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Barriers to the Diffusion of Medical Technologies Within Healthcare: A Systematic Review

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ABSTRACT Implementing medical devices into a clinical setting is a complex and lengthy process. Existing models, such as Rogers' Diffusion of Innovation, try to elucidate this process, however, need to be updated to the evolving healthcare context as fewer than 7% of devices achieve implementation. The aim of this systematic review was to describe the barriers to diffusion in relation to this model to understand why so few technologies are implemented and how to address these challenges to mitigate risk during the translation process. To do this, we searched PubMed, Medline, and Embase databases for studies published between 01/01/1999 – 30/10/2019. Theoretical and application studies were included, and thematic analysis was employed using the Braun and Clarke framework to generate broad themes from the specific concepts described by included studies. A total of 33 articles were eligible for inclusion. Innovation processes constituting an obstacle to diffusion included: technology-specific challenges (8/33), clinical evidence/uncertainty (5/33), regulatory affairs (6/33), health technology assessment (7/33), reimbursement (15/33), and adoption (6/33). The factors that contributed to these themes were identified as being associated to the 11 tenets of Rogers' Diffusion of Innovation. This allowed the discussion of the identified barriers to medical device diffusion in relation with the Rogers' model. This analysis enabled the development and proposal of a framework that incorporates considerations within commercialization and translation strategies for these barriers to ultimately facilitate medical technology implementation.

INDEX TERMS Medical technology, medical device, innovation, diffusion, implementation, challenges, barriers, healthcare, strategy, adoption.

I. INTRODUCTION

Presently, the medical device industry globally is in a stage of accelerated growth with a compounded annual growth rate of 5.3% and is projected to be worth 674.5 billion USD by 2022 [1]. The industry is primarily composed of small and medium size enterprises [80% (SMEs)] which historically have had a strong commitment to research and development (R&D) [2]. As the industry develops, there appears to be a disconnect between new product development and the diffusion and implementation of innovations in clinical settings [3]–[7]. Understandably, this disconnect affects the

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sustainability of SMEs since there is a complex and invisible process which they must navigate to achieve a sustained clinical presence, impact, and commercial success.

However, this challenge goes beyond the MedTech industry as it is heavily influenced by the healthcare industry. A notoriously conservative and risk-averse industry, healthcare has a tendency to favor the status quo [8], [9]. This behavior is similar to the technology management concept of a 'dominant design' [10]. In this paradigm, once an innovation (such as a technology, drug, surgical intervention, or procedure, etc.) is widely accepted, it establishes its dominance over competing innovations to set the standard upon which further innovations and processes are based [11]–[13]. This dominance is often observed by the reduced probability

of success of subsequent innovations that offer a different solution to the same problem [14]. This does not mean that innovating novel solutions has limited value. In fact, novel solutions are sometimes required to inspire change and eliminate outdated designs [15], [16]. However, considerable effort is required to divert the markets' preferences away from the dominant design, and towards the solution the innovator is proposing. This is especially true for novel innovations that require significant changes during implementation to become the new dominant design [15], [17].

According to the US Food and Drugs Administration (FDA), ~22,000 premarket submissions are made per year [18]. However, fewer than 7-9% of these products reach the market – a lengthy process that can take up to 17 years for innovations including devices [19]–[24]. Whilst the 'dominant design' of the existing healthcare practices certainly plays a role in the low proportion of innovations being implemented, it is likely that other factors are also responsible. However, without achieving diffusion, it is unlikely for any of these products to have a chance at becoming the new dominant design [25].

A. DIFFUSION OF INNOVATION

The process of diffusion can be characterized as the spreading and accepting of an idea/technology in a system. In the healthcare setting, the diffusion and implementation of a technology is one that is influenced heavily by multiple factors such as the nature of the intervention, the healthcare system and local context, and the views and characteristics of the adopters [19], [26], [27]. The extent to which an innovation is diffused is associated with its ability to challenge the dominant design, build upon it, or create a 'window of opportunity' to become one [11], [13]. We hypothesize that understanding diffusion will enable us to appreciate how a technology is adopted and implemented by a healthcare system, and in turn, this knowledge can be used to inform the strategies employed by product developers.

One of the most prominent theories which aids in rationalizing this complex area is the Roger's Diffusion of Innovation, which was first conceptualized in the 1960s [28]. In this paradigm, adopters (ie. an individual, an organization, or a cluster within a network) form the basic functional unit of the diffusion process. Over time, with the presence of communication channels, and external and internal influences; an innovation can be adopted by other stakeholders who make acceptance decisions. In the context of healthcare, this would equate to the acceptance and continued use of novel medical devices within clinical practice. Figure 1 illustrates the characteristics of the various adopter groups affecting diffusion of a novel innovation.

In the healthcare context, the process of diffusion is more complex than suggested by the Rogers model. There are a range of stakeholders including the adopting organization, clinicians, and the payers who all have different characteristics, preferences, and motivations. With increasing numbers of new medical innovations, reducing healthcare budgets,

and changing motivations/processes of decision-makers [19]; the healthcare landscape has changed considerably since the Rogers' model's conception in the 1960s [29], [30]. Thus, there is a need for an update of these diffusion models.

B. STUDY OBJECTIVES

The medical technology industry and government organizations are trying to understand and improve the diffusion of developed medical devices into clinical practice [3], [31]. In doing so, it is hoped that venture viability will be enhanced and lead to more technologies generating positive clinical impact. To this end, research has focused heavily on the facilitators and impediments to adoption and diffusion [3], [19], [32]. A lot of this work, however, neither serves to provide context towards broader implementation within healthcare nor imparts developers with the tools to overcome them.

The objective of this study was to identify and delineate the barriers to the diffusion of developed medical devices and the factors of the innovation process that contribute to these barriers. Through this, the intent was to demonstrate the importance of specific innovation strategies that, if optimized and applied by developers, can improve the pathway for clinical implementation of healthcare technologies. In doing so, it is hoped that key stakeholders (ie. medical device companies, clinicians, and patients) can benefit from the innovations.

II. METHODS

This systematic review was conducted in accordance with the PRISMA guidelines [33].

A. DATA SOURCES AND SEARCH STRATEGY

For this review, a search was conducted independently by Ritesh Rikain Warty (RRW) and Vinayak Smith (VS) across three databases (PubMed, OVID Medline, and Embase) for papers published between the 1st of January 1999 and the 30th of October 2019. Articles were restricted to the English language. The search strategy implemented across all databases was: (Diffusion OR innovation) AND (medical device OR medical technology) AND (barrier* OR obstacle* OR issue*). A detailed analysis of the search strategy may be found in Supplementary Material A.

Theoretical and application studies were considered suitable for this systematic review. Application papers were defined as any study which utilized empirical data in formulating their conclusions. All other papers were considered theoretical in nature.

