Complex interventions and service innovations: development and application of the COMPLETE framework for patient-centered and justice-oriented design

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Abstract

Background.

The field of implementation research has recently seen considerable, and long overdue, interest in equity, with a strong emphasis on recognizing and responding to disparities in care. The COMPLETE (COMPLEx inTERvention and service innovation) framework is intended to support inclusive intervention and service design. The aim is the development of a patient-centered and justice-informed framework for the design of complex healthcare interventions and innovations in service design.

Methods.

We undertook three studies. (1) We operationalized constructs from sociological theories of inequality, implementation processes, social roles and expectations, to build a Matrix Model of mechanisms that drive the embedding of disparities in complex healthcare interventions and service innovations. (2) We developed patient-centered and justice-informed principles for design that form a Theory of Change that can be applied in intervention and service design. (3) We then linked the Matrix Model and the Theory of Change together with core elements of theories of prefigurative design and research justice, to build a Transformational Design Cycle for complex interventions and service innovations around a set of critical questions about the implications.

Results.

The COMPLETE framework focuses on the ways health inequalities and inequities are brought into being by systemic mechanisms within health services; are then propagated and normalized through implementation mechanisms; and are then realized and normalized in practice through institutionalized expectations of patients and caregivers. The framework provides tools to resist the naturalization of inequities and inequalities.

Conclusion.

We developed a framework for intervention and service design that consists of three components: a conceptual model of the translation of social determinants of health through organizational mechanisms that shape patient and caregivers’ lived experience of disparities in health and healthcare; a transformational theory of change; and a set of principles for design that seeks to place restitution for disparities at its center.

CONTRIBUTION TO THE LITERATURE

- The COMPLETE framework acknowledges that inequity, inequality and disparity in care are inadequately conceptualized and investigated in implementation science.
- COMPLETE provides three theory-based toolkits to identify and mitigate systemic mechanisms that lead to inequity, inequality and disparities in care.
- COMPLETE emphasizes the need to incorporate principles that drive towards equity through user-centered co-creation and co-design.
- COMPLETE opens a pathway for implementation design and evaluation that works towards restitution for injustice.

BACKGROUND

What would a patient-centered and equity-informed way of thinking about complex interventions, and innovations in service design, in Implementation Science and other areas of health services research look like?

In this paper, we present the COMPLETE (COMPLEx inTERvention and service innovations) Framework. This offers a set of tools to support patient-centered and equity-informed intervention and service design and development, alongside a theoretical framework that identifies the conditions and contexts in which they may be applied and offers ways of thinking through their implications. Thinking about the design and implementation of complex healthcare interventions and innovations using these tools can help us bridge the gap between two important questions about the problem of patient-centeredness in contemporary healthcare, proposed by Montori [1]. He asks, how can we best care for this patient (through patient-centered individualized care)? These questions are at the heart of the shift to evidence-based care [2], which is the foundation not just of Implementation Science as a field of research and development [3], but also of Improvement [4], and Prevention [5], sciences. Indeed, it is increasingly the foundation for all healthcare work. Similarly, they are found at the heart of debates about what patient-centeredness can actually mean at scale in complex, organizational settings [6], as well as the immediate relationship between practitioner and patient [7].

Experiences of inequalities in the design, quality, and outcomes, of healthcare are equally fundamental to these questions. Disparities, inequities, and inequalities can be defined and mapped against many different practices of categorization and stratification, including socioeconomic status, race and ethnicity, disability and health status, sex and gender, age, and religion [8, 9]. Examination of reviews of commonly used frameworks and theories in implementation science [10-13], reveal that problems of inequity have infrequently been considered, a point forcefully made by Snell-Rood et al., [14]. Their absence has important implications for the framework described in this paper.

These forms of categorization are sometimes seen as blunt instruments, since the lived experiences and identities they represent intersect with, and may amplify, each other in complex ways [15, 16]. Here, societal determinants of health and wellbeing are translated and propagated through ensembles of organizational, material, and conceptual practices of healthcare design and delivery [15]. Wien et al., [17] draw our attention to the importance of this when considering the ways that structural racism affects health. They reflect on the work of Crear-Perry et al., [18] who assert that,
Individuals are unlikely to be able to control directly many of the upstream determinants of health: governance, policy, and cultural or societal norms and values that shape who has access to health-promoting resources and opportunities and who does not. Beginning from this vantage point allows an understanding of why social determinants are born from structural determinants and cannot be addressed separately. In other words, no matter how empowered, knowledgeable, or willing someone is to change their behavior, they may not be able to do so because of structural determinants of health inequalities [18] (p. 231)

These practices—and the assumptions that underpin them—shape the landscape on which intervention design and services are played out, and so affect our lived experiences of care. (Because important terms are often used interchangeably in debates about disparities and inequalities, a glossary is provided in Table 1.)

