TITLE
Creating value through clinical operations management: lessons from Multiple Myeloma

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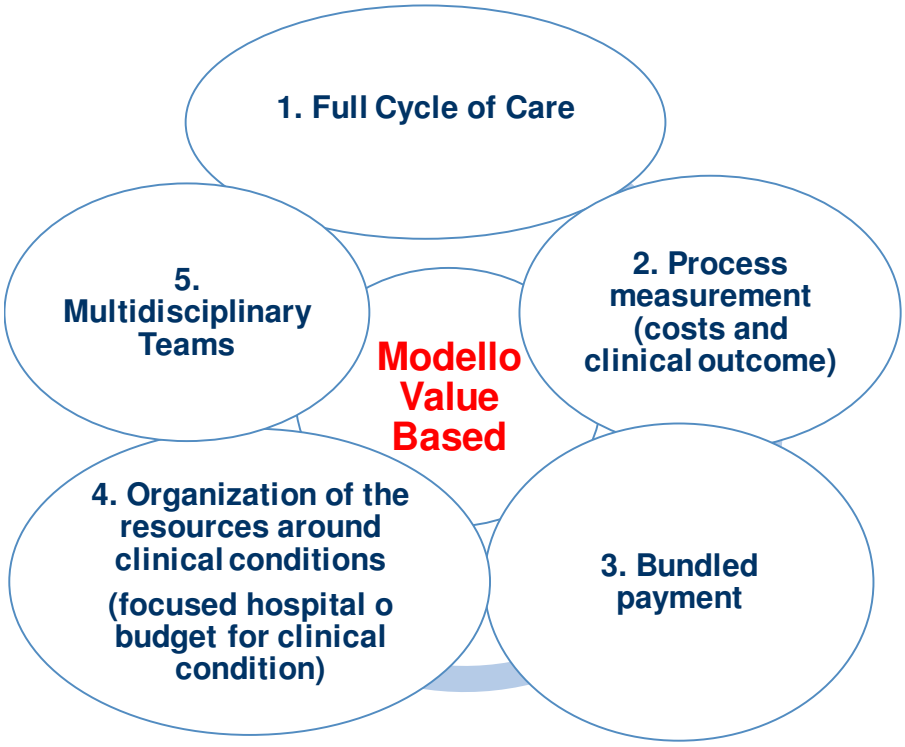
Abstract
The paper tries to test the applicability of the value-based health care model to the case of an oncological disease (Multiple Myeloma). This model sustains it is necessary to reorganize operations around clinical conditions.
To achieve this goal authors have adopted a multiple-case study approach combining qualitative and quantitative methodologies.
The contribution goes along three different directions.

1. it is relevant to standardize the clinical decisions making process also because different clinical decisions do have an impact on costs;
2. the operations management system should better support the clinical processes;
3. the current information and reimbursement represent a relevant gap.

THEORETICAL BACKGROUND
In the current healthcare context, the challenge is to keep up with the demand and expectations of patients with shrinking available resources.
In this regard, a wide debate has recently developed around the concept of Value Creation - intended as clinical outcome achieved per resources used - which has become a focus of attention for all healthcare stakeholders (e.g. health care providers, industries, policy makers, etc.) especially in some Countries such as US and Scandinavian countries.
The proposal of a healthcare delivery based on value creation actually wants to highlight that value creation is possible only if providers organize their delivery model around a medical condition and provide services that consider the so-called "full cycle of care", also interpreted as the overall needs of the patient related to a certain clinical condition.

As represented in the Figure 1 the value health care model is often summarized in five key principles: (i) Full Cycle of Care; (ii) Process measurement (costs and clinical outcome); (iii) Bundled payment; (iv) Organization of the resources around clinical conditions (focused hospital o budget for clinical condition) and (v) Multidisciplinary Teams.

Figure 1 – The key principles of the value-based health care model



PURPOSE

After defining the general drivers for the creation of value within healthcare firms, particularly in hospitals, we will analyze the clinical and operational drivers that allow the creation of a greater value for patients, and subsequently verify their application to the case of "multiple myeloma".

The present paper tries to address two different questions:

1. Which are the critical operational drivers to redesign operations around clinical conditions?
2. What is the economic and organizational impact of different clinical and organizational decisions along the full cycle of care?

RESEARCH DESIGN

To address these two research questions authors have adopted a multiple-case study approach combining qualitative and quantitative methodologies.

The clinical condition selected is Multiple Myeloma (MM) a neoplastic pathology triggered by proliferation of a plasma cells neoplastic clone.

