Improvement Science: conceptual and theoretical foundations for its application to healthcare quality improvement

Ciência da Melhoria do Cuidado de Saúde: bases conceituais e teóricas para a sua aplicação na melhoria do cuidado de saúde

Ciencia de la Mejora del Cuidado de la Salud: bases conceptuales y teóricas para su aplicación en la mejoría del cuidado de salud

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Abstract

The development and study of healthcare quality improvement interventions have been reshaped, moving from more intuitive approaches, dominated by biomedical vision and premised on easy transferability, to gradually acknowledge the need for more planning and systematization, with greater incorporation of the social sciences and enhancement of the role of context. Improvement Science has been established, with a conceptual and methodological framework for such studies. Considering the incipient of the debate and scientific production on Improvement Science in Brazil, this article aims to expound its principal conceptual and theoretical fundamentals, focusing on three central themes: the linkage of different disciplines; recognition of the role of context; and the theoretical basis for the design, implementation, and evaluation of interventions.

Health Care; Quality Improvement; Quality of Health Care; Sustainable Development; Innovation

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Introduction

Healthcare quality problems result in missed opportunities to produce better outcomes, in avoidable harm to patients and unnecessary cost increases for providers, third-party payers,and society. Meanwhile, actions that seek to introduce changes to deal with such problems in healthcare organizations are commonly based on intuition rather than theories [1], with little accumulation in the generation of scientifically based knowledge. Initiatives in healthcare quality improvement and patient safety frequently produce limited changes, largely unsustainable and difficult to replicate [2,3], especially for different contexts from those for which they were initially conceived.

The concept of quality of care and its dimensions have changed over time, taking on a broad or narrow connotation and with distinct meanings for different authors and actors [4,5,6]. A seminal author in the area of quality of care, Donabedian [4] defined quality care as that capable of maximizing the patient's well-being, after taking into account the balance between the expected gains and losses in all stages of the process. The author defined quality as a central attribute of healthcare, based on two essential axes: (i) application of scientific knowledge and technological resources and (ii) quality of the patient-healthcare professional interpersonal relationship. Blumenthal [6], analyzing the variety of definitions and meanings for the concept of quality of care, pointed to the proposal by the U.S. Institute of Medicine (IoM) as one of the most widely used beginning in the 1990s [7,8]. More recently but compatible with the work of Donabedian [9], the definition of IoM indicates that quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge [8]. Six dimensions are intrinsic to this definition: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity [10].

Healthcare quality improvement, in turn, is translated into changes that directly or indirectly produce better health outcomes [11], incorporating technical elements that are amenable to a certain degree of standardization, but mainly personal interactions interwoven with the context [12,13,14].

The idea of a Science of Improvement, first proposed by Langley et al. [15] in 1996 in the first edition of *The Improvement Guide*, assumes that improvements in any area of activity derive from the development, testing, and implementation of changes, and that basing improvement processes on science reasoning assure more effective results. The application of the Science of Improvement to each specific area should be informed by the experience, knowledge, and intuition of experts that are closest to each of their problems.

Improvement Science, applied to healthcare, has gained identity and visibility in the last eight years [12,16,17], and has been described as an evolving area, focused on the development and evaluation of interventions for healthcare improvement, on the explanation of how such interventions work and produce the expected results and under which contextual conditions, and the identification of strategies for their dissemination [18]. Studies have multiplied in the area, featuring the development of an explanatory theory for a successful project in reducing central venous catheter infections in intensive care units (ICUs) in Michigan, USA [19], and a study on the attempt to replicate the Michigan results in England [20]. Another example focused on the project for improvement of discharge summaries from ICUs in England [21]. A consistent international effort has been made to establish guidelines for publications in the area [22,23,24].

Improvement Science identifies three key elements: the intervention's technical component, the implementation strategy, and the context in which the intervention is implemented [20]. Still, a known tension exists between the urgency of acting on quality of care problems and the insufficiency of scientific evidence for basing such measures [17]. Improvement Science is structured on the theoretical-methodological-conceptual knowledge consolidated in other fields to deal with specificities of the health area, particularly those of healthcare. Improvement Science also interacts with related health disciplines such as "health services research", "quality assurance", or "quality of care evaluation" [9,25,26]. Its identity relies on the focus on healthcare improvement interventions, systematic studies of the mechanisms of change in such interventions, and the conditions for their functioning.

Healthcare quality improvement interventions are predominantly complex, with multiple components that can act independently or interdependently, leading to interactions capable of dynamically modifying the intervention itself [27,28,29,30]. Such components can act on the health system, the organizations, the behavior of health professionals, the way patients are cared for in health services, or even patients' behavior [13,31].

