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Expert Panel on Effective Ways of Investing in Health (EXPH) Hearing on value-based healthcare

Brussels, 4 June 2019

Aim and objectives

The Opinions of the Expert Panel on Health support the Commission by providing the views of the Panel, informed by evidence, on issues that can make a real change to health systems reforms and investments within the EU.

The aim of the Hearing was to provide stakeholders with an opportunity to share their views on the draft Opinion of the Expert Panel on Defining value in “value-based healthcare”; the draft Opinion was made available on the Panel website prior to the hearing.

Presentation of the draft Opinion

Panel members: Prof. Claudia Wild (presenter/rapporteur), Prof. Jan De Maeseneer , Prof. Lasse Lehtonen, Prof. Luigi Siciliani, Dr Dionne Kringos, Dr Aleš Bourek, Prof. Walter Ricciardi, Assoc. Prof. Liubove Murauskiene

Prof. Lehtonen opened the hearing and introduced the members of the Panel. He also emphasised that the hearing is not a debate on the interesting subject at hand, but rather a hearing focused on the draft Opinion.

Prof. Wild started with a presentation on the Opinion of the working group on value-based healthcare, first introducing the members of the working group and its working principles. Since value-based healthcare is such a wide topic, three external experts were added to the working group.

Prof. Wild first pointed out that while there is an inflation in the usage of the term, there is also a concurrent dilution of its contents, which has been the subject of research itself. This is also why the European Commission tasked the group with evaluating what is the ‘value’ in ‘value-based healthcare’. Other questions they were tasked with included how the concept can be precisely defined and, once defined, put to use for Member States and policies towards improving the resilience of the healthcare systems.

Prof. Wild continued with the working group’s proposed definition for the term ‘value-based healthcare’ (VBHC): *a **comprehensive concept** built on four value-pillars: appropriate care to achieve EACH patient’s personal goals (personal **value**);*

achievement of best possible outcomes with available resources (technical value); equitable resource distribution across all patient groups (allocative value) and contribution of healthcare to social participation and connectedness (societal value).

Prof. Wild further brought out the principles for achieving value. One of the key principles is to improve awareness of health as an essential investment in an equal and fair European society and to the centrality of European values of solidarity. Health is wealth. To achieve the goal of moving from a low value care system to a high value care system, a long-term strategy must be developed.

In terms of methodology of the working group, they first analysed the current situation: they identified other initiatives working to increase value; they appraised established instruments and methods; identified key values and made proposals and recommendations for principles of implementation.

She further elaborated that the analysis of the current situation proved that there is a lot of inefficiency and wasteful spending. The OECD report on “Wasteful Spending in Health” from 2017 drew attention to the fact that inappropriate care and wasted resources make up between 10% and 34% of expenditures. There are multiple reasons for this, such as the unwarranted variation in investment, activity, access and outcomes. Another contributing factor is the underuse of effective interventions, such as prevention or detection. On the other hand, there is the overuse of resources, such as overdiagnosis and overtreatment.

Prof. Wild further explained that since there is an enormous rise in the volume and intensity of activity in the health care system, it has moved beyond the point of optimality: the cost is always growing, but the health effects are marginal and sometimes even harmful. There are numerous other initiatives looking at the issue of wastefulness, which the working group identified, looking at various sides of the picture: patient-centred initiatives; initiatives looking at different outcomes; initiatives looking at unwarranted variation; so-called payers and also clinicians’ initiatives, such as Choosing Wisely. In collaboration with the Choosing Wisely initiative, there is the Preventing Overdiagnosis conference, which looks at winding back the harms of too much medicine. On the other side of the coin, there is corruption, fraud and misuse, which is leading to wasting public resources. The European Healthcare Fraud and Corruption Network (EHFCN) developed a good network for identifying corruption, fraud and misuse.

Prof. Wild referenced Mariana Mazzucato’s publication “The Value of Everything – Making and Taking in the Global Economy”, which focuses on waste in R&D, and the fact that there is little return on public investments in healthcare. Prof. Wild also noted on the existing initiatives in the form of public policies tackling the issue of inequity by disease. The working group’s proposal is program budgeting by disease to close the gap on different funding by disease.