Acknowledging the ways in which the effects of societally produced disparities are propagated through structures and policies of healthcare organizations, requires a fundamental shift in approach to the design of complex interventions and innovations in service. Working towards that shift, the COMPLETE Framework is a theory-informed set of conceptual tools to support patient-centeredness and social justice in the design and delivery of complex interventions and innovations in services.

Like the Theoretical Domains Framework [19], the Consolidated Framework for Implementation Research [20], and most recently, the PROLIFERATE Framework [21], the COMPLETE framework operationalizes constructs drawn from diverse bodies of theory. In particular, it combines constructs from theories of inequalities, theories of implementation processes and user experiences [22], and theories of social justice. This means that it contributes to solving an important problem in implementation research. Additionally, theory-informed frameworks are generalizable and transportable between contexts. This means that the use of the framework is not restricted to complex healthcare interventions and service innovations but can be applied more widely in human services improvement and technological development. The framework consists of discrete three components that can be used together, or separately.

- COMPLETE I offers a set of analytic propositions and a Matrix Model that make it possible to map the processes and mechanisms through which societal health inequalities and inequities are propagated within health services; are mobilized through implementation and normalization mechanisms; and are realized in practice through institutionalized expectations of patients and caregivers.
- COMPLETE II presents a Transformational Theory of Change. It offers design principles for building patient-centeredness that can counter societal inequalities and inequities propagated through healthcare organizations’ policies and practices. These offer an approach to design that does more than ensure the technical efficiency of an intervention or service, and promotes the accommodation of patients and caregivers in existing models of practice.
- Finally, COMPLETE III lays out a Translational Design Cycle that includes critical questions that can inform understanding of the implications of intervention and service designs for equity and inequalities. Importantly, these questions frame the ethical obligations of intervention and service design teams to build equitable interventions that are inclusive and that work towards restitution for disparities and inequalities.

**METHODS**

**Role of patient and public participants**

The COMPLETE framework brings together learnings from our participation in multiple research studies and innovations in service delivery, in different healthcare systems, over a period of more than twenty years. Each of these studies had input from patient and public representatives. They taught us four important lessons. First, that health services and technological innovations are often designed into interventions and services, leading to processes that discount and amplify the effects of difference. Second, patient-centered services can be created without reference to patients, leading to organizationally attractive but often fictitious claims about the possibility of participation. Third, inequalities can be amplified through unanticipated consequences of interventions and service designs. Finally, health disparities are experienced by individuals at a micro-level in ways that recursively shape opportunities for access to services, received quality of care, and health outcomes. These important observations preceded and informed the work described below.

**COMPLETE I**

We built a Matrix Model [23], of mechanisms shaping the complex, dynamic, and multi-layered problems of social determinants, health systems organization and delivery, lived experience of patients and caregivers, and theory-informed design. To underpin this, we identified a set of well-evidenced, action-oriented, and middle-range sociological theories [24-38]. Included theories are summarized in Table 2. We extracted from these theories relevant constructs, and then tested these by coding them against articles collected in qualitative evidence syntheses of studies informed by Normalization Process Theory [12, 39], and Burden of Treatment Theory [31]. The Matrix Model was used as a coding framework for directed content analysis [40-42]. Criteria for search strategies, criteria for inclusion, and quality assessment are described elsewhere [39, 43]. This work led to a matrix model of mechanisms that motivate and shape implementation processes, intervention components, and implementation outcomes. The results of this interpretive process are presented as a conceptual toolkit for tracing and mapping mechanisms that drive inequity in Table 3. This work also led to a set of propositions that form a conceptual model of factors that promote or inhibit the mobilization of interventions and services through which inequities and inequalities in care are realized in practice.

**COMPLETE II**

In this research we built on methods that some of us had previously successfully employed in qualitative syntheses aimed at developing robust conceptual models and middle range theories [36, 44, 45]. In the light of earlier theory and its empirical interpretation, a set of patient-centered and justice-informed generative principles for design [46, 47] were proposed. Generative principles are theoretically coherent propositions that guide analysis towards the implications of phenomena of interest, and that may also suggest pathways along which explanation of those phenomena may take place [48]. These were
clarified through email discussion within the study team, in webinars and conference presentations (see acknowledgements), and in iterations of comments on the manuscript of this paper.

