Existing and emerging frameworks for the adoption and diffusion of medical devices and equipment in low-resource settings: a scoping review

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REVIEW PAPER

Existing and emerging frameworks for the adoption and diffusion of medical devices and equipment in low-resource settings: a scoping review

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Abstract

Purpose Properly functioning health systems globally require medical devices and equipment for vital care. Despite promising innovations, many medical devices face adoption barriers such as regulatory issues, interoperability and data exchange challenges. In low-resource settings, contextual factors influencing adoption and diffusion have not been synthesized into an overview to guide future medical device and equipment suppliers. Our study provides a scientific inventory of frameworks, theories, models, and guidelines describing the adoption and diffusion of medical devices and equipment in low-resource settings.

Methods We searched both the PubMed and Scopus databases to identify studies within the health and broader non-health domains. Our search yielded 2.124 results after de-duplication. Extended attributes on the type of the paper, adoption and diffusion focus, medical devices and equipment use cases, and country settings revealed patterns of underpinning and emerging frameworks for adoption and diffusion.

Results We included 28 studies in our review. The most researched device types were telemedicine, telehealth, m-health, and e-health. Among a larger variety, the most utilized underpinning frameworks were the Diffusion of Innovation Framework, and the Technology Acceptance Model. These frameworks led to the development of emerging models, such as a modified version based on Kifle's Adoption Model or the Intervention-Context-Actors-Mechanism-Outcome Model.

Conclusions Our findings offer initial insights for further research in identifying mechanisms for improving access to and utilization of medical devices and equipment in low-resource settings. Researchers can use this comprehensive review to guide continued research, addressing gaps in theoretical understanding and empirical evidence on medical device adoption and diffusion in low-resource settings.

Keywords Frameworks · Adoption · Diffusion · Healthcare · Medical device equipment · Low-resource settings

1 Introduction

According to the World Health Organization (WHO), health technology and medical devices and equipment perform a crucial role in the prevention, diagnosis, and treatment of diseases, as well as patient monitoring [1, 2]. This positions medical devices and equipment as an essential component within a functioning socio-technical health system. Furthermore, medical devices and equipment are not only linked to personal health and safety, but also to cost-effectiveness, purchasing [3], and innovative design, while governed by strict regulations [4–6]. However, despite promising innovations, many medical devices and equipment face adoption barriers such as regulatory issues, interoperability and data exchange challenges. In low-resource settings, many of these challenges are specific to the contextual factors aiding or impeding adoption and diffusion. For example, despite the increase in mobile phone use in sub-Saharan Africa [7], and improved internet connectivity, digital health solutions such as telemedicine have not yet seen widespread adoption [8, 9].

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1.1 Motivation for this review

Considering adoption and diffusion as gradual steps in the lifecycle of medical devices, it is important to understand why efforts fail, and how to overcome the various obstacles in ensuring sustained integration of medical devices and equipment for researchers studying innovation, technology developers creating innovation, NGOs using innovation, and global health organizations, supporting innovation. Benefits from medical device developments are often not realized if medical devices and equipment are not adopted or diffused [10]. Frequently, this is due to the lack of necessary utilization, leading to a distinct characteristic between implementation (the process of putting the decision to adopt into effect) and adoption (cumulative process among stakeholders on accepting and rejecting technology) [11]. Despite their vital role, the adoption and diffusion of medical devices and equipment vary significantly between high-resource and low-resource settings. This contributes to the emergence of improper health disparities, societal challenges, adverse patient outcomes, and risks to national security [12]. Previous studies show that 70% of medical equipment from high-income countries does not work in hospitals of low-income settings due to "unique design barriers, lack of reliable power, infrastructure, technical expertise, and required consumables" [13]. According to Piaggio et al., a socio-economic imbalance becomes apparent, considering that most of the global population is located in resource-poor settings, while over 80% of the entire medical devices and equipment market share remains in high-income countries [14]. Furthermore, literature describing the development and implementation of complex health interventions in "under-resourced settings" remain minimal [15].

However, to our knowledge, there is no study aggregating evidence and knowledge to understand the adoption and diffusion of medical devices and equipment specifically in low-resource contexts. Our aim is to aggregate the academic literature on frameworks, theories, models, and guidelines used in academic studies for the adoption and diffusion of medical devices and equipment in low-resource settings. To do this, through a scoping review of the literature, we (i) identify and categorize existing underpinning concepts used for empirical studies, (ii) identify any self-developed, emerging frameworks, theories, or guidelines developing in studies, and (iii) draw associations between underpinning and emerging frameworks, theories, and guidelines, all in the context of adoption and diffusion of medical devices and equipment in low-resource settings. We map these studies according to medical devices and equipment type, adoption and diffusion focus, low-resource context, and type of paper, along with all identified underpinning and emerging frameworks.

1.2 Key definitions used in our review

Medical devices and equipment A standardized definition of medical devices and equipment in low-resource settings is still debated, while current definitions and classifications of medical devices are complex and mostly apply to regulators [16]. In this paper, we follow the description of the WHO, defining a *medical device* as "an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose" [1, 17]. In contrast, *medical equipment* or health care technology, considers organized knowledge and skills for devices, medicines, vaccines, procedures, and systems, mostly requiring calibration maintenance, repair, user training, and decommissioning efforts, handled by clinical engineers.

As a health sub-function of "resources", medical equipment represents a key construct of the Health Systems Performance Framework (HSPA) and Universal Health Care (UHC) framework [18]. Both terminologies are also closely linked to healthcare innovation, an under-researched area, which remains a "driving force" in the balance between cost containment and healthcare quality [19].

A key peculiarity of medical devices is that they have a highly user-centered perspective, resulting in a heterogeneous group of individuals and entities involved. Typically, they encompass primary and secondary user groups such as healthcare professionals, patients, carers, individuals with disabilities and special needs, and professionals allied with healthcare [20]. Taking into account the needs of medical devices, the involvement of users during the early stages of development, has demonstrated an increased likelihood of successful production and adoption, as supported by a growing body of evidence [21–23].

Adoption and diffusion We identify the adoption of innovation as a multiphase, decision-making process, which individuals and organizations go through by using several mental steps. This involves knowledge of prior conditions, attitude and affection, decision-making capabilities, implementation, and confirmation [24]. In contrast to adoption, diffusion can be viewed as an enhanced process, by which an innovation is also communicated among the members of another social system. Diffusion considers the broader stakeholder environment, an ecosystem, in which members of a social system communicate via channels over time [24, 25]. Typically, this includes the regulatory and financing system, culture, as well as structures of organizations. Gaining insight into the determinants of innovation diffusion allows decision-makers to foster technology acceptance through the development of effective policy initiatives from a systems perspective [26, 27]. It is assumed that both, adoption and diffusion can contain barriers and facilitators, contributing to or hindering the respective decision-making process.

Low-resource settings The term low-resource setting refers to a constrained area (rural or urban) in which human, economic, and environmental constraints prevail [28]. In the WHO Compendium of innovative health technologies, low-resource settings are defined with a focus on limited infrastructure, e.g. no running water, unstable or unavailable electricity, or lack of healthcare professionals [17]. The term shall demarcate different types of low- and middle-income countries (LMICs), as defined by the World Bank, because of its sole economic property aspects [29].