Improvement Science aims to reconcile knowledge originated in practice with scientific systemization [12,32]. It values the design and evaluation of local interventions and their potential for large-scale application. It postulates that well-systematized learning in health organizations has much to contribute to generalizable knowledge. Meanwhile, it emphasizes the importance of knowing the active components, that is, those capable of

producing changes and that characterize the intervention (e.g., training to increase the healthcare team's ability to deal with a given situation) and mechanisms by which it acts to effectively promote the intended changes (e.g., education, persuasion, incentives, etc.) [33]. It overlaps with disciplines, such as Implementation Science [27,34,35,36] and Translational Research [35,37,38].

Considering the incipience of the debate and scientific production on Improvement Science in Brazil, this article aims to address its principal characteristics, based on a review of the international literature, with a focus on three central themes: (1) articulation of different disciplines; (2) recognition of the role of context; and (3) the theoretical basis for designing, implementing, and evaluating interventions.

Articulation of knowledge and approaches from different disciplines

Improvement Science has flourished in an environment of recognition of the importance and complementariness of professional and organizational approaches to the identification and management of healthcare quality problems. This environment features, side-by-side, the valorization of processes of care that prioritize clinical effectiveness oriented by scientific evidence and organizational contexts based on responsibility and accountability concerning the results obtained [39,40].

Disciplines like quality management, epidemiology, program evaluation, psychology, and social sciences are articulated to identify interventions capable of producing positive changes in healthcare quality, measurement of such changes, explanation of the mechanisms involved, and characterization of the contextual conditions for their functioning and sustainability. However, the complementariness of views is not always congruent, which generates tensions and fragmented perspectives [17,32,41]. The search for some harmonization between distinct visions is a work in progress, involving the combination of diverse theoretical [42,43,44] (Table 1) and methodological approaches [32].

The scope of Healthcare Improvement Science includes quality improvement projects, predominantly developed at the local level, which value the conception and implementation of incremental changes and the learning acquired through such experience [32,45]. These projects, characterized by their pragmatic perspective, derive from quality management and most probably are at the root of the name "Science of Improvement" in a broader context, in combination with the dynamic process of testing and adjusting changes.

The theoretical-conceptual framework for the System of Profound Knowledge elaborated by Edward Deming is one of the fundamentals of quality improvement [12,15,16,46]. It includes four interrelated pillars [12,16,17,47]: (1) a system vision, defining system as a network of interdependent components that interact to achieve a specific objective; (2) alignment between proposed actions and the relevant available knowledge, knowing that people's perception of the knowledge impacts their learning and decision-making; (3) understanding of variations in the processes and results, distinguishing between variations that are inherent to the process and those that are not typically part of it; and (4) grasping means to engage people in processes of change, considering that social and interpersonal structures impact the process or system's performance. In methodological terms, such projects highlight, among others, application of Plan-Do-Study-Act (PDSA) cycles in testing and adjusting interventions [12,15,16] and statistical control techniques in monitoring relevant process and result indicators for evaluating the implementation and effects of interventions [48,49,50]. Consecutive PDSA cycles should display dependency, simulating the scientific method; hypotheses should be described, tested, and analyzed, and the results should foster learning and a knowledge base for new cycles [16].

The literature suggests that the intervention's design should begin with careful analysis of the desirable changes, contextual conditions, and theories (organizational, behavioral, social, innovation-related, etc.) that underpin hypotheses on the pertinent mechanisms of change. A theory of change should be formulated *a priori* [19], and a theory of change proposed a posteriori, at the end of the tests. The capacity to generate knowledge and its potential generalization derives from the accumulation of local experiences and consistent compilation of the resulting theories of change, the center of which is the well-based explanation of the respective mechanisms of change.

However, the scope of Improvement Science, applied to healthcare, when compared to that of Science of Improvement, is expanded by the inclusion of studies to evaluate interventions for improvement of care, focused on questions concerning their process of implementation and effectiveness, efficiency, and sustainability. In this sense, disciplines such as health services research, epidemiology, and health technology assessment contribute to the tradition of studies on healthcare quality, including quantitative scientific approaches with experimental, quasi-experimental, and observational designs [51,52,53], as well as evaluation models like those proposed by Donabedian [26]. A recent review mapped different types of studies,

Table 1

Theories applicable to the field of quality of care improvement.

