POSITION PAPER

VALUE-BASED HEALTHCARE

ABIMED

Development:

Execution:

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PREFACE

In the context of the pandemic caused by the new coronavirus, SARS-CoV2 and the increased pressure and demand on public and private health systems, value-based healthcare is once again a focus when we refer to the sustainability of the health system and more efficient and innovative forms of payment models.

We know that the concept of value in health is clear, especially for patients who have always wanted the best care for themselves and their loved ones. But this perception of quality was often not the focus of assistance, due to misalignments in the incentives of the volume-based payment model (ex: fee-for-service). Thus, in recent years attention has turned to how health expenditures are in fact providing value to patients and society at large, and this new look has directed efforts to develop new value-based compensation (VBHC) models. This focus on measuring results is in line with the concept of health that seeks to improve the health of the population, improve the patient experience and reduce the cost of health care.

However, there are some important risks and precautions to consider when implementing these emerging models. While exploring new business models may be of interest to some stakeholders, approaches that focus only on transferring risk from payers to hospitals or from hospitals to suppliers can lead to care rationing and blind cost-cutting, negatively affecting health outcomes regarding health professionals and in individual and population levels. Thus, although it is more difficult to measure, these new models require a complete approach to value, including evaluation of social and qualitative costs and benefits, in addition to only the direct impact of a product or service on the health system. It should also be considered that many factors need to be discussed by countries and health systems when establishing what will work best for their local context (for example, aligning value-focused incentives, defining health outcomes, ensuring appropriate data infrastructure, training and capacity building of care teams etc.).

Within this context, ABIMED's value in health group sought to understand how the medical equipment industry was inserted in the discussions already underway on VBHC in order to position itself as an important stakeholder and thus contribute to the development of the health ecosystem, communicating its role within this scenario.

To this end, the development of this document was structured on three major fronts, resulting in a collaborative and proactive work that discussed the different actions, processes, projects and models involving a value model (VBHC) and how the medical technology industry fits into this new context, considering the particularities and needs of the Brazilian health system. For this, the bibliographic baseline consists of extensive literature research that aimed to understand which national and international publications addressed the main concepts of value, in addition, to the understanding of the current scenario in Brazil. The work team considered it crucial to capture the perception of the various actors in the health production chain about the processes and models based on value in Brazil, which was carried out through interviews with more than 30 leaders in the sector throughout 2020, in several states of the country, including hospitals representative, private health agreements, public health managers, medical and academic societies and human resources (HR) managers.

Thus, this document aims to bring insights from the medical technology industry on the paths needed to conduct Value-Based Care in Brazil, bringing to light trends and the role of the industry as a promoter of value models.

ABIMED Health Value Committee

EXECUTIVE SUMMARY

With increasing pressures on the health ecosystem in recent years, the transition to value-based care (VBC) models has emerged as an alternative to maintain the long-term sustainability of health systems in several countries, including Brazil. Value-based health care can be defined as the relationship between clinical outcomes and the full cost of the care cycle to achieve them, focusing on obtaining results that are important to patients.

With the change in the care paradigm and the redirection of the focus on value, new compensation models also evolve as an alternative to the traditional volume payment system, which has been the predominant model in Brazil in both public and supplementary health systems. This way, we start to value not the number of procedures performed but the quality in the delivery of outcomes in an integrated way throughout the care chain. These changes in compensation models bring a greater sharing of responsibilities and risks among all roles in the care chain, and it is necessary to clearly realign and understand these roles.

In this context, the medical technology industry is also included, whose products and services have great potential to add value to care, impact the quality and overall cost of care and contribute to the sustainability of the health system in several ways. Nevertheless, decision-makers do not always recognize medical technologies as an important point for effective care delivery. In this way, it is imperative for the medical technology industry to clearly articulate how its offerings can not only improve patient outcomes, but also improve the effectiveness and efficiency of care delivery to providers or payers and create value for each of the key stakeholders in the health care delivery chain.

Thus, the Brazilian Association of the High Technology Industry of Health Products (ABIMED), launches this initiative of Strategic Value, in which the points of view of several actors were incorporated into the process of construction of the study, intending to encourage the adoption of the proposed principles and supporting the practices in existing structures as they evolve. The industry understands that effective communication on how the medical technology industry understands value and participates in the implementation of value propositions will drive appropriate adoption of medical technologies and support continued investment in innovations to benefit patients and the health system.

INTRODUCTION

Globally, there is a growing concern with health services, since care costs have increased faster than the rest of the economy in countries around the world, especially those with low and medium income (1). However, although the increase in costs is accompanied by an increase in demand, it is not necessarily associated with improvements in the availability of quality services, raising the need to rethink the traditional structure of health systems so that they deliver quality in care and the results obtained for the patient.

This revision of the care model is also necessary in Brazil, where the health system faces the recurrent challenge of improving the health of the population and, at the same time, keeping costs under control and adding quality to the delivery of the service provided. The demand for health in the country has increased, especially with the aging of the population and the greater load of chronic non-communicable diseases (2), bringing medical needs that increasingly require the promotion of integrated health, from primary care to networks of medium and high complexity, with the use of more complex health services and technologies, more sophisticated diagnostic technologies and chronic treatments. The pressure on the Brazilian health system, which had already been suffering from the country's economic and political crisis in recent years, became even more evident with the situation generated by the Covid-19 pandemic in 2020/2021, where health services operated at the limit of operational and economic capacity. In this scenario, generating value in the care service becomes increasingly relevant to maintain the sustainability of the health system.

In view of this, it is essential to understand how the health chain is financed in Brazil, since it impacts the quality of services provided and the clinical outcome of the patient. Health services in the country are offered in the public sphere, through the Universal Health System (SUS), and in the private sphere, through the supplementary health sector and the provision of services with direct disbursement by users (out-of-pocket expenses). Despite covering only a quarter of the Brazilian population, the private sector is responsible for more than half of health spendings in Brazil (3). In this segment, there has been a predominance of the care model focused on the provision of focal care, with little integration into a care network, and which has gained solidity in execution with the model of remuneration for services, the so-called fee-for-service (FFS). By focusing on the volume of procedures performed, regardless of the quality of the service provided and the health outcome brought to the patient, this model does not consider the treatment in an integral way and carries with it the risk of overuse of services and the inefficient use of resources (4). For example, it is estimated that 19.1% of care expenditures on Brazilian supplementary health in 2017 came from undue spending on fraud and waste (5).

In response to the need for a more efficient care system, the adoption of the value-based health care (VBHC) model has been increasingly present in institutions. In this approach, the improvement of the health system is focused on obtaining better results for patients in an efficient and sustainable way for the health system, increasing the value in the care delivered, without focusing on the simple reduction of direct costs (6,7). With the redirection of the focus on value and quality, new archetypes of compensation models evolve as an alternative to FFS, such as "service packages" (""), which seek to cover the needs of a line of care in a shared way throughout the care chain.