Models, theories, frameworks and guidelines For a clear, analytical understanding of frameworks, theories, and models, we follow Ostrom's and Schlager's guidance, characterizing these concepts as "nested sets", ranging in different degrees from the most general to the most detailed types of assumptions [30, 31]. In general, a framework pairs the structure of ideas, intuitions, and incentives with key individuals. In specific, Ostrom argues that "frameworks support the identification of universal elements and respective relations, organized in an organization and prescriptive manner" [32]. Our analysis differentiates between underpinning and emerging frameworks. While the former utilizes concepts from ontological, epistemological, and methodological assumptions [33], providing a comprehensive understanding of specific phenomena, emerging frameworks serve as consecutively processed and aggregated versions based on underpinning frameworks.

To generate a theory, analyzing existing phenomena by identifying relevant framework elements is essential. Because theories will only focus on a subset of framework elements, a careful selection is required. This stands in contrast to models, which do not constitute thorough concepts, but rather the requirement for precise assumptions, variables, factors, and parameters, organized in a logical mostly quantifiable manner.

Guidelines constitute a rigorously constructed documentation, characterized by methodological rigour, evidence-based principles, and transparency in its development process. They imply a subjective character in the form of a plan or rule, providing guidance on, e.g. policies, safety guidelines [34], or any course of action. Typically, guidelines serve as directives aimed at enhancing health outcomes across diverse populations and cohorts, supported by frameworks, theories, and models. In our comprehension, we approach guidelines with a focus on practicality rather than clinical perspectives, hence labeling them as practical guidance.

Figure 1 summarizes our conceptual understanding.

2 Methods

We followed Preferred Reporting Items for Systematic Reviews – Scoping review extension to guide our search. Since our focus is to identify studies within the health domain, we have searched both the PubMed and Scopus databases. We have yielded 2.124 results after de-duplication in our search, conducted in August 2022. Table 1 outlines the search strings for Scopus and Pubmed databases.

2.1 PRISMA flowchart diagram

Figure 2 shows the PRIMSA flowchart diagram for the scoping review [35].

2.2 Inclusion and exclusion criteria

We have included reviews (systematic and non-systematic), empirical studies (all types of research methods), conceptual, and commentary papers based on the English language, with no limitation of time periods. Contextually, we focus on LMICs (country or regional), following the definition of The World Bank [29].

Articles have been selected if they present existing frameworks, guiding the study or if they proposed new, emergent, theoretical, or analytical frameworks, models, theories, or guidelines for the introduction, implementation, adoption, or diffusion of medical devices and equipment. Pharmaceutical papers have been excluded. Table 2 provides an overview of the key identified concepts and our selection decision.

2.3 Study selection

We used Rayyan, an online application for knowledge synthesis, to remove duplicates and to screen titles and abstracts. To pilot the screening, based on eligibility criteria before conducting sensitive screening, we first collectively and subsequently individually assessed a subset of titles and abstracts. Articles of uncertainty were labeled and discussed to establish consensus and clarify the inclusion and exclusion criteria. During the screening, all articles were first assessed by NK and a random sample of 141 studies each checked by JD and 59 by SHK. All finally included studies during title/abstract/keyword screening were checked by CA. This includes a subset of 710 articles, that have been checked by NK and CA. Discrepancies were resolved by discussion with three reviewers, CA, JD, and

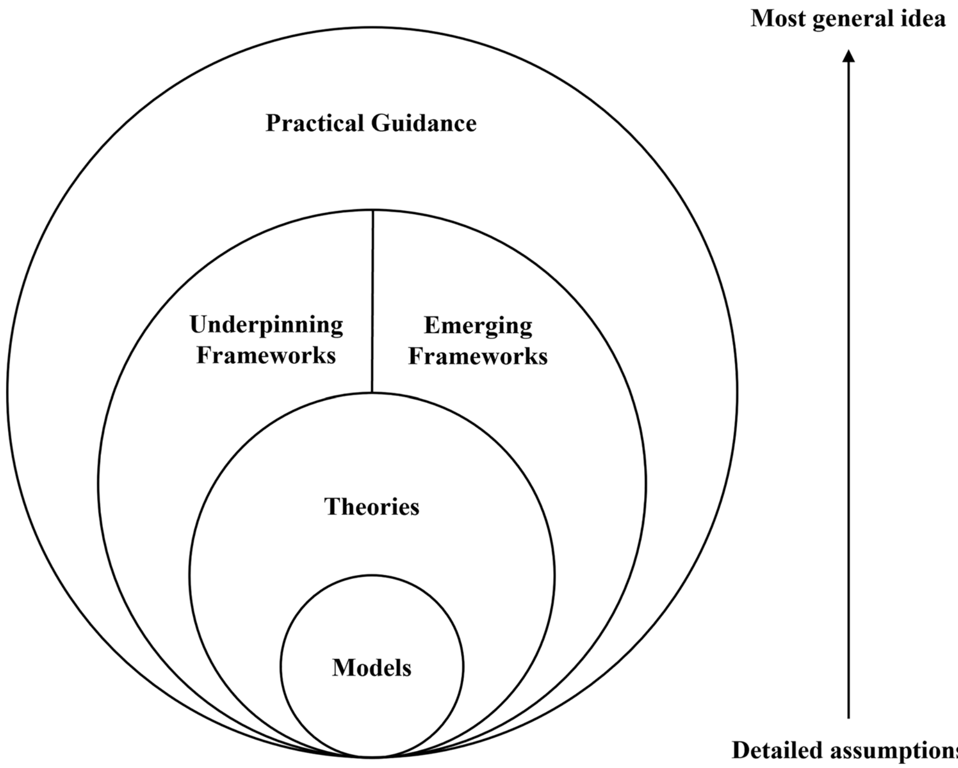

Fig. 1 Conceptual understanding (source: authors' own work inspired by Ostrom et al.)

Table 1 Search strings for the two databases searched

Database	Search string	Number of studies retrieved
Scopus	TITLE-ABS-KEY ((((((medical* OR health*) AND (technol* OR device OR equipment)) AND (purchas* OR procurement OR operationalise OR operationalize OR acquire OR acquisition OR use OR usage OR diffus* OR adopt* OR embed* OR implement*) AND (lmic* OR "low and middle income countr*" OR "resource limited countr*" OR "resource poor countr*" OR "low resource countr*" OR "lower income countr*" OR "low income countr*")))))	1.516
Pubmed	((((((medical*[tiab] OR health*[tiab]) AND (technol*[tiab] OR device[tiab] OR equipment[tiab])) AND (purchas*[tiab] OR procurement[tiab] OR operationalise[tiab] OR operationalize[tiab] OR acquire[tiab] OR acquisition[tiab] OR use[tiab] OR usage[tiab] OR diffus*[tiab] OR adopt*[tiab] OR embed*[tiab] OR implement*[tiab]) AND (lmic*[tiab] OR "low and middle income countr*"[tiab] OR "resource limited countr*"[tiab] OR "resource poor countr*"[tiab] OR "low resource countr*"[tiab] OR "lower income countr*"[tiab] OR "low income countr*"[tiab])))))	1.607

SHK, who collectively decided to include or exclude respective frameworks.

2.4 Data synthesis

We extracted the data from the literature into tables. Due to the diverse study designs, among the limited included studies, we refrained from performing an in-depth quality assessment. Nevertheless, we list the type of paper, underpinning and emerging frameworks, adoption and diffusion focus, medical devices and equipment types, and the low-resource context. Data preparation was conducted in Microsoft Excel, data visualization was performed using R.