Focuses/Theories	Elements addressed
Individual/Professional	
Cognitive theories [43]	These deal with mechanisms present in thinking and acting processes. The decision-making process may be rational, the result of a balance between advantages and disadvantages, based on consistent and current information, or not necessarily rational, but based on experience, contextual information, or pressures – needs, opinions, etc.
Educational theories	These focus on needs for individual learning, learning styles, and motivation to learn and change. Learning is a process of active knowledge-building, in which new knowledge links to preexisting knowledge. In addition to cognition, the motivation to learn is important. People learn more and become more motivated to change if the knowledge provides elements for solving problems in daily practice. Individual learning style is relevant (active, reflexive, theoretical, or pragmatic)
Motivational theories [43]	These theories focus on the role of attitudes, perceptions, and intentions in relation to the desired performance. One of the most widely used is planned behavior theory, which emphasizes individual intentions as determinants of behavior, shaped in turn by attitudes, perceived social norms, exerted or perceived control, or expectations of self-efficacy. They address differences in motivation between individuals and between motivational stages through which individuals pass until actually making the change. They suggest phases that need to be experienced in order to reach new phases
Context and social interaction	
Communication theories	These highlight that communication can influence attitudes and behaviors and seek to identify how they do so. The characteristics of the message, the way it is processed, and the characteristics of the message's sender and receiver matter for its acceptance and sustainability. The capacity of the message to convince depends on the validity, personal relevance, and functionality of the information and the credibility and status of the party providing it
Social learning theory	As an extension of classical behavioral theory and planned behavior theory, this theory explains individuals' behavior based on personal, behavioral, and contextual factors. Personal factors involve personal skills for learning by experience, by doing, and by observing the behavior of others; behavioral factors include possibilities of demonstrating the desired performance; contextual factors are those that reinforce the performance (material rewards, behavior modeling by others)
Theories on influence and social network	These establish that the adoption of new actions is heavily influenced by the social network's structure and by specific individuals within and on the fringes of this network. Individual behavior cannot be considered isolated from the behavior of other individuals in the social network. Focus on the weakness or strength of ties, differences in individual attributes, and previous experience with the incorporation of innovations. The prevailing norms, values, and culture in social networks also matter. Problems and uncertainties are resolved by exchange of opinions between peers in the network, in formal or informal encounters. These theories value consensus-building and local communication. The opinion of leaders is particularly important, since it carries great weight and can facilitate change
Teamwork theory	Patient care is the responsibility of a healthcare team. The team serves as a way to address fragmentation of care. Factors that influence teamwork include team vision, information sharing, trust in effective participation, task orientation (objectives and goals known and shared), and support for innovation
Professionalization theories	Based on the premise that professionals have a command of specialized, complex, and difficult-to-grasp knowledge that requires years of training for its adequate application. The organizations in which they work are known in the organizational literature as professional organizations [44]. Professionals have a monopoly on their practice and great autonomy in relation to their peers and leaders in the clinical decision-making process, granting them considerable power
Leadership theories	Formal or informal leaders can influence processes of change in clinical practice. This capacity to influence others (power) draws on different sources: formal authority, control of scarce resources, knowledge, capacity to establish internal and external alliances, and belonging to the dominant culture. Some authors distinguish between 2 types of leadership: transactional (supporting the achievement of specific goals) and transformational (lending support to cultural changes in the organization)

(continues)

Table 1 (continued)

Focuses/Theories	Elements addressed
Organizational context	
Theory on innovative organizations	Supports appreciation of the role of extension of specialization, decentralization, professionalization, and functional differentiation, internal and external communication, and type of organization, large or small, for-profit or not-for-profit. Some organizational characteristics facilitate implementation of innovations
Quality management theory	Addresses organizational culture, leadership, team characteristics, organization of the process of care, and client focus. Emphasizes understanding and improvement in the work process and systems to achieve improvement in the organization's quality as a whole. Inadequate organizational performance is not an individual problem but a systemic failure, and change only happens by changing the system
Reengineering theory	Focuses on more efficient design of processes of care, flows, and multidisciplinary collaboration
Complexity theory	Focuses on interaction between the parts of a complex system and behavior patterns. Health systems and their component units are a collection of individual agents with freedom to act in ways that are not always predictable, and whose actions interconnect such that action by one agent changes the context for other agents
Organizational learning theory	Concerned with the organization's capacity to stimulate continuous learning and information exchange at all organizational levels. Individuals and organizations are capable of learning. Individuals learn, and even if they leave the organization, they leave behind a store of acquired knowledge. The limits between organizational learning and knowledge are not totally clear. The first relates more to training, with organizational and human resources development. The second is associated more with technology, intellectual capital, and the use of information systems
Organizational culture theory	Changes in organizational culture are prerequisites for performance changes, especially in teamwork culture, flexibility, and outward orientation
Economic context	
Economic theories	Individuals orient their behavior to optimize their objectives and decrease their risks. Different payment modalities lead to different incentives. Adequate rewards and financial incentives can influence professional and organizational performance
Contractual theories	Contractual arrangements can orient professional and organizational behavior to meet the population's needs and achieve quality standards

Source: adapted from Grol et al. [42].

highlighting their principles, advantages, and disadvantages and the opportunities for methodological improvement with a view towards the evaluation of interventions for healthcare quality improvement [32].