Further, there is an initiative since 2016 for innovative payment methods for fair access, for example, fair pricing initiatives, which are now being regionally implemented through platforms such as BeNeLuxA, NLP, Valletta and Visgard.

Prof. Wild talked about the big question of “value”: whose values are we talking about? One of the base values of the European Union is solidarity, the concept of solidarity is enshrined in the EU Treaties, including the values and objectives of the Union, which include **solidarity “between generations”** and **“among Member States”**, while Chapter IV of the **Charter of Fundamental Rights** is entitled **Solidarity**, and covers rights at work, family life, welfare provision and **health**. **The European Pillar of Social Rights** states that “Everyone has the right to timely access to affordable, preventive and curative healthcare of good quality”. **Universal healthcare** is one of the policy priorities of the European Union to build a more inclusive and fairer European Union and to ensure social cohesion within the EU. The big question is, whether this principle still holds true and whether we really feel it. According to the European Social Survey of 2002 and 2016, many countries are increasingly in favour of redistribution of income. This result demonstrates that the idea of solidarity is still very much alive in Europe. But how can solidarity be implemented in healthcare? How can it be operationalised and measured? Prof. Wild explained that the working group has three guiding principles for measuring solidarity in healthcare:

- 1) whether the healthcare system is accessible;
- 2) what is the quality and performance level, is it responsive to patients’ needs; and
- 3) the efficiency and productivity of the healthcare system, whether the resources are distributed optimally. Health is the ultimate precursor to citizens trying to achieve a good life, and universal healthcare is deemed to achieve equitable access to health, not just health care, and that is the basis to solidarity.

Prof. Wild explained that when looking at the instruments in place to achieve those values, whether they are individual, mezzo-level or macro-level, there are many already in place. While the instruments in place may deliver on cost, they are falling short in terms of a wider definition of value or the perception of VBHC. The literature, she explained, has two broad streams of definitions, which fall either under the narrow, price-based ‘value’ or ‘values’ (allocative, technical or personal). The working group added the ‘societal value’ dimension to this stream of definitions.

Prof. Wild then explained that the EXPH therefore proposes defining valueS-based healthcare (VBHC) as a **comprehensive concept** built on four value pillars:

- 1) *appropriate care to achieve EACH patient’s personal goals (**personal value**);*
- 2) *achievement of best possible outcomes with available resources (**technical value**);*
- 3) *equitable resource distribution across all patient groups (**allocative value**)*
- 4) *and contribution of healthcare to social participation and connectedness (**societal value**).*

Prof. Wild then outlined the working group’s **recommendations for implementing valueS-based healthcare**.

- 1) (to ensure societal value): Creating greater **awareness of health as an essential investment** in an equal and fair European society (“health is wealth”), of the centrality of health as a European value, and of the commitment in the Sustainable

- Development Goals, to achieving universal health coverage (UHC). She added that this process will provide **clear narratives** setting out how the financial sustainability of existing progress towards **universal health care is endangered** by: overdiagnosis leading to overtreatment; inequity by disease and “voiceless” patient groups; unwarranted variation in healthcare interventions; unreasonable prices of treatments; waste arising from inefficiencies, fraud and corruption.
- 2) (to ensure all four pillars of values: personal, technical, allocative and societal value): Develop a **long-term strategy** for a step-by-step value(s)-based approach towards change of culture, which entails:
 - developing a **consistent language**;
 - training “**change-agents**” (**leaders**), who assess the risks and opportunities that exist and contextualise the change process in EU member states;
 - defining a **series of goals** that support the long-term objective of change, moving forward step-by-step on a work plan basis, for example, using analyses of regional variation of, say, the 20 most frequent Diagnostic Related Disease Groups (DRGs);
 - investing in research and development of **methodologies, in appropriateness and implementation research** (H2020 and later framework programmes);
 - piloting needs-based public R&D for **true innovative technologies** and considering as innovations **social interventions** as much as technology-based interventions;
 - orientating **digital interventions** in ways that genuinely support high value care;
 - monitoring the **effects of large-scale implementation** by using existing data sources (e.g. quality registries in Finland, Sweden, etc.) and existing methodologies (e.g. indicators);
 - and to create mechanisms to further guide the direction of change.
 - 3) (to ensure all four pillars of values: personal, technical, allocative and societal value): Support Research and Development on/of **methodologies on appropriateness** and unwarranted variation. For example, through creating **fora for exchange** and stimulating **data analyses**.
 - 4) (to ensure allocative and societal value): Support the **creation of Learning Communities** to bring together the best expertise, experiences and practices and to learn from each other by measuring, benchmarking and implementing across the EU. Member States should take the lead in identifying and pinpointing the most important tasks, the EC should create a supportive and facilitating environment for the establishment of those Learning Communities. This can be done by:
 - identifying, **sharing and celebrating** examples of good practice;
 - **Rewarding** (co-funding, awareness and publicity, etc.) countries taking **systematic** approaches to developing and disseminating good practice;
 - stimulating exchange on **managerial techniques** (financial incentives, regulatory mechanisms and managerial instruments) for **shifting resources from low to high value care** and on measuring the effects,