COMPLETE III

The Matrix Model developed in COMPLETE I shows how structural and organizational mechanisms have cumulative effects for patients and caregivers, but it also suggests opportunities for prefigurative design. In COMPLETE III we explored ways of translating those opportunities into a set of provocative questions to inform design and evaluation of complex interventions and innovations in service provision. In particular, we sought to link problems of patient-centeredness, the design principles suggested by Asad [37], and the broader precepts of social justice theory [38]. This was not an exercise in abstract theory-building: our intention was to identify simple, practical, questions about the implications of interventions and services. Once again, these were clarified through email discussion within the study team, in webinars and conference presentations (see acknowledgements), and in iterations of comments on the manuscript of this paper.

Online supplementary documentation

In online supplementary documentation, we present results of the use of the Matrix Model for coding of included evidence syntheses (Additional file 1). Further, we show examples of the use of the coding matrix to interrogate included evidence syntheses on processes through which inequalities are propagated through health care services (Additional file 2), and are revealed through considering design principles (Additional file 3). An important feature of these evidence syntheses is their seeming exclusion of questions about disparities. This had been observed before the development of the COMPLETE framework, and forms an important part of the justification for qualitative inferential analysis of constructs of theories rather than primary studies.

RESULTS

THE COMPLETE FRAMEWORK

The field of implementation research has recently seen considerable, and long overdue, interest in equity, with a strong emphasis on recognizing and responding to racial disparities in care [14, 49-52]. At the same time, increasing interest in co-design, co-production and patient and public representation [53-56], and participatory action learning and design [57-61], all seem to promise a greater emphasis on practices of inclusion across the design and development of complex healthcare interventions and services, and across multiple dimensions of inequity and inequality. The COMPLETE framework offers a positive approach to thinking through these problems. The framework thus consists of three theory-informed toolkits, and while these are presented as three discrete components, they are intended to be used together to inform equitable patient-centered design.

COMPLETE I: Understanding mechanisms that propagate inequities through health interventions and services.

COMPLETE begins with a question. How are disparities, inequalities, and inequities reproduced and normalized within health services, and how do these shape service providers expectations of patients and caregivers? To begin to answer this, we offer a conceptual model of negotiable elements of interventions, health services, and their contexts, that can drive thinking around the sources of inequity and the potential for change. In this work, we draw on results of studies intended to understand how the successful implementation of complex interventions and service designs results from collective action and collaborative work around complex bundles of implementation components [34], and how the path to outcomes for this work is shaped by processes of translation and mobilization [62]. In parallel, some of us have sought to better understand how healthcare services and professionals delegate to patients and caregivers the work of effective participation in care [63], and as they do so, assign to them social roles [32], and call upon them to manage and meet systemic expectations of their performance [36, 64].

Different kinds of inequalities and inequities often appear to be inevitable or even natural. They are the taken-for-granted background of lived experiences of health and illness, made evident in the practical organization and delivery of health and services, and in the structures and direction of government policies. There is a longstanding tradition of research in health and healthcare that shows how health inequalities are products of political and economic structures and processes that affect populations by acting as social determinants of health [30, 38, 65, 66]. These are important because they point to fundamental structural causes of disparities [66]. For patients, caregivers, and practitioners, the interaction of social determinants of health and healthcare are realized through the ways in which disparities are reproduced and generated within healthcare organizations and are then translated into the experiences of the communities they serve. This leads us to our first proposition.

Proposition 1: Societal determinants of healthcare inequalities and inequities are propagated through the institutional structures and social relations that make up healthcare systems.

Healthcare systems are not isolated from their social contexts. This proposition recognizes that healthcare disparities are not random or accidental, but rather are the result of the political choices, social structures, and economic processes that perpetuate them (see Columns A, B and C in Table 3). Relational Inequalities Theory [26-29], and Health Power Resources Theory [30], describe mechanisms through which societal determinants of healthcare inequalities, such as race, gender, class, and geography, are translated into normalized organizational behaviors and are propagated through healthcare institutional structures and social relations. This leads to our second proposition.

Proposition 2: Implementation of complex interventions and innovations in services intended to mitigate inequalities may bring about new disparities or the reproduction and reinforcement of old ones.
This proposition acknowledges that healthcare interventions and services are not neutral and may produce or reinforce healthcare disparities (see columns D and E in Table 3), and that these disparities may themselves be cumulative. Implementation processes themselves can be characterized as the ‘translation of the strategic intentions of one group of actors into the everyday practices of others’ [34] (p. 147). These processes are the—often unanticipated—results of political and economic choices. The strategic intentions of interventions and service designers encompass ensembles of social and material artifacts, practices, values, and normative ideas and behaviors that make up a strategic action field of organization, and that shape its rules, relations and resources [24, 25]. It is impossible to consider them without also considering questions about power, and how this shapes both interventions and their contexts [30]. It is equally impossible to consider the contexts of intervention without also seeking to understand the implicit assumptions about patients, caregivers, and practitioners that are embedded within them [67, 68]. This leads to our third proposition.