B. STUDY SELECTION

The inclusion criteria for this review was any article discussing at least one aspect of the medical device innovation process and explicitly analyzing a factor, process, or innovation/translation step as a barrier to diffusion [34]. In addition, grey literature or articles of relevance identified from the reference lists of studies or independent searching were suitable for inclusion as well. Any medical devices discussed

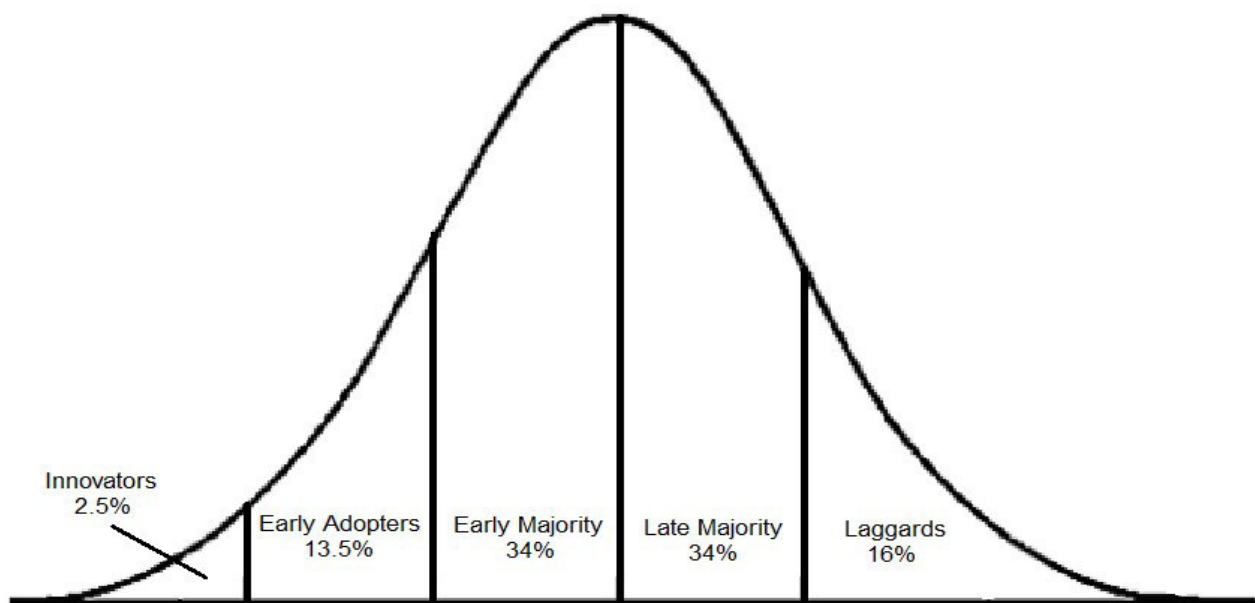


FIGURE 1. The adoption curve as adapted from Rogers' diffusion of innovation [28]. Innovators are pioneers who readily adopt innovations; Early adopters are individuals who act as change leaders; the Early majority are those who are welcoming to innovation, however, possess a degree of risk aversion and only adopt after witnessing successful outcomes; Late majority are those who are highly risk averse and suspicious of innovation, only adopting after observing safe implementation by earlier adopters; and laggards are those who are highly conservative or too socially isolated for communication to occur effectively. The process of diffusion is often initially slow due to the limited number of early adopters. However, there is always the potential for the rate of adoption to increase as the adopter majorities and laggards become more accepting of an innovation.

were at Technology Readiness Level 8 and above, which corresponds to the stages of device production and regulatory approval [35]. Devices of all regulatory classes and device types are considered. Studies that did not focus on medical devices, including electronic health/medical records, digital health, information and communication technologies, telemedicine, and tissue engineering; were excluded from the analysis.

Citation screening was performed by RRW and Mohamed Salih (MS) to determine the suitability of an article for full-text review, and a set of eligible articles was created. Following shortlisting, the full-text articles were read thoroughly by RRW, MS, and VS. Inclusion of an article for the review was based on consensus between these authors.

C. DATA COLLECTION

Given the nature of the topic and that the available evidence is primarily qualitative, a qualitative approach was employed for evidence synthesis.

Articles shortlisted for inclusion were read by RRW, MS, and VS in tandem. In line with the objectives of this study, the articles were examined for references to medical devices and the barriers to their diffusion. Thematic content analysis was then performed by the authors for each article for coding and data interpretation. This was to reduce researcher biases in summarizing the content of the various sources of literature and increase credibility of the findings of this study [36].

Reflexivity, a process which attempts to address self-bias, preferences, and theoretical predispositions during qualitative

analysis procedures, was employed as well [36], [37]. As most of the authors are involved in the innovation of medical devices, their anecdotal feedback and experiences could affect the interpretation of the data. To address this, preliminary reading of the available literature was undertaken to inform the initial research question and limit the perpetuation of any preformed hypothesis in the early development stages. Subsequent re-reading of the articles was used to provide an in-depth understanding and more detailed analysis.

Independent analyses were then compared for commonalities and differences through discussion by the 3 lead authors and a consensus summary for each article was compiled in Supplementary Materials B and C. The data items of interest, which are also presented in these supplementary files, were:

- Year of publication
- Article type (theoretical or application) and study design
- Issue/s raised (themes detailing the barriers)
- Factors contributing to issue
- Immediate relationship of issue with diffusion
- Supplementary information (including article focus, country/region, any other information).

D. QUALITY ASSESSMENT

Assessment of study quality was performed using the NICE (UK) Qualitative Appraisal Checklist (Supplementary Material D). A qualitative appraisal tool was selected as the majority of included studies were qualitative in nature. The assessment was carried out by RRW and MS individually and consensus was reached in discussion before an overall score

was given for the quality of the study. VS acted as a third assessor in the event a consensus could not be reached.

E. SYNTHESIS OF RESULTS

Using the initial thematic analysis as a foundation, a second and more comprehensive thematic analysis was performed by RRW and MS to fulfil the primary objectives of this review. This second thematic analysis followed the Braun and Clarke framework [38]. These two authors independently analyzed the included studies and classified them into the themes presented in Supplementary Material B. Reflexivity was taken into consideration using VS as a moderator for the themes.

These analyses were then compared for similarities and differences to identify recurring themes and subthemes that could be developed to establish data that was generalizable and theoretically grounded. All themes were ultimately created in accordance between RRW, MS, and VS.

Themes were defined as topical areas which were identified by at least three papers as a stage in the innovation process that delays or obstructs the diffusion of a developed medical device. Subthemes were defined as the factors/processes/problem areas that contribute to the issue and were discussed in at least two papers.

The final step of the analysis involved determining the relationship between each theme and 11 tenets of the Rogers’ Diffusion of Innovation model: relative advantage; trialability; observability; communication channels; homophilous groups; complexity; pace of innovation or reinvention; norms, roles, and social networks; opinion leaders; compatibility; and infrastructure [39]. This was performed by RRW and VS, and is presented in Supplementary Material C.

III. RESULTS AND DISCUSSION

A. OVERVIEW

A total of 33 studies were deemed suitable for inclusion in this review with the years of publication ranging between 2000 and 2019 [4]–[9], [30], [32], [40]–[64]. Figure 2 depicts the flow of information through the phases of the systematic review. 18 (54.5%) of the included studies were theoretical papers and 15 (45.5%) were application papers. Of the application papers, the data collection methods employed included: a combination of semi-structured interviews and questionnaires [42], only semi-structured interviews [44], [62], only questionnaires [54], [56], [61], [64], a combination of literature reviews and questionnaires [47], only a literature or systematic review [5], [6], [32], [55], and workshops [59], [60], [63].

The extracted data for all the included articles may be found in Supplementary Material B and was used to generate the themes and subthemes of this review.

B. QUALITY ASSESSMENT

Table 1 and Figure 3 present the results of the quality assessment that was performed using the NICE (UK) Qualitative

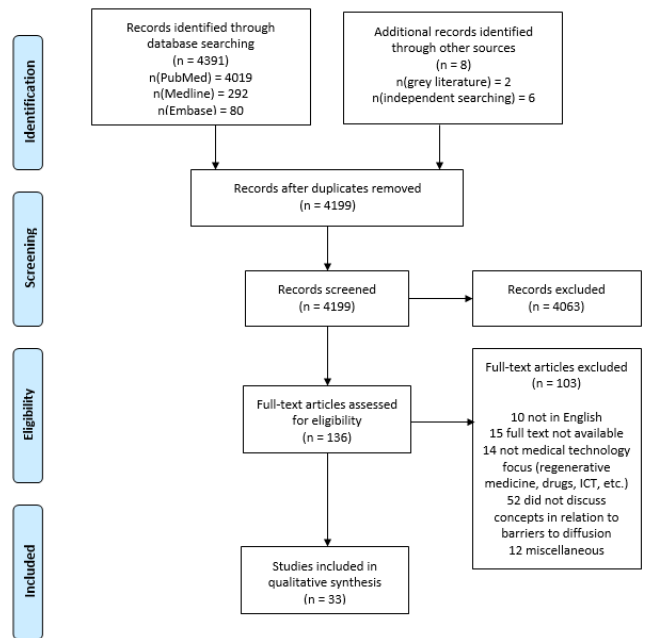


FIGURE 2. PRISMA flow diagram illustrating how articles were screened for inclusion in this review.

