

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

(EXPH)

Opinion on
Defining value in “value-based healthcare”

The EXPH adopted this opinion at the XXth plenary on XX Month 2019
after public hearing on 4th June 2019

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

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

39
40 The core element of the Expert Panel's mission is to provide the Commission with sound
41 and independent advice in the form of opinions in response to questions (mandates)
42 submitted by the Commission on matters related to healthcare modernisation,
43 responsiveness, and sustainability. The advice does not bind the Commission.

44
45 The areas of competence of the Expert Panel include, and are not limited to, primary
46 care, hospital care, pharmaceuticals, research and development, prevention and
47 promotion, links with the social protection sector, cross-border issues, system financing,
48 information systems and patient registers, health inequalities, etc.

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61 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.

62 **ACKNOWLEDGMENTS**

63
64 Members of the Working Group are acknowledged for their valuable contribution to this
65 opinion.

66
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94 https://ec.europa.eu/health/expert_panel/wg-value-based-healthcare_en

95
96

97 **EXECUTIVE SUMMARY**

98

99 **Background and Mandate:**

100

101 All healthcare systems today are under pressure to spend their resources wisely and
102 efficiently. Though great improvements have been achieved by strategies to enhance
103 cost-effectiveness and performance of healthcare services within the last 20 years, an
104 OECD report on "Wasteful Spending in Health" (2017) presented alarming data on
105 inappropriate care and wasted resources with estimations ranging from a conservative
106 10% up to 34% of expenditures. Ever more often the concept of "value-based
107 healthcare" is discussed as idea to improve resource allocation. However, there is no
108 single agreed definition of value-based healthcare or even of what value means (for
109 whom) in the health context. Therefore, the Expert Panel on Effective Ways of Investing
110 in Health (EXPH) was requested to provide an analysis on "How to define value in "value-
111 based healthcare (VBHC)" and "How to inform healthcare decision making to become
112 more effective, accessible and resilient".

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

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

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

129 The concept of solidarity is deeply rooted in European history and the perceptions of
130 European citizens on solidarity have – according to recent research results – not changed
131 over time. The political commitment to universal healthcare is enshrined in Art 35 of the
132 Charter of Fundamental Rights of the European Union. The concept of solidarity can be
133 perceived not only as a value as such but also as a structuring principle for practices,

134 regulations and institutions: access and equity, quality and performance, as well as
135 efficiency and productivity can be seen as indicators for achieving the goal of a fair
136 distribution of solidarity-raised healthcare resources to those in need.

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

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

147
148 The EXPH therefore proposes to define “value-based healthcare (VBHC)” as a
149 **comprehensive concept** built on four value-pillars: appropriate care to achieve
150 patients’ personal goals (**personal value**), achievement of best possible outcomes with
151 available resources (**technical value**), equitable resource distribution across all patient
152 groups (**allocative value**) and contribution of healthcare to social participation and
153 connectedness (**societal value**).

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

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

163 The EXPH recommends to support the R&D of **methodologies on appropriateness of**
164 **care** (measuring and monitoring patterns of clinical practice and unwarranted variation
165 as well as inequity by disease as a basis for a potential to reallocate resources), to
166 support the creation of **Learning Communities** to bring together the best expertise,
167 experiences and practices and to measure, benchmark and to learn from each other
168 putting in place actions in the EU (incl. the shifting of resources from budgets where
169 there is overuse to disease groups where there is evidence of underuse and inequity), to
170 encourage **health professionals to take responsibility and feel accountable** for
171 increasing value in health care for populations, which may require freeing resources from

172 low-value care to reinvest in high-value care and finally to support **patients’ initiatives**
173 **for engagement** in shared decision-making (SDM), recognising the importance of
174 patients’ goals, values and preferences, informed by high quality information.
175 To conclude, increasing value in our healthcare systems will require strong collaboration
176 and intensive liaison that encompasses evaluation of interventions (to distinguish true
177 innovation and identify low value interventions), monitoring healthcare services delivered
178 (healthcare services research and planning to identify unwarranted variation and care of
179 high value) and surveys of providers (ensuring that personal value by providing person-
180 centered information to patients).

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311 **1. TERMS OF REFERENCE**

312 The landmark 2017 OECD report on “Wasteful Spending in Health” [1] presented
313 alarming data on inappropriate care and wasted resources. The report stressed that a
314 significant amount of health spending is “at best ineffective and at worst wasteful”.
315 Estimations of wasted healthcare resources range from a conservative 10% [1] up to
316 34% in the USA [2]. On the other hand, many patients’ needs for care remain unmet: it
317 is estimated that one in three patients is not offered the care he/she needs [3]. Without
318 policy interventions European healthcare systems are in danger of delivering an
319 increasing amount of low value care, while insufficient resources are left for care of high
320 value. Many European regional or national initiatives have started to tackle the problem
321 of wasteful spending by identifying low value care, but only a few (if any) have actually
322 started to take action to redirect it to high value care.

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

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

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

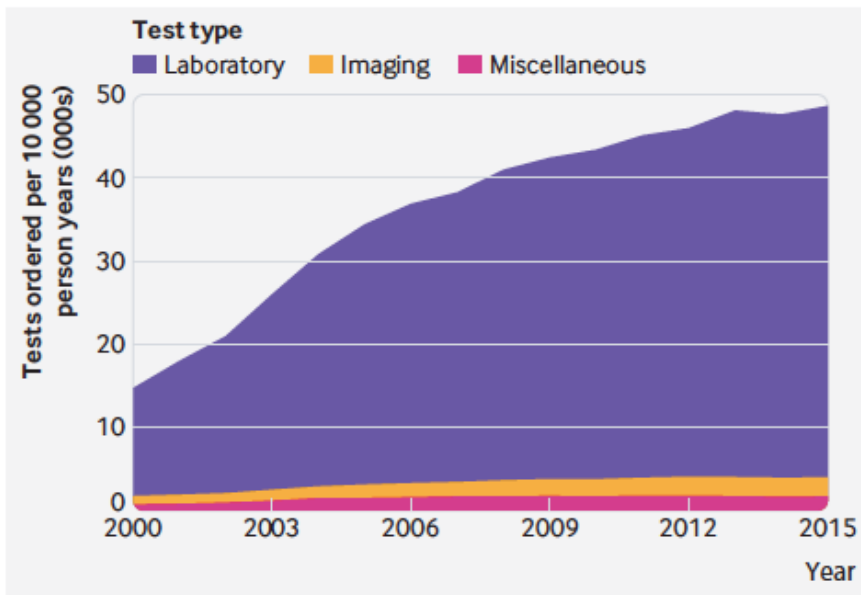
342 **2. BACKGROUND ON WHY THE NEW PARADIGM OF VALUE BASED HEALTHCARE**
343 **IS ESSENTIAL**

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

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

373

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



375

376 Source: O’Sullivan 2018 [5]

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

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

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

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

398 1. One of these problems is unwarranted variation, namely variation in investment or
399 access or activity or outcome that cannot be explained by either variation in need or
400 the explicit choice of the populations served. It is important to recognise that this is
401 different from variation in quality and safety, in which there is clear agreement on
402 what constitutes good or bad levels of performance for example

- 403 • A high percentage of patients with stroke being admitted to a stroke unit is
404 good, and
- 405 • A low percentage of people who have had a joint replacement needing
406 corrective surgery is good.

407 However, there is no agreement on the right rate in a population of, for example,

- 408 • Antidepressants prescribing
- 409 • MRI and other radiological examinations
- 410 • Knee replacement
- 411 • Cataract operation
- 412 • PSA testing
- 413 • Palliative home care interventions
- 414 • The amount of investment for people with musculoskeletal problems

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

417 2. Underuse of effective interventions which results in

- 418 ○ failure to detect, address (treat) or prevent the diseases and disability that
419 healthcare can detect, address (treat) and which may also aggravate ...
- 420 ○ inequity, e.g. "inequity by disease", in patients with the same functional status
421 but due to different 'diagnosis', especially when the diagnosis is conditional to
422 the reimbursement of interventions.

423 3. Overuse which always results in

- 424 a) waste, that is anything that does not add value to the outcome for patients or
425 uses resources that could give greater value if used for another group of
426 patients and may also result in ...

427 b) patient harm in terms of over-diagnosis, anxiety, overtreatment, and side
428 effects of unnecessary care, even when the quality of care is high

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

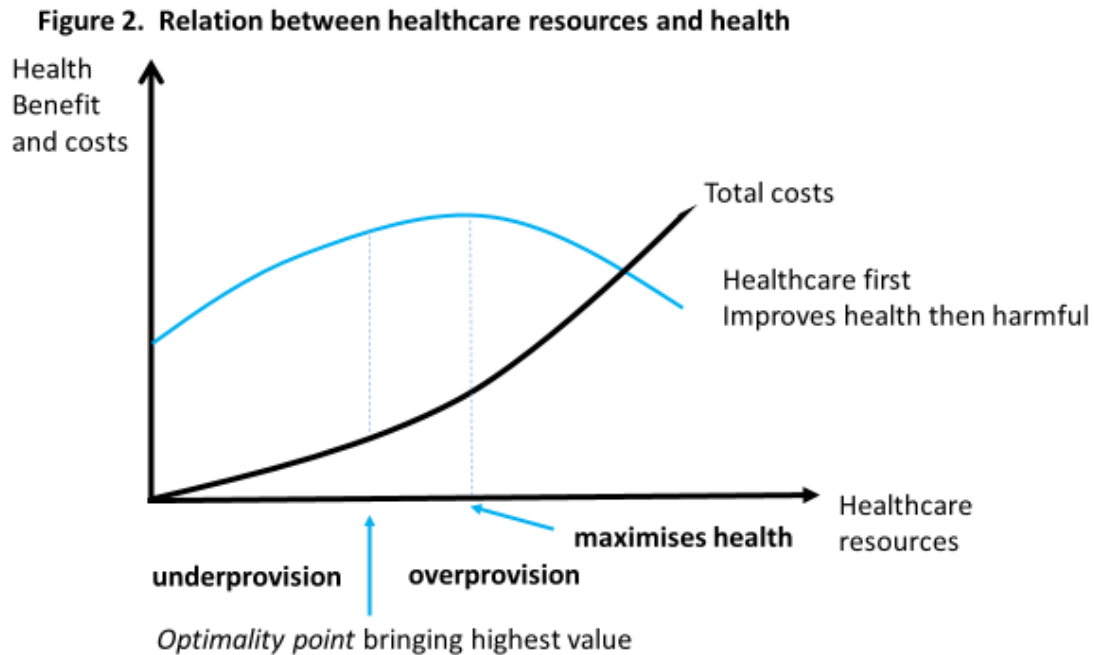
432 **The extent of lower value care and therefore the scope for reinvestment**

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

440

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441 Figure 2: (Theoretical) Illustration of relation between healthcare resources and health
442 benefits and costs



443
444 Source: own presentation based on A. Donabedian [7]

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

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

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

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

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

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

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

473 **3. OPINION**

474 **3.1.Guiding values for European healthcare systems**

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

485 **Box 1: History of concepts of solidarity**

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

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

506
507 Though rooted in European history, memories do, however, fade and it cannot be
508 assumed that the motivations that were present in the 1950s have persisted. In
509 particular, there have been concerns that the European model of solidarity may be
510 challenged by increasing ethnic diversity, drawing on work comparing Europe with the
511 USA, which provided compelling evidence that the failure to create a European style
512 welfare in the latter reflected an unwillingness of an ethnically diverse and divided
513 society, and in particular a dominant racial group to invest in public goods that would
514 benefit everyone [11].

515 Research undertaken in Europe a decade ago suggests that this has not (yet) happened
516 [12], although those findings predated the recent migration crisis and the rise of populist
517 politics. Recent data from the Social Survey (2016) show that representatives of all
518 European countries agree or agree strongly between 44.5% (Czech Republic) to 88.9%
519 (Portugal) that the "state should redistribute income", while between 12.3% (Lithuania)
520 and 55.5% (Czech Republic) disagree (Table 1). Figure 2 shows, for those countries
521 participating in both waves, the change between 2002 and 2016. This shows that there
522 have been changes, in both directions, in different countries.

523

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524 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%

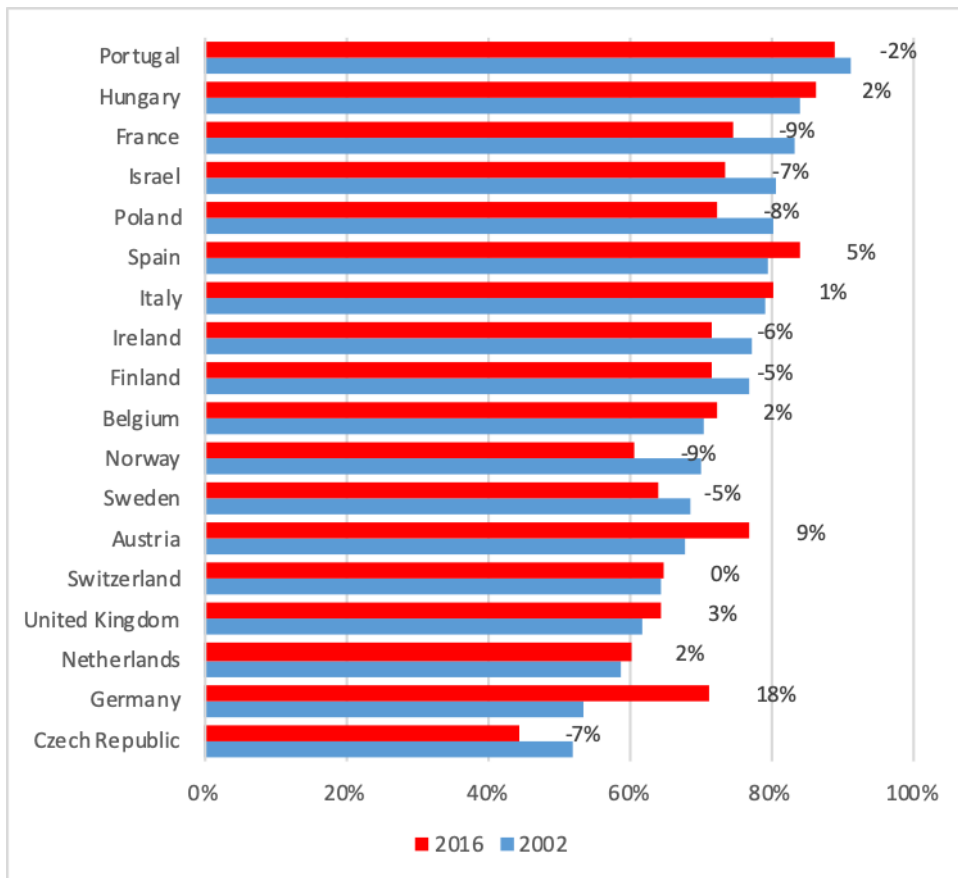
525 CL confidence limit; Figures weighted for design weight

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

527

528

529 Figure 3: Change in percentage in "agreement to redistribution of income" in rounds 1
530 (2002) and 8 (2016) of European Social Survey



531
532 Figures weighted for design weight

533 Source: European Social Survey

534
535
536 These are important figures, even though the data on support for income redistribution
537 cannot be applied directly to support for solidarity in healthcare, but can be perceived as
538 indication of shared values in Europe. As solidarity is the underlying concept for a
539 redistribution of healthcare resources towards those members of society in need, the
540 principles for reallocation of resources will be considered in the next section.

541 **3.1.1. Solidarity in practice: the principles of access and equity,**
542 **quality, efficiency**

543 On the basis of Art 35 of the *Charter of Fundamental Rights* of the European Union [9]
544 and the *European Pillar of Social Rights* stating that "Everyone has the right to timely
545 access to affordable, preventive and curative healthcare of good quality", healthcare is
546 one of the policy priorities of the European Union to build a more inclusive and fairer
547 European Union and to ensure social cohesion within the EU [13]. The concept of
548 solidarity underlying these political commitments can be perceived not only as a value as

549 such but also as a structuring principle for practices, regulations and institutions [14,
550 15]: the development and policies and institutions to increase social justice and help to
551 create the political and economic circumstances that allow societies to operationalize the
552 concept of solidarity.

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

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

569 With increasing examples of “unsustainable prices” for the treatment of some patients,
570 “access to medicine(s)” has become a major topic in recent political discussions. Already
571 within the Belgian EC-presidency (2010) [18], later by the Dutch EC-presidency (2016)
572 [19] and lately the Austrian EC-presidency (2018) the topics of “equitable access and fair
573 pricing” have gained prominence in discussions about innovative policies, as set out in an
574 earlier EXPH opinion [20] that examined initiatives to promote the rational and
575 responsible use of valuable innovative medicinal products so as to obtain an optimal
576 clinical outcome and efficient expenditure (in terms of affordability, accessibility and
577 sustainability). Lack of (public and personal) affordability is a major barrier to access and
578 equal access to high value care.

579 **Quality and performance:** The principle of high quality, and well performing health
580 systems relate to the question of whether the healthcare provided is fit for purpose, and
581 therefore contributes to the goal to provide optimal (and safe) care to all who need it.
582 Health systems vary widely in performance, and countries with similar levels of income

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).

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

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

605 **3.1.2. Ethics of resource allocation in favour of population health**

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

612 Regardless of the funds available for healthcare, the concept of opportunity costs, both
613 within the health sector and across the whole of government investments is key.
614 Opportunity costs are based on the reality that by investing resources in one way, some
615 opportunity for benefit through investing those resources elsewhere will be lost.
616 Opportunity costs of spending more on a particular health intervention occur both outside
617 the healthcare sector (less spending on other valued goods, like education or transport
618 infrastructure) or within (less spending on care for other people). Within limited budgets
619 this concept is the underlying driving force for "ethical resource allocation" to gain the

620 most health benefit for the population, though "most health" does not address
621 distribution as such. Wasting healthcare resources on interventions with small effects
622 (low-value care) is considered undesirable, when the same resources could be invested in
623 healthcare services with greater effects, all else being equal. But even if it is the general
624 public's will to put more societal resources into healthcare services, and not only the will
625 of the providers, the allocation or reallocation/shift must be reasonable and based on
626 arguments of benefits [21]. Equally, pursuing measures that create less health can be
627 justified if the health gain achieved is of higher societal value (e.g. in vulnerable groups
628 or more severely ill).