**Proposition 3. Inequitable expectations of patient and caregiver participation are defined and negotiated within the everyday transaction spaces of healthcare.**

This proposition highlights that patient and caregiver participation is a critical component of healthcare delivery, and that inequitable expectations of their participation can contribute to healthcare disparities (see Columns F and G in Table 3). There is a longstanding body of work that explores how patient and caregiver participation in processes of care is shaped and directed not just by changing ideas about the sick role [35, 36], but also by the incorporation of patients and caregivers themselves into complex processes of formal and informal labor within healthcare organizations [69]. Increasingly, patients and caregivers are assigned administrative and treatment burdens that give institutional structure and organizational meanings to their participation in healthcare itself [63, 70-72].

The processes of assigning administrative and treatment workload to patients and caregivers can themselves become causes of healthcare disparities. Healthcare providers therefore need to critically examine how their expectations of patient and caregiver participation are constructed and negotiated, and work to identify and promote actions that make equitable participation possible. Of particular relevance here is the concept of devitalization, introduced by Reynolds [30]. She asks how relational inequalities are experienced by patients and caregivers, and points to the ways that their effects may lead to incorporation in processes that are sufficiently socially exhausting to ‘deprive actors of vitality, vigor, or effectiveness’ [30] (p. 501).

The propositions presented in this section of the paper set out a broad structure for conceptualizing the translation of societal determinants of healthcare inequalities and inequities within organizational mechanisms, through which they are realized in practice. In Table 3, we have set out a conceptual toolkit for tracing the operation of these mechanisms. This takes as its starting point processes that shape healthcare institutions; and working through processes through which disparities in care are generated and experienced, and through which (in)equitable care is translated and delivered in service settings. It also draws attention to processes that shape the ways that (in)equitable care is mobilized and enacted in practice settings, and in which systemic expectations of patients and caregivers’ participation in care are formed and framed.

**COMPLETE II: Transformational Theory of Change**

The second question that COMPLETE asks is, how can the situated knowledge and experience of patients and caregivers be mobilized to support change? To begin to answer this, we present a transformational theory of change built up around three principles for the equitable co-creation of patient-centered and justice-oriented design. This acknowledges that what patient-centered care can mean in an era of industrialized and commodified health care [1, 73-75] is contested, and that the explanatory content of empirically grounded theories [32, 36, 63, 71], can be difficult to translate into action. Thus, our theory of change is organized around a set of design principles that enable exploration of the design of health services that center on caregivers, patients and social justice, by calling for attention to designs based on civility, dependability, simplicity and subtraction (see Table 3, Column F).

We set out three guiding principles below to inform a Transformational Theory of Change. These draw on ideas about co-creation and co-design [76-78], patient-centeredness and patient and caregiver workload [79], and a critical theory of prefigurative design that responds to disparities and inequities that are grounded in economic disadvantage, race, and gender [37]. The Theory of Change is designed to be applied in any context of healthcare delivery where individuals interact with formal organizations. It calls on intervention and service designers to center the experiences of marginalized communities. Centering those experiences goes beyond incorporating representatives of those communities in design processes, to the creation of interaction spaces in which genuine mutual engagement and co-learning can take place through the use of participatory principles and practices [80]. Their emphasis on mutuality recognizes that design processes and products are not just directed at patients but intended to transform the ecosystem of care according to principles of justice.

**Design Principle 1. It is possible to co-create and co-design interventions and services in ways that encourage equitable civility and dependability in interactions characterized by inequalities of power and knowledge.**

Attending to this principle begins the process of transforming social relations between patients, caregivers, healthcare professionals, and healthcare provider organizations. This is necessary because structurally induced disparities inevitably lead to experienced disadvantages. Civility matters because when services are respectful of providers and users, they restate the value and moral meaningfulness of participation in care. But also, a lack of civility signals a lack of respect. Dependability matters because interventions and services often fail because they may not do the work that they promise the user or because they simply do not work. When services rethink the number and density of intervention components, and the interfaces between them, they can eliminate opportunities for systemic failure. But when services or interventions cannot be depended upon, then the possibility of care becomes a matter of chance. Taken together, investment in civility and dependability enhances opportunities for respectful participation and meaningful care.

**Design Principle 2. It is possible to co-create and co-design interventions and services in ways that encourage equitable clarity of purpose, easy navigation of services, and continuity of care.**

For patients, caregivers, and frontline healthcare professionals, this principle calls for critical attention to interactions characterized by disparities in access and service provision. This can drive a process of building workable counter-structures for equitable care within healthcare provider organizations. Simplicity...
matters not just because when services are simplified, they encourage clarity of purpose, ease of navigation, and continuity of care, but because investment in purpose, navigation, and continuity, enhances the possibilities for effective integration into the processes through which care is defined and delivered.

