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A systematic research methodology for business model decision making in commercialising innovative healthcare diagnostic technologies

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Abstract. Business models and decision making play a vital role in the delivery and implementation of technological innovations in the healthcare industry, especially for entrepreneurs, healthcare providers, managers, researchers and policy makers. However, despite its significance, current conceptualisations of business models do not adequately guide in designing business models particular to the complex and dynamic healthcare environment. With the exploratory nature and lack of research in this area, this paper aims to design a new methodology to develop business models incorporating multidimensional implications of various stakeholder perspectives. A systematic literature review of existing methods in business models and decision making has been done and a new methodology has been proposed, entitled Thematic+TISM+MICMAC = TTM methodology. An application of this method has been tested with empirical findings from the healthcare diagnostics value chain to establish the key factors of innovative business model development in healthcare decision making. Limitations, future directions and challenges in the proposed methodology are also discussed. It is hoped that this study will guide practitioners in future work towards advancement of these techniques and will help the managers to select better decisions by making use of these methodologies.

Keywords: Business Model, Decision Making, Healthcare Value Chain, Innovative Diagnostics, Medical Device, Success Factors.

1 Introduction

Healthcare is a very dynamic and innovative field despite its bureaucratic nature. The innovation ranges from new medical technologies to clinical services emerging from a wide range of inputs and stakeholders such as scientists, engineers, clinicians and most importantly, patients. Technological advances, disease outbreak, demographics and patient demands are main drivers of innovations in this segment. However, due to the complex nature of the healthcare environment including technical, societal,

institutional, and political considerations creates difficulties for diffusion of innovations [1]–[3] and change initiatives intended to make improvements [4], [5]. To understand why this happens, it is essential to examine the implicit and explicit business models (BM) and understand how innovation actually takes place.
BM design and innovation are crucial for a firm's performance and success [6]–[8] and to adapt to changing environments [9], [10]. In every business venture established, it either explicitly or implicitly employs a particular BM [11], and for a venture to become viable, a sound BM is required [12]. A BM can be defined as "the logic of how an organisation creates, delivers, and captures value" [13]. BM design and innovation are crucial for a firm's performance and success [6]–[8] and to adapt to changing environments [10], [14]. 'Designing' a business is an iterative task that shall be flexible and adaptive to the competitive environment [11]. While the BM concept first became popular in the Internet bubble era in the late 1990s and has rapidly been researched in a wide range of businesses, it was rarely studied in the healthcare industry.

With the exploratory nature and lack of research in this area, this paper aims to design a new methodology to develop business models incorporating multidimensional implications of various stakeholder perspectives. Specific objectives include:

- Identification of factors influencing BM design for innovative healthcare technologies
- Establishment of factor relations and ranking using TISM methodology
- Classification of factors based on their driving and dependence power using MICMAC analysis
- Derivation of practical implications

A systematic literature review of existing methods in BM healthcare and decision making has been done and a new methodology has been proposed, entitled Thematic+TISM+MICMAC = TTM methodology. An application of this method has been tested with empirical findings from the healthcare diagnostics value chain to establish the key factors of innovative business model development in healthcare decision making.

1.1 **Research context**

As the healthcare value chain is a complex web of interconnected entities working collaboratively to develop and link the medical diagnostic device to patients, a comprehensive and deep understanding of the medical device business model can only be reached by probing healthcare value chain stakeholders' thoughts, values, prejudices, views, feelings and perspectives. In this study, the motivation comes from the EU Horizon 2020 Project entitled, AiPBAND (An Integrated Platform for Developing Brain Cancer Diagnostic Techniques), which aims to advance the early diagnosis of brain tumours using molecular biomarkers in the blood with state-of-the-art technologies.

Brain cancer market, research and developments

Treatments for cancer have been advancing at an accelerated pace in recent years, offering clinical progress, as well as increased specificity through selection according to biomarkers, or through engineered cell or gene therapies. Drivers of diagnostic technology innovation and adoption includes (1) Rapid and significant advances in test technologies and related bioinformatics and connectivity capabilities, (2) Increases in numbers of tests performed and (3) Pressure from patients and carers for more accurate and rapid diagnosis [14]. By 2023, it is estimated that the brain tumour therapeutics market globally will grow at a compound annual growth rate (CAGR) of 12.9%. Global spending on cancer therapies and supportive care drugs exceeds £100 ($133) billion, as the value of these medicines is recognized and a greater share of drug budgets is allocated to these products. AiPBAND Project is an example of this initiative that focuses on brain cancer diagnostic technologies, where the researcher is also involved as the BM researcher. It is crucial to integrate BM thinking towards commercialisation and linking the value created to the key beneficiaries especially in these types of research collaborations. BM concept has become a popular tool in business practice because it can help to successfully analyse and handle these complexities. Therefore with the reduction of complexity and the resulting focus on essential information, the quality of decision-making can be enhanced [15].