For this to occur, it is essential that there are joint efforts among all actors in the health chain, with clear understanding and alignment of their roles. This also includes the medical technology industry, whose products and services can add value to the delivery of care and provide good health services that contribute to the sustainability of the health system as a whole, when they are selected and used appropriately, based on scientific evidence and good practices (8). An example of this are in vitro diagnostic tests, which, when used with established diagnostic algorithms, can reduce direct and indirect health costs, generate better results and thus add value to the entire health chain (9). However, medical technologies are not always recognized as an important point for the effectiveness of care delivery and a critical factor for decision making or influence. In this way, it is essential for the medical technology industry to understand, demonstrate and clearly articulate how its offerings can improve not only outcomes for patients, but also create value for each of the key stakeholders across the health care delivery chain.

Thus, the Brazilian Association of the High Technology Industry of Health Products (ABIMED), representing the medical technology industry, being one of the actors in the health ecosystem, promoted this initiative in order to discuss value-based health care in Brazil, inserting in this context the proposed role and how collaboration between all actors, including the medical technology industry, can encourage and accelerate such discussions, in order to allow the implementation of a value-based model aimed at access to quality health in the Brazilian scenario for the sustainability of the health system.

CONSTRUCTION PROCESS

The construction of this document was structured on three major fronts, resulting in a collaborative and proactive work of ABIMED that discusses the different actions, processes, projects and models involving VBHC and how the medical technology industry is inserted in this new context, considering the particularities and needs of the Brazilian health system.

Literature review

The basis of this document resides in national and international publications, reviewed to explore the main concepts, the current Brazilian scenario and the performance of the medical technology industries in the implementation of projects involving VBHC in the country.

Interviews with sector leaders

One of ABIMED's concerns in the preparation of this document was to capture the perception of the various actors in the health production chain about processes and models based on value in Brazil. To this end, throughout 2020, interviews were conducted with more than 30 sector leaders in several states of the country, including representatives of hospitals, health operators, public health managers, medical and academic societies and human resources (HR) managers of companies.

Workshop with representatives of the medical technology industries

To contemplate the perceptions of the medical technology industries, a workshop was organized with ABIMED associates to discuss, in view of the perceptions of the other actors in the value chain, the necessary paths for the propulsion of value-based care in Brazil.

More details about the construction process of this work can be found in the ***Methodological Notes*** *at the end of this document.*

WHAT IS VALUE-BASED CARE?

Literature

The beginning of an effective discussion about value in health and the necessary paths to be followed starts from the understanding of the main concepts, both from a theoretical perspective and from the point of view in the practice of the actors in the health chain in Brazil.

According to the concept introduced by Porter and Teisberg in 2006, value is defined as the relationship between clinical outcomes and the integral cost of the care cycle to achieve them, focusing on results of importance to patients (10). A third dimension is added to this, which evaluates the relevance of the services performed to achieve the best outcomes for that patient. Thus, the value equation has three main components,

$$\frac{Outcomes}{Costs} \times Relevance = Value$$

Image 1. Definition of Health Value according to concepts of Porter and Teisberg

These three components must be linked by the fundamental principle of value vision, which is the patient at the center of care. Listening to their perspective is important to bring better clinical outcomes and quality to the service. Thus, it becomes increasingly relevant to evaluate measures reported by patients, both in terms of outcomes (Patient-Reported Outcomes Measures, PROMs) and in relation to their experiences (Patient-Reported Experience Measures, PREMs) (11,12). The concept of value delivery in patient-centered health services later expanded to a population approach with Triple Aim, which aims to optimize the performance of health systems with the search for three dimensions: improving the patient's experience with medical care, improving the health of the population and reducing the health care cost per capita (13,14). It is also possible to add a fourth dimension (Quadruple Aim): improving the experience of care delivery by health professionals. With the implementation of processes that enable a quality work from the clinical staff, without overloading it, professionals feel more satisfied, valued and positively engaged to deliver value in care (15,16) (Image 2).

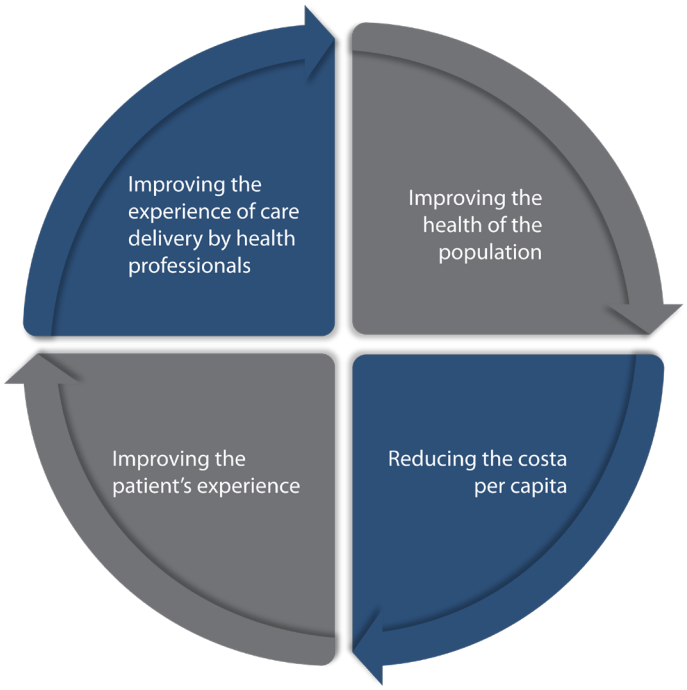

Image 2. Quadruple Aim. Source: Own development

as shown below.

This global optimization of quality, population health and costs involve interdependent dimensions that result from collaborative and integrated action (14). That means that only increasing the quality of care will not imply effectiveness or improvement of population health, as well as excessive concern with costs can lead to a false economy that limits the supply of

More information

If you are interested in going deeper into the concepts of value in health, Triple Aim/ Quadruple Aim, presented in this section, we suggest some references in the "Useful Resources" section.

Perspective of respondents

However, the actors of the health ecosystem have various objectives, which has led to divergent approaches that delay the optimization of the performance of the health system (18), reinforcing the need for alignment around a definition of value in health.

In Brazil, the number and heterogeneity of actors in the health chain may hinder this alignment. Among the leaders interviewed throughout this work, the majority (85%) stated that the practice of value-based health care is part of their work scope. However, the understanding of the concept and the degree of direct involvement varied among respondents, especially in the profile of society (public managers,

medical and academic societies) and in the HR business sector. Among managers of operators and health care providers, 20% of each profile stated that they observe

internal discussions and are aware of the topic, but do not act directly with it in their work institution. On the other hand, 3% of the total respondents, belonging to the HR business sector profile, have no direct involvement with the generation of value in health and admit that they have little knowledge on the subject. (Image 3).