**Design Principle 3.** It is possible to co-create and co-design interventions and services that encourage equitable reduction of workload and that minimize system complexity for all service users.

Attending to this principle focuses attention on the redistribution of cognitive and material resources belonging to healthcare provider organizations, amongst patients, caregivers, and healthcare professionals. This matters because when services reduce burdensome workload, they restore both agency and capacity to patients, caregivers and professionals. But also, because investment in minimizing system complexity and its consequences enhances the possibilities for interventions and innovations to be experienced as practically workable.

**COMPLETE III: Restoring patient-centeredness and social justice in intervention and service design.**

Finally, we are confronted with the key problem, how can we detect the potential for exacerbation of inequities, inequalities, or disparities within a proposed or existing interventions and services, and, how can we mobilize against them? To begin to answer this question, in COMPLETE III, we propose a translational design cycle, organized around three key critical questions, that enhance capacity to think through—and thus work towards mitigating—the ways that interventions and services can deny dignity and amplify inequity. This draws on research that explores the ways in which implementation science models, frameworks, and theories are implicated in the reproduction of racial inequities and disparities in the lived experience of complex interventions and health system innovations. This design cycle is built up around a set of critical questions about the implications of interventions for their user communities. Incorporating ideas about prefigurative design and social justice, COMPLETE III presents a set of principles that can inform patient-centered and justice-oriented interventions and services in healthcare. It is described in Figure 1.

[Insert Figure 1 around here]

The design cycle rests on the idea that mobilizing patient and caregivers’ situated knowledge and practice through justice-oriented design will guide patient and caregiver-centered change. Design processes are often simplified by thinking about interventions and services innovations as technical problems of practice—the aim is always to identify and deliver the most effective form of care whilst at the same time also calling on the fewest resources. In the real world, it is hard to argue against this view. At the same time, however, it opens up an important set of problems, because in practice implementation and mobilization is complex, dynamic, and often unpredictable and has unanticipated and often unwanted consequences (see Column G in Table 3). We can frame these as a set of questions that are useful both to interrogate existing contexts, interventions and services toward adaptation and to think through the implications of creating new ones altogether. It recognizes that patient and caregiver perspectives and experiences are essential to (re)designing healthcare interventions and service designs that are patient-centered and equitable. It is oriented around three critical questions.

**Critical question 1. What does this intervention or service do to overcome relational inequalities generated within healthcare provider organizations and the disparities in health power resources experienced by patients and caregivers?**

In design, this means that it is important to think through the extent to which an intervention or service contributes to enhancing the capabilities of patients and caregivers, and how to mitigate the risk of (mis)allocation of advantage that creates disparities.

**Critical question 2. What does this intervention or service do to help patients and caregivers to overcome barriers to effective participation in care?**

Tracing the ways that an intervention or service contributes to patient-centeredness and social justice by engaging the preferences of patients and caregivers is complex. It needs to be a central component of design processes: not doing so leads to the risk of (mis)implementation of practices that can create or perpetuate injustices.

**Critical question 3. What does this intervention or service do to shape the ways that patients and caregivers identify themselves and manage the expectations of others?**

Patients and caregivers are defined, shaped, and organized through the knowledge, practice, and policies applied by health professions and health services. This means that designing interventions and services that contribute to patient-centeredness and social justice needs to genuinely engage with the values of patients and caregivers. Failure to do so means that patient and caregiver identities, roles, and responsibilities, are likely to be (mis)identified in ways that promote sustained inequity.

Finally, in relation to these three critical questions, we should also ask, how an intervention or service can make restitution for the misallocation of advantage, the misimplementation of practices, and the misidentification of its users? Does this work contribute to patient-centeredness by ensuring the dignity of patients and caregivers? Or, does it lead to new systemic inequalities and inequities in experiences of care, and burdens of responsibilities that cannot be mitigated? Underpinning these critical questions is a broader responsibility for intervention and service designers to attend to, identify, and correct the ways that misallocation, misimplementation, and misidentification become embedded in health services. Once embedded, they shape lived experiences of disparities and difference. In Figure 1, we show that opening up the ways that disparities in resources for care and experiences of care are built in to whole services can begin the long walk towards not just mitigating inequalities, but also thinking about ways of ensuring restitution for their persistance.

