CONtextual analySis in implEmeNtation Science (CONSENS)

Development of a methodology for studying context and application in transplantation intervention research

Inaugural dissertation

to

be awarded the degree of Dr. sc. med.

presented at

the Faculty of Medicine

of the University of Basel

by

Juliane Mielke

From Munich, Germany

(Basel, March 2022)

Approved by the Faculty of Medicine

On application of

Supervisor:	Prof. Dr. Sabina M. De Geest
Co-Supervisor:	PD Dr. Franziska Zúñiga
External expert:	Prof. Dr. Byron J. Powell
Further Advisor:	Prof. Dr. Leah L. Zullig

Basel, 21.03.2022

Dean

Prof. Dr. Primo Schär

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Acknowledgements

A dissertation is like a journey, “you cannot go far alone. You enjoy your journey better if you have people by your side” (Karan Patel). Now that this part of my journey is coming to an end, I would like to thank all the people who have accompanied me and who have contributed to the success of this thesis in many different ways.

First and foremost, I thank my PhD committee, Prof. Dr. Sabina De Geest, PD Dr. Franziska Zúñiga, Prof. Dr. Leah Zullig, and Prof. Dr. Byron Powell, all of whom supported this dissertation with their immense knowledge and plentiful experience. I am deeply indebted to them for their consistent support and guidance over the last 3.5 years.

I would also like to express my deepest appreciation to my first supervisor, Prof. Dr. Sabina De Geest. Without her visionary thinking and boundless enthusiasm for implementation science, this dissertation would never have been possible. I am also grateful for supporting and mentoring me, which fuelled my learning and progress on various levels throughout my PhD, for inspiring and challenging my thinking, and for guiding, encouraging and demonstrating patience when “being in the cloud”. I would also like to extend my profound gratitude to my second supervisor, PD Dr. Franziska Zúñiga, who extended a tremendous amount of assistance. Her constructive criticism and feedback stimulated me to think outside the box. I also wish to express my sincere thanks to Prof. Dr. Leah Zullig, for her continuous support, invaluable advice and encouraging feedback through every phase of this PhD. And to Prof. Dr. Byron Powell, who has very kindly agreed to act as the external expert for my PhD defense.

I also wish to thank all the other people who played decisive roles. I am extremely grateful to Prof. Dr. Michael Simon for his helpful contribution to our evidence gap map. I truly appreciate his advice and practical recommendations, which helped to overcome challenges in identifying literature. This pushed my PhD project one giant step forward. I am also grateful to Dr. Sandra Staudacher who introduced me to the complex but interesting world of social sciences. Her experience and advice were instrumental in increasing BANANA's overall quality. Special thanks go to Dr. Thekla Brunkert who always supported and motivated me throughout my PhD. I also very much appreciated her stimulating questions and fruitful discussions, as well as her helpful feedback and advice on my work. It was a great pleasure working with Dr. Lisa Pfadenhauer, whose work greatly influenced my dissertation's conceptual underpinnings. Her passion for research was both inspiring and motivating, many thanks. Special thanks also to Prof. Dr. Mieke Deschodt, Dr. Sarah Musy and Prof. Dr. Hayden Bosworth for their thoughtful comments and support.

Further, I would like to express my warmest thanks to my colleagues Sabine Valenta, Lynn Leppla, and Janette Ribaut: scientifically and personally, their support was an invaluable resource. Throughout this PhD, I have especially appreciated their constructive feedback, confidence and motivation. Special thanks also to Dr. Sonja Beckmann, Dr. Kris Denhaerynck and Olivia Yip for all the stimulating exchanges, constructive feedback and support. All my present and former PhD fellow students and colleagues from the Institute of Nursing Science also deserve thanks, particularly for their critical but helpful feedback and discussions during our doctoral seminars and research meetings. Likewise, I gratefully acknowledge the value of my many constructive discussions and valuable exchanges with the members of the “Leuven Basel Adherence Research Group”. Special thanks also to the SMILe Leuven Team, Prof. Dr. Hélène Shoemans and Kristina Arnahoutova for their valuable feedback on BANANA. To our A-team—Tina Attinger, Juliane Barnick, Heike Heinemann, Michael Huber, Cornelia Kern, Michelle Killenberger, Yulya Senft, and Greet Van Malderen—I owe many thanks for their dedication and support through the last years. And of course, I thank Chris Shultis for the incredible job he did in editing this thesis.

Finally, I wholehearted thank my family for their never-ending patience, their emotional and practical support and their encouragement throughout this PhD journey.

Juliane Mielke, March 2022

List of Abbreviations

aOR	Adjusted odds ratio
AHRQ	Agency for Healthcare Research and Quality
alloSCT	Allogeneic hematopoietic stem cell transplantation
BANANA	Basel Approach for coNtextual ANAlysis
BMC	BioMed Central
BMJ	British Medical Journal
CA	Contextual analysis
CICI	Context an Implementation of Complex Interventions framework
CFIR	Consolidated Framework for Implementation Research
CHERRIES	Checklist for Reporting Results of Internet E-surveys
COVID-19	Coronavirus disease 2019
D4DIS	Designing for Dissemination, Implementation, and Sustainability
eCCM	eHealth Enhanced Chronic Care Model
EGM	Evidence Gap Map
EIC	European Implementation Collaborative
EPIS	Exploration, Preparation, Implementation, Sustainment
EPOC	Effective Practice and Organization of Care
ERIC	Expert Recommendations for Implementing Change
FIRE	Facilitating Implementation of Research Evidence Study
FRAME	Expanded Framework for Reporting Adaptations and Modifications to Evidence-based Interventions
FRAME-IS	Framework for Documenting Modifications to Implementation Strategies in Healthcare
HRA	Human Research Act
ICM	Integrated care model
IF	Impact factor
INSPECT	ImplemeNtation science State of research ProjECT
INSPIRE	Implementation of a nurse-led community care program for senior citizens in Baselland

INTERCARE	INTERprofessional CARE for better resident outcomes
IMPACT	Swiss Implementation Science Network
i-PARiHS	Integrated Promoting Action on Research Implementation in Health Services
IQR	Interquartile ranges
IS	Implementation science
JDR	Journal of Dental Research
MeSH	Medical subject heading
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NIRN	National Implementation Research Network
PARiHS	Promoting Action on Research Implementation in Health Services framework
PMID	PubMed IDentifier
PPI	Patient and public involvement
PRISMA–ScR	Preferred Reporting Items for Systematic reviews and Meta-Analyses–Scoping Reviews Checklist
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
SIRC	Society for Implementation Research Collaboration
SD	Standard deviation
SMART	Sequential, multiple-assignment randomized trial
SMILe	SteM cell transplantatIon faciLitated by eHealth
SMILe-ICM	Integrated care model in allogeneic SteM cell transplantatIon faciLitated by eHealth
StaRI	Standards for Reporting Implementation Studies
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
T-CaST	Implementation theory comparison and selection tool
TDF	Theoretical Domains Framework
TMF	Theory, model or framework
RAPICE	Rapid Assessment Procedure–Informed Clinical Ethnography
RCT	Randomized controlled clinical trial

SAMS	Swiss Academy of Medical Sciences
UK	United Kingdom
USA	United States of America

Summary

As the implementation of interventions—whether that means procedures, programs, products, policies, pills, practices or principles (the 7 P`s)—takes place in real-world settings, its success and sustainability depend heavily on the context in which they will be delivered. Context is “a set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded.” Context is multi-level, multi-dimensional and dynamic; it interacts with an intervention and its implementation in the “physical location in which the intervention is put into practice,” i.e., its setting. Thus, context has received significant attention in implementation science, which is “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence to improve the quality and effectiveness of health services and care”.

Nevertheless, context remains understudied in implementation science: many researchers fail either to consider or to report contextual information, thereby transforming most of their findings into leaks in the research pipeline, and adding them to what has become an ocean of research waste. Indeed, as few as 14% of evidence is ever implemented into real-world settings. Even then, their sustainability is often limited and the mean lag between the publication of high-level evidence and its implementation has been estimated to be 17 years.

Overcoming these challenges, i.e., reducing research waste, bridging the research-to-practice gap and speeding the translational pipeline, requires a rethinking of current approaches in implementation science. Specifically, this includes recognizing context as the key determinant of implementation science projects' success and a major source of information relevant to all of its phases, i.e., intervention development/adaption, selection/adaption of implementation and sustainability strategies, and interpretation of implementation and effectiveness outcomes. In fact, the successful translation of an intervention to a real-world setting always depends on the characteristics of the context, an intervention that fits those characteristics, and which contextually adapted implementation strategies are employed to support intervention's adoption, implementation and sustainability. Therefore, a thorough contextual analysis of the multilevel system in which an intervention will be delivered is a key method of ensuring an implementation's success and sustainability.

However, contextual analysis is currently a weak part in implementation science methodology. The concept of context lacks a unifying theoretical and operational definition and terms used to denote context vary across studies and frameworks. These and other conceptual inconsistencies challenge researchers' efforts to find and access implementation science-relevant content and contextual information. Additionally, methodological guidance for conducting a contextual analysis is lacking. And, reflecting

a post-positivist understanding, researchers often consider individual aspects of context rather than its complex and dynamic interactions.

Therefore, this dissertation's overall aim was to strengthen the theoretical and methodological foundations for contextual analysis in implementation science. It is structured in seven chapters, of which chapters 1 and 2 provide introductory information:

Chapter 1 provides a general introduction on the concept of context and contextual analysis as presented by implementation science methodology. It includes current approaches for contextual analysis and their limitations. It also describes *The Context and Implementation of Complex Interventions* (CICI) framework, which is the basis of this dissertation's conceptualization of context. After briefly introducing key elements of implementation science it outlines this dissertation's guiding rationale and the research gap it attempts to bridge.

Chapter 2 describes this dissertation's aims.

Chapter 3 reports on a cross-sectional online survey of 56 international implementation science experts. Given a list of journals that publish implementation science-relevant content, and that can be included in IS-relevant search strategies, respondents were asked to specify which of the listed journals they considered relevant to their work. While considerable variability was found regarding most of these journals' relevance, 97.1% of the respondents rated two—*Implementation Science* and *BMC Health Services Research*—as relevant. They also proposed additional journals that they considered relevant to specific clinical fields and health science disciplines. Via PubMed and Google searches, we also identified 53 implementation science-focused special issues.

Chapter 4 describes contextual analysis as a dedicated phase within an implementation science project—one that serves as the foundation, and that informs all subsequent phases. It also presents the Basel Approach for coNtextual ANAlysis (BANANA), a comprehensive, stepwise approach to guide contextual analysis in implementation science projects. Building on previous work by Stange and Glasgow on patient-centered medical home research, BANANA grew out of brainstorming sessions with implementation science experts and a medical anthropologist. It involves six steps: 1) choice of a theory, model or framework; 2) use of empirical evidence; 3) stakeholder involvement; 4) study design for contextual analysis; 5) determination of relevant contextual factors for implementation strategies/outcomes and intervention co-design; and 6) reporting of the contextual analysis.

The first three steps partly run simultaneously, and form the informational basis for the next steps. Each step is described in detail, and a case example demonstrates a successful application of BANANA in an ongoing implementation science research project, the SteM cell transplantatIon faciLitated by eHealth (SMILe) project.

Chapter 5 describes our development of an evidence gap map (EGM) that summarizes and graphically depicts the methodological approaches to contextual analysis applied in the mapped implementation intervention studies, as well as highlighting notable gaps in those approaches. As part of this work, a novel approach to literature searches and a framework for summarizing and evaluating methodological approaches for contextual analysis is provided. Our search for publications from the previous six years (2015–2020) yielded 15,286 publications. Utilizing a step-wise approach, we first selected, then screened a random sample of 3017 records–20% of the studies from each year of our search. The screening process left 110 implementation intervention studies for our analysis.

Assembling the EGM, we found that only 24 of the 110 included studies (22%) reported on context. Among those reporting on contextual analyses showed we noted high variability both in methods used and in contextual factors assessed. Only one study explicitly reported the use of a theoretical framework for contextual analysis. And while several reported stakeholder involvement, their actual participation was quite limited. Also, those that included contextual analyses gave only sparse descriptions how they used the results. By depicting the publications' data graphically, the EGM literally shows their gaps and heterogeneity. To counter these shortcomings, there is clearly a need to promote standardized approaches to contextual analysis as foundational for the success and quality of implementation science projects.

Chapter 6 reflects on limitations of current approaches to contextual analysis—particularly those driven by a post-positivist understanding of context—and describes how the addition of a constructivist perspective would complement these approaches. Five constructivist concepts are introduced that can contribute to a more comprehensive and multilayered understanding of context and can reveal complex dynamics not visible via the post-positivist perspective, i.e., interactions involving individuals and/or contextual factors: 1) social space; 2) social place; 3) agency; 4) sensation; and 5) embodiment. After illustrating how these concepts can be integrated into existing conceptualizations of context, this chapter uses COVID-19 vaccine hesitancy as a case example to demonstrate the value the constructivist perspective adds to contextual analysis. Further, methodological and practical considerations, e.g., regarding data collection and analysis, are discussed.

Chapter 7 first discusses and synthesizes the dissertation's major findings in light of current evidence, then outlines implications for research and practice. Strengths and limitations regarding the methods and the applied framework are indicated. Further considerations regarding methodological approaches and designs that help address the complexity of context and to accelerate contextual analysis are described. Finally, a push-pull-capacity model is used to indicate local-, regional- and national-level factors

that support capacity-building both for contextual analysis and for implementation science in ways that improve the translational pipeline's performance.

This dissertation`s contribution is threefold. First, it presents a case for applying contextual analysis as a separate, foundational implementation science project phase, the results of which inform all subsequent phases. While conducting a contextual analysis requires additional time and financial investments, the results will enhance the quality and speed of intervention translation into real-world settings, thereby enhancing its societal impact. Second, we describe a methodology to guide researchers to conduct a contextual analysis (BANANA). We illustrated its application to an ongoing implementation project (the SMILe project). Third, we suggest ways that contextual analysis can be enhanced–particularly to overcome the shortcomings of the current positivist perspective. Overall, this dissertation both provides a foundation to support enhanced uses of contextual analysis and strengthens implementation science methodology. Ultimately, we are confident that these developments will improve the overall quality and success of implementation science projects.

Zusammenfassung

Da die Implementierung von Interventionen–dies können Verfahren, Programme, Produkte, Strategien, Medikamente, Praktiken oder Leitlinien sein–unter realen Bedingungen stattfindet, hängt ihr Erfolg und ihre Nachhaltigkeit stark von dem jeweiligen Kontext ab in dem sie angewendet werden. Kontext wird als eine „Reihe von Merkmalen und Gegebenheiten [definiert], die aus aktiven und einzigartigen Faktoren bestehen, in die die Implementierung eingebettet ist“. Kontext ist mehrschichtig, mehrdimensional und dynamisch. Er steht in Wechselwirkung mit der Intervention und ihrer Implementierung. Diese Interaktion findet im Setting statt, das ist der „physischen Ort, an dem die Intervention implementiert wird.

Obwohl der Kontext in der Implementierungswissenschaft–das ist die „wissenschaftliche Untersuchung von Methoden, die eine systematische Umsetzung von Forschungsergebnissen und anderen evidenzbasierten Praktiken in die tägliche Praxis fördert und somit zur Verbesserung der Qualität und Wirksamkeit von Gesundheitsdiensten und -versorgung beiträgt“– zunehmend an Bedeutung gewonnen hat, wird Kontext nach wie vor zu wenig untersucht. In vielen Studien wird der Kontext nicht berücksichtigt oder kontextbezogene Informationen nicht berichtet. Dies trägt zur Entstehung von vermeidbaren, sogenannten „Forschungsabfällen“ bei, die Leckagen in der Forschungspipeline darstellen und zu erheblichen Verlusten von Ressourcen führen. Tatsächlich werden nur 14% der Evidenz jemals in der Praxis implementiert. Die Nachhaltigkeit der Implementierung ist oft nur begrenzt, während die Zeitspanne zwischen der Publikation hochrangiger Evidenz und ihrer Implementierung auf durchschnittlich 17 Jahre geschätzt wird.

Die Bewältigung dieser Herausforderungen, d.h. die Reduktion von Forschungsabfällen, die Überbrückung der Kluft zwischen Forschung und Praxis, sowie die Beschleunigung der Translation, erfordert ein Neudenken der derzeitigen implementierungswissenschaftlichen Ansätze. Dazu zählt insbesondere die Anerkennung des Kontexts als entscheidender Faktor für erfolgreiche Implementierungsprojekte, sowie seine Relevanz, alle nachfolgenden Phasen eines Implementierungsprojektes zu informieren, d.h. die Entwicklung/Adaptierung von Interventionen, die Auswahl/Adaptierung von Implementierungs- und Nachhaltigkeitsstrategien, als auch die Interpretation von Implementierungs- und Wirksamkeitsergebnissen. Eine erfolgreiche Implementierung von Interventionen in der Praxis beruht immer auf einem Zusammenspiel vom Kontext, einer an den Kontext adaptierten Intervention, sowie kontextuell angepassten Implementierungsstrategien (d.h. Methoden die eine Übernahme, Implementierung und Nachhaltigkeit von Interventionen in der Praxis unterstützen). Die Durchführung einer gründlichen Kontextanalyse, die das mehrschichtige System, in welchem eine Intervention

angewendet wird berücksichtigt, ist daher ausschlaggebend für den Erfolg und die Nachhaltigkeit der Implementierung.

Die Kontextanalyse stellt jedoch eine Schwachstelle in der implementierungswissenschaftlichen Methodologie dar. Das Konzept des Kontextes ist nicht einheitlich theoretisch definiert und operationalisiert; Begrifflichkeiten, die Kontext beschreiben, variieren je nach Studie oder Framework. Diese konzeptionellen Unstimmigkeiten erschweren das Auffinden und den Zugang zu relevanten implementierungswissenschaftlichen Inhalten und kontextbezogenen Informationen. Für die Durchführung einer Kontextanalyse fehlt es an methodischen Orientierungshilfen. Darüber hinaus werden, geprägt durch ein vorrangig post-positivistisches Verständnis des Kontexts, häufig nur einzelne Aspekte des Kontexts untersucht, anstatt komplexe und dynamische Interaktionen im Kontext zu berücksichtigen.

Das übergeordnete Ziel dieser Dissertation war es daher, die theoretischen und methodologischen Grundlagen für die Kontextanalyse in der Implementierungswissenschaft zu stärken.

Die Dissertation gliedert sich in sieben Kapitel, wobei die Kapitel 1 und 2 zunächst einleitende Informationen geben:

Kapitel 1 bietet eine allgemeine Einführung zum Konzept des Kontexts und der Kontextanalyse als Teil der implementierungswissenschaftlichen Methodologie, einschliesslich aktueller Ansätze für die Kontextanalyse sowie deren Limitationen. Ferner wird das Context and Implementation of Complex Interventions (CICI) Framework beschrieben, auf welchem die Konzeptualisierung von Kontext in dieser Dissertation basiert. Zusätzlich werden die wichtigsten Elemente der Implementierungswissenschaft kurz vorgestellt, sowie die Forschungslücke und die Begründung für diese Dissertation dargestellt. Im Anschluss daran werden in **Kapitel 2** die Ziele der vorliegenden Dissertation dargestellt.