TABLE 1. NICE qualitative appraisal checklist ratings for studies included in review.

NICE Qualitative Assessment Rating	Number of studies	Percentage of all studies (%)	Studies
++	10	30.3%	[5, 32, 42, 44, 54, 59-62, 64]
+	18	54.5%	[4, 6-9, 40, 43, 46, 47, 49-53, 55-58]
-	5	15.2%	[30, 41, 45, 48, 63]
Total:	33	100%	

Appraisal Checklist. The (++) rating was awarded if a study fulfilled at least 11 out of 14 checklist criterion and (-) was awarded if less than 3 criteria were satisfied. Table 1 illustrates that 15.2% of studies were of a low quality, whilst 84.8% were sufficiently presented to achieve a moderate rating at the very least. Despite the sizeable number of low quality of studies, these papers were included on the basis of the valuable concepts contained within.

In Figure 3, each of the 14 criteria are listed with a graphical representation of the proportion of articles that fulfilled, failed to fulfil, or had uncertainties regarding fulfilment of a criterion. As may be observed, most articles did not report a methodology (items 3-8), although this is due to the commentary nature of the theoretical studies included. Ethics was not reported in most studies although this may not be relevant given the research methodologies and objectives of the included studies.

C. ANALYSIS OF THE BARRIERS TO DIFFUSION

A graphical representation of the themes (barriers) and subthemes (contributing factors) identified in the analysis of the

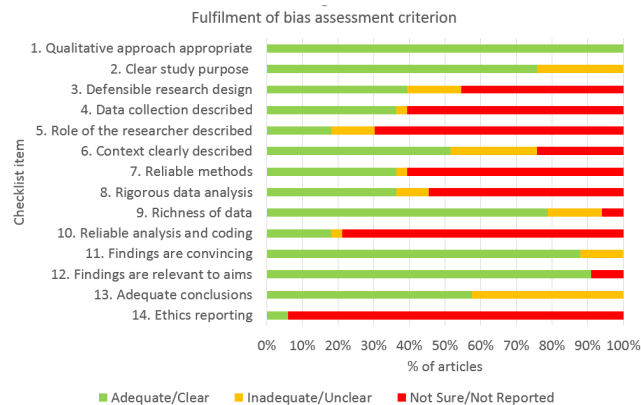


FIGURE 3. Graph detailing the percentage of articles that fulfilled, did not fulfil, or were uncertain in their fulfilment of a checklist criterion.

articles is provided in Figure 4. It should be noted that the presented themes and subthemes are derived from the literature landscape and how often a topical area was discussed. Each identified barrier was then explored in more detail.

1) TECHNOLOGY-SPECIFIC CHALLENGES

As a theme, ‘**technology-specific challenges**’ relates to technological issues of a device which affect diffusion. These were considered in 24.2% ($n = 8$) of studies [4], [32], [43], [52], [55], [59], [61], [63].

In developing any new device there are invariably challenges associated with the specific characteristics of the device which affect its diffusion. Some of these challenges are within the control of the innovator, such as the usability, human factors considerations, and the clinical use case definition, and their subsequent impact on implementation by adopters. Other challenges are out of the innovators control and include the influence of historical failures of a related technology on the concerns and perceptions of adopters. In these instances, considerable effort is required by developers to positively shift adopter attitudes [52], [65]–[67].

The first subtheme generated by the analysis was ‘**device characteristics**’, which was evident in 50% ($n = 4$) of studies [52], [55], [59], [61]. From the extracted data, the most common barrier characteristics were associated with the types of materials used for implant technologies. This was shown to be due to a limited understanding of a material, historical shortcomings and failures of specific classes of materials, or an inadequate exploration during the R&D phase of alternative materials [52], [59]. For wearable technologies, Baig *et al.* identified additional concerns related to the potential artefacts (noise) when collecting biomedical signals, wireless connectivity data loss and network reliability/capabilities, and the speed and accuracy of data intensive processing tasks [55].

This demonstrates the impact of the adopters’ perceptions of a technology. A device which performs unreliably or has a negative reputation will have a heightened perception of risk that will limit adoption (and ultimately diffusion) [68]. Examples include the polymeric total disk replacement devices

which come to the market with the recognition of issues associated with total knee replacements and total hip replacements [52]; or the QUASAR ECG, where issues in detecting the p-wave impeded the signal interpretability and ultimately, restricted clinical adoption [55], [69], [70].

Similarly, technologies which are not easy to integrate into the healthcare system have been shown to face challenges with implementation. In the case of ‘**innovation characteristics**’, which was discussed in 37.5% ($n = 3$) of studies [4], [32], [43]), the associated costs such as need for new facilities, ongoing costs, and extent of the resources needed to support the innovation, act as barriers to adoption [32], [43]. Volpatti and Yetisen and Scott *et al.* further identified that issues with integrating the technology into existing systems or creating a device that cannot fulfil clinical needs or wants, and thus require additional resources such as external equipment, significant changes in protocol or need for staff training, all disincentivize adoption [4], [71].

Often, these issues are identified in the implementation stages of the adoption process, but can be attributed to device design and validation, or more appropriately, an inadequate determination of the clinical need and use case. During the early stages of the innovation process, innovators must develop an understanding of the required specifications for the device [34]. It is straight forward to determine that there is a clinical problem and identify a technological solution. However, designing a solution such that it not only addresses the problem, but fits into the healthcare value chain is important and can be a significant barrier to diffusion if not completed effectively [68], [72].

2) CLINICAL EVIDENCE

‘**Clinical evidence**’ relates to the uncertainty associated with a device’s performance, safety, and effectiveness; as well as the dissemination of clinical information that could address that uncertainty [51]. This theme was described independent of other processes by 15.2% ($n = 5$) of studies [51], [52], [54], [61], [63], and focuses on the lack of timely, high quality evidence and its impact on the decision making process.

As outlined by the identified studies, the ability of decision-makers to provide recommendations for adoption or pass final adoption judgements is curtailed by limitations in the validity and quality of the clinical evidence that is available as part of the assessment process [52], [61], [63]. To further compound this, there are varying requirements each stakeholder has for evidence which makes developing a one-size-fits-all clinical evidence strategy difficult.

It has also been identified that issues such as slow publication times and inefficient communication channels further limits the decision-making process and the ability of the innovation to spread due to a lack of awareness/knowledge [51], [54], [61].