**DISCUSSION**

Theories and frameworks in implementation science are often most useful when they provide tools to think with, rather than hypotheses to test, or boxes to tick. The COMPLETE framework aims to guide thinking about promoting patient-centeredness, and mitigating inequalities, through three components.
Using the complete framework

First, COMPLETE I consists of a set of theoretical propositions that support critical analysis of proposed complex interventions and innovations in service delivery. These can also be applied to existing services to consider the extent to which they propagate and naturalize disparities in care. To make this work more concrete, in Table 3, we have translated the framework into a set of constructs that can be used to support design and evaluation. This is not a validated quantitative research instrument, but is rather a tool for critical qualitative interpretation. A potential application of the framework is therefore to use the constructs set out in Table 3 as a framework for empirical investigation. It can be used as a tool to map the pathways along which different elements of an intervention or service shape disparities in the lived experiences of patients and caregivers.

COMPLETE II offers a Transformational Theory of Change. This provides a set of guiding principles for work to co-create equitable interventions and services. Principles like this are needed because they make clear that conditions for inclusive and equitable participation precede considerations for clinical and cost effectiveness and organizational efficiency. A clinically and cost effective intervention or service that excludes its potential users or that amplifies disparities is a problem, not a solution. We cannot hope to solve all of the societal inequalities that are reflected in lived experiences of healthcare in a single intervention or service design. However, we can start the journey of working towards equity under conditions of constraint by using the principles of this Transformational Theory of Change to begin discussions with patients, caregivers, and others. The challenge that stems from this is one of meaningfully incorporating principles that drive towards equity in user-centred co-creation and co-design.

Finally, COMPLETE III offers a way of thinking through a translational design cycle that incorporates a clear picture of patient-centeredness and social justice (Fig. 1). Once again, this mobilizes a theory-informed set of questions. These lead us to some key points to incorporate in the practices of intervention design. The central objective of the framework, however, is not to create a clear pathway not just towards the mitigation of disparities and injustices, but also towards actions that might lead to their restitution. Incorporating the COMPLETE framework in intervention and service design is intended to sensitize those processes to the ways that inequities are implemented and naturalized in healthcare practice. Conversations about achieving that objective are no doubt likely to be challenging.

**Strengths and limitations of the framework**

We have described the development of a framework to inform the design and delivery of complex interventions and innovations in service delivery. An important strength of this work is that it offers a practical and theory-informed way of thinking about, and prospectively analyzing, the ways that disparities, inequalities, and inequities, become embedded and naturalized in complex interventions and health services. We chose theories on this basis, but acknowledge that there is already a numerous and diverse body of theories, frameworks, and models from which we could have selected. Whether this is a strength or a weakness is an empirical question to be answered by further research.

An interesting feature of the framework is that it has been developed abductively [81], through the application of middle-range sociological theories. This has involved repurposing some constructs of these theories, and their application in contexts for which they were not originally intended. Because problems of inequity, inequalities, and disparities—especially related to race and ethnicity—are infrequently investigated in the implementation science literature, we have focused on making inferences from relevant theories rather than from primary research.

A weakness of the COMPLETE framework is that it fails to offer any easy answer to a complicated and very challenging set of problems. There are no magic bullets through which health services can suddenly be made equitable and disparities broken down. A century of research on health services and health inequalities has shown that large-scale change and system transformation are often achieved through small advances in many different contexts that accumulate over time. Our aim therefore is to support minor miracles rather than grand designs.

**CONCLUSION**

We have set out a Framework for analyzing the dynamic processes through which inequities arising from social determinants of health are translated into lived experiences of people using healthcare interventions and services. Against this background, we have offered a generalizable Theory of Change, and a set of critical questions about design that highlight the potential for the production of disparities and the potential for restitution. This framework adds functionality to interventions that seek to consider equity in implementation science, as well as in the prevention, improvement, and safety sciences. In this context, the COMPLETE framework provides a structure for the equitable design and application of minimally disruptive and patient-centered interventions and services. These come together in a set of tools that support thinking through the design and consequences of complex healthcare interventions and innovations in service delivery for the propagation and normalization of inequalities and inequities in design. While the framework is built around problems in implementation and mobilization of complex healthcare interventions and service innovations, its constituent propositions, principles, and critical questions are written in a way that makes possible their transferability to a wider range of human services contexts, such as social care, education, and criminal justice.

This framework underscores both the importance of action and the moral obligation on researchers and practitioners to take it. This means recognizing and addressing the social determinants of healthcare disparities by designing in measures to mitigate their effects. It means critically evaluating healthcare interventions and service designs to ensure they are fit for equitable participation, and it means mobilizing patient and caregiver knowledge and practice to inform patient-centered and equitable healthcare delivery.