In Kapitel 3 wird eine Online-Querschnittsbefragung von 56 internationalen Expert*innen aus der Implementierungswissenschaft beschrieben. Die Ergebnisse der Studie veranschaulichen die von den Expert*innen eingeschätzte Relevanz von Zeitschriften, die implementierungswissenschaftlich relevante Inhalte publizieren. Diese Zeitschriften können in Suchstrategien einbezogen werden, um die implementierungswissenschaftliche Evidenz identifizieren zu können. Die Relevanz der Zeitschriften wurde sehr unterschiedlich bewertet. Insgesamt 97,1% der Expert*innen erachteten die Zeitschriften *Implementation Science* und *BMC Health Services Research* als relevant. Darüber hinaus wurden weitere relevante Zeitschriften aus verschiedenen klinischen Bereichen und gesundheitswissenschaftlichen Disziplinen vorgeschlagen. Zudem wurden in PubMed und Google-Suchen 53 Sonderhefte identifiziert, deren Inhalt sich auf die Implementierungswissenschaft fokussiert.

In **Kapitel 4** wird die Kontextanalyse als separate Phase innerhalb eines implementierungswissenschaftlichen Projektes definiert, die als Grundlage für alle nachfolgenden Phasen dienen kann. Ferner wird der Basler Ansatz für die KoNtextANAlyse (BANANA) vorgestellt, ein schrittweiser Ansatz, der die Kontextanalyse in implementierungswissenschaftlichen Projekten anleitet. BANANA wurde in Anlehnung an die Forschung von Stange und Glasgow (2013) auf dem Gebiet des patientenzentrierten medizinischen Zuhauses (Patient Centered Medical Home) in gemeinsamen Brainstorming-Runden mit Expert*innen der Implementierungswissenschaft und einer Anthropologin entwickelt. BANANA umfasst sechs Schritte: 1) Auswahl einer Theorie, eines Modells oder eines Frameworks; 2) Verwendung empirischer Evidenz; 3) Einbeziehung von Stakeholdern; 4) Studiendesign für die Kontextanalyse; 5) Beurteilung der Relevanz von Kontextfaktoren für die Co-Kreation von Interventionen, die Implementierungsstrategien und Ergebnisse; 6) Berichten der Kontextanalyse. Die ersten drei Schritte erfolgen zum Teil simultan und bilden die Grundlage für die nächsten Schritte von BANANA. In diesem Kapitel wird jeder Schritt detailliert beschrieben und die erfolgreiche Anwendung von BANANA wird in einem derzeit laufenden implementierungswissenschaftlichen Projekt, dem SMILe Projekt (SteM cell transplantatIon faciLitated by eHealth) demonstriert.

In **Kapitel 5** wird ein Evidence Gap Map (EGM) beschrieben, welches die bestehenden methodischen Ansätze für die Kontextanalyse in Implementierungsinterventionsstudien zusammenfasst und Defizite in den aktuellen Ansätzen aufzeigt. Im Rahmen dieser Arbeit wird ein neuartiger Ansatz für die Literatursuche und ein Framework für die Zusammenfassung und Bewertung methodischer Ansätze für die Kontextanalyse vorgestellt. Mithilfe eines schrittweisen Ansatzes wurde aus den ursprünglich 15`286 identifizierten Studien eine Zufallsstichprobe von 3017 Studien–20% pro Jahr (2015-2020)–ausgewählt und gescreent. Insgesamt wurden 110 Implementierungsinterventionsstudien in die Analyse eingeschlossen. Aus den Ergebnissen des EGM geht hervor, dass nur 24 der 110 eingeschlossenen Studien (22%) über den Kontext berichteten. Diejenigen, die eine Kontextanalyse durchführten, wiesen Unterschiede in den verwendeten Methoden und den untersuchten Kontextfaktoren auf. Nur eine Studie berichtete ausdrücklich über die Verwendung einer theoretischen Grundlage für die Kontextanalyse. Der Einbezug verschiedener Stakeholder innerhalb der Studien war unzureichend und die Beschreibung, wie kontextbezogene Informationen verwendet wurden spärlich. Die Ergebnisse dieses EGM machen deutlich, dass die derzeitigen Ansätze für die Kontextanalyse als Grundlage für den Erfolg und die Qualität von implementierungswissenschaftlichen Projekten weiterentwickelt werden müssen.

Kapitel 6 befasst sich mit den Grenzen aktueller Ansätze zur Kontextanalyse, die auf einem post-positivistischen Verständnis von Kontext beruhen und beschreibt, wie diese Ansätze durch eine konstruktivistische Perspektive unterstützt werden können. Es werden fünf konstruktivistische Konzepte vorgestellt, die zu einem umfassenderen und vielschichtigen Verständnis von Kontext beitragen, indem sie komplexe Dynamiken zwischen Individuen und Kontext aufzeigen. Diese Konzepte sind 1) sozialer Raum; 2) Ort; 3) Agency; 4) Selbstwahrnehmung; und 5) Embodiment. Das Kapitel veranschaulicht, wie diese Konzepte in bestehende Konzeptualisierungen von Kontext integriert werden können und zeigt am Fallbeispiel der zögerlichen Bereitschaft für eine COVID-19-Impfung, den Mehrwert der konstruktivistischen Perspektive für die Kontextanalyse. Darüber hinaus werden methodische und praktische Überlegungen, z.B. im Hinblick auf die Datenerhebung und -analyse, diskutiert.

In **Kapitel 7** werden die wichtigsten Ergebnisse der Dissertation im Kontext aktueller Erkenntnisse diskutiert und zusammengefasst und Implikationen für Forschung und Praxis aufgezeigt. Es wird auf Stärken und Grenzen der Methoden und des angewandten Frameworks hingewiesen. Des Weiteren werden Überlegungen in Bezug auf methodische Ansätze und Designs, die der Komplexität des Kontext Rechnung tragen können oder die Kontextanalyse beschleunigen können, angeführt. Abschliessend werden anhand eines Push-Pull-Kapazitätsmodells Faktoren auf lokaler, staatlicher und nationaler Ebene aufgezeigt, die den Aufbau von Kapazitäten für die Kontextanalyse und die Umsetzungswissenschaft unterstützen, um so die Leistungsfähigkeit der Translationspipeline zu erhöhen.

Die vorliegende Dissertation leistet hierzu einen Beitrag in dreifacher Hinsicht. Erstens wird die Kontextanalyse als eine separate Phase betrachtet, die für alle nachfolgenden Phasen eines implementierungswissenschaftlichen Projektes grundlegend ist. Die Durchführung einer Kontextanalyse erfordert zwar zusätzlichen Zeitaufwand und finanzielle Ressourcen, trägt aber zu einer besseren und schnelleren Umsetzung von Interventionen in der Praxis bei und erhöht somit deren gesellschaftliche Nutzen. Zweitens haben wir eine Methodik entwickelt, die eine Hilfestellung für die Durchführung einer Kontextanalyse (BANANA) bietet und deren Anwendung in einem laufenden Implementierungsprojekt (SMILe-Projekt) veranschaulicht. Drittens zeigen wir auf, wie die Kontextanalyse in Zukunft weiterentwickelt werden kann, um Unzulänglichkeiten zu überwinden, die sich aus der derzeitigen positivistischen Perspektive ergeben können. Insgesamt schafft die Dissertation nicht nur eine Grundlage zur Verbesserung der Kontextanalyse, sondern trägt auch zur Stärkung der implementierungswissenschaftlichen Methodologie und auch zur Qualität und dem Erfolg von implementierungswissenschaftlichen Projekten bei.

Chapter 1.

Introduction

1.1 The relevance of context for implementation endeavors

As implementation of evidence-based interventions—these can be procedures, programs, products, policies, pills, practices or principles (the 7 P`s)—takes place in real-world settings, its success and sustainability depend heavily on the context where it is delivered (1-3). Context is defined as “a set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded” (4). It is multi-level, multi-dimensional and dynamic, interacting with an intervention and its implementation in the “physical location, in which the intervention is put into practice”, i.e., its setting (4). Thus, context is a key determinant that eradicates to all parts of an implementation science project (i.e., intervention development, selecting implementation strategies, evaluation of implementation success) (5-12).

Implementation science refers to “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence to improve the quality and effectiveness of health services and care”. Although contextual analyses have gained significant attention in implementation science over the past two decades, context remains understudied in implementation science: many studies fail either to consider or to report contextual information (1-3, 13-15). Factors that contribute to this under-recognition include conceptual ambiguities, the lack of methodological approaches and shortages of the necessary resources. As these factors impair the success of implementation efforts, they contribute to research waste (16-18).

1.2 Preventing research waste

Research waste is generally divided into two types. “Research waste 1” amounts to over 85% of flawed or otherwise unusable research: it is not based on systematic reviews of existing evidence, it is never published, shows serious bias or is badly reported (16, 19, 20). “Research waste 2” refers to published evidence, that is well conducted but remains on book shelves and is either never implemented or proves unsustainable in real-world settings (21). While both types are largely avoidable, they represent leaks in the research pipeline that lead to major resource losses (20, 21). Indeed, as few as 14 % of evidence is ever implemented into real-world settings with sustainability often limited. The time lag between the publication of high-level evidence and implementation has been estimated to be on average 17 years (22-24). In addition, as real-world conditions are typically more chaotic and less resourced than those in highly controlled studies, they both challenge implementation success and reduce the intervention effect along the translational pipeline (25). As a result, many effective treatments or interventions are never adopted for patient care, while about 10 % harmful interventions persist in clinical practice as not being de-implemented (19, 26). These failures in translation have been referred to as research to practice gap that contributes to the development of research waste and lengthens the translational pipeline (Figure 1.1) (21).

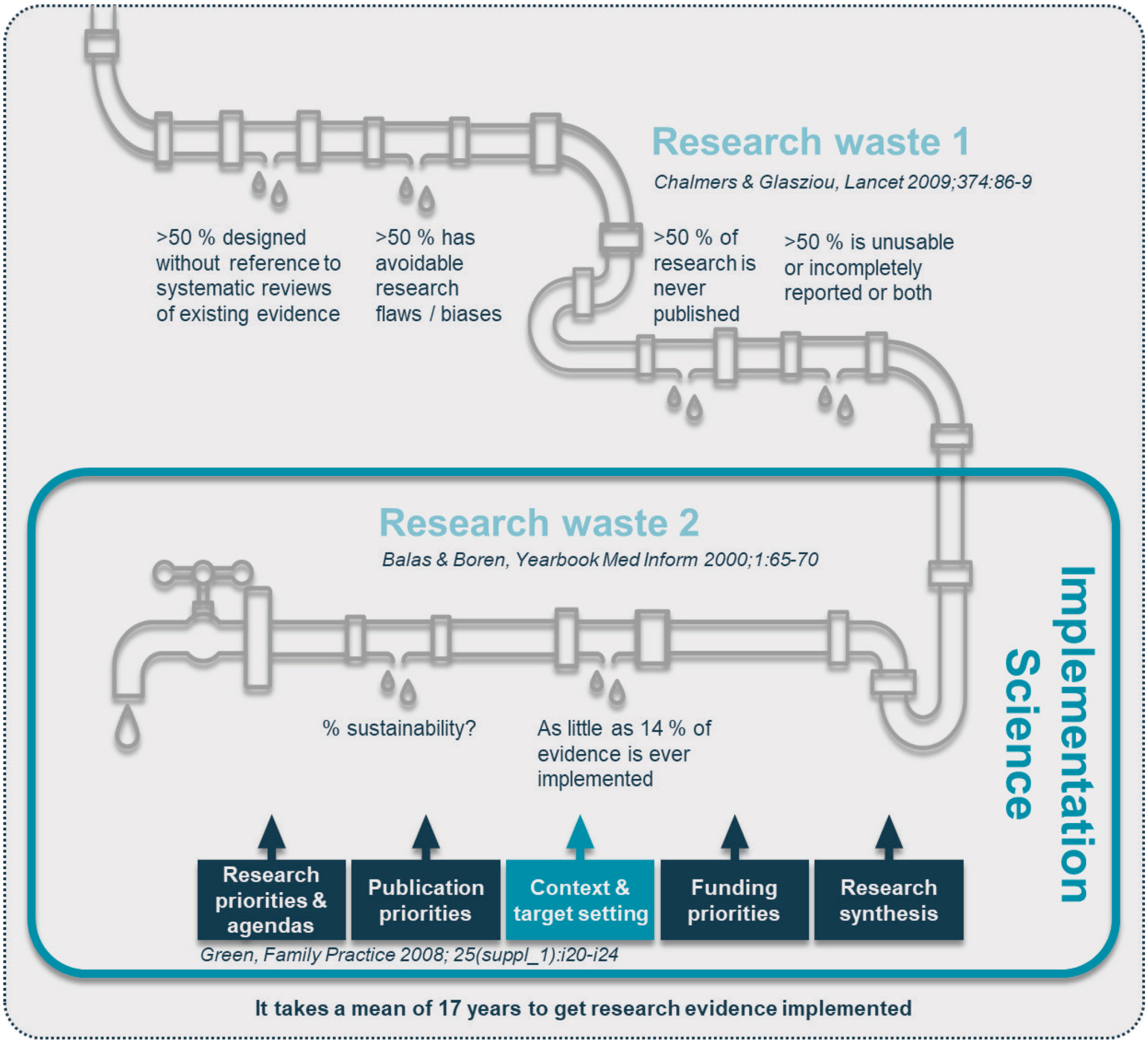

Figure 1.1. The "leaky" research pipeline – Indicating the potential of implementation science to overcome research waste 2. Adapted from De Geest et al. (21) with permission of the first author Sabina De Geest.
(Pipeline graphics adapted from Shakeel Ch., Vectorstall, Vectors Point, Bartama Graphic and designvector from the Noun Project)

Attempts to reduce research waste 1 have already been made. They include initiatives to improve peer-review, to develop reporting guidelines, to improve trial registration, and even to establish funder forums focused on increasing research value by reducing research waste (16). Research waste 2 is driven by numerous factors, including research priorities and agendas, publication and funding priorities, research synthesis as well as the context into which evidence will be transferred (21).

In order overcome these challenges, i.e., to bridge the gap between trial and real world, to reduce research waste and to speed translation of evidence into practice, implementation science has gained momentum in the past decades in healthcare research and beyond (8, 21, 27, 28, 29). In order to enhance the fit of interventions to the context and choosing appropriate implementation strategies, conducting a thorough contextual analysis has become increasingly important as part of the implementation science methodology critical for implementation success, sustainability and scale-up of interventions in healthcare (8-12).

The following two case examples illustrate the relevance of context in implementation science projects. While the first case example focusses on the development of an intervention (i.e., health information communication technologies), the second deals with the translation of an already developed and initially tested intervention (i.e., novel lipid treatment) in practice.

Case example 1 – Development of information and communication technology for the ageing population in Europe

A lot of financial resources are spent for health care research, however, the societal return of investment of such research funds is often suboptimal due to research waste. Van Grootven and van Achterberg, 2019 examined the impact of The Ambient Assisted Living Joint Programme, for which 600 million euros were allocated by the European Union (30). The program aimed to foster “the emergence of innovative ICT-based products [ICT: information and communications technology], services and systems for ageing well at home, in the community, and at work”. Of the 152 projects, only 2 succeeded in developing a marketable product, many of the other products did not get beyond testing and piloting. Thus, the impact of this program remains limited in regard to its aim. In conclusion, the study's authors emphasize the need for a stronger focus on understanding the implementation context and adapting the interventions to the individual needs of the users and the respective context (30).

Case example 2 – Implementation of a treatment for dyslipidaemia in primary health care in England

Inclisiran is a novel treatment for dyslipidaemia that represents a potential game-changer in the prevention of cardiovascular disease (31, 32). It differs from other currently available treatments in that inclisiran is not taken daily but is administered by injection at 0, 3 and 6 months and biannually thereafter (33, 34). Thus, it is expected to improve drug adherence and prevent cardiovascular events (32, 33). Inclisiran has been approved by the National Institute for Health and Care Excellence (NICE) in England, which recommends that inclisiran may be administered in primary care settings rather than secondary care (32). Yet, the British Medical Association and the Royal College of General Practitioners warn over the rollout in primary care (33, 35). In addition to a lack of long-term data on efficacy and safety, they are most concerned about the additional resources and capacity needed to cope with high demand and staff shortages (33). For this reason, Novartis and Health Innovation Manchester launched the VICTORION-SPIRIT to examine the facilitators and barriers to the implementation of inclisiran in primary care while evaluating its efficacy and safety (36). While this study will contribute to the successful implementation of inclisiran, late consideration of the implementation context delays its implementation in primary care

Overall, both case examples, demonstrate the necessity of considering context, in order to fit interventions accurately to their contexts (Case example 1), to support implementation in practice (Case example 2) and by that potentially shortening the translational pipeline (8-12).

Successful translation of interventions in practice is a function of context, intervention and implementation. Implementation science provides methods supporting to bridge the research to practice gap. Contextual analysis presents a key tenet of implementation science supporting a successful and sustainable implementation in practice and thus reducing research waste.

In the following paragraphs an introduction to implementation science, the concept of context and contextual analysis will be provided.

1.3 Implementation science

In health care, implementation science has been shaped by diverse research fields and disciplines. With input from sources including public health, education, social work, environmental science, political science, psychology, among others, it has developed rapidly over the last two decades (37-39).

1.3.1 Defining implementation science - A tower of Babel?

While no standard definition of implementation science yet exists, many researchers favor that of Eccles et al.: “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence to improve the quality and effectiveness of health services and care” (37). In addition, the terms used to signify what we call “implementation science” vary across disciplines and geography (e.g., “dissemination and implementation science”, “knowledge translation”, “research utilization”, “diffusion research”, “improvement science”). The result is a “Tower of Babel“ (40): multiple redundant terms signify some concepts; in other cases, a signal term can signify diverse concepts or issues (40-44). To further complicate the matter, overlapping methodologies from other research areas (Figure 1.2) add their own language and labeling (44, 45).

Analyzing this situation, Mitchell and Chambers found two major overarching concepts: dissemination and implementation research (44). While implementation research focusses on processes and factors that influence interventions` integration into specific target settings, dissemination research focuses how each intervention can be spread to its target population (46). Within dissemination research, health communication studies focus on “effective ways of making evidence available, understandable, and actionable for both patients and providers” (44).

Also, “quality improvement science” and “quality improvement” both function as subcategories of implementation research. While they originate in separate paradigms, both share the implementation research goal of improving patient care and outcomes (47-49). However, while implementation science starts with evidence-based interventions to be implemented into practice and tries to do so in a generalizable way, quality improvement science focusses on solving problems within local clinical practices (i.e., specific problems in specific settings) (47, 49). Quality improvement science is distinguishable from quality improvement in that the former employs more scientific and rigorous methods (e.g., experimental or quasi-experimental studies, theoretical models) (47).