Figure 1 presents a general flow of healthcare innovations in medical technology development from discovery to market.

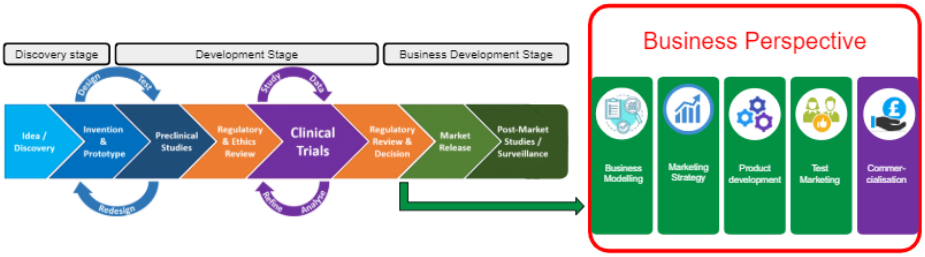

Fig. 1. The stages of medical technology development.

The first two stages are focused on the life sciences perspective, which includes the discovery and clinical validation. In the development of these devices, collaborations are necessary between academia, healthcare providers (e.g. hospitals, clinicians) and industry in the development of these devices. Medical and information technology adoption decisions differ when made by individuals or organisations. Beyond that distinction, the number of stakeholders potentially affected by any technology adoption decision varies greatly. Once a clinician decides to use a new device or piece of technology, the clinician must often consider not only the impact on the patient and on the practice but also what it means for reimbursement, health care policy, and the organisation in which the clinician works.

2 Review of Literature in Healthcare BM

A systematic literature review (SLR) has been conducted to explore the current BM applications in healthcare decision making. The method allows answering a specific research question adopting an evidence-based approach [15], [16]. SLR approach performs a key role in identifying, selecting and analysing the most relevant papers in the research area [17]. Systematic reviews differ from traditional narrative reviews in that they adopt a replicable, scientific and transparent process, intended to minimise bias through extensive searches and by providing an audit trail of the reviewers' steps, strategies, procedures and decisions [18]. The SLR phases used are shown in the diagram below (see Figure 2).

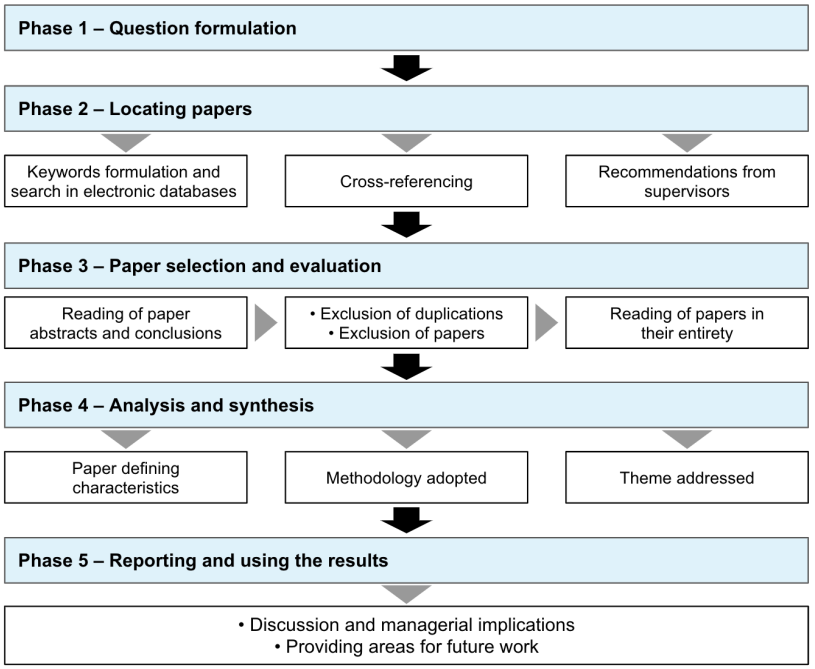

Fig. 2. The process of systematic literature review (adopted from [15])

According to a systematic review done by the authors, 38 papers are conceptual studies while 12 are empirical papers. All papers selected for this study were compiled using Mendeley reference manager by Elsevier then imported to NVivo 12 software, version 12.1.1.256 by QSR International to qualitatively review and analyse the studies in a more organised manner. The papers were coded and classified according to the following criteria:

- Defining characteristics: the selected contributions were classified according to their general details – year of publication, first authors' country/nationality.
- Classification of papers: two research methodologies were distinguished: conceptual papers and empirical papers case studies/interviews. In the case of multiple methodologies, each paper was classified according to the primary methodology used.
- Themes addressed: finally, the collected papers were classified according to the focus of each study and the key issues investigated.