**Abbreviations**

COMPLETE COMPLEx inTerventions and service innovation
**Declarations**

**Ethics approval and consent to participate:** Not applicable.

**Consent for publication:** Not applicable.

**Availability of data and materials:** All data generated or analyzed during this study are included in this published article.

**Competing interests:** Not applicable.

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**Authors’ contributions**

Conceptualization: CRM, CLB, KB, AH, KIG, KCG, CC-G, EG, KL, AR, AMacF, CMM, FSM, VMM. Methodology: CRM, AH, KCG.

Formal analysis: CRM, AH, KCG.

Investigation: CRM, AH, KIG, KCG, RS.

Resources: CRM.

Writing - Original Draft CRM.

Writing - Review & Editing: CLB, KB, AH, KIG, KCG, CC-G, KL, FS, AMacF, CMM, FSM, AR, VMM. Supervision: CRM.

Project administration: AH, KCG.

Funding acquisition: CRM.

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Tables

Table 1: Glossary

<table>
<thead>
<tr>
<th>Complex Intervention</th>
<th>An intervention characterized by many interacting components that target different behaviors and expertise, across multiple contexts [82].</th>
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<tr>
<td>Health Disparities</td>
<td>A particular type of difference in health in which disadvantaged social groups persistently experience social disadvantage or discrimination and thus worse health or greater health risks than more advantaged social groups [8].</td>
</tr>
<tr>
<td>Health Inequalities</td>
<td>Avoidable and unjust differences in health between individuals or populations [9].</td>
</tr>
<tr>
<td>Health Inequities</td>
<td>The presence of unfair and avoidable or remediable differences in health among social groups [9].</td>
</tr>
<tr>
<td>Implementation Framework</td>
<td>An analytic device to support, analyze or evaluate implementation processes. Normally composed of a taxonomy of theoretical constructs or empirical observations drawn from different sources [83].</td>
</tr>
<tr>
<td>Middle-range theory</td>
<td>A theory that is ‘sufficiently abstract to be applied to different spheres of social behavior and structure’ but does not offer a set of general laws about behavior and structure at a societal level. Its scope is defined by a limited set of assumptions from which can be derived hypotheses that may be confirmed or disconfirmed by empirical investigation [84].</td>
</tr>
<tr>
<td>Minimally disruptive care</td>
<td>A clinical method that seeks to operationalize patient-centeredness whilst also seeking to reduce the personal workload involved in effective participation in care [79, 85].</td>
</tr>
<tr>
<td>Patient-centeredness</td>
<td>An approach to care that emphasizes the importance of patient (and caregiver) dignity, values, preferences, and capabilities, and which seeks to work from a holistic perspective [75].</td>
</tr>
<tr>
<td>Social Determinants</td>
<td>Social causes of health and the social factors determining the distribution of these causes between more and less advantaged groups [86].</td>
</tr>
<tr>
<td>Social Inequalities</td>
<td>Differences in health between different socioeconomic groups within a society [86].</td>
</tr>
</tbody>
</table>

Table 2: Synopsis of theories and models operationalized in this paper
<table>
<thead>
<tr>
<th>Theory</th>
<th>Definition and Synopsis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strategic Action Field</strong></td>
<td>Explains how institutional fields are formed in which collective actors mobilize norms and values that stabilize the environments in which operate, and provide a secure basis for goal-oriented outcomes [24, 25]</td>
</tr>
<tr>
<td><strong>Relational Inequalities</strong></td>
<td>Explains how meso-level economic and social disparities are produced and reproduced within organizations. Identifies mechanisms through which organizations construct, produce, and legitimize material inequalities in the allocation of resources and rewards [26-29].</td>
</tr>
<tr>
<td><strong>Health Power Resources</strong></td>
<td>Explains population-level disparities in power and resources. Identifies mechanisms that shape micro-level lived experience of health-related structural inequities, their stratification and distribution across populations, and their effects on the mobilization of personal resources [30].</td>
</tr>
<tr>
<td><strong>Burden of Treatment</strong></td>
<td>Explains mechanisms that motivate and shape the ways that the work of care and self-care can be delegated to patients and caregivers by healthcare providers. Situates agency within formal structures and informal networks that can frame capacity to effectively participate in care [31, 32].</td>
</tr>
<tr>
<td><strong>Administrative Burden</strong></td>
<td>Explains how eligibility for, and access to, care is realized through different policy and bureaucratic systems. Shows how effective participation in care can be experienced as onerous, and has learning, compliance, and psychological costs for patients and caregivers [82].</td>
</tr>
<tr>
<td><strong>Normalization Process</strong></td>
<td>Explains mechanisms that motivate and shape implementation processes. Focuses on the social organization of collaborative work and collective action through which strategic intentions can be realized and implementation processes can be accomplished [33, 34].</td>
</tr>
<tr>
<td><strong>Sick role theory</strong></td>
<td>Provides a framework for understanding societal, organizational, and professional constraints on patients and caregivers that frame the ways that they navigate and negotiate healthcare providers' normative expectations of their beliefs and behaviors, and the ways that these are practically operationalized within social roles [35, 36].</td>
</tr>
<tr>
<td><strong>Prefigurative Design</strong></td>
<td>Provides a framework for translating values and aspirations for social justice into the design or material artifacts, human services, and organizational structures. Argues that interventions and service design are not neutral, natural, or inevitable but instead can embody injustices. Proposes a set of responses to these that can be incorporated into design [37].</td>
</tr>
<tr>
<td><strong>Social Justice Theory</strong></td>
<td>Provides a framework for understanding how historical processes and contemporary institutions create practices through which disadvantage is formed around race and ethnicity; sexuality, sex and gender; disability, age and other demographics. Proposes an overarching theory of justice through which inequalities and inequities can be identified, characterized and acted upon [38].</td>
</tr>
</tbody>
</table>

