Opinion Paper

Access to Medical Technology Innovations: A Proposal for a Value of Innovation and Partnership Model

Lieven Annemans

February 2021

Background & objectives

In the light of the present and future challenges faced by health systems across Europe, transitioning to value-driven decision making – as opposed to a focus on price and volume as the only decision criterion for healthcare spending – is critical[1]. This will allow health systems to improve healthcare in general as well as to foster continued investment, adoption, and uptake (routine usage) of high-value healthcare innovation in particular. Such high-value healthcare innovation can contribute not only to healthy living and the well-being of all citizens, but also to maintaining health systems' sustainability[2].

A shift towards value-driven decision making would have particular implications for truly innovative medical technology offerings and their financing, adoption, and ultimately uptake within the health system. As opposed to sustaining (or continuous) innovations, truly innovative medical technology offerings can either be transformative or disruptive[3] in nature. Indeed, whilst ensuring patients' good health, they have the potential to significantly advance the delivery of high-quality care in a cost-effective way. These 'innovations in care delivery'[4] are increasingly solutions-oriented rather than product-driven, and as such combine products (technologies) and services to solve specific shortcomings in care delivery. Due to their high potential of innovativeness, these medical technology offerings are likely to have a significant impact on patients, care delivery, health systems and/or society. In this capacity, these innovations may require additional investment and/or structural changes in the healthcare delivery system in Europe.

Suppliers of such truly innovative medical technology offerings seek to have a reasonable return on their investment. At the same time, healthcare decision makers and budget holders (payers) want to align funding decisions with societal values and obtain value for the money spent. These considerations become particularly relevant in the European context where health systems are guided by principles of solidarity and universal health coverage (UHC), which are anchored in Article 35 of the EU Charter of Fundamental Rights: 'Everyone has the right to timely access to affordable, preventive and curative healthcare of good quality'[5]. Therefore, the key challenge for health policymakers is to provide incentive structures that ensure healthcare innovation, but also health systems' sustainability and timely access to affordable yet high-value care. Successfully tackling this trade-off requires partnership and dialogue among all relevant actors in the health system, from health authorities and payers to care providers and the medical technology industry.

As a response, this paper introduces the so-called value of innovation and partnership access model (hereafter: VIP-model) for the adoption and uptake of medical technology innovations. While this model puts a particular emphasis on the timely introduction of medical technology offerings that claim to be truly innovative, it also accounts for those that show other levels of innovativeness such as sustaining/continuous innovation.

The COVID-19 pandemic has put health systems across Europe under severe stress and added to the already existing pressures stemming from ageing populations and chronic diseases. Moving forward, maintaining sustainability of healthcare budgets, and strengthening health systems' resilience to external shocks will become all the more important. The EU4Health programme (2021-2027), with an investment volume of €5.1 billion, is the largest health programme ever in monetary terms in the history of EU health policy, reflecting the urgency of the situation[6]. The VIP model aims to ensure both value-based investments in healthcare and timely access to innovation for the benefit of patients, healthcare providers, citizens, and society across the EU. As such, it seeks to contribute to addressing the fundamental challenges that health systems in Europe currently face.

1) https://www.medtecheurope.org/wp-content/uploads/2019/06/2019_MTE_incorporating-value-in-investment-decisions-in-health-across-Europe.pdf

2) ibid

3) https://thenextwavefutures.wordpress.com/2018/03/30/review-transformative-innovation-international-futures-forum/

4) https://www.medtecheurope.org/wp-content/uploads/2019/06/2019_MTE_incorporating-value-in-investment-decisions-in-health-across-Europe.pdf

5) https://ec.europa.eu/info/aid-development-cooperation-fundamental-rights/your-rights-eu/eu-charter-fundamental-rights_en

6) https://ec.europa.eu/health/funding/eu4health_en

Characteristics of medical technology innovations and their current access model

Before introducing the proposed VIP model, it is useful to describe the particular characteristics of innovative medical technology offerings, especially in comparison to pharmaceutical innovations, as well as the key features of their current access model in the EU.

Characteristics of medical technology innovations

Medical technology innovations can come in various forms, including medical equipment, medical devices, in-vitro diagnostic tests and digital health technologies (all of which can be a product or part of a solution)[7]. In the following, the main characteristics of medical technology offerings are outlined with a particular focus on the comparison with pharmaceuticals in order to stress the need for a different approach concerning their adoption and uptake:

1. While medical technology offerings and medicines share the common goal of being effective, they can differ in the mechanism of action with which they achieve their effect. Medical technologies can exhibit mechanical or electrical modes of action to restore functionality, or microbiological ones, which can also take place outside the human body (in-vitro). These are easier to prove than pharmacological, immunological, or metabolic mechanisms of action claimed by medicines[8].