In program evaluation [2,32], Improvement Science has searched for elements for a theoretically oriented approach, aimed as grasping the mechanisms of change involved and how and why they work in healthcare quality improvement interventions. Program evaluation values the dynamic nature of a program's implementation, recommending the registration of its development over time, appreciation of the degree to which the implementation departs from the initial plan, and identification of inherent characteristics of the program and of the setting in which it is implemented associated with its success (or failure). In short, it proposes the formulation of a "small explanatory theory" for each program [2,54].

Additionally, Improvement Science explicitly acknowledges the importance of understanding behavioral and social phenomena pertaining to the promotion of changes for a healthcare quality improvement intervention (Table 1). Psychology [55,56,57,58,59] has especially backed the implementation of interventions, based on the understanding that quality improvement depends fundamentally on people's behavior. Meanwhile, the social sciences expand the understanding of quality improvement as a social and political process, considering power relations and social interactions [22] intrinsic to the intervention itself and to the context of its implementation.

The incorporation and sustainability of an intervention for improvement depends on the degree to which its underlying knowledge is scientifically validated, and how and to what extent individuals/professionals absorb this knowledge and thus start to apply it in daily practice. The heart of quality improvement processes lies at the intersection between the belief (expressed in the action) and the scientific evidence that sustains an intervention [16]. In the health field, at least partially, the evidence originates in clinical research. The human sciences contribute to the understanding of how professionals absorb and apply this new knowledge, valuing the dynamic

nature of the processes of change, as well as the inherent conflicts.

Valorization of the role of context

The search for understanding the mechanisms of change and identifying obstacles and levers of the implementation and dissemination of interventions incur in the valorization of the context by Improvement Science [60,61,62,63], defined by some authors as all factors that are not part of the improvement intervention itself [27,60].

An interest in the role of the setting or context in organizations' performance first emerged in the organizational field with the system and contingency theories beginning in the 1950s, when organizations came to be seen as open systems which, in order to achieve their objectives expressed in their products and services, need resources or elements found in their inner and outer setting. Organizational performance depends on adequate interaction established between such elements, hence their importance. The concern lies less in defining setting or context and more in identifying and understanding the characteristics of these internal and external elements [44,64,65].

Although the distinction between internal and external is not a consensus in the literature, some healthcare quality improvement authors highlight its usefulness for understanding the internal and external effects and constraints and especially for identifying which ones are modifiable or negotiable [31,61,62,66].

External elements are defined as socio-political-economic, cultural, regulatory, professional, and technological aspects or conditions, including healthcare system characteristics and financing, among others. Meanwhile, internal elements include structural characteristics, the nature of the work processes, network and communication, and organizational culture and climate. Also considered are the characteristics of individuals involved, i.e., their interests, knowledge, belonging, motivation, and values [61,66].

Quality improvement thus results from organizational interventions that are contingent on the context in which they occur or, more specifically, contingent on the characteristics and interactions established among their internal elements and between the latter and external elements. Although the distinction between intervention and context of intervention is somewhat arbitrary, the identification of internal and external factors or elements can shed light on the necessary conditions for being successful in the intervention implementation [31].

In short, healthcare quality improvement interventions do not happen in a sterile or labora-

tory setting [63]. Factors facilitate or hinder implementation of the intervention, influencing its effectiveness and financial and temporal sustainability. In general, the limit between intervention and context is tenuous. Interactions among contextual factors themselves and between contextual factors and the implementation process are dynamic, modifying the process over time and frequently requiring adjustments to the intervention's components [28].

In order to understand the context in greater detail, some authors distinguish between the structural and psychological perspectives, related to the objective context (structure or resources) and subjective context (actors' behavior, organizational climate, and assimilative capacity), or "hard" and "soft" contextual factors [61,62,66]. Robert & Fulop [62] and Bate [61] advocate for the need to combine the notion of contexts that are receptive or nonreceptive to change, with new contributions from psychology, based on behaviors involved in readiness to change and emotional receptiveness at the individual and organizational levels (Table 1).

Little is known about which contextual elements are most important for success, whether they change in different improvement initiatives, or even whether their importance changes over time [31]. Recognition of their importance raises two concerns, the implementation strategy and the organizational change [27,62,66], since an intervention's implementation assumes some organizational change, with adaptation and rearrangements in the intervention itself for its assimilation in different contexts.