including positive incentives (e.g. cash) and negative ones (restriction on certain interventions);

- creating a learning community on the **piloting of programme budgeting** within and **across diseases** and accordingly for the **shifting of resources from budgets** where there is overuse to disease groups, where there is evidence of underuse and inequity;
- and exchanging on strategies for **changing attitudes** and rethinking value in our medical culture.

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

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

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

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

- Promoting effective patient and **public dialogue about societal goals** and priorities.

Concluding the presentation, Prof. Wild pointed out the main finding of the work carried out by the EXPH for the Opinion: there is a need for **a reallocation of resources** – the freeing of resources and accordingly the reinvestment – from low to high value care. This is perceived by the EXPH as the **utmost necessity for sustainable and resilient European healthcare systems**.

Prof. Walter Ricciardi thanked Prof. Wild for the thorough presentation and addressed the participants to ask about developing a policy toolkit for the Opinion. This toolkit could be used for the funders, the politicians, the stakeholders, citizens, etc., to translate the Opinion into practical guidelines to share the glossary – since it is a lot of work, Prof. Ricciardi also asked the participants to consider the need for such an undertaking.

Open discussion: stakeholders' views

Prof. Jan de Maeseneer chaired the discussion and opened the floor for questions and comments from the participants of the hearing on the Opinion.

Mr Gregory Katz, Consortium VBHC France, President. Mr Katz admitted that he did not identify the topic as he knows it in the report and gave some of the reasons. First, the chart with a definition of value taken from the literature is incorrect. The Panel presented that value is 'quality divided by cost' and 'quality' is defined as health outcomes and patient experience, and on the denominator there are direct and indirect costs for the intervention. Over the past 7 years in many hospitals and clinical sites, Mr Katz explained, he has seen the implementation of a different definition of value-based health care: health outcomes that matter to patients. PREM is not part of the equation, quality is an ill-defined concept. It is health outcomes that matter to patients, divided by the cost of the full cycle of care. If we narrow down the denominator to the intervention, then the definition becomes hospital-centric. This is why hundreds of hospitals are using the ICHOM standard sets, with this value equation.

Mr Katz continued by making a clear distinction between PROM and PREM. They are not twins, he explained, and clear priorities need to be established. PREMs are administrative outputs that matter to the hospital administrator. PROMs are clinical outcomes that matter to healthcare professionals and patients. The confusion between them comes from the fact that those indicators are reported by the patients, which is correct. However, there is a hierarchy in terms of priorities. Patients do not go to hospitals to enjoy a nice experience, he explained, a good hospital is one where the patient does not have to ever go back. This is why the command from this report, according to Mr Katz, should really focus on patient reported outcomes, especially since there is tremendous traction – hundreds of hospitals are leading the way across Europe, adopting those standard sets. Choosing Wisely is a good program, but it is a list of things to avoid, while the standards set is exactly the opposite. It is a tool for self-evaluation and

