

Towards Value-Based Healthcare and the Role of Regional Agencies: the Approach of the Veneto Region

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The rapidly changing healthcare scene represents a current challenge for all actors involved in care processes, from physicians to regulatory agencies. In particular, several problems affect modern healthcare: general population aging, increased comorbidities, increased attention to targeted medicine and to informing patients, regional differences in healthcare delivery and spending constraints. In this framework, the economic balance of health spending has become a fundamental objective that can combine accessibility and sustainability.

The sustainably achievement of positive health outcomes and the overcoming of unjustified health inequalities are goals of every health system, particularly of those that embrace the challenge of value-based healthcare (VBHC). This approach was proposed by Porter in 2004 to support the best allocation of limited resources [1]. According to this approach, the “value” results from the relationship between health outcomes that are important for the patient (favorable outcomes - adverse events) and costs incurred by the system. These costs can be estimated for both the whole care path and the single healthcare service (drug, diagnostic test, surgery, etc.) [2]. Patients’ outcomes are exclusively considered in this approach, such as the reduction of symptoms, pain, adverse events, mortality and complications, and the improvement of disease prognosis, quality of life and functional capability. Then, as stated by Porter, the value is given by positive health outcomes achieved per dollar spent. In this way, the best resources allocation is that from which the maximum value is gained.

Thus, it is important to quantify outcomes and costs of selected interventions or care pathways to assess healthcare value. It is also very important to compare the ratio between outcomes and costs among different care services or interventions provided. If costs are easier to compute because they are numbers [3], it follows that healthcare outcomes are more difficult to quantify because health is a highly complex concept [4].

Health can be deemed at the same time as an objective parameter, a personal experience, and a societal goal, and its value cannot be quantified exclusively on an economic level. For this reason, the outcomes deriving from an intervention should be considered in terms of effectiveness (a value linked to the intervention itself), utility (a “functional” value) and benefit for the whole community (a monetary value) [5].

From this point of view, the best value is given by benefits that should be shared among all stakeholders involved in the process of care, from patients to providers and suppliers. VBHC implementation is particularly tricky for healthcare services because there is not a single outcome for the evaluation of a clinical condition; rather, outcomes are both condition-specific and multidimensional [2]. Indeed, the care pathway related to a single healthcare service increasingly provides the involvement of different operating units, but none of these units, considered singularly, represents the exclusive place in which the outcome is achieved and, therefore, where value is created [2].

Several initiatives aim to identify both standard indicators that could be suitable for integrated outcomes and globally recognized thresholds for the comparison of these outcomes among different interventions [6]. On one hand, there are different tools (disease-specific and generic) that try to capture a patient's point of view on the personal functional status and health-related quality of life (patient-reported outcome measures, PROMs) or on health-care delivery characteristics (patient-reported experience measures, PREMs) [7].

A more structured approach is that of the International Consortium for Health Outcomes Measurement (ICHOM) [8]. This Consortium developed several Standard Sets, each consisting of a list of standardized outcomes, measurement tools and risk adjustment factors associated with a specific clinical condition. These outcomes are defined by a multidisciplinary pool of physicians, patient representatives and registry leaders. Therefore, health care providers can measure, analyze and improve their performances by implementing these standard sets, taking into account the patient as the center of an effective and coordinated process of care delivery.

There have been more contributions towards improving cost-effectiveness throughout the entire process of care, including recently in the field of laboratory medicine [5]. As the authors underlined, the VBCH approach can effectively improve the relevance of laboratory medicine as any other medical specialty and decrease the risk of inappropriate test requests and interpretations [9].

Valid aid in implementing a VBHC approach in the practice of health services is provided by real-world data (RWD) and Big Data. These concepts are becoming increasingly concrete in the modern health services – but not only - scenario. If adequately oriented to outcomes measurements, RWD can effectively guide the development of valid algorithms able to improve care appropriateness and value. However, even with enthusiasm for the enormous potential of RWD and Big Data, the main limitations of their current use should be taken into account. Indeed, it is necessary to strengthen professional skills in order to collect and manage them in terms of quality, security and analysis. Furthermore, the integration of RWD and Big Data as sources aim to develop innovative approaches in healthcare necessarily requires them to be adequately accessible, in terms of internal management and interinstitutional availability [10].

THE VENETO EXPERIENCE

Since 1997, the Veneto region has set a goal of encouraging scientific research (initially in the field of organ and tissue transplants, promoting the establishment of the "Consortium for Research on Organ Transplantation (CORIT)", with headquarters in Padua). The Consortium, which is configured as a structure with high scientific

competence and a proven ability to transfer technological innovations to the health of citizens, changed its name in 2016 to 'Consortium for Health Research – CORIS,' thus expanding its corporate purpose and operative area to research in health and healthcare.

Among the CORIS activity areas, one regards the planning, coordination, partnership and scientific evaluation of research projects. Within this area, the Consortium acts as the coordinator of several working groups aimed at investigating both clinical and health regional situations. One of these working group is currently focused on the *Value Based HealthCare* (VBHC).

The aim of the VBHC working group, with a patient-centered approach, is to define relevant clinical outcomes for homogeneous cohorts of patients affected by specific diseases and to measure and monitor these outcomes over time. The final objective of this working group is the assignment of a *value* (according to its VBHC definition) to the whole clinical path in order to develop an innovative regional procurement model focused on the considered value. In this context, patient care is valued using a comprehensive approach considering clinical, social and economic aspects.

The rationale of adopting this approach is the attempt to change the way healthcare services are provided, moving from "a silos" conception (i.e., that considers single clinical specialties) to one in which the patient, with her/his needs, is central in her/his own therapeutic pathway. Thus, from taking charge, to discharge, and up to home management is now evaluated by focusing on clinical outcomes rather than on the individual services provided, as suggested by Porter [2].