Within the various methodologies, combined with the multitude of terms in use, inconsistencies in operationalization limit any capacity to assess the overall state of

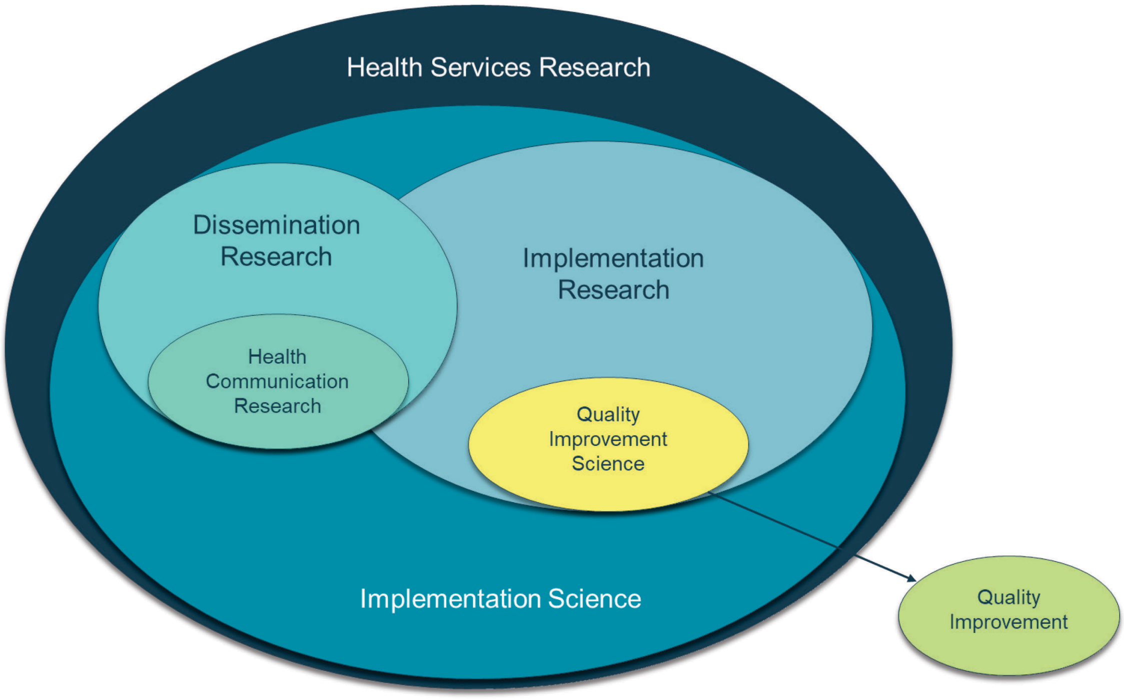

Figure 1.2. Research areas within implementation science
(From Mitchell SA, Chambers DA: Leveraging Implementation Science to Improve Cancer Care Delivery and Patient Outcomes. J Oncol Pract 2017, 13(8):523-529. Printed with permission from the publisher. The Creative Commons license does not apply to this content. Use of the material in any format is prohibited without written permission from the publisher, Wolters Kluwer Health, Inc. Please contact permissions@lww.com for further information.)

implementation science and related gaps. As an essential first research step, identifying and synthesizing evidence helps a research team ensure the relevance of the available evidence. This both, eases the translation of their findings into practice and forms a basis for further development. However, literature searches in implementation science often produce a huge number of hits, many of which are irrelevant. Sensitivity- and specificity-related problems have been described elsewhere by Lokker et al. and McKibbon et al. (50, 51).

Thus far, search strings for clear, well-defined concepts, such as randomized clinical trials (RCTs) show very high sensitivity and specificity (> 99% each); in comparison, search strings specifically developed for implementation science are both less sensitive (85%–90%) and less specific (65%–75%) (50-53). Additionally, in 2019, to aid identification of implementation science articles, the MeSH term “implementation science” was introduced for PubMed searches; however conceptual inconsistencies and challenges to access mean implementation science studies published before 2019 still require innovative methods for literature searches.

Chapter 3 describes how to identify journals that publish implementation science-relevant content. These can be included in search strings to support searches of implementation science evidence. This information reflects the results of an online survey of 56 international implementation science experts regarding their strategies to identify and prioritize journals that publish implementation science articles. We also assessed which journals have published special issues about implementation science over the last 20 years.

(Article title: "Relevant Journals for Identifying Implementation Science Articles: Results of an International Science Expert Survey)

1.3.2 Key elements of implementation science

Implementation science adds specific methodological considerations to clinical research methods, as it explicitly focusses on external validity and combines a variety of methods and strategies that allow to successful cross from the trial to the real-world settings. Therefore, recent decades have seen the emergence of implementation science aspects that are highly relevant to existing clinical research methods and principles. Starting from the strength of the intervention evidence, implementation science now covers seven distinct aspects. These are presented below in the Basel Heptagon of Implementation Science (Figure 1.3).

1.3.2.1 Implementation science theories, models and frameworks

Using theories, models and frameworks (TMFs) as a theoretical basis is essential to guide different phases of an implementation science project (54, 55). Numerous TMFs have been developed to advance the theoretical basis of implementation science (54, 55). These can be broadly categorized into five groups: process models, determinant frameworks, classic theories, implementation theories and evaluation frameworks. According to Nilsen (2015), process models can be used to guide or describe the implementation of innovations in real-world practice (e.g., *EPIS* – Exploration, Preparation, Implementation, Sustainment (56)). In addition to determinant frameworks (e.g., Consolidated Framework for Implementation Research (*CFIR*) (57)), classical (e.g., *Theory of Diffusion* (58)) and implementation theories (*Normalization Process Theory* (59)) help to understand or explain influences on implementation outcomes. Likewise, evaluation frameworks can guide the evaluation of implementation success (e.g., *RE-AIM framework* – Reach, Effectiveness, Adoption, Implementation, Maintenance (60)) (61).

Figure 1.3. The Basel Heptagon of Implementation Science indicating the key components of implementation science from De Geest et al. (21)

1.3.2.2 Contextual analysis

As implementation is a social process that transpires in real-world settings, it includes a dynamic interplay between the intervention, the implementation strategies and the target context (4, 18, 57, 62). This interaction does not stop with adoption, but continues for as long as the intervention remains in place (4, 63). In fact, accurate contextual adaptation of the intervention and implementation strategies contribute tremendously to the success and sustainability not only of the implementation, but also of its scalability. Therefore, building a thorough understanding of the target context is a central pillar of implementation science methodology (8, 64-66).

1.3.2.3 Patient and public involvement

Patient and public involvement (PPI, also known as stakeholder involvement) belongs to a new research paradigm that values stakeholder input at each step of the research cycle, i.e., identifying and prioritizing research objectives, commissioning research, designing and managing research, undertaking research, disseminating findings and evaluating impacts, including those of stakeholder involvement (67, 68). Within implementation science projects, stakeholders can be any individuals or organizations a) that are targeted or affected by the intervention (e.g., patients and their families) or b) that either implement the intervention in practice (e.g., health care professionals) or decide on its implementation (policy makers, funders) (4). Stakeholders can specifically contribute to contextual analysis, intervention development, choice of implementation strategies, interpretation of results and dissemination of findings. Their involvement is instrumental to implementation success: it improves implementation outcomes including acceptance, adoption and feasibility, and facilitates dissemination and sustainment (69).

Still, while stakeholder involvement can add tremendous value to a research project, maximizing that value requires skills and preparation. For each research project that involves stakeholders, a specific stakeholder strategy must be developed. This specifies which stakeholders will be involved at each stage, their tasks, and the methods to be applied to coordinate their involvement. However, as there is currently a lack of guidance on PPI specifically within implementation science projects, existing PPI frameworks (e.g., INVOLVE (68), PARADIGM (70)) can be applied.

1.3.2.4 Implementation strategies

Implementation strategies are methods or techniques used in conjunction with an intervention to improve its adoption, implementation, and sustainability in practice (71). Terms and definitions regarding implementation strategies vary widely through the implementation science literature, as evinced by the existence of concurrent schemes to classify them (72-74). Commonly used taxonomies include the *Expert Recommendations for Implementing Change* (ERIC) (75) and *Effective Practice and Organization of Care* (EPOC) (76).

Building on the CFIR framework, the ERIC taxonomy defines a set of 73 implementation strategies that can be grouped into 9 categories (75): use evaluative and iterative strategies, provide interactive assistance, adapt and tailor to the context, develop stakeholder relationships, train and educate stakeholders, support clinicians, engage consumers, utilize financial strategies, change infrastructure (75, 77, 78). The EPOC taxonomy was developed by the Cochrane EPOC Group to help reviewers classify health systems interventions. It includes 22 implementation strategies targeted at healthcare organizations, healthcare workers and specific types of practice, conditions or settings (76, 79). However, implementation strategies' effectiveness depends on evidence, theoretical underpinning, contextual appropriateness and stakeholder s' input (80, 81). Thus, it is essential to have a thorough understanding not only of the context in which an intervention is to be implemented, but also of the underlying mechanisms and processes (i.e., theory) through which the strategies can exert their effects (81-83).

1.3.2.5 Implementation outcomes

One characteristic unique to implementation studies is that, in addition to service (e.g., patient-centeredness), effectiveness and health outcomes (e.g., satisfaction, function, health status), they measure and report implementation outcomes (84). As “the effects of deliberate and purposive actions to implement new treatments, practices, and services” (84) implementation outcomes can serve as indicators for the likelihood of intervention success, or proximal indicators for the four phases of implementation processes—exploration, adoption, implementation and sustainability (56)—and as indicators for success either of implementation or of implementation strategies (7, 84).

Proctor et al. developed a taxonomy of eight implementation outcomes: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability. Furthermore, over 150 measures now assess those outcomes; however, these often lack conceptually bases or convincing evidence of their psychometric properties (85).

1.3.2.6 Hybrid designs and other types of implementation science designs

Several experimental (e.g., sequential, multiple-assignment randomized trials (SMART)) and quasi-experimental designs (e.g., stepped-wedge design, interrupted-time series) exist, that can be applied in implementation science research (7, 86-88). Further, specific research designs have emerged combining a dual focus on effectiveness and implementation outcomes of interventions (i.e., hybrid designs). One of such designs' advantages is that, by effectively fitting two studies into one, they accelerate the implementation process considerably (89). Curran et al. distinguish between three types of hybrid designs (89).

Hybrid 1 designs focus primarily on testing clinical interventions' effectiveness, and secondarily on exploring implementation-related factors (e.g., facilitators and barriers). In practice, though, we observed hybrid 1 designs manifesting as two distinct types—1 and 1+. Although both 1 and 1+ focus on generating evidence on an intervention's effectiveness—the “usual” one (type 1) retrospectively assesses contextual influences, e.g., as part of a process evaluation. (Process evaluations are conducted alongside intervention trials. Depending on the stage of research, they gauge the implementation's fidelity and quality, contextual factors influencing implementation and other outcomes—information that will inform the intervention's further development (90).) In contrast, the hybrid type 1+ already includes a thorough prospective contextual analysis, based on which the intervention (and possibly even implementation strategies) will be developed in collaboration with the relevant stakeholders (co-creation). This approach may allow more effective implementation.

Hybrid 2 designs focus on two tasks concurrently: while testing their intervention's effectiveness, they assess one or more implementation strategies. I.e., hybrid 2 designs test for initial evidence regarding the intervention's effectiveness and evaluate implementation determinants. They also allow investigation of implementation strategies' overall feasibility in the given context.

Hybrid 3 designs focus primarily on testing implementation strategies that are randomized on one specific level (e.g., provider, clinic or system); their secondary focus is on intervention effectiveness. This design is usually applied when sufficient evidence is available regarding an intervention’s effectiveness and the research team wishes to test how intervention effectiveness varies depending on implementation strategies.

The choice of which hybrid type (1, 2 or 3) is most appropriate is driven by the research objective and the strength of the evidence (89). Reflecting an updated vision of the research pipeline, hybrid designs are no longer positioned between clinical effectiveness and implementation research, but now start within efficacy research (hybrid 1) (39, 91).

1.3.2.7 Transdisciplinary research

The early involvement (e.g., in efficacy research) of implementation scientists in the planning of projects developing an intervention is key (92). The combination of clinical effectiveness research and implementation research raises research questions that require quantitative, qualitative and/or mixed methodologies from multiple research fields. Covering such wide-ranging methodological requirements without sacrificing analytical rigor demands a multidisciplinary research team with diverse competencies (e.g., clinical and health services researchers, health economists, social scientists, biostatisticians, implementation scientists, behavioral scientists, epidemiologists) (49, 93).

1.3.3 Positioning implementation science along the research pipeline

The healthcare research process has often been conceptualized as a linear process (“the research pipeline”), with implementation science at its end (89, 94). Prior to considering the implementation of an intervention into practice, its efficacy and effectiveness must first be tested via trials. Efficacy studies focus strongly on internal validity; under strictly controlled laboratory conditions, they test whether an intervention works (49, 89). Effectiveness (or “pragmatic”) trials, are conducted in real-world settings, but under controlled conditions. This allows the researchers to gauge the circumstances under which an intervention is effective for specific individuals of interest (49, 89).

However, in cases where effectiveness trials return negative results, those results say nothing of whether the tested intervention's effectiveness is limited by implementation-related challenges. Implementation science's capacity to show such differences has made it an important component of the research pipeline. In contrast to efficacy studies, implementation science studies are conducted in real world settings; and unlike pragmatic trials, they do not aim simply to measure an intervention's effectiveness. Instead, they also examine how interventions work in real-world settings in terms of implementation outcomes (e.g., acceptability, adoption, feasibility, sustainability) (7, 84, 95).

Meanwhile, the “pipeline mindset” has been criticized as promoting a reductionist and mechanistic understanding—one that overlooks the complexity of real-world implementation settings and increases the research-to practice gap (via research waste 2) (96). Regardless of how we visualize the implementation pathway, though, one excellent way to bridge that gap is by preparing for it as early as possible: in parallel with efficacy and effectiveness research, then, consideration of implementation aspects should start at the beginning of the research pipeline (21, 89, 96) (Figure 1.4).

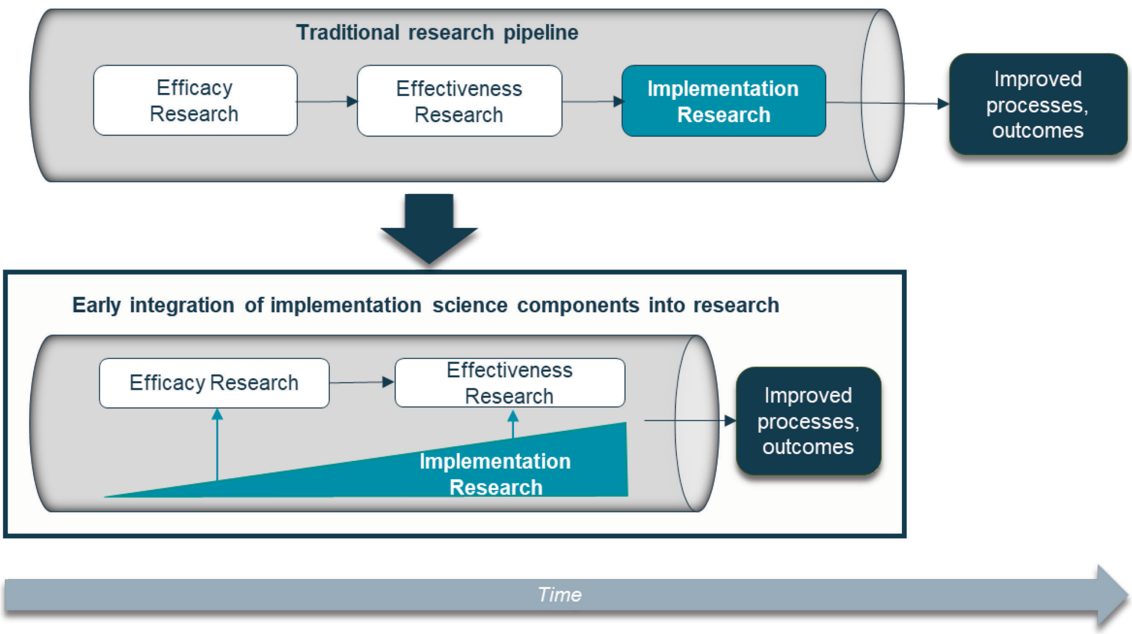

Figure 1.4. Improving implementation success and speeding up translation by considering implementation relevant components early on in research (i.e., stakeholder involvement, contextual analysis, intervention and implementation strategies).

> *Implementation science combines a variety of methods and strategies that allow successfully translate interventions in real-world settings. As in real-world interactions between the intervention, implementation and context are given, careful consideration of context is indispensable for a successful and sustainable implementation science project.*

1.4 Concept of context

Within in implementation science, the concept of context is partially mature, it lacks a unifying theoretical and operational definition (5, 17, 18, 23, 97). Terms used to denote context which all vary across studies, theories, models and frameworks (TMFs) each of which provides a slightly different perspective (e.g., setting, (external) environment, system characteristics, inner and outer setting, external barriers, organizational drivers, environmental factors, situation) (2, 18, 23). Few studies provide a definition of context; most refer to its characteristics.

Context entails an ecological perspective, i.e., it is multidimensional and multilevel, with interactions constantly occurring between and within the various levels and domains (2, 18, 98). Contextual domains include geographical, epidemiological, socio-cultural, socio-economic, political, legal and ethical aspects on multiple levels (4). The *macro level* represents the external system (e.g., health care system, policy, community) in which the intervention is implemented, (2) the *meso level* involves organizational characteristics, and the *micro level* characteristics of the clinical setting, patients and providers (2, 4, 99). Some studies describe additional levels (e.g., the team-level), or distinguish the patient-level from the micro level or focus on level-spanning (multilevel) contextual factors (2, 17, 99, 100). Based on empirical evidence or stakeholder interviews, commonly reported macro-level contextual factors include professional influences, political support, social climate, local infrastructure, policy and legal climate, relational climate, target population, and the funding and economic climate (1, 15, 101, 102). On the meso level, contextual factors include organizational culture and climate, networks and communication, leadership, resources (financial, staffing and workload, time), with organizational leadership identified in many studies as a key factor for implementation (15, 17, 97, 102-104). Micro level factors include motivation, individual autonomy, self-efficacy, or individual knowledge, attitudes and beliefs (1, 15, 102).

Context is dynamic and interrelated: interactions are common between context, intervention and implementation (5, 6, 18, 23, 104, 105, p. 24-25). And as context, implementation and intervention are tightly linked, changing one of these aspects can also cause changes in others. For this it is irrelevant whether the intervention is simple or complex, the implementation of an intervention will always change the context and vice versa (63, 106, 107). Thus, context is often referred to as a complex adaptive system, that is constantly evolving in a nonlinear and unpredictable way (106, 108).

Context *embodies social systems*. It includes social rules, interactions and relationships of individuals in a system that shape the context as much as an individual's response to and implementation of an intervention (4, 109, 110, p. 70).

Context comprises more than a physical location. It embodies both, a concrete, physical location (described in the following as *setting*) in which an intervention is delivered (e.g., hospital setting) and that is rather related to structural aspects as well as a global dimension (referred to in the following as *context*), that refers to more abstract aspects, such as social, cultural, economic factors (4, 18, 111).

1.5 Contextual factors relevant for implementation

In general, evidence on micro-, meso- and macro-level contextual factors influencing implementation is limited. In addition, various terms are used and further levels of contextual factors described (e.g., team-level, multi-level factors), resulting in conceptual inconsistencies. Table 1.1 provides an overview of contextual factors that were most commonly reported in empirical evidence to influence implementation (17, 23, 97, 101).

Some of these factors are most widely addressed in implementation determinant frameworks, such as organizational support, financial resources, social relations and leadership (2). Contextual factors are interrelated, and interact within and across level to influence implementation. In particular, leadership has been described as key factor exerting its influence on culture, teamwork, collaboration, communication and resources (97). Yet, few studies consider interactions of contextual factors, particularly interactions across levels. Further, there is limited evidence on the influence of contextual factors on implementation outcomes.