comparison. Mr Katz elaborated that transparency is a key ingredient of value, however, there is no value without comparison, without disclosing outcomes, without calibrated instruments that are already on the shelf – available through open access. The only weakness from ICHUM is that this is an initiative that mostly stems from the US. Mr Katz suggested that a closer look should be taken at the standards from a point of view of adherence by hospital staff. Otherwise, it will be a case of reinventing the wheel. Furthermore, Mr Katz expressed concern over the timeline that the Opinion would create in terms of lagging behind by creating a delay of adoption by the medical community. The same definition of ‘value’ has now been in use for 15 years, and redefining it is, of course, possible, but the fact that this definition is embedded in the formula “health outcomes that matter to patients, divided by the full cost of the cycle of care” creates consensus. He ended by stating that we tend to speak the same language, and this language is also valuable.

Prof. de Maeseneer summarised the topics as follows: 1) the definition of ‘value’ and how to conceptualise the calculation, goal-oriented care, outcomes that matter to patients; 2) the difference between PROM and PREM, with an emphasis on PROM; 3) transparency and alignment with what is being done in other parts of the world. He then turned the floor over to the Panel members for first reflections.

Prof. Wild explained that if it didn’t come across in the presentation, the definition of VBHC given by Mr Katz has its role, however, it is a narrow role – it is one instrument, not *the* instrument. However, if it has not been stated enough, she concluded, it must be clarified in the Opinion.

Prof. Ricciardi added that what the European Commission tasked the Panel to perform is to come up with a European definition – it does not matter if it is a new one. He pointed at the example of the United States where a lot of resources were wasted, and 20% of the GDP spent on something that doesn’t grant universal coverage, leaving 45 million people uninsured or underinsured. So, the Panel was asked to develop a new definition that includes the values of solidarity and equity, which are even written in the Charter of Fundamental Rights of the European Union, and which is what they did. The aim is to produce a new definition that is going to shape the actions of the politicians, to fund and to invest, rather than considering healthcare as just a cost. The simple reduction of the definition of VBHC to improving efficiency does not satisfy the value that we have in Europe. It is understandable that some actions in Europe have for years been shaped by the Porter approach, later improved by Muir Gray in Oxford, which started to include the personal value for the patients, including the outcomes that are of value to the patients. The Panel is proposing an improvement on the methodology, so Prof. Ricciardi confirmed that they will take all the positive parts of Mr Katz’s comments. He noted, however, that change is necessary, because if the things move in the same direction as they are concerning value, sustainable solutions are not going to be found.

Prof. Siciliani added that he did not see an incompatibility between the definition given by Mr Katz and that in the Opinion. He explained that at the Panel level, they tried to

look at a very broad range of definitions. Concerning the formula proposed, it seems consistent with the Panel's definition.

Prof. de Maeseneer added that the fourth dimension they contributed – the societal value – also is of utmost importance. There is increasing evidence of health systems not contributing to social cohesion and rather moving towards dividing society into those who have access to care and those who do not, due to their status and financial possibilities. Therefore, it is important to make sure that the health system contributes to connectedness and social cohesion. Recent election results are enough to demonstrate that this is an important issue for building a society based on solidarity.

Mr Katz explained that the formula “health outcomes that matter to patients, divided by the full cost of the cycle of care” is not just a cost containment measure. The health policy impact in terms of social cohesion is part and parcel of this definition. It is possible to overcomplicate things, divide and subdivide the concepts, but the real interest in the definition is that it is integrative, it has a lot of traction already, and that is something to ponder before introducing new concepts, which will take time to validate and calibrate. He opined that it could create tremendous turmoil and delay for European hospitals.