By valuing the role of context, healthcare improvement interventions are viewed less from the angle of normative or prescriptive decisions and more as a complex and multifaceted strategy for organizational change, contingent on the context [62]. An additional challenge is to deal with the socio-technical nature and complexity of tasks and work processes in health organizations. The factors require a specific multidimensional approach to the type and scope of the change/intervention itself [62].

Theoretical basis for the design, implementation, and evaluation of interventions

Theories link interrelated concepts and proposals capable of explaining or predicting events based on the specification of relations between variables, inherent to which is the perspective of generalization or broad application and testability [55,67]. But it is also useful the understanding, as "theoretical", of that which simply provides an assertive of a signifi-

cant interaction between variables, or a coherent conceptual framework, in the shape of a map or model, of a phenomenon or complex interaction, describing how an independent variable changes the behavior of a dependent variable [2].

Davidoff et al. [2] refer to the need to demystify the use of theories in the area of healthcare quality improvement, underlining that they, whether formal or informal, provide the rationale for any human endeavor, so that the relevant question in quality improvement processes is whether the theory or theories used are explicitly stated. The authors differentiate heuristically between grand theories, mid-range theories, and program theories (small theories). In the first, they highlight the high level of abstraction and the capacity for generalization to different domains; in mid-range theories, the application to delimited areas and the intermediary position between minor working hypotheses and the all-inclusive speculations comprising a master conceptual scheme; and in small theories, the pragmatism and the specificity associated with each program or intervention [2,54]. The theory of the diffusion of innovations and normalization process theory are cited as examples of mid-range theories that provide frameworks for understanding the problem or guidelines for the development of interventions. Meanwhile, in the development, implementation, and evaluation of healthcare quality improvement interventions, the small theories related to specific interventions describe the intervention's composition, expected results, mechanisms of change, and methods to assess the results.

In designing interventions, theories are thus expected to furnish the basis for defining the mechanisms of change to be considered, and, indirectly, for proposing components to be incorporated. Testing these interventions in a given context would thus function as a test of hypotheses concerning the predicted mechanisms of change under the observed conditions. As mentioned above, theories of change are defined a priori and updated a posteriori, with the capacity for generalization deriving from accumulation of experiences in different contexts [19]. Ideally, theories should also back the implementation and evaluation of interventions, providing elements for grasping plausible mechanisms of change and for explaining their success or failure.

The literature presents a set of studies identifying theories [35,58,66,67,68,69] for the prediction and explanation of mechanisms of change associated with healthcare quality improvement interventions at the macro political, organizational and social context and individual behavior levels (Table 1).

Implementation Theory defines implementation as a social process of collective action whose central concepts derive from sociological theories of social fields and systems and cognitive theories of psychology. Based on these theories, a more comprehensive explanation of these elements constituting implementation process could be built [35]. The implementation process is explained as the interaction between "emerging expressions of agency" (or what people do in order to make something happen, and how they deal with different components of a complex intervention) and the context's dynamic elements (the socio-structural and socio-cognitive resources people draw on to perform their actions of agency). Agency expresses people's capacity and ability to achieve certain objectives based on their own actions in a complex context with constraints (Table 1).

The implementation is begun deliberately by the agents that intend to introduce a new practice or modify institutionalized practices, developed by themselves or by other agents, which modifies the social system. The implementation will imply changes that can impact individual, organizational, and societal behavior. Agents, individuals or groups engaged in the mobilization of material and cultural resources, seek to ensure the consent, cooperation, and knowledge of other agents that coexist in the context in which implementation of the practice takes place [35].

Intrinsic to this concept of implementation are two central concepts: social system and mechanisms. Social system is defined as the set of contingent, dynamic, and socially organized relations that shape the structure in which agents (individuals or groups) act, interacting among themselves, for the expression of agency. Systems are emerging, continuously shaped in time and space by endogenous and exogenous factors, with a relatively unpredictable future. And within these emerging structural conditions, mechanisms operate, defined as the processes that promote or hinder a change in an actual system, unfolding over time and expressing contributions by the agency (human intervention). The focus on the mechanisms helps understand the means for promotion of changes projected in the interventions, the circumstances in which they act, and how they attempt to shape them [35]. In short, based on the above-mentioned theory, the effective implementation of a healthcare quality improvement intervention is conditioned by human behavior and the functioning of groups and organizations and their contexts, and can be explained from different points of view.