629 The prioritisation of public resources determined by a democratic participatory process
630 with the aim of an objective benefit is always necessary even though this prioritisation
631 often takes place implicitly or intuitively. Prioritisation decisions under difficult conditions,
632 such as under economic pressure, are often referred to as *rationing* because
633 interventions with little (sometimes even of no proven) benefit or too high price
634 compared to the benefits are not prioritised. In democratic societies, these decisions
635 require not only fundamental trust in the legitimacy of the decision-making institutions
636 (ministries, social insurance funds, health funds, parliaments), but also the legitimacy of
637 the decisions themselves through disclosure of the rationalities (principles and criteria)
638 employed in these prioritization decisions. Many countries have explicitly stated principles
639 that underpin priority setting, such as solidarity, severity, human worth/dignity, cost-
640 effectiveness etc. [22], while many have (also) implemented procedural criteria, such as
641 Accountability for Reasonableness (A4R). A4R provides a procedure for just priority
642 setting with four characteristics for enhancing fairness and legitimacy of decisions [23-
643 25]:

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

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

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

661 **3.2. Intrinsic and extrinsic Value**

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

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

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

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

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

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

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

710 **3.2.1. Concepts of Value(s)-based healthcare**

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

724 From the earliest days of the evidence-based medicine (EbM) there has been a focus on
725 value. Despite having been accused of cookbook medicine, because the evidence was
726 based on a study of patient groups with one common characteristic, the definition of

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

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

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

760

761 Box 2 Multiple uses of the term “value” with narrow and comprehensive definitions
 762
 763

<p>Generic definitions (Oxford Dictionary):</p> <p>Values vs. Value</p>	<p>Values: Beliefs and attitudes a person holds that lead to the judgement of what is important (in one’s life).</p> <p>Value: the importance and worth or usefulness of something to a person.</p>
<p>Narrow (price-based) utilisation of “Value”</p> <p><i>Value-based healthcare</i> [31]</p> <p><i>Value-based pricing</i> [38]:</p>	<p>Value defined as the health outcomes achieved per dollar spent</p> <p>Value = $\frac{\text{Quality (outcomes + patient experience)}}{\text{Cost (direct + indirect costs of the intervention)}}$</p> <p>Process whereby pricing and reimbursement of a service (e.g. drug, medical device) are regulated according to its therapeutic value</p>
<p>Comprehensive (normative) utilisation of “Value”</p> <p><i>Value-based healthcare</i> [39]:</p>	<p>Allocative Value: ensuring that all available resources are taken into account and distributed in an equitable fashion. This concept is also referred to by economists as “allocative efficiency”.</p> <p>Technical Value: ensuring that the allocated resources are used optimally (no waste).</p> <p>Personal Value: ensuring that each individual patient’s values are used as a basis for decision-making in a way that will optimise the benefits for them.</p> <p>Societal Value: ensuring that the intervention in healthcare contributes to connectedness, social cohesion, solidarity, mutual respect, openness to diversity.</p>

764
 765

766 A decade later, in 2017, after the start of the public debate on VBHC, work in England,
 767 Wales, Italy, and Scotland led to the concept of value-based healthcare (VBHC) with
 768 three distinctive aspects of value (personal value, meaning that an individual receives
 769 appropriate care; allocative or population value, referring to the optimal distribution
 770 among population sub-groups; utilisation value, relating to the best outcomes with the
 771 available resources, see 3.2.2).

772 This broader and more comprehensive definition of VBHC, balancing individual quality of
 773 care, including patient experience, population health and wellbeing outcomes, with
 774 sustainability (financial, resource and environmental considerations) is discussed and
 775 accepted by prestigious institutions such as the Royal College of Physicians of the United
 776 Kingdom [40] the Berlin Chamber of Physicians [41] and the Istituto Superiore Sanita in
 777 Italy. The Academy of Medical Royal Colleges in the UK (AoMRC) very explicitly connect

778 the discussion of value with considerations about waste and fair distribution by stating
779 *"...avoiding waste and promoting value are about the quality of care provided to patients*
780 *– which is a doctor's central concern. One doctors' waste is another patient's delay.*
781 *Potentially, it could be that other patient's lack of treatment"* [42]. There is a clinical cost
782 to wasted resources and also, as the report shows, a cost to the environment.

783 **3.2.2. Value(s)-based healthcare for universal health coverage**

784 To summarize, the term value in the healthcare setting, as used in much of the literature
785 from the United States would be classified as (technical) efficiency in countries
786 committed to universal health coverage (UHC). In such countries value includes
787 efficiency but also includes the need to ensure that the resources have been allocated
788 and used to treat those people who would benefit most and to reduce inequality. It is
789 often people from the most deprived subsections of the population who are not referred
790 or are receiving inappropriate care (see above on access, equity, quality and efficiency).
791 Within this broader context Porter's VBHC and Values-based pricing (VBP) falls short,
792 since it is only based on assessment of individuals, not populations of patients and does
793 not address values such as equity and affordability.

794 The approach adopted in the UK and Italy [39] has three distinctive aspects of value in
795 what is called the "Triple Value" Model....

- 796 • **Personal value**, meaning that an individual receives appropriate care and is
797 determined by how well the outcome relates to the value and goals of individual
798 patients, considering both good and bad outcomes. This requires shared decision-
799 making [SDM] based on full information on relative benefits and risks/harms of
800 different options, including option of doing nothing – communication and
801 elicitation of preferences. For example, knee replacement may provide increased
802 flexibility in the joint but unless it has resolved the problem that was bothering
803 the patient most it is of little or no value.
- 804 • **Allocative value**, determined by how equitably the resources are distributed to
805 different subgroups in the population, for example to people with different
806 conditions, such as cancer or mental illness, or to groups defined by socio-
807 demographic characteristics. When there are large differences in allocation of
808 resources to one group of patients , "inequity by disease" may occur [43].
- 809 • **Technical value or utilisation value**, relating to achieving the best outcomes
810 with the available resources and determined by how well the resources allocated
811 for investment for a particular subgroup of the population, defined by their
812 condition, are used for all the people in need in the population. This aspect of
813 triple value includes the need to identify and minimise inequity for example under

814 referral and treatment of people from the most deprived sub groups of that
815 population.

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

- 818 • **Societal Value**, relating to whether the impact of the intervention in
819 healthcare contributes to social cohesion, based on participation, solidarity,
820 mutual respect, and recognition of diversity.

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

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

- 830 • The CHC Botermarkt is a not-for-profit organization, operating since 1978 in
831 Ledeborg, at the time a deprived area of the city of Ghent. The inter-professional
832 team is composed of family physicians, nurses and assistant-nurses, social
833 workers, dentists, oral hygienists, nutritionists, tabacologists, psychologists,
834 receptionists and health promoters. The comprehensive person-centred approach
835 by a team, taking care of very vulnerable people, required in-service training of a
836 lot of disciplines, in order to respond to the professional challenges. A new
837 discipline of health promoters was introduced, that put the preventative role of
838 Community Health Workers in practice. The Centre takes care of 6200 patients,
839 representing 95 nationalities, and of 250 “undocumented” people. Further, it is
840 responsible for health promotion activities for a community of 10,000 people
841 (**Allocative value**: *distribution of the resources*) (**Societal value**: *access for*
842 *vulnerable people*).
- 843 • The Centre delivers integrated Primary Health Care-approach through promotion,
844 prevention, curative care, rehabilitation, palliative care and social care [44].
845 Accessibility (no financial, geographical or cultural threshold, but “proportionate”
846 efforts e.g. through interpreters, video-translation) and quality are central and an
847 inter-professional comprehensive person-centred eco-bio-psycho-social frame of
848 reference is used. Special focus is on strengthening health literacy and
849 empowerment (**Personal value**: *appropriate care is delivered*).
- 850 • An inter-professional electronic goal-oriented health record [45], accessible for the
851 patient and for all involved health care providers, documents the episodes of care
852 (**Personal value**: *orientation towards achievement of patient’s goals*).
- 853 • All patients are registered on a patient-list, open to all people living in the defined
854 geographical area. Payment is through a monthly integrated needs-based
855 capitation (taking into account socio-demographical, epidemiological, contextual
856 and income variables). This financing method stimulates task-shifting and
857 competency sharing and strengthens prevention (**Allocative value**: *cost-effective*
858 *distribution of resources according to needs*).

- 859 • Participation of the population and the community is of utmost importance. CHC
860 Botermarkt implements Community-Oriented Primary Care, and regularly, local
861 stakeholders meet in a Network on "Society, Welfare, Health". Based on
862 epidemiological, sociological and practice-based information, they perform a
863 'Community Diagnosis' and develop programs that tackle the upstream causes of
864 ill-health (e.g. poverty, traffic unsafety, lack of playgrounds, bad housing
865 conditions, epidemics, oral health). This strategy increases social cohesion
866 (**Societal value: contribution to connectedness and social participation**).
- 867 • An analysis of the performance of CHCs (compared to usual practices in fee-for-
868 service) in Belgium concluded that the Centers score excellently in access,
869 especially for vulnerable groups, demonstrate good quality of preventive services,
870 rational antibiotic prescription and other indicators and patients in CHCs cost less
871 than usual practices in utilisation of secondary care services [46] (**Allocative**
872 **value: cost-effective and evidence-based use of resources**).
- 873 • There are clear indications that this PHC-approach contributes to social cohesion
874 and connectedness in a very diverse population, increasing the resilience of the
875 community and facilitates development of innovative policy-projects (e.g.
876 integration of public health and primary care) (**Societal value: social**
877 **participation and innovation**).

878
879 It is important to note that the value attached to health gains by patients and by society
880 can conflict (given collective financing and the need to trade-off interventions and
881 patients): small increases in health/lifetime can be seen as highly valuable by patients,
882 but as less valuable by society. Both values should, - in theory - be captured and, where
883 necessary, trade-offs be balanced to achieve allocative efficiency. Also, distributing
884 resources by need assumes equal (marginal) effectiveness of interventions anticipating
885 that by redistribution no additional value would be produced (allocative value). Societal
886 value goes one step further than allocative value by explicitly encompassing the broader
887 aspects of health as enabler for wellbeing, productivity and social cohesion and that for
888 eventually equally effective interventions those socially deprived might need to be
889 prioritized.

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

899 Given the different aspects of value, many of which are dependent on different
900 stakeholder interests, it is important to define different conceptions of value and develop
901 a more comprehensive view of value in a wider health system context, encompassing the
902 aspects mentioned above and taking into account **societal values such as solidarity** in

903 European welfare states. Such definitions will be a prerequisite for assessing how the
904 concept of value can help achieve the Commission's goal of supporting effective,
905 accessible and resilient health systems.

906 When seeking to deliver value-based healthcare, it is important to take into account the
907 diverse values that come into play in healthcare and health policy. Health professionals
908 have a range of values, such as the value of diagnostic and therapeutic strategies [47].
909 Health economists, Health Technology Assessment agencies and health policy makers
910 have their own heuristic and moral goals [48]. Moreover, a wide range of biases can
911 distort rational priority setting [49, 50]. This seems to be crucial as it has been
912 documented that there is little evidence that the establishment of a values framework for
913 priority setting has had any effect on health policy, nor that priority setting exercises
914 have led to the envisaged ideal of an open and participatory public involvement in
915 decision making [51].

916 **3.2.3. A Framework for Implementation of Value(s)-Based Healthcare**

917 Though no generally agreed definition exists, the concept of "value-based healthcare
918 (VBHC)" is used in an inflationary manner or – as one author calls it "the dilution of value
919 in healthcare" [52]. Some proclaim VBHC as "the strategy that will fix healthcare" [53],
920 others warn of a reduced (efficiency) approach to "value" [54] and stress the relevance
921 of the relationship between VBHC and EbM. The question of who is to benefit from VBHC
922 (individual patients or the total diseased patient population) and the role of values,
923 especially the value of solidarity with the severely ill and the socially deprived, has been
924 the focus of recent debates.

925 Discourses about value in healthcare tend to focus on reducing costs, increasing
926 efficiency [31] and, more recently, minimizing unwarranted variation in healthcare
927 utilization [55]. But to really understand value, we also need to develop a deeper
928 understanding of what patients (and clinicians), citizens and societies value most from
929 their healthcare.

930 Value of healthcare for an individual can be interpreted as directly relating to the *health*
931 benefit, the difference in health with and without healthcare (benefit from recovering
932 health). But value for individuals can also include non-clinical components of benefit that
933 relate to patient experience and responsiveness [56, 57]: timeliness of the treatment,
934 whether the patient was involved in the decision, treated with respect, and amenities etc.
935 Moreover, it can include indirect benefits, such as increased productivity and income due
936 to better health. Health and non-health benefits translate into higher (subjective) well-
937 being (or utility in economics jargon) which can also be thought of as the value of
938 healthcare for the individual. Several metrics have been developed to measure the health

939 of individuals; some are disease specific and others are generic (e.g. Quality-adjusted life
940 year – QALY, and Disability-adjusted life year - DALY), which in turn can be used to
941 measure the benefits from healthcare. More recently, capability measures for adults like
942 the ICECAP have been developed to capture the broader impact of health and social care
943 on wellbeing of patients (beyond health).

944 Value of healthcare for an individual may differ from the perspective of an individual who
945 already has an illness (ex-post perspective) as opposed to that of individuals who have
946 not yet experienced a specific illness (ex ante perspective). Most countries use ex ante
947 valuations in the context of HTA and economic evaluations, although this may be debated
948 [58]. A further consideration beyond the source of valuation of health gains (patients or
949 general public), as health benefits do not reflect ability to pay health benefits are valued
950 equally across otherwise similar people even with different income levels. This is an
951 important deviation from normal market based distributions of goods and value [59]. It is
952 an expression of the solidarity within healthcare systems and views of equality of people
953 within healthcare.

954 At the individual level, the benefits of healthcare, including the value of increased health,
955 need to be traded off against the (individually relevant) costs of receiving the care. This
956 could include aspects like travel and time costs, out of pocket payments, the
957 (un)pleasantness of the process of receiving care, etc. In principle, people will only
958 demand healthcare if the benefits exceed the costs for them. One could view this as a *net*
959 value of healthcare (i.e., benefits minus costs). Note that in the literature value and net
960 value are not always distinguished.

961 Similarly, at higher levels of decision making, the benefits of healthcare also need to be
962 traded off against the associated costs. The value of health and wellbeing produced is a
963 central element in those decisions as well. The elements considered may be broader than
964 at the individual level, including all relevant impacts on society, ranging from health
965 benefits and increased productivity, to solidarity and social cohesion. For a final trade-off,
966 policy makers taking a system, population and societal perspective need to consider both
967 health benefits and costs of healthcare. There are different approaches to taking benefits
968 and costs into account. One way of trading off benefits and costs is through cost-
969 effectiveness or cost-utility analysis, a method of comparing the costs (or opportunity
970 costs) and benefits of alternative healthcare treatments. In such evaluations health
971 effects (expressed in non-monetary terms) are compared to costs in monetary terms.
972 Note that cost-savings or broader benefits, like the monetary value of productivity gains,
973 are captured on the cost-side of these evaluations. Effects are expressed in terms of
974 natural units, like life years saved or hip fractures avoided in cost-effectiveness analysis.
975 In cost-utility analysis health effects are expressed in terms of Quality-Adjusted Life-

976 Years (or – though rarely - Disability Adjusted Life Years). Such outcome measures
977 combine length and quality of life, and are based on preferences of people for different
978 health states. Like indicated, most ex ante preferences are used for this [58]. They
979 measure health benefits in a generic way, so that outcomes for different programs and
980 diseases can be compared. When incremental costs of a new intervention versus a
981 relevant comparator have been calculated (net of savings) they can be divided by the
982 incremental gain in health effects, resulting in an incremental cost-effectiveness ratio
983 (ICER).

984 This ICER should then be compared to a cost-effectiveness threshold decided by a
985 policymaker. In general, two approaches are taken in setting these thresholds, one is to
986 base it on a (societal) willingness to pay, while the other one calculates the opportunity
987 costs of healthcare spending (how cost-effective is current care). Both can be seen as a
988 kind of approximation of an appropriate societal monetary valuation of health gains, that
989 is subsequently used regardless of, for instance, income levels of patients treated.
990 Without further adjustments, these methods can be used to help policymakers maximise
991 the health of their population, and arguably increase the value of healthcare provided. In
992 some countries, thresholds are varied to take account of equity considerations, for
993 instance allowing higher ICERs for interventions that benefit people who are younger at
994 the end of life, or disadvantaged on grounds of characteristics such as disability or
995 ethnicity. Importantly, this variation is not directly based on individual willingness or
996 ability to pay, but on notions of equity, justice and solidarity. It allows maximising
997 societally valued health, recognising that some gains may be more valuable than others.

998 Besides the traditional clinical outputs or (cost-) benefit measures, patient-reported
999 outcome measurements (PROMs), patient reported experience measurements (PREMs)
1000 and – as proposed later – patient-defined outcomes can and should be taken into
1001 consideration. A framework for the implementation of the four pillars of a value(s)-based
1002 healthcare the goals and the means (instruments) to achieve the goals is proposed as
1003 follows.

1004

1005 **3.2.4. Goals and values of people concerned: patients, physicians,**
1006 **planning, and policy**

1007 While values are the fundamental driving forces of individuals and institutions, goals
1008 define the direction of concrete activities; those goals are the specific ways we intend to
1009 execute the values. Those concerned in healthcare (patients, clinicians, payers, etc.) are
1010 led by different goals and - also - those goals might change over time. The following
1011 chapter intends to shed some light on the goals of the different actors and their methods
1012 to achieve their goals.

1013

1014 **Relationship between values, principles and goals**

1015 **Values** are the underlying and fundamental basic goals and are closely associated with
1016 our principles. Preferences are expressions of values.

1017 **Principles** are the operational rules that guide persons and/or institutions.

1018 **Goals** are specific aims and objectives that define a direction of activities of persons
1019 and/or institutions.