2. The research and development (R&D) model of the medical technology industry is very different from that of the pharmaceutical sector. Medical technology innovations are typically available to users and patients within 18-24 months of previous iterations in a competitive market setting. In contrast, pharmaceuticals tend to have longer product life cycles with improvements measured in decades and sold under the conditions of market exclusivity if patent protection has been granted.

3. (Clinical) outcomes of innovative medical technology offerings, which are relevant to patients, often depend on contextual factors such as training, competence, and experience of the user. In contrast to medicines, the user is not necessarily the patient but may well be a healthcare professional (e.g., the surgeon implanting a device). One can think of learning curve effects whereby the quality of care improves over time due to increased experience with the technology or solution. In other words, medical technology offerings are part of the whole healthcare delivery system and their effectiveness evolves over time, influenced by, for example, the skills and experience of the healthcare professional, the quality of the hospital or other setting where they are applied. This also implies that modifications to the medical technology offering can continuously occur over time, while competitive offerings may also enter the market after a while. All these aspects impact the evidence generation as well as the determination of the actual value created. As a consequence, in contrast to medicines, there is often an initially limited availability of large, randomised, clinical studies to demonstrate the comparative clinical effectiveness and full added value.

4. Alongside the lack of availability, there are also methodological challenges arising when conducting large, randomised controlled trials on medical technology offerings. For ethical or practical reasons, double blinding (often seen as an important element in clinical trials as it reduces measurement bias related to the observer's, physician's, or patient's subjectivity) is often more difficult to perform[9]. Problems include for instance: 'what would have been a comparator for an implantable cardiac defibrillator' or 'how would one implant a placebo hip[10]?'. In the light of these difficulties, alternative approaches to trial design for medical technology innovation need to be considered.

5. The direct costs of these medical technology offerings often comprise both the initial purchasing cost, including associated infrastructure, as well as running costs such as maintenance, consumables or added services, which affect the frequency with which the offering is used.

The characteristics of the current access model for medical technology offerings

These characteristics make medical technology innovations unique and hence need to be considered in health system and patient access decisions. The current access model for (innovative) medical technology offerings in the EU as described in figure 1 consists of three main elements (regulatory approval, reimbursement, and procurement). It is important to note that access pathways vary depending on type of offering (e.g., medical device or in-vitro diagnostics), the care setting (e.g., out-patient care/community care or hospital/in-patient care) and the organisation of the health systems itself.

Upon EU-wide regulatory approval (CE-mark[11]) ensuring safety, clinical performance, and benefit as claimed by the manufacturer, the main (yet not exclusive) access channel for medical technology offerings takes place via hospitals and healthcare institutions (70 to 80 percent are procured by them)[12]. Typically, to adopt an innovative medical technology[13] or solution in the hospital setting, the hospital (or more generally, the provider) will be reimbursed as part of either a Diagnosis Related Group (DRG), a global budget or product class. Provided that the offering can be included in the existing reimbursement system, the funding decision can often be made swiftly and without too many hurdles. For truly innovative medical technology offerings, however, adjustments to the existing reimbursement schemes or even the introduction of a novel reimbursement pathway/financing scheme may be required (e.g., a new DRG code, inclusion on the reimbursement list or in the healthcare basket, or special innovation schemes). It can then potentially enter procurement processes, whereby a tender allows the purchaser to choose the preferred offering and the respective supplier.

---

7) Solution: technology plus service or program

8) https://www.tandfonline.com/doi/pdf/10.1080/17434440.2016.1224644

9) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5597993/

10) https://www.medtecheurope.org/news-and-events/press/european-parliaments-resolution-on-pip-received-with-mixed-feelings-by-industry/

11) Under the new EU regulations, for medical devices (MDR) to be implemented in 2021 and for in-vitro diagnostics (IVDR) to be implemented in 2022.

12) https://www.medtecheurope.org/access-to-medical-technology/

13) This also applies to non-innovative, me-too, medical technology offerings.