Table 1.1. Overview of micro-, meso-, and macro-level contextual factors most commonly reported influencing implementation of interventions in real-world settings

Micro-level (17)	**Meso-level** (15, 17, 97)	**Macro-level** (15, 101)
Individual autonomy Self-efficacy Individual knowledge Attitudes and beliefs Interpretation of individuals about the initiative Socio-economic background of participants	Organizational culture and climate Networks and communication Leadership Resources	Professional influences Political support Societal influences Local infrastructure Policy and legal climate Collaboration Target population Funding and economic climate

1.6 Implementation science frameworks incorporating context

In a recent scoping review, Nilsen and Bernhardsson (2019) identified 17 determinant frameworks that include 12 different contextual factors on multiple levels (2). Of these, the most commonly-cited are organizational support, financial resources, social relations and support, leadership, organizational culture and climate and organizational readiness (2). However, as the terminology applicable to contextual domains and factors varies across frameworks, it is difficult to compare results and understand whether similar or different aspects of context were assessed (23).

1.6.1 The Context and Implementation of Complex Interventions framework

The understanding and conceptualization of context in this dissertation is based on the *Context and Implementation of Complex Interventions* (CICI) framework (Figure 1.5) (4). Of all implementation science frameworks currently available, CICI pays most attention to context, while acknowledging the dynamic interplay of context, intervention and implementation (4). It also considers other independent interventions targeting the same population or setting that influence context and implementation. As a meta-theoretical framework derived from empirical evidence, CICI can serve as a determinant or evaluation framework, i.e., it can be applied to understand influences on implementation outcomes and to evaluate implementation (61). Its authors define context as an “overarching concept, comprising not only a physical location, but also roles, interactions and relationships” (4). CICIs perspective on context is ecological, i.e. context is multi-level (micro-, meso-, and macro-level), multi-dimensional and dynamic. In this case, context covers seven domains: geographical, epidemiological, socio-cultural, socio-economic, ethical, legal, and political; each of which includes several contextual factors. In the CICI framework context is distinguished from the setting, which is “the specific physical location, in which the intervention is put into practice and interacts with context and implementation” (4).

Evidence shows that implementation science researchers and practitioners attach some importance to setting factors such as facility characteristics, health professional characteristics, resource access, or work structure, however, in relation to recent implementation science TMFs, setting is generally treated as minor concern and lacks operationalization (2, 15, 102). One notable exception is the CICI framework. While "setting" and "context" are often used interchangeably, CICI differentiates the two concepts quite well. In fact, with its clear definitions, CICI can be used to operationalize context and provide a firm foundation for its assessment. Further, placing existing evidence regarding contextual factors within the CICI framework highlights differences in the conceptualization of context, while exposing inconsistencies in contextual factors that impact implementation (e.g., ethical aspects). As CICI was initially developed in the field of public health, it has stronger recognition of macro-level factors than other TMFs. However, it also shows certain important limitations. For example, interactions between context, implementation and intervention are well described; however, due to a lack of evidence, those among contextual factors and across context levels are not considered.

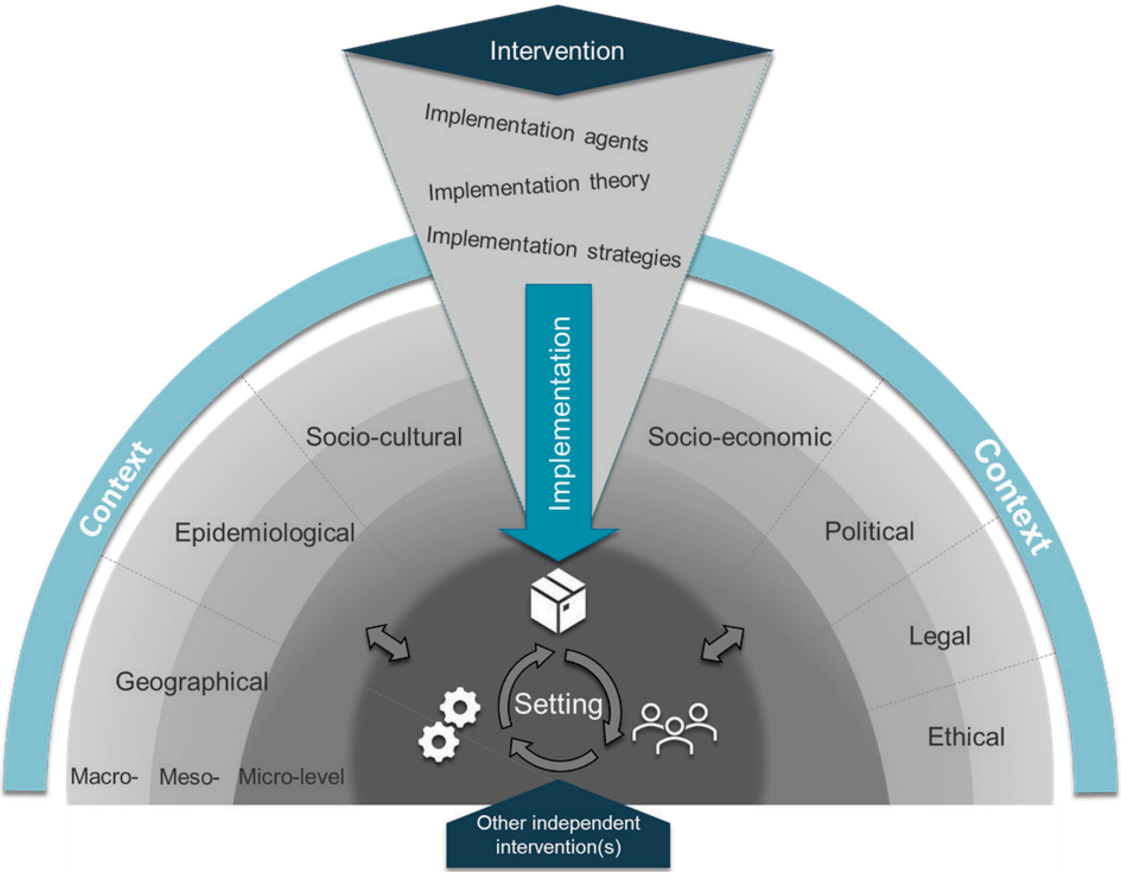

Figure 1.5. Context and Implementation of Complex Interventions (CICI) framework (4) (Figure printed with permission of the first author, Lisa Pfadenhauer)

Further elaboration of the concept of setting is needed, as well as some discussion of how to deal with changes in context over time.

1.6.2 Overview of further implementation science frameworks incorporating context

Besides CICI several implementation frameworks exist that incorporate context. Further, one characteristic common to all of these frameworks is that all consider context a major factor for implementation, but none focus on the interactions between context, implementation and intervention.

The *Promoting Action on Research Implementation in Health Services* (*PARiHS) framework* describes successful implementation as a function of the evidence (quality and type), the context and the facilitation of evidence (112). In the revised (2016) version, the *integrated-PARiHS* (*i-PARiHS*), context includes the target setting—both inner (local- and organizational level) and outer (external health system)—and is defined as the resources, culture, leadership, and orientation to evaluation and learning that are relevant within that setting (113).

The *Consolidated Framework for Implementation Research (CFIR)* is a meta-theoretical framework that combined all evidence available at the time of its writing (19 frameworks and models, including PARiHS). With a strong focus on the meso level, it covers five domains: (1) intervention (e.g., complexity, cost); (2) outer setting (e.g., patient needs and resources); (3) inner setting (e.g., structural characteristics of the healthcare organization); (4) individual characteristics (e.g., individual beliefs about the intervention, self-efficacy); and (5) process (e.g., planning the intervention implementation) (57). Each domain consists of multiple constructs, each influencing implementation without further specification of the interaction between those constructs (57). While the developers of CFIR mention differences between context ("set of circumstances and unique factors that surround a particular implementation effort") and setting ("environmental characteristics in which implementation occurs") (57), it is not reflected in the framework. Context is represented by inner and outer setting. While inner setting factors are related to the organization in which an intervention will be implemented (e.g., the implementation climate within an organization), the outer setting focusses on relationships of organizations (e.g. networking, peer pressure) and external policies or incentives that forces organizations to implement an intervention (57). Very recently, the developers of CFIR announced to develop CFIR 2.0, in order to clarify conceptual distinctions e.g., between contextual determinants for the intervention and implementation (114).

While the concept of context is partially mature and lacks a standard definition, important characteristics of context include its ecological perspective, being dynamic and interrelated, embodying social systems, and encompassing more than one physical location. Several implementation frameworks incorporate context, and various multi-level factors that influence implementation have been identified.

1.8 Making the invisible visible - Contextual analysis in implementation science

Contextual analysis is a foundational part of the implementation science methodology, to identify relevant factors influencing the implementation in real-world settings—i.e., to make the invisible visible.

1.8.1 Defining contextual analysis

Various terms have been applied to the assessment of context. Among others, these include *contextual analysis*, *pre-implementation phase*, or *contextual inquiry* (39, 115, 116). In the absence of a standard term we will use contextual analysis. Within implementation science projects, a contextual analysis usually focusses on the assessment of multidimensional and multi-level (micro-, meso-, macro-level) contextual factors (often referred to as facilitators and barriers) that are relevant for the implementation of an intervention in a specific setting (4, 39, 115). Findings of the contextual analysis are relevant to inform all subsequent phases of the project (15, 56, 65, 114, 115, 117):

1) Based on available evidence, findings of the contextual analysis, as well as the stakeholders' preferences, *intervention components* can be selected or adapted to the context (117-119). These include intervention core elements, which are essential to achieve a desired effect, and adaptable components, which can be selected and tailored to fit the context (100).
2) Further, context-specific *implementation strategies* can be selected, to support an interventions' implementation (71, 81, 120, 121). A program theory can be developed to describe relationships between context, intervention components and chosen implementation strategies as well as to explain how and why an intervention works (90).
3) Contextual information can help to explain how *effectiveness outcomes and implementation outcomes* are influenced by the context and what impact the context had on the outcomes (2, 11, 122). These findings are important, for example, to inform scale-up of interventions in other settings, e.g., they allow decision makers to judge the applicability of findings and the likelihood of successful implementation in their own context (8, 11).
4) Regarding sustainability, based on the results of the contextual analysis, specific strategies can be chosen to help ensure that the intervention is implemented sustainably in that particular context, i.e., *sustainability strategies* (11, 25, 119, 123, 124).

1.8.2 Current approaches for contextual analysis

Awareness has spread in recent years as to context's importance regarding implementation. This is evident, for example, in the increasing number of implementation TMFs that include context (2). Still, studying and reporting context remains poor (1, 4, 13-15, 62, 125). For example, a recent review on medication adherence intervention trials showed that only two of the 23 included studies described contextual information, hindering successful implementation of these intervention into clinical practice (126).

Few journals require contextual analysis as part of intervention study papers, and even implementation science reporting guidelines rarely consider it (6, 125). The Standards for Reporting Implementation Studies (StaRI) recommends the CFIR framework to report contextual factors, yet it provides no guidance for reporting contextual analyses as such. This reflects the fact that contextual analyses have not yet been well conceptualized; however, frameworks and methods used to conduct them are under construction (8, 12, 17).

Shaped by a post-positivist paradigm, implementation scientists tend to focus on single factors (commonly referred to as facilitators and barriers) (2, 17, 85). This reductionist and simplistic view on context neglects that the interaction of contextual factors may differently impact on implementation success than an individual factor alone (2, 98). Further, the selection of factors for analysis is often not theory based and findings of the contextual analysis are rarely used as a basis for further project phases (e.g., intervention development) (23, 62, 127-132). Indeed, the latter is often true when context is studied retrospectively e.g., as part of a process evaluation (133, 134). Thus, intervention and implementation strategies never quite fit the context (1, 15, 120, 135). The obvious consequence of inadequate attention to the context is that interventions or implementation strategies successfully implemented in one setting will be unsuccessful in others (62, 128, 130, 136, 137).

Commissioned by the Agency for Healthcare Research and Quality (AHRQ), Stange and Glasgow (2013) provided an initial attempt to describe a step-wise approach on assessing and reporting on context in patient-centered medical home research during all phases of an research project (65): 1) identification of relevant contextual factors based on theory, local history and stakeholder input at the beginning of a project; 2) data collection and analysis at multiple timepoints during the study, and 3) reporting of contextual factors and how they affect important processes and outcomes. However, although this approach forms an important basis for contextual analysis, some limitations have to be acknowledged. The approach entails no operationalization of context (and setting) and relevant aspects of context to be studied. Further, no specific methods to collect and analyze contextual information are described. As the approach was not initially developed for implementation science, specific guidance on how contextual and setting information can inform further phases of an implementation project (e.g., choosing implementation strategies) is missing.

Chapter 4 describes first the development of the Basel Approach for coNtextual ANAlysis (BANANA), a six-step process to guide contextual analysis in implementation science. BANANA elaborates on previous work by Stange and Glasgow (2013) (65). The conceptual understanding of context in BANANA is based on the CICI framework (4).

Second, the application of BANANA in the SMILe project (Development, implementation and testing of an integrated model of care in allogeneic SteM cell transplantatIon faciLitated by eHealth) (138) is described.

(Article title: Unravelling implementation context: The Basel Approach for coNtextual ANAlysis (BANANA) in implementation science and its application in the SMILe project)

1.8.3 Methods to study context

As several methods are available to study context, some implementation scientists recommend a combination of qualitative, quantitative or even mixed-methods designs (13, 63, 139-141). To understand the organizational social context in a sample of child-serving agencies, for example, Beidas et al. assessed quantitative data collected via the *Organizational Social Context Measure*, which they complemented with direct qualitative observations regarding contextual conditions. By combining quantitative and qualitative methods, they identified aspects (e.g., cultural diversity, distrust and affect, leadership) that would have gone unnoticed had they applied a single method in isolation (139). In general, it is evident that the most comprehensive contextual analyses result from combinations of methods. For the moment, however, conceptual inconsistencies and the broad heterogeneity of methodological approaches limit progress.

1.8.3.1 Identifying relevant contextual factors

Implementation science TMFs are available to guide the selection of relevant contextual factors and stakeholder involvement has been described as an essential element for contextual analysis (116, 134). Stakeholders can help to prioritize study-relevant contextual factors, monitor changes in context, and support interpretation and dissemination of findings (65, 142). They can also open up unanticipated paths of understanding. For example, when Squires et al. conducted semi-structured interviews with international health system stakeholders they hoped to identify contextual factors relevant to implementation efforts in healthcare (102). In addition to the target information, stakeholders' input led to the identification of contextual aspects (e.g., job autonomy, provincial responsibility) not considered in current frameworks such as the CFIR (102).

In addition, further guidance as to which contextual factors to assess at what time and how often during implementation is currently missing. To address this shortfall, the Atlas Initiative launched by Ariadne Labs aims to identify the contextual factors most strongly related to implementation success over a series of analytical timepoints (pre-implementation, six weeks post-implementation and monthly after that) (143, 144). Further, a data repository will be established to build a comprehensive dataset on relevant contextual factors for various types of interventions and settings.

1.8.3.2 Measurement tools to assess context

Several available measures assess various levels of contextual factors, implementation outcomes, implementation processes or intervention characteristics. Within the *Society for Implementation Research Collaboration (SIRC)* Instrument Review Project, over 420 measurement tools were identified that relate to 34 of the 37 CFIR framework constructs (145). Of these, many were designed for the CFIR's inner setting domains, e.g., readiness for implementation (n=16), implementation climate (n=15), networks and communication (n=11), and culture (n=10). For other aspects of context no tools exist. Most measures originate in the field of psychology and focus on meso-level (organizational) factors (e.g., organizational climate, readiness for implementation); relatively few focus on macro- (e.g., social network, policy and regulation) or micro- (individual-) level aspects (e.g., readiness for change, capacity to adopt) (145-149). These findings reflect the tendency of determinant frameworks and gatherers of empirical evidence to focus on meso-level factors, whereas macro-level factors are rarely considered (2, 97, 101, 147, 150-153).

Besides primarily focusing on certain contextual levels, the identified measurement instruments tend not to focus on broad ranges of contextual factors, instead capturing individual aspects of context, e.g., readiness for change. In addition, the majority have psychometric and theoretical deficits that limit or negate their value regarding contextual analysis (104, 149-151). To allow development of psychometrically strong measures, researchers will need first to work out the conceptual inconsistencies regarding context, then to ensure that future development has firm theoretical groundings (101, 146, 148).

Chapter 5 provides an overview of existing approaches to contextual analysis within implementation intervention studies. It also highlights the limitations of contextual analyses performed to date by mapping identified results against the BANANA approach. Further, it presents an evidence gap map developed to navigate current approaches to contextual analysis and allow initial development of an evidence base.

(Article title: Methodological approaches to study context in implementation intervention studies: An evidence gap map)

1.8.4 Limitations based on the prevailing post-positivist paradigm in implementation science

Implementation science's evolution from its post-positivist origins is reflected both in current TMFs and in the approaches implementation scientists commonly apply to their studies of context (63). The postpositivist paradigm focusses on generalizability of findings and the establishment of causal mechanisms (154, p.59). Context is often reduced to individual factors (i.e., facilitators or barriers) and treated as a confounding factor that needs to be controlled for (1, 63, 127, 130, 155). Implementation science studies often examine context either retrospectively or as part of a process evaluation—their objective being to explain the influence of context on implementation processes and outcomes (130, 133, 156). Similarly, contextual analysis is usually conducted once. However, context is dynamic and evolves over time: it requires longitudinal assessments (65, 130). The linear and reductionist conceptualization limits how context is characterized. That is, without taking the dynamic and complex interactions between context, intervention and implementation into account, researchers overlooked its value (2, 96, 155).

Further, by neglecting the fact that implementation takes place in social contexts, researchers also neglect the existence of mutual interactions between individuals and context, i.e., context influences individuals' actions; likewise, individuals can shape their contexts. Consequently, synergistic effects that result from such interactions may go unrecognized. With no adjustment is made for those effects, the most likely outcome of any measures taken (e.g., implementation strategies chosen) is that they will not enhance implementation success and sustainability, i.e., that they will fail (2, 157-160).

To acknowledge context as a multilevel, dynamic and complex concept would require a new paradigm. Opening up for a constructivist perspective allows scientists to conceptualize context as a social construct based on interactions and social processes. This new paradigm also necessitates certain methodological considerations. For example, Haines et al. recently suggested the use of ethnographic approaches to contextual analyses, as they can uncover differences between what people say and what they do (134).

However, considering that resources (e.g., funds, staff, time) are usually constrained within implementation science projects—particularly so for contextual analysis—decisions need to strike a balance between speed and rigor of contextual analysis (161). Therefore, increasingly rapid qualitative or ethnographic methods are recommended. One likely candidate is the *Rapid Assessment Procedure–Informed Clinical Ethnography (RAPICE)* instrument, which combines rapid assessment procedures with an ethnographic focus (161, 162).

Also, initial evidence that rapid research methods can be as effective and rigorous as traditional deductive approaches (content analysis) was recently reported by Nevedal et al.. Comparing a CFIR-guided rapid deductive approach to semi-structured interview data (notes and audio recording) (163) to the traditional deductive approach (using verbatim transcripts), they found the rapid approach more time- and cost-effective. However, they also noted that this rapid approach demands considerable skills in qualitative methods and experience with the CFIR framework (163).

Chapter 6 reflects how a constructivist perspective can facilitate a rich contextual analysis. We propose five constructivist concepts, and illustrate how each can complement recent conceptualizations of context. To illustrate the added value of the constructivist paradigm for contextual analysis, we include a case example.