1020

1021 In the second half of the 20th century, the concept of patient-centeredness became
1022 important in healthcare. In medicine, a lot of attention was paid to training physicians in
1023 "communication-skills", promoting the patient's role in the consultation. Increased
1024 "health"-literacy, fueled by access to the internet, demanded new approaches to
1025 communication to put "patient-centeredness" in practice. In 1991, Mold [60] proposed a
1026 "goal-oriented approach" that is well-suited to a large variety of healthcare issues, that is
1027 more compatible with a team approach, and places a greater emphasis on physician-
1028 patient collaboration. As described earlier, value based healthcare encompasses personal
1029 value and "goal-oriented care" by determining "what matters" to patients.

1030 **Goals and values of patients:** Each individual will pursue to live a good life, as defined
1031 by the individual. Living a healthy life is a prerequisite and a key part for most people.
1032 Characterized by a greater emphasis on individual strengths and resources, this approach
1033 represents a more positive concept for healthcare. The measure of success in "goal-
1034 oriented care" is the patient, not the physician/professional. This innovative approach,
1035 however, was not adopted at large scale. One of the reasons was probably that
1036 "evidence-based medicine" [61], was sometimes interpreted and implemented in a
1037 reductionist way, even though EbM always intended to incorporate the patient's
1038 preferences. Healthcare outcomes are decided by how the patient and the doctor
1039 perceive health and disease, and this perception needs to shift from problem-orientation
1040 to goal-orientation. Moreover, it is important to complement "medical evidence" with
1041 "contextual evidence" and "policy evidence" [62]. Since 2010, the challenge of multi-
1042 morbidity has led to further interest in "goal-oriented care": in each consultation, a clear
1043 exploration of what really matters for the patient is required. Very often, the patients'
1044 goals are related to being able to function and to social participation, for instance a
1045 patient with Parkinson's may have the goal to achieve independence when for using the
1046 bathroom or when walking to church. [63].

1047 **Goals and values of Clinicians:** Physicians and clinicians may have many different
1048 goals. At the forefront of physicians' goals is the individual patient's wellbeing, balancing
1049 potential benefits and, taking account of the patients' preferences and their individual
1050 goals. This is for example expressed in the principle of beneficence. Gaining reputation as
1051 an "innovative" practitioner, trying new interventions lacking evidence, might be a goal
1052 for some physicians and clinicians. To act and to help, e.g., to "give something" even
1053 when no treatment is indicated, can influence the goals and values. Additional, increasing
1054 the physicians' and clinicians' income by maximizing fees, status and prestige can also
1055 be considerations [64, 65].

1056 **Goals and values of Provider/ institution:** The goals of organizations include
1057 providing beneficial interventions to many patients at "reasonable" cost and enhancing
1058 the profile of one's institution as one providing high value care (low re-admission or low
1059 recurrence rates). To achieve these goals, cost-effectiveness analyses and budget impact
1060 analyses are conducted to inform priorities for investments. Of course, many payment
1061 systems simply pay for activity and even if the payer requires certain quality levels to be
1062 met, the provider institution is not incentivized to optimize value for the population as a
1063 whole because of the focus on ensuring quality only for those patients who obtain that
1064 specialist service.

1065 **Goals and values of payers and planning (tax and insurance):** The goal of payers
1066 is to maximize health from a given budget in the whole population, and not only a few
1067 patients. To achieve these goals, priorities have to be set (expressed implicitly or
1068 explicitly) in order to define the inclusion or the exclusion of services in benefit
1069 catalogues and policies incentivizing the utilization of high value, but low cost
1070 interventions may still be introduced or perpetuated. On the one hand, prevention
1071 programs are launched and on the other hand increasingly risk-sharing financial
1072 arrangements for costly interventions are initiated. The issue is more complicated in
1073 insurance based health services where the budget for a defined population is not so
1074 clearly visible but there is increasing interest in value as costs and co-payments increase
1075 faster than income levels or pension levels.

1076 **Goals and values of Industry:** The goals of industry may involve maximizing profits
1077 (increasing the value to the shareholders or to the owners of companies) in the case of
1078 for-profit organizations or other objectives, in the case of not-for-profit entities. Not-for-
1079 profit organizations may include access to care and/or progress in knowledge. To achieve
1080 their objectives, health care providers have to offer products and services that are
1081 purchased or reimbursed by payers. Providers of health care will make different decisions
1082 regarding products and services offered and related investment also according to their
1083 perspective. Providers that face pressure to produce short-term financial results are likely

1084 to conduct business differently from those that take a long-term perspective. Forms of
1085 ownership and management that lead to a focus on short-run profit maximizing will have
1086 different goals from those that take a long-term view. The decisions that matter relate to
1087 R&D efforts, range of services and/or products provided and their pricing.

1088 **Goals and values of HealthCare Planning and Health Policy:** Health policy seeks to
1089 create a regulatory environment and governance structure to maximize health from a
1090 given budget for the whole population. To achieve the goals of equity of access, high
1091 quality performance as well as efficiency, an appropriate legal and regulatory framework
1092 is required. There is a need for long-term strategies based on data-collection for need
1093 assessment in and across disease-groups, innovation strategies based on Technology
1094 Foresight & Horizon Scanning to facilitate reallocation of resources based on program
1095 budgeting.

1096 **Policy/ Government Goals:** Finally, the goals of governments include social cohesion
1097 and equity across generations. This requires finding a balance between the many policy
1098 areas competing for the national budget. The concept of "Health in All Policies" calls on
1099 governments to consider the impact of new policies (regulation, budgets, strategies) on
1100 health as one major contributor to the progress of nations.

1101 Table 2 gives a (non-comprehensive) overview of the many methodologies and
1102 instruments applied to achieve one's specific goals. In the toolbox of potential
1103 instruments "value based pricing" is one among many approaches to achieve prices
1104 based on actual benefits accrued in individual patients and has its place as management
1105 tool. In the context of a broader discourse on value-based healthcare the EXPH proposes
1106 not to use the wording "value-based pricing", but rather a broader view of pricing
1107 strategy. Note that prices do not create value per se, they divide value generated among
1108 the different agents. Prices may influence value indirectly by the reactions and
1109 adjustments that different pricing systems induce. Different pricing strategies will,
1110 therefore, have distinct implications for the several goals of a health system.

1111

1112 Table 2: Typology of means (instruments) to achieve the goals of different stakeholder in
 1113 healthcare

1114

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
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

1115 Source: own presentation

1116 **3.3. Initiatives to increase value in healthcare**

1117 As described in the introduction, over- and underuse of healthcare interventions are
 1118 increasingly perceived as major contributors to the waste of public resources. Overuse is
 1119 defined as the provision of medical services that are more likely to cause harm than good
 1120 [66]. The harm might be physical, psychological, financial or societal (e.g. inequity).
 1121 Overdiagnosis is perceived to be the driver of "too much medicine", the subject of major
 1122 campaigns by the BMJ, the Dartmouth Institute and many other organisations against
 1123 the harm and cost implications of overtesting and overtreatment [67]. Overdiagnosis
 1124 turns people into patients unnecessarily. Incidental findings due to overuse of diagnostics
 1125 have become a serious problem: there is a large variability across different imaging
 1126 techniques, but "incidentalomas" occur in 5% – 42% of imaging procedures, many of
 1127 them of uncertain potential seriousness [68].

1128 Underuse is defined as the failure to use effective and cost-effective medical
 1129 interventions that are likely to avoid morbidity and mortality [69]. Causes of underuse of

1130 effective and affordable interventions might be lack of access (lack of coverage, financial
1131 barriers, administrative barriers, remoteness, immigration-status), lack of availability
1132 (limited resources or regulatory control), clinical uptake of evidence-based interventions
1133 (inconsistent use of interventions, inappropriateness) and patient adherence (non-
1134 acceptance or non-compliance due to culture, stigma, language, socio-economic status).
1135 Underuse is generally more a problem of low and middle income countries (LMIC), but
1136 the underuse of effective non-pharmacological or non-clinical interventions (in
1137 prevention, in rehabilitation, but also in treatment of chronic diseases etc.) is common in
1138 high-income countries, often reinforcing inequalities.

1139 There is a need for reallocation of resources away from low value care towards high value
1140 care. However – under resources constraints –, the acceptance of the need for
1141 reallocation will require a culture that prioritizes what matters to patients, taking account
1142 of their preferences and their goals.

1143 **3.3.1. Patient-centered definitions to increase value in healthcare**

1144 From a patient's perspective, if it is to deliver high value the healthcare system needs to
1145 shift from a "disease-centered" to a "person-centered" approach, where patients are
1146 equal and active partners in their care. Care at all levels needs to be driven by patients'
1147 needs, goals, priorities and preferences – starting from ensuring that not only patients'
1148 needs drive research and development (R&D) of new therapies, but also by embedding
1149 patient-centered practices at the clinical and organizational levels and in governance.
1150 There is accumulating evidence [70] on the key role of patients in defining what value
1151 actually means in value-based healthcare, contributing their own experiential knowledge
1152 and expertise acquired through living with a disease or condition. This is reflected in both
1153 the policy discourse and in practice, albeit to date in a somewhat piecemeal fashion. For
1154 a patient, innovation in healthcare is not only about new treatments, but better
1155 treatments and quality of life – from medicines, non-pharmaceutical options, self-
1156 management support, or change in the way care is delivered and organized.

1157 Much of the resource invested in research may be classified as waste [71]: an important
1158 factor, besides weak methodology and design, unnecessary duplication, and failure to
1159 publish, is that research is too rarely driven by patients' identified priorities, nor does it
1160 routinely include measures of outcomes and quality of life that are meaningful for
1161 patients [72]. Partnering with patients in research to deliver value is a promising area
1162 that is being prominently driven by organizations such as INVOLVE in the UK, promoted
1163 by the BMJ [73], which requires submissions to document how they involved patients in
1164 the study (e.g. in setting research questions, outcome measures, design, implementation
1165 and dissemination).

1166 There is acknowledgement by many stakeholders involved in the life cycle of medicines
1167 (industry, regulators, the HTA community, payers, healthcare professionals), that the
1168 end points that matter to patients should be central to decision-making processes, and
1169 even more fundamentally, patients should be involved in identifying unmet medical
1170 needs and research prioritization. There are sterling examples of where this is happening
1171 throughout Europe, but generally it remains ad hoc and fragmented.

1172 The Patient and Consumer Working Party at the European Medicines Agency (EMA) is
1173 drafting a reflection paper on enhancing the patient perspective in the regulatory process
1174 – this paper, which should be submitted to a public consultation in early 2019, aims to
1175 bring greater clarity on how to increase both the quantity and quality of the patient
1176 contribution. Of course, this is not only a responsibility of the Regulator –the industry
1177 needs to integrate patients’ perspectives much earlier in the process.

1178 There is a need for a structured and systematic approach to addressing this and several
1179 IMI (Innovative Medicines Initiative) projects – including PARADIGM (Patients Active in
1180 Research and Dialogues for an Improved Generation of Medicines: [https://imi-
1181 paradigm.eu/](https://imi-paradigm.eu/)) on patient engagement – are helping to close this gap, also exploring the
1182 ‘return on engagement’. This more robust approach to meaningful patient involvement
1183 could and should go beyond medicines to research on technology, systems, and social
1184 innovation.

1185 Unfortunately, patients’ preferences can be influenced by a wide range of stakeholders
1186 (e.g. industry, media), hopes and expectations, as well as cognitive/ emotional biases.

1187 **Potential impact of greater patient involvement/empowerment on reducing** 1188 **waste/increasing value**

1189 Empowered, active patients are not necessarily “cost-drivers”: in fact, when patients are
1190 given full information and a range of choices, they often prefer the less invasive, less
1191 intensive option [74]. The 2017 OECD report also cites substantial, largely unwarranted
1192 geographic variations in rates of certain procedures. A study from Denmark that focused
1193 on elective surgery showed that, when patients were involved in shared decision-making,
1194 they were less likely to choose surgery [75]. The results were echoed in a Cochrane
1195 review on the topic [76].

1196 Another example is patient safety. According to the OECD’s 2017 report on waste in
1197 healthcare, adverse events happen in 1 out of 10 hospitalizations and they add 13-17%
1198 to hospital costs. Up to 70% could be avoided. Little attention has been paid so far to the
1199 contribution that patients’ and families’ involvement and empowerment can make to
1200 improve patient safety in different healthcare environments [77].

1201 So far, patient-targeted interventions – primarily self-management and improving
1202 information or health literacy for the patient – have received most attention both in the
1203 academic literature [78]; shared decision-making is relatively neglected, though it is
1204 arguably fundamental to driving change in clinical practice (the UK seems to be a front
1205 runner in this regard).

1206 Arguably, there is still too little evidence on the economic benefits at micro or macro
1207 level of patient involvement. However, a 2018 review of patient involvement in clinical
1208 research estimated that the return in terms of value of involving patients can significantly
1209 exceed the initial investment [79].

1210 **Measuring what matters**

1211 “What can be counted, counts,” and “what gets measured, gets done”, so it is vital to
1212 identify the right outcome measures for assessing healthcare performance, reflecting on
1213 what outcomes patients find most important. The problem is that many, if not most, of
1214 the commonly used outcome measures were never co-designed with patients in the first
1215 place, so they often reflect the priorities of professionals or what well-meaning
1216 professionals assumed would matter to patients.

1217 The role of patients in defining outcomes that matter to them is integral to the OECD’s
1218 PaRIS initiative [80], which will conduct a cross-country survey on assessing health
1219 system performance from the perspective of the patient, focusing both on outcomes that
1220 matter to patients and on patient experiences of care. Whilst the purpose of PaRIS is to
1221 provide comparative information for high level policymakers, it is hoped that it will also
1222 help drive change in healthcare practice on the ground.

1223 While a focus on outcomes is welcome, process also matters. The experience of care is
1224 often equally important to patients [81]. Improving process can also contribute to
1225 improved outcomes; the much-cited example of the Martini Klinik in Germany shows that
1226 it was a change in process and a transformation in the culture of the organization that
1227 made improved outcomes possible [82].

1228 Patient experience cannot be fully captured in indicators and requires in-depth
1229 exploration using interactive tools, based on real engagement with the patients. Patient
1230 narratives can be a very useful tool: National Voices in the UK has developed a “narrative
1231 on person-centered, integrated care”, and a similar effort is underway in Ireland. These
1232 narratives describe what “good” looks like through a patient’s eyes and can help in the
1233 development of appropriate measures [83].

1234 Some ground-breaking work has examined the role of patients and their representative
1235 organizations in health system transformation, contributing to the shift towards patient
1236 value-based healthcare. This requires a step beyond „patient-centered“ care which tends

1237 to be defined by other stakeholders than patients, towards an unequivocal commitment
1238 to patient empowerment, as a move toward value based healthcare and sustainable,
1239 quality health systems of the future.

1240 The Empathie Study [84] highlighted the role of patient empowerment, at both individual
1241 and collective levels, in understanding and incorporating the patient's perspective and
1242 the patient's voice. Three tenets of patient empowerment were defined in the study:
1243 health literacy and access to quality information; meaningful dialogue with medical
1244 professionals and shared decision-making; and self-management, with a focus on
1245 behavior, attitudes and the potential of new technology and digital health in enhancing
1246 patient empowerment. Further examples [85] [86] provide compelling evidence.

1247 Education and communication are moving forward – both the education of patients to be
1248 able to contribute as effectively as possible their expertise and know-how, and the
1249 education of all other health professionals involved in delivering value-based healthcare,
1250 to enable them to work with patients in an optimal and ethical way. The EUPATI project
1251 (<https://www.eupati.eu/>) provides an example in the sphere of patient education on
1252 therapeutic innovation. A fundamental challenge is to effect change in clinical practice so
1253 that healthcare becomes “in reality” a dialogue, a conversation focusing on “what matters
1254 to you” rather than “what is the matter with you”. Patients' involvement in health
1255 professionals' education is a relevant and very under-explored area.

1256 Ultimately, to achieve value (for patients, and for society), patient perspectives need to
1257 be embedded at every level in the health system, from therapeutic R&D and research
1258 across the whole medicines and medical devices lifecycle, but also in clinical practice,
1259 service design and evaluation, and the design of infrastructures. Many indicators,
1260 preconditions, and precursors of disease perceived as important to health professionals,
1261 may not be of value to the individual patient, but leading to overdiagnosis [87]. The
1262 discourse now needs to move beyond „patient-reported“ outcomes and start prioritizing
1263 „patient-defined“ outcomes. Digital technologies will eventually play an important role in
1264 measuring what matters to patients [88]: The potential of digitalization in value-based
1265 healthcare will only be realized if both health care professionals and patients trust that
1266 this will lead to better outcomes, and have confidence in the processes and the tools.
1267 This requires leadership, effective cultural change management, and eHealth literacy
1268 skills building.

1269 Last, but not least, the “value” discussion must also consider affordability of healthcare –
1270 to patients and to society. The patient community in Europe sees value, and indeed
1271 values, embedded, for example, in the target on Universal Health Coverage for all in the
1272 framework of the Sustainable Development Goals. It could be argued that a pre-requisite
1273 for value-based healthcare is Universal Health Coverage, based on values such as

1274 solidarity, fairness and equity [89]. Last but not least there is the "invisible" value of
1275 financial protection.

1276

1277 Box 4: Case study "Social Prescribing": a way to integrate medical and social services,
1278 England

1279

1280 Under the motto "there is more than medicine", "Social Prescribing (SP)" - practised in
1281 England since the 1990s - attempts to support people with physical or mental health
1282 problems, for whom medical treatment did not lead to any improvement in the conditions
1283 and social isolation additionally aggravates the condition (possibly causes them), by
1284 means of "referral" to local, non-clinical centres. In general, a distinction is made
1285 between different models of "social prescribing", which differ mainly in the degree of
1286 cooperation between general practitioners' practices and SP centres. The ultimate goal of
1287 SP is to promote well-being and health by helping patients to gain more control over
1288 their own health and also to satisfy social needs. Consequently, SP can lead to the relief
1289 in the outpatient sector and in primary care, according to evidence from accompanying
1290 research.