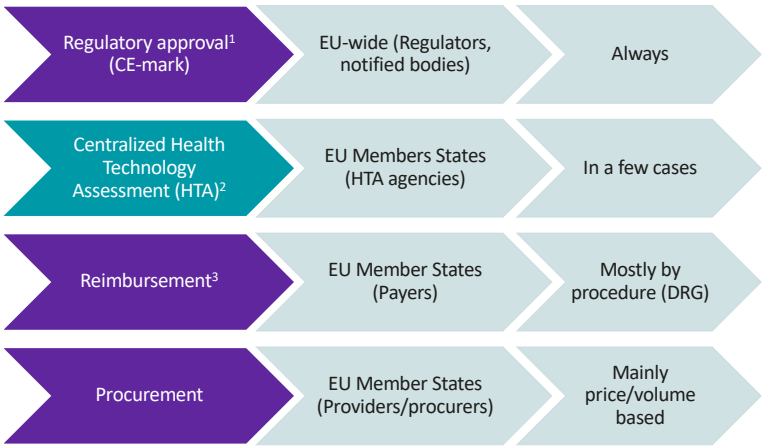

Figure 1: *current access model in the EU – aspects of initial access, adoption, and uptake of medical technology innovation*

Overall, this access model has been well suited to the above-mentioned shorter innovation cycle of medical technology offerings, and generally enables timely access while ensuring competition and budget control. Yet, the current model also shows a couple of weaknesses. These especially refer to medical technology offerings that are potentially truly innovative. While claiming to provide high added value, these innovations may require additional investment and/or structural changes in the healthcare delivery system in Europe. While these technologies may warrant a particular reward, they are increasingly facing difficulties in achieving health system and patient access.

Limitations to the current access model for medical technology offerings

A first challenge arises at the stage of regulatory approval where the full added value of the innovative medical technology offering is not entirely known as its use in practice has been limited. This creates an initial lack of effectiveness data. The use in practice, and thus the possibility to generate effectiveness data, only starts with the adoption and uptake of the medical technology innovation in the health system. However, the successful adoption and uptake of this innovation are hampered if the payer/budget holder requests data on its effectiveness already upon initial market entry as a condition for any decision on funding or reimbursement. This is the case in a few countries and for a selected number of medical technology offerings. Here, an evaluation is conducted after market entry at a national level to determine the incremental effectiveness and cost-effectiveness ratio of the innovation (e.g., via centralised Health Technology Assessment (HTA)). This, in turn, can lead to a delay in terms of the access to the innovation. Moreover, with this approach, one needs to take into consideration that capturing the full added value of the technology is not possible at this stage. A second challenge for these innovations is the way the procurement process is applied, whereby procurement criteria are increasingly centralised and often purely price-based with the aim of reducing procurement budgets. With such a price-based approach, medical technology offerings with high added value (potentially being truly innovative) are likely to miss out on winning a tender, thus slowing or impeding their access to the health system.

Towards a new access model for medical technology offerings

In light of these challenges as well as the specific nature of (innovative) medical technology offerings, there is an increased need for truly implementing value-based healthcare. This paradigm shift in healthcare will, in turn, impact the way the access model and its respective incentive structure should evolve. Such a new model requires changes on all sides. On the one hand, the medical technology industry will have to shift from simply being a supplier of technological innovation (beyond a plain product-selling or push model) to become a committed partner in healthcare, focusing on value propositions that truly respond to the needs of citizens, patients, professional users, and society. On the other hand, policymakers and payers will need to apply a more value-based investment approach to healthcare. This requires the development of an appropriate incentive structure that allows for timely access to valuable medical technology innovation, while rewarding the value delivered. All in all, this calls for the creation of partnership between industry and other healthcare actors as well as the introduction of value-based partnership agreements[14] throughout the innovation's life cycle, providing appropriate and continuous rewards in line with the value observed.

14) Value-based partnership agreements are comprehensive legal agreements to contractually align economic interests between the contracting authority and supplier based on the delivered quality, outcomes, and other award criteria of a medical offering in practice. Value-based partnership agreements reward the value of the technology or solution offered, possibly complemented by value-based incentives/disincentives schemes.

Introduction to the value of innovation and partnership access model

Striving towards the triple objective of:

(1) rewarding high-value medical technology innovations (and in particular those that claim to be truly innovative);

(2) providing timely health system and patient access to such innovations; and

(3) maintaining affordable care and health systems' sustainability,

requires better integration of value, swift accessibility, and partnerships in the existing access model.