(Article title: Understanding dynamic complexity in context – enriching contextual analysis in implementation science from a constructivist perspective)

Contextual analysis is foundational to all phases of an implementation science project. Several approaches and methods have been described to study context, but guidance for planning, performing and reporting contextual analyses is lacking. Furthermore, current approaches reveal limitations due to the prevailing post-positivist paradigm in implementation science.

1.9 Research gap and rationale for this dissertation

Since two decades, implementation scientists have been laying down a rigorous scientific foundation for implementation processes that are measurable and generalizable yet significant methodological gaps remain in the implementation, sustainment and scale-up of evidence in practice (26, 54, 164). Those implementation failures are often based on a lacking understanding of the implementation context and not integrating contextual knowledge into next phases of an implementation science project (e.g., intervention development) (23, 62, 127-132).

Therefore, contextual analysis is a key element of implementation science: it informs the necessary methodology and provides foundational support for the successful and sustainable implementation of interventions in real-world settings. A comprehensive understanding of context is essential to the development of interventions, choices of implementation and sustainability strategies and interpretation of outcomes. However, context remains understudied and underreported in implementation science studies, limiting the goal of reducing research waste.

Various factors contribute to the under-recognition of context in implementation efforts:

First, in implementation science, context is a treacherous field to navigate, as its concepts and methods are only partially explored. Not even a common definition exists to delineate its characteristics and boundaries. And while various theories, models and frameworks exist to study it, prospective users must first untangle multiple competing systems of terminology and conceptualization. And for the moment, no guidance exists on how to operationalize or measure it.

Second, methodological guidance on conducting contextual analyses is scant (e.g., regarding measurement timepoints). And while a plethora of measurement tools exist, few are theoretically based and psychometrically sound. Moreover, analytical guidelines commonly focus only on individual factors or single context levels.

Third, influenced by a post-positivist perspective, the common understanding of context is rather reductionist and linear. In order to account for complexity and dynamic interactions in context, we propose reorienting current approaches to contextual analysis to start from a constructivist perspective.

This thesis will advance the field of implementation science in view of methods for contextual analysis. Our work will result in the Basel Approach for coNtextual ANAlysis (BANANA), a guide for future implementation science projects. A practical example will showcase BANANA's value. We will conclude by describing how contextual analyses will benefit from a constructivist perspective—how this new paradigm allows richer, more meaningful contextual knowledge to inform all phases of implementation science projects. This will greatly reinforce current efforts toward successful implementation and sustainability as well as speeding up the translational pipeline.

1.10 References

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Chapter 2.

Aims

Study aims

The overall aim of this dissertation is to strengthen the theoretical and methodological foundations for contextual analysis in implementation science:

1. To identify journals publishing implementation science related content to be included in strategies supporting searches of implementation science evidence.

2. To describe the state of science in view of contextual analysis in implementation science (e.g., theoretical frameworks and methodological specifications) and identify steps for guiding contextual analysis.

3. To review and map implementation science studies in view of methodological approaches used for contextual analysis.

4. To strengthen the conceptualization of contextual analysis by enriching a constructivist perspective.

Chapter 3.

Relevant journals for identifying implementation science articles: Results of an international implementation science expert survey

Juliane Mielke[1], Thekla Brunkert[1,2], Leah L. Zullig[3], Hayden B. Bosworth[3,4], Mieke Deschodt[1,5], Michael Simon[1], Sabina De Geest[1,6]

[1] Institute of Nursing Science, Department Public Health, University of Basel, Basel, Switzerland

[2] Manitoba Centre for Health Policy, Department of Community Health Sciences, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, Canada

[3] Center for Innovation to Accelerate Discovery and Practice Transformation (ADAPT), Durham Veterans Affairs Health Care & System; and Department of Population Health Sciences, School of Medicine, Duke University, Durham, NC USA

[4] Division of General Internal Medicine, Department of Medicine, Duke University School of Medicine, Durham, NC, USA; School of Nursing, Duke University, Durham, NC, USA; and Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

[5] Department of Public Health and Primary Care, Gerontology and Geriatrics, KU Leuven, Leuven, Leuven, Belgium; and Healthcare and Ethics, Faculty of Medicine and Life Sciences, UHasselt, Hasselt, Belgium

[6] Department of Public Health and Primary Care, Academic Center for Nursing and Midwifery, KU Leuven, Leuven, Belgium

Published in Frontiers in Public Health 2021, 9(458); DOI:10.3389/fpubh.2021.639192

3.1 Abstract

Background

In implementation science (IS), conducting well-targeted and reproducible literature searches is challenging due to non-specific and varying terminology that is fragmented over multiple disciplines. A list of journals that publish IS-relevant content for use in search strings can support this process.

Methods

We conducted a cross-sectional online survey of 56 Australian, European, and North American IS experts to identify and prioritize relevant journals that publish IS articles. Journals' relevance was assessed by providing each with a list of 12 journals, to which they were encouraged to add additional journal names and comments as free text. We also assessed which journals had published special IS-focused issues—identified via PubMed and Google searches—over the last 20 years. Data were analyzed descriptively.

Results

Between February 28 and March 15, 2020, a purposive sample of 34/56 experts participated in the survey (response rate: 60.7%). Implementation Science and BMC Health Services Research were perceived as relevant by 97.1% of participants; other journals' relevance varied internationally. Experts proposed 50 additional journals from various clinical fields and health science disciplines. We identified 12 calls and 53 special issues on IS published within various journals and research fields. Experts' comments confirmed the described challenges in identifying IS literature.

Discussion

This report presents experts' ratings of IS journals, which can be included in strategies supporting searches of IS evidence. However, challenges in identifying IS evidence remain geographically and interdisciplinary. Further investment is needed to develop reproducible search strings to capture IS evidence as an important step in improving IS research quality

3.2 Introduction

Bridging the gap between research and practice using scientific methods is the central aim of implementation science (IS) which can be defined as the “scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care” (1). IS studies typically require an expansive cross-disciplinary understanding of relevant empirical findings and of whether and where they have been implemented. To ensure that research is novel, necessary, and attentive to existing work, each research project should begin with a search of relevant IS literature (2). However, this search process is hampered by a lack of unified definitions and conceptualizations, as well as by suboptimal indexing: a plethora of terms are used across disciplines, varying over time and geography (e.g., dissemination and implementation science, knowledge translation, research utilization) (3-5). This lack of consistency applies not only to terminology, but also to the definition of IS itself (6). In addition, some aspects of the IS methodology overlap with methods from other fields, all of which have their own specific language and labeling (e.g., improvement science) (7, 8).This results in heterogeneity and inconsistencies in operationalization challenge the development of precise search strings, thereby impacting the identification of relevant literature (9).

Problems with the sensitivity and specificity of systematic IS literature searches were already being reported in 2010 (10, 11). In response, Lokker et al. and McKibbon et al. developed search filters to identify different types of IS articles (general, theoretical, IS instruments, application-focused) from CINAHL and MEDLINE (10, 11). For MEDLINE, these filters’ sensitivity ranged from 85%–90%, with specificity ranging from 65%–75% depending on the type of article (11). For CINAHL, their retrieval efficacy was comparable, i.e., they resulted in a large number of results, many of which were irrelevant (10). In contrast, search strings for clear, well-defined concepts, such as *randomized clinical trials* (RCTs), showed both sensitivity and specificity over 99%. Concepts with a high variability of search terms such as patient and public involvement reach comparable retrieval rates as IS search strings (12-14).

Challenges in developing precise IS search strings are also described in other systematic reviews (15, 16) and similar to our own experience in an ongoing mapping review project, the *ImplemeNtation science State of research ProjECT (INSPECT)* (17). INSPECT involves a group of experts in nursing, health services research, implementation science, public health and health policy who guided the formation of an extensive search string intended to capture the existing status of IS as a scientific discipline. In contrast to previous work, this INSPECT concerns the total IS literature identified through our search string. However, similar to prior reviews, the INSPECT project is affected by limited sensitivity and specificity which challenges the identification of relevant IS literature.

Over the past two decades, IS has gained increasing importance in various health related disciplines and other fields (e.g., environmental sciences) (18). This importance is reflected in the expanding number of journals not only addressing IS specifically but publishing special issues to showcase IS studies and methodological issues in IS in their respective fields. In a field as broad and rapidly evolving as IS, a growing number of empirical and theoretical IS papers are scattered over diverse peer-reviewed journals (19). In combination with the indistinct terminology identification of relevant evidence is even more challenging.

In 2019, the National Library of Medicine introduced ‘implementation science’ as a medical subject heading (MeSH) in PubMed. This will aid literature searches considerably and should eventually decrease the challenge of finding IS-related articles in the future.

In order to access relevant IS literature published before 2019 (and probably also after until some congruence in labelling is adopted internationally), a more targeted approach is needed. One pragmatic step in this targeted direction is to compile a list of relevant journals for IS search strategies, which will help to narrow the search. Further, as studies in various fields have demonstrated that articles published in special issues are often published more quickly and with higher impact (citation rate per article) than regular articles, (20, 21) these special issues might be particularly useful to help identify relevant evidence.

Therefore, our primary objective was to identify and prioritize journals that publish IS articles with the goal of summarizing current journals where IS research may be located from an IS expert viewpoint. We further assessed which journals have published special issues about IS over the last 20 years.

3.3 Methods

3.3.1 Design, Setting, Sample

We developed and administered a cross-sectional online survey targeting international IS experts and invited a purposive sample of 56 from Australia, Europe, and North America to participate. To achieve a high level of expertise, the sampling pool was composed of IS practitioners and researchers, we identified from the collaboration networks published by Norton et al. (22), and on the website of the European Implementation Collaborative. Since implementation scientists are disproportionately concentrated in the US and Europe, we included experts with guidance from the articles’ authors, to ensure international geographic representation and balance the sample to the extent possible. While there are many complementary disciplines, e.g., improvement science, our research objective focused specifically on identifying IS literature. Therefore, we engaged experts working specifically in IS. The reporting of this study adhered to the STROBE Statement as well as the Checklist for Reporting Results of Internet E-surveys (CHERRIES) (23, 24).

3.3.2 Variables and measurement

First, we assessed the perceived relevance of journals identified in a literature search for INSPECT (17). An extensive search string was developed, using text words and MeSH terms referring to IS (Table 3.1). Almost 11000 hits (N=10904) were identified, published in 2461 various journals. We selected the 12 journals most commonly identified (more than 60 times), which represent 31.4% of all hits. Experts could rate the relevance of each journal on a 4-point Likert scale. Perception responses ranged from 1 ('not at all') to 4 ('definitely'), with 5 signifying 'journal not known'. Perception scores were dichotomized as either 'relevant' (ratings of 3 or 4) or 'not relevant' (ratings of 1 or 2); ratings of 5 were set as missing. Next, experts were invited to indicate any other journals they deemed important for the identification of IS articles. Finally, demographic characteristics including country of residence, field of research, and years of experience in implementation research were gathered.

Table 3.1. Search string INSPECT project in PubMed until 31.12.2019 achieved 10,904 hits

diffusion of innovation*[Title/Abstract] OR dissemination science[Title/Abstract] OR Implementation research[Title/Abstract] OR Implementation science[Title/Abstract] OR "implementation science is"[Journal] OR Improvement science[Title/Abstract] OR Knowledge to action[Title/Abstract] OR Know-do gap[Title/Abstract] OR Knowledge transfer[Title/Abstract] OR knowledge translation[Title/Abstract] OR Knowledge utilization[Title/Abstract] OR Research implementation[Title/Abstract] OR Research utilization[Title/Abstract] OR "translational behavioral medicine"[Journal] OR Translational science[Title/Abstract]

3.3.3 Data collection

Data were collected between February 28 and March 15, 2020. A closed survey was developed using the online https://www.umfrageonline.com/ software and its usability and technical functionality was pilot-tested by this report's three authors (LL, TB, SDG). A personalized letter (English) describing the study and providing a survey link was emailed to the experts. To prevent entries to the survey for a second time, the online software tool used cookies and IP addresses. After one week, a reminder was sent to all IS experts because the survey was de-identified.

Participation in the online survey was entirely voluntary, with consent implied by answering and returning the survey. Data were fully anonymized. Following Swiss ethical standards, Art. 2, Federal Act on Research involving Human Beings (Human Research Act, HRA), we neither required nor requested ethical approval.

3.3.4 Data analysis

The anonymized data were analyzed descriptively using IBM® SPSS® 25.0.0. Means and standard deviations (SDs) were reported for normally distributed, and medians and interquartile ranges (IQR) for non-normally distributed data. Expert comments were analyzed using content analysis (25, 26). Categories were created based on inductive approach.

3.3.5 Web-based search for implementation science special issues

Via PubMed and Google, we searched for IS special issues using the search terms ‘special issue’ AND ‘implementation science’. All special issues related to IS in healthcare from 2000 until March 2020 were included. Additionally, we manually searched all journals listed in our survey and suggested by IS experts. Information on journal name, special issue title, volume (issue), publication or submission date, number of papers included in the special issue, the journal’s impact factor and *h*-index, and country were extracted and presented in a table.

3.4 Results

3.4.1 Implementation science experts’ characteristics

Of the 56 invited IS experts, 34 experts from twelve countries, participated in the study, corresponding to a response rate of 60.7 % (Supplementary Figure S3.1). Their fields of professional activity included public health (n = 9; 26.5%), social science (n=6; 17.6%), mental health (n = 4; 11.8%), acute care (n = 2; 5.9%), psychology (n=2; 5.9%), primary care (n=1; 2.9%), social work (n=1; 2.9%), or other (n=9; 26.5%). They had a median of 12 years’ experience in implementation research (IQR = 12.8; range 4–30).

3.4.2 Perceived relevance of journals

The perceived relevance of the listed journals regarding IS article identification ranged from 26.5% to 97.1% (Figure 3.1). Overall, *Implementation Science* and *BMC* (BioMed

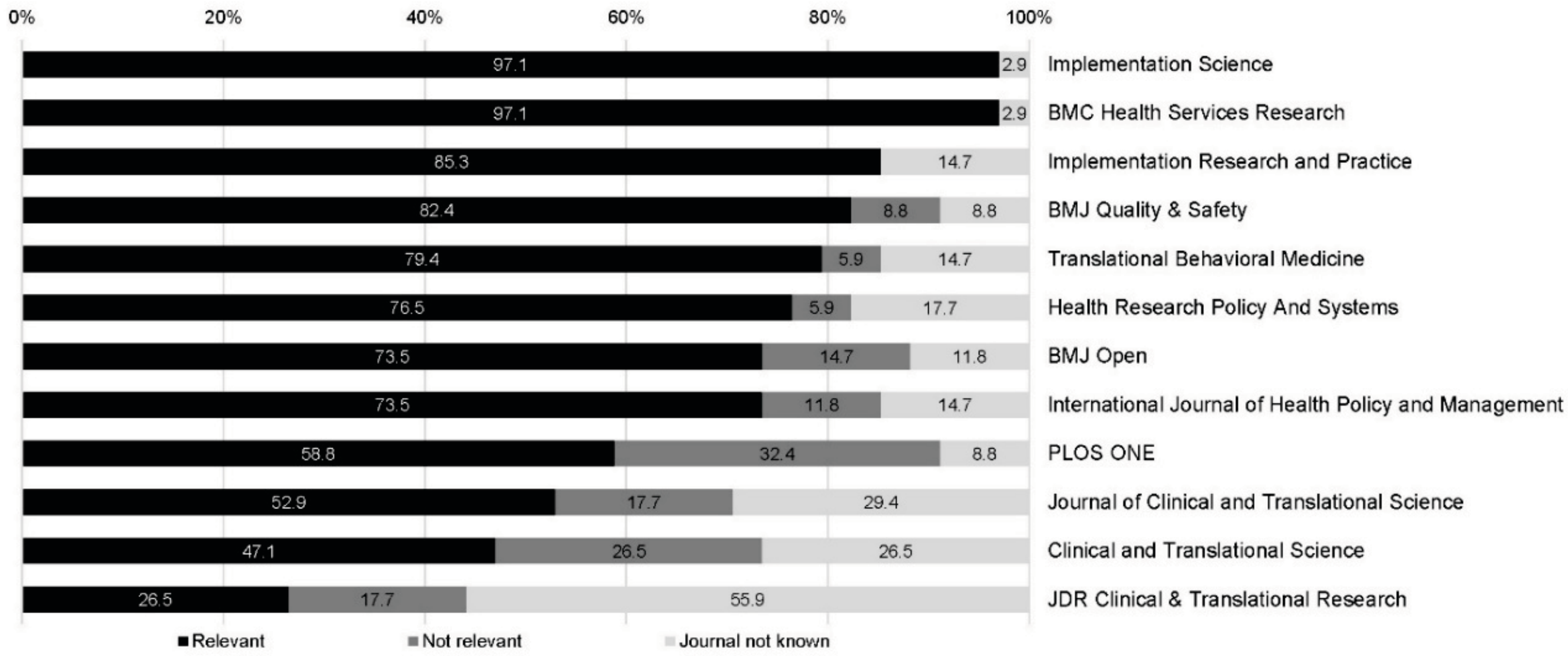

Figure 3.1. Perceived relevance [a] of IS journals (in %) to identify IS articles in total (N = 34).
[a] dichotomized as 'relevant' ('definitely' or 'somewhat') and 'not relevant' ('very little' or 'not at all').

Central) *Health Services Research* were perceived as relevant by 33 experts (97.1%), followed by *Implementation Research and Practice* (*n*=29; 85.3 %) and *BMJ* (British Medical Journal) *Quality and Safety* (*n*=28; 82.4%). Two journals received relevance ratings below 50%: *Clinical and Translational Science* and *JDR* (Journal of Dental Research) *Clinical & Translational Research,* which was unknown to over half (55.9%) of the participants. Also, European and North American experts' perceptions varied strongly regarding three other journals: *BMJ Quality and Safety* (respectively 76.5% vs. 50%), *Translational Behavioral Medicine* (respectively 58.8% vs. 100%), and *PLOS ONE* (respectively 47.1% vs. 68.8%) (Figure 3.2).