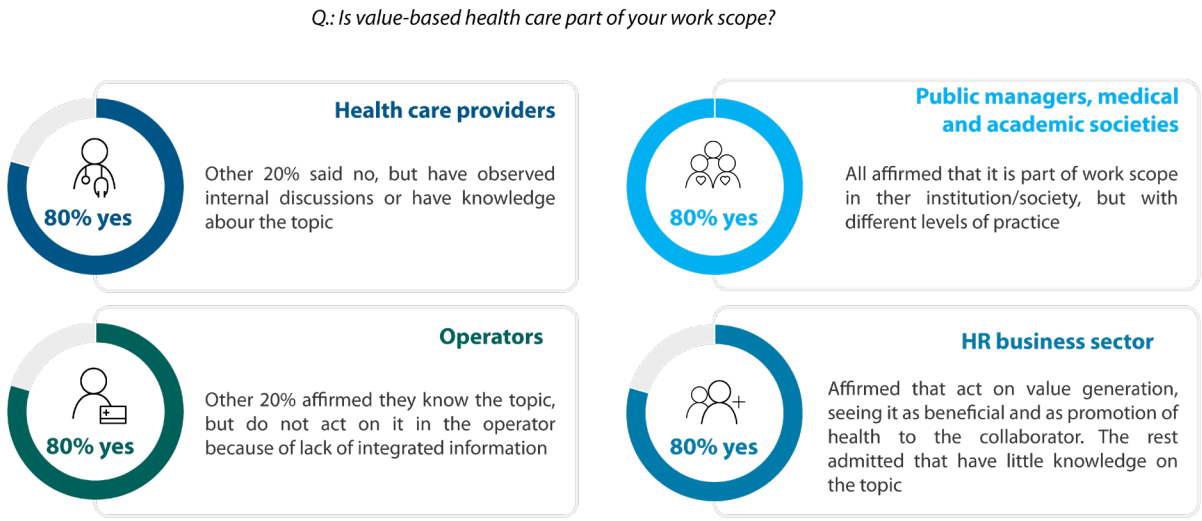

Image 3. Interaction of different players with the practice of value-based health care in the Brazilian context

The general view of the concept of value in health among the interviewees agrees with the importance of optimizing the delivery of quality outcomes to the patient, which eventually leads to the optimization of the use of resources and costs. However, there are variations between the definitions between agents in the same segment, and some interviewees pointed out that they have already witnessed situations of divergences and misinterpretations of the concept. Sometimes, the issue of resource optimization appears as a priority measure, although it does not necessarily reflect greater efficiency and quality in the patient care cycle.

It was also observed that most opinions on the concept of value in health – in different degrees of understanding – came mostly from operators and providers. The decrease in loss ratio and long-term financial sustainability appeared as one of the main motivators of operators in the search for alternative value-based payment models. Among the providers, a great motivator was the search for ways to differentiate themselves from the competition in delivering results to patients, since the quality of care, with delivery of better outcomes and reduction of waste in the use of resources, are factors that increasingly influence the choice of a service provider, both by the patient and by the operators.

Still within the scope of supplementary health, the companies, which are the source of payment of most health plans (about 67% of beneficiaries have business plans (19)), have little involvement in this type of discussion, with few having in-depth knowledge on the subject. Conversations with stakeholders in the business sector reveal that the main perception of value for companies is to offer a good network of coverage for their employees, considering quality, scope and cost. Although costs regarding health and benefits are one of the most relevant for companies, discussions between companies and operators still focus much more on loss ratio and controlling the use of resources than on the generation and delivery of value. In the public

sector, the interviewees' view is that the discussion about value in health is still moving forward slowly, both in federal and state management.

The medical technology industry is also moving towards a more extensive participation in the discussion of value-based healthcare. As occurs among other actors in the value chain, the level of engagement in the discussion varies between the different subsectors of this industry, according to perceptions brought by the workshop participants. However, in general, the participation of the medical technology industry in value propositions is still little perceived or understood by other actors in the care chain.

Industry Perspective

Understanding the value provided by medical technologies, in the paradigm of a value-based care model, should extend beyond the process of evaluating health technologies traditionally applied to medications. Since equipment and medical technologies have distinct characteristics from medications, their value should also be evaluated differently (20,21). Clinical and non-clinical impacts on patients and caregivers, in addition to impacts on operational efficiency, delivery of care and the health system involved as a whole, should be considered for a complete approach to the value delivered by medical technology. Medical equipment and devices can contribute to obtaining better health results without necessarily entailing incremental costs for providers, operators and patients themselves. An example of this are in vitro diagnostic tests, which make up a critical part of medicine and an indispensable tool in diagnosis, prognosis and monitoring. According to a study conducted in the United States and Germany, this type of technology governs about 66% of clinical decision-making, while it accounts for approximately 2% of health spending. When used with established diagnostic algorithms, they can reduce direct and indirect health costs, generate better clinical results and thus bring value to the entire health chain (9). Medical technologies can also help optimize patient navigation through the health system, for example, by identifying in primary care situations of high risk and redirect patients to appropriate care anticipating possible complications (22,23), in addition to enabling the rapid recovery of quality of life and function, leaving patients satisfied with the care provided (24). Innovations in the sector also bring the possibility of expanding access to diagnosis and treatments in environments with limited resources (25).

However, although these studies are important, it is known that the implementation of the value agenda ina the country depends on a range of factors that encompass not only the available evidence and data, but also enabling actions and conditions, such as the engagement of the actors in the chain with the theme for changes to happen. In addition to understanding the basic concepts, it is important to understand what initiatives are already being adopted in Brazil, as well as the challenges and opportunities for the medical technology industry to contribute more and more to generate value in the chain.

[a] The strategic components that define the value agenda can be found in the appendix at the end of this document.

CURRENT SCENARIO OF IMPLEMENTATION OF INITIATIVES IN BRAZIL

Based on the literature review and interviews, initiatives aimed at value-based care in the health chain were mapped and developed in Brazil. There was a stronger movement in the private sector, between providers and operators, although most are still internal projects, such as processes of continuing education and culture change within the organization itself. Although some institutions and companies present a greater degree of progress in the implementation of the value agenda, most still have incipient initiatives or do not develop projects involving VBHC.

As part of the process of cultural transformation, some institutions have established nuclei exclusively dedicated to value in health projects, with the objective of disseminating culture and aligning the concepts of VBHC throughout the hospital organization (26). Others reported that, despite not having a "value office", they began to incorporate the clinical staff in discussions on the topic from the beginning in order to disseminate the change in culture and the engagement of professionals involved in the execution of activities.

In the private sector, providers cited pilot experiences involving mapping and collecting data on clinical outcomes in specific lines of care, including patient-reported outcomes. Some private hospitals and the National Association of Private Hospitals (ANAHP) have begun to implement the sets defined by International Consortium for Health Outcomes Measurement (ICHOM) (27), an international initiative that has already defined sets of outcome standards for 28 medical conditions, covering more than 50% of the global disease burden by 2019 (28,29). The use of such standardized outcomes will allow the comparison of indicators and results between these different institutions, as well as the sharing of experiences and benchmarks. Also, there are initiatives in hospitals structuring lines of care based on scientific evidence, which reshape horizontal patient care, as seen in the case of bariatric surgery, implemented by Hospital Care at the Baía Sul Hospital.