The conceptual studies consist mainly of author perspectives based on their expert opinion and literature, while empirical papers adopted case study and interviews. It means that Majority of the publications are from the USA (26), followed by Netherlands (5), Canada (3), France (2), Sweden (2), then each of the following countries have one: UK, Switzerland, South Korea, India, Iran, Ireland, Malaysia, Australia, Austria, Belgium and 2 not specified. Value based healthcare models have been distinguished as a trend in the BM of innovative treatments/diagnostics. While its mostly on a conceptual basis, its adoption in the healthcare setting is a challenge. This calls for a dynamic perspective in designing business models, taking into account the different healthcare stakeholders such as the patients, care professionals, care providers, technology companies, payers, and the society.

2.1 **Thematic analysis: Identifying value components of the business model**

Several definitions for the business model exist in the literature. The interest of academia and practitioners in the field of novel business models is ever-increasing. This is evidenced by the numerous definitions provided in scientific journals such as Journal of Cleaner production, Long Range planning, Journal of business models, etc. Based on the systematic literature review and thematic analysis, four value components form a business model: the (1) value offering, (2) value delivery, (3) value network, (4) value capture as visualised in the BM full value circle in Figure 3. Building on the BM, the 10 key factors of each component have been identified, shown in the outer layer of the BM circle.

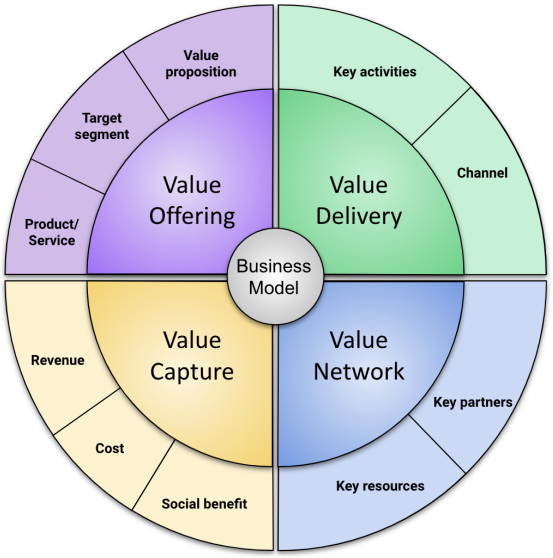

Fig. 3. Business model full value circle (by authors).

Value Offering
The value offering in a business model includes the product or service offered, identification of target segment and value proposition. Product or service offered entails solutions that may address needs in the current standard of care, enable innovation and offer innovativeness. Target segment is the customer of the new value proposition who receives the value but also may contribute by co-creating or delivering information. Value propositions are used to describe what value an organisation creates for its customers by providing goods or services, and how important that value is to the customer that helps customers get a job done more effectively, conveniently, and affordably.

Value Delivery
The value delivery is how the value is delivered to customers and it comprises the key activities and channel. The key activities involve the main activities necessary for a business to provide its offerings while the channel. BMs not only serve their target customers but also improve the entire healthcare system in the respective target market [19].

Value Network
Typically involve different stakeholders with different needs, hence value propositions are required to create value for the network of participating organisations. Key partners and resources build up the value network component. Particularly in healthcare supply chains, processes that integrate a smooth and continuous flow of materials, information and services are crucial. This sector stems

from the complexity of technologies and the multiple stakeholders aspects such as building relationships.

Value Capture
Answers the question how value is generated back to the business for it to be sustainable in terms of revenue, cost and social benefit. From an economic perspective, value capture includes revenue model and cost structure, while in a social perspective, it entails the social benefits captured by the firm.

3 Research Methodology

This section comprehensively describes and justifies the methodological framework used for this study in order to achieve the research objectives and answer the research questions. The overall research design is divided into 3 phases as presented in Figure 4.