The proposed VIP model considers two parameters:

1. Level of innovativeness[15]: One can differentiate between three distinct forms of innovativeness in healthcare: transformative innovation (delivering a fundamental shift towards new patterns of healthcare delivery and requiring investment and structural changes in the delivery of care and/or the health system overall); disruptive innovation (having the potential to 'shake things up', albeit only with temporary impact on healthcare delivery until the next innovation hits the market); and sustaining or continuous innovation (improving existing structures and processes in healthcare delivery, often resulting in increased efficiency)[16]. For the purpose of this model, both transformative and disruptive innovation are defined as (potentially) 'truly innovative'.

2. Type of innovative medical technology offering: The term 'medical technology offering' encompasses medical equipment and medical devices as well as in-vitro diagnostics and digital health technologies. Furthermore, it considers the fact that, with the advent of digitalisation and the ability to integrate care, more and more medical technology innovations become solutions-oriented rather than 'only' product-driven to solve specific shortcomings in care delivery. These solutions often combine products with services and programmes. Hence, one can distinguish between product-based and solution-based innovations, which can be either transformative, disruptive, or sustaining/continuous in nature.

In its simplest form, the VIP model then consists of two phases: (1) the research and innovation phase which is followed by (2b) the routine usage phase. This standard version of the model with only two phases (1; 2b) can be applied to most innovative medical technology offerings which claim to deliver sustaining/continuous innovation to the health system and thus are expected to automatically fit into the existing reimbursement system (e.g., DRG-based). Equally, these kinds of innovations are considered to be routinely applied in procurement processes. However, in order to appreciate new value propositions and the potential of the innovations delivered, these procurement processes will need to evolve towards value-based procurement[17], resulting in a Most Economically Advantageous Tender (MEAT). In April 2014, three new EU directives on procurement came into force, aiming to modernise procurement. The directive 2014/24/EU on public procurement emphasises the importance of value for money and quality, making MEAT best price/quality ratio the default criteria[18]. Value-based procurement will enable this approach and can thereby be supported by value-based agreements between the manufacturer and the procurer/provider. It is expected that especially solutions-oriented innovations will leverage such value-based approaches in procurement.

For certain medical technology offerings, it is proposed to introduce an intermediate phase (2a) right after the research and innovation phase (1) and before entering the routine usage phase (2b). This would apply to technologies claiming to be truly innovative and which are anticipated (but uncertain) to have a very high impact on patients, care delivery, health systems and/or society and, in that capacity, potentially require additional investment. This intermediate phase (2a) is called the health system accessibility phase. Introducing this phase is key to allow for timely access to these innovations, while determining the added value of the innovation and hence addressing the uncertainties that exist on both sides up to this point. Manufacturers face uncertainty as to the return on investment while budget holders/payers face uncertainty in seeking to balance societal values and patient benefits with value for the money spent.

The three phases of the VIP model (1, 2a & 2b) are summarised in figure 2.

15) In terms of added value for patients, healthcare actors, health systems, and society

16) Definitions based on 'Transformative Innovation: A Guide to Practice and Policy for System Transition' by Graham Leicester: https://thenextwavefutures.wordpress.com/2018/03/30/review-transformative-innovation-international-futures-forum/

17) VBP is a multidisciplinary procurement approach for collaboration between healthcare providers, procurers and medtech suppliers in all phases of the procurement process with the aim of achieving better quality of care, outcomes from different perspectives and cost-efficient care, resulting in the most economically advantageous purchasing (MEAT). The basis for VBP is laid down in the multi-layered framework taking into account selected criteria of the outcomes that matter to patients, key healthcare stakeholders (such as the healthcare providers, the provider organisation and the healthcare system) and to society as a whole (e.g. socio-economic impact, innovation and environmental/social sustainability), the cost along the full process care delivery and the price of the technology which are of value and for which there is a willingness to pay.

18) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014L0024-20180101

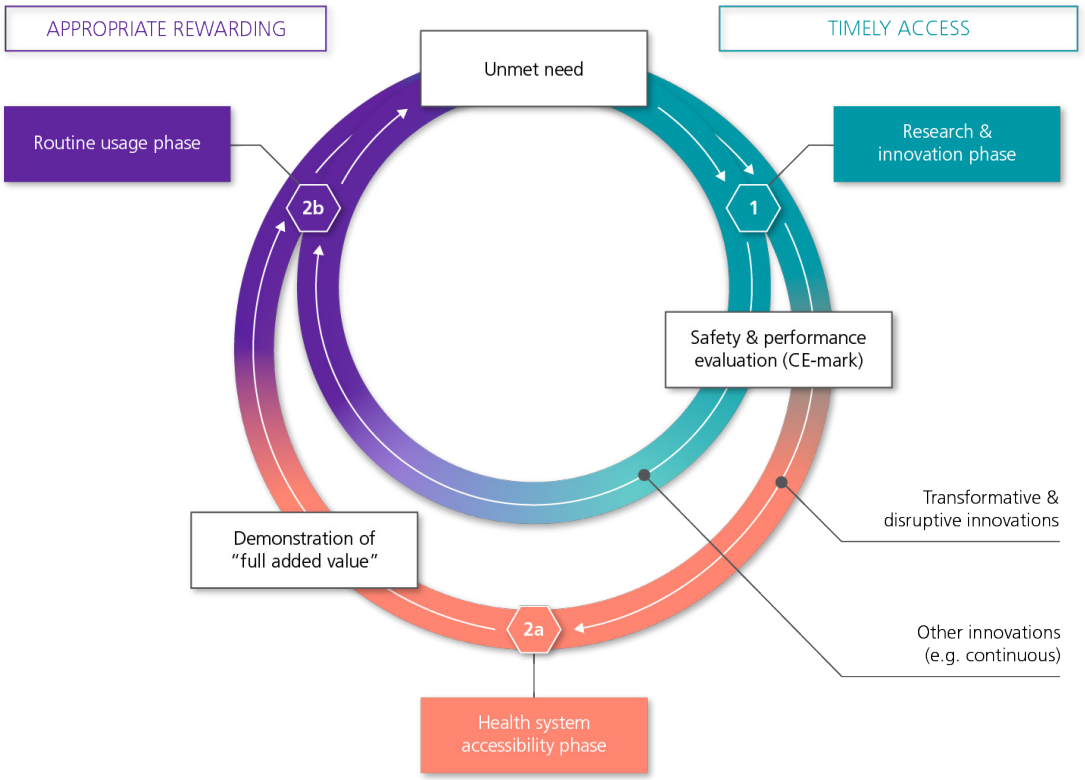

Figure 2: *the different phases (1, 2a & 2b) of the VIP model*

1. Research and innovation phase

The research and innovation phase is the traditional and generally applied phase whereby evidence about 'safety, clinical performance and claimed benefit' is gathered for a new medical technology innovation. At this stage, the focus is on showing an acceptable benefit-risk ratio. While EU directives have governed this process for many years, new EU regulations are to be implemented in 2021 for medical devices (MDR) and in 2022 for in-vitro diagnostics (IVDR). These regulations aim to enhance the ability to introduce medical technology innovations, while monitoring safety and performance throughout their lifecycle, as well as ensuring increased transparency and continuous reporting on clinical benefits[19].

The level of innovativeness of the technology or solution (in terms of how much value is added to patients, health systems and society) is generally still unknown at this point in time. This will be determined using comparative data from settings that are as close as possible to a real-world environments, and pertinent to the national, regional, and local organisation of healthcare delivery[20].

It is important here to distinguish between the clinical investigations performed as defined in the directives/regulations to prove the manufacturer's claim when the innovation is used as intended, and the further demonstration of the added value when used in the specific (healthcare) setting. This is about recognising the difference between efficacy and effectiveness. In an efficacy trial, the patient population is highly selected, the outcomes parameters are often surrogate endpoints specific to the claims made, and the protocol of the study is rather artificial (with for instance several mandatory visits and tests which would not be performed in the real world). In an effectiveness trial, however, the patients and the care delivery are closer to real-life, the outcomes are based on clinically or other relevant endpoints and the protocol involves a schedule of visits, investigations and follow-up that more adequately reflect a real-world setting[21].

Within a model seeking to incorporate value, it is vital that the manufacturer engages in developing well worked out value propositions as well as an early (model-based) value analysis. On the part of the manufacturer, this will require a good understanding of the current needs of patients, the burden of disease, the inefficiencies of/shortcomings in current care and their impact on quality of life and costs, and an estimate of the potential of the innovative medical technology offering to tackle them.

Partnerships between the manufacturer and provider, and hence co-creation, can already be sought in this phase. In this regard, Pre-Commercial Procurement (PCP)[22] initiatives (both at EU and national level) and the very recent, so-called, Innovation Partnership Programmes may help to foster this.