1291

1292 Over the years, more than 100 such SP centres have been established in England, which
1293 together offer a wide range of different therapies in the areas of volunteering, creative
1294 activities, joint learning, gardening, sports, etc. [90]. In the programme "Green Dreams
1295 East Lancashire", for example, patients are brought into regular contact with nature
1296 (walking together, gardening): this showed a positive effect on physical and
1297 psychological well-being and significantly reduced their stress level. At the same time,
1298 this offered a good opportunity for socially isolated patients to make new contacts.
1299 Another example, the "Creative Alternatives Selfton" programme, showed that active
1300 creative activity not only improved the well-being, health and quality of life of patients,
1301 but also their social capital. In "The Workers' Educational Association" programme, joint
1302 learning for adults is promoted, which has a positive effect on smoking and sports
1303 behaviour, as well as on the life satisfaction of the participants. But it is not only the
1304 patients who report the SP's successes; informal carers (family members and relatives)
1305 also play a role in these programmes. An example is the "Carer Resilience Service",
1306 through which relatives of dementia patients are offered support in the area of care,
1307 which has had a positive effect on health and safety, as well as on the relationship
1308 between caregiver and patient.

1309

1310 A number of qualitative studies on effects and outcomes show that SP generally has a
1311 positive effect on the mental health, well-being and social capital of many patients.
1312 According to the evidence from accompanying studies, fewer doctors are consulted, less
1313 medication is prescribed and fewer emergency services are used, which is accompanied
1314 by a reduction in health expenditure [91]. However, robust and systematic evidence on
1315 the effectiveness of SP is limited and proof of cost-effectiveness has not yet been
1316 provided [92] [93].

1317

1318 All in all, however, the concept of SP comes close to the goal of personalized healthcare,
1319 where services are tailored to an individual whose aspirations, needs and capital are
1320 aligned, and thus points to an alternative path of healthcare for everyone.

1321

1322

1323 **3.3.2. Quantifying and categorising loss of value**

1324 A 2017 OECD report found that up to a fifth of health spending could be channeled to
1325 better use [1]. Three main categories of wasteful spending:

- 1326 • Wasteful clinical care covers instances when patients do not receive the right care.
1327 This includes duplicate services, preventable adverse events – for instance,
1328 wrong-site surgery and many infections acquired during treatment – and low-
1329 value care – for instance, medically unnecessary caesarean sections or imaging,
1330 or patient’s psychological suffering due to inappropriate communication and/or
1331 low quality provider/patient relationships.
- 1332 • Operational waste occurs when care could be provided using fewer resources
1333 within the system while maintaining the benefits. Examples include situations
1334 where pharmaceuticals or medical devices are discarded unused or where lower
1335 prices could be obtained for the inputs purchased (for instance, by using generic
1336 drugs instead of originators). In other instances, costly inputs are used instead of
1337 less expensive ones, with no additional benefit to the patient. In practical terms,
1338 this is often the case when patients seek care in emergency departments or are
1339 admitted to hospital with preventable exacerbations of chronic diseases that could
1340 have been treated at the primary care level, or cannot be released from a hospital
1341 in the absence of adequate follow-on care.
- 1342 • Governance-related waste pertains to resources that do not directly contribute to
1343 patient care. This category comprises unneeded administrative procedures, as
1344 well as fraud, abuse and corruption, all of which divert resources from the pursuit
1345 of healthcare systems’ goals.

1346
1347 To tackle waste and loss of precious resources many national and supranational activities
1348 have been initiated as follows, and will be described in more details below:

- 1349 • Health Policy Planning analyzing unwarranted variation, to identify over- and
1350 underuse
- 1351 • Health Policy initiatives investigating disinvestment for re-investment
- 1352 • Policy and provider institutions analyzing corruption, fraud, misuse of public
1353 resources
- 1354 • Research Policy to reduce waste and increase public value in biomedical and
1355 health research
- 1356 • Clinician led initiatives to “choose wisely” as basis for communication with patients
1357 to reduce overuse
- 1358 • Health and regulatory policies for better access to high-value (but costly)
1359 medicines

- 1360 • Health, finance and regulatory policies for better incentives in favour of fair
1361 distribution and optimal use of resources

1362 **3.3.3. Health Policy and Planning: Unwarranted variation, over- and**
1363 **underuse**

1364 Unwarranted variation has been defined by the originator of health atlases, John
1365 Wennberg, as:

1366 "Variation in the utilization of healthcare services that cannot be explained by
1367 variation in patient illness or patient preferences." ³

1368 Unwarranted variation is unacceptable: it wastes resources, and it is the hallmark of
1369 poor-quality and lower-value healthcare. The prime importance of investigating the
1370 causes of variation is that it offers the opportunity of identifying and eliminating lower
1371 value activity.

1372 It could be argued that health services have adapted to, and learnt to tolerate,
1373 unwarranted variation rather than explore and address the problem. Professionals –
1374 clinicians and managers alike – frequently dispute the existence of unwarranted
1375 variation, often alleging fault with the data which could be seen as justification for
1376 maintaining current practice. Such responses are understandable but, in the context of
1377 increasing need and increasing demand for healthcare, together with calls for increased
1378 efficiency, those responses can no longer be supported. Indeed, a paradigm shift is
1379 required if health services are to face the challenges of identifying, classifying and
1380 reducing unwarranted variation in order to increase value for individuals and populations.

1381 Unwarranted or warranted variation should be managed in different ways, as set out in
1382 Table 3 [94] adapted from Wennberg et al. [95]. There are some services, such as
1383 clinically proven effective services, for which evidence-based medicine (EbM) provides
1384 reference standards, making it possible to agree what constitutes good and bad
1385 performance. Persistent and significant deviations from the standard is to be considered
1386 as negative and is therefore to be avoided since it might impact negatively on patient
1387 health, and patient safety (letter A of Table 3). Another category of services comprises
1388 those where low-cost care settings can produce the same outcome (letter B of Table 3).
1389 Performance evaluation systems (PES) especially focus on monitoring results for the
1390 above mentioned typologies of services (letters A and B) and urge health systems to
1391 constantly improve in order to achieve the reference standards. There are instead other
1392 services (letters C and D of Table 3), which have no reference standard; however, they
1393 have rates unevenly geographically distributed for the same need [96-98].

1394 Table 3 Variation in different health services categories

³ <http://www.dartmouthatlas.org/>

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

1395
1396 Source: [94]

1397
1398 Interventions for reducing unwarranted variation differ according to health service
1399 categories. For services belonging to categories A and B, where standards and EBM
1400 protocols are available, measurement and dissemination of information can help to
1401 reduce geographic variation, but if knowledge is to lead to to change, measuring and
1402 disseminating results must be supported by other policy and managerial mechanisms.
1403 For services belonging to categories C and D, as demonstrated in numerous studies,
1404 geographic variation in the provision of care cannot be completely explained by patient
1405 characteristics and preferences but instead is mainly influenced by differences in
1406 clinicians’ behaviour and judgment. Clinicians, in turn, often do not realize that their
1407 treatment decisions vary greatly across geographic areas and have relevant impact on
1408 healthcare costs [94].

1409 Variations in quality are inevitable. Healthcare is delivered by human beings, and even if
1410 they use the same equipment, the quality of care, that is, the degree to which it meets
1411 pre-set standards, will vary [99]. Variations in expenditure, activity and outcome rates
1412 are more difficult to understand than variations in quality (see Box 5 on Quality
1413 Registries as one tool for disclosing unwarranted variation). In measuring quality there is
1414 clear agreement on what constitutes good and bad, for example a high rate of
1415 admissions to stroke units is good and a low level of screening coverage is bad but for
1416 many services and interventions the issue is not clear cut and

- 1417 • A high level of intervention may be good, or may represent overuse, which always
- 1418 wastes resources and may do harm whereas

- 1419 • A low level of intervention may be good or may represent underuse of high value
1420 healthcare, perhaps compounded by inequity if rates are particularly low in
1421 deprived sections of the population.

1422 Box 5: Quality Registries as one tool for disclosing unwarranted variation

1423 Registries are systems for the collection of logically coherent, related data with some
1424 inherent meaning, typically reflecting events that have occurred. Quality registries, in
1425 particular, seek to use systematic data collection to improve quality of care. They
1426 contain data (diagnosis, events, treatments, outcomes) on individual patients within
1427 the health care system, including individualised data concerning patient problems,
1428 medical interventions, and outcomes after treatment. National Quality Registers are
1429 used e.g. in the Nordic countries to improve outcomes of medical care and enhance
1430 patient participation.

1431
1432 In Sweden, an agreement between the Swedish state and the Swedish Association of
1433 Local Authorities and Regions states that Quality Registries aim to support clinical
1434 improvement and research in order to provide patients with the best possible
1435 healthcare. Sweden has a legal framework for Quality Registries and a national
1436 organisation with a clear remit to support such registries. The Swedish Quality
1437 Registries include data at individual level, collected within the healthcare system. The
1438 data responsibility for Quality Registries lies with the respective regional and local
1439 authorities ("CPUA"-central
1440 personuppgiftsansvarig)([https://www.nordforsk.org/en/programmes-and-
1441 projects/projects/project.2017-11-06.6533047689?set_language=en](https://www.nordforsk.org/en/programmes-and-projects/projects/project.2017-11-06.6533047689?set_language=en)).
1442

1443 Norway and Denmark have systems and definitions that are similar to Sweden's. In
1444 Norway, the main purpose of the Quality Registries is to improve quality in medical
1445 practice. From a legal perspective, the systems in Sweden, Norway and Denmark
1446 resemble each other but are not identical. For example, in Denmark it is mandatory
1447 for hospitals, other health care institutions and practicing professionals to collect data
1448 on patients for the Quality Registries. In Finland, university hospitals have voluntarily
1449 set up clinical quality registries and the National Institute of Health is now setting up
1450 national quality registries resembling those in Sweden.

1451 National Quality Registries are used in an integrated and active way for continuous
1452 learning, improvement, research and management to create the best possible health
1453 and care together with the individual. National Quality Registries are also very
1454 important for disclosing unwarranted variation in the use and outcomes of healthcare
1455 services.
1456

1457
1458 Differences in expenditure - or investment to use another term - on a disease, or a group
1459 of diseases such as respiratory disease, is a function of two variables:

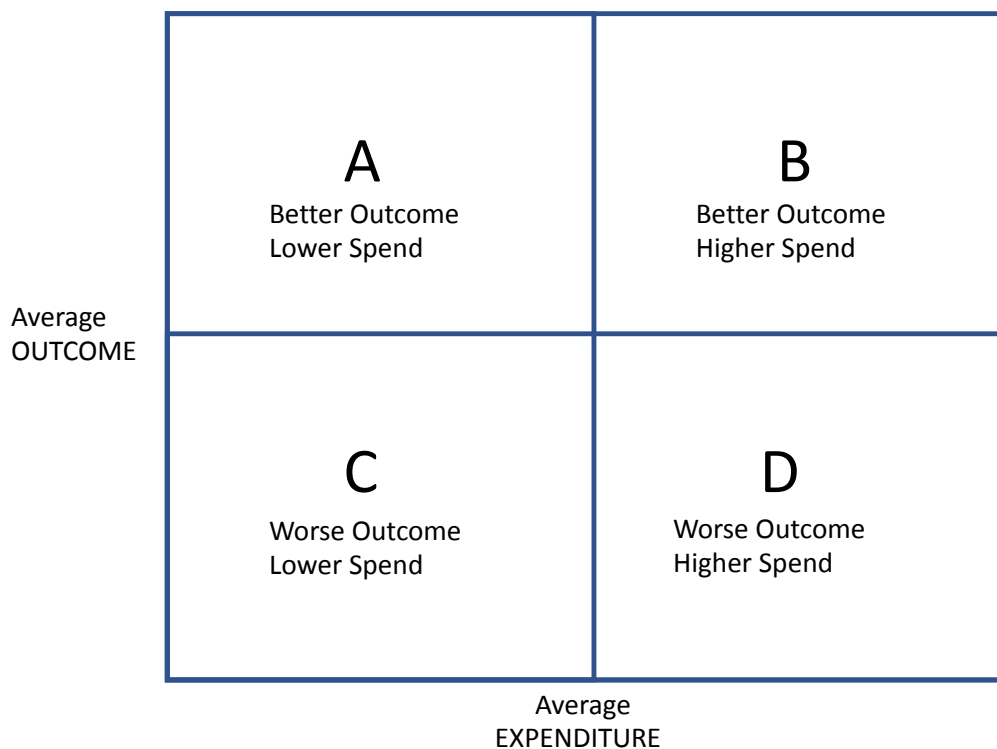
- 1460 1. The amount of resource allocated to spend on that particular group of diseases, or
1461 programme;
1462 2. The cost of each unit of treatment.

1463 Measures to reduce cost can increase productivity but a much greater issue is the
1464 variation in investment in different subgroups of the population, sometimes called
1465 programme budgeting. In countries where the budgeting systems allow this type of

1466 comparison the expenditure by different jurisdictions on different subgroups, such as
1467 people with cancer or people with mental health problems varies from 1.5 to 2 fold,
1468 implying the risk of 'inequity by disease' [43].

1469 Increasingly variations in outcome are being measured. These are, of course, in some
1470 way the result of variations in quality, but they are also influenced by variations in the
1471 severity of the disease in the patients treated. For example, where there are high levels
1472 of investment, people with lower levels of need will be treated. For the population, value
1473 is measured by the relationship between outcome and investment, and when spend and
1474 outcome are plotted the performance of different population based services can be
1475 classified using the framework shown below:

1476 Figure 4: Value as relationship between outcome and expenditure



1477

1478 Source: NHS England Rightcare Programme (<https://www.england.nhs.uk/rightcare/>)

1479 For each of these four types of service a different strategy is needed.

1480 • Services in group A should be praised and encouraged to write up their methods
1481 and processes for sharing with others

1482 • Services in group B should be praised but should be encouraged to review their
1483 investment and see if there are ways in which costs could be reduced without
1484 affecting outcome or if increased need, for example from population ageing could
1485 be met without additional resources

- 1486 • Services in group C should be encouraged to learn from group A before simply
1487 asking for more resources
- 1488 • Services in Group D need a major review

1489 The investigation of variation in healthcare is not a new undertaking, but is based on
1490 decades of research, particularly in the USA and the UK. It is also important to bear in
1491 mind that variation for certain reasons is positive (e.g. variations in the context of
1492 patient-centred and goal-oriented care implementation); if all reasons for variation were
1493 negative, it would be easier to take action to remedy it [100]. Some variation is
1494 inevitable, some is random, and perhaps some is an outcome of differing rates of
1495 innovation and improvement, both essential pillars of a modern healthcare system.

1496 Box 6: Case study on the diabetic foot pathway in Tuscany, Italy

1497 This section presents the experience conducted in Tuscany Region on the diabetic foot
1498 care pathway. This experience started in 2012 with the aim to explore the determinants
1499 of regional variation in the population outcomes results and improve value for patients
1500 [101]. The outcome measure that was taken into account to evaluate the pathway
1501 performance is the hospitalization rate for diabetes-related amputations. Considering
1502 2012 data, Arezzo LHA was the best performer with no more than 18.78 diabetes-related
1503 amputation rate per million residents, while Pisa LHA had the highest recourse to this
1504 surgical intervention delivering 100,43 amputations per million residents.

1506 This outcome result was analyzed also in terms of resources allocated to the services
1507 related to the diabetes-foot pathway. Figure 1 shows the two different cost items related
1508 to the clinical pathway examined: i) severe amputations and ii) preventative treatments
1509 (i.e. revascularization).
1510
1511

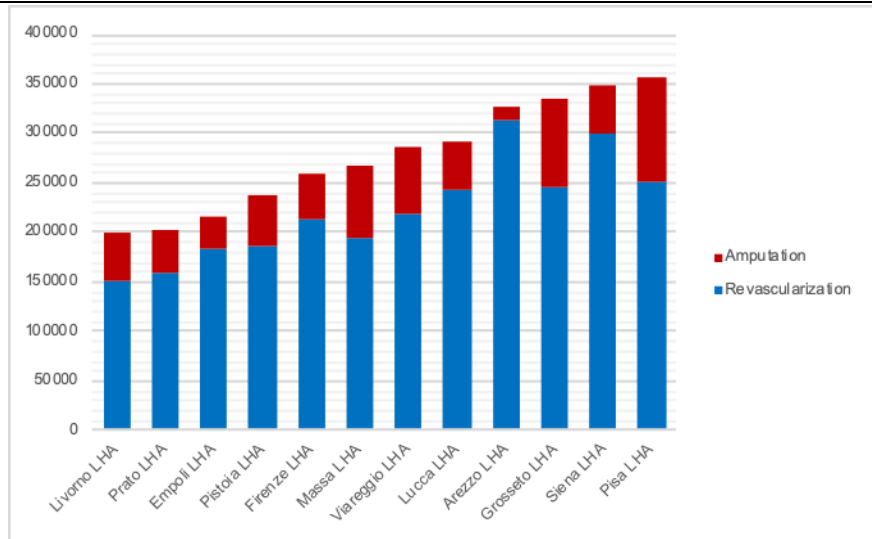
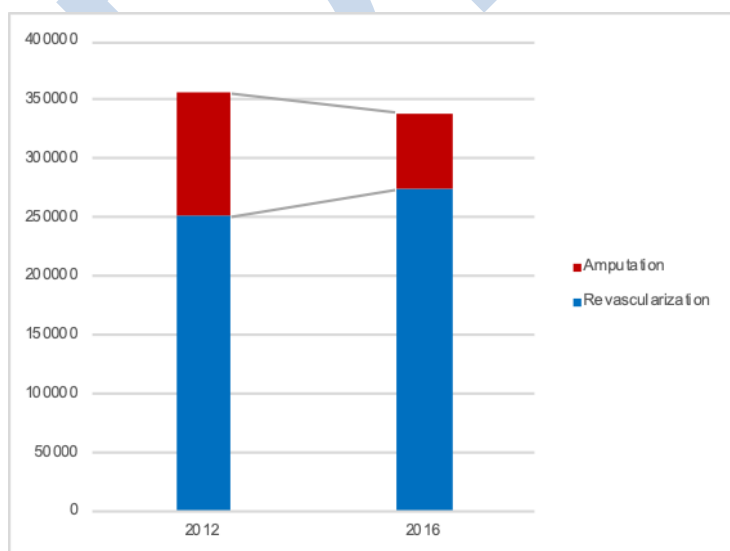


Figure B 1: Estimated LHA expenditure of hospitalizations for diabetes-related revascularizations and lower limb amputation per 100,000 residents – Average of the four-year period between 2009 and 2012.