Table 3: The COMPLETE Framework
1. Healthcare systems create inequitable contexts for care through processes which healthcare institutions and practices are shaped.

2. Healthcare systems normalize inequities through implementing processes and practices in which disparities in care are generated and experienced [26-30].

3. Healthcare systems embed inequities in social relations through implementing processes and practices in which (in)equitable care is translated and delivered in service settings [33, 34].

4. Health professionals and administrators transfer inequities to patients and caregivers through processes that shape the ways that (in)equitable care is mobilized and enacted in practice settings. [31, 32]

5. Patients' and caregivers' perform the work of participation in care in inequitable circumstances by actively responding to systemic expectations of their roles and contributions [35, 36].

6. Health services can promote patient-centeredness and social justice by design.

A1. Controls on activity and expenditure; constraints on specific treatments or services; changes to the healthcare labor force; and redistribution of the burden of work and expenditure [83].

B1. Methods of stratifying a populations' access to care and ways of categorizing problem groups interact to define who should (and should not) benefit from an intervention.

C1. Implementation of interventions and services that bring about relational change in the ways services are organized.

D1. Real and virtual relations between participants are mobilized through interaction strategies in ways that define participants' assumed capabilities.

E1. Patients and caregivers demonstrate co-operative active engagement in their interactions with health systems, providers, and practitioners.

F1. Civility: interventions and services that are respectful of providers and users, that reinstate the value and moral meaningfulness of participation in care.

A2. The biomedicalization and commodification of healthcare creates large-scale, complex, task-allocated, and process-oriented services and inflexible pathways through care [84].

B2. Distribution of high value resources and rewards (skills, goods, and services) distributed through an intervention or service.

C2. Implementation of interventions and services that leads to the creation of value as they undergo normalization in practice.

D2. Logics of practice that are produced through formal and informal agreements and values. These give cognitive authority to participants, and assign meaning to their actions.

E2. Patients and caregivers show resourcefulness, to operationalize knowledge and practice and link themselves to changing patterns of service provision.

F2. Dependability: interventions and services designed to eliminate opportunities for systemic failure.

A3. The strategic expansion of the healthcare sector in the face of epidemiological, demographic, and socio-technical challenges [85]

B3. Principles of eligibility and access that are built into an intervention or service.

C3. Implementation of interventions and services that brings about performatve change in the ways that work is done, over time and across settings.

D3. Concrete and virtual ensembles of beliefs, behaviors, and material practices, are mobilized through objects and procedures.

E3. Patients and caregivers seek expertise, and to possess condition and service specific knowledge.

F3. Simplicity: interventions and services that are simplified, and encourage clarity of purpose, ease of navigation, and continuity of care.

A4. Health services' obdurate corporate structures create administrative and treatment burdens for patients and caregivers [82].

B4. System capabilities that are realized in the design and delivery of interventions and services.

C4. Implementation of interventions and services that brings about normative change, by modifying the rules and resources that govern action.

D4. Formal and informal changes in norms and roles, information and material resources, shape practice and participants' delegated accountabilities.

E4. Patients, caregivers and practitioners demonstrate prudence to minimize the calls they make on formal healthcare provision.

F4. Subtraction: interventions and services that reduce workload, and restore agency and capacity to patients, caregivers and professionals.

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**Figures**
Figure 1
Legend not included with this version.

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

- COMPLETEFrameworkAdditionalfile1.docx
- COMPLETEFrameworkAdditionalfile2.docx
- COMPLETEFrameworkAdditionalfile3.docx