19) https://ec.europa.eu/growth/content/medical-devices-regulationin-vitro-diagnostics-regulation-mdrivdr-roadmap_en
20) https://www.dovepress.com/efficacy-and-effectiveness-trials-have-different-goals-use-different-t-peer-reviewed-fulltext-article-POR
21) https://www.dovepress.com/efficacy-and-effectiveness-trials-have-different-goals-use-different-t-peer-reviewed-fulltext-article-POR
22) https://ec.europa.eu/digital-single-market/en/pre-commercial-procurement

2a. Health system accessibility phase

While the CE mark (see research and innovation phase) is granted at EU level, enabling initial access to the European Single Market[23], the actual introduction of the innovation takes place at the individual Member States level (in accordance with the EU's subsidiarity principle)[24]. Different EU countries apply different processes and levels of decision making related to the coverage, reimbursement, and funding of innovative medical technologies or solutions. For the introduction of medical technology offerings claiming to be truly innovative, this heterogeneity can be challenging because data must be provided to meet different requirements, depending on the EU country's jurisdiction. In some EU countries, there might not be a mechanism or programme to support a controlled introduction and/or a broader opportunity for investment in truly innovative medical technology offerings.

Nevertheless, healthcare budget holders/payers such as national public or private health insurance bodies across the EU share some common ground regarding the open questions (as an expression of remaining uncertainty) that need to be addressed before they decide to fully introduce and fund (and hence incorporate into their reimbursement systems) a particular innovation. Such questions can include, 'what is the added clinical and patient value compared to current care for the population we cover and how strong is the underlying evidence'; 'what is the medical and therapeutic need'; 'what is the value for money when investing in this innovation'; and 'what will be the impact on the budget'. These questions become especially relevant for the introduction of potentially truly innovative medical technology offerings which claim to have a high impact on patients, care delivery, health systems and/or society, and potentially require significant investment to innovate and ultimately transform care delivery.

This opens up the possibility of applying some common principles and approaches in order to meet the objectives formulated in the introduction: ensuring that all patients in the EU who can benefit from these truly innovative medical technology offerings obtain timely access to them provided that they offer a high benefit-risk ratio, optimal added value, and acceptable costs to patients, health systems and society. To that end, special innovation access programmes need to be put in place, with sufficient capacity and funding, so that the efficient, progressive adoption of truly innovative technologies/solutions across the EU can be achieved. Such programmes address remaining uncertainties regarding the innovation's use in practice before it is adopted as standard of care.

To find answers to the above questions and the claimed value, some might advocate (instead of such programmes) in favour of a generalised and systematic use of HTAs at this stage. However, it is argued in this paper that a full and decisive HTA can be an option only in the end stage of the health system accessibility phase (right before entering the routine usage phase), namely once the data (ideally with the aid of real-world evidence) on the true effectiveness and full value and value for money of the innovation is available. To capture the full breadth of value of truly innovative medical technology offerings, contextual and confounding factors need to be taken into consideration. Likewise, understanding the differing care pathways and the learning curve of healthcare professionals or patients using the innovation need to be acknowledged. In other words, if a full HTA is to be conducted, it needs to consider best available and pragmatic evidence (including real-world evidence generated during the health system accessibility phase), which is only available at a later stage in the innovation's lifecycle.

It is therefore suggested that, once the (claimed) truly innovative technology/solution has passed regulatory approval, one possibility should be to apply for what can be called Accelerated Coverage Pathways for Innovations (ACPIs). ACPIs progressively introduce the innovation to the health system under certain well-defined conditions (in the form of agreements between the manufacturer and the payer) regarding coverage and funding as well as its modalities of usage. A jointly conducted early value analysis can serve as a basis for an agreed temporary market entry at a given reimbursement level. This would describe the conditions to address remaining uncertainties before the necessary investments can later be made to achieve the transformation in care delivery and full adoption/uptake by the health system.

Some countries in Europe have already implemented ACPIs and several taxonomies on these have been developed[25]. They imply (or should imply) that a point of verification is set in the future (for instance after one or two year(s)), whereby the real-world outcomes of all or a sample of patients treated with the truly innovative technology/solution are observed between programme launch and the point of verification. If the key outcomes of the innovation are in line with the value assumptions initially made, its value is confirmed, and it can move (according to this model) to the routine usage phase. Once the value verification has been successful, it means that the necessary investment to support the transformation of care delivery, and hence the adoption and uptake of this innovation in the health systems, will take place (see routine usage phase).

If the key outcomes, however, are below expectations, it will affect the incentive/reimbursement level and/or the definition of the target population for the medical technology/solution, as well as payers' willingness to invest in organisational change in the healthcare delivery system. With these modified conditions, the technology/solution might still enter the routine usage phase, but it is likely that the extent of its adoption and uptake will then be diminished.