Still in the private sector, operators reported that they have already started to implement alternative payment models to the traditional FFS model in partnerships with specific providers, including risk-sharing models, bundled payments and the adoption of the DRG (Diagnosis Related Groups) methodology for categorization of hospital patients. Although DRG is an important step to create incentives for hospital efficiency, in order to effectively create value, it must be combined with the measurement of care outcomes, ensuring that the cost savings do not compromise the quality of care provided (30).

However, in 2018, only 4% of the amounts paid to service providers in supplementary health had been done through other remuneration models alternative to the fee for service, according to data from the National Agency of Supplementary Health (ANS) (31). Since 2016, ANS has been discussing the implementation of alternative compensation modelsb and, in 2019, published the Guide for the Implementation of Value-Based Compensation Models, also selecting thirteen pilot projects to monitor implementation and execution (31,32). In the previous year, the agency had also opened the discussion to grant economic and financial incentives to operators that

b A summary of the compensation models was made available in the "Appendix" at the end of this document. Learn more about the ANS guide under "Helpful Resources"

prove positive health results, stimulating value-based competition in favor of beneficiaries (33). The 2019 ANS initiative to identify, select and monitor pilot projects of innovative and value-based compensation models of health plan operators, along with their health service providers, aims to support strategies to enable their effective implementation. Focused on the perspective of improving the quality of health care and sustainability in the scope of supplementary health, the approved projects receive an incentive in the score of the Quality Dimension in Health Care – IDQS from the Supplementary Health Performance Index – IDSS (32). Despite encompassing important initiatives, focusing on Primary Health Care (PHC) and population health (32), there was no involvement of industries for co-creation and/or partnerships, also evidencing a possible lack of knowledge about the relevance of the influence of the equipment and medical technologies on the outcomes.

Operators and companies contracting the plans have also invested in joint actions focusing on primary care and preventive medicine, offering, for example, specific campaigns, lectures, physical activity services and mental health support. There are also population health management programs, such as the Care Program for employees of the Brazilian Israeli Beneficent Society Albert Einstein (SBIBAE), in which the care from primary to tertiary is guided by a regulatory center in partnership with a health insurer (34).

In the public sector, there are movements by the Ministry of Health to structure and standardize lines of care, describing the most appropriate path that the patient should take or the referral by the care network that the health team should prescribe, promoting the integration of actions and services in the care network. There are also pilot projects in public hospitals to measure the actual costs and time spent throughout the care cycle of a specific condition (e.g. coronary procedures) through the Time Driven Activity Based Costing (TDABC) approach, that makes it possible to evaluate and estimate opportunities to reduce costs obtained with an optimization of the line of care, contributing to increasing the value in the delivery of services (35). Value-based health care was also the subject of PROADI-SUS, bringing the debate on this management model to the public sector. However, the implementation of alternative models still comes up against important legal aspects, such as rigid bidding processes, public procurement inspections and even the fact that the Ministry cannot receive financial returns (“paybacks”) in the case of poor treatment performance (considering, more specifically, performance-based payments).

Societies and institutes have also been active in promoting studies, courses and workshops focused on value-based and patient-centered care, as well as discussions on value-based compensation models, in line with the perception that it is necessary to broadly align and disseminate the concepts of value in health in the country. In 2017, the Health Coalition Institute (ICOs) published a Technical Note discussing perspectives and actions to be led by several actors in the health chain in the search for the adoption of value-based payment models. Among the topics discussed, the main elements for the construction of these models are punctuated, as well as the critical factors to achieve success with value-based models (30). It is also possible to mention the TDABC in Healthcare Consortium, a collaborative group of researchers who have promoted courses and projects that support value-based health programs (36).

Although still little discussed, the medical technology industry has been actively involved in the design and implementation of value-based compensation models. It is possible to mention the case of bariatric surgery at Hospital Alemão Oswaldo Cruz (HAOC), in which the implementation of a bundle and risk-sharing model resulted in the significant optimization of the use of resources and more robust clinical outcomes compared to traditional models (37,38). The

bundled payment, associated with a diabetes education, diagnosis and treatment program, is also being implemented at Albert Einstein Hospital with a partner industry, with which they also have pilot projects in the care for aortic stenosis and coronary disease (39). Within this context, the role of the industry is to act as a facilitator, providing new more cost-effective technologies and assisting in the training process so that the responsible professionals acquire a better technique capable of delivering satisfactory outcomes.

Based on the mapping done in this work, there is a progressive movement towards a value-driven health model in Brazil, with initiatives that constitute important benchmarking for the implementation of future proposals. However, as important as knowing what initiatives are being implemented is to understand what are the ideas that permeate these projects and what are the pillars for successful implementations.

PILLARS FOR EFFECTIVE IMPLEMENTATION OF VBHC INITIATIVES: CHALLENGES AND OPPORTUNITIES

Based on the perception of the leaders interviewed and the observation of current initiatives, and in line with the strategic points of the implementation of the value agendac, this work listed the **five main pillars** for **concepts to be transformed into effective actions** (Image 3), as well as the main challenges and opportunities for improvement related to these pillars.

Figure 4. Pillars for effective implementation of VBHC initiatives

Stakeholders' alignment and engagement

Much has been discussed about the need for cultural change to implement the restructuring of the health sector focused on value-based care. However, it is also evident in these discussions that the very concept of value is not always understood unanimously among all parts of the same sector. As a result of the heterogeneity of knowledge about value-based health care, it is clear that there is still confusion regarding its concepts and methodologies. It is necessary to consolidate the understanding that the delivery of value is not limited to a reduction of individual costs, but rather to an optimization of resources that brings value to the patient in treatment, considering both health outcomes and costs throughout their journey. And there are already methodologies and implementation cases, both national (including those cited throughout this work) and international (including practical experiences in Europe and the United Statesd (40–43)), which can serve as an example for future local initiatives. This way, the establishment of spaces to share experiences between institutions and services benefits everyone.

The engagement of senior leadership has also been a path adopted until now to start value projects in institutions, since international and national experiences place this factor as a key to success given that the return of value projects are medium-long term (44). However, although senior leadership might be engaged, if the other project participants have not clearly internalized the concepts and objectives of a new value-based model, it is bound to have a time-consuming and unsuccessful implementation, with resistance to change and lack of perception on how the project

c The strategic components of the value agenda can be found in the appendix at the end of this document.

d Learn more about international experience case studies by going to the Useful Resources section.

will bring advantages to the institution. Thus, internal communication, disseminating information and ongoing initiatives to engage all employees, aligning concepts and the value agenda itself, are fundamental. The clinical and non-clinical staff (but linked to the care service) of the providers, for example, must be involved in the discussions and aligned with the changes from the beginning, since they will directly affect their clinical practice. Even in a hospital with centers dedicated to the implementation of value-based care, it is possible to see that awareness on the subject is not yet well disseminated among physicians with less involvement in decision-making (45), emphasizing the importance of a strong and continuous process of communication, education and training.