This pathology has been selected since it is characterized by all the main challenges of the modern healthcare systems particularly:

- holistic and integrated approach;

- coordination and networking between different providers;
- multidisciplinary approach;
- stewardship of innovation.

The study has been conducted in three different hospitals. The choice of the cases included in the analysis was based on three different criteria:

1. relevance of the center in the management of MM based on overall number of cases and clinical reputation;
2. availability of clinicians to collaborate in the research;
3. availability of hospital Information Offices to provide data on costs.

Consistent with the replication logic (Yin, 2009), we stopped the analysis to three cases when we considered to have reached reasonable in-depth knowledge about the process flow for MM patients. In each hospital, we carried out ten semi-structured interviews to all the different actors (physicians, nurses and pharmacists) involved in the entire healthcare chain for these patients.

To calculate the economic impact of different clinical decisions we used the Time-Driven Activity Based Costing (TD-ABC) approach. This cost accounting methodology allows the costs allocation to the various activities of the care process based on time (Keel et al. 2017). According to this methodology indirect costs (mainly infrastructure costs and personnel) are assigned to the process of care based on the driver of time; in order to calculate the time spent by the patients, in each facility and with the different healthcare professionals, across the entire cycle of care, authors have combined interviews with direct observation at hospital floor.

It should be noted that, in order to guarantee an objective and comparable cost data between the various treatment centers, some general overhead costs have not been taken into account, including for example: energy, water, heating.
The TD-ABC methodology was used, in this study, as a tool, for evaluating resource allocative efficiency in relation to the various therapeutic alternatives of the treatment pathway.
The phase of data collection, through semi-structured interviews, has been divided into 4 steps:

i) Definition of the actual care pathway and identification of the therapeutic phases (flow-chart): through the administration of a semi-structured questionnaire to the various actors of the care process, we examined phases and activities for the patient affected by MM.
The design of the actual clinical path was, subsequently, validated by the physicians of the three structures in two different Advisory Boards.

ii) Creation of the resource / activity matrices for each therapeutic phase: on the basis of semi-structured interviews and direct observation we computed the time of each activity along the full cycle of care.

iii) Collection of data cost: collection of data through the collaboration of the accounting office of each hospital.

iv) Analysis of data cost and calculation of the full cost of therapeutic alternatives.

FINDINGS

The study shows that, in order to realize the receipt proposed by the value based model, it is very much important to preside the relationships between the clinical decisions making process and the operations management system.

As for the clinical decision making process, the analysis of the clinical operations clearly shows that there are five **clinical decision nodes** that it is important to control and standardize:

1. choice of the main therapeutic treatment: transplant vs. pharmaceutical treatment;
2. typology of apheresis;
3. option for a follow-up transplant;
4. choice of the pharmaceutical treatments and route of administration: (i) oral; (ii) subcutaneous and (iii) intravenous;
5. choice of type of setting for the pharmaceutical treatment: (i) ordinary beds; (ii) day-hospital and (iii) outpatient.