Considering the lack of convincing evidence that some theories are more explanatory than others, Grol et al. [42] propose and describe groups of applicable theories for the area of healthcare quality improvement, from different perspectives (Ta-

ble 1): (1) individual professionals; (2) social context and interaction; (3) organizational context; and (4) economic context. The first block includes cognitive, educational, and motivational theories that seek to explain how professionals make their choices and decisions. The second block includes theories that focus on the influence of the social context in the process of change (social norms and values within a social network, leadership, peers, and the role of models), that interact with actions by individuals in the implementation processes. They are the theories of communication, social learning, influence, social network, teamwork, professional development, and leadership. The third block focuses on the organizational context involving the theories of innovative organizations, quality management, reengineering, complexity, organizational learning, and organizational culture. Theories on the influence of economic factors focus on market regulations, competition, payment systems, and financial incentives, factors to be identified in the implementation of changes although they are largely beyond the control of the agents that promote them.

Improvement Science also adds theoretical frameworks for the implementation of healthcare quality improvement interventions, although it acknowledges their inherent limitations, due both to simplification and non-exhaustiveness, which impacts their applicability [61,62,70]. Such theoretical frameworks feature Promoting Action on Research Implementation in Health Services (PARIHS), the Consolidated Framework for Implementation Research (CFIR), the Theoretical Domains Framework (TDF), and the Model for Understanding Success in Quality (MUSIQ) (Table 2).

PARIHS, proposed on the basis of initiatives for the implementation of clinical guidelines, adopts evidence, context, and facilitation as pillars, where context consists of receptiveness to the intervention/change, organizational culture, leadership support, and capacity for evaluation [71,72,73].

CFIR [27,61,62,74] is based on approaches and empirical evidence examined by 19 preceding theoretical models, including PARIHS [27]. Implementation is seen as a social process, where context is the set of unique circumstances or factors surrounding an effort at a given implementation. This conceptual framework contains five domains: intervention, outer setting, inner setting, characteristics of the individuals involved, and the implementation process – with correlated constructs described. The central point of CFIR is the intervention's local adaptation, minimizing individuals' resistance (analyzed in light of agency and planned behavior theory) [27].

TDF [55,56] concentrates on the explanation of prevailing behaviors or readiness for change. In the current version, it is structured in 14 domains (Table 2), describing mediators of behavior change in healthcare [75].

MUSIQ [66,70] addresses contextual variables classified according to the level of the system in which they operate: microsystems, consisting of small groups that work directly in healthcare provision; macrosystems, which include various microsystems or organizations; and the outer setting, involving characteristics of the society in which the macrosystems act. It is assumed that factors pertaining to microsystems and healthcare quality improvement teams have a direct influence, while organizational factors and the outer setting indirectly influence the intervention's success.

Lukas et al. [76] identify five critical factors in the inner setting: impetus for change; leadership committed to quality; professionals' engagement in problem-solving; organizational alignment of objectives, resource allocation, and actions at all levels of the organization; and integration of the organization's individual components, overcoming traditional intraorganizational barriers.

Specifically on patient safety, Taylor et al. [77] proposed four contextual domains: culture of safety and involvement of the team and leadership in the unit; structural characteristics of the organization; external factors; and availability of management and implementation tools (personnel training, internal auditing, existence of persons in charge, and degree of customization of the intervention).

Conclusions

New challenges for the quality of care field are raised by the recognition that clinical and organizational approaches are complementary in healthcare quality improvement and that the availability of scientific evidence in favor of given processes is not sufficient to promote changes in healthcare. The magnitude of efforts and initiatives over the years and the mismatch in the effects obtained raise new questions for the healthcare quality improvement agenda. In this sense, approaches with a predominantly biomedical vision and premised on easy transferability have gradually given way to proposals that aim to deal with the complexity of the phenomena at stake, formulated with more planning and systemization, incorporation of new knowledge from the social sciences, and appreciation of contextual aspects and the implementation process itself.

From this perspective, Improvement Science is building a conceptual and methodological framework for interventions focused on health-

Table 2

Theoretical frameworks for quality improvement interventions in healthcare.