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).



1534 Figure B 2: Estimated LHA expenditure of hospitalizations for diabetes-related
1535 revascularizations and lower limb amputation per 100,000 residents in Pisa – Average of
1536 the four-year period between 2013 and 2016.

1537 Finally, thanks to a large sharing process among all the clinicians involve in the diabetic
1538 foot care pathway and the different resource allocation the Pisa LHA amputation rate
1539 decreased from 100,43 in 2012 to 51,98 in 2016.

1540 Source: [102]

1541 **The importance of national and local clinical cultures**

1542 Sometimes variation is warranted by differences in need, but much of the variation is
1543 unwarranted. Wennberg attributed this not to poor quality care but to differences in
1544 clinical culture [97]. When it is clear that everyone needs an intervention – to have their
1545 blood pressure measured, for example – then everyone knows what to do. As soon as
1546 judgement is required, however – about which people with moderately raised blood
1547 pressure should be treated – then culture becomes important. Obviously one doctor's
1548 interpretation of the evidence can vary from another's which explains variation between
1549 clinicians, but what Wennberg found was that a different culture could be identified in
1550 different clinical communities. In some communities of practice, surgery for back pain
1551 was viewed as something to offer early. In others it was regarded as a last resort. He
1552 demonstrated that there was a certain way of working that he described as a surgical
1553 signature that described the pattern of intervention in a population.

1554
1555 'Surgical signatures reflect the practice patterns of individual physicians and local
1556 medical culture, rather than differences in need – or even differences in the local
1557 supply of surgeons.'

1558 The development of this culture takes time, and the culture endures because the
1559 community of practice often relates to one medical school that plays an important role in
1560 the development of the culture by ensuring new entrants to the specialist training
1561 programmes develop the signature of that programme. Then, when one community
1562 needs to recruit a new specialist, they choose the applicant from a shortlist, all of whom
1563 have been trained and inculcated in the style of practice promoted by the medical school,
1564 because they are closest to the preferred local variant of the style of practice.

1565 Most clinicians are unaware of how they compare with other clinicians, not in terms of
1566 quality but in terms of value. This requires performance to be related to the population
1567 served and not to the number of patients treated, which measures quality not value. It is
1568 important to emphasise that, although some variation results from financial incentives in
1569 health services which have fee-for-service payment of doctors, unwarranted variation is
1570 found in services which have doctors paid by capitation or salary with no financial

1571 incentive to do more. The wish to do good and the belief that more is better leads to a
1572 drift in the threshold at which an intervention is offered.

1573
1574

DRAFT

1575 Box 7: Case Study on Reduction of unwarranted variation of IZZI/ Zinnige Zorg
1576 ("Sensible Care"), The Netherlands

1577 In 2013, the "Zinige Zorg" program - based at the Dutch Zorginstituut (ZIN) - was
1578 established: it has the task of systematically determining the appropriateness of
1579 interventions with large variances in practice - despite age and morbidity standardization
1580 - and consequently to reduce inappropriate medical services. This is being attempted in a
1581 multi-stage process: Through this program the Dutch healthcare system is systematically
1582 analyzed, per ICD-10 domain, to identify and remove inappropriate care. Interventions
1583 with large differences in specific indication areas (hip and knee surgery, aftercare for
1584 primary breast cancer or skin cancer, care for lung and terminal colon cancer) are
1585 identified via data analyses of Dutch social security funds. The data analyses and the
1586 corresponding scientific evidence from guidelines will be handed over to the respective
1587 medical societies for a period of about 12 months in order to develop criteria for
1588 appropriate indications and ultimately to implement them in conjunction with a further
1589 process step of development of patient information for shared decision-making.

Methodology

Purpose: promoting appropriate care in the consultation room



1590 Additionally, an IZZI reference network of European Healthcare Institutes has been
1591 established aiming to discuss, support and develop similar initiatives that stimulate
1592 appropriate care.
1593 See more details in Appendix
1594
1595

1596 The impact of unwarranted variation on individuals

1597 To regard the values of an individual and the values of a population as separate issues is
1598 misguided. As the intensity of healthcare interventions changes, so the relationship
1599 between the benefit and the harm for a population changes, and the balance between the
1600 probability of benefit and the probability of harm for an individual patient also changes.

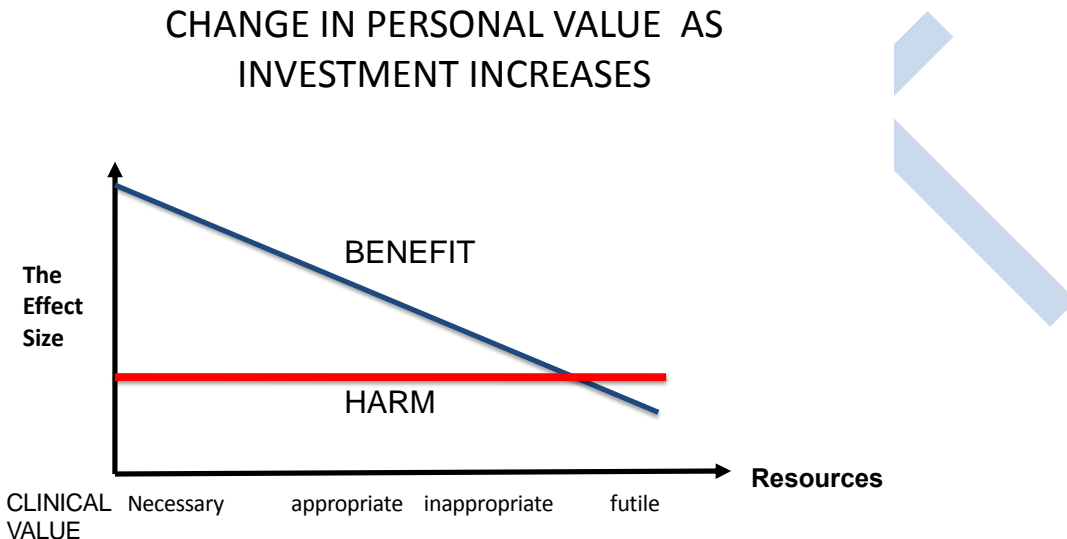
1601
1602 What has emerged is a recognition that changes in value at a population level are
1603 accompanied by changes in clinical practice and decision making

- 1604
- As more resources are invested in a system of care
 - 1605 • Treatment is offered to people who are less severely affected
 - 1606 • Such people will receive less benefit because their problem is less but

1607 • The probability and magnitude of harm they might experience , for example form
1608 an operative complication, is the same as for people who are more severely
1609 affected

1610 A new language has emerged with concepts of appropriateness and futility. The changing
1611 relationship can be expressed diagrammatically

1612 Figure 5: Concepts and terminologies in defining clinical value



1613 Source: own presentation M. Gray

1614
1615
1616 Al Mulley and his colleagues, at Dartmouth University, have coined the term 'the silent
1617 misdiagnosis' [103] to describe the common situation in which clinicians have accurately
1618 diagnosed a disease but have failed to identify the patient's preferences, goals and
1619 values. They argue that not only do decisions need to be based on the best current
1620 evidence but also that decision-making needs to be sensitive to the preferences of
1621 individual patients. When seeking to explain the causes of unwarranted variation,
1622 Wennberg noted that patients' preferences were often either not elicited or, if they were,
1623 their preferences were ignored.

1624
1625 "...elective, or "preference-sensitive" care, interventions for which there is more
1626 than one option and where the outcomes will differ according to the option used
1627 because patients delegate decision making to doctors, physician opinion, rather
1628 than patient preference, often determines which treatment patients receive. I
1629 argue that this can result in a serious but commonly overlooked medical error:
1630 operating on the wrong patients – on those who, were they fully informed, would
1631 not have wanted the operation they received" [104].

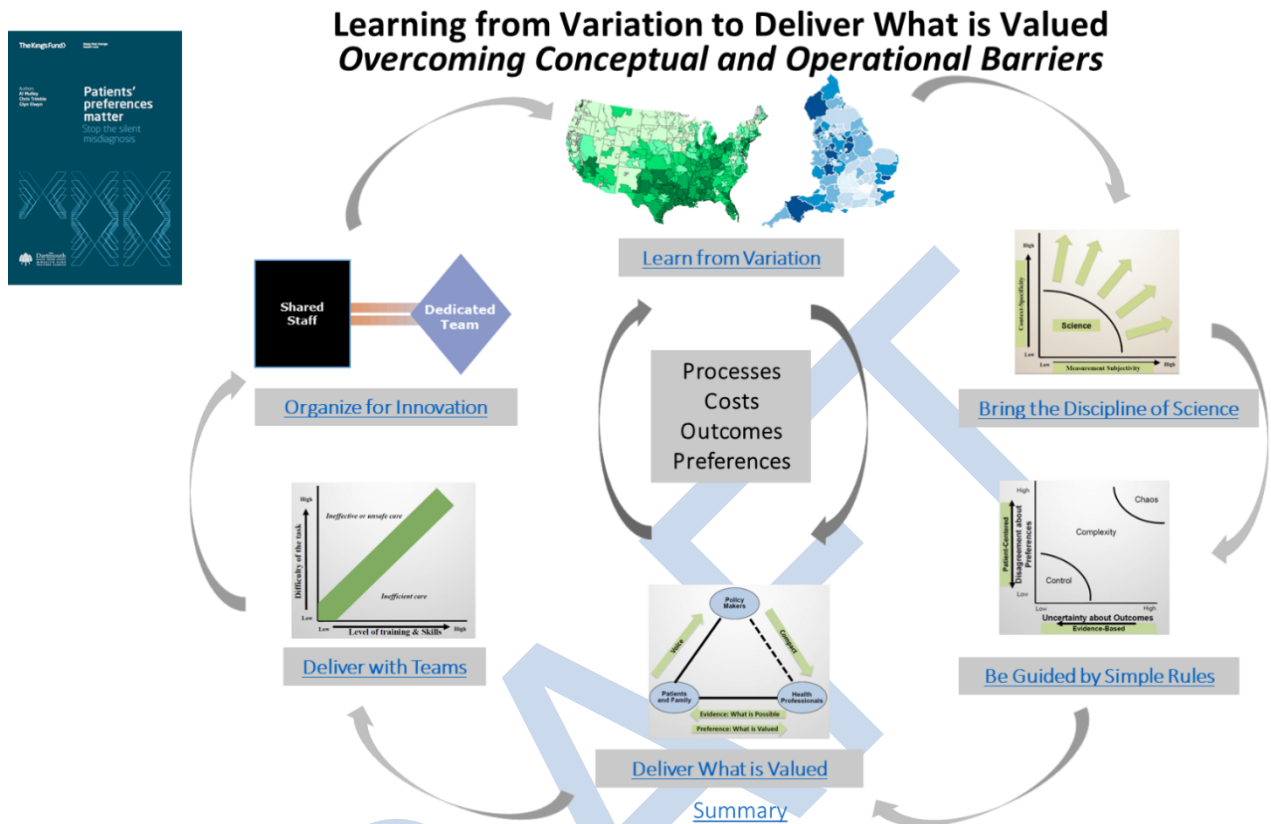
1632 From the perspective of the patient, the value of the care received is measured not only
1633 by its outcome but also by the way it is delivered. The value that patients are prepared
1634 to place on the care received will be reduced if they feel that:

- 1635 • their time has been wasted waiting in a clinic for a consultation at which
1636 laboratory results were unavailable;
- 1637 • they were treated rudely and impersonally;
- 1638 • they did not receive as much information as they wished.

1639 In all health systems, patients' perceptions of the value of services are of central
1640 importance. Good outcomes are necessary but not sufficient; good patient experience is
1641 of central importance to the 21st century patient, and therefore to those who provide and
1642 pay for their care.

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1643 Figure 6: Unwarranted variation: Learning cycle for better understanding and increase of
 1644 high value care



1645
 1646 Source: [103]

1647 **3.3.4. Less might be more: Disinvestment for reallocation**

1648 In 2004, Johnston affirmed that “increasing value requires experimentation and careful
 1649 performance measurement using actionable and specific indicators. Benchmarking within
 1650 and across countries, and sharing information can help” [105]. Indeed, benchmarking
 1651 can play an important role in disinvestment decisions because it helps to identify where
 1652 resources can be freed. This means that disinvestment includes both service reductions
 1653 due to inappropriateness and savings achieved through better efficiency identified
 1654 through benchmarking (e.g. lower cost for the same output) [106]. In this sense, the
 1655 overlap between disinvestment and rationing could be avoided. Although freeing
 1656 resources does not necessarily mean savings, it allows governments to reallocate
 1657 healthcare workers. A 2007 study estimated that the amount of resources, which could
 1658 be disinvested and then reallocated within the Tuscany Region varied between 2–7% of
 1659 the total regional healthcare budget. A similar approach was applied to care provided to
 1660 patients with chronic heart failure pathway, seeking to reduce differences between
 1661 patients of high and low socio-economic status. Reducing inequity frees financial
 1662 resources for reallocation [107]. This approach stresses a specific aspect of

1663 disinvestment: improving performance on indicators that have a positive return on
1664 efficiency. Disinvestment has numerous synonymous terms such as "withdrawing from a
1665 service and redeploying resources", "decommissioning", "delisting", "resource release",
1666 and "defunding", while the term "disinvestment" is not used consistently. Elshaug [108]
1667 defines "disinvestment [as] the process of (partially or completely) withdrawing health
1668 resources from any existing healthcare practices, procedures, technologies, or
1669 pharmaceuticals that are deemed to deliver little or no health gain for their cost and thus
1670 are not efficient health resource allocation".

1671 **Box 8: Initiatives on Polypharmacy and De-Prescribing**

1672 Polypharmacy is commonly defined when a patient is simultaneously taking five or more
1673 medicines. Widely recognized polypharmacy-related concerns, particularly in elderly, are
1674 addressed by deprescribing. It focuses on withdrawing non-beneficial or even harmful
1675 medications. For instance, in Canada, an approach to include deprescribing into all
1676 treatment guidelines had been suggested. As an example, deprescribing
1677 recommendations enriched dementia care guidelines.
1678 In the structured medication management perspective a wide range of guidelines and
1679 screening tools are available for deprescribing like BEERS criteria, STOP/START criteria,
1680 Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE), STRIP,
1681 NO TEARS, STOMP, Appropriate Medications for Older people (AMO)-Tool, Prescribing
1682 Optimizing Method (POM), ARMOR, etc.
1683
1684 In addition, a variety of computerized prescription tools brought into practice in many
1685 countries have shown their positive effects at least in reducing prescription errors. Some
1686 of the above-mentioned tools are categorized as explicit or criteria-based in contrast to
1687 implicit ones. The latter include the patient preferences to judge the choice. To facilitate
1688 practical applications, Ottawa innovation program introduced credible and relatively
1689 simple guidelines to support medical professionals in reducing or stopping medications in
1690 five particular drug classes. Moreover, the guidelines are accompanied with decision
1691 support tools and those for communication with patients.
1692 Due to recognizing a value of shared-decision making in reducing unnecessary
1693 medications various approaches, particularly more active ones, to improve
1694 communication with patients are tried. Furthermore, innovations in education for health
1695 professionals as well as providers' networking in the field of deprescribing should be
1696 considered [109, 110].
1697
1698

1699 Activities which can all be summarized under the umbrella term "Dis-Investment" or
1700 omission and withdrawal of inappropriate technology have been subject to increased
1701 research since 2006 [111]. In particular, Health Technology Assessment (HTA) which was
1702 initially used to support "investment" decisions, recently started to be used for "dis-
1703 investment". A crucial issue in disinvestment is the need to involve health-care providers
1704 and commissioners in decision-making processes [112]. The inclusion of health
1705 professionals and patients in disinvestment decision making is proposed as one strategy
1706 to overcome these diverging interests, while facilitating transparent identification of
1707 candidates for disinvestment. However, previous studies show that health professionals
1708 are reluctant to disinvest, as this can be perceived as a rationing instrument, which will

1709 restrict clinical autonomy and reduce patient choice [111]. In this context, socio-technical
1710 approaches may help to engage stakeholders with conflicting objectives in confronting
1711 tightening budgets. Airoldi (2013) argued that well designed socio-technical approaches
1712 can overcome stakeholder resistance because of (1) the collective character of the
1713 deliberations; (2) the analysis of the whole pathway; (3) the involvement of patients;
1714 and (4) the development of a model based on cost-effectiveness analysis principles,
1715 which provided a credible rationale for difficult decisions [113].

1716 Since disinvestment requires, at least initially, an increase in resources and capacities,
1717 additional funding should be assigned to institutions conducting disinvestment activities,
1718 as powerful interest groups can make disinvestment challenging.

1719 Box 9: Research findings on aggressive vs. palliative end-of-life care

1720
1721 Care for cancer patients near the end of life has two major goals: extending life and
1722 managing symptoms to maintain quality of life. The potential survival benefit of
1723 anticancer therapy (including conventional chemotherapy, hormone therapy, and
1724 targeted therapy—collectively referred to as “systemic therapy” hereafter) for patients
1725 with advanced disease is modest, especially in later lines of therapy toward the end of
1726 life, and statistically significant improvements observed in clinical trials are not
1727 necessarily clinically significant. Recently approved drugs for advanced cancer have
1728 demonstrated increased toxicity independent of clinical effectiveness, suggesting that the
1729 balance of harms to benefits might be worsening. The use of systemic therapy near the
1730 end of life can expose cancer patients to severe toxicity for minimal survival gain and
1731 comes with a high cost. Early palliative care is recommended, but there is evidence that
1732 aggressive care remains common [114].

1733
1734 The well acknowledged landmark study by Temel et al. could demonstrate that patients
1735 assigned to early palliative care had a better quality of life than did patients assigned to
1736 standard care. In addition, fewer patients in the palliative care group than in the
1737 standard care group had depressive symptoms. Additionally, despite the fact that fewer
1738 patients in the early palliative care group than in the standard care group received
1739 aggressive end-of-life care, median survival was longer among patients receiving early
1740 palliative care [115]. Several later randomized studies involving patients with advanced
1741 cancer show that integrating specialty palliative care with standard oncology care leads
1742 to significant improvements in quality of life and care and possibly survival [116, 117].