For promising, and therefore potentially truly innovative, medical technology offerings, ACPIs are an impactful instrument for both payers and manufacturers. They can address the uncertainties on relevant outcomes that healthcare budget holders/payers face during the initial access period, while evidence on these elements is being collected. Ultimately, it will be patients who are able to access these high-end innovations in a timely, albeit progressive, manner through such ACPIs. Thus, an acceleration of ACPIs is now needed in Europe with appropriate capacity. In order for them to be successful, a structured dialogue between manufacturers and payers as well as the application of key criteria of value, to which all parties can agree, are fundamental prerequisites.

Another possibility to be explored during the health system accessibility phase is dedicated innovation procurement programmes (e.g., Public Procurement of Innovative solutions (PPI)) for innovative solutions[26]. PPIs (both at EU and national level) can be facilitated by value-based partnership agreements between the procurer/provider and the manufacturer. In some cases, payers (in the form of national health authorities) can also be involved to provide innovation budgets that can ensure direct adoption of the solution. Similar to ACPIs, the respective agreement between these parties then outlines the required value demonstration and incentive mechanism. PPIs have only been applied more broadly in the recent past, pointing to the increasingly strategic importance of procurement for the introduction of, and timely access to, innovative solutions in health systems.

---

23) Article 114 Treaty on the Functioning of the European Union (TFEU): https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A12008E114

24) Article 168 TFEU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12008E168

25) https://www.medtecheurope.org/resource-library/taxonomy-of-value-based-access-programs-funding-for-innovation/

26) https://www.medtecheurope.org/access-to-medical-technology/value-based-procurement/

2b. Routine usage phase

In this phase (upon successful completion of the ACPI programme), the truly innovative technology/solution can be routinely adopted into the health system and respective reimbursement can be granted or a new financing scheme applied. Yet, even in this phase and depending on the health system, there may still be restrictions regarding the modalities of use of the innovation.

During the routine usage phase, MEAT value-based procurement will need to be applied. The truly innovative technology/solution is thus in competition with others, respecting comprehensive value frameworks for procurement that include quality of care, quality of life, total healthcare costs, and broader socio-economic value considerations associated with the use of a given technology/solution[27].

Finally, it is recommended that the agreed KPIs of the innovation continue to be tracked during this routine usage phase, not only in light of a possible value-based partnership agreement as mentioned above (e.g., as part of ACPIs or PPIs) but also for the sake of health systems and innovations being permanently evaluated and improved.

27) https://www.medtecheurope.org/access-to-medical-technology/value-based-procurement/

Necessary conditions for implementation

In order for the above model to work, some conditions are required:

a. Partnership-driven: ongoing dialogue and an evidence generation plan related to the key performance indicators (clinical, healthcare or socio-economic)

b. Evidence-driven: data quality and data governance

c. Valuing innovation: financial incentives for swift access to innovation and rewarding of the value created as well as regular updates of the prevailing incentives/reimbursement systems

a. Partnership-driven: ongoing dialogue and an evidence generation plan related to the key performance indicators (clinical, healthcare or socio-economic)

Dialogue between manufacturers and payer/provider (procurer) is crucial within the VIP model. A good example is the 2014 EU public procurement directive which clarified and strengthened the legal framework and procedure by which procurers and medical technology companies can talk to each other before and after issuing a formal tender[28].

The rationale behind that was that through pre-tender market consultations and expanded in-tender dialogues, procurers gain critical insights from suppliers about market readiness in terms of available or adaptable relevant innovations and how these offerings can improve health and economic outcomes. This will allow them to take a proactive and internal multi-stakeholder approach also involving e.g. clinicians or nursing staff. At the same time, medical technology companies obtain a better understanding of the concerns and challenges of providers and of health authorities (payers/budget holders).

It is recommended to conduct such dialogues in a broader context than merely tenders, and to apply them already during the research and innovation phase of medical technologies/solutions that are potentially truly innovative, followed by further ongoing dialogues during the health system accessibility and the routine usage phases.