Considering these limitations, it can be said that decisions are being made with some degree of uncertainty. However, this introduces the question of: ‘How do we balance the clinical evidence needs for each stakeholder whilst providing

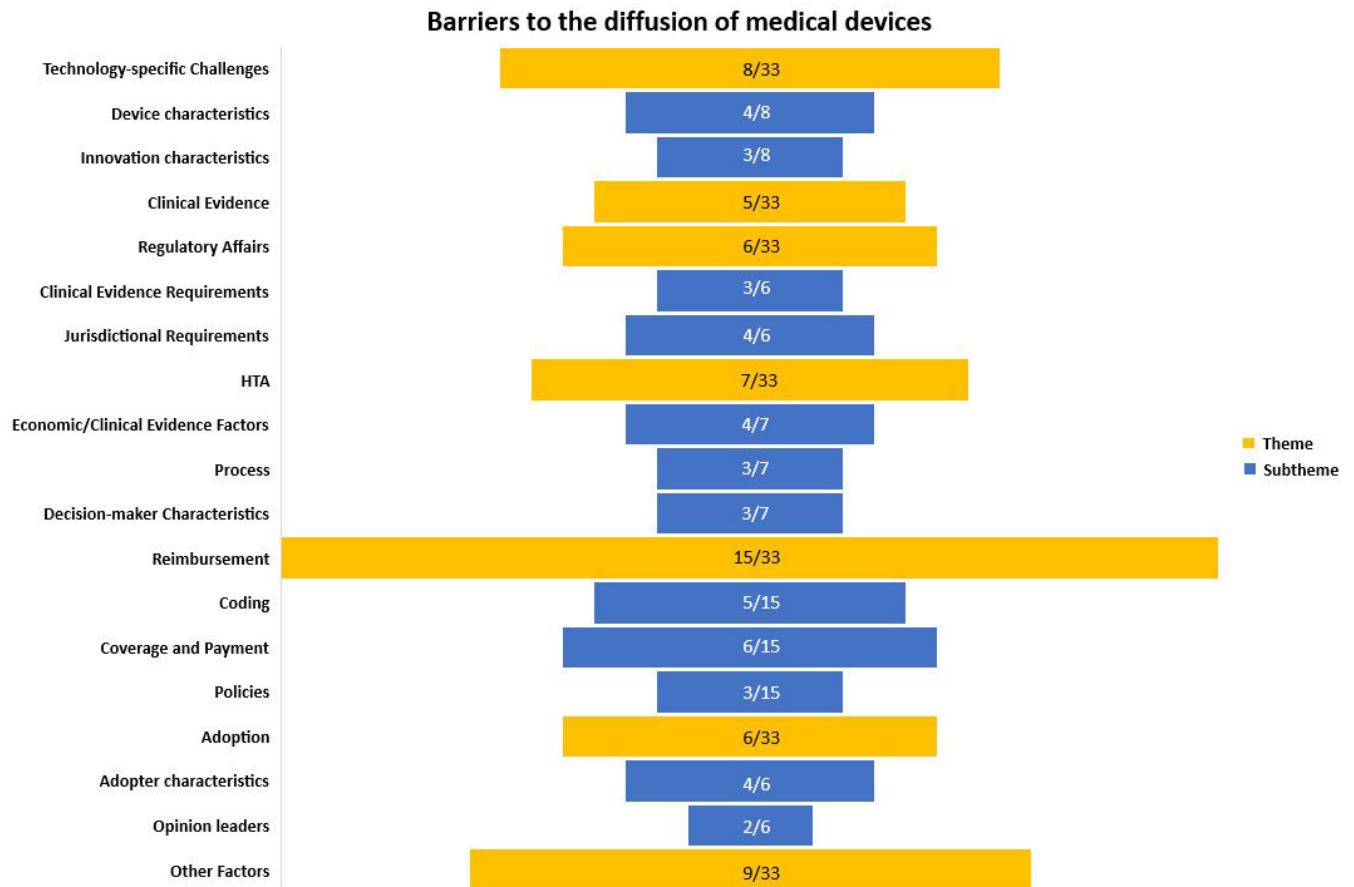


FIGURE 4. Barriers to the diffusion of medical devices. Themes (yellow) represent the number of papers discussing a topical area and are a fraction of all the studies included in this review. Subthemes (blue) are the papers within a theme discussing a factor contributing to the existence of the barrier.

access to valuable and potentially lifesaving novel technologies?’ [72]. Though seemingly obvious, some of the first steps that innovators must do in answering this question is identify who these stakeholders are (eg. regulatory body, assessment agencies, reimbursement payers, or clinicians), the commonalities and differences in their requirements, and then prioritize if and how each requirement should be addressed. Using this information, innovators can then design their clinical trials and overarching clinical strategies, particularly from an early stage of development, to meaningfully address this aspect of the diffusion curve and ensure success.

The importance of this factor cannot be further emphasized, with it recurring in themes such as ‘regulatory affairs’, ‘HTA’, and ‘reimbursement’.

3) REGULATORY AFFAIRS

The influence of regulatory oversight, henceforth described as ‘regulatory affairs’, appeared in 6 studies (18.2%) [8], [41], [53], [58]–[60]. Regulation in medical technology is vital to ensuring patient safety and the effectiveness and quality of devices that are applied clinically. However, without the approval of a regulatory body e.g. US FDA, Australian Therapeutic Goods Administration (TGA), or EU Notified Bodies, a device may not be used on patients of that jurisdiction.

Due to the critical nature of this process and its impact, it is essential for innovators to have a basic appreciation of regulatory affairs from the early stage of product development. In doing so, developers can design their devices such that they fulfill the intended purpose whilst safely fulfilling clinical and commercial needs in accordance with the requirements from the appropriate regulatory classification.

However, it has also been acknowledged that the processes, timelines, and requirements of regulating a medical device constitute significant barriers to clinical implementation [39]. In this review, it was identified that ‘clinical evidence requirements’ (n = 3, 50%) [8], [41], [53] and ‘jurisdictional requirements’ (n = 4, 66.7%) [41], [58]–[60] impeded diffusion.

When considering ‘clinical evidence requirements’ as a potential barrier, it must be understood that clinical evidence plays a vital role in medical product development. However, strict regulations can signify costly delays in market access as medical devices must undergo valid clinical trials and pivotal studies to demonstrate their effectiveness [41], [53]. This is especially true for devices that undergo the stringent pre-market approval pathways, where large, multicenter randomized controlled trials are the norm and represent the greatest risk and cost in the innovation process [72].

Although a majority of devices are either of low-moderate risk or are based on earlier devices (thus, eligible for concessions for evidence generation through schemes such as the 510(k)) [53], [72]; this highlights the importance of developing a strong clinical strategy that involves understanding the pathways and schemes of each target jurisdiction. Furthermore, this demonstrates how these strategies should ensure the collection of high quality data to prevent having to redo a clinical trial and minimize time loss [41].

Just as important is understanding the variation in requirements between regulatory bodies (**'jurisdictional requirements'**). Despite attempts to harmonize the requirements of each regulator through initiatives such as the International Medical Device Regulators Forum (IMDRF), the extent to which harmonization has truly occurred is still limited. This poses significant implications for innovators as some jurisdictions are easier to enter than others. Bergsland *et al.* provides the example of how stricter clinical evidence requirements of the FDA has caused manufacturers to align their focus to the European market first, despite the incentives afforded by the US market, due to simpler requirements for CE marking [8]. Due to this lack of harmonization, developing regulatory strategies that are catered to the target markets must be performed to accelerate global diffusion and enhance clinical accessibility [72].

4) HEALTH TECHNOLOGY ASSESSMENT (HTA)

21.2% (n = 7) of studies identified **'HTA'** as a barrier to medical device diffusion [5], [6], [9], [42], [44], [45], [48].

Mainstream HTA is a process that commences from the clinical research stage and continues throughout the product lifecycle [34]. The purpose of HTA is to assess the clinical, sociological, and economic impacts of a technology and inform relevant stakeholders such as healthcare providers, reimbursement assessors, and insurers of its implementation value. If performed effectively, HTA can enable timely access to cost-effective technologies that improve patient outcomes whilst preventing the adoption of ineffective or harmful devices.