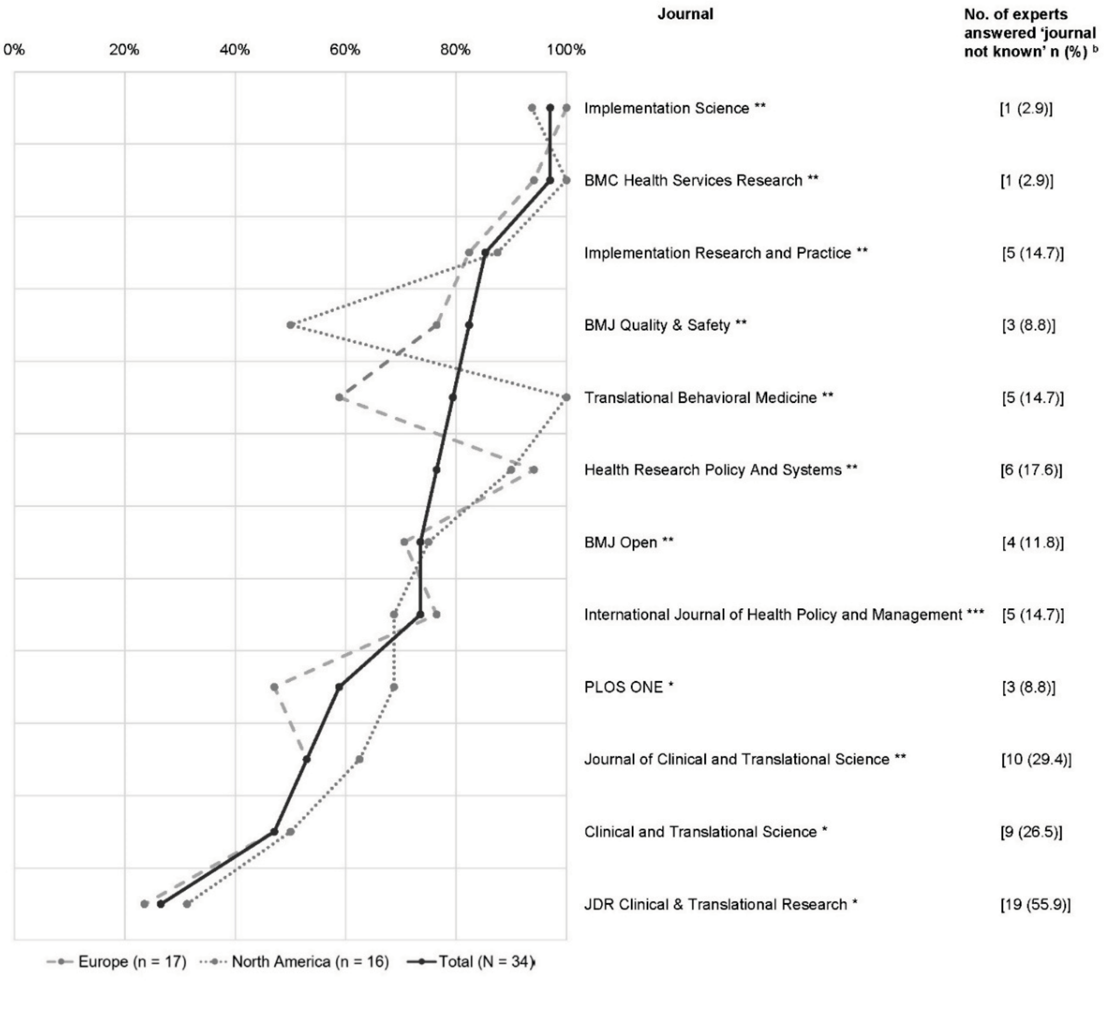

Figure 3.2. International variation in perceived relevance [a] of journals by European and North American experts.
[a] dichotomized as 'relevant' ('definitely' or 'somewhat'); [b] answer option 'journal not known' set as missing when calculating percentages
Country of publication: * USA, ** Europe, *** Iran

3.4.3 Other relevant journals

Forty-seven other relevant journals publishing IS articles were suggested by 31 experts, referring to various fields of research (e.g., public health, mental health, or psychology) (Table 3.2). Most suggested journals oriented primarily towards clinicians in a particular field, such as internal medicine or mental health, but that publish implementation-relevant work. These journals included, for example, the *American Journal of Public Health*, the *Journal of General Internal Medicine*, and *Psychiatric Services*.

Table 3.2. Other journals experts deemed important in view of identification of IS articles (*n* = 31).

Journals that were denoted more than once each			
	n (%)		**n (%)**
Implementation Science Communications	16 (51.6)	Journal of the American Medical Association (JAMA)	2 (6.5)
Administration and Policy in Mental Health and Mental Health Services Research	12 (38.7)	American Journal of Preventive Medicine	2 (6.5)
American Journal of Public Health (AJPH)	5 (13.5)	Frontiers in Public Health	2 (6.5)
Journal General Internal Medicine	3 (9.7)	JAMA Internal Medicine	2 (6.5)
Prevention Science	3 (9.7)	Journal of Community Psychology	2 (6.5)
Evidence & Policy	3 (9.7)	Milbank Quarterly	2 (6.5)
Psychiatric Services	3 (9.7)	World Views on Evidence Based Nursing	2 (6.5)
Journal of Medical Internet Research (JMIR)	2 (6.5)		
Journals that were denoted once each			
BMC Public Health		JMIR Formative Research	
American Journal of Community Psychology		Joint Commission Journal on Quality and Patient Safety	
BMC Globalization and Health		Journal of Acquired Immune Deficiency Syndromes (JAIDS)	
BMC Medical Education		Journal of Clinical Child & Adolescent Psychology	
BMJ		Journal of Evidence-Based Social Work	
Cancer		Journal of Evidence-Informed Social Work	
Clinical Psychology: Science and Practice		Journal of Health Services Research & Policy	
Community Mental Health Journal		Medical Care	
Ethnicity and Disease		Palgrave Communications	
Health Affairs		Pilot and Feasibility Studies	
Health Behavior Research		Psychological Services	

Table 3.2. Continued: Other journals experts deemed important in view of identification of IS articles (*n* = 31).

Journals that were denoted once each	
Health Services Research	Research on Social Work Practice
International Journal for Equity in Health	Social Science & Medicine
International Journal of Mental Health Systems	Stanford Social Innovation Review
JAMA Dermatology	The Gerontologist
JAMA Oncology	The Journal of Behavioral Health Services & Research

3.4.4 Comments of experts

Using a free-text comment box, twelve experts provided comments and confirmed the described challenges in identifying IS literature. Using content analysis, we developed three categories: 1) A plethora of terms used for IS: “IS articles are highly variable […] depending on how one interprets IS (even within the context of the Mittman & Eccles definition) […] It is really soiled, and even articles that appear as IS are sometimes (or even often) not really IS (i.e., way outside the conceptualization of IS, such as only focusing on implementing something vs. studying the implementation of it)” (#3; Other). 2) Methodological overlap of IS with other fields of research and scattering of IS evidence across disciplines: “There are hundreds [refers to journals; author`s note] as in my experience implementation-relevant work is now being published in almost every field […]. IS is very much an integrative field” (#1; Other). 3) Individual considerations to access relevant IS literature: “So for me it depends on the field of research: for my area, I would add the specific journals that I know where such research is published, although it might be only 2-3 articles per year” (#10; Other).

3.4.5 Journals with special calls for implementation science

We identified 12 calls for ongoing IS special issues with papers to be submitted from May 2020 to January 2021 (Supplementary Table S3.1), as well as 53 others published between 2000 and 2020 (Supplementary Table S3.2). These special issues are linked to 49 journals from various fields of research. Nine journals have published two or more IS-focused special issues: *Administration and Policy in Mental Health and Mental Health Services Research* (*n*=4); *American Journal of Preventive Medicine* (*n*=3); *Clinical Psychology: Science and Practice* (*n*=2); *Frontiers in Public Health* (*n*=4); *Health Psychology* (*n*=2); the *International Journal of Environmental Research and Public Health* (*n*=4); the *Journal of Clinical Child & Adolescent Psychology* (*n*=2); the *Journal of Community Psychology* (*n*=2); *Nursing Research and Practice* (*n*=2). The geographical location of these journals is Europe (*n*=24), US (*n* = 23) and Africa (*n*=2). They publish in open access (*n*=11), hybrid open access (*n*=31) or non-open access (*n*=7).

3.5 Discussion

Accessing and synthesizing available evidence is an essential first step in research and required to successfully bridge the gap between research and real-world settings. However, challenges to the identification of available IS evidence were already being reported a decade ago and continue to cause avoidable research waste (2, 8-11, 27). To ensure effective retrieval and reproducibility of searches, a search strategy should entail all relevant search terms for a concept to be studied—both text words and MeSH terms—that can be combined using Boolean operators. Further validated filters can be applied to support finer targeting. Previous studies about IS search filters provide an overview of relevant terms to build up search strings to identify various types of implementation research (10, 11). In addition, the recent introduction of 'implementation science' as a MeSH term for PubMed searches will certainly support researchers' literature searches.

Still, the challenge of conceptual inconsistency remains. To cope with this inconsistency, journals can be included in search strings to supplement searches using text words and MeSH terms. Our cross-sectional online survey of international IS experts provides a basic selection of such journals.

Journals identified via the work reported here correspond partly to the findings of Norton et al. (22), providing an overview of the 20 journals in which researchers focusing on dissemination and implementation most frequently found IS articles. Of Norton et al.'s 20 journals, thirteen were also considered relevant by this study's experts (22). Inter-study differences in those journals' perceived relevance may be due to sampling differences: 73.6% of Norton et al.'s participants were from the US. Our study shows that some studies' perceived relevance depends on the experts' geographical location, which might be related to geographic differences in IS operationalization.

Another challenge in identifying IS-relevant evidence is the heterogeneity and fragmentation of IS across research fields and disciplines which is highlighted by the variation of journals identified in our survey (4, 6, 10, 11). Our experts also noted and reflected on this, as evidenced by their comments and journal recommendations. As IS is inherently multidisciplinary, articles can be published in diverse journals and databases. This is reflected in the wide and growing range of journals publishing special IS issues. This heterogeneity and rapidly increasing complexity are not only major challenges to IS researchers, but indicators of the barriers other clinical researchers also encounter daily in their fields. And if these challenges impede researchers' access to effective evidence, then the first crucial step of research—identification of that evidence—is impossible.

This work's most notable strength is its inclusion of an international expert panel. We had a high response rate. However, our sampling approach might have resulted in underrepresentation of IS experts from Canada or Australia and underrepresentation from some regions (e.g., Africa, Asia, or South America) as we were not able to identify IS experts in the latter continents. Our difficulty to identify experts in certain parts of the world might point to the major potential for IS activities in those areas (28, 29). Further, we carefully selected our 12 pre-defined journals based on a prior systematic literature search. However, as mentioned by our experts, the survey list focused almost exclusively on IS-specific journals, excluding subject-specific journals, which are also publishing increasingly articles on IS. To maintain a flexible perspective, we provided a free text box to add further journals perceived as relevant by the experts. But no major additions appeared, despite the journals Implementation Science Communications and Administration and Policy in Mental Health and Mental Health Services Research. By that, our search strategy provides a very pragmatic approach to assessing relevant IS evidence effectively. To ensure a more comprehensive identification of specific subject related IS studies, further journals might be added to our list. In that regard, a network analysis might be an objective way forward to evaluate journal`s influences and relationships. Network analysis requires a subset of all possible IS-related journals. However, identification of all relevant journals through a literature search in a field as scattered and as fast evolving than IS would be prohibitive. Therefore, our list of ranked journals might inform network analysis about IS journals as already published in the field of information systems (30). In accordance with the regulations of the University Ethics Committee, our survey was anonymized. Therefore, we were not able to account for nonresponse bias, i.e., to assess how respondents vary from non-respondents, which might potentially bias the results.

Since IS rapidly develops, terminology evolves and further journals will arise. Our approach to access relevant IS evidence should be further developed or alternative approaches considered. Testing those approaches against each other will help to quantify differences in effectivity. As subjectively derived search strings (expert based) are often prone to methodological criticism, the development of objectively derived search strategies (research based) could be an alternative approach to identify IS journals (31). This approach entails a four-step process: first, a subset of IS journals is generated, of which a search strategy is developed in a second step to identify this subset journals. Third, the developed search strategy is validated against a validation set containing different journals and finally the process is documented (31). However, key for developing empirical search strings is the availability of papers relevant to the studied topic in order to achieve sufficient sensitivity (close to 90%).

3.6 Conclusion

Overall, based on expert ratings, this study illustrates the perceived relevance of journals publishing IS-relevant articles. We found considerable international variability in these journals' relevance ratings. Considering literature searches' importance to the research process, this information will simplify and accelerate the development of reproducible searches for IS articles.

However, variations in terminology and conceptualization cause inconsistency in interregional and interdisciplinary research; challenges in identifying and reviewing IS evidence from outside the most accessible sources remain. Investing more time to develop reproducible search strings to capture IS evidence would be an important step in improving IS research quality.

3.7 References

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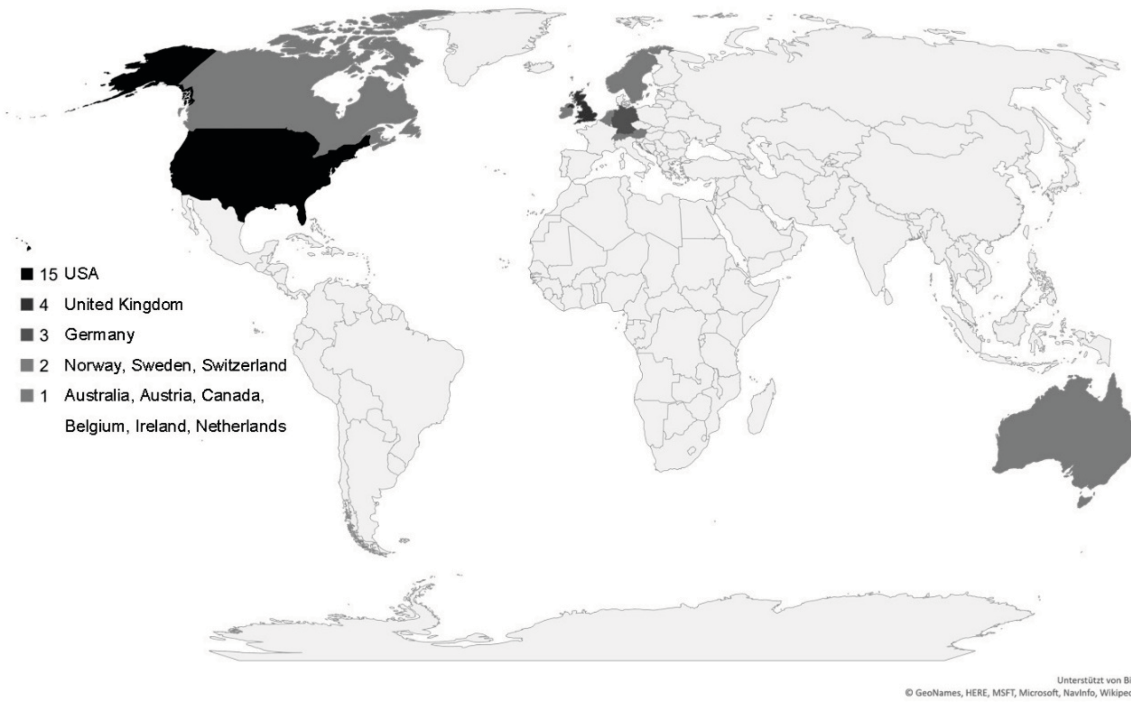
3.8 Supplementary Material

3.8.1 Supplementary Figure S3.1



3.8.2 Supplementary Table S3.1. Overview of calls for implementation science special issues (from year 2000 to January 2021)

Journal name	Title special issue	To be submitted	IF [a] / *h*-index [b]	Country
Pilot and Feasibility Studies *	Implementation science and practice: pilot and feasibility studies from the field	2020	1.760 / 12	UK
Journal of Alternative and Complementary Medicine *	Effectiveness, Implementation and Dissemination Research in Integrative Health	May 2020	1.868 / 80	US
International Journal of Environmental Research and Public Health	Closing the Implementation Gap in Reproductive, Maternal, Newborn and Child Health in Low- and Middle-Income Countries	June 2020	2.620 / 78	CH
Journal of Clinical Medicine Section Oncology *	Cancer Rehabilitation and Survivorship	Jul 2020	5.688 / 16	CH
Journal of Health Organization and Management **	Implementation Science in Health Care Organization, Management and Policy	Aug 2020	1.470 / 35	UK
Journal of General Internal Medicine **	The Inaugural Special Issue for Implementation and Quality Improvement Sciences: A New JGIM Area of Emphasis	Sep 2020	2.390 / 161	DE
Ethnicity & Disease **	Social Determinants of Health and Implementation Research: Three Decades of Progress and a Need for Convergence	Nov 2020	1.014 / 61	US
Palgrave Communications *	Expertise in Integration and Implementation for Transformative Research	Dec 2020	- / -	UK
Journal of Health Organization and Management **	Implementation Science to Practice in Healthcare Organization and Management	Dec 2020	1.470 / 35	UK
International Journal of Environmental Research and Public Health *	Air Pollution Interventions: Implementation Research and Data Driven Studies	Jan 2021	2.2620 / 78	CH
Health Psychology **	Reverse Translation: Bridging the Practice-to-Research Gap	ongoing	3.530 / 148	US
Worldviews on Evidence-Based Nursing **	Implementing and Sustaining EBP in Real World Healthcare Settings - Worldviews on Evidence-based Nursing	ongoing	2.650 / 40	UK

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is “obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times” (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020)

3.8.3 Supplementary Table S3.2. Published implementation science special issues (from year 2000 to March 2020)

Journal name	Title special issue	Volume (issue)	Published	No. of papers [c]	IF / *h*-index	Country
Journal of School Psychology **	Implementation Science in School Psychology	-	in progress	6	3.920 / 83	UK
Frontiers in Public Health; Public Health Policy *	Implementing Public Health Policy Initiatives	-	closed	2	1.680 / 28	CH
Health Policy and Planning **	Innovations in implementation research in low- and middle-income countries	-	closed	-	2.717 / 80	UK
Journal of Clinical and Translational Science *	Dissemination and Implementation Sciences in Translational Science	-	closed	-	- / -	UK
Administration and Policy in Mental Health and Mental Health Services Research **	From Research Training to Scientific Advancement: Contributions from the Implementation Research Institute	47(2)	2020	15	2.550 / 58	DE
Frontiers in Public Health -Public Health Policy & Frontiers in Pharmacology - Pharmaceutical Medicine and Outcomes Research *	New Horizons in Health-Promoting: From Methods to Implementation Science	-	2020	2	1.680 / 28	CH
International Journal of Environmental Research and Public Health *	Implementation of Interventions in Public Health	17(4), 1281	2020	6	2.620 / 78	CH
Journal of Community Psychology **	Applications of translation and implementation science to community psychology	-	2020	13	2.120 / 76	US
Journal of Nursing Scholarship **	Special Issue – Journal of Nursing Scholarship: Implementation Science	52(1), p. 1-123	2020	13	2870 / 72	UK

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is “obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times” (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020); [c] number of papers published in the special issue

Journal name	Title special issue	Volume (issue)	Published	No. of papers [c]	IF / *h*-index	Country
Psychiatry Research **	Introduction to Implementation Science: Increasing the Public Health Impact of Research	283	2020	13	2.370 / 118	NL
AIDS and Behavior **	Project SOAR: using implementation science to accelerate progress toward achieving the 90-90-90 goals	23(2), Suppl.	2019	13	2.950 / 90	NL
Frontiers in Public Health; Public Health Education and Promotion; Aging and Public Health *	Use of the RE-AIM Framework: Translating Research to Practice with Novel Applications and Emerging Directions	-	2019	15	1.680 / 28	CH
Frontiers in Public Health; Translational Medicine; Public Health Education and Promotion *	Methods and Applications in Implementation Science	-	2019	20	1.680 / 28	CH
International Journal of Environmental Research and Public Health *	Implementation Research in Chronic Disease Prevention and Control	16(8), 1403	2019	6	2.620 / 78	CH
Journal of Acquired Immune Deficiency Syndrome (JAIDS)	Implementation Science in the HIV Response: Methodological Challenges and Novel Directions	82, Suppl. 3	2019	24	3.863 / 142	US
Preventive Medicine **	Implementation science and population approaches to improve equity in cancer prevention and control	129, Suppl.	2019	14	3.470 / 154	US
Annals of the New York Academy of Sciences **	Implementation Research and Practice for Early Childhood Development	1419	2018	19	4.320 / 225	US

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is “obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times” (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020); [c] number of papers published in the special issue