Mr Thomas Allvin, European Federation of Pharmaceutical Industries and Associations (EFPIA), Executive Director, Strategy and Healthcare Systems. Mr Allvin thanked the Panel for the presentation and the draft Opinion, and then moved on to going back to Michael Porter's definition of VBHC (patient-relevant outcomes, divided by the costs per patient across the full cycle of care). He opined that there are definitely pros and cons to taking a wider perspective and discussing the values that underpin our healthcare systems. However, there are some questions. When looking at the definition, how do the values rank in terms of priority, since there are some that potentially conflict (e.g. personal v. allocative values)? There are also different levels – the personal/technical values are at a provider level, whereas allocative/societal values are at a higher, policy level, where the policymakers decide on core values and resource allocation. Mr Allvin also pointed out that one of the drawbacks of a wider view is that there is a risk of losing sight of some of the good practices on how to focus on patient value. Of course, there are several organisations like ICHOM working on common standards, so when it comes to the recommendations, the same thing applies – many are good ones that should be implemented, however, the recommendations could be more concrete on how to make healthcare delivery more centred on patients, how to implement outcomes and measurements, measuring the cost in a holistic way. Making the outcomes transparent is extremely important. Sweden is a good example of the power of transparency – when hospital outcomes started to be published, it created a race to the top. In addition, the incentives models are important to look at, so they would move towards a more outcomes-based model. He also mentioned another OECD report on “Better ways to pay for care”, which deals with the issue of having more outcomes-based healthcare payment models. The key issue is making all stakeholders ‘do the right thing’ and the patient outcomes could be the incentive to achieve that, because it is something that everyone can agree on and VBHC requires multi-stakeholder implementation. He also mentioned

the Paradigm project and the Innovative Medicines Initiative – these are good examples of initiatives that involve the patients from the very beginning, the research phase.

Prof. De Maeseneer summarised the points made as follows: 1) there can be conflicts between the different values, which should be addressed; 2) the importance of data that matters; 3) be more concrete in recommendations, when looking at transparency, cost and incentives contributing to VBHC; 4) have a multi-stakeholder dialogue. He added that the current dialogue is, of course, a way to fulfil the fourth recommendation.

Mr Jaques von Haller, Standing Committee of European Doctors (CPME). Mr von Haller stated that it is really good to discuss values at an EU level, especially not just economic ones. Values are being defined all over Europe. As a physician, he said that ethical values must come first. Economic cannot be prime drivers in healthcare systems, which should be emphasised in the report. For instance, solidarity might mean more means, but not always the budget cuts and administrative measures are the solutions.

Another point he wanted to stress was asking patients and politicians for solutions for being more efficient and having added value, which they fully support. At the same time, he stressed that medicine is a science, he gave an example of vaccination. If matters go beyond the scope of science, there can be difficulties. It must be practiced economically, but by specialists and considering scientific aspects.

The last point he mentioned was regional variation, for which there are no easy solutions. So, when there is no clarity on what to address, bureaucratic measures should not be taken.

Prof. De Maeseneer summarised his points as follows: 1) the importance of ethical values, which should be dominant to economic values; 2) medicine is science, the spread of such information is of utmost importance at a time of conflicting information available; 3) regional variation should be left aside, due to its complexity, in terms of offering simple solutions.

Prof. Ricciardi confirmed that the Panel fully supports the comments made, however, he added that in addition to doctors being the practitioners, they nowadays also have to become the stewards of the system. Doctors are trained to be good doctors, not leaders, visionaries or stewards. It is a call for the schools of medicine to train doctors more in line with today's requirements, as the old ways increase disparity. The values are the same, but the times are changing.

Prof. De Maeseneer added that an increasing amount of the work will be done by teams and noted that the following day there will be another discussion on task shifting in healthcare.

Mr von Haller said that he is a fan of physicians being involved in society and politics, since doctors see many people and have a good overview of society, and he is in full agreement with the idea.

Mr Hans Winberg, Leading Health Care Foundation, Secretary General. Mr Winberg first remarked that they just completed an evaluation of VBHC for the Swedish state, from an organisational standpoint, which will be published in three weeks and in the European Observatory on health systems and policies in the autumn. According to Porter, VBHC is a productivity tool – what we get for resources put in, in terms of cost. However, the whole cycle must be looked at, so many steps go towards getting the denominator right. In the end, it is hard to see what money produces. When talking about values, there are different sets at different levels, so on micro, macro and mezzo levels values should be looked at and defined differently. He opined that policy goes too far down the system, which stresses out the workers on all that they have to report.