In short, with the engagement of all actors and dissemination of information, through education and sharing of experiences, it will be possible to have fair and transparent discussions for the search for value-driven models. With the consolidation of this pillar, it becomes possible to manage changes, since value-based models, with integral care, require alignments of incentives different from those practiced until then in the traditional FFS model, with a greater sharing of risk among all actors in the chain (industry, health care providers, doctors and operator).

Measurement of costs and clinical outcomes

The measurement of costs associated with health care, outcomes of technologies used, and standards for treatments are essential tools for the introduction of value-based care. The outcomes to be considered should be significant for the patient, which means that they should add, in fact, benefits and quality to their treatment and recovery. Health professionals play a key role in this model, as they guide medical practice by valuing the patient and seeking results that add value to the treatment. Thus, it is necessary to strive for the continuing education of these professionals and for the effective integration of the humanization of care. Responsibilities should also be shared in the development of clinical protocols and care packages to avoid unnecessary waste and costs, guided by the practice of evidence-based medicine.

The generation and collection of real-world data (RWD) is also an essential tool for measuring costs and outcomes. Real-life data provide information closer to clinical practices and allow risk factors to be assessed, disease and treatment patterns to be described, health outcomes to be assessed and monitored, among others. Such information assists providers in choosing the most appropriate treatment based on performance evaluation; supports the decision of payers regarding the value of new health technologies; and begins to have increasing relevance in regulatory decision-making. The possibility of monitoring data in real-time also opens possibilities to rethink care strategies during and not only at the end of the care cycle, in addition to being useful to measure performance and cost in various contexts, including shared risk agreements.

Finally, after data collection, they need to be structured to be used, either in the personalized follow-up of the patient or for medical use in the decision-making regarding the best treatment. Therefore, it is important that institutions define a purpose for data collection and analysis, collaboratively sharing their experiences and showing what has been done, encouraging the path to change. Today, in Brazil, there is still little structured quality data in the real world, which makes it difficult to understand and monitor the outcomes related to costs: few institutions measure standardized and clinically relevant outcomes for the

patients' journey and there is still a lack of clarity in the objectives outlined in the collection of these outcomes. These difficulties act as barriers in the adoption of robust and effective innovative trading models, especially between technology providers and payers (46).

Information technology

Linked to the structuring of data for measurement, another fundamental tool for the implementation of a value-based care strategy are information technology platforms that support an integrated multidisciplinary health system. Ideally, these platforms should: cover the comprehensive care cycle of patient treatment, use standardized terminologies and definitions, include different types of patient data (from medical observations to laboratory tests), enable access to medical records by all agents involved in care, and allow the extraction of information, facilitating the measurement of outcomes and costs.

Currently, Brazil has data platforms with structured real-world information, such as DataSUS and D-TISS. DataSUS is a platform for collecting and providing real-world information about care to the patient in the public system, containing information on outpatient and hospital use, as well as anonymous demographic data of the patients. In parallel, the ANS provides data and indicators of the supplementary health of the TISS (Standard for the Exchange of Supplementary Health Information), referring to the care provided by the operators of private plans. However, the integration of data between different platforms and databases remains a major challenge, hindering the longitudinal evaluation of patients. In general, since the current information platforms are administrative in nature, they are not yet focused on the collection and analysis of clinical outcomes. In this scenario, the stakeholders involved today present investment initiatives in technologies and partnerships to find and structure digital solutions that help improve the efficiency of the service provided and assume a more proactive role in patient care.

Thus, for a complete and successful implementation of value-based care, it is essential to create and develop a digital system that enables the measurement of outcomes, allowing better capture of patient data, both in volume and quality, as well as simplified management and more efficient monitoring of these data for new value-based health models.

Value-Based Compensation Models

Another important aspect for the transition to the value-based care model is the willingness of agents to change from the traditional volume-based payment model to alternative compensation models based on improved coordination of care and improvement of clinical outcomes with capture of outcomes, contributing to the reduction of avoidable complications. An example is the performance-based risk-sharing arrangements. The proposals of these agreements should be well established from the point of view of what the expected outcomes will be, whether these outcomes will have significant relevance to the patient, as well as defining how and with what frequency the measured data will be collected and made available, among other operational issues. The implementation of these agreements needs to be done with the appropriate tools, with collaboration and transparency, to avoid the risk of regressing the discussion on value-generating mistrust and lack of engagement between the parties involved. In this sense, it is crucial to maintain an open and transparent communication between stakeholders, as well as aligning the responsibilities of each one in the process from the beginning.

The perception of the leaders interviewed in this work is that the unique existence of the traditional model of volume payment is no longer sustainable and that there is a gradual change towards a future in which there will be several types of concomitant models. It is important to reinforce that in this scenario there will still be space and the need for the traditional FFS model, since each medical service will fit into different payment model architectures. Risk-sharing is a model that will be applied in specific areas and with well-defined agreements, but in the long term, the ideal is that there are several payment models, which will depend on the structuring of the lines of care, the profile of the target population defined and the time when each of the players will be positioned in the value agenda.

The risks involved in the transition to a value-based care model can be shared or transferred among the actors in the health chain, depending on the architecture of the model chosen and respecting the maturity and capacity of each of the actors. It is noteworthy that such risks can be shared among all actors, including the paying source, hospitals, health professionals, and the industry. In this sense, the medical technology industry, when sharing such risks, must have an involvement that goes far beyond the simple supply of inputs, also actively acting in the design of compensation models, sharing the know-how related to its technologies to identify the best outcomes and assist other actors in predicting results and improving protocols.

Integration of Health Services

Assistance to a medical condition usually involves multiple specialties and interventions segmented into stages during the patient's journey. The value generated, however, should consider the combined efforts throughout the service cycle. Thus, integrated practice units should share the responsibility for generating value in total patient care, including possible complications (18).

In contrast, the health system in Brazil is currently fragmented in both the public and private sectors. In the SUS, the fragmentation of the care network impairs access and referral between the different levels of care complexity. The complexity and logistics of the system also hinder the longitudinal monitoring of the patient by the physician: patients undergo treatments and examinations in institutions of different instances, and the data are spread across several institutions, making it difficult to visualize the journey as a whole.

Patients cared for by supplementary health also face problems in their journey through a decentralized and fragmented system, where procedures are performed in different institutions, with no consolidated record of medical history. This lack of standardization and consolidation of the journey hinders the monitoring of the patient and sometimes incurs unnecessary repetition of exams and procedures. Traditionally, only the events that generate the payment are observed, and the patient's journey and the outcome generated at the end of the care are not followed up. Even verticalized institutions, which theoretically would have all the data of the patient's journey within their own network, report difficulties to monitor outcomes and costs with this comprehensive view of care.

Thus, there is a growing perception among the leaders interviewed from the health sector that it is necessary to redesign the care process to another model, with primary care as

the guiding care and an increasing focus on preventive medicine, in order to anticipate the needs of patients, avoiding complications and negative outcomes. An important step would be to standardize the data, to allow the evaluation of the patient's journey in a continuous way in the health systems. Another key point to address the search for tools is the search for qualified partners who are prepared to provide the services necessary to implement a value-based health strategy.