Model/Domain	Constructs/Factors/Elements
PARHIS [71,72,73]	
Evidence and characteristics of the intervention	Published research and guidelines; clinical experience and perceptions; patient's experiences, needs, and preferences; local information practice; characteristics of the intervention (relative advantage, observability, compatibility, complexity, testability, presentation, cost)
Contextual readiness	Leadership support, culture, evaluation capacity, receptiveness to innovation/change
Facilitation	Facilitator's role; purpose; external or internal role; expectations and activities; facilitator's skills and attributes; experience demonstrated by facilitator
Implementation	Intervention plan and execution; incorporation of evidence-based innovations; results for the patient and organization
CFIR [27]	
Characteristics of the intervention	Source of the intervention; strength and quality of evidence; relative advantage; adaptability; testability; complexity, presentation, cost
Outer setting	Patient's needs and resources, cosmopolitism; peer pressure; external regulation and incentives
Inner setting	Structural characteristics – social architecture, age, maturity, size and degree of the organization's specialization; networks and communications; culture; climate for implementation; readiness to implement
Characteristics of individuals	Knowledge and beliefs concerning the intervention; self-efficacy; stage of individual change; individual's identification with the organization; other personal attributes (tolerance of ambiguity; intellectual skills, motivation, values, competence, capacity, entrepreneurship, learning style)
Process	Planning; engagement; execution; reflection and evaluation
TDF [55,56]	
Knowledge	Knowledge of the condition and scientific rationale; procedural knowledge; knowledge of the setting for the practice
Skills	Skills; development of skills; competence, interpersonal skills; experience, evaluation of skills
Social/professional role and identity	Professional identity; professional role; social identity; identity; professional limits; professional confidence; group identity; leadership; commitment
Beliefs concerning capacities	Self-confidence; perceived competence; self-efficacy; perceived behavioral control; beliefs, self-esteem; empowerment; professional confidence
Optimism	Optimism; pessimism; unrealistic optimism; identity
Beliefs concerning consequences	Beliefs; expectations concerning results; characteristics of expectations concerning results
Reinforcement	Prizes, incentives; punishment; contingency; sanctions
Intentions	Stability of intentions; stages in the model of change
Objectives	Distal and proximal objectives; priorities, target setting; autonomous and controlled objectives; action plan; intent to implement
Memory, attention, and decision-making processes	Memory; attention; attention control; decision-making; cognitive overload/fatigue
Environmental context and resources	Stressful environmental factors; resources; organizational culture; relevant events/ critical incidents; interaction between individual and setting; barriers and levers
Social influences	Social pressure; social norms; group conformity; social comparisons; group norms; social support; power; inter-group conflicts; alienation; group identity
Emotion	Fear; anxiety; affect; stress; depression; negative/positive effect; emotional overload
Behavioral regulation	Self-monitoring; breaking with habit; action plan

(continues)

Table 2 (continued)

Model/Domain	Constructs/Factors/Elements
MUSIC [70]	
Outer setting	External motivators – external pressures and incentives; project sponsorship – human and financial resources, knowledge, equipment, etc.
Organization	General management governance; commitment by senior leadership; culture of support for quality improvement; maturity of the organizational quality improvement program; payment structure for physicians
Capacity and support for quality improvement	Data infrastructure; availability of resources; workforce focus on quality improvement
Microsystem	Microsystem leadership; culture of support for quality improvement (teamwork, communication, decision-making freedom, and commitment to improvement); quality improvement capacity; motivation to change
Quality improvement team	Diverse team membership; physicians' involvement; specialists in the focus area; previous experience with teamwork; previous experience with quality improvement; leadership; team decision-making process; team norms; skill in the use of quality improvement methods
Miscellaneous	Event that triggers emphasis on quality improvement; work perceived as part of the organization's strategic objectives

CFIR: Consolidated Framework for Implementation Research; MUSIQ: Model for Understanding Success in Quality; PARIHS: Promoting Action on research Implementation in Health Services; TDF: Theoretical Domains Framework.

care quality improvement. The current review has prioritized three axes which in a sense provide the basis for Improvement Science. Still, they are intrinsically interwoven, delimited by fuzzy borders and, generally, complementary. The first axis, based on the articulation of different disciplines and approaches, seeks a more comprehensive understanding of the processes involved in healthcare quality improvement. The second, which can be seen as the result of advances in the first, is the explicit recognition of the critical role of context in the success or failure of initiatives for healthcare quality improvement. Finally, the third calls attention to the importance of a theoretical foundation for the design, implementation, and evaluation of interventions.

The available literature on Improvement Science provides contributions that we have reviewed systematically here. Although some of these contributions may sound commonsensical and in fact refer to aspects that are widely recommended in various areas of knowledge, we have valued them here as posing concrete challenges for the practice of healthcare quality improvement. What still predominates, especially in Brazil's reality, are healthcare quality improvement initiatives developed intuitively by "trial and error", without a more systematic anticipation of how and why the desired change will be promoted and without systematic follow-up of its implementation and results.

Improvement Science wagers on the possibility of agile learning based on local healthcare quality improvement interventions, without waiving scientific rigor to guarantee the findings' validity in a given context and its generalization to other settings [12,13,17,18]. In this sense, Improvement Science also sees potential for closer contact between "implementers" of local healthcare improvement interventions and researchers involved in the production of generalizable knowledge concerning such interventions.