3 Results

The included studies ($n = 28$) encompass 65 unique underpinning frameworks, guidelines, or models. Within the included studies, 24 emerging frameworks have evolved. Table 3 summarizes all studies ($n = 28$), which have been reviewed for data extraction and interpretation.

3.1 Distribution of included studies encompassing study type, focus, and medical devices and equipment type

Figure 3 summarizes the distribution of included studies, encompassing study type, focus, and medical devices and

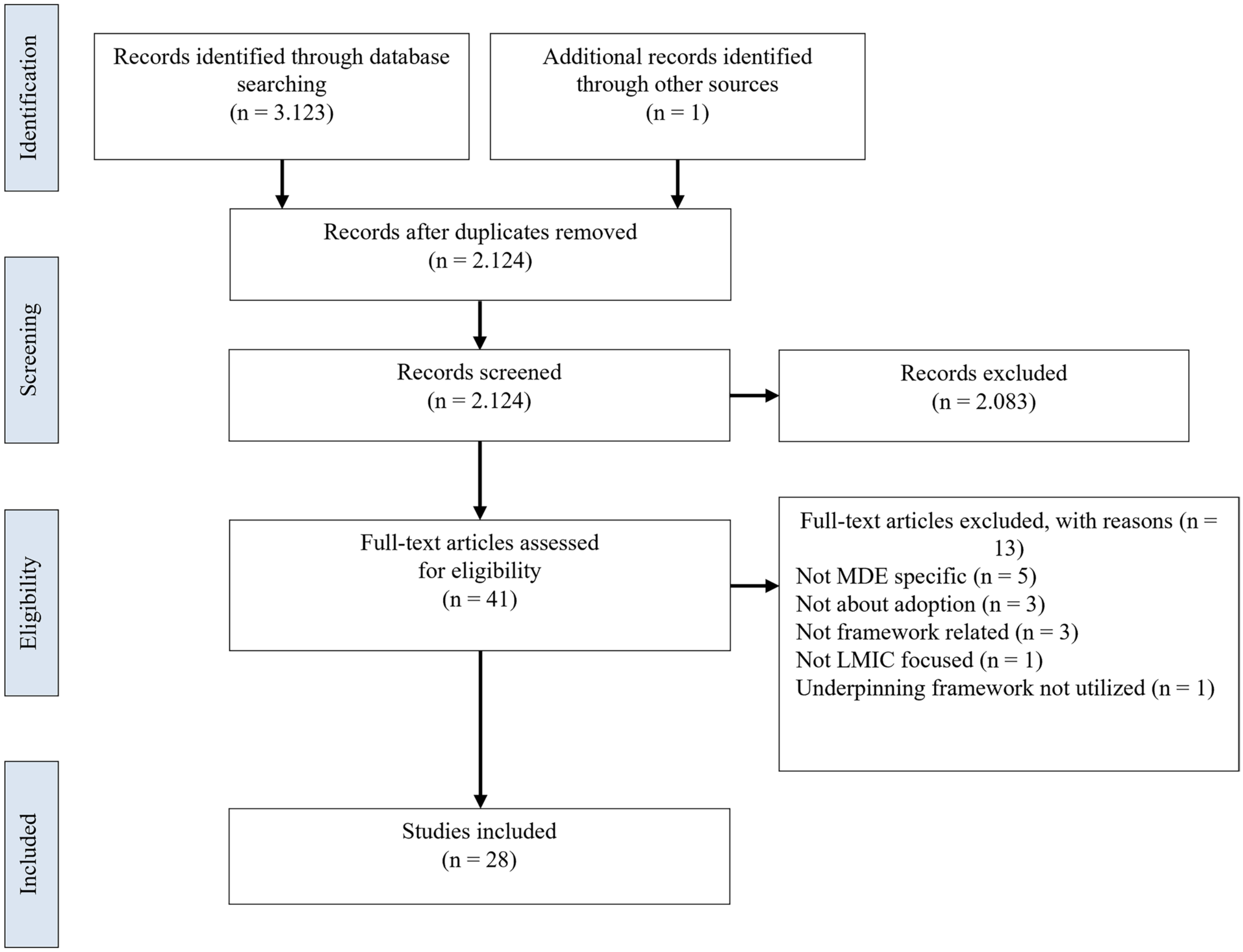

Fig. 2 PRISMA flowchart diagram for scoping reviews

Table 2 Overview on concepts and selection decisions

Concepts						Selection Decision
Topic			Process		Context	
Framework/ Model/ Guideline	Under-pinning Framework*	Emerging Framework*	Adoption/ Diffusion Focus	Medical devices and -related	Low-Resource Context	
No	-	-	Yes	Yes	Yes	Exclude
Yes	No	Yes	Yes	Yes	Yes	Include
Yes	Yes	No	Yes	Yes	Yes	Include
Yes	Yes	Yes	No	Yes	Yes	Exclude
Yes	Yes	Yes	Yes	No	Yes	Exclude
Yes	Yes	Yes	Yes	Yes	No	Exclude

*Framework or other guidelines, models, theories to explain the adoption and diffusion process

equipment type. The results have been classified into empirical ($n = 14$), conceptual ($n = 7$), review ($n = 6$), and commentary ($n = 1$) articles. Empirical studies verify and validate developed concepts, encompassing a clear definition of the population, behavior, and methodologies involved. This stands in contrast to conceptual work

Table 3 Included studies ($n=28$) which have been reviewed for data extraction and interpretation

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Mengesha GH, Garfield MJ. A contextualized IT adoption and use model for telemedicine in Ethiopia. Information Technology for Development. 2018;25(2):184–203; https://doi.org/10.1080/02681102.2018.1461057	Empirical Study	Technology Acceptance Model (TAM), Unified theory of acceptance and use of technology (UTAUT), Performance Expectancy, Compatibility beliefs theorization including core compatibility constructs	N/A No new framework developed, but individual constructs have been validated, e.g. compatibility with existing practice, preferred work style, and values	Adoption Focus	Telemedicine	Ethiopia
Abejirinde IOO, Ilozumba O, Marchal B, Zweekhorst M, Dieleman M. Mobile health and the performance of maternal health care workers in low- and middle-income countries: A realist review. International Journal of Care Coordination. 2018;21(3):73–86; https://doi.org/10.1177/2053434518779491	Review	Fit between Individuals, Task and Technology framework (FITT), Self-efficacy theory by Bandura, Technology-to-performance chain (TPC), PESTELI typology (political, economic, social, technological, environmental, legal, and infrastructural), Technology acceptance model (TAM)	Three-stage framework, populated via explanatory configurations of Intervention–Context–Actors–Mechanism–Outcome. The framework examines what works, for whom, in what contexts, to what extents, how and why	Adoption Focus	m-Health	Uganda, Burkina Faso, Rwanda, Tanzania, Indonesia, Sri Lanka, Liberia, Ethiopia, Papua New Guinea, South Africa, Ghana, Nigeria, India
Gladwin J. Implementing a new health management information system in Uganda. Health Policy and Planning. 2003;18(2):214–224; https://doi.org/10.1093/heapol/czg026	Empirical Study	Rogers's diffusion of innovation framework, Leavitt's concept of organizational forces in equilibrium (used for context perspective)	N/A No particular framework examined, but implications for practice are identified	Adoption Focus	Health Management Information System	Uganda
DePasse JW, Lee PT. A model for "reverse innovation" in health care. Globalization and Health. 2013;9(1):40; https://doi.org/10.1186/1744-8603-9-40	Commentary	Business concepts of revers innovation, Rogers Diffusion of innovation theory, Gladwell Innovation adoption, Berwick's seven rules to nurture innovation, Govindarajan & Trimble: Price, Infrastructure, Sustainability, Regulations, Preferences	New framework is based on Reverse Innovation, consisting of four steps: Problem identification, LIC innovation and spread, crossover, and HIC innovation and spread	Diffusion Focus	Unspecified medical devices and equipment	LMICs Examples used for testing the model are India, Kenya, Haiti

