Expensive medicines for castration refractory prostate carcinoma (CRPC) After care for Breast cancer</p>	<p>Evaluation Hip and Knee replacement</p>

Research: In a systematic screening various forms of research are used, including an analysis of national and international guidelines; systematic reviews of (cost-)effectiveness; an analysis of claim data. Claim data (from the Claim Information System [DIS], Care Services and Claims [ZPD], and Pharmaceutical Products and Medical Devices Information Project [GIP]) is used to gain insight into care in practice. Claim data reflect registration practices and not necessarily the care actually provided. Nevertheless, these data do form an important source of information, sometimes the only one, and can provide valuable signals relating to care quality. Safeguarding privacy is of paramount importance. Personal data used are therefore pseudonymised and cannot be traced back to individuals.

Sources: <https://english.zorginstituutnederland.nl/zinnige-zorg> and <https://english.zorginstituutnederland.nl/zinnige-zorg/publications/leaflets/2018/08/27/working-method-for-the-zinnige-zorg-appropriate-care-programme>

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