He also pointed out that economics is not about money, but more a philosophy, ethics, what is good and bad. Money is a tool to see if we can fulfil people's dreams and the society's expectations. No model *per se* can do the trick, which is where social sciences should be figured in. It has a lot to do with the culture of the organisation, how patients are viewed. It is not impossible, since there is knowledge on how to work with culture, however, it must be done, and the work is complicated. Much of the confusion around VBHC stems from the multitude of interpretations, which is why values should be well defined. VBHC is similar to methods such as Total Quality Management, LEAN, and person-centred care, which all have roots in the 50s and 60s. So, it is nothing new, but it focuses on the patient, which is good. It focuses on resource use, which is also good, but more tools should be used.

Prof. De Maeseneer noted that they also struggled with the issue of defining 'values-based' vs 'value' in healthcare, and the Panel also tried to focus on the micro, mezzo and macro levels. Looking today at burnout, reporting stress, for example, it describes the tension at the micro level.

Prof. Wild added that as a social scientist, she shares what was commented, however, seeing as it was not the mandate, they could not work on values in healthcare. The notion they were tasked to cover was VBHC. She asked the commenters about how the Porter definition of VBHC tackles the issue of the voiceless, since it is a management tool for pricing strategies, and does not address the issue.

Prof. De Maeseneer recalled from the intervention of Mr Winberg the topic of people's dreams, patients' goals, what really matters to people. He agreed that economy is a social issue, which is why the societal dimension was added to the three existing ones, implicitly emphasising the notion of culture, which perhaps could be more explicit. On the need for contextualisation, he also confirmed that context is an important aspect for understanding the facts and data.

Mr Winberg added a reply to Prof. Wild's question about Porter's tool – he stated that it is not a tool for management, but a tool for governance, because Porter's deals with how in a market economy the whole system works, which is a founding design for the model. However, it has been then used as a management tool. For example, a study of three

university hospitals in Sweden, among them Karolinska, shows that they do not manage on values and the result is a mess. Other models such as Total Quality Management and LEAN look at how to design processes, work flow, teamwork, but Porter's tool is for measuring the results of that teamwork.

Prof. Siciliani reminded that the perspective taken was a health system level, so it might be a bit different from the narrower perspective, which is not necessarily incompatible. The Panel was trying to look at the international level, which means taking a broader view and reflecting on values. Another comment Prof. Siciliani added touched on the Porter definition of value and the division of health by cost or vice versa – these are concepts that are in natural use and are familiar, regardless of which is divided by which.

Ms Sandra Gaisch-Hiller, Baxter, Senior Director, Government Policy, Advocacy and Reimbursement, EMEA region. Ms Gaisch-Hiller thanked the Panel for the Opinion and stated that they support a lot of the recommendations it contains. They had some questions regarding the broadness of some of the definitions and what it means for industries – what is expected of industries, does it mean that they have to go into evidence generation for societal impact and into the product levels, because that would be very complex and beyond the capacity of industry alone. Welcome elements included the empowerment of patients, or shared decision-making. She asked how the Panel plans to integrate the two Opinions, which have a lot of overlap, for example, on the topics of waste and efficiencies. The solution is a combination of both. She gave the example of their company, which makes products that can be used at home and at the hospital, but it requires systems change, empowerment of patients, which is not simple. Ms Gaisch-Hiller asked about the potential policy toolkits – is it something that will go to the Council, are there guidances in the plans? How can stakeholders contribute comments aside from the current forum?

Dr Bourek thanked all the commenters. The task shifting and VBHC exercises were done because of a fundamental question – how is the system doing, which is hard to answer also because the system operates on two subsets: 'value' and 'values'. Values are weighed, while value is calculated based on numbers. If both approaches are not used for taking decisions, it creates problems. So, the essential question is how to improve decision making, in order to either address issues that are already called problems or to prevent issues from becoming problems. Social sciences must be considered, and the work must be done by communities that become teams, because without teams it is just a group of people, which is not efficient. Therefore, it is important for policy makers to allow for such forums to come together, discuss, and understand that decisions will be based on values of different weights to the stakeholders. The task shifting issue will be used for creating teams, and the values-based issue will determine what these teams will work on, so that is how it all comes together.