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Olayele Adelakun, Kallio P, Garcia R, Fleischer A. Telemedicine Adoption and Sustainability in Extreme Resource Poor Countries. 2016	Empirical Study	Unified Theory of Acceptance and Use of Technology (UTAUT), Rogers Diffusion of Innovations theory, Technology Acceptance Model (TAM), Modified Theory of Planned Behavior (TPB), Theory of interpersonal behavior (TIB), Poignant Factors, Kifle's adoption model	Modified model based on Kifle's model: Additions focus on perceived sustainability: Behavioral Intention, Perceived usefulness	Diffusion Focus	Telemedicine	Haiti
Teriö M, Eriksson G, Kamwesiga JT, Guidetti S. What's in it for me? A process evaluation of the implementation of a mobile phone-supported intervention after stroke in Uganda. BMC Public Health. 2019;19(1); https://doi.org/10.1186/s12889-019-6849-3	Empirical Study	Promoting Action on Research Implementation in Health Services (i-PARIHS), Medical Research Council (MRC) guidance frameworks	Combined Framework encompasses: Perceptions on facilitation, using scientific experience based knowledge, tailoring the intervention, supportive working culture, barriers to service delivery, implementers interaction with the intervention, perceptions on motivation and values, improving the model and enabling sustainability	Adoption Focus	Mobile-phone supported intervention	Uganda Urban Kampala and within 40 km of the city

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Alami H, Rivard L, Lehoux P, et al. Artificial intelligence in health care: laying the Foundation for Responsible, sustainable, and inclusive innovation in low- and middle-income countries. Globalization and Health. 2020;16(1); https://doi.org/10.1186/s12992-020-00584-1	Conceptual	N/A	Self-developed framework, guiding development and implementation of responsible, sustainable, and inclusive Artificial Intelligence in healthcare Framework consist of: Training and retention of local expertise, robust monitoring system, systems-based approach to implementation, responsible local leadership inclusive of all stakeholders	Unspecified	Unspecified	LMICs
Oosting RM, Dankelman J, Wauben LSGL, Madete J, Groen RS. Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide. IEEE Xplore; https://doi.org/10.1109/GHTC.2018.8601913	Conceptual	Managing the mismatch' issued by the WHO, WHO manual for surgical care, WHO guideline on medical device regulations, European safety regulations	Self-developed roadmap consists of four phases: Identify a clear need for certain surgical equipment in a specific context, understand the context of global surgery, determine the implementation strategy and design requirements, and act, build prototype, establish partnerships	Adoption & Diffusion Focus	Surgical equipment	LMICs
Khatun F, Heywood AE, Ray PK, Bhuiya A, Liaw ST. Community readiness for adopting mHealth in rural Bangladesh: A qualitative exploration. International Journal of Medical Informatics. 2016;93:49–56; https://doi.org/10.1016/j.ijmedinf.2016.05.010	Empirical Study	mHealth Readiness Conceptual Framework	Self-developed community readiness framework encompassing: Core readiness, technological readiness, human resource readiness, motivational readiness	Adoption Focus	Mobile health	Bangladesh Chakaria sub-district

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Mitchell-Gillespie B, Hashim H, Griffin M, AlHeresh R. Sustainable support solutions for community-based rehabilitation workers in refugee camps: piloting telehealth acceptability and implementation. Globalization and Health. 2020;16(1); https://doi.org/10.1186/s12992-020-00614-y	Empirical Study	RE-AIM Framework, Dynamic Sustainability Framework (DSF)	N/A Both underpinning frameworks guided procedural design, survey development, data collection, data evaluation, and increase success of telehealth implementation. However, a separate new framework has not been developed	Diffusion Focus	Telehealth intervention	Jordan
Nandakumar AK, Beswick J, Thomas CP, Wallack SS, Kress D. Pathways Of Health Technology Diffusion: The United States And Low-Income Countries. Health Affairs. 2009;28(4):986–995; https://doi.org/10.1377/hlthaff.28.4.986	Conceptual	N/A	Self-developed conceptualization that is provided, assembled to summarize key components of identified examples (maternal health, smallpox, Vitamin A). However, this model lacks completeness and validation in other scenarios	Diffusion Focus	Maternal health, smallpox, and vitamin A products and services	USA, Nepal (Vitamin A), India (Maternal Health), 31 countries (Smallpox)
Rahman AE, Ameen S, Hossain AT, et al. Introducing pulse oximetry for outpatient management of childhood pneumonia: An implementation research adopting a district implementation model in selected rural facilities in Bangladesh. eClinicalMedicine. 2022;50:101511; https://doi.org/10.1016/j.eclinm.2022.101511	Empirical Study	WHO's implementation research framework	Self-developed implementation district model consisting of four components: Sensitization of district- and sub-district managers and IMCI service-providers via workshops, capacity development of IMCI service-providers, supervisors, data officers and district- and sub-district managers, health system strengthening to improve IMCI service readiness and distribution, and follow-up support to IMCI service-providers	Adoption Focus	Pulse oximetry	Bangladesh Kushtia district)

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Brown DW, Shulman A, Hudson A, et al. A framework for the implementation of new radiation therapy technologies and treatment techniques in low-income countries. Physica Medica. 2014;30(7):791–798; https://doi.org/10.1016/j.ejmp.2014.07.004	Empirical Study	Recommendations from various sources encompass, training programs in Radiation Therapy, ESTRO's core curricula, AAPM's report on education and training for Medical Physicists, IAEA documents describing training for Medical Physicists	Self-developed framework for implementing new technologies and treatment techniques. Framework is mostly based on authors collective experience in implementing new technologies	Adoption Focus	Radiation therapy technologies	Experience for the framework stems from Dakar, Senegal Framework can be generally applied in HIC and LMICs
Marcelo, A., Adejumo, A., & Luna, D. (2011). Health informatics for development: a threepronged strategy of partnerships, standards, and mobile Health. Yearbook of medical informatics, 20(01), 96–101	Conceptual	N/A	Self-developed three-pronged strategy to facilitate development of health informatics consisting of the following strategies: Establish partnerships, standards for interoperability, Mobile Health Technology that people can understand and manage	Diffusion Focus	Health informatics and biomedical health informatics	Latin America, Africa, Asia

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Kabongo EM, Mukumbang FC, Delobelle P, Nicol E. Explaining the impact of mHealth on maternal and child health care in low- and middle-income countries: a realist synthesis. BMC Pregnancy & Childbirth. 2021;21(1):1–13; https://doi.org/10.1186/s12884-021-03684-x	Review	Context (C) + Mechanism (M) (resource + reasoning) = Outcome (O) Following frameworks have purposely excluded. They largely ignore contextual elements in triggering identified mechanisms: The Fogg Behavior Model (FBM), The Fit between Individual, Task and Technology (FITT) framework, The Technology Acceptance Model (TAM)	Self-developed model: Intervention-Context-Actors-Mechanism-Outcome (ICAMO) Intervention (I): Characteristics of various mHealth interventions such as type of technology, co-interventions, and modalities Context (C): conditions required for program mechanisms to activate or not Actors (A): Individuals, groups, and institutions that play a role in the implementation and uptake of interventions Mechanism (M): Refers to causal forces, powers, processes or interactions that generate behavioral change Outcomes (O): mechanisms activated within specific contexts. Outcomes are anticipated and unanticipated (emergent) consequences of interventions	Diffusion Focus	m-Health	Sub-Sahara Africa, Asia Pacific, Latin America