Journal name	Title special issue	Volume (issue)	Published	No. of papers [c]	IF / *h*-index	Country
Behavior Therapy **	The Intersection of Implementation Science and Behavioral Health	49(4), p. 477-642	2018	8	3.550 / 97	US
Clinical Psychology: Science and Practice **	What are we even trying to implement? Considering the relative merits of promoting evidence-based protocols, principles, practices, or policy	25(4)	2018	11	5.800 / 96	US
Journal of Social Work Education **	Integrating Evidence-Based Practice and Implementation Science into Academic and Field Curricula	56, Suppl. 1	2018	11	1.110 / 49	UK
Substance Abuse	Implementation and Quality Improvement: Applying and Advancing Best Practices in Opioid Use Disorder and Addiction Treatment	39(2)	2018	22	2.350 / 39	US
The Journal of the American Board of Family Medicine *	Advancing the Science of Implementation in Primary Health Care	31(3)	2018	21	1960 / 73	US
Pan American Journal of Public Health *	Improving Program Implementation through Embedded Research (iPIER)	41	2017	12	0.930 / 51	US
Prevention Science **	Challenges to the Dissemination and Implementation of Evidence-Based Prevention Interventions for Diverse Populations	18(6)	2017	13	2.740 / 76	NL
Research in Social and Administrative Pharmacy **	Implementation Science	13(5), p. 889-1036, A1-A8	2017	18	3.130 / 37	NL

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is “obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times” (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020); [c] number of papers published in the special issue

Journal name	Title special issue	Volume (issue)	Published	No. of papers [c]	IF / *h*-index	Country
Administration and Policy in Mental Health and Mental Health Services Research **	System-Level Implementation of Evidence-Based Practices	43(6)	2016	14	2.550 / 58	DE
Journal of Substance Abuse and Treatment **	Introduction to the Special Issue on the Studies on the Implementation of Integrated Models of Alcohol, Tobacco, and/or Drug Use Interventions and Medical Care	60, P1-5	2016	15	2.620 / 93	NL
International Journal of Behavioral Medicine **	Research to Reality: The Science of Dissemination and Implementation in Behavioral Medicine	22(3)	2015	16	1.990 / 56	US
Journal of Clinical Child & Adolescent Psychology **	Toward Implementing Physiological Measures in Clinical Child and Adolescent Assessments	44(2)	2015	11	4.240 / 122	US
Maternal and Child Nutrition *	Learning to Effectively Deliver and Promote Adherence in Micronutritient Powder Programs Through Implementation Research	15, Suppl. 5	2015	8	3.350 / 51	UK
Research on Social Work Practice	Houston Bridging the Research–Practice Gap Symposium	25(4)	2015	16	1.430 / 56	US
Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen **	Das Hohelied der Implementierung wissenschaftlich gesicherter Maßnahmen in die Gesundheitsversorgung [Song of songs about implementation of proven health careinterventions]	109(2), p. 93-194	2015	14	0.820 / 26	NL

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is “obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times” (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020); [c] number of papers published in the special issue

Journal name	**Title special issue**	**Volume (issue)**	**Published**	**No. of papers [c]**	**IF / *h*-index**	**Country**
Journal of Clinical Child & Adolescent Psychology **	Mixed methods and qualitative research in dissemination and implementation science	43(6)	2014	7	4.240 / 122	US
Journal of Evidence-Based Social Work **	Implementation Research	11(1-2)	2014	19	- / -	US
Administration and Policy in Mental Health and Mental Health Services Research **	Optimizing Mixed Methods for Implementation Research in Large Systems" and "Regular Papers"	42(5)	2013	14	2.550 / 58	DE
American Journal of Preventive Medicine **	Implementing Pre-Exposure Prophylaxis (PrEP) in the U.S.: Moving From Evidence to Practice	44(1), Suppl.2, S59-S172	2013	22	4.435 / 193	NL
Clinical Psychology: Science and Practice	Advances in Applying Treatment Integrity Research for Dissemination and Implementation Science	20(1), p. 1-126	2013	10	5.800 / 96	US
International Journal of Nursing Studies **	Implementation Science	50(4), p. 443-582	2013	14	4.030 / 91	UK
Nursing Research and Practice *	Dissemination and Implementation Research: Intersection between Nursing Science and Health Care Delivery	2013	2013	8	- / -	EG
American Journal of Community Psychology **	Advances in Bridging Research and Practice Using the Interactive System Framework for Dissemination and Implementation	50(3-4)	2012	24	2.120 / 99	US
Depression Research and Treatment *	Implementation Research: Reducing the Research-to-Practice Gap in Depression Treatment	2012	2012	11	2.170 / 21	EG

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is “obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times” (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020); [c] number of papers published in the special issue

Journal name	Title special issue	Volume (issue)	Published	No. of papers [c]	IF / *h*-index	Country
Administration and Policy in Mental Health and Mental Health Services Research **	Implementing Evidence-Based Practices	38(1)	2011	6	2.550 / 58	DE
New Directions for Evaluation	Knowledge Utilization, Diffusion, Implementation, Transfer, and Translation: Implications for Evaluation	2009(124)	2009	8	0.220 / 35	US
Research on Social Work Practice **	-	19(5)	2009	19	1.430 / 56	US
Journal of Public Health Management and Practice **	Accelerating the Management from Research to Practice	14(2)	2008	18	1.050 / 46	US
American Journal of Preventive Medicine **	The Dissemination and Utilization of Prevention Research: Increasing Our Knowledge and Understanding	33(1), Suppl., S1-S80	2007	7	4.435 / 193	NL
Nursing Research and Practice *	Knowledge Translation Research: Advances in Theory and Methods	56, Suppl. 1 4	2007	13	- / -	EG
AIDS Education and Prevention	-	18(4), Suppl. A, 1-2	2006	16	2.040 / 68	US
American Journal of Preventive Medicine **	Diffusion and Dissemination of Physical Activity Recommendations and Programs to World Populations	31(4), Suppl.	2006	12	4.435 / 193	NL
American Journal of Public Health **	Diffusion of Innovations	96(2)	2006	23	4.210 / 236	US
Health Psychology **	Dissemination	24(5)	2005	11	3.530 / 148	US

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is “obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times” (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020); [c] number of papers published in the special issue

Journal name	Title special issue	Volume (issue)	Published	No. of papers [c]	IF / *h*-index	Country
Journal of Health Communication **	-	9, Suppl. 1	2004	14	1.773 / 75	UK
Journal of Community Psychology **	Bridging the Gap Between Research and Practice in Community Based Substance Abuse Prevention	28(3), p. 237-373	2000	10	2.120 / 76	US

* Open access; ** hybrid open access; [a] IF = impact factor; [b] *h*-index = indicates the journals scientific impact (number of publications) and productivity (number of publications), it is defined as the maximum value of *h* which is "obtained if [a journal] has [*h*] publications that have all been cited at least [*h*] times" (1), the journals` *h*-index were obtained from Scopus (last update 28.05.2020); [c] number of papers published in the special issue

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Chapter 4.

Unravelling implementation context: The Basel Approach for coNtextual ANAlysis (BANANA) in implementation science and its application in the SMILe project

Juliane Mielke[1], Lynn Leppla[1,2], Sabine Valenta[1,3], Leah L. Zullig[4], Franziska Zúñiga[1], Sandra Staudacher[1,6], Alexandra Teynor[5], Sabina De Geest[1,7]

[1] Institute of Nursing Science, Department Public Health, University of Basel, Basel, Switzerland

[2] Department of Hematology, Oncology, and Stem-Cell Transplantation, Medical Center Freiburg, University Hospital Freiburg, Germany

[3] Department of Theragnostic, Hematology, University Hospital Basel, Switzerland

[4] Center for Innovation to Accelerate Discovery and Practice Transformation (ADAPT), Durham; Veterans Affairs Health Care & System; and Department of Population Health Sciences, School of Medicine, Duke University, Durham, NC USA

[5] University of Applied Sciences Augsburg, Faculty of Computer Science, Germany

[6] Department of Health Services Research, Care and Public Health Research Institute, Maastricht University, 6229 GT Maastricht, The Netherlands

[7] Academic Center for Nursing and Midwifery, Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium

Manuscript will be submitted to Implementation Science

4.1 Abstract

Background

Designing intervention and implementation strategies with careful consideration of context is essential for successful implementation science projects. Although the importance of context has been emphasized and methodology for its analysis is emerging, researchers have little guidance on how to plan, perform and report contextual analysis. Therefore, this study's aim was to describe the Basel Approach for coNtextual ANAlysis (BANANA) and to demonstrate its application on an ongoing multi-site, multiphase implementation science project to develop/adapt, implement and evaluate an integrated care model in allogeneic SteM cell transplantatIon facILitated by eHealth (the SMILe Project).

Methods

BANANA builds on a guidance for assessing context by Stange and Glasgow (2013). Based on a literature review, it was further developed in ten discussions with implementation science experts and a medical anthropologist to guide the SMILe project's contextual analysis. BANANA's theoretically basis is the Context and Implementation of Complex Interventions (CICI) framework. Working from an ecological perspective, CICI differentiates clearly between context and setting (the implementation's physical location).

Results

BANANA entails six steps: 1) choose a theory, model or framework (TMF) to guide the contextual analysis; 2) use empirical evidence derived from primary and/or secondary data to identify relevant contextual and setting factors; 3) involve stakeholders throughout contextual analysis; 4) choose a study design to assess context and setting; 5) determine contextual factors' relevance to implementation strategies/outcomes and intervention co-design; and 6) possibly in a separate paper, following appropriate reporting guidelines, report on the contextual analysis as part of the implementation study. Partly run simultaneously, the first three steps form a basis both for the identification of relevant contextual and setting factors and for the next steps.

Discussion

Understanding contextual factors is indispensable for a successful implementation science project. BANANA provides much-needed methodological guidance for contextual analysis. In subsequent phases, it helps researchers apply the results to intervention development/adaption and choices of contextually tailored implementation strategies. For future implementation science projects, BANANA's principles will guide

researchers first to gather relevant information on their target context, then to target their use of that information to fulfill their implementation goals.

4.2 Contributions to the literature

- We provide a comprehensive, stepwise approach to guide contextual analysis in implementation science, i.e., the Basel Approach for coNtextual ANAlysis (BANANA).
- BANANA specifically provides guidance on how to combine theories, models and frameworks, how to use empirical evidence in contextual analysis, how to choose a study design for assessing context and setting, how to use findings from the contextual analysis to inform subsequent phases of an implementation science project (e.g. intervention development/ adaption, implementation strategies), and how to report contextual analyses.
- Using a case example, we demonstrate a successful application of BANANA in an ongoing implementation science research project.

4.3 Background

Over the past two decades, the importance of context and setting for a successful and sustainable implementation has gained significant attention in implementation science (IS) (1-3). Context can be defined as “a set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded” (4). Context is multi-level, multi-dimensional and dynamic. It interacts with an intervention and its implementation in the setting, i.e., the “physical location, in which an intervention is put into practice” (4).

Contextual analysis is increasingly recognized as vital to IS methodology; yet no unified definition of contextual analysis in IS yet exists. We understand contextual analysis as a separate phase within IS projects to which specific research questions and IS theories, models or frameworks (TMFs) are applied (2, 5, 6). It entails the mapping of relevant qualitative and quantitative information about the context and setting (e.g., implementation determinants, practice patterns) in which an intervention will be delivered. Starting (prospectively) at the beginning of each IS project, the results of the contextual analysis become the basis of all subsequent phases of an IS project: they inform intervention development or adaption, guide choices regarding implementation strategies, help their users interpret implementation and effectiveness outcomes, and clarify possible sustainability strategies (7-10). As the context evolves additional assessments throughout the project might be necessary.

While contextual analyses' value is widely accepted, guidance on how to conduct one is lacking. Conceptual inconsistencies between the applied methods and approaches hamper the development of a standardized approach (11). In their systematic review of 64 empirical implementation studies, Rogers et al. identified over 40 distinct strategies to study context via quantitative, qualitative and mixed-methods approaches (11). Whereas assessment of contextual factors often focuses on the meso level (e.g., organizational culture and climate, readiness for implementation), macro-level factors (e.g., political and economic climate) are rarely considered (12-16).

Theories, models and frameworks (TMFs) can provide guidance on which contextual factors to study, but not on how to study context *per se* (17-19). Commonly applied TMFs that incorporate context include the Consolidated Framework for Implementation Research (CFIR) (20), the Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework (21) or the Theoretical Domains Framework (TDF) (22). This emphasis on theory contrasts with an increasing number of IS studies that focus on mapping single facilitators and barriers to implementation, but that follow no specific theory. This absence both obscures the researchers' rationale for choosing their variables and limits theoretical development based on empirical evidence. Along with any multi-level perspective, they also commonly lack assessments of interactions between context, intervention and implementation (11, 15, 23-27). And what contextual information they generate is rarely linked to subsequent phases in their IS project (28). In cases where contextual analysis is treated not as a separate foundational phase of an implementation science project, but as an add-on, contextual data are commonly only performed retrospectively, as part of a process evaluation (19, 29). This obviously excludes any chance of applying any contextual information to the IS project`s next phases. Further, as findings of contextual analyses are rarely published, valuable methodological observations cannot be applied to later projects to scale the implemented interventions up (30).

As part of a series of guidelines commissioned by the Agency for Healthcare Research and Quality, Stange and Glasgow (2013) (31) attempted to provide an initial step-wise approach to assessing and reporting contextual factors throughout the phases of patient-centered medical home research. While this approach was not initially developed for implementation science projects, it lacks further details on the operationalization of context/setting, specific methods to assess context and the use of contextual information to inform later IS project phases. To fill these gaps, we developed the Basel Approach for coNtextual ANAlysis (BANANA), a six-step approach to contextual analysis in IS projects. Accordingly, this paper has two objectives: first, to describe the six steps of BANANA; and second, to describe its application of BANANA to the SMILe project (Table 4.1).

Table 4.1. Description case example SMILe project (1-3)

Background

Follow-up care of allogeneic hematopoietic stem cell transplanted (alloSCT) patients is challenged due to growing numbers of alloSCT transplant survivors who have complex care needs. Current follow-up models are biomedically driven rather than focusing on behavioral, psychosocial and self-management support elements.

Aim SMILe project

SMILe is an implementation science project to develop, test and implement an eHealth facilitated integrated care model (ICM) in allogeneic stem cell transplantation (SMILe–ICM).

Methods

SMILe is a multi-site project consisting of Phase A (contextual and technology acceptance analysis and development of intervention and implementation strategies) and Phase B (implementation and testing of the intervention). Phase A has been completed in two transplant centers in Germany and Switzerland, further centers in Belgium and Switzerland will follow. The SMILe–ICM is currently being implemented and tested (Phase B) using a hybrid type 1

Table 4.1. Continued: Description case example SMILe project (1-3)

effectiveness-implementation design at two study sites in Germany and Switzerland, first results are expected in 2022 and 2023.

Intervention

The SMILe–ICM is based on the eHealth enhanced Chronic Care Model and targets patients, health care providers and the system (4). It includes a human and an eHealth component. The human component is an Advanced Practice Nurse (SMILe Care Coordinator), who provides self-management support and health behavior promotion via face-to face visits (2, 5). The SMILe App (eHealth component) allows the patient to enter values on a daily basis and send them to the transplant center. Via SMILeCare, the Smile Care Coordinator can overview incoming data regularly, allowing early detection of health deterioration. Face-to-face visits can be adapted according to patients' needs.

Contextual analysis – aims

The aims of the contextual analysis were as follows: (1) to identify the target organization's structural characteristics and practice patterns in view of chronic illness management; (2) to assess how self-management and behavioral support is currently supported; (3) to assess the technology openness of clinicians and alloSCT patients regarding eHealth use along the eCCM dimensions; and (4) to explore facilitators and barriers to SMILe-ICM implementation (only assessed in second study site to date).

4.4 Methods

To develop BANANA, we used a multiphase approach. First, we conducted a literature review, focusing on methodological IS papers available via major electronic data bases (PubMed, EMBASE and Web of Science). In order to identify existing methodological approaches for contextual analysis, we also and screened the identified papers' reference lists. The only authors to provide an overview of an entire contextual analysis was Stange and Glasgow (2013) [32]; others addressed only individual aspects such as use of TMFs, or methods to study context (2, 11, 31). Therefore, we based BANANA on their approach, adapting it as necessary to guide a contextual analysis first for the SMILe project, then for implementation science projects in general. Briefly, SMILe is a multi-site, multiphase IS project. Its aim is to develop/adapt, implement and test an integrated care model (ICM) in allogeneic SteM cell transplantatIon faciLitated by eHealth (SMILe–ICM) (32, 33). Phase A of the SMILe project entailed analyzing the context and target users' technology acceptance, as well as developing, adapting and extending the SMILe-ICM and its setting-specific implementation strategies (34-37). In fact, BANANA was originally developed to guide contextual analysis in this phase (34). Phase B focused on the SMILe-ICM's implementation and evaluation using a hybrid effectiveness-implementation randomized controlled trial (32, 33).

Second, research group members (SDG, LL, SV, AT, JM) consulted with IS experts (LLZ, FZ) and a medical anthropologist (SS) in iterative discussion sessions about the identified literature and how to elaborate Stange and Glasgow's approach for SMILe.

Our understanding of context was theoretically based on the Context and Implementation of Complex Interventions (CICI) framework (4). CICI is a meta-framework that explicitly focuses on the multilevel, dynamic context, i.e., interactions between intervention, implementation and context. CICI operationalizes context across seven domains (geographic, epidemiological, socio-cultural, socio-economic, political, legal-ethical). Each of these entails micro-, meso-, and macro-level contextual factors. CICI differentiates between setting and context, defining it as the physical location in a context in which an intervention is implemented (4). In the setting interactions between the intervention, the implementation and the other contextual factors occur. Thus, contextual analysis includes an assessment not only of contextual aspects but also of the setting in which the implementation takes place. After ten discussion rounds between all study authors, we reached consensus on BANANA. After that, no further adaptions were made.

4.5 Results

The BANANA approach entails six steps (Table 4.2): 1) choosing a theory, model or framework (TMF); 2) using empirical evidence; 3) involving stakeholders; 4) designing a study specifically for the contextual analysis; 5) determining the relevance of contextual factors for implementation strategies/outcomes and intervention co-design; 6) reporting on the contextual analysis. BANANA is explained in detail below; for each step, an example from the SMILe project is provided (Table 4.1). For each of these steps, further key resources (e.g., papers or websites) can be found in Additional file 1.