Prof. De Maeseneer asked Prof. Ricciardi to talk about what stakeholders can do, whether the result of this work will be taken to the Council.

Prof. Ricciardi reflected on the fact that it is now time to create some practical tools, in order for the result to steer policy makers in the right direction. The first recommendation is to invest – considering the healthcare sector as an investment, “health is wealth”. This discussion has been ongoing for 20 years with some results, but now we have a different setting politically as well. Japan, for example, for the first time has taken it to the G20 and made this kind of approach a priority. Also, the Finnish Presidency has set the issue as a priority, so for the first time we have political commitment, politicians leading the way, so the healthcare community has to help. Prof. Ricciardi added that to avoid ending up in a situation like in the United States, where people are not getting the insulin they need to survive, Europe has to transform governance and management in healthcare to be values-based. Last, but not least, clinicians want to be engaged in the discussion, but are not trained to participate. The patients also sometimes are not able to refer to what they want, so we have to be able to work with them. The main challenge is to make the system operational for the day-to-day life of citizens. As a community, the Panel and those gathered have to provide practical tools to politicians, managers, clinicians and patients. The right time is now, because otherwise definitions and attitudes will remain where they are. The work is not yet at the level, where the Council will have something they can use, but work will continue towards that goal.

Prof. De Maeseneer thanked Prof. Ricciardi for the reference to goal-oriented care, because at the end of the day, people want to function in their everyday lives, the social participation aspect is an important one that the medical community at times does not address.

Ms Nicola Bedlington, External Expert involved in drafting the opinion, **European Patient Forum**, Special Advisor. Ms Bedlington added a brief comment about the raised issue of shared decision-making, which the Panel is looking at on the micro level, and that is all part and parcel of the whole patient empowerment agenda, which in her opinion has been very well embedded in the report. The whole area of patient engagement and involvement is a crucial one for strengthening health systems, their design and the design of health services. That is where the patient-relevant outcomes need to come to the fore, and that has been clearly embedded into the report and the recommendations.

Mr Katz added that there are two levels to this discussion. The major goal of the equation is to reduce the variation of outcomes across practitioners and across medical centres. Today quality registries are used to measure outcomes, and results show substantial variations across medical sites. Mortality rate for lung cancer, for example, varied from 1 to 4, according to the site of treatment, other locations and conditions show even wider differences, which is not acceptable. Every patient has to have access to the best possible treatment and outcomes, which is why the measured outcomes have to be made public. This is where the process becomes instrument-centric, which ICHOM has done. If the work produces a score card, for example, the involvement of patients is needed to define what matters to them. As was mentioned earlier, this is when the involvement of patients is crucial, in selecting the indicators that matter to them and eliminating excessive ones. When this level of practical measurement is done, the definition becomes clearer. This solution is practical, while the current discussion is theoretical. Mr Katz recommended

going back to the ICHOM set, drilling down to see how they are used in practice. He explained that his daily work involves working with clinicians to implement the standards and digitalise the outcomes. Then it can be seen how the outcomes can be improved through transparency. He added a humble suggestion moving forward – the Panel could propose that there is at the European level a body that centralises the outcomes of different sites to standardise the instruments, collection, and enable medical sites to make comparisons with risk adjusted data. Calibrated instruments and validated data/translations are needed, so if at the European level, the data input would be standardised, it would allow for comparison and if an independent body would standardise and capture the data, with full integrity and audits, it would mean substantial progress towards the emergence of outcome-based registries that are patient-reported. It is a practical step that could be included as a recommendation in the report.

Prof. De Maeseneer summarised the points as follows: transparency and standardisation, used as a tool for improving practices at different sites.