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Bolton WS, Aruparayil N, Quyn A, et al. Disseminating technology in global surgery. British Journal of Surgery. 2019;106(2):e34-e43; https://doi.org/10.1002/bjs.11036	Review	IDEAL Framework (Idea, Development, Exploration, Assessment, Long-term Follow-up), Global Competency Framework for Clinical Research, WHO Medical Device Technical Series, WHO Health Technology Assessment (HTA) of Medical Devices guidelines	Self-developed three factor model for innovating and diffusing global surgery: Data-Evidence-Value-Impact, technology, collaborate	Adoption & Diffusion Focus	Technologies and medical devices for surgical and perioperative care and training	LMICs
Sung M, He J, Zhou Q, et al. Using an Integrated Framework to Investigate the Facilitators and Barriers of Health Information Technology Implementation in Noncommunicable Disease Management: Systematic Review. Journal of Medical Internet Research. 2022;24(7):e37338; https://doi.org/10.2196/37338	Review	Consolidated Framework for Implementation Research (CFIR), Levels of Change Framework, Reach Effectiveness Adoption Implementation Maintenance, Socioecological model	Integrated framework (based on CFIR and Levels of Change framework) encompassing: Intervention, Outer setting, Inner setting, Characteristics of the individual, Process	Adoption & Diffusion Focus	Health information technology (HIT)	LMICs
Spicer N, Hamza YA, Berhanu D, et al. "The development sector is a graveyard of pilot projects!" Six critical actions for externally funded implementers to foster scale-up of maternal and newborn health innovations in low and middle-income countries. Globalization and Health. 2018;14(1); https://doi.org/10.1186/s12992-018-0389-y	Empirical Study	N/A	Self-developed analytic framework to aid cross-country comparisons for scaling. Elements encompass: Designing innovations for scale, generating evidence to influence and inform scale-up, harnessing the power of individuals, being prepared and responsive, ensuring continuity, embracing the principles of aid effectiveness	Adoption and Diffusion	Maternal and newborn health innovations	Northeast Nigeria, Ethiopia, Uttar Pradesh India

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Ekie J, Ekie T. Delivering together: A framework for sustainable ownership of early warning and health emergency surveillance technologies in low- and middle-income countries. Journal of Public Health in Africa. 2022;13(1); https://doi.org/10.4081/jphia.2022.2168	Conceptual	N/A	Self-developed framework for health emergency surveillance technology encompassing: Expectations of the framework, implemented tools, capacity building, and documentation	Adoption Focus	Early Warning and Health Emergency Surveillance systems	LMICs
Duke T, Hwaihwanje I, Kaupa M, et al. Solar powered oxygen systems in remote health centers in Papua New Guinea: a large scale implementation effectiveness trial. Journal of Global Health. 2017;7(1); https://doi.org/10.7189/jogh.07.010411	Conceptual	N/A	N/A	Adoption Focus	Oxygen concentrator	Papua New Guinea
O'Donnell A, Kaner E, Shaw C, Haighton C. Primary care physicians' attitudes to the adoption of electronic medical records: a systematic review and evidence synthesis using the clinical adoption framework. BMC Medical Informatics and Decision Making. 2018;18(1); https://doi.org/10.1186/s12911-018-0703-x	Review	Roger's Diffusion of Innovations (not applied), Consolidated Framework for Implementation Research (not applied), Technology Acceptance Model (not applied)	Clinical Adoption (CA) Framework encompassing three dimensions: Micro-level, meso-level, macro-level	Adoption Focus	Electronic Medical Records (EMRs)	USA, Europe, Canada, Saudi Arabia, Brazil, Hong Kong, Israel

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Leonard E, De Kock IH, Bam WG. Investigating the relationships between health and innovation systems to guide innovation adoption. 2019 IEEE International Conference on Engineering, Technology and Innovation (ICE/ITMC). Published online June 2019; https://doi.org/10.1109/ice.2019.8792677	Conceptual	National Innovation System (NIS), Regional Innovation System (RIS) approach, Sectoral Innovation System (SIS) approach, Technological Innovation System (TIS) approach, Jabareen's conceptual framework methodology	Conceptual Health Innovation System framework encompassing: Innovation, source of the innovations, institutions, knowledge, relations and networks, actors, context, functions, components, goals, and objectives	Adoption and Diffusion	medical devices and equipment general	LMICs
Shanko G, Negash S, Bandyopadhyay T. Mobile healthcare services adoption. International Journal of Networking and Virtual Organisations. 2016;16(2):143; https://doi.org/10.1504/ijnvo.2016.076485	Empirical Study	Technology Acceptance Model (TAM), Task Technology Fit (TTF) Framework, UTAUT2 Model	Version of the Technology Acceptance Model (TAM) to study adoption from the perspective of the healthcare professionals. Two additional constructs have been added: Infrastructure services in terms of quality of mobile network and facilitating condition integrates contextual bearings and challenges	Adoption Focus	e-Health, PDA, mobile phones	Ethiopia
Leonard E, de Kock I, Bam W. Barriers and facilitators to implementing evidence-based health innovations in low- and middle-income countries: A systematic literature review. Evaluation and Program Planning. 2020;82:101832; https://doi.org/10.1016/j.evalprogplan.2020.101832	Review	Consolidated Framework for Implementation Research (CFIR), Integrated Promoting Action of Research Implementation in Health Services (i-PARIHS) framework	Conceptual framework defining a health innovation system encompassing: Context, components, and functions	Adoption Focus	Health innovations general (can include medical devices and equipment)	North America, South America, Low-resource settings, general LMIC context, Asia, Oceana, Middle east

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Archer N, Lokker C, Ghasemaghaei M, DiLiberto D. eHealth Implementation Issues in Low Resource Countries: A Model, Survey and Analysis of User Experience. Journal of Medical Internet Research. Published online August 20, 2020; https://doi.org/10.2196/23715	Empirical Study	Fit-variability model, Task-technology fit Model, eHealth readiness assessment framework for developing countries (not used for building emergent framework), 5 mobile health and telehealth success factors (not used for building emergent framework), Electronic Medical Record. Adoption Model (not used for building emergent framework)	Structural equation model of eHealth implementation in LMICs encompassing: Task characteristics, user characteristic, perceived technology infrastructure, perceived privacy, perceived security, eHealth usability, concerns and uncertainties, perceived implementation effectiveness, eHealth utilization	Adoption Focus	eHealth	India, Egypt, Nigeria, Kenya
Ngassa Piotie P, Wood P, Webb EM, Hugo JFM, Rheeder P. Designing an integrated, nurse-driven and home-based digital intervention to improve insulin management in under-resourced settings. Therapeutic Advances in Endocrinology and Metabolism. 2021;12:204201882110546; https://doi.org/10.1177/20420188211054688	Empirical Study	Medical Research Council Framework, SWOT Analysis	N/A	Adoption Focus	App-based, insulin management intervention	South Africa
Subramanian S, Sankaranarayanan R, Esmy PO, Thulaseedharan JV, Swaminathan R, Thomas S. Clinical trial to implementation: Cost and effectiveness considerations for scaling up cervical cancer screening in low- and middle-income countries. Journal of Cancer Policy. 2016;7:4–11; https://doi.org/10.1016/j.jcpo.2015.12.006	Empirical Study	N/A	Framework for cost and effectiveness: Access to care, quality of care, adherence to care	Diffusion Focus	Cervical cancer screening system	LMICs