In the first early dialogue, it is advisable that uncertainties, which need to be addressed, are understood and that the evidence generation plan for the new truly innovative technology/solution is developed in partnership, indicating which evidence is going to be collected. At this point, it could also be decided whether the technology/solution is a candidate for entering the health system accessibility phase. Further dialogues are then required to set up the agreement during the health system accessibility phase and to define the criteria for assessing the real-word performance of the technology and/or solution. Building out an appropriate dialogue platform with the payer community and ensuring multidisciplinary platforms will be crucial in the VIP model. Any multidisciplinary engagement and interaction must be ethical and professional at all times (code of conduct)[29]. The EU procurement directive (2014/24/EU) has put forward a framework to conduct such dialogues, describing the modalities of competitive dialogues and negotiated procedures[30].

b. Evidence-driven: data quality and data governance

Gathering real-world data is the cornerstone of the VIP model, especially for truly innovative medical technology offerings during the health system accessibility phase. It is suggested to follow six key principles when collecting real-world data[31]:

1. Define the scope

2. Set up the right governance

3. Establish fair and transparent financing amongst all the parties

4. Ensure collection of quality data and data protection

5. Make data available and report data

6. Guarantee the right education and qualification

When collecting data during the health system accessibility phase, it should be acknowledged that there may be issues of missing data, which leads to biased estimates of real-world performance. Also, many confounders may influence the final outcomes in real life. Patient co-morbidities, patient behaviour, physician usage patterns etc. are just a few of these. Hence, the agreements described in this paper need to build in exceptions – for instance, situations whereby the agreement is not valid. The quality of the contract also relates to the selection and clear definition of key performance indicators to be assessed, clear communication about the consequences if expectations are not met, and the list of exceptions and engagements from both parties to work together to improve clinician and patient behaviour. The key elements that must be included in the ACPIs need to be defined. Finally, the agreements need to be sufficiently pragmatic and based on incentives/disincentives.

This requires again good governance, and several key principles that should apply, including scientific rigour of data management and analysis; access to and availability of the data; considerations concerning the cost of data collection; integrity and privacy issues; and standards for collaborating on data access.

---

28) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0024

29) https://www.medtecheurope.org/resource-library/medtech-europe-code-of-ethical-business-practice/

30) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0024

31) https://www.medtecheurope.org/wp-content/uploads/2017/07/Medical-Technology-Registries-Six-Key-Principles-170509.pdf

c. Financial incentives for swift access to innovation and rewarding of the value created as well as regular updates of the prevailing incentives/reimbursement systems

In the current EU setting, there is still a lot of room for improvement in providing the right incentives to reward value without hampering timely access to medical technology innovations. Regarding one of the main reimbursement mechanisms (DRG systems), it is striking that some countries or regions have not updated their DRG systems for the last 10 years; others have made some form of adjustment, while still others have put in place a review of tariffs or established a complementary system with separate lists of reimbursement for certain innovative medical solutions.

But generally, there is a lack of incentives that encourage investment in innovating the delivery of care and thus the routine usage of value-added innovative technologies and solutions. Yet, for the VIP model to work optimally, financial incentives and policies to foster healthcare innovation and to reward value need to be in place. For instance, if an innovation leads to less readmissions to the hospital, this should not financially penalise the hospital. Innovative payment systems such as bundled services payments and pay for quality programmes need urgently to be considered in those jurisdictions where they are not yet available. Any financing linked to these programmes may well come from innovations that address inefficiencies in the health system (reduction of waste, avoidance of costs etc.) and hence free up resources to be spent where maximum value can be created[32].

Conclusion

The VIP model translates key principles of value-based healthcare into the adoption and uptake of innovative medical technologies/solutions – with a particular focus on those that promise to transform or disrupt healthcare as delivered today. Applying a partnership approach, it seeks to provide the right incentive structure which can ensure value-based investments in healthcare and timely access to innovation for the benefit of patients, healthcare providers, citizens, and society across the EU. While respecting the specificities of each Member States' health system, this model provides a solid framework to harmonise processes and criteria within the EU for broadly introducing medical technology innovation in care delivery.

About this paper:

While the opinion paper has been commissioned by MedTech Europe, it represents the author's own views.

By introducing the VIP model, this opinion piece seeks to stimulate re-thinking access, adoption, and uptake of (innovative) medical technologies/solutions in the European market. The author welcomes any considerations concerning the proposed model via:
CreatingValue@medtecheurope.org

About the author:

Lieven Annemans is a Senior Full Professor of Health Economics at the Faculties of Medicine at Ghent University and Brussels University, Belgium. With twenty-five years of experience in international health economics research, he has published more than 300 papers and four books on health economics.

He also served as president of ISPOR, The International Society for Pharmacoeconomics and Outcomes Research, acted as advisor to the Belgian Minister of Health from 2001 to 2003 and as president of the Flemish health council from 2003 to 2009. He frequently provides lectures on health economics and health technology assessment.

32) https://www.medtecheurope.org/wp-content/uploads/2017/07/Medical-Technology-Registries-Six-Key-Principles-170509.pdf