The most common subtheme observed was **'economic/clinical evidence factors'** (n = 4, 57.1%) [5], [6], [42], [48]. Like the clinical evidence issues identified in **'regulatory affairs'**, poor evidence can be associated with the implementation of inadequate clinical strategies. In the four studies discussing evidence limitations in HTA; the clinical evidence requirements of regulators were considered insufficient for HTA agencies. This suggests a disconnect between regulatory affairs and HTA and that the evidence used as part of regulatory submissions, if insufficient, can cause uncertainty down the innovation pipeline. This also indicates that the consequences associated with the introduction of innovations are often poorly understood and that HTA agencies may be unaware of attempts innovators may make to mitigate undesirable consequences [28]. For innovators, this signifies the value of intimately understanding the target markets and the jurisdictional needs of the regulatory body vs local HTA

assessors, to incorporate considerations into their clinical strategies and prepare robust HTA submissions.

The subtheme of **'process'** (n = 3, 42.3%) [42], [44], [45] related to limitations in HTA processes that delay access to a technology due to several issues including the complex submission requirements and overall lack of transparency/clarity for timelines and evaluation processes. Additionally, **'decision-maker characteristics'** (n = 3, 42.3%) [5], [9], [44] can be associated with the HTA process, as biases, a lack of appropriate expertise, or the general backgrounds and training of members in the assessing committees can influence the final decision. Though these highlight systemic flaws, the broader industry can use this as an opportunity to collectively lobby HTA organizations for transparent and efficient assessments and guidelines that benefit both, HTA agencies and industry.

5) REIMBURSEMENT

As a theme, a considerable number of studies (n = 15, 45.5%) identified **'reimbursement'**, or the fiscal compensation associated with providing care, as a key area that influences the diffusion of medical technologies [7], [8], [30], [40], [43], [45]–[50], [52], [56], [57], [60]. When considering the subthemes, the presence and appropriateness of **'coding'** (presence of billing codes which healthcare providers use to claim payment from 3rd party payers) appeared in 5 studies (33.3%) [43], [45], [46], [49], [60], whilst factors relating to the **'coverage and payment'** (agreement of and extent to which a 3rd party payer will pay for a medical service) and reimbursement **'policies'** were discussed in 6 (40%) [7], [8], [30], [43], [50], [57] and 3 (20%) [47], [56], [57] of studies, respectively.

Often considered a facilitator of diffusion, reimbursement is essential for the commercial success of a medical technology as it represents a means of generating revenue for providing a service. However, the reimbursement landscape is evolving such that accommodating a new technology clinically can be challenging. It is generally easier for a company to integrate new technologies into a market when it fits within the existing reimbursement coding, coverage, and payment paradigms. However, if this is not possible, the reimbursement strategy of the company can prove critical and could even pose implications for the clinical use case of a device.

In the case of coding, a lack of fixed and accepted procedural codes can result in a technology not being used and face significant delays due to the long and complex processes associated with the creation and acceptance of new, relevant codes [43], [45]. This holds especially true for disruptive devices, eg. 3D-printed implants, which may not fit any existing paradigm due to the enormous gap between the existing dominant design and the disruptive innovation. Thus, access may only be provided to patients who can afford payment or under clinical trial access schemes [60]. Thus, there may be benefit in developing the reimbursement strategy as early as initial product development to have the opportunity to

understand and prepare for the potential impact on development and commercialization.

Additionally, limited or no coverage by payers can limit adoption and patient accessibility, even if the technology is recommended in clinical guidelines. One aspect of this issue is that the clinical and economic evidence assessed are not robust enough to justify reimbursement [7], [57], which relates back to limitations in an organizations' clinical strategy and the approach developers use for HTA submissions. Another aspect is associated with payment as the design of the payment system (prospective systems can disincentive adoption) or low/insufficient payment rates due to the prices set by companies and reimbursement assessors can reduce device usage [50].

The final subtheme, '**policies**', relates to the heterogeneity of reimbursement systems between jurisdictions, eg. varying mechanisms in Europe for sourcing funding and its impact on implantable cardioverter defibrillators and coronary stents utilization; as these factors can create inequalities between healthcare systems and affect patient accessibility [47], [56], [57].

6) ADOPTION

The final distinguishable theme was '**adoption**' which was discussed in 18.2% (n = 6) of studies [32], [43], [54], [60], [62], [64]. This theme related to the factors that influence the decision of a potential user to accept or reject an innovation. Given that adoption can be considered as the basic unit of the diffusion process, the factors that influence the rate of adoption ultimately affect diffusion.

From the generated subthemes, the lack of '**opinion leaders**' (as described in 33.3% (n = 2) of studies [60], [62]) is a contributing factor as such individuals tend to be respected in their field and can act as champions for a technology. Without these individuals, garnering support for an innovation can be difficult, especially in the healthcare environment where there is an inherent conservatism to innovative behavior. As innovators, it is important to appreciate the risks associated with being an opinion leader, as well as develop strategies to mitigate their concerns.

A more commonly discussed point was the '**adopter characteristics**', which was deliberated in 66.7% (n = 4) of studies within this theme [32], [43], [62], [64]. This subtheme includes individuals and organizations under the classification of the adopter. When considering individuals; factors such as age, time since training completion, the type of training/qualifications, academic affiliations, innovativeness and perception of innovation, workflow, and fear of bad outcomes including litigation, all impact the clinical implementation of a technology. Previous research has also placed value on understanding potential consequences to the adopter's professional identity and job security [68]. On an organizational level, Rye *et al.* discusses how an organization's innovative behavior is associated with the degree of centralization and formalization, professionalism, internal communication, and structure influence adoption [32]. Greenhalgh *et al.* elaborate

on this by describing the impacts of weak, risk-averse, or conservative leadership, resource limitations, and a lack of shared vision can impact diffusion [73].

7) OTHER FACTORS

Other barriers (such as rising costs, market factors, education/practice norms etc.) were identified by 9 studies (27.3%) [4], [8], [32], [43], [51], [52], [59], [60], [63]. They are not represented as they did not meet the criteria for generating a theme.

D. RELATING THEMES WITH ROGERS' DIFFUSION OF INNOVATION

To analyze and bring all of the findings of this review together so as to be easily utilized by a developer, we have attempted to fuse the identified themes with the eleven tenets of the Rogers' Diffusion of Innovation model: Relative Advantage; Trialability; Observability; Communication Channels; Complexity; Homophilous Groups; Pace of Innovation/Reinvention; Norms, Roles, and Social Networks; Opinion Leaders; Compatibility; and Infrastructure [39], [74]. This relationship is presented in Supplementary Material C and summarized in Table 2.

1) RELATIVE ADVANTAGE

A total of 19 (57.6%) studies discussed impeding factors that could contribute to the difficulty in determining the relative advantage of a technology over existing solutions. These studies were distributed across all the generated themes: '**technology-specific challenges**' (n = 3, 15.8%); '**clinical evidence**' (n = 4, 21%); '**regulatory affairs**' (n = 1, 5.3%); '**HTA**' (n = 5, 26.3%); '**reimbursement**' (n = 9, 47.4%); and '**adoption**' (n = 1, 5.3%).

2) TRIALABILITY

Only 1 study (3.0%) considered the effect of trialability on medical device diffusion. This tenet relates to the ability of a user to trial an innovation without significant investment or commitment.

3) OBSERVABILITY

15.2% of studies (n = 5) across the themes of '**clinical evidence**' (n = 3, 60%), '**reimbursement**' (n = 1, 20%), and '**adoption**' (n = 1, 20%) discussed the effect of observability on diffusion.

4) COMMUNICATION CHANNELS

This tenet was identified in 3 (9.1%) studies, under the theme of '**clinical evidence**' and related to the issues with the methods of disseminating clinical data associated with innovations.