POSITIONING OF THE MEDICAL TECHNOLOGY INDUSTRY

Considering the current scenario in Brazil, there are several opportunities for improvement to have effective implementation of the value agenda, from cultural changes, with the preparation of leaders to deal with more dynamic and creative processes, to technological and digital transformations. Such changes can begin with small steps, as seen in the pilot projects and initiatives being implemented in the country, combined with effective and transparent communication between the actors involved in the health ecosystem.

In this scenario, the industry, as a provider of health technologies with the potential to add value to care, can play an active role in building initiatives and value propositions with its partners. Bringing to this perspective the discussions generated from the interviews and literature review, it is important that all players clearly understand how new medical technologies can not only improve patient outcomes, but also generate value for the health chain. The workshop with representatives of the medical technology industry, ABIMED associates, was an important event for discussion among industry stakeholders on the main points of attention for the industry to increasingly act in the promotion and implementation of value-based health projects, generating positive impacts on the health system as a whole. Thereby, the main positions of the sector are listed below.

Value Proposition and Evidence Generation

New compensation models embedded in the value-based care paradigm have led providers and payers to reassess their own performance, including how they select and use medical technologies. Thus, an adequate understanding of the "value proposition" of medical technologies is increasingly needed. ABIMED believes that an effective medical technology evaluation process suitable for each type of procedure will result in a final analysis of the expected "value proposition" and aligned with the new compensation model, which includes:

• Explicit description of how the medical technology will cause clinical impact, along with scenarios to describe the magnitude of the impact (in relation to quantitative and qualitative metrics, when appropriate) and the costs of acquiring the technology, as well as other compensations (such as changes to existing care protocols that require providers to train their staff prior to implementation);

• Consideration of the relevant time during which the impact is expected to occur;

• Explicit recognition of relevant patient subpopulations if impacts are significantly higher or lower than the scenario included in the baseline assessment.

To perform these value analyses, there is a consensus in the industry that one of the key success factors is the availability of structured clinical-economic data. This is because an information system with interoperability can integrate data from the clinical record with billing to enable an analysis and management of population and predictive data. As today our health system is decentralized and the data are fragmented, the care team does not have integrated access to data from patients' medical records, exam reports and drug information, unless they have been administered in a single location.

Furthermore, it is known that in the medical technology industry, the evidence may represent a limitation to the evaluation of value impact, such as the unavailability of randomized clinical trials (RCTs)and a type of study whose design, unlike what occurs for medications, is not always feasible for medical technologies, involving from difficulties of blinding and randomization of groups to ethical issues. Therefore, there are other types of evidence that can, independently or collectively, be used to support decision making on medical technologies, such as real-world studies and other available retrospective and/or observational evidence, as well as other types of study design, such as inputs from experts in the field on the benefits of technology. Well-structured record studies, for example, can provide useful data on the use of medical devices in the real world, in terms of safety, clinical outcomes and those reported by patients (47). Within this context, the industry must act in proximity to providers and payers so that there is more and more decision making based on real world data, which are published as evidence, as well as other types of data and structured inputs that are not restricted to RCT evidence.

Moreover, it is also important to consider that medical devices should be evaluated from a different perspective from medications, following specific methodological guidelines and with a broader view that encompasses, in addition to the evaluation of clinical effectiveness, all the complexity involving medical devices (where they are used, in which situations, who uses them and who they are used in) (48). Unlike medications, whose outcomes are primarily linked to administration and adherence to treatment, the outcomes of medical technologies are influenced by the context in which they are inserted, which means that they depend on factors such as the dexterity of the clinical team, the infrastructure of the place, the management of the operating room and the learning curve of professionals who perform the procedures and handle the medical devices. Thus, it is necessary to evaluate this entire set of variables, with the establishment of clear and adequate criteria for each type of medical technology (diagnostic or therapeutic).

In parallel, it is important to invest in the elaboration of economic evaluations that support the decision-making of health managers and highlight the positive impacts of the allocation of financial resources for the adoption of new technologies. Medical equipment, devices and systems that have been developed and improved by the industry do not only bring better clinical outcomes and better quality of life, and are not only better perceived by patients, but can also bring cost savings, simplification of processes and procedures and can increase the range of tools that health professionals have available to deliver better care. It is possible to seek some economic studies, such as cost-effectiveness analyses, conducted from the international and national perspectives, that show benefits in diagnostic (22,49-52), monitoring (53–56) and surgical (57–60) procedures.

Considering the points discussed, given the value proposition of medical technologies, we can list some guiding principles that should be taken into account in the evaluation of these technologies:

a) Patient-centered value drivers and their relevance and importance for different stakeholders should be considered, taking into account the impact of the device on the clinical outcome aligned with the incentives and prioritization of the stakeholders involved;

e More information on study designs can be found in the suggested support references under the Useful Resources section

b) Consideration should be given to the available evidence, and they vary according to the type of technology and potential risk to patients;

c) Costs incurred and avoided overtime periods determined for the technology should be considered (including, when available, costs incurred and avoided outside the health system – out-of-pocket);

d) It should be taken into account the target populations and applicable times for measuring the impact on the patient;

e) The perspectives of different stakeholders in the construction of value messages and visions should be considered, providing an opportunity for everyone to be involved in the process and comment on the construction;

f) It must be transparent, with documentation of the entire process and analyses carried out, as well as the methodology and literature used;

g) The frameworks built should be updated as new significant evidence is generated.

Discussions and sharing among players

ABIMED understands that the change process to a VBHC model is gradual. Although the generation of evidence is fundamental to value proposition, the chain as a whole must be engaged in the change and willing to contribute. Thus, **the institution and its members propose to foster discussions** with payers, providers or even groups of patients about the aforementioned value proposition, bringing a broad perspective on drivers that should be applied to the evaluation of medical technologies. For **senior leadership engagement**, in these proactive discussions to be promoted by ABIMED, members must also be willing to share success stories and completed studies, both international and national. The sharing of successful cases in the implementation of value-based payment models has been increasingly encouraged in Brazil, such as recent calls from the Health Coalition Institute (61) and the Brazilian Institute of Value in Health (62).

This tangibility of the concepts in real cases will give greater visibility to the sector leaders of how industries can be inserted in this construction of a sustainable health system. This alignment contributes so that, in future discussions, there is greater leveling of understanding and active involvement in a value proposition. It also clarifies about the use of the various types of existing qualitative and quantitative evidence.

PROFESSIONAL EDUCATION AND PARTNER SUPPORT

Medical technology companies recognize that managers, providers and payers need to carefully evaluate technology choices, but reinforce the need for them to consider levels and types of evidence to support the value equation without forgetting that the evidence used in a value assessment is rarely an autonomous solution. This is because medical equipment is inserted in complex care processes involving a variety of different health care providers with different levels of experience with the technology.

Within this context, another important role of the industry is inserted from the perspective of ABIMED, which is to promote professional education in order **to expand the knowledge of medical technologies and equipment and optimize the surgical technique to achieve the best possible outcomes**. Engagement with physicians and other health professionals in this regard is important, as they are the agents whose routine practice is directly involved with the use of the technologies offered that can be used to deliver value in the patient's journey.