Mr Yves Verboven, MedTech Europe, Director of Market Access and Economic Policies. Mr Verboven welcomed the fact that the Expert Panel place such emphasis on value and values-based decision making, because in their belief it offers promise to transform and innovate the delivery of care. From MedTech Europe's perspective, there are already multiple initiatives ongoing, so they are committed to value and becoming a partner for the transition to steer European healthcare systems towards value. He gave the example of a reflection paper they commissioned on incorporating value in investment decisions in health across Europe, which will be available soon. Among other issues, it looks at the values that drive decisions, as well as the embedding of value in policy and investments. Mr Verboven's second point was the objective to co-create multiple instruments to translate value-driven thinking into healthcare practices, such as the area of economically the most advantageous value-based procurement and innovation partnerships. In his opinion, those instruments will be important to see the values translated into practice. He added that they have several companies already implementing the value-driven approach within the different offerings.

Mr Verboven drew attention to a couple of points in the report. First, when it comes to defining value, they are pleased to see the Panel taking such a wide view and encompassing the societal aspect. They would advocate to even further broaden the definition towards microeconomic factors and put additional focus on the disease stages, with an aim to foster primary and secondary prevention, to keep people in good health. Second, they also welcome the Panel's recognition of shared decision-making and greater patient involvement. Access to high quality information was another key point they were glad to see in the report, since as an industry, they are constantly driving to increase the value of diagnostic information (IVDs, AI, etc.). Since this is an element so critical to decision-making, they would welcome a more balanced approach towards the role of laboratory and diagnostic tests. Mr Verboven elaborated that from the industry side, there is the constant flow of innovation, however, in addition to technical innovation, industry is increasingly also looking at value propositions that could be provided, by adding services and solutions to the offering. For example, in helping the transition from in-

hospital to outpatient care, so there is an evolution going on. The industry is also focusing more on patient-centred integrated care, which also includes social care, and new schemes are being built up with this offering.

Mr Verboven's final point touched on the methodologies and instruments used to assess value, there is a lot of work still needed to capture full value. Within that context, they would like to advocate for a value-based procurement done in an economically most advantageous way, as has been put forward by the European Commission as one of the key instruments to bringing innovation to the systems.

Prof. De Maeseneer summarised the points as follows: to look at primary and secondary prevention, the importance of patient involvement and the importance of access to information and value propositions in innovations and procurement.

Ms Dorota Sienkiewicz, EuroHealthNet, Policy Coordinator. Ms Sienkiewicz thanked the Panel for the hearing and the Opinion and echoed the aforementioned idea that different sets of values should be looked at different levels. Her first question touched on the living conditions of people, whether there are plans to include those issues in the report. Second, she mentioned that prevention and health enhancing policies to keep people healthy are also in their focus. Ms Sienkiewicz praised the Panel for widening the definition of VBHC to include the societal aspect. She asked how the traditionally non-health care professionals can participate in the cross-sectoral co-creation of health.

Prof. De Maeseneer summarised that this contribution supports the taken approach and looking at the cross-sectoral approach is important also to address the social determinants of health. Looking at different aspects of wellbeing is indeed an urgent message.

Prof. Lehtonen, in his concluding remarks, thanked all the contributors for their very valuable comments and informed participants of how the work will proceed. Later the same day, there is a working group meeting for VBHC, where the comments from the hearing will be considered. The final opinion will go to the expert Panel plenary on 26 June for approval, so that the Opinion could be finalised in the following weeks.

Prof. Wild summarised some of the topics mentioned: credit was given to the inclusion of everything around patient co-creation, shared decision-making and the social circumstances, so it was a good idea, not to leave it out of the report. However, there was some criticism that it was too vague and not practical enough. Prof. Wild responded also to the previous question about what is in the report that the industry should be aware of: she explained that they took the system perspective, which meant stepping back, which the industry can do as well, to look at the principle of solidarity. We do not want to change our healthcare systems in the other direction and that might be the message for industry: even if healthcare systems are your market, we would not like to see the solidarity system change. This is why a value-based pricing strategy should not be used to calculate up to the willingness and ability to pay. We are all sitting in one European boat. She confirmed that the comments are well noted and will be taken into account, and that they would make sure that VBHC in Porter's sense would also have its place.

Mr Sylvain Giraud (DG SANTE) added that the current membership of the Panel will be coming to an end in November 2019 and informed participants that soon there will be a call for applications for new members published with a deadline of mid-July.