Table 3 (continued)

Source	Type of Paper	Underpinning Framework	Emerging Framework	Adoption/ Diffusion Focus	Medical devices and equipment Type	Low-Resource Context
Yakubu A, Paloji F, Bonnet JPG, Wetter T. Development of an Instrument for Assessing the Maturity of Citizens for Consumer Health Informatics in Developing Countries: The Case of Chile, Ghana, and Kosovo. Methods of Information in Medicine. 2021;60(01/02):062–070; https://doi.org/10.1055/s-0041-1731389	Empirical Study	Unified theory of acceptance and use of technology (UTAUT), UTAUT2 Model, UTAUTe, Patient Activation Measure, Consumer Health Informatics: Levels of Service (CONSHI)	Conceptual model of factors predicting citizens maturity in LMICs encompassing: 26 items from UTAUT2, 21 items from PAM, 5 items from UTAUTe, 12 new items, 14 demographic variables	Adoption Focus	Consumer Health Informatics	Chile, Ghana, Kosovo

considering the development of new concepts or abstract ideas, aiming to explain an identified phenomenon without conducting empirical tests or experiments. Reviews contain a comprehensive analysis of the existing literature and follow a discussion of published articles or trials.

Furthermore, articles have been classified based on their focus (adoption or diffusion). Adoption focus ($n=15$) considers the implementation of innovation as managed action, overcoming barriers. This considers the user's knowledge of the advancement of technology and the ability to use and accept the technology comprehensively [36]. Diffusion focus ($n=7$) reflects the diffusion of innovation within the market and communication networks in the targeted healthcare system. In addition, our findings identified studies that have both, adoption & diffusion focus ($n=5$), and unspecified articles ($n=1$).

A total of unique medical devices and equipment types ($n=42$) have been identified based on their naming convention mentioned in each article, mostly encompassing use cases on m-Health ($n=2$), telemedicine ($n=2$), e-Health ($n=2$), various other medical devices and equipment-related interventions ($n=34$), and not specifiable types ($n=2$). Given the wide spectrum of medical devices and equipment types, we have categorized them into higher-order clusters, outlined in the outer circle of Fig. 3.

3.2 Underpinning and emerging frameworks found in literature

The most often used underpinning frameworks are the Diffusion of Innovation Framework (DoI) [37, 38] ($n=3$), the Technology Acceptance Model (TAM) [39, 40] ($n=3$), the Consolidated Framework for Implementation Research (CFIR) [41, 42] ($n=2$), the Promoting Action on Research Implementation in Health Services Framework (i-PARIHS) [40, 43] ($n=2$), the Task Technology Fit Framework (TTF) [39, 44] ($n=2$), the Unified Theory of Acceptance and Use of Technology (UTAUT) [45] ($n=2$), and the Unified Theory of Acceptance and Use of Technology 2 Model (UTAUT 2) [39, 44] ($n=2$). Various other uniquely specified frameworks ($n=41$) have been identified and used for the creation of emerging frameworks.

The relationships between the underpinning and emerging frameworks, as depicted in Fig. 4, reveal that a diverse range of foundational frameworks have been used or adapted to create a new or 'emerging' framework for demonstrating the factors that lead to the adoption or diffusion of medical devices and equipment in low-resource contexts. As seen from Table 3, most of these studies are empirical, which

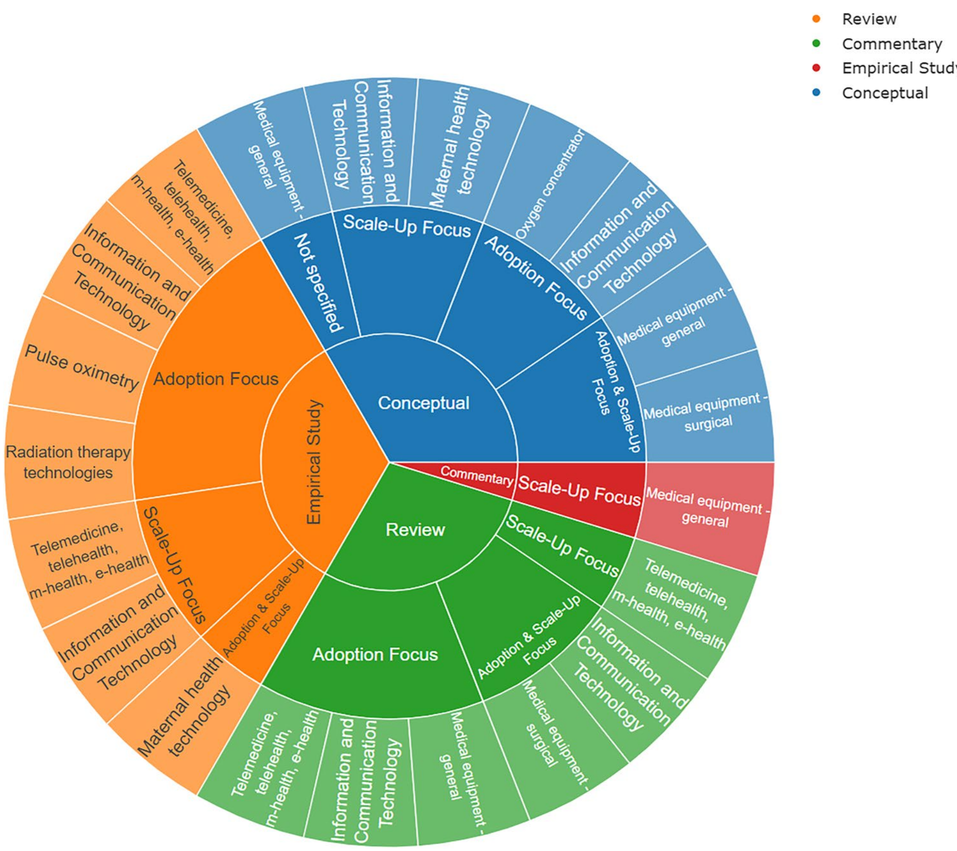

Fig. 3 Distribution of included studies encompassing study type, focus, and medical devices and equipment type

means they either tested or applied an existing framework for adoption or diffusion, but still generated a new framework based on their experiences and insights gained during their studies.

In Fig. 4, we classified and aggregated the underpinning frameworks, grouping them by commonalities in scope and intent, and linked them to the resulting emerging frameworks. We observe, that the authors' intended use of some underpinning frameworks lead to a consequential application of aggregated frameworks. However, some authors developed emerging frameworks, in which the intended focus and the consequential use remain distinct.

3.3 Core constructs within the frameworks found in studies

In Table 4 we took a small selection of studies based on the most commonly found underpinning frameworks and identified core constructs, namely UTAUT, DoI, TAM, TPB, TIB, Poignant Factors, Kifle's Adoption Model, CMO framework, Fit-variability model, Task-technology fit model, NIS, RIS, SIS, TIS, and Jabareen's conceptual framework methodology. We observe and argue, that social aspects are underrepresented in the context of adoption and diffusion theories.