A true transformation of the healthcare system towards a VBHC approach is only possible through the governance of 4 strategic areas: (i) data availability; (ii) outcome definition; (iii) development of an innovative financing model; (iv) implementation of an innovative procurement model.

Data availability

The ambitious goal of making health data structured and available is very difficult for all stakeholders. As already mentioned, health data analysis involving real-world information is complex. The fragmentation of data in different platforms, the lack of interoperability among these structures, the use of non-updated infrastructure and software and last, but not least, the evidence of high development and maintenance costs are only some potential issues that may arise on this topic. Given the data fragmentation, a single web platform is not feasible. To overcome these issues, the only option is to develop a portal that lives in a layer above the existing ones and acts as an aggregator, which is able to capture the data under a centralized control and maintenance. This infrastructure

should monitor the entire process of care of each patient, collecting any related data (diagnostic tests, interventions, drugs, laboratory tests, etc). In this way, it will be possible to overcome the “a silos” organization with its different noncommunicating data platforms. Therefore, this central-regulated platform should be available to any structure or professional involved in the process of care and its analysis, providing a “user friendly” interface for data consulting and extraction.

Outcome definition

At a national level, the Piano Nazionale Esiti (PNE) can be considered as an example of outcome definition: this program identifies the relevant outcomes for patients (depending on the pathology they are affected by) and measures/assesses them over time. However, it is exclusively based on administrative data. As stated above, these data are useful for developing indicators that measure a structure’s efficiency; however, they only provide partial information on the true care process of patients and, more importantly, scarce clinical information. Consequently, this data source should be integrated either with the clinical databases (digital and structured data collections) existing in hospitals or owned by the Health Authorities, and the clinical information gathered from prospective data collections (including PROMs data), in order to overcome the limits of the PNE model.

Finally, using the joined administrative and clinical data related to homogeneous cohorts of patients, it will be useful to develop specific algorithms to predict the clinical outcome and useful as health planning tools.

Financing model

According to VBHC approach, the financing system of National Health Service should also evolve, moving from a “rate-per-service” system oriented to pay for the single service provided towards bundle payments aimed at rewarding the overall patient’s management along the whole process of care. Such an innovative financing system, linked to the patients’ taking charge and not to the single services provided, could allow the establishment of a more advanced reward mechanism based on the achievement of the abovementioned clinical outcomes, that is, on the true value-for-patient.

Procurement model

To modify existing procurement models in the light of the produced value-for-patient produced is necessary for the Regional (and also National) Healthcare System transformation process. This renewal can undeniably take

place only after the development of the three previous steps in order to guarantee quality and sustainability to the healthcare system. The development of a procurement model based on the observed results could represent an important element for the implementation of innovative processes of care, possibly more appropriated and efficiently responding to populations’ needs than the current ones. Moreover, implementing a procurement model focused on the outcomes could actually lead the Healthcare System to a care delivery strategy that gives priority to the acquisition of technologies associated with the achievement of better clinical results (once again, enhanced value-for-patient). To date, public Italian purchasing systems have been calibrated to buy products instead of value (i.e., guaranteed outcomes to the patient), and the transformation illustrated above becomes fundamental, especially in the field of medical devices.

APPLICATIONS

The Veneto Region, through the VBHC working group, is currently developing a pilot project in the field of cardiology and cardiac surgery, including in the study cohort patients who underwent transcatheter aortic valve implantation (TAVI). The project involves the Operational Units of Cardiology and Cardiac Surgery, where the TAVI intervention is realized within the regional boundaries.

A multicenter, retrospective, observational study has been planned to collect clinical data from the Operational Units and link them with administrative data already available at a regional level. The main aim of the project is to define, through a joint analysis of clinical and administrative data, a model that can predict short, medium and long-term outcomes in these patients.

Then, a traditional clinical analysis, including outcomes and risk factors, will be integrated with an economic analysis in order to quantify the costs associated with the cohort enrolled and to allow stratification based on their cost profiles. The impact of risk factors and pre-intervention conditions on any economic differences will also be assessed.

As a last step, a procurement model based on the results obtained from previous phases will be defined and purposed.

Since there is not currently a common structured computerized database used in all healthcare units, and in some cases it is necessary to digitally transfer information contained in medical charts, a dedicated application has been developed to automatically enter data into the Patient Health Record (a regional structured computerized medical record for which information can be seen – with the patient’s consent – by the healthcare facilities that treat the patient). This procedure automatically includes the anonymization of the clinical data with the same key used for the administrative ones in order to link, obtain

and provide the information about patients' whole care process.

CONCLUSIONS

In the Veneto Region the VBHC working group is currently defining and measuring selected outcomes for specific patient cohorts. Each outcome will be associated with the corresponding generated costs, in order to constantly assess the value that is the performance measure given by the relationship between the health outcomes and the costs [2]). This approach will generate information that is necessary to continuously improve the Healthcare System. Outcomes to be measured are based on patients' clinical conditions rather than on the service provided (single exam or intervention). At the same time, the collection of cost data should cover the whole process of care and not only the spending of the single department or service.

Furthermore, this project seeks to underline the importance of adopting a financing model that encourages both improvement of health outcomes and reduction of the related costs. Finally, the ultimate goal is implementation at the regional level of a procurement model based on value in order to reward the whole process of care for a specific clinical condition. In other words, it aims to abandon reimbursement approaches based on individual performance.

From a public health perspective, the goal of this VBHC approach is sustainability of the health system both from clinical (better outcomes for patients) and economic (lower costs for the system) points of view through an improved resource allocation policy.

Conflict of interests

None

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