Phase 1
Qualitative data were collected using semi-structured interviews regarding the interviewees' opinion on the aspects of designing BM for innovative healthcare technologies. In order to obtain accurate and meaningful results, the matching qualitative data analysis technique was adopted, specifically by performing a thematic analysis. Several BM factors have been identified from the literature in the previous section, which will be used during the empirical stage (such as product/ service, target segment, value proposition, channel, key activities, key partners, key resources, revenue, cost and social benefit), newly identified factors in this stage were categorised into either existing or new groups, depending on whether the existing BM value component encompassed the new factors. If new categories emerged during the interviews, they were noted and eventually added to the theoretical framework via coded data, and categorised as appropriate. 30 interviews have been conducted from companies/ firms, research institutions and healthcare organisations involved in the biomedical industry. Profiles of the interviewees are 12 top level management (CEO, Founder, Cofounder, Professors), 8 middle management level (project managers, team lead) and 10 low management level (researchers, staff). Data was gathered from across the EU (Germany, Italy, Netherlands, Slovenia, Switzerland and UK) and Asia (India, Philippines and Turkey). Interviews have been transcribed, consent form and proper ethical documentation have been followed.

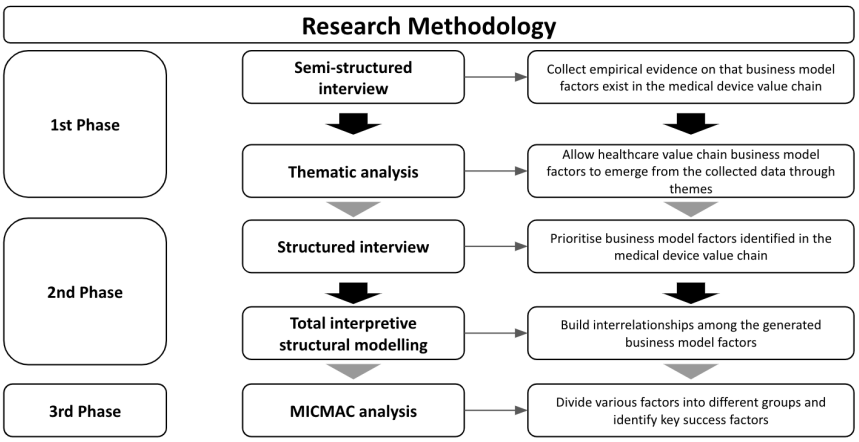

Fig. 4. Research design.

Phase 2

After identifying and validating the BM factors in Phase 1, a structured interview has been done to prioritise and understand the interrelationships among the 34 BM factors. Interviewees from the Phase 1 and other recommended references were invited and 5 experts agreed to participate. The TISM methodology adopted in the study is an extension of interpretive structural modelling (ISM) [20], which explicitly captures the causal thinking behind the interrelationship during data collection. Flowchart of the TISM is visualised in Figure 5.

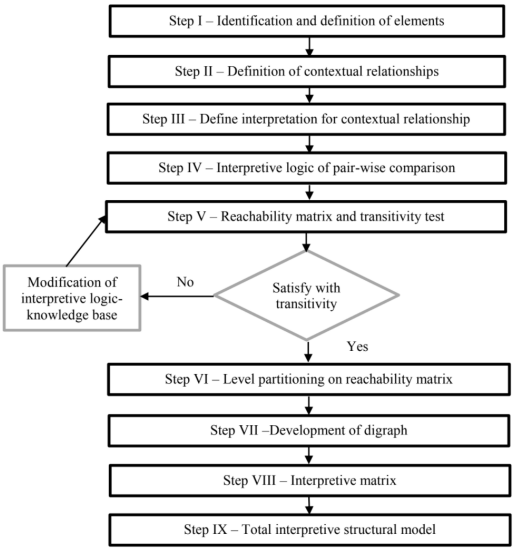

Fig. 5. TISM approach. Adopted from [20].

Phase 3
The final phase is the MICMAC analysis, which stands for *Matrice d'Impacts croises-multipication appliqu'ean classment* (cross-impact matrix multiplication applied to classification). It is used to analyse the driving power and the dependence power of the factors in order to find the most important factors within the system.

4 Data analysis and findings

4.1 Thematic Analysis

34 factors have been identified which are relevant to the study as enumerated in Table 1. Categorising these factors back to the BM value components: factors 1 to 9 are in Value Offering, factors 10-23 for Value Delivery, 24-30 in Value Network and 31-34 in Value Capture.