5) COMPLEXITY

This tenet was identified in 4 (12.1%) studies and related to the theme of '**technology-specific challenges**' due to its

TABLE 2. The 11 tenets of the rogers’ diffusion of innovation theory and the studies and themes identified as discussing a factor relevant to each tenet.

Diffusion of Innovation Tenet	Studies related to tenet	Related Themes					
		Technology-specific challenges	Clinical evidence	Regulatory Affairs	HTA	Reimbursement	Adoption
<u>Relative advantage</u> <i>Ability to judge the benefits of a technology against the risks, and identify if any other advantage (technological, economic, social etc...) exists.</i>	[5-9, 30, 40, 41, 44, 48-52, 54, 57, 59, 60, 63]	X	X	X	X	X	X
<u>Trialability</u> <i>Ability to trial an innovation with minimal commitment and investment.</i>	[40]					X	
<u>Observability</u> <i>Extent to which potential adopters can witness adoption of innovation by others.</i>	[49, 52, 60, 61, 63]		X			X	X
<u>Complexity</u> <i>Degree to which an innovation is perceived as relatively difficult to understand and use.</i>	[4, 43, 52, 61]	X					
<u>Communication Channels</u> <i>Pathways which permit information about an innovation to be communicated between a knowledgeable individual and a potential adopter.</i>	[54, 60, 63]		X				
<u>Homophilous Groups</u> <i>Different perspectives, training, and modus operandi between decision-makers results in slower and more complex diffusion.</i>	[9, 32]				X		X
<u>Pace of Innovation/Reinvention</u> <i>Degree to which an innovation evolves or is reinvented affects diffusion.</i>	[5, 7, 48, 49]				X	X	
<u>Norms, Roles, and Social Networks</u> <i>Uptake is shaped by the rules, formal hierarchies and informal mechanisms of communication in the social system.</i>	[40, 42, 44, 47, 57, 61]		X		X	X	X

TABLE 2. (Continued.) The 11 tenets of the rogers’ diffusion of innovation theory and the studies and themes identified as discussing a factor relevant to each tenet.

<u>Opinion Leaders</u> <i>Individuals whose opinions affect the pace of diffusion.</i>	[43, 60, 62]						X
<u>Compatibility</u> <i>Ability of an innovation to coexist with existing technologies and social patterns to integrate into a system.</i>	[4, 32, 43, 46, 55, 57, 59-64]	X					X
<u>Infrastructure</u> <i>Presence of some form of infrastructure that support introduction of the innovation.</i>	[7, 8, 41, 42, 44-47, 49, 50, 53, 56-60]			X	X	X	

association with the difficulties adopters may perceive about its implementation or use.

6) HOMOPHILOUS GROUPS

Homophily (or degree of similarity between adopter groups) was discussed in two studies (6.1%) and were related to the themes of ‘HTA’ (n = 1, 50%) and ‘adoption’ (n = 1, 50%).

7) PACE OF INNOVATION/REINVENTION

12.1% of studies (n = 4) considered how design iterations of a device during, or after, the development and clinical trial stages can impact its assessment during adoption. These studies were classified under the themes of ‘HTA’ (n = 2, 50%) and ‘reimbursement’ (n = 1, 50%).

8) NORMS, ROLES, AND SOCIAL NETWORKS

6 studies (18.2%) could be associated with this tenet and were distributed across the themes of: ‘clinical evidence’ (n = 1, 16.7%); ‘HTA’ (n = 2, 33.3%); ‘reimbursement’ (n = 3, 50%); and ‘adoption’ (n = 4, 66.7%).

9) OPINION LEADERS

All 3 studies (9.1%) that could be attributed to this tenet were associated with the theme of ‘adoption’.

10) COMPATIBILITY

This tenet had 12 studies (36.4%) that had contributing factors affecting the compatibility of an innovation. These studies were associated with the themes of: ‘technology-specific challenges’ (n = 5, 41.7%), ‘reimbursement’ (n = 4, 33.3%), and ‘adoption’ (n = 4, 33.3%).

11) 11) INFRASTRUCTURE

16 studies across the themes of ‘regulatory affairs’ (n = 6, 37.5%), ‘HTA’ (n = 3, 18.8%), and ‘reimbursement’ (n = 8, 50%) could be associated with this tenet.

E. DISCUSSING THE RELATIONSHIPS BETWEEN THE BARRIERS AND THE ROGERS' MODEL

Due to the breadth and complexity of this topic, the relationship between the themes and the tenets of Rogers' Diffusion of Innovation are analyzed in-depth in Supplementary Material E. This provides developers with strategies to potentially address and overcome these barriers. The discussion presented here continues that analysis to provide innovators with a framework for facilitating diffusion.

1) A STRATEGY FRAMEWORK

When considering the clinical implementation barriers of a medical technology, it is clear that the commercialization strategies of developers play a significant role in the diffusion process. In this context, Figure 5 contains a strategy framework proposed to address the challenges identified by this review.

This figure details the tenets of Rogers' Diffusion of Innovation that associate with the factors contributing to a barrier. In addressing these factors with strong strategies, it is likely that the tenets which govern the diffusion process can be addressed. The discussion, and Supplementary Materials C and E may prove useful for innovators when forming these strategies. Supplementary Material F especially details specific techniques for the consideration of innovators.

F. IMPLICATIONS

Previous models for innovation diffusion primarily focused on either understanding technology adoption by individual users or comprehending implementation strategies for diffusion through organizations [75]. The presented framework, when used in conjunction with Supplementary Materials E and F, provides a comprehensive model for diffusing innovations by amalgamating technology adoption with implementation science using the prominent Rogers' model as a foundation. The implications of this model are targeted towards core innovation and commercialization strategies medical technology ventures should develop if they are to achieve penetration and dominance in a market.

1) CLINICAL USE CASE AND DESIGN STRATEGY

The clinical use case and design strategy is crucial as it defines device development and the other commercialization strategies. Given this is typically developed at the earliest stages of the innovation process, inadequate definition can produce disastrous results, be it venture failure or the need for considerable resource or financial investment for salvaging or pivoting the venture. However, adequate definition will ensure that the innovation will be closer to the product-market fit and will reduce the likelihood of such issues.

We noted that the '**device characteristics**' and associated '**innovation characteristics**' affect the relative advantage, compatibility, and perceived complexity behind the innovation. This is simple to understand because any technology which does not fulfill a need, is at-risk or prone to failure,

is difficult to integrate or requires additional resources, or is complex and time-consuming to use will not be adopted, irrespective of industry (healthcare, automotive, telecommunications, etc.). Thus, innovators must provide consideration to user feedback on potential intended uses, the target clinical environment, technical competence of their device and its features (and potential adverse events), usability factors, and most importantly, understand the clinical need and the innovation's impact on the user. To help with this, focus groups with key stakeholders, literature reviews, multi-disciplinary discussions between engineers, clinicians, and business executives, and embedding design engineers into clinical environments to develop situational empathy can all provide valuable inputs for making this strategy.

Next is the relationship of the use case and achieving '**reimbursement**', as questions such as "who is actually paying for the device", "is there a reimbursement infrastructure that is applicable to my device's intended use?", "how does the reimbursement infrastructure affect my use case scenario?", and "how can I develop my use case such that I achieve reimbursement?" arise. As we have illustrated, part of achieving the product-market fit for medical technologies involves attaining a positive coverage decision so that adopters are incentivized to use a new technology. By answering these questions, innovators can understand the influence of a reimbursement systems' design on their clinical use case scenario and hopefully can use this information to fulfill this need of the adopter.