4 Discussion

4.1 Frameworks and terms are not consistently applied

We assert that the frameworks presented are not consistently applied. Adelakun et al. have generated a diffusion-focused, aggregated framework using elements from the UTAUT Model [38]. The case study uses qualitative and quantitative methods for a telemedicine project between partners in the United States and Haiti. The diffusion focus stands in contrast to the UTAUT's intention to progress towards a unified view of "user acceptance", implying an adoption focus [55]. Gladwin et al. have used the Diffusion of Innovation Framework to articulate implementation suggestions for a change from a centralized health information system towards a health management information system, focusing on a technological adoption [37]. In our view, using Rogers Diffusion of Innovation Framework in this context appears limited, as it primarily addresses how innovations spread within a social system rather than how individuals or organizations make decisions to adopt them. This distinction may lead to gaps in understanding the factors, influencing successful implementation in various contexts. We found that some authors use "scale-up" or "scale" to describe the notion of diffusion, but these terms are often used

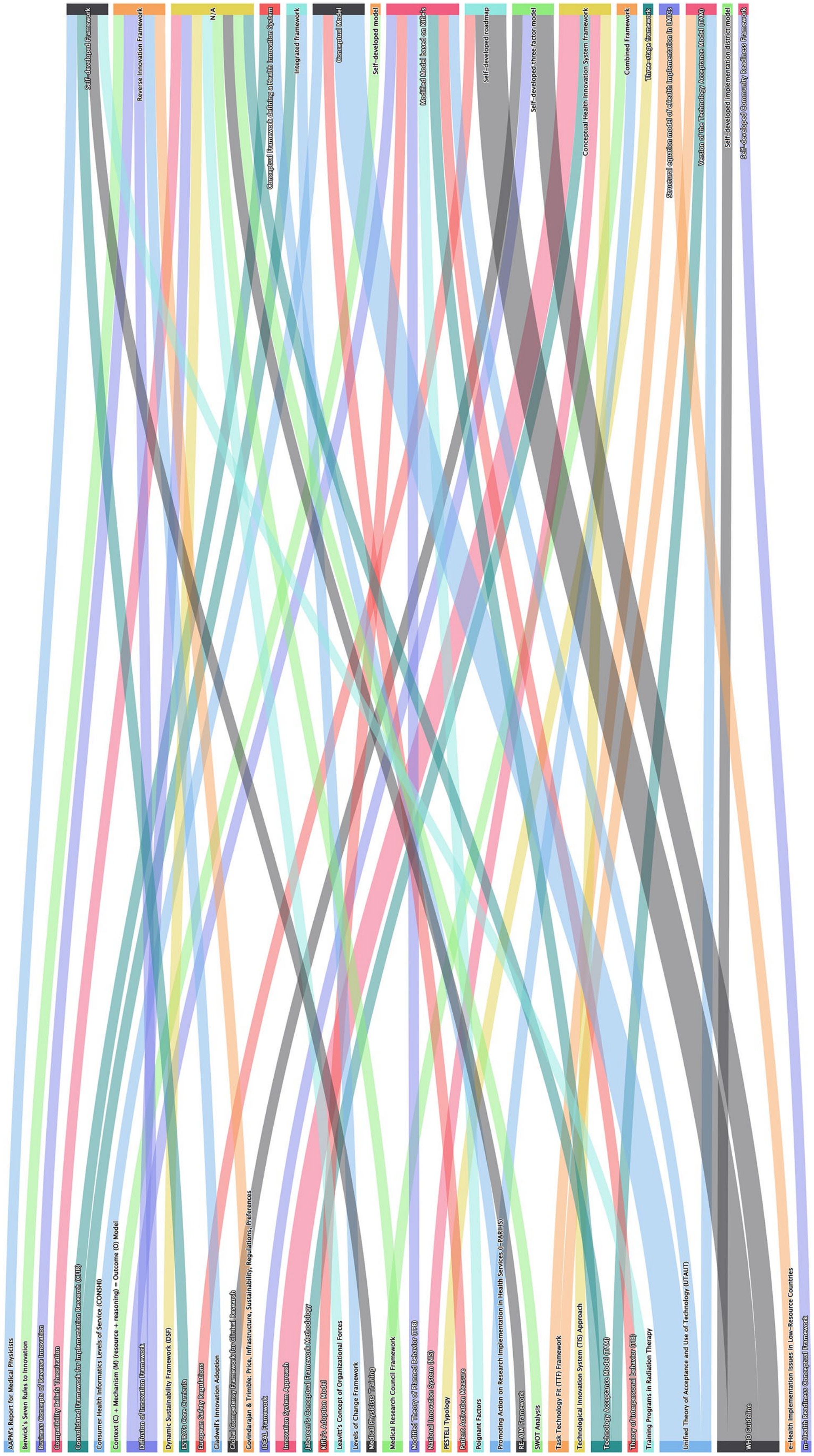

Fig. 4 Relationships between underpinning and emerging frameworks

Table 4 Theory-oriented building blocks

Source	Underpinning Framework	Core Constructs	Emerging Framework	Core Constructs
Olayele Adelakun, Kallio P, Garcia R, Fleischer A. Telemedicine Adoption and Sustainability in Extreme Resource Poor Countries. 2016	Unified Theory of Acceptance and Use of Technology (UTAUT) [45]	• Performance expectancy • Effort expectancy • Social influence • Facilitating conditions	Modified model based on Kifle's model	• Behavioral Intention: Social influence, anxiety, perceived sustainability, perceive voluntariness of use • Perceived usefulness: Perceive compatibility, perceive ease of use, computer self-efficacy
	Rogers Diffusion of Innovations Theory (DoI) [15]	• Relative advantage • Ease of use • Image • Visibility • Compatibility • Results demonstrability • Voluntariness of use		
	Technology Acceptance Model (TAM) [46]	• Perceived usefulness • Perceived ease of use • Subjective norm		
	Modified Theory of Planned Behavior (TPB) [47]	• Attitude toward behavior • Subjective norm • Perceived behavioral control		
	Theory of interpersonal behavior (TIB) [48]	• Perceived social norms • Personal normative belief • Self-identity • Facilitating conditions • Perceived consequences • Intention • Behavior • Affect • Habit		
	Poignant Factors	• Image • Perceived ease of use • Usefulness • Social influence • Perceived voluntariness of use • Behavioral intention to adopt • Anxiety • Experience		
	Kifle's Adoption Model [49]	• Cultural differences among extreme resource poor countries • Cost and technology availability were not tested as one of the primary factors		

Table 4 (continued)

Source	Underpinning Framework	Core Constructs	Emerging Framework	Core Constructs
Kabongo EM, Mukumbang FC, Delobelle P, Nicol E. Explaining the impact of mHealth on maternal and child health care in low- and middle-income countries: a realist synthesis. BMC Pregnancy & Childbirth. 2021;21(1):1–13; https://doi.org/10.1186/s12884-021-03684-x	Context (C) + Mechanism (M) (resource + reasoning) = Outcome (O) Framework [50]	• Context (C) • Mechanism (M) • Outcome (O)	Self-developed model: Intervention-Context-Actors-Mechanism-Outcome (ICAMO)	• Intervention (I): Characteristics of interventions, e.g. type of technology, co-interventions, or modalities • Context (C): Conditions required for program mechanisms to activate or not • Actors (A): Individuals, groups, and institutions involved in the implementation and uptake of interventions • Mechanism (M): Causal forces, powers, processes or interactions, generating behavioral change • Outcomes (O): mechanisms activated within specific contexts
Archer N, Lokker C, Ghasemaghaei M, DiLiberto D. eHealth Implementation Issues in Low Resource Countries: A Model, Survey and Analysis of User Experience (Preprint). In: Journal of Medical Internet Research. 2020; https://doi.org/10.2196/23715	Fit-variability model [51]	• Technological viability • Economic viability • Organizational viability • Societal viability • Technological fit • Economic fit • Socio-cultural fit • Service view • Stakeholder view	Structural equation model of eHealth implementation in LMICs	• Task characteristics • User characteristic • Perceived technology infrastructure • Perceived privacy • Perceived security • eHealth usability • Concerns and uncertainties • Perceived implementation effectiveness • eHealth utilization
	Task-technology fit Model [52]	• Task characteristics • Technology characteristics • Individual characteristics • Precursors of utilization - Expected consequences of utilization - Affect toward using - Social norms - Habit - Facilitating conditions		