Table 1. BM factors identified based on empirical data

No	BM factor	No	BM factor
1	Addresses needs in the current standard of care	18	Clear customer needs
2	Enabling innovation	19	R&D sustaining innovations
3	Innovativeness	20	Regulatory approval
4	Identified market based on health focus	21	Timely delivery of value
5	Early detection	22	Training support (internal)
6	Ease of use	23	Awareness initiatives
7	Cost effective	24	Health champions for technology adoption
8	Platform for collaboration	25	Outsourcing value creation
9	Portability	26	Sustaining value ecosystem
10	Satisfied regulatory clearance	27	Team expertise
11	Earning trust of stakeholders	28	Culture and values
12	Adoption of innovation	29	Intellectual property
13	Satisfying customer requirement	30	Funding
14	Managing collaborations	31	Adaptive revenue stream
15	Training and support provided	32	Investors support
16	Onboarding customers	33	Knowledge exchanges
17	Effective sales channel	34	Managing costs

4.2 TISM Results

All 34 elements from empirical data have been considered for TISM evaluation. Here, the contextual relationships among the various BM factors have been studied. For the present study, the following structure for defining the contextual relationships among various BM factors has been considered: "Whether one BM factor influences the other one?" Figure 6 showcases the final TISM model of the 34 factors with 11 levels and 93 links.

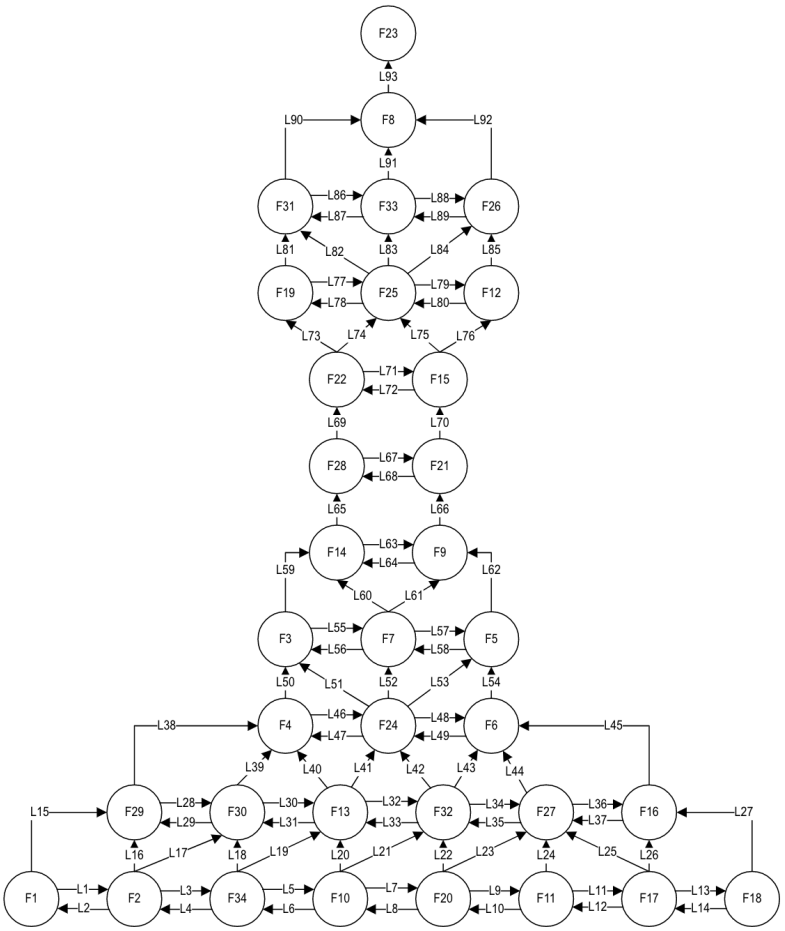

Fig. 6. TISM Model for the BM factors. (11 levels)

4.3 MICMAC Analysis

The factor dependencies are established using Total Interpretive Structural Modelling (TISM) methodology. MICMAC analysis is used to classify the factors based on their ability to influence other factors. The output of TISM forms the input for MICMAC analysis. Based on their driving power and dependence power, the factors have been classified into four categories shown in Figure 7.

(a) First quadrant (Quadrant I): This is an autonomous quadrant. The factors placed in this quadrant have less driving power and dependents and because they do not have much influence on the system. In the present study the absence of factors in the first quadrant shows that all considered enablers are significant. Therefore, all selected 34 factors have an important influence in designing BM for innovative diagnostic devices.