In addition to the education of professionals, it is important that the collection and analysis of data and outcomes by service providers, for example, is well delineated and has a clear objective. The medical technology industry, in turn, **can contribute knowledge, technologies and tools that support partners in the process, supporting the greater availability of data**. In addition, industry and partners, in the search for alternative compensation models, must act together in understanding the **various existing value models and seeking those that are more feasible to the local reality**. Risk-sharing arrangements would be the next step after consolidating the other pillars of the value agenda, but they are not the only solution. In addition to risk-sharing, there are other value-based models that can be explored, such as outcome-based agreements, depending on the context and needs of each situation.

It is worth remembering that each scenario has different characteristics and needs depending on the stakeholders involved. Thus, there is room for the medical technology industry to act in a decentralized manner. In the public system, for example, in addition to understanding the existing legal principles for the implementation of innovative remuneration models, it is also important to understand the regional profile needs, especially at the municipal level in order to make proposals appropriate to the local scenario, seeking the best implementation strategy and ensuring long-term continuity. This way, the search for partnerships with state and municipal public offices is an important means of communication that allows the industry to get closer to these managers. At the same time, within the scope of supplementary health, the proposals should be customized and linked to the needs of each business model of health operators, since each modality has its particularities and differences in operation.

ALIGNMENT OF ROLES AND RESPONSIBILITIES BETWEEN PLAYERS

It is important that the medical technology industry, through due scientific basis and the evidence generated and existing in the market, demonstrate how its products generate value to the patient; or how its technologies can act as tools to capture data, helping to analyze costs and outcomes in real-time. This must be done in line with the real needs of the system.

Based on the understanding of the effectiveness of technologies in the patient's journey, it is extremely important to **align concepts, roles and responsibilities of each player** in any value-based agreements, considering privacy and confidentiality limitations. This means that the industry can support the process so that its partners can have more operational predictability, which will support value models, but it is necessary to remember that it also has limitations regarding how much data can be made available – and this needs to be clear in the definition of each agent's roles.

Based on the interviews conducted with the leaders of the sectors, it is noted that the active proposal of partnerships by the medical technology industry is welcome, whether with operators, consortia, providers, public managers, municipal and state health departments, social organizations, research centers. Some medical societies also assist in the promotion and mediation of partnerships with industries, healthtech companies and health providers to implement new technologies that bring value to the patient's journey. The proposals presented must always be clear and concrete, defining what is being offered, demonstrating the added value with technology (through the scientific basis) and what it is proposed to do in practical terms, aligning the expectations of each agent involved and the result that is expected to be obtained with the proposal.

EDUCATION AND INTERNAL COMMUNICATION

Alongside external engagement, industries also need to reinforce internal alignment. It is essential to ensure that industry leaders are engaged with the value agenda and to disseminate leadership information to the rest of the organization as a whole. In all the initiatives under development observed, such alignment was essential to implement changes oriented to the value-based care mindset. In this way, ABIMED supports and encourages the medical technology industries to invest in specific initiatives **of continuing education and strong internal communication**, aiming at the engagement and alignment of all areas in the necessary changes. Effective implementations of value in health require an organizational cultural change.

CONCLUSIONS

Value-based approaches are gaining increasing importance in the discussion about the optimization of treatment and the provision of comprehensive care to the patient. There is also growing recognition of the importance of using real-world data and other available evidence (whether retrospective, observational, experience reports, and patient perspective) in health decision making, whether to identify the most appropriate treatments, to assist in optimizing health outcomes and resource use, or even to support regulatory decision making.

However, for effective implementation of a value-based health model, it is necessary that all those involved – whether industry, service providers, payers, government agents, managers, physicians or patients – are engaged in the construction of this new model, with effective and transparent communication, guided by the common principle. There must be incentives and legal support from health sector regulatory institutions to facilitate and encourage the adoption of alternative models for both the private and public sectors. The main goal of the services is to maximize the supply of value, with cost reduction guided by the search for better health outcomes for patient-focused treatment.

In addition, as an important part of the value chain, it is important to give visibility to the positioning and performance that the medical technology industry can have in this process, since its active participation in the implementation of value propositions can be challenging, but essential for the evolution of our health system towards a sustainable model that really adds value to the Brazilian patient journey.

USEFUL RESOURCES

About value-based health: **https://www.vbhc.nl/what-is-value-based-healthcare**

About the "value agenda": The Strategy That Will Fix Health Care

About Triple Aim/Quadruple Aim:

• Institute for Healthcare Improvement (IHI): **http://www.ihi.org/**

• Berwick, D et al. The Triple Aim: care, health and cost. Health Aff (Millwood). 27(3):759-69, 2008. DOIi: 10.1377/hlthaff.27.3.759. **https://pubmed.ncbi.nlm.nih.gov/18474969/**

• Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. Ann Fam Med.12(6):573-6, 2014. doi: 10.1370/afm.1713. **https://www.annfammed.org/content/12/6/573**

International Consortium for Outcomes Measurement (ICHOM): **https://www.ichom.org/ benchmarking/**

National Health Agency (ANS) Compensation Model Guide: **http://www.ans.gov.br/gestao-em-saude/projeto-modelos-de-remuneracao-baseados- em-valor**

Health Coalition Institute (ICOs) - Value-based payment models: **http://icos.org.br/wp-content/uploads/2018/02/ICOS-02_02_2018.pdf**

Brazilian Institute of Value in Health – Value-based health cases: **https:// ibravs.org/**

About scientific study designs: **https://doi.org/10.1590/S0102- 86502005000800002**

World Health Organization (WHO). Initiatives to ensure innovation and access to medical equipment and technologies: **https://www.who.int/medical_devices/ innovation/en/**

Case studies of international experiences in the implementation of value-based health care (VBHC):

• Learnings from the implementation of VBHC in four different health systems: Massachusetts (United States), the Netherlands, Norway and the United Kingdom (41) **https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0530**

• Martini-Klinik Center (Germany) experience, focused on prostate cancer care (40): **https://eithealth.eu/wp-content/uploads/2020/05/Implementing-Value-Based-Healthcare-In-Europe_web-4.pdf**

• Experience from the Diabeter clinics (Netherlands), with an integrated care model for type 1 diabetes, and the Nederlandse Obesitas Kliniek clinic (Netherlands), with an integrated care model for morbid obesity and bariatric surgery, together with Medtronic (40,63): **https://eithealth.eu/wp-content/uploads/2020/05/ Implementing-Value-Based-Healthcare-In-Europe_web-4.pdfhttps://www.medtronic.com/content/dam/medtronic-com/global/transforming-healthcare/documents/patient-centric-obesity_paper_mdt_av_corpmark_201711219.pdf?bypassIM=true**

• Experience of the Shouldice Hospital (Canada), specialized in hernia surgeries (64).