1743
1744 Ever more international quality initiatives develop indicators that measure the quality of
1745 cancer care. The most commonly used generic quality indicator relates to end-of-life
1746 care: Death in a bed in acute care, intensive care and systemic therapies in the last few
1747 weeks of life is associated with negative quality of care [118]. Recent analyses of routine
1748 data from Switzerland or seven Western countries show that in Belgium, Canada,
1749 England, Germany and Norway (38.3–52.1%) the proportion of those who died in
1750 hospitals was significantly higher than in the Netherlands and the USA (29.4% and
1751 22.2%, respectively) [119].

1752

1753 Box 10: Case study on second medical opinions before elective surgery, Germany

1754 Each year more than 13 million operations are carried out in Germany (Federal Statistical
1755 Office 2010). From 2005 to 2008 their number increased by about 1.5 million. Operations
1756 on the musculoskeletal system are the most common [120]. The leading interventions
1757 are arthroscopic interventions (approximately 600,000): on articular cartilage, menisci,
1758 synovialis and in the form of arthroscopic joint revision. Critical assessments and data
1759 available do not support some of the therapies in specific indications. A randomized study
1760 in 2002 showed that arthroscopic lavage or debridement was not more effective than
1761 sham surgery in patients with knee pain and joint arthrosis [121]. A subsequent
1762 randomized study confirmed that the efficacy of arthroscopic intervention combined with
1763 conservative therapy was no greater in knee osteoarthritis after six and 24 months than
1764 in conservative therapy alone [122]. Also, the effectiveness of vertebroplasties is
1765 controversial. Two randomized studies published in 2009 could not find a significant
1766 effect on pain and spinal function by injection of bone cement in osteoporotic vertebral
1767 fractures. Germany has eight times as many vertebroplasties per million inhabitants as
1768 France.

1769
1770
1771 The increasing amount of some elective surgeries, some of them prone to frequent
1772 suspicion to questionable indications, has resulted in the explicit offer of second opinions
1773 of many German health insurances to their patients. These second medical examinations
1774 and consultations have a considerable influence on the treatment: According to Barmer-
1775 GEK, three quarters (72%) of those affected will make a new therapy decision.
1776 Operations in which a second opinion is often helpful: Knee (meniscus, cruciate ligament,
1777 etc.), back / spine, hip and disc, shoulder and neck as well as dental prosthesis [123].

1778
1779 Patient-driven second opinions are also increasingly sought in oncology, the reported
1780 disagreement between the first and second opinion (2%-51%) range widely. The primary
1781 motivations of patients are a need for certainty, lack of trust, dissatisfaction with
1782 communication, and/or a need for more (personalized) information [124].
1783

1784 **3.3.5. Corruption, Fraud, misuse**

1785 Another area of waste arises from corruption, fraud and misuse. In recent years, the
1786 fight against corruption in the healthcare sector has intensified due to the growing
1787 recognition that corruption in its various forms heavily distorts national healthcare
1788 programs, undermines the aims of health policy, and obstructs reforms, leading to a
1789 tremendous waste of resources. Recent reports estimate the cost of fraud in healthcare
1790 as between 3% and 8% of national health expenditures [125]. Estimates from the
1791 European Healthcare Fraud and Corruption Network (EHFCN, <http://www.ehfcn.org/>)
1792 calculate an approximate €56 billion annual loss to Europe as a result of corruption. To
1793 promote understanding of the complexity and the interconnection of corrupt activities,
1794 we present healthcare related corruption typologies of the European Union and EHFCN
1795 [126, 127]: along a spectrum in which waste (loss of value) is distinguished from
1796 corruption, fraud, misuse and error (See Appendix for main categories and definitions of
1797 corrupt activities according to the European Union (EU) typology).

1798

1799 Table 4: The main categories and definitions of corrupt activities according to the
 1800 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'

1801
 1802 Evidence of the connections between corruption, scientific fraud, and lack of transparency
 1803 (undisclosed conflicts of interest, paid guidelines, selective publication, etc.) is abundant
 1804 [128, 129] and provided the rationale for regulations to disclose payments made to
 1805 healthcare professionals, such as sponsorship to attend meetings, speaker fees,
 1806 consultancy and advisory boards. The demand for transparency arose from the
 1807 perception that a lack of transparency creates a "culture of opportunity". In addition to
 1808 frank corruption there are numerous examples of scientific fraud: While clearly
 1809 counterfeit studies are considered wrong, tendentious and / or selective reporting and
 1810 the publication of the work of ghostwriters under their own name is still seen by some as
 1811 a minor offence.

1812 **3.3.6. Clinician’s initiatives to “choose wisely” as basis for**
 1813 **communication with patients**

1814 A growing number of international initiatives are rising to the challenge to reduce low
 1815 value medical care and overuse. What is completely new, however, are initiatives that
 1816 are not motivated by health administration and policy, but are supported by the
 1817 providers of medical services, i.e. by clinicians themselves. These activities aim to
 1818 identify and avoid inappropriate health interventions. The "Choosing Wisely" initiative,
 1819 launched in 2012 by the American Board of Internal Medicine (ABIM) under Christine
 1820 Cassel, has received a great deal of attention since its inception and has already
 1821 attracted a number of imitations in North America (Canada) and Europe (Switzerland,
 1822 Germany, The Netherlands). None of the initiatives is about reducing health services on a

1823 large scale or even removing them from the service catalogues. In most cases, only a
1824 targeted and needs-based provision of services (today often referred to as patient-
1825 centered) is to be achieved. The fact that costs are saved is a welcome side effect. The
1826 intention of all initiatives is to reduce wasteful overprovision and overtreatment; some
1827 want to achieve this with the help of joint decision-making between patients and doctors.
1828 It is also about improving the quality of care, patient satisfaction through education and
1829 co-determination and, last but not least, increased safety for patients.

1830 At first glance, the various initiatives follow a fundamentally similar path [130]. First,
1831 ineffective services are identified and supported by literature reviews and communication
1832 with service providers (physicians and other interest groups). The result is a list of
1833 services that need to be questioned. However, the main differences lie in the details, for
1834 example in the addressees (only doctors, or also patients and consumers), in the breadth
1835 and depth of the underlying sources of information for identification (evidence analyses
1836 for identification with subsequent involvement of "stakeholders" or identification by
1837 service providers with subsequent evidence analyses), in methods of prioritization (use of
1838 prioritization instruments with criteria vs. instruments for consensus finding) and not
1839 least in dissemination and implementation strategies (dissemination in conferences and
1840 specialist committees vs. linking to guidelines, data analyses with formulation of target
1841 application values) [130].

1842 Analyses of the impact of the initiatives and of implementation barriers are not yet
1843 available. For some initiatives, this would still be too early. Criticism is mainly levelled at
1844 the fact that most of the services identified as ineffective or inappropriate have been
1845 known for a long time and that initiatives for implementation, rather than identification,
1846 are needed (See Appendix for Initiatives by clinicians to identify low value interventions).

1847 **3.3.7. R&D: Initiatives to create public value in healthcare research**

1848 The concept of value has risen in importance in discourse on research for innovation,
1849 primarily because of concerns about the very large sums reported by pharmaceutical
1850 companies as necessary to develop new medicines, which must then be recouped from
1851 sales that are, in many countries, largely paid for from the public purse. These concerns
1852 are coupled with questions about the extent to which the resulting products represent
1853 added value, given the lack of pipelines for certain products where there is a clear need,
1854 such as new antibiotics, while some manufacturers concentrate on what are termed "me
1855 too" products, adding little, if anything, to what already exists. This issue has attracted
1856 even greater prominence following proposals for new ways to pay for innovative
1857 medicines and, in particular, what has been termed "value-based pricing", where the
1858 price of a medicine is linked to the "value" that it provides. The basic reason to have such

1859 a link is to provide a higher reward for a better, higher-value, innovation. The economic
1860 principle behind it is that profit-maximizing companies will naturally invest more if a
1861 higher price is allowed, meaning that prices based on value would provide a strong signal
1862 for higher-value innovation to be pursued.

1863 A quite distinct argument is that prices should be set equal, or close, to value of
1864 products. Such a rule naturally respects that prices should be different according to value
1865 to serve as a guide for innovation. However, it brings in another issue, the extraction of
1866 economic rents (also termed sometimes excess profits) by companies providing these
1867 innovations. That is, the same prices that guide innovation also have the role of dividing
1868 the value created between healthcare payers (representing the population covered) and
1869 innovative companies. The two effects, providing correct signals for R&D efforts and
1870 economic rents extraction (value split across economic agents), should be clearly
1871 separated.

1872 The role of value in discussions regarding innovation has been extremely controversial
1873 and has led to a reassessment of the meaning of value in this concept, most notably in
1874 the work of Mazzucato. In her earlier work she challenged the widely held view that most
1875 innovation was a result of entrepreneurial activity by highly competitive private
1876 companies, instead showing, for example with reference to the iPhone, that while Apple
1877 developed the final product, this was only possible because many of the technological
1878 developments that go into it were developed in universities and government institutions,
1879 and largely with public funding [131]. More recently, she has turned her attention to
1880 pharmaceutical innovation and pricing and, in particular, the concept of value-based
1881 pricing.

1882 Her most recent study on the concept of value traces how this has changed markedly
1883 over time [132], from the writings of classical economists such as Smith, Ricardo, Marx
1884 and others, whereby the value added was a function of the inputs used to produce
1885 something, in labour and, originally, the land from which agriculture came or minerals
1886 extracted, to the relatively recent neo-classical idea that equates value with the price
1887 that someone is willing to pay. What they will pay is, however, determined by a process
1888 of negotiation in which the manufacturer maintains property rights, in the form of
1889 patents, over the product in question. This system, it is argued, is necessary for
1890 innovation to occur (otherwise, absent any significant reward, including the possibility to
1891 recoup the cost of R&D investment, innovators would not produce the innovation in the
1892 first place). Yet, as she argues, it is questionable whether this system promotes
1893 innovation as widely as is claimed, citing examples where patents block future advances.
1894 However, she takes particular aim at value-based pricing.

1895 Noting how an Executive Vice President of Gilead sought to justify the extremely high,
1896 and also controversial [133] price of Sovaldi, contending that “pricing is the wrong
1897 discussion... value should be the subject”, while a former vice president of Pfizer argued
1898 that “in the mind of patients, physicians, and payers, the pricing of drugs should have
1899 little to do with the expense of biomedical R&D, nor should be associated with recouping
1900 R&D investment. Pricing should be based on only one thing – the value that the drug
1901 brings to healthcare...”.

1902 She notes how the application of the existing model can, in certain settings, limit prices,
1903 as in England where NICE will not support payment if a medicine exceeds a certain cost-
1904 utility threshold, but at the cost of excluding individuals from coverage. Where such
1905 institutional arrangements do not exist, however, as in the USA, this model can allow
1906 manufacturers to charge astronomic prices that bear no relationship to their costs. Noting
1907 how, if the logic was followed through, basic therapies such as vaccines would be
1908 incredibly expensive, she argues for a fundamental reassessment of the concept of value
1909 that recalls its original meaning in classical economics.

1910 The institutional mechanisms using cost-utility thresholds often allow prices to go up until
1911 they meet this threshold. At a more general level, this calls for a reassessment of the
1912 mechanisms that set prices, breaking the implicit idea of price being defined as the
1913 maximum monetary value society is willing to pay. This point was discussed in EXPH
1914 (2018) [20] in more detail. The issue is not the definition of value, but rather accepting
1915 as adequate and reasonable the transfer of full surplus through prices to the producer.
1916 Using the right notion of value is important, but insufficient to deal with the issues
1917 associated with price determination (as a tool to divide value between relevant economic
1918 agents).

1919 Besides criticism of research priorities by pharmaceutical companies, the “waste in
1920 research” has become a widely recognized and discussed issue. The lack of clear research
1921 priorities, failure to publish negative results, and the inaccessibility of some clinical
1922 research, duplication of studies that have already been done, and finally the lack of
1923 research providing worthwhile achievements were discussed at length in a Lancet series
1924 on “Research: increasing value, reduce waste” in 2014 that was preceded or
1925 accompanied by initiatives such as Research Reporting Guidelines, EQUATOR or the
1926 AllTrials” Campaign. It has been estimated that 85% of research is wasted, usually
1927 because it asks the wrong questions, is badly designed, not published or poorly reported
1928 [71]. While this primarily diminishes the value of research, it also represents a significant
1929 financial loss (See Appendix for Initiatives by researchers against waste and for
1930 increasing value research).

1931 Further activities resulted in scientific papers on overdiagnosis and –treatment (BMJ,
1932 JAMA) and the launch of an annual conference providing space for research results on the
1933 impact on patients’ harm due to “accelerated” (diagnostic creep: widening disease
1934 definitions) medicine.

1935 **3.3.8. Initiatives to increase policies for better value**

1936 Several policies (or groups of policies) aimed at obtaining better value per unit of health
1937 spending had unexpected results in the medium and long-run, as providers, being
1938 economic agents, adjust their decisions to the context of these policies. This has
1939 resulted, over time, in perverse effects (that is, contrary to those intended when the
1940 policies were initiated and adopted). Three relevant examples are pay-for-performance,
1941 cost-effectiveness thresholds and value-based healthcare.

1942 Pay-for-performance (P4P): Paying according to results has been introduced over the
1943 years as a guiding principle in the acquisition of health services in some settings.
1944 Payment systems have to be grounded in observable and verifiable elements. Thus, pay-
1945 for-performance often uses activity measures that are readily available instead of
1946 outcome measures (difficult to define and to observe precisely). This leads to incentives
1947 to greater activity, without necessarily corresponding to better outcomes. This may lead
1948 to unintended effects such as more activity, and more healthcare costs, without matching
1949 benefits (e.g. offering musculoskeletal operations without effectively improving
1950 mobility/pain levels).

1951 **Box 11: Perverse incentives**

1952
1953 Sometimes the incentives to increase the value of healthcare may lead to adverse
1954 effects. In such cases, the incentives might be described as “perverse”.

1955 The high efficacy of the health system is a desirable feature. Efficacy, however, is
1956 measured as units produced in relation of resource use. If for example GP:s are
1957 evaluated of the basis of the number of patient visits, their way to maximize the efficacy
1958 might be to see the same patient many times (instead of more time requiring new cases)
1959 or have many uncomplicated patients visiting instead of one complicated one, who would
1960 require a lot of time and effort. In this type of performance assessment, the most
1961 “efficient” activity would actually lead to waste of resources, while the health demands of
1962 some patients would not be satisfied at all.

1963
1964 The quality of surgical operations requires that one doctor performs an adequate number
1965 of operations annually. If, however, the activities of a hospital are made dependent on
1966 the number of certain surgical procedures, the indications for those operations are easily
1967 diluted. I.e. instead of following the accepted standards, the surgeons start to operate
1968 milder cases than usual to have adequate numbers of operations for the hospital license.
1969 Sometimes there are incentives that try to cover the whole care path. Emergency room
1970 visits often correlate to the poor quality of care of chronic diseases. However, if the
1971 payment for a healthcare provider is diminished on the basis of the number of
1972 emergency room visits, he might try to prevent doctors to send patients to hospital even
1973 when they desperately need acute care. This might lead to excess mortality instead of
1974 better care of chronic diseases.

1975
1976

1977 Cost-effectiveness thresholds as implicit rule to define prices: The use of cost-
1978 effectiveness thresholds by health authorities, where cost from the perspective of the
1979 healthcare payer is determined to a considerable extent by the prices set by providers of
1980 care, creates an incentive for privately determined prices to rise up to the point of
1981 meeting the threshold. This is an unintended consequence. In the absence of price
1982 competition on the provision of the product or service, a common situation in the case of
1983 new products or services, this constitutes an undesirable side effect from the payer's
1984 perspective.

1985 The discussion of value-based healthcare has centred mostly on the valuation of benefits.
1986 Although quite important, solely focusing on benefits neglects the role of underlying
1987 (opportunity) costs in the decision-making process of choice of where to allocate funds in
1988 healthcare. This "distraction" introduces the potential for bias in decisions regarding both
1989 prices and access conditions of new products and services. Reacting to this "distraction"
1990 on the micro-level of decision-making (e.g. investments in hospitals) programme
1991 budgeting has been introduced in some taxed based National Health Systems (NHS)
1992 supporting decisions on the macro-level (e.g. allocation of resources to patient
1993 populations).

1994

1995 Box 12: Programme budgeting

1996

1997 In the last few decades, the focus on strategies in healthcare has been placed on the
1998 improvement of quality, safety, effectiveness and efficiency: the targets of interest being
1999 the organisations that pay for and supervise healthcare and the institutions (hospitals,
2000 primary care health centres) that provide primary, secondary and tertiary prevention and
2001 care. However, progress has been made: a re-organisation of structures has been a
2002 feature of many services, together with managerial changes in funding designed to
2003 stimulate greater efficiency.

2004

2005 Nonetheless, this is not perceived as sufficient and a shift in focus on population health is
2006 now needed [134, 135]: Programme budgeting puts the focus on (patient) population
2007 funding. A program budget is a framework by which the health system administration
2008 allocates the available resources to different patient populations and activities. In the
2009 context of intense budget expenditure invested in very small patient populations (e.g. in
2010 oncology 30-40% of in-hospital drug expenses for 5% of the hospital patient population),
2011 which generates only small clinical benefits, programme budgeting facilitates a re-
2012 focusing and reallocation of resources.

2013

2014 The populations are defined by need, ranging from people with asthma or people with
2015 back pain to people with frailty in the last year of life. This additional population-based
2016 dimension facilitates the development of value-based healthcare. This requires a change
2017 in prioritisation from institutional budgeting to programme budgeting, by identifying all
2018 the resources invested in services for all the people in need, be it cardiovascular disease

2019 or cancer. This allows not only the estimation of value but also the involvement of
2020 clinicians, since clinical behaviour determines much of how resources are employed and
2021 therefore the investment pattern. Hence, the responsibility for the stewardship and for
2022 the freeing of resources for reinvestment lies with the clinicians, instead of being based
2023 on explicit decisions made by payers [136].
2024

2025 **3.3.9. Initiatives for fair access to value-based products and**
2026 **innovative payment methods**

2027 Health systems have the goals of providing access to affordable necessary care to people
2028 and ensuring financial risk protection. In this context, if there were no concerns
2029 regarding promotion of R&D of new products and services, prices should approximate to
2030 opportunity costs of production, irrespective of how benefits from its use are distributed.
2031 In particular, two products or services with the same production costs should have
2032 similar prices, even though patients (and/or society) may value them differently.
2033 Otherwise, if prices are significantly above the opportunity costs of production, the result
2034 is either lower access or redistribution of value from people (either patients, taxpayers or
2035 contributors to health insurance protection systems) to companies (providers). It is the
2036 need for adequate incentives for R&D of new products and services that leads to a
2037 departure from this view.