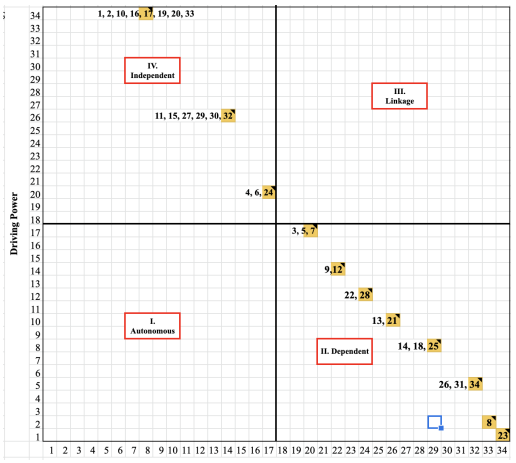

Fig. 7. MICMAC diagram of BM factors

(b) Second quadrant (Quadrant II): This is a dependent quadrant with low driving power and high dependence. According to the present study, seventeen BM factors, including F1 Addresses needs in the current standard of care, F2 Economic and political consideration, F10 Regulatory approval, F16 Effective sales channel, F17 Earning trust of stakeholders, F19 Clear customer needs, F20 Satisfied regulatory clearance, F33 Managing costs, F11 Satisfying customer requirement, F15 Onboarding customers, F27 Team expertise, F29 Intellectual property, F30 Funding, F32 Investors support, F4 Identified market based on health focus, F6 Ease of use, F24 Health champions for technology adoption, F3 Innovativeness, F5 Early detection, F7 Cost effective, F9 Portability, F12 Managing collaborations, F22 Timely delivery of value, F28 Culture and values, F13 Training support (internal), F21 Training and support provided, F14 R&D sustaining innovations, F18 Adoption of innovation, F25 Outsourcing value creation, F26 Sustaining value ecosystem, F31 Adaptive revenue stream, F34 Knowledge exchanges, F8 Platform for collaboration and F23 Awareness initiatives. In the TISM model, these factors form the top levels which need other BM factors that collectively act to influence BM design.

(c) Third quadrant (Quadrant III): This quadrant is known as linkage. Factors with high driving power and high dependence fall in this quadrant. No factors fell in this cluster.

(d) Fourth quadrant (Quadrant IV): This is an independent quadrant which has strong driving power but weak dependence power. According to this study, 17 factors appear in this quadrant including F3 Innovativeness, F5 Early detection, F7 Cost effective, F9 Portability, F12 Managing collaborations, F22 Timely delivery of value, F28 Culture and values, F13 Training support (internal), F21 Training and support provided, F14 R&D sustaining innovations, F18 Adoption of innovation, F25 Outsourcing value creation, F26 Sustaining value ecosystem, F31 Adaptive revenue

stream, F34 Knowledge exchanges, F8 Platform for collaboration and F23 Awareness initiatives.

5 Conclusion

Business models allow entrepreneurs to explore the market and commercialise their innovations [21] and hence, their design is critical [22], [23]. Business model design is a key decision for a new firm entrepreneur and a crucial - perhaps more difficult - task for managers charged with rethinking an old model to make their firm fit for the future [23]. A business model is geared toward total value creation for all parties involved. It lays the foundations for the focal firm's value capture by co-defining (along with the firm's products and services) the overall 'size of the value pie,' or the total value created in transactions, which can be considered the upper limit of the firm's value capture potential.

It is important for researchers and practitioners to have a deep understanding and knowledge of interrelationships among different BM factors. This has been achieved with 30 in-depth semi-structured interviews with experienced stakeholders in the healthcare value chain. 34 BM factors were identified through thematic analysis. After that, another round of data collection with structured interviews were applied to TISM to uncover the potential interrelationships among the identified BM factors. Finally, MICMAC analysis to identify the key factors in various categories. The results indicate that the following factors were the key elements for the healthcare BM: Addresses clinical need, Satisfied regulatory clearance, Earning trust of stakeholders, Effective sales channel, Regulatory approval, Managing costs, and Economical, political environment have the highest driving power and lie at the lowest level of the TISM hierarchy; thus, they should be given top priority.

This study contributes to research on decision support for designing BM incorporating healthcare stakeholders' views. The TTM methodology proposed in this study can also be used by academic researchers and managers to identify the most important factors and determine the dependencies of factors among themselves. Other sectors and industries can also adopt this systematic methodology for establishing relationships among factors and prioritising them. The limitations of the study offer several future research avenues to explore and validate the outcomes.

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