Context is crucial to interventions. Healthcare organizations are open sociotechnical systems in which the degree of complexity in the introduction of changes is conditioned by the nature of their technical work (more or less amenable to standardization), internal and external power relations (more or less concentrated), cultural characteristics (beliefs, values, rituals, and practices that generate behavior patterns), and characteristics of the setting.

Our review pointed to the articulation, in the scope of Improvement Science, of quality management, health services research, epidemiology, program evaluation, psychology, and social sciences. Other disciplines could certainly be added, but we believe that the ones addressed here, combined with what they themselves bring from other fields, provide substantial backing for Improvement Science. We should thus not shrink from the persistent challenge involved in the articulation and synthesis of such different visions, coming from disciplines that still appear in fragmented and often contradictory forms. Among the challenging questions for Improvement Sci-

ence, some are suggested as its amplitude is captured and compromise between pragmatism ans scientific rigor is searched.

An adequate balance between standardization and customization in healthcare quality improvement processes should be pursued wisely, avoiding both the assumption that each case is absolutely unique and, at the other extreme, that an intervention is always the same, regardless of the context. This concern is valid for healthcare quality improvement interventions with a direct focus on patients, health professionals, the organization, or any other level. While all individuals or organizations essentially have their own specificities, healthcare quality improvement depends on the systemization of generalizable knowledge based on an understanding of how mechanisms of change act in classifiable cases. It is thus important, in the description of interventions, to identify both essential and more peripheral components, as well as highly context-sensitive components.

It is also important to continuously mature a way of building of generalizable knowledge based on local healthcare quality improvement process-es. The path identified here is that of theoretical formulation defined a priori and testing of hypotheses concerning mechanisms of change and their robustness in the face of diverse conditions [12,17]. However, this path is not entirely linear, and much progress is still needed in actually incorporating, as proclaimed, theoretical backing for healthcare improvement. Meanwhile, randomized clinical trials are still important in their capacity to infer causality, but are often inefficient in grasping contextual effects, thus highlighting the need for methods capable of compensating for this limitation [12].

In short, there is still a considerable distance between progress in scientific knowledge on best healthcare practices and the care that is actually provided to patients. Using established knowledge and methods, Improvement Science seeks to explain and shorten this distance. It proposes the construction of a theoretical and methodological framework that assists the design, implementation, evaluation, dissemination, and sustainability of quality improvement. This is probably the main contribution and innovation of Improvement Science.

Contributors

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Resumo

O desenvolvimento e estudo de intervenções para a melhoria do cuidado de saúde tem ganhado novo contorno, movendo-se das abordagens mais intuitivas, com domínio da visão biomédica e assentadas no pressuposto de fácil transferibilidade, para gradativamente reconhecer a necessidade de mais planejamento e sistematização, com maior incorporação das ciências sociais e valorização do papel do contexto. A Ciência da Melhoria do Cuidado de Saúde vem se estabelecendo, propiciando referencial conceitual e metodológico para tais estudos. Considerando a incipiência do debate e produção sobre Ciência da Melhoria do Cuidado de Saúde no Brasil, este artigo objetiva discorrer sobre as principais bases conceituais e teóricas que a sustentam, com foco em três temas centrais: a articulação de diferentes disciplinas; o reconhecimento do papel do contexto; e o embasamento teórico para o desenho, implementação e avaliação das intervenções.

Atenção à Saúde; Melhoria da Qualidade; Qualidade da Assistência à Saúde; Desenvolvimento Sustentável; Inovação

Resumen

El desarrollo y estudio de intervenciones para la mejora del cuidado de la salud está perfilándose de otras maneras, moviéndose desde los enfoques más intuitivos, con dominio de la visión biomédica y asentados en el presupuesto de su fácil transferibilidad, hacia el reconocimiento gradual de la necesidad de más planificación y sistematización, con una mayor incorporación de las ciencias sociales y valorización del papel del contexto. La Ciencia de la Mejora del Cuidado de Salud se va estableciendo, propiciando un referencial conceptual y metodológico para tales estudios. Considerando la insipiencia del debate y producción sobre Ciencia de la Mejora del Cuidado de Salud en Brasil, este artículo visa discurrir sobre las principales bases conceptuales y teóricas que lo sostienen, enfocándose en tres temas centrales: la coordinación de diferentes disciplinas; el reconocimiento del papel del contexto; y el fundamento teórico para el diseño, implementación y evaluación de las intervenciones.

Atención a la Salud; Mejoramiento de la Salud; Calidad de la Atención de Salud; Desarrollo Sostenible; Innovación