2038 Under decentralized models of R&D, intellectual property rights (IPR), mainly patents,
2039 has two important roles to perform. First, prices that are set under patent protection
2040 provide a way for companies to recover and have a return on the R&D costs they
2041 incurred. It provides the financial incentive to firms to invest in R&D. Second, the relative
2042 prices accruing to new discoveries will guide the efforts toward one type or another of
2043 innovation. Prices have also the role of guiding the type of innovation pursued. For equal
2044 amount of R&D costs, companies (or profit-oriented research units) will be guided by the
2045 higher price (or prospective price) of a particular innovation. Pricing according to the
2046 value of the innovation then guides R&D efforts to higher value innovations.

2047 This role only requires that a higher price is positively correlated with a higher value of
2048 the innovation. It does not require that price equals value, which would mean total value
2049 extraction by which entity owns the innovation.

2050 This simplified view highlights the fundamental trade-off to be addressed: prices both
2051 distribute value and provide signals for R&D efforts. The pricing mechanisms need to
2052 explicitly address both concerns. One needs to recognize that value-based pricing, in the
2053 sense of prices reflecting value, is to be understood as a relative statement: different
2054 prices for different innovations, according to the difference in value they bring.

2055 As detailed in EXPH (2018) [20], there is a role for price negotiation, on top and above
2056 HTA methodologies to screen the contribution of each innovation, and a role for more

2057 transparency in R&D costs, as this will reveal the distribution of monetary value that is
2058 generated. Cost transparency does not mean that prices should be set against R&D costs
2059 directly. Cost-plus pricing of innovation would just stimulate higher-cost R&D efforts,
2060 irrespective of contribution to society. A broad knowledge of the R&D costs would,
2061 nonetheless, provide information on margins earned, and disclosure of this information
2062 would allow for affordable access to new products.

2063 Focusing the discussion only on value and measuring it, however accurately, does not
2064 ensure fair access. High prices of new products and services lead payers to limit patient
2065 access. Patients tend to identify value with satisfaction with health outcomes, irrespective
2066 of the underlying costs and of whether, or not, paying for their care displaces healthcare
2067 provided elsewhere in the health system. In addition, as pointed out in Mazzucato and
2068 Roy (2017) [137], value-based pricing as a result of a (particular) value-based
2069 healthcare approach does not recognize the role of public funds (the “entrepreneurial
2070 state”) in value creation.

2071 As argued in EXPH (2018) [20], pricing mechanisms need to address several concerns,
2072 and value-based pricing does not follow automatically from value-based healthcare
2073 considerations as the pricing mechanism that best achieves health systems’ goals.

2074 Several initiatives have emerged in recent years to meet the concern with high prices
2075 and patient access to innovation. These initiatives can be divided into two broad groups.

2076 1. On the one hand, international organizations have promoted discussions on the
2077 issue (OECD 2017, EXPH 2018, WHO 2015, the Fair and Affordable Pricing
2078 initiative, the WHO collaborative procedure, among others).

2079 2. The second group is constituted by the initiatives of countries creating joint
2080 actions: the BeneluxA initiative, the Visegrad group, the La Valletta group, the
2081 FINOSE group, and the Baltic partnership.

2082 Box 13: Initiatives to increase Access to Medicines

2083 **BeNeLuxA** (<http://www.beneluxa.org>): Belgium, Netherlands, Luxembourg, Austria and
2084 Ireland. While recognizing that price and reimbursement decisions are retained at the
2085 country level, the group jointly negotiates prices of innovative drugs, aiming for a lower
2086 value (more affordable access to innovation). Cooperation extends to horizon scanning,
2087 health technology assessment (aiming for joint analysis) and information sharing.
2088 According to the information publicly available, joint negotiation in the context of the
2089 Beneluxa group of a price for a new product was done successfully by Belgium and the
2090 Netherlands.

2091 **FINOSE** (<https://www.tlv.se/in-english/international-collaboration/finose---a-nordic-cooperation.html>): Finland, Norway and Sweden. The initiative from countries’ authorities
2092 aims to harmonize and share health economic analyses of new products, providing a joint
2093 assessment by the three agencies. It started in March 2018 and it will run as a pilot
2094 project for two years.
2095
2096
2097

2098 **Valletta:** Croatia, Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Slovenia and
2099 Spain. The objectives of the initiative include joint clinical assessment and economic
2100 evaluation. Joint work already started (at late 2018) on several pharmaceutical products.
2101

2102 **EUnetHTA** (<https://www.eunethta.eu/>): Another initiative worth mentioning is the
2103 health technology assessment regulation proposal at the European Union level, building
2104 on the EUnetHTA experience of coordination of collaboration that will enforce the
2105 harmonization of methodologies, reporting and finally uptake of the collaborative
2106 assessments.
2107

2108 **Fair And Affordable Pricing (FAAP):** Hungary, Lithuania, Poland, Slovakia, Czech
2109 Republic (observer status) and Latvia (invited guest). The initiative also aims at
2110 cooperation across countries in pricing of new (pharmaceutical) products. As in other
2111 initiatives, cooperation in technical aspects is the first step. The pricing decisions are kept
2112 at the national level, with no joint negotiation (at least for the moment).
2113

2114 **Nordic Pharmaceuticals Forum (NLF):** Norway, Iceland and Denmark, Sweden
2115 (observer). The initiative started as an informal space for cooperation among the Nordic
2116 countries, concerned initially with security of supply. The Nordic Pharmaceuticals Forum
2117 (NLF – Nordisk Legemiddel Forum) started in 2015
2118 <http://www.amgros.dk/en/areas/nordic-collaboration>). It has the goal of analysing the
2119 possibilities of joint tendering procedures for pharmaceuticals, as the concern on security
2120 of supply is related to older drugs, at the end of their life cycle. It is driven by Amgros,
2121 the pharmaceutical procurement office for the five regional health authorities in
2122 Denmark.
2123

2124 On **joint health technology assessments**, the **BeNeLuxA** initiative is already active,
2125 while the **FINOSE** and **NLF** initiatives are progressing in that direction.
2126

2127 On **joint price negotiations**, the **BeNeLuxA** initiative has concluded successfully one
2128 case, while the **NLF**, **Valletta** and **Visegrad** initiatives are still progressing towards it.
2129 The last two groups also announced the intention of moving to joint procurement
2130 (implying common prices for the group of countries involved).
2131

2132 The Baltic partnership is already active in **joint procurement** but collaboration did not
2133 extend to more areas, explored by other initiatives.
2134

2135 On **horizon scanning** (a forecast to highlight important pharmaceutical innovations
2136 before they reach the market), the BeNeLuxA, NLS, Valletta and Visegrad initiatives have
2137 an interest in pursuing it, while this aspect is left out by the FINOSE and the Baltic
2138 partnership.

2139 **4. CONCLUSIONS and RECOMMENDATIONS**

2140 The European Commission (EC) aims to support the Member States in achieving
2141 effective, accessible and resilient health systems. Effectiveness refers to the health
2142 system's ability to produce positive health outcomes, i.e. to improve the health of the
2143 population. Access is the ease with which individuals in need can obtain health care and
2144 is a function of provision of services, availability (including travel time and opening
2145 hours), and affordability. Resilience is the ability of the health system to adapt effectively
2146 to changing environments and apply innovative solutions to tackle significant challenges
2147 with limited resources. This last section of the opinion will conclude and provide answers
2148 to the questions of the mandate.

2149 In 2017, the OECD report on "Wasteful Spending in Health" [1] brought the topic of
2150 waste of enormous amounts of public resources (estimation of 10% to 30%) to the
2151 agenda of a broader public, emphasising the need for health systems to focus on
2152 spending their resources wisely and efficiently. But awareness of how the scale of low
2153 value care, coinciding with inadequate resources for care of high value, poses a threat to
2154 universal health coverage has been well known for many years by experts in the field. In
2155 this context, the concept of value-based healthcare (VBHC) has developed over time
2156 (since 2001) and many regional and national initiatives started to tackle the problem of
2157 overdiagnosis and -treatment, unwarranted variation, etc. Few of those small scale
2158 initiatives have gone one step further to actually reallocate resources from low value to
2159 high value care.

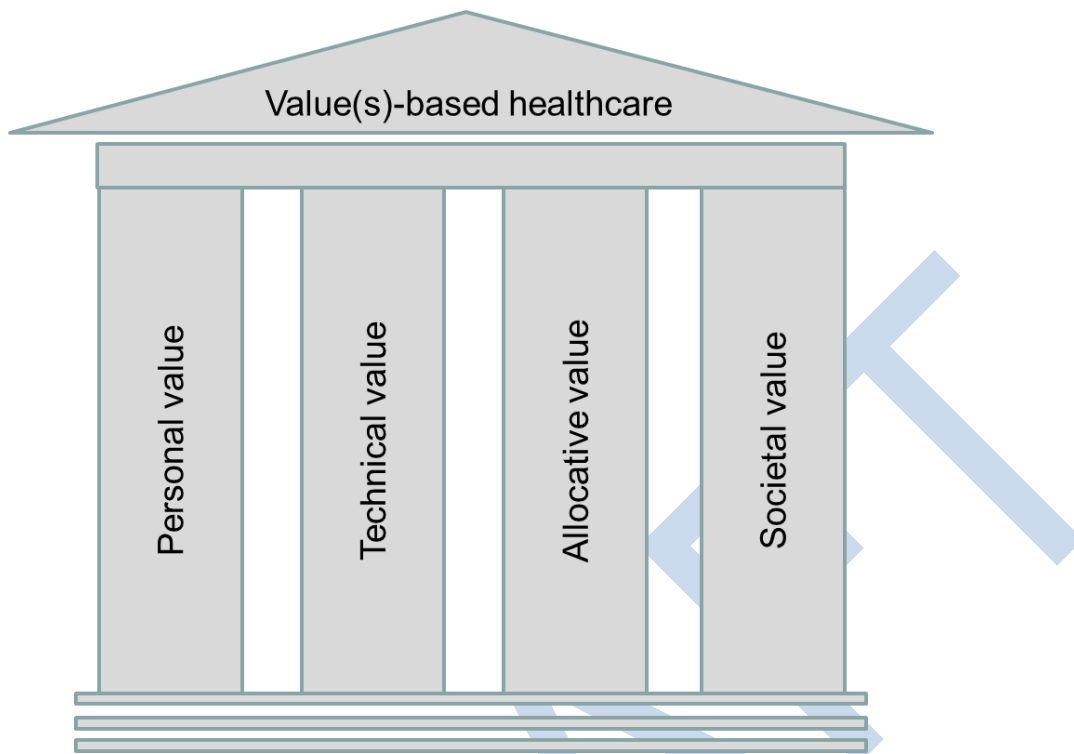
2160 In the meantime, the notion of "Value based healthcare (VBHC)" is increasingly used in
2161 public discourse, although – at least in the European understanding – in a distorted
2162 manner; some would even call it a "hijacking" of the notion of value. For that reason the
2163 EXPH has been asked to clearly define "value" in value-based healthcare.

2164 (a) How do you define value in "value-based healthcare"? What aspects of
2165 health systems could the different definitions cover?

2166 The EXPH emphasizes the value that underlies European healthcare systems, the concept
2167 of solidarity and the commitment to universal health coverage, laid down in the Charter
2168 of Fundamental Rights (2000 [9]) and in the European Pillar of Social Rights (2017 [13]).
2169 As such the European definition of VBHC encompasses the four aspects of value:
2170 personal value (meaning that an individual receives appropriate care), allocative value
2171 (referring to the optimal distribution among patient populations), technical value (relating
2172 to the best outcomes with available resources) and societal value (referring to the
2173 intrinsic value of good health as enabler to participate in society and solidarity as
2174 contributor to social cohesion of equal individuals).

2175

2176 Figure 7: the four value pillars for a values(s)-based healthcare in Europe



2177

2178 This comprehensive European concept of value(s)-based healthcare combines the narrow
2179 definition of VBHC, which only focuses on a particular economic value (whereby an
2180 intervention generates a benefit for an individual which has a value that can be
2181 monetarised), with the European societal values of solidarity (access and equity, quality
2182 and performance, efficiency and productivity). In order to avoid the further distortion and
2183 inappropriate utilisation of the notion "value", "value(s)-based healthcare" should
2184 preferably be used in its comprehensive meaning, as laid down in this opinion, when
2185 used in European public debate, in particular in discussions on strategies for
2186 sustainability of universal health coverage.

2187

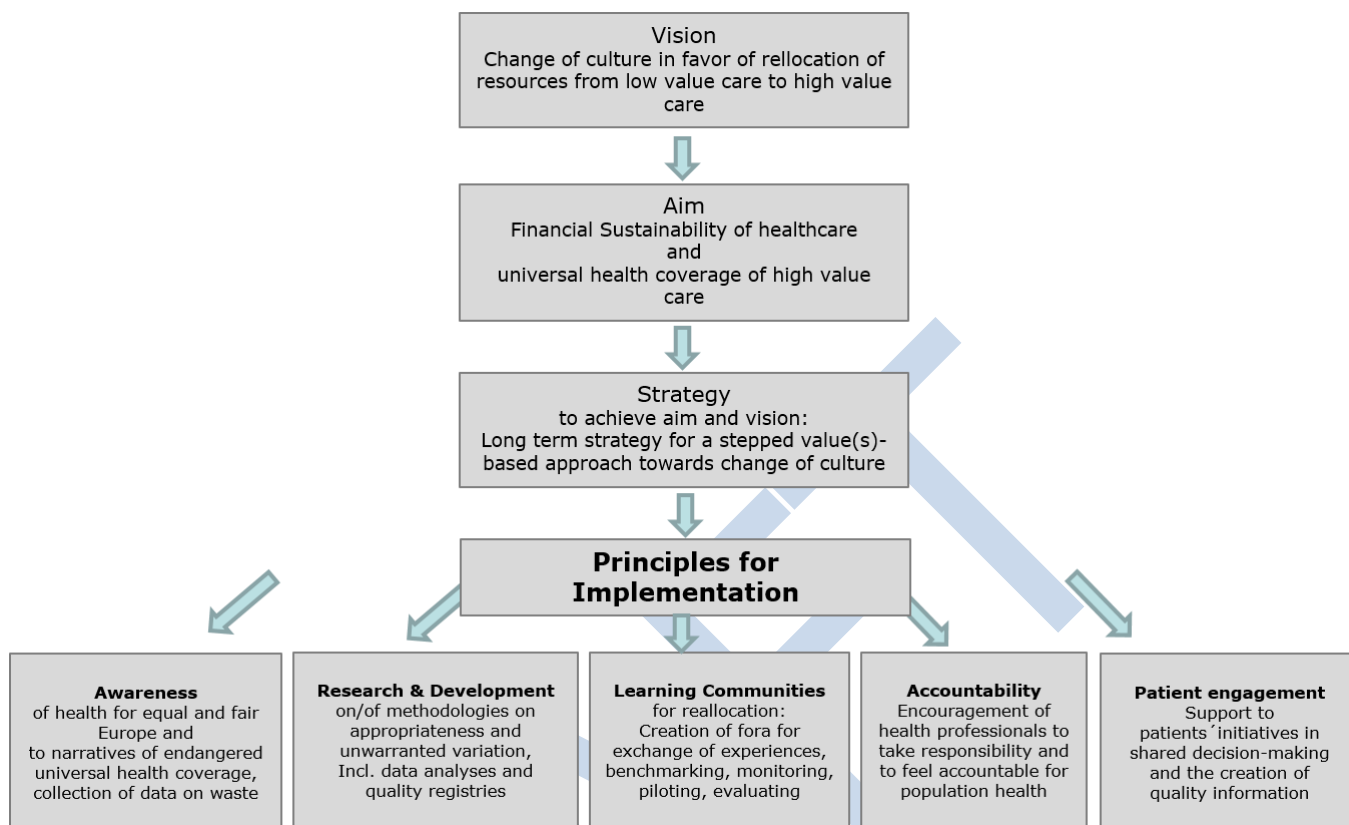
2188 (b) How can "value-based healthcare" inform decision making, contribute to
2189 health system transformation, and help health systems across the
2190 European Union become more effective, accessible and resilient?

2191 Strategies to support effective and resilient healthcare for all citizens in the European
2192 Union have so far focused on the principles of access and equity, quality and
2193 performance, efficiency and productivity. A recent addition to those guiding principles is
2194 an increasing focus on reallocation from low value to high value care. Concerns have
2195 been raised that many high-risk, high-cost healthcare services and products are

2196 overused while basic needs stay unmet: there is considerable evidence of inequity by
2197 disease (e.g. it is easy to raise (R&D, treatment-related) funds for lung cancer, but not
2198 for COPD) leading to a lack of allocative and societal value from the utilisation of
2199 resources. A cultural shift is required to make it possible to ask not whether a treatment
2200 or procedure is possible, but whether it provides real value to the patient and genuinely
2201 improves the quality of their life or their prospects for recovery [42]. The EXPH argues
2202 for a strong system of governance to support this new paradigm of shifting resources
2203 from low to high “value” in VBHC by steering (methodological and disease-based) public
2204 research on high value healthcare, by stimulating the implementation of regulatory
2205 instruments that favour accountability for improving the health of entire populations, by
2206 supporting targeted actions by member states and finally by giving clear warnings to
2207 industry about unsustainable pricing policies.

DRAFT

2208 Figure 8: From vision to implementation: a multistep strategy



2209

2210

2211 The EXPH recommends a strategic long-term plan to facilitate a culture that enables the
2212 freeing of resources for reinvestment in high-value care and for effective reallocation
2213 towards a value(s)-based healthcare.