• Wales (England) National Health Service (NHS) experiences to create a universal value-based health model (40) **https://eithealth.eu/wp-content/uploads/2020/05/Implementing-Value-Based-Healthcare-In-Europe_web-4.pdf**

• Value-based care pilot projects for inflammatory bowel diseases in North American centers (United States) (65) **https://pubmed.ncbi. nlm.nih.gov/30418558/**

• Pilot implementation of bundle payments in the care of head and neck cancer in the United States (66) **https://pubmed.ncbi.nlm.nih.gov/29272202/**

• True Performance Program, a value-based compensation model implemented by Highmark (payer) with its primary care provider network (67) **https://content.highmarkprc.com/Files/EducationManuals/ProviderManual/hpm-chapter5-unit7.pdf**

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METHODOLOGICAL NOTES

Interviews with leaders

To capture in depth the perception of the health production chain about processes and models based on value in the country, individual interviews were conducted between May and September 2020 with more than 30 leaders in the sector, with representatives of hospitals, health operators, public health managers, medical and academic societies and human resources (HR) managers of companies in some states of Brazil, distributed homogeneously among these profiles. Image 5 shows the distribution of participants by state and by profile. About half of the interviewees work in São Paulo.

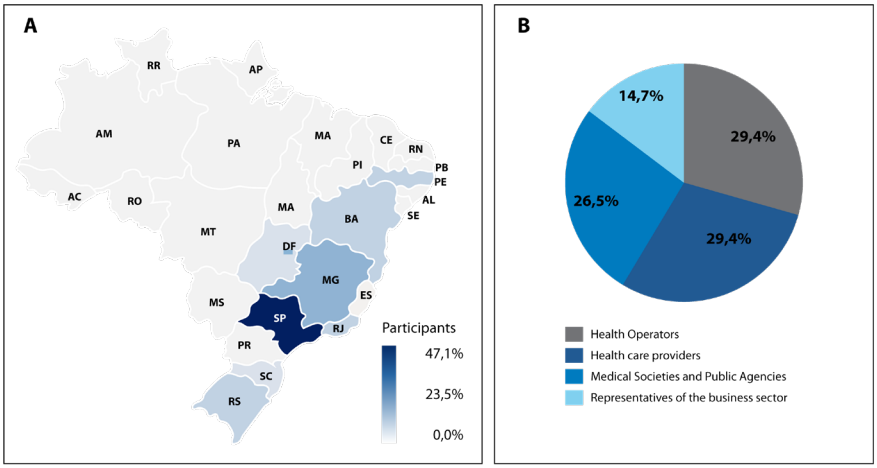


Image 5. A: Distribution of participants interviewed by state. B: Distribution of participants by profile

Four specific questionnaires were developed to each professional profile that would direct the interview according to the participant's involvement or not with projects and processes of VBHC. Among the points explored in the interviews, we sought to understand the experience and performance of professionals, their understanding on health value, how their institution has acted in the development and implementation of actions involving VBHC, what are the main internal and external barriers encountered and the opportunities and changes that are still necessary to foster even more initiatives involving VBHC within the institution. Some additional points explored were the interviewee's perception of how the high-tech medical industry has been involved in the theme, what is expected of this industry and what are the main points of attention for it to have more presence in VBHC projects.

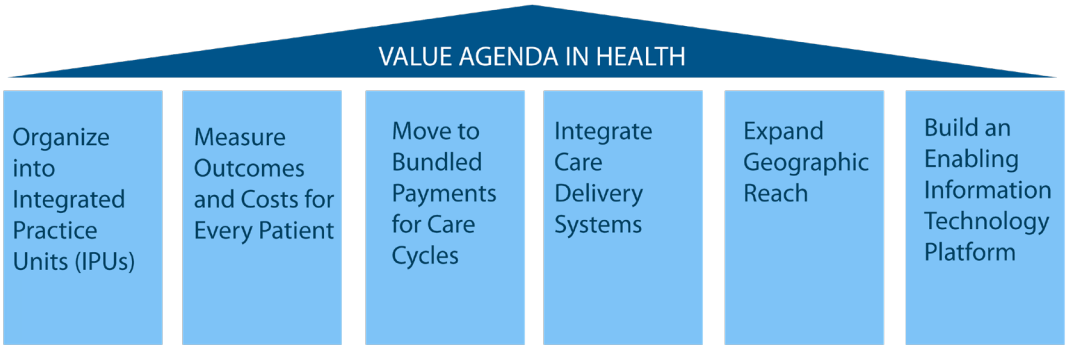
Workshop with ABIMED associates

In order to contemplate not only the perspective of the other actors in the value chain (operators, providers, societies and the business sector), but also the perceptions of the medical technology industries, a workshop was organized in October 2020 with ABIMED associates to discuss, in view of the perceptions obtained in the interviews, the necessary paths for the propulsion of value-based care in Brazil. The current scenario for the implementation of VBHC initiatives in the country and the pillars for their effective implementation were discussed, as well as the possibilities for the medical technology industry to act in these scenarios.

APPENDIX

VALUE AGENDA

To establish a value-based line of care, institutions must observe and implement six key strategic components that constitute the so-called "value agenda" (68):



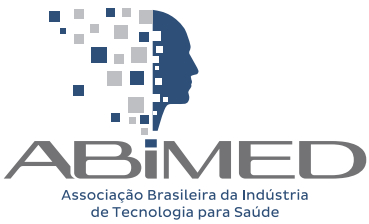
Learn more about the value agenda at: The Strategy That Will Fix Health Care

HEALTH COMPENSATION MODELS IN BRAZIL

Type	Short Description
Fee for service (FFS)	Individual retrospective payment for services to patient
Pay For Performance – P4P	Compensation adjusted by the performance/ goals of the service providers, through some method that already exists.
FFS with performance bonus	
(FFS + P4P)	It follows the same pattern as FFS (Open Account Template) with bonuses for achieving previously defined clinical outcome indicators.
Capitation	Fixed payment per individual (per capita) for a set of health services previously contracted, for a defined population, in a specified period of time.
Global and partial budgeting	Single payment for the total care of the assisted population, estimated through a budget schedule with values usually based on previous payments.

Type	Short Description
Diagnosis Related Groupings (DRG)	DRGs constitute a patient classification system built from the perspective of instrumentalizing hospital management, enabling the measurement and evaluation of the performance of hospitals. It was not originally designed to compose a compensation model.
Wage-earning	Remuneration according to the number of hours worked, regardless of the production of services.
Shared Savings/Shared Risk	Payment model in which service providers continue to be paid according to the Fee For Service system, but receive a bonus or a penalty if the total expenses of the paying source are less than or greater than the amount that the payer calculates and that would have spent in the absence of the program. The bonus or the penalty is proportional to the difference between the projected spend and the actual spend.
Bundle or grouping	Healthcare providers are held accountable for the cost and quality of care recipients received during a care episode, which usually begins with a triggering health event (such as hospitalization or chemotherapy administration) and extends for a limited period of time.

Adapted from the Guide to Value-Based Compensation Models, ANS, 2019 (32)



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