2) CLINICAL STRATEGY

It is important to understand that the clinical strategy is not only about validating that a device works or is safe, but that it also affects other barriers such as '**regulatory affairs**', '**HTA**', '**reimbursement**', and the '**adoption**' and diffusion of a device. This is because '**clinical evidence**' forms the backbone of the diffusion process as it facilitates assessment of the innovation by various stakeholders and provides a reference point for adopters to communicate with other potential adopters. If the evidence does not fulfil the needs of each stakeholder, the stakeholder will not adopt the innovation and will either search for an alternative or continue favoring the dominant design. The challenge here is that the disconnect between the needs of each stakeholder complicates clinical development, and that any deficiency could negate the ability to acknowledge a technology's true value and relative advantage.

As a result, investing in resources and consultants that facilitate understanding the needs of each stakeholder (regulatory bodies, reimbursors, HTA assessors, and the various adopter groups such as clinicians, administrators, etc.) will help to reduce uncertainty about an innovation. For the clinician and regulator, performance, safety, and effectiveness may be all that they need. However, reimbursors, HTA assessors, and administrators may be concerned about the cost-effectiveness and broader consequences of implementing an innovation. As a result, it is important for innovators to

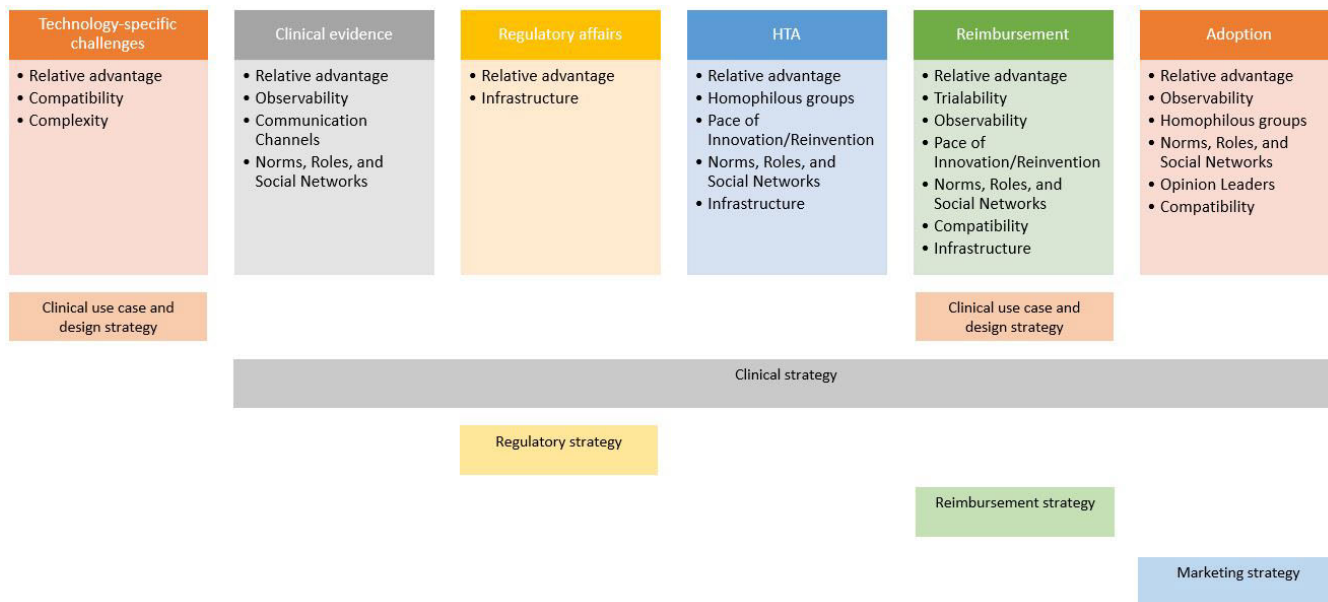


FIGURE 5. Proposed strategy framework that summarizes the relationship between the themes, rogers’ diffusion of innovation, and the key strategies that innovators should develop. The top box represents the barriers to diffusion and the associated tenets of the rogers’ model (as per Table 2). When developing the strategies, innovators should include considerations to the corresponding barrier and understand the relationship between their considerations and each tenet. In doing so, innovators can increase the likelihood of achieving widespread clinical implementation.

consider these differences and factor them into their strategies for developing high-quality, robust evidence.

Further consideration should be provided to dissemination of this evidence as adopter groups often will support their arguments for an innovation using clinical evidence. Thus, the medium (communication channel) through which information is presented could be an important factor. There is a tendency for clinicians to rely on trial data from scientific journals, however, high-quality journals often have a long peer-review time, which can delay information dissemination and impact social distribution of the innovation between adopter networks. As such, the pros and cons of each method should form part of the clinical strategy.

3) REGULATORY STRATEGY

‘Regulatory affairs’ is a barrier that is heavily associated with the infrastructure that exists in a region. As a serious barrier that must be overcome, defining the regulatory strategy is not only required for ensuring a smoother introduction of an innovation, but also is a requirement with experienced investors. As a result, it is worthwhile developing a strong strategy that will encourage investment and facilitate the acquisition of approvals for clinical use.

From this review, we identified that ‘jurisdictional requirements’ pose a significant challenge due to the lack of harmonization. As such, it is extremely important that regulatory strategies define their target markets, all applicable regulations, and schemes that apply to a specific innovation. These requirements will also influence the clinical strategy as the availability of predicate devices and schemes similar to the 510(k) can save time and resources that would

otherwise be required to undergo a full pre-market assessment. Additionally, it is important for innovators to determine the order in which to access their target markets as some pose strategic advantages that can facilitate global diffusion. These strategic advantages should be based on factors such as ease-of-process, costs and time required preparing submissions, market size and benefits, as well as treaties and relationships between regulators (e.g. Australian TGA regulations align with EU Notified Bodies requirements, and thus it is easier to gain approval in Australia if a device is approved in the EU) [76]. Similarly, post-market data from the EU could be used in regulatory submissions to the US FDA.

4) REIMBURSEMENT STRATEGY

Achieving ‘reimbursement’ is another infrastructural challenge that ventures must develop strategies for in order to secure investment and facilitate clinical implementation. Due to a lack of adequate reimbursement codes, limited-to-no coverage, various payment systems and insufficient payment rates; users have little incentive to adopt novel innovations. Hence, reimbursement strategies should include provisions for understanding the reimbursement landscape in their target markets (due to jurisdictional variations) and seek pathways for obtaining optimal coverage and payment.

To do so, a reimbursement consultant may be required. However, when assessing the reimbursement landscape, innovators must first understand the payment systems that are in place for public and private healthcare providers. In doing so, innovators can assess codes for each provider to target their strategies towards. It is also important that coding compliance should be factored into this analysis as low compliance will

impact clinical usage. Ideally, when selecting codes to target, ideally, they should have a positive coverage decision and offer maximal payment to reduce out-of-pocket expenses for patients and 3rd party payers.

Another consideration that should be provided is in understanding the impact of HTA on decisions for reimbursement and inclusion in clinical guidelines. In countries such as the UK and France, HTA agencies (NICE and Haute Autorité de santé (HAS), respectively) play a gatekeeper role in determining which innovations should be reimbursed. For such markets, including provisions in the reimbursement strategy for addressing the needs of these agencies can facilitate diffusion.

5) MARKETING STRATEGY

Having a strong marketing strategy for raising awareness is vital for ensuring the adoption and diffusion of innovations. However, the marketing process should commence during the clinical needs' assessment and stakeholder engagement stages as the individuals interviewed can form part of the early adopter population or be opinion leaders and champions for an innovation. In doing so, ventures can encourage the more social aspects of diffusion and increase the likelihood of leaping over the chasm between early adopters and the early majority.