2214 **Recommendation 1** (to ensure societal value): Creating greater **awareness of health**
2215 **as an essential investment** in an equal and fair European society ("health is wealth"),
2216 of the centrality of as a European value, and of the commitment, in the Sustainable
2217 Development Goals, to achieving universal health coverage (UHC).

2218 This process will provide **clear narratives** setting out how the financial sustainability of
2219 existing progress towards UHC is endangered by

- 2220 ○ Overdiagnosis leading to overtreatment
- 2221 ○ Inequity by disease and "voiceless" patient groups
- 2222 ○ Unwarranted variation in healthcare interventions
- 2223 ○ Unreasonable prices of treatments
- 2224 ○ Waste arising from inefficiencies, fraud and corruption

2225

2226 **Recommendation 2** (to ensure all four pillars of values: personal, technical, allocative
2227 and societal value): Develop a **long-term strategy** for a step-by step value(s)-based
2228 approach towards change of culture.

2229 By 2030, this should have created a movement that

- 2230 ○ Develops a consistent language to capture the drive towards sustainability
2231 of universal health coverage,
- 2232 ○ Train “change agents” (leaders), who assess the risks and opportunities
2233 that exist and contextualize the change process in the EU member states,
- 2234 ○ Define a series of goals that support the long-term objective of change,
2235 moving forward in small steps (work plans), for example using analyses of
2236 regional variation of, say, the 20 most frequent Diagnostic Related Disease
2237 Groups (DRGs),
- 2238 ○ Invest in research and development of methodologies, in appropriateness
2239 and implementation research (H2020 and later framework programmes),
- 2240 ○ Pilot need-based public R&D for true innovative technologies and consider
2241 as innovations social interventions (see box 4 on social prescribing) as
2242 much as technology-based interventions,
- 2243 ○ Orientate digital interventions in ways that genuinely support high value
2244 care [88]
- 2245 ○ Monitor the effects of large scale implementation by use of existing data
2246 sources (e.g. quality registries in Finland, Sweden etc.) and existing
2247 methodologies (e.g. indicators [3]) and
- 2248 ○ Create mechanisms to further guide the direction of change.

2249
2250 **Recommendation 3** (to ensure all four pillars of values: personal, technical, allocative
2251 and societal value): Support Research & Development on/of **methodologies on**
2252 **appropriateness** and unwarranted variation.

2253 Examples of actions are

- 2254 ○ Creating fora for exchange on measuring and monitoring patterns of
2255 clinical practice, regional variation, appropriateness research (specifically in
2256 multi-morbidities) and inequity by disease as a basis for a potential to
2257 reallocate resources,
- 2258 ○ Stimulating data analyses and the use of quality registries for identification
2259 of regional variation and outcomes.

2260
2261 **Recommendation 4** (to ensure allocative and societal value): Support the **creation of**
2262 **Learning Communities** to bring together the best expertise, experiences and practices

2263 and to learn from each other by measuring, benchmarking and implementing actions
2264 across the EU. Member States should take the lead in identifying and pinpointing the
2265 most important tasks, the EC should create a supportive and facilitating environment for
2266 the establishment of those Learning Communities.

2267 This can be done by

- 2268 ○ Identifying, sharing and celebrating examples of good practice,
- 2269 ○ Rewarding (co-funding, awareness and publicity, ...) countries taking
2270 systematic approaches to developing and disseminating good practice
2271 (such as the Dutch prototype known as “Zinnige Zorg”, see Box 7 and
2272 A2/Appendix on IZZI),
- 2273 ○ Stimulating exchange on managerial techniques
2274 (financial incentives, regulatory mechanisms and managerial instruments)
2275 for shifting resources from low to high value care and on measuring the
2276 effects, including positive incentives (e.g. cash) and negative ones
2277 (restriction on certain interventions),
- 2278 ○ Creating a learning community on the piloting of programme budgeting
2279 (see Box 12: Programme budgeting) within and across diseases and
2280 accordingly for the shifting of resources from budgets where there is
2281 overuse to disease groups where there is evidence of underuse and
2282 inequity, finally
- 2283 ○ Exchanging on strategies for changing attitudes and rethinking value [137]
2284 in our medical culture.

2285

2286 **Recommendation 5** (to ensure allocative and societal value): Encourage **health**
2287 **professionals to take responsibility and feel accountable** for increasing value in
2288 health care, which may require freeing resources from low-value care to reinvest in high-
2289 value care. Health professionals hold a key role in advocating a change of culture.

2290 Examples of actions are

- 2291 ○ Stimulating a reflection process on the accountability for resources as a
2292 core aspect of professionalism by medical, nursing, and other societies
- 2293 ○ Developing training in stewardship, emphasising the importance of health
2294 professionals becoming accountable for the health of the population,
2295 including equitable distribution of resources for those with different
2296 diseases,
- 2297 ○ Steering clinician leadership to ensure acceptance of responsibility for
2298 allocative efficiency and for the social (i.e. not only the individual patient

2299 but wider society) impact of their decisions, encompassing positive and
2300 negative freedom in clinical decision-making (see Box 9: End-Of-Life Care),
2301 ○ Strengthen professional integrity.

2302
2303 **Recommendation 6** (to ensure personal value): Support **patients’ initiatives for**
2304 **engagement** in shared decision-making (SDM), recognising the importance of patients’
2305 goals, values and preferences, informed by high quality information.

2306 Action points include

- 2307 ○ Co-creating models of care with the patient community (including families
2308 and informal carers) , and adopting a framework for meaningful patient
2309 and public involvement in health systems and services design (in evidence
2310 requirements, M&E, policy discussions and decision-making), leading to
2311 value-based healthcare in its wider sense.
- 2312 ○ Developing, together with patients’ organisations, authorities in Member
2313 States, and other stakeholders, a comprehensive strategy to implement
2314 empowering practices and goal-oriented person-centred care.
- 2315 ○ Ensuring appropriate involvement of patients and their communities in the
2316 creation and implementation of patient-defined outcome measures and
2317 experience measures (PROMs and PREMs)
- 2318 ○ Exploring alternative ways of encouraging research and innovation that
2319 meets patients and societies’ needs and goals, while ensuring solidarity
2320 and equity, including partnerships that fully involve patients.
- 2321 ○ Involving patients in the training and continuous professional development
2322 of all stakeholders involved in value-based health care, resource allocation
2323 and disinvestment
- 2324 ○ Promoting effective patient and public dialogue about societal goals and
2325 priorities.

2326 Increasing value in our healthcare systems will require strong collaboration and intensive
2327 liaison that encompasses evaluation of interventions (to distinguish true innovation and
2328 identify low value interventions), monitoring healthcare services delivered (healthcare
2329 services research and planning to identify unwarranted variation and care of high value)
2330 and surveys of providers (ensuring personal value by providing person-centred
2331 information to patients).

2332

2333 **LIST OF ABBREVIATIONS**

2334	COPD	Chronic obstructive pulmonary disease
2335	DALY	Disability-adjusted life year
2336	DRG	Diagnostic related groups
2337	EbHC	Evidence based healthcare
2338	EbM	Evidence-based medicine
2339	EU	European Union
2340	GNP	Gross National Product
2341	HTA	Health Technology Assessment
2342	ICECAP	Capability measure for Adults
2343	IPR	Intellectual property rights
2344	MRI	Magnetic resonance imaging
2345	OECD	Organization Organisation for Economic Co-operation and Development
2346	P4P	Pay-for-performance
2347	PREM	Patient Reported Experience Measures
2348	PROM	Patient Reported Outcome Measures
2349	QALY	Quality adjusted life years
2350	PSA	Prostate specific antigen
2351	R&D	Research and development
2352	SDG	Sustainable Development Goals
2353	UHC	Universal health coverage
2354	UN	United Nations
2355	VBHC	Value based healthcare
2356	VbM	Values based Medicine
2357	WHO	World Health Organisation
2358		

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2698 **GLOSSARY**

2699 ***Appropriate/inappropriate***

2700 A procedure is termed appropriate if its benefits sufficiently outweigh its risks to make it
2701 worth performing, and it does at least as well as the next best available procedure. A
2702 procedure is termed inappropriate if the risks outweigh the benefits.

2703
2704 ***Cost-effectiveness***

2705 Cost-effectiveness relates the outcomes of a service to the costs. When measuring cost-
2706 effectiveness both beneficial and harmful outcomes need to be included.

2707
2708 ***Effectiveness***

2709 The effectiveness of an intervention, from single treatments through to services including
2710 the professionals within them, is the degree to which the desired outcomes are achieved
2711 in clinical practice.

2712
2713 ***Efficacy***

2714 The magnitude of the benefit demonstrated in the research setting is sometimes referred
2715 to as the efficacy of an intervention.

2716
2717 ***Equality***

2718 It is important to distinguish between two similar-sounding, but quite different, concepts:
2719 "equality" and "equity". The former implies equal shares of something; the latter, a "fair"
2720 or "just" distribution, which may or may not result in equal shares.

2721
2722 ***Equity in health***

2723 Equity in health can be defined as the absence of systematic disparities in health (or in
2724 the major social determinants of health) between social groups who have different levels
2725 of underlying social advantage/disadvantage—that is, different positions in a social
2726 hierarchy.

2727
2728 ***Healthcare opportunity cost***

2729 The concept of opportunity cost is fundamental to the economist's view of costs. Since
2730 resources are scarce relative to needs, the use of resources in one way prevents their
2731 use in other ways. The opportunity cost of investing in a healthcare intervention is best
2732 measured by the health benefits (life years saved, quality adjusted life years (QALYs)
2733 gained) that could have been achieved had the money been spent on the next best
2734 alternative intervention or healthcare programme.

2735
2736 ***Integrated care***

2737 Integrated care is an organising principle for care delivery with the aim of achieving
2738 improved patient care through better coordination of services provided. Integration is the
2739 combined set of methods, processes and models that seek to bring about this improved
2740 coordination of care.

2741
2742 ***Overuse***

2743 Overuse is the provision of medical services for no benefit or for which harms outweigh
2744 benefits.

2745
2746 ***Personal value***

2747 Improving the outcomes that matter to an individual for a given amount of resources
2748 (money, leadership, time, assets and carbon) used not only by the health and social care
2749 system but also by the individual and their family, recognising that the experience of care
2750 is a critical element.

2751
2752 ***Population value***

2753 Investing resources (money, leadership, time, assets and carbon) reasonably within a
2754 health and social care system to optimise the outcomes for the population for which the
2755 health and social care system is responsible.

2756

2757 **Programme budgeting**

2758 Programme budgeting is a technique that enables personnel in a health service, and
2759 those who use the health service, to identify how much money has been invested in
2760 major health programmes, with a view to influencing future investment.

2761

2762 **Quality**

2763 The quality of a service is the degree to which it conforms to pre-set standards of care.

2764

2765 **Reasonableness**

2766 Accountability for reasonableness is the idea that the reasons or rationales for important
2767 limit-setting decisions should be publicly available. In addition, these reasons must be
2768 ones that 'fair-minded' people can agree are relevant to pursuing appropriate patient
2769 care under necessary resource constraints

2770

2771 **Safety**

2772 Patient **safety** can, at its simplest, be defined as: The avoidance, prevention and
2773 amelioration of adverse outcomes or injuries stemming from the process of healthcare. ...
2774 the reduction of harm should be the primary aim of patient **safety**, not the elimination of
2775 error.

2776

2777 **Shared decision-making**

2778 In a shared decision, a healthcare provider communicates to the patient personalized
2779 information about the options, outcomes, probabilities, and scientific uncertainties of
2780 available treatment options, and the patient communicates his or her values and the
2781 relative importance he or she places on benefits and harms.

2782

2783 **Stewardship**

2784 Stewardship is to hold something in trust for another.

2785

2786 **Sustainability in healthcare**

2787 Quality services and systems include sustainability as a fundamental principle. This
2788 means minimising environmental impacts, enhancing health and building resilience with
2789 individuals and their communities.

2790

2791 **Technical value**

2792 Net benefit derived in return for a given resource use.

2793

2794 **Underuse**

2795 Underuse is the lack of provision of necessary care (eg no aspirin prescribed after
2796 myocardial infarction),.

2797

2798 **Unwarranted variation**

2799 Variation in the utilization of healthcare services that cannot be explained by variation in
2800 patient illness or patient preferences.

2801 **Waste**

2802 "wasteful" are: i) services and processes that are either harmful or do not deliver
2803 benefits; and ii) costs that could be avoided by substituting cheaper alternatives with
2804 identical or better benefits. Linking actors – patients, clinicians, managers and regulators
2805 – to key drivers of waste – errors and suboptimal decisions, poor organisation and co-
2806 ordination, incentives misaligned with healthcare system goals, and intentional deception
2807 ...

2808

2809 **APPENDIX 1:**

2810 Links for further reading on initiatives

2811 Table A 1: Examples of initiatives for evidence-based patient-information and patient
2812 initiatives in R&D

2813 Cochrane (plain language summaries):

2814 [https://community.cochrane.org/review-production/production-resources/plain-](https://community.cochrane.org/review-production/production-resources/plain-language-summaries)
2815 [language-summaries](https://community.cochrane.org/review-production/production-resources/plain-language-summaries)

2816
2817 Germany: <http://gesundheits-fuchs.com/>, <https://www.gesundheitsinformation.de/>
2818 <http://www.patientenleitlinien.de/>; <https://www.awmf.org/index.php?id=70>

2819
2820 England: <https://www.nice.org.uk/about/nice-communities/nice-and-the-public>
2821 Etc.

2822

2823 Table A 2: Initiatives by clinicians to identify low value interventions

2824 2012 Choosing Wisely (AIMB), USA: <http://www.choosingwisely.org/>

2825 2012 Choosing Wisely (OMS+ ZONMW), NL: <https://www.demedischspecialist.nl>

2826 2012 NPS MedicineWise/ AU: <http://www.nps.org.au/>

2827 2013 Slow Medicine, IT: <http://www.slowmedicine.it/>

2828 2013 Too Much Medicine, GB (BMJ): 4 [http://www.bmj.com/specialties/too-much-](http://www.bmj.com/specialties/too-much-medicine)
2829 [medicine](http://www.bmj.com/specialties/too-much-medicine)

2830 [2013](http://www.preventingoverdiagnosis.net/) Preventing Overdiagnosis: Winding back the harms of too much medicine, GB +
2831 USA: <http://www.preventingoverdiagnosis.net/>

2832 2013 Lown Institute: Right Care Movement, USA: [http://lowninstitute.org/take-](http://lowninstitute.org/take-action/join-the-right-care-alliance/)
2833 [action/join-the-right-care-alliance/](http://lowninstitute.org/take-action/join-the-right-care-alliance/)

2834 2014 Choosing WiselyCA, CA: <http://www.choosingwiselycanada.org/>

2835 [2014](http://www.smartermedicine.ch/) Smarter Medicine, CH: <http://www.smartermedicine.ch/>

2836 2015 Klug entscheiden (DGIM, AWMF), DE: <http://www.dgim.de>,

2837 <https://www.awmf.org/medizin-versorgung/gemeinsam-klug-entscheiden.html>

2838 2015 Choosing Wisely, UK (AoMRC): <http://www.aomrc.org.uk/>

2839 2016 Prudent Healthcare/ Wales-UK: <http://www.prudenthealthcare.org.uk/>

2840 2017 Gemeinsam gut entscheiden, AT (DUK/IAVEM), [https://www.gemeinsam-gut-](https://www.gemeinsam-gut-entscheiden.at/)
2841 [entscheiden.at/](https://www.gemeinsam-gut-entscheiden.at/)

2842 Sources: [130, 138, 139], own searches

2843 Table A 3: Initiatives by researchers against waste and for increasing value research

2844	2004	James Lind Alliance for Priority Setting Partnerships: http://www.jla.nihr.ac.uk/about-the-james-lind-alliance/
2845		
2846	2006	EQUATOR-Network: Enhancing the QUALity and Transparency Of health Research: https://www.equator-network.org/
2847		
2848	2013	AllTrialsCampaign: http://www.alltrials.net and TrialsTracker: https://trialstracker.net/
2849		
2850	2013	Conferences "Overdiagnosis: Winding back the harms of too much medicine": https://www.preventingoverdiagnosis.net/
2851		
2852	2014	Lancet Series "Research: increasing value, reduce waste and the REWARD Alliance: http://rewardalliance.net/
2853		
2854	2014	BMJ series: Too much medicine; JAMA series: overdiagnosis

2855 2018 Public Return on public Investment (Mazzucato)

2856 Sources: [140], own searches

2857 Table A 4: Initiatives by Health Policy to identify low value interventions

2858	2001	Over-, under- and inappropriate care (SVR), G: http://www.svr-gesundheit.de
2859	2006	NICE „DoNotDo“ Database, UK: http://www.nice.org.uk/ (Savings and Productivity)
2860		
2861		NICE "DUETS" Datenbank, UK: http://www.library.nhs.uk/duets/
2862	2007	GuNFT(Guideline for Not Funding existing health Technologies) and PriTec Tool, SP
2863		
2864	2008	SBU "Uncertainties" and Disinvestment-project, S
2865	2010	PBAC: Disinvestment of drugs and vaccinations; Framework for reviewing existing MBS items: PBMA (PBMA – Program Budgeting and Marginal Analysis
2866		
2867	2013	Zinige Zorg Initiative (ZIN), NL: https://www.vgz.nl/zinnige-zorg
2868		

2869 Sources: [111, 130]

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APPENDIX 2:

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Good Practice Casebook

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

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

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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:

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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.

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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.

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Figure A 1: PDCA Zinnige Zorg circle



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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:

Screening phase (selecting the topics for in depth)	In depth phase
Blood and Immunity system	Cervical abnormalities
musculoskeletal system and connective tissue	Pelvic floor complaints
Skin and subcutaneous tissue	Venous thrombosis and pulmonary embolism
infectious and parasitic diseases	Lower respiratory tract infection and pneumonia
Eye and Adnexa	Urinary tract infection?
Ear and mastoid process	Asthma
digestive system	COPD
	Implementable cardioverter defibrillator
	Lower back complaints
	LVB
	Sleep Apnea
	Osteoporosis
	Psychosis
	Posttraumatic Stress disorder (PTSD)
Implementation	Evaluation
PAOD	Hip and Knee replacement
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	

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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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