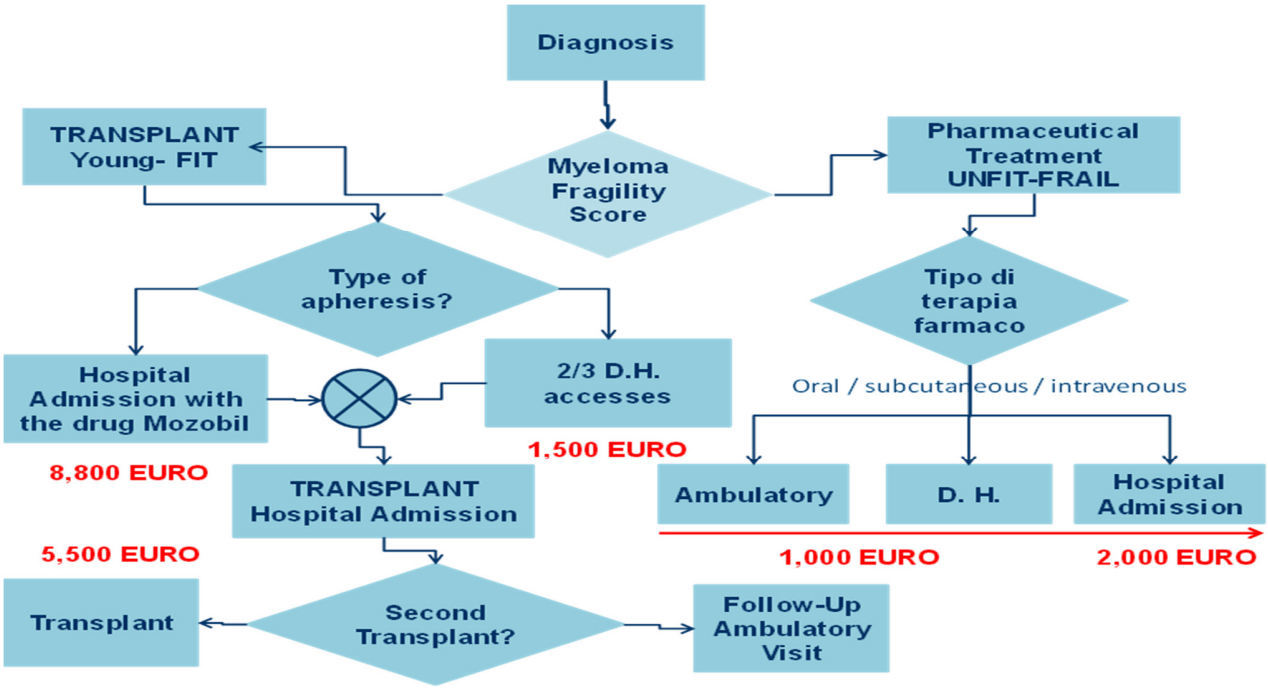
The MM clinical pathway should be, then, supported by an operations management system capable to support clinical operations, in particular, around five different aspects: (i) timelines of access of care; (ii) hospital networking, (iii) multidisciplinary teams, (iv) involvement of nurses; (v) integration between acute and primary care

Furthermore, the costs analysis shows that different choices along these five decision nodes do have a relevant economic impact, for example:

- the phase of apheresis conducted at outpatient level costs roughly 1,500 EURO while the apheresis conducted at hospital level with the use of the drug Mozobil costs up to 8,800 EURO;
- the decision of making a follow-up transplant has an additional cost of 5,500 EURO;
- the same pharmaceutical treatment administered at day hospital has a cost of 2,000 EURO but it costs 1,000 EURO more if the same treatment is administered in a regular floor.

The analysis shows that different organizational care models present different costing profiles, while, on the other end, assuming a certain organizational model, there are no significant differences across the three different hospitals.

Figure 2 – Process of care for MM patients: possible clinical decisional nodes and economic impact



CONTRIBUTION

The contribution of the present paper goes along **three different directions**.

On the side of **clinical management**, the study shows that there is room to standardize the clinical decision making process. In general, operations professionals agree that standardizing processes can be a great method of reducing costs and increasing quality (Boyer and Pronovost, 2010).
In all the three cases analyzed the clinicians do agree on the assumption that clinical evidence should guide the decision making process but also argue that, considered the complexity of the pathology, in some cases it is difficult to establish golden rules and best practices.

It is, thus, important creating a clinical pathway in order to (i) integrate and coordinate the different activities along the full cycle of care and (ii) define the best logical-temporal sequence of medical interventions, nursing and all the other health care workers involved in the treatment of a medical condition.

Secondly the study indicates some gaps that still need to be filled in order to fully implement the value-based health care model. In particular, the analysis of the three cases shows two important limitations:

1. **the current information system** is still vertically organized and not designed around processes of care; it is, thus, difficult to gather reliable information on costs and clinical outcome of the overall cycle of care for specific clinical conditions;

2. **the financing system influences**, in certain circumstances, the overall decision-making process. As pointed out by Kaplan and Porter (2011), the reimbursement system, whose characteristics are mainly linked to the institutional environment, has repercussions on different levels: i) Financial, ii) Operational management, iii) Provision of healthcare services. In fact, as empirically underlined by S. J. Lee et al. (2016), funding policies, or payment processes, can have a significant impact on the implementation of the optimal care process and, consequently, on the health outcomes obtained. In light of this, it is necessary that the managers of operational management (see Operations Manager) and the clinicians, in order to provide a service based on appropriateness, must pay particular attention to the influence of the financing system within the decision-making process.

Finally, the cases' analysis shows that, besides considerations about cost and clinical outcome other dimensions rightly step into the process, in particular (i) **patient's satisfaction and (ii) organizational efficiency.** To this extent it is important to consider two aspects:

1. patient preferences vary highly across the individual physicians;
2. organizational efficiency is taken into consideration only partially and on the basis of the contingent priorities of the top management.

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