As the venture looks towards market access, dissemination of clinical evidence, marketing materials, and advertisement strategies become increasingly vital. Clinical evidence is often distributed in scientific papers, however, additional media, such as social media and mainstream media present great channels of raising awareness and generating hype around a product amongst clinicians and the general public in a manner through which direct-to-customer prohibition laws are not violated. Additionally, established marketing strategies employed by the pharmaceuticals industry and established medical device developers could be useful guides for creating this strategy.

When marketing directly to adopters, we noted that adopter demographics could influence adoption. Broadly speaking, adopters prefer listening to sales personnel of similar professional backgrounds. However, for individuals, we discussed several factors that impact clinical implementation. To address this, ventures must understand the motivations and concerns of individuals who could fall under an adoption-averse category. In doing so, the venture can develop techniques for incentivizing such individuals such that they have a higher chance of adoption. However, more research into this is needed.

When addressing challenges due to organization culture, the strategic position and clinical focus of healthcare providers (do they advertise their technological capacity?, do they pride themselves as changing healthcare?, do they provide clinical services that are in your area?, etc.), their innovativeness, and degree of innovation-friendliness of the CEO can be useful guides for a venture's marketing plan. Generally, the more innovative the CEO and provider,

the easier it will be to implement a technology. If not, the venture must develop techniques that demonstrate the product's market fit to the organization and how the organization will benefit from its use. One way could be to demonstrate to this organization the benefit another organization is achieving using the innovation (observability). An additional way is to understand the broader situation of health services in a target market and understand how they evaluate the clinical need for acquiring innovations. In following guides such as that from World Health Organization, ventures can tailor their strategies around the target market to improve local diffusion [77].

6) CASE STUDY: THE EARLY DAYS OF MRI IN THE US

Theoretically, any medical device that has been implemented has overcome these barriers, particularly if the adopters belong to the Early Majority, as the rate of diffusion rapidly increases until around the time the adopter population are the Laggards [78]. Interestingly, the strategies innovators employ will influence this rate of diffusion and this can be observed in one of the most highly used diagnostic technologies.

Over the years, magnetic resonance imaging (MRI) has become so widely accepted and used that it is difficult to imagine that this technology once faced the barriers identified by this review.

Yet, in a comparative analysis by Hillman *et al.*, it was identified that computed tomography (CT) experienced a considerably higher rate of diffusion than MRIs in the early days, and in fact limited MRI uptake by becoming a dominant design. In part, this was due to the marginal relative advantage MRI had over CT, as well as technological uncertainties, clinical evidence limitations, considerably higher cost of acquisition and installation, and lower profitability [79]. However, as technology advanced and clinical evidence was developed, the perceptions of potential adopters and the surrounding stakeholders improved.

In addition, when CT and MRI first penetrated the market, they each faced different reimbursement systems. Whilst CT was implemented under a retrospective payment system which rewarded hospitals for continued usage and thus facilitated uptake; MRI faced a diagnosis-related group-based prospective payment system, in which the diagnosis determines the payment a hospital receives for providing care [79]. Given that prospective designs inhibit adoption, MRI manufacturers had to account for this in their strategies [7], [32]. Examples included the provision of discounts or manufacturer rebates for research usage [79]. Hillman *et al.*, then goes on to emphasize the impact to the regulatory strategies for MRI introduction due to the establishment of Certificate-of-Need and pre-market approval programs to signify the impacts of changing regulations [32], [79]. This last point reiterates the subtheme of '**jurisdictional requirements**', as different regulators will have different requirements which can either promote or restrict diffusion in a market, but were accounted for by MRI manufacturers, resulting in the

technology being one of the most widely recognized medical technologies in the healthcare system.

All in all, innovators must critically reflect on the nature of their innovations, the potential pathways to translation, and factors that could influence the clinical uptake of their technologies; ideally at an early stage of the innovation process and as they progress. In doing so, they can identify potential challenges and develop strategic considerations that fulfill the needs for enhancing the likelihood of successful diffusion to better mitigate risk and improve their journey towards implementation.

G. LIMITATIONS AND FUTURE RESEARCH

A key limitation of this study is the search strategy that was employed. Although in line with the PRISMA guidelines and the inclusion criteria was expanded to relevant grey literature, relevant sources of information from engineering databases such as IEEE Xplore could have yielded a more comprehensive analysis of the topic.

Secondly, the quality assessment tool (NICE (UK) Qualitative Checklist) was employed to provide an overview about the overall quality of the included studies. As identified, 15.2% of studies were of low quality. This was in part due to the nature of the examined studies, which included commentaries and opinion pieces. Although limited by their quality, the information contained within these studies was highly useful in formulating the presented themes by providing additional, non-typical sources of data.

Thirdly, given the nature of the topic and style of research, investigator bias and reporting bias as part of the thematic analysis requires consideration. As a result, there is the potential for certain elements to be over- or under-represented in the data. To reduce the effect of this, the research team, consisting of biomedical engineers and clinicians who are actively involved in medical device innovation, to identify the presented themes and subthemes. Similarly, the themes that were generated are not representative of the importance of a barrier but rather how often a barrier was discussed in literature. As a result of this, there is an under-representation of certain diffusion barriers in this paper due to the limited attention paid to them by researchers. However, these data points are presented in Supplementary Materials B and C.

Finally, due to this under-representation of concepts in the included literature, the social aspects of the Rogers' model are not adequately discussed. This is significant as the Rogers' model places considerable value on the communication channels and social networks between individual adopters as they exchange information that can lead to the spread of an innovation [28], [80].

One research direction that will significantly benefit innovators is the development of specific frameworks and optimized strategies for clinical evidence generation and for compiling regulatory, HTA, and reimbursement submissions such that the barriers to diffusion are considered and addressed. Furthermore, understanding the actual clinical need for an innovative solution, and developing formalized

frameworks will increase the likelihood of success. In doing so, researchers can produce models and formulaic methods that are narrower in scope than the model proposed in this review.

Another aspect is expanding the focus of the clinical use case analysis of a device from just the product's features, market size, existing competitors, and anticipated clinical outcome, to also consider the regulatory, HTA, and reimbursement landscapes [34]. In doing so, diffusion could be enabled through adaptations to the design of the device and/or the commercialization strategy. For example, through a regulatory classification that is reduced and thus, the device undergoes a simpler assessment; or the device can fit into a reimbursement code and receive an optimal coverage decision for both, the manufacturer and clinician.

IV. CONCLUSION

Understanding the Rogers' Diffusion of Innovation model in the context of the modern healthcare system can increase the clinical implementation of medical technologies. Unsurprisingly, the findings of this review demonstrated that the areas in which translation is impeded are associated with concerns about the technology; uncertainty; deficiencies in regulation, HTA, and reimbursement; and with the adoption process itself. This highlights the importance of developing commercialization strategies at an early stage and the value in understanding which strategies to employ (as outlined in the framework) and how to incorporate suitable considerations (as provided in Supplementary Material F). In doing so, innovators will be able to comprehend the challenges they face, as well as the opportunities, so that they can de-risk their innovation process and enhance diffusion.

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FOOTNOTES

AUTHOR CONTRIBUTIONS

Ritesh Rikain Warty and Vinayak Smith designed the study and were involved in data collection. Ritesh Rikain Warty, Vinayak Smith, and Mohamed Salih performed the data analysis. Ritesh Rikain Warty, Vinayak Smith, Mohamed Salih, Deborah Fox, Sally L. McArthur, and Ben Willem Mol wrote, reviewed, and edited the manuscript.

CONFLICT OF INTEREST

All authors declare no competing interests.

DATA AND MATERIALS AVAILABILITY

All data associated with this study are available in the main text or the supplementary materials.

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