Table 4 (continued)

Source	Underpinning Framework	Core Constructs	Emerging Framework	Core Constructs
Leonard E, De Kock IH, Bam WG. Investigating the relationships between health and innovation systems to guide innovation adoption. In: 2019 IEEE International Conference on Engineering, Technology and Innovation (ICE/ITMC). 2019; https://doi.org/10.1109/ice.2019.8792677	National Innovation System (NIS) [53]	• Innovation stimulation • Innovation governance	Conceptual Health Innovation System framework	• Components - Relations and networks - Innovation - Institutions - Knowledge - Actors • Functions - Organizational activities - Knowledge development - Knowledge exchange - Guidance of search - Market formation - Resource mobilization - Creation of legitimacy - Health service delivery - Monitoring and evaluation • Context - Economic - Political - Sociodemographic - Epidemiology - Geographic • Goals and Objectives - Improved health status - Access - Quality - Safety - Efficiency - Social and financial risk protection - Equity - Consumer Satisfaction
	Regional Innovation System (RIS) approach [54]	• Cultural and institutional environments assisting or hindering innovation		
	Sectoral Innovation System (SIS) approach [54]	• Collection of firms that are involved in producing and using a sector's technologies • Can cross geographic boundaries and contains numerous technologies		
	Technological Innovation System (TIS) approach [54]	• Collection of actors and guidelines • Specific technology as boundary of innovation system		
	Jabareen's conceptual framework methodology [33]	• Phase 1: Mapping of innovation system • Phase 2: Categorization of innovation approaches • Phase 3: Functions and components of innovation system • Phase 4: Deconstructing functions and components • Phase 5: Integration of health system concepts • Phase 6: Synthetizing • Phase 7: Validation • Phase 8: Rethinking		

interchangeably with differing nuances. While both concepts deal with the broader application of practice, diffusion tends to imply a more organic, decentralized process, whereas "scale-up" suggests a managed effort. Diffusion of medical devices is closely linked to existing diffusion models of innovation, with the peculiarity that medical devices are embedded in complex, risk-averse, clinical settings with lengthy implementation processes. It is estimated that only 7% of devices achieve implementation in a healthcare context due to concerns about product features, competitors, deficiencies in regulation, lack of health technology assessment, and a challenging reimbursement landscape [56, 57].

Another observation is that there is no overlap between identified reviews, conceptual, and commentary studies from a theoretical point of view. It appears that these studies have disparate foundations. In contrast, there is overlap in empirical work, with a tendency to highlight theoretical underpinnings, compared to reviews and conceptual discussions.

Further knowledge gaps of other emerging frameworks encompass problems with implementation and testing [37, 38], the relationship between adoption and performance effects of co-intervention [42, 58, 59], unavailable high-quality data, and small sample sizes to empirically proof proposed frameworks [40, 41, 60–62]. Furthermore, emerging frameworks have shown limitations of maintenance or contributions to understanding their position within the lifecycle of medical devices and equipment.

4.2 Lack of low-resource specificity

While we do celebrate the diversity and plurality of frameworks, we argue that the applicability of the most dominant ones (DoI [36, 37], TAM [38, 39], CFIR [40, 41], i-PARIHS [40, 42], TTF [39, 43], UTAUT [44], and UTAUT 2 [39, 44]) are not well suited for medical devices and equipment adoption and diffusion in LMICs, given their unique socio-economic, cultural, and infrastructural contexts prevalent in high-income settings.

Furthermore, Rogers DoI concentrates on organizational goals [54] rather than political elements, while research has shown that the adoption of medical devices and equipment also depends on insufficient political support [63, 64]. It also fails to anticipate the necessary organizational changes when introducing a specific innovation [36].

The TAM models the behavior of the user by subjective means and behavioral intention, such as interpersonal influence, which is constrained by norms and values of societies as well as personal attributes and traits [65].

4.3 Limitations

There are several limitations to this study. First, we limited our inclusion criteria to studies that include some form of frameworks, guidelines or models of adoption/diffusion within the title and abstract screening phase. This would have excluded other studies that also included such information, but it was not included in the title/abstract. A full review of any studies that used and applied such frameworks would have also provided rich contextual information that also contributed to the emergence of frameworks and theories in this field. We did not capture those. Furthermore, it was not always certain to what extent identified frameworks influenced emerging frameworks. It remains unclear if other sources of influence have been used.

Secondly, the studies were limited to those in English language, and the string included the phrases related to low-resource or low- and middle-income countries. Many studies that stated the country of interest would have not been captured in our search.

We therefore caveat that our study is only a start – the first synthesis of the existing guidelines and frameworks for medical device and equipment adoption and diffusion in a low-resource context, which serves as a starting point for further research and debate about the current state of the research in this domain.

5 Conclusion

Existing literature on medical devices and equipment comprises of a diversity of theories, frameworks, guidelines and models that explain their adoption and diffusion. A large number of studies focused on telemedicine, telehealth, m-health, e-health, and the most utilized underpinning frameworks were DoI, TAM, CFIR, i-PARIHS, TTF, UTAUT, and UTAUT 2. We argue that the applicability of these underpinning frameworks are inadequate for the adoption and diffusion of medical devices in low-resource settings due to their unique socio-economic and cultural contexts. The included studies also highlight the development of new emerging frameworks built on existing theoretical foundations, demonstrating that this research domain is in itself emerging, which is encouraging. We look forward to future empirical studies with insights from stakeholders in low-resource settings directly involved in implementing medical devices and equipment technologies, as their involvement is crucial for gaining a deeper understanding of the practical challenges and dynamics associated with their adoption. A higher resolution of socio-technical contexts, multi-actor systems, and their interplay in low-resource ecosystems is required. This can involve a demarcated categorization of existing conceptual frameworks, including their objectives, constructs, and applications.

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Author contribution SHK and JD jointly led the study's design, formulated the research question, oversaw the review process, ensured the study's relevance, and contributed to the interpretation of the findings. NK was primarily responsible for conducting the database searches in PubMed and Scopus, managing the data extraction, conducting the review process, and proposed inclusion and exclusion criteria. CA was responsible for drafting the manuscript, formalizing the inclusion and exclusion criteria, synthesizing the results and key findings, and contributing input on the study's limitations and future research directions. CA contributed to the development of the conceptual understanding and analyzed adoption and diffusion frameworks, focusing on identifying gaps in empirical research and theoretical foundations. All authors reviewed and approved the final version of the manuscript.

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Data availability The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

Declarations

Ethical approval Not Applicable.

Consent to participate Not Applicable.

Consent to publish Not Applicable.

Competing interests The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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