Table 4.2. Description of the six steps of Basel Approach for coNtextual ANAlysis (based on Stange and Glasgow, 2013 (1))

Step 1	**Choice of a theory, model or framework (TMF)** Considerations when selecting a TMF for contextual analysis – TMF acknowledges the multidimensional, multilevel and dynamic nature of context – TMF fits the intervention and/or setting in which the intervention will be implemented *Consider combination of a context and setting specific TMF*
Step 2	**Use of empirical evidence** Identification of empirical evidence on relevant contextual and setting factors for implementation using – Local data and information – Professional knowledge/clinical experience – Patient experiences and preferences – Research (primary or secondary data)
Step 3	**Stakeholder involvement[1]** – Identification and listing of relevant stakeholders for contextual analysis (target group, implementers, decision makers, other) from different levels (micro-, meso-, macro) – Mapping of stakeholders in a stakeholder matrix specifying their characteristics (e.g., influence, role, activity, product) – Visualizing stakeholder characteristics in an influence-interest-capacity matrix – Verifying stakeholder availability and commitment – Developing a stakeholder strategy specifying stakeholder tasks, timepoints and methods for involvement – Evaluation of stakeholder involvement and adaption if needed
Step 4	**Study design for contextual analysis** Data collection is guided by theory, empirical evidence and stakeholder input Choice appropriate methods to answer the research questions such as – Quantitative methods (e.g., survey, routine data) – Qualitative methods (e.g., interview, focus group, observation) – (Rapid) ethnography *Consider several timepoints for data collection (e.g., prior, during and at the end of the project)*

Table 4.2. Continued: Description of the six steps of Basel Approach for coNtextual ANAlysis (based on Stange and Glasgow, 2013 (1))

Step 5	**Determining relevance of contextual factors for implementation strategies/outcomes and intervention co-design** Findings from the contextual analysis can be used for: – Development/adaption of the intervention – Choice/adaption of implementation strategies – Interpretation of implementation and effectiveness outcomes – Choice of sustainability strategies *Consider development of a program theory or a logic model to describe/visualize causal pathways between intervention components, implementation strategies and contextual factors*
Step 6	**Reporting of contextual analysis** Reporting contextual analysis as part of the implementation intervention study (detailed findings can be reported in a separate paper) Suggestions for reporting based on BANANA: – Definition of context and operationalizations of contextual and setting factors studied – TMF applied for contextual and setting analysis and description how it was used – Overview of empirical evidence identified and used – Stakeholder involvement (i.e., stakeholder strategy) – Reporting methods applied for data collection and analysis (e.g., study design, measures used, contextual and setting factors assessed) – Use of findings from the contextual analysis for subsequent project phases (cf. step 5)

Note. [1]Adapted from Barkhordarian et al. (2)

4.5.1 Step 1. Choosing a theory, model or framework (TMF) to guide contextual analysis

4.5.1.1 Identification and selection of TMFs

In general, the use of TMFs is essential in IS studies. They inform and guide all phases of implementation projects and increase the findings' generalizability (24, 38-40). Regarding contextual analysis, a TMF can serve as “a comprehensive starting point” in order to identify contextual factors that influence implementation.

The selection of a framework is often perceived as difficult, as a large number of IS and other TMFs are available (24, 38, 41, 42). Therefore, following Moullin et al.'s recommendations (43), we suggest considering four criteria when selecting a TMF: 1) it is intended/designed for contextual analysis context; 2) it acknowledges the multidimensional, multilevel and dynamic nature of context; 3) it includes guidance on operationalization of concepts (e.g., contextual factors); 4) it fits the intervention and setting.

Resources that provide an overview of TMFs or support the identification, selection and combining of TMFs include key IS papers (2, 24, 41, 44) and websites such as https://dissemination-implementation.org/. To justify and report TMF selection, the implementation theory comparison and selection tool (T-CaST) can provide useful guidance (38). Based on 16 criteria relating to applicability, usability, testability and acceptability, T-CaST provides a first attempt to select and compare TMFs (38). Further, to ensure a TMF's fit and applicability for a specific setting and/or context, stakeholders can be involved (cf. Step 3) (43).

4.5.1.2 Combining of TMFs for context and setting

As context differs from the setting where the intervention is delivered, we suggest the combination of a context- and setting-specific TMF, as such combinations enhance the granularity of contextual analysis. While context-specific TMFs provide an overview of factors that may influence implementation (e.g., socio-cultural characteristics), setting-specific TMFs indicate factors that influence a specific intervention's implementation in a specific setting (e.g., site characteristics, practice patterns, work flows and processes within that setting). A broad variety of TMFs are available for specific settings and/or interventions, e.g., the Chronic Care Model (45), or the Primary Care Practice Development Model (46).

Case example – Use of TMFs in the SMILe project

In the SMILe project, we chose the CICI framework as an overarching framework for contextual analysis. In our view, as it acknowledges contextual dynamics and distinguishes between context and setting, it is currently the most mature framework available. Working with the CICI framework, we assessed relevant micro- and meso-level contextual factors from the three context domains—geographic (i.e., internet access, type of connection), epidemiological (i.e., patient demographics), and socio-cultural (i.e., self-management, health behavior). We did not explicitly assess further contextual factors. As SMILe project leaders are themselves part of the transplant teams, they have been working for years within the SMILe-ICM's implementation setting. Thus, they had implicit contextual knowledge, for example, of the organizational culture, leadership and legal aspects (macro-level factors).

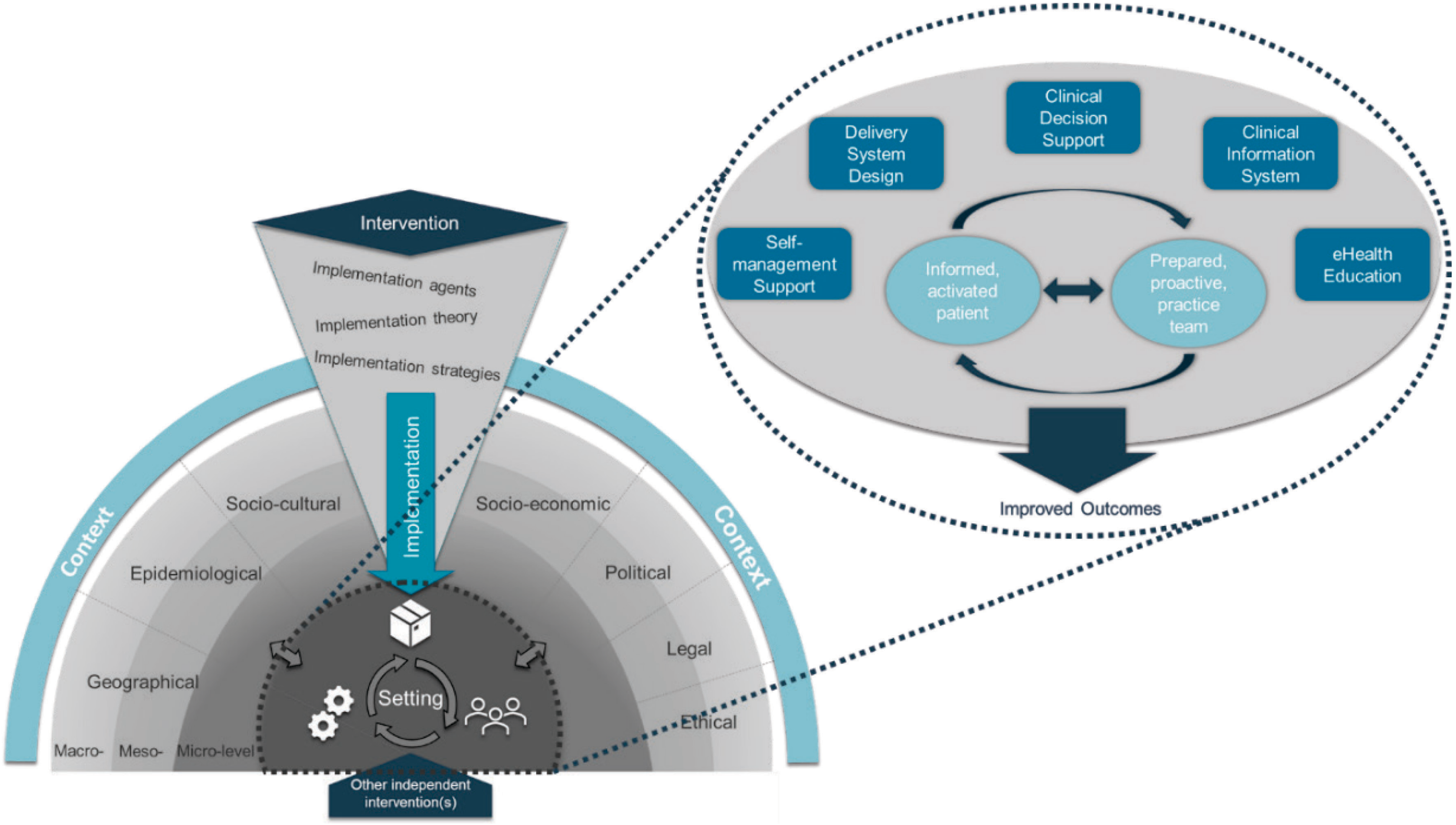

Figure 4.1. Combination of the Context and Implementation of Complex Interventions (CICI) framework (4) and the eHealth Enhanced Chronic Care Model (eCCM) (47) to guide contextual analysis within the SMILe project
Figure adapted from Pfadenhauer et al. (4) and Gee et al. (47)

As the SMILe project's focus is on developing and implementing an eHealth ICM, we combined the CICI framework with the eHealth Enhanced Chronic Care Model (eCCM) to gain a deeper understanding of the target setting (the stem cell transplant center) (Figure 4.1) (4, 47).

The eCCM supports the re-design of acute care-oriented processes towards chronic illness management (45, 47). The SMILe researchers assessed factors from the model's five building blocks (i.e., self-management support, delivery system design, clinical decision support, clinical information systems, eHealth education). Micro-level factors of interest included self-management support and technology openness; on the meso level, they included transplant center structural characteristics, practice patterns in follow-up care, the level of chronic illness management, team composition and clinician demographics (47). Macro-level factors were considered but not explicitly assessed and reported (e.g., legal aspects).

4.5.2 Step 2. Using empirical evidence for contextual analysis

TMFs provide a comprehensive overview of how context is conceptualized and which context factors are relevant for implementation. However, not all aspects mentioned in the TMFs are relevant to each IS project therefore using empirical evidence can foster decision making on which factors to include (4). Four sources of evidence exist, that is 1) local data and information; 2) professional knowledge/clinical experience; 3) patient experiences and preferences; and 4) research (48). The first three can be considered through stakeholder input (cf. step 3); local data can be also identified e.g. by studying audit and performance data. To assess evidence from research, a literature review can be conducted and relevant contextual factors influencing implementation can be identified (4, 11, 49). Additional file 2 provides an overview of the micro-, meso- and macro-level implementation-influencing contextual factors we identified (via our systematic review) as the most commonly reported (11, 13, 27, 50). Additionally, Rogers et al.'s review identified team-level factors (e.g., team characteristics and teamwork, team stability, morale) important to implementation (11).

Reviews such as these provide broad views of relevant contextual factors. However, whenever possible, researchers need to consider evidence on implementation determinants for specific interventions, target groups or settings. Such reports might provide precise information e.g., on specific facilitators and barriers, that apply directly to other contexts. For example, Evans et al. developed a research toolkit to study organizational contextual factors influencing the implementation of ICMs (51). That toolkit includes a framework as well as an overview of measurement tools and methods to study those factors.

Case example – Use of empirical evidence in the SMILe project

In order to optimally target the SMILe contextual analysis, all sources of evidence were used. First, a literature review revealed limited evidence on follow-up practice patterns in allogeneic stem cell transplanted patients. This indicated a need to assess those patterns as part of our contextual analysis (52). Other identified studies reported on challenges with eHealth implementation (e.g., high drop-out rates in studies, low adoption rates of eHealth interventions and problems with acceptance) (53-56), including relevant contextual factors that tend to hinder implementation (e.g., technology acceptance, interoperability of technology, financial resources) (57-61). Based on the factors identified, questionnaire surveys and interview guides for contextual analysis were chosen—and, if necessary, complemented—to clarify our picture of the studied context. For example, as part of the contextual analysis, target patients' technology openness was assessed and patients' and clinicians' experiences using eHealth to support health or healthy behaviors explored (34, 62).

Second, in addition to the literature review, our studies in allogeneic stem cell transplantation as well as clinical experience of the SMILe team and patient feedback highlighted the challenges patients face in trying to improve their self-management behavior, e.g., medication non-adherence or physical activity (52, 63). Based on this evidence, we added specific questions about self-management challenges and how to overcome them to our interviews and focus groups (34).

Finally, information on the setting`s resources (e.g., financial, staffing) and operability of the IT system were gained in individual, informal stakeholder meetings.

4.5.3 Step 3. Stakeholder involvement in contextual analysis

Stakeholder involvement is essential at every step of a contextual analysis. Stakeholders are “those individuals [or organizations] without whose support and feedback an organization, or a project within an organization [or beyond] cannot subsist” (64). They can be individuals or organizations targeted or affected by an intervention (e.g., patients and caregivers), actively implementing an intervention (e.g., health care practitioners), or deciding on whether it will be implemented (e.g., organizational leaders, policy makers) (4, 65-68). It is also possible to ask input from specific experts (e.g., epidemiologists, researchers) on dedicated topics.

4.5.3.1 Identification of stakeholders and development of a stakeholder strategy

The matter of which stakeholders to involve in contextual analysis always depends on the project's specific focus (64). Essentially, stakeholder selection must be systematic. This means involving multiple stakeholder perspectives from every relevant level (micro, meso, and/or macro), while balancing power and bridging inter-group disparities, e.g., between patients and care specialists. Identified stakeholders can be mapped on a matrix that specifies their characteristics, e.g., role, degree of influence, anticipated effects and outcomes of involving them (64). An influence-interest-capacity matrix can be useful for this purpose (64). To help ensure productive and robust stakeholder involvement, one key tool is a well-developed stakeholder strategy. This indicates which and how stakeholders will be involved at each step of the contextual analysis, specifies each group's tasks, and outlines methods or tools to involve each group.

Throughout the project, continuous changes in context require continuous involvement of the stakeholders, for example, via regular stakeholder meetings (10, 30). Furthermore, their needs must be continuously evaluated and adapted as necessary.

4.5.3.2 Stakeholder tasks and tools for involvement

Currently no specific guidance is available regarding stakeholder involvement in IS projects. However, general guidelines such as INVOLVE (69) or the PARADIGM Patient Engagement Toolbox (https://imi-paradigm.eu/) can support researchers to identify relevant stakeholders for contextual analysis, plan stakeholder tasks throughout contextual analysis and choose tailored tools for stakeholder involvement.

Within a contextual analysis, stakeholder tasks can include helping to choose a TMF, identifying/selecting relevant contextual factors for analysis, and evaluating and monitoring those factors throughout the project. By helping research teams interpret the findings of the contextual analysis, stakeholders can also deepen their understanding of inherent inter-factor relationships. Further tasks include supporting the development of contextually adapted intervention and implementation strategies (31, 43, 65, 70). In these ways, stakeholder involvement can contribute to interventions' acceptance, adoption and feasibility. I.e., engaged stakeholders will add considerably to an intervention's successful implementation and sustainment (71).

Case example – Stakeholder involvement in the SMILe project

The SMILe project involves stakeholders at multiple levels both in its contextual analysis and throughout the project (34, 37). Potential stakeholders were identified in brainstorming sessions and via one-to-one in-depth discussion. Selections were based on expert opinions provided by the SMILe research team, project leaders and clinicians working in the field. The final stakeholder group included the target group (stem cell-transplanted patients), implementers (transplant team members, e.g., in- and outpatient nurses, physicians and psycho-oncologists), decision makers (e.g., transplant directors, nursing directors and head nurses), and other stakeholders including hospital IT and medical controllers, and patients' family members. In addition to being tremendously useful in identifying the most appropriate participants for focus groups, they participated in data collection, supported interpretation of study findings, helped develop/adapt the

SMILe–ICM and helped choose/adapt implementation strategies (34, 37). Over the course of the contextual analysis, other stakeholders, including experts in medical device regulation and health insurers, were involved via individual in-depth interviews. All told, stakeholders ensured an excellent fit between the SMILe-ICM and its end-users' needs. Further, they supported its acceptability and adoption and will greatly enhance its sustainability beyond the study phase.

4.5.4 Step 4. Study design for contextual analysis

As a contextual analysis functions as a separate, ongoing study within an implementation project, it requires additional considerations regarding study design and research questions. Data collection concerning relevant contextual factors is based on theory, empirical evidence and stakeholder input (steps 1-3). The choice of methods is driven by the research questions. In addition, considering that available resources (time, funding, personnel) for contextual analysis are usually constrained, researchers need to strike a “balance between speed and rigor” (72). This balance will influence how extensively a contextual analysis can be carried out and which methods can be applied (73).

4.5.4.1 Methods and measurement tools to study context

To deepen the research team's understanding of the context, a combination of quantitative and qualitative methods is typically used (11, 74, 75). Where mixed-methods approaches are used (76-79), the overall focus can be on quantitative data, qualitative data, or any supported mix of the two (76, 80).

Quantitative methods include numerous types of surveys (e.g., online surveys, paper-pencil questionnaires, telephone surveys), systematic interviews, direct observations, or routine data. Quantitatively assessed contextual factors include implementation climate, organizational culture and climate, available resources, and readiness for change.

Several reviews provide overviews of current measurement tools and their psychometric properties (14, 15, 25, 81-86). Further—for instance, on the CFIR and EPIS framework project websites (respectively, https://cfirguide.org/ and https://episframework.com/)—measurement and data extraction tools are available to assess aspects of context mentioned in the frameworks. However, before applying any such measurement tools, research teams must ensure that they are appropriate for their intended use, produce psychometrically sound results, and will be used consistently over time to ensure comparability of results (cf. timepoints for data collection) (16).

To explore qualitative contextual factors, interviews (unstructured or semi-structured), focus groups, observations or document analysis can be applied (87). Qualitative methods are particularly suitable to identify stakeholders' preferences and needs, values, beliefs and attitudes and how these influence their behavior. Published recommendations for the use of qualitative methods in IS include a white paper by the National Cancer Institute (87-90). Further, for certain frameworks, such as the CFIR or CICI, interview guides have been developed to guide exploration of context constructs (4, 91).

Some of these quantitative and qualitative approaches have been criticized for focusing only on specific levels (e.g., the meso/organizational level) or “only provid[ing] a cursory view of complex and dynamic contexts” (29). However, alongside quantitative and/or qualitative methods, ethnographic methods can complement both these types of data, thereby facilitating in-depth insights in organizational and contextual processes that influence implementation. An ethnographic approach can help highlight interactions within context that remain undetected by other methods, but that may have substantial impact on the intended implementation (29). Further, details that may not be obvious to the interviewee (e.g., ritualized everyday actions, cultural and social norms) or differences between what is said and what is done can be identified via ethnographic methods (92-94).

Considering the limited resources available for contextual analysis, the current trend is toward increasingly rapid qualitative or rapid ethnographic approaches. For example, the Rapid Assessment Procedure-Informed Clinical Ethnography (RAPICE) method combines rapid assessment procedures with ethnography (72, 95). Initial evidence suggests that rapid research methods can be as effective and rigorous as traditional approaches but more time- and cost-effective (95-97). However, a research team planning on using these methods for the first time should be aware that applying them effectively and efficiently may require special training, multiple attempts and methodological adaptions to fit their research setting (96-99).

4.5.4.2 Timepoints for data collection

BANANA focusses on the prospective assessment of context, however as context evolves further timepoints for considering context should be planned through the IS project. Currently, little guidance is available regarding which contextual factors to record at which timepoints and how frequently (31, 100). Further insights may be gained from Ariadne Labs' Atlas Initiative that aims to develop a data repository of contextual factors related to the implementation success of different interventions in different settings and at different timepoints of analysis (before implementation, six weeks after implementation and monthly after that) (101, 102).

Case example – SMILe project data collection and analysis

For the SMILe contextual analysis, an explanatory mixed-methods (quantitative/qualitative) design was applied (34). Specific aims of this analysis are described in Table 4.1. Data collection and analysis were guided by the eCCM and the CICI framework. First, questionnaire surveys were conducted with each participating center's patients, clinicians and transplant director. In addition to measuring how important respondents considered eHealth applications, these questionnaires allowed us to assess each center's structural characteristics, practice patterns regarding chronic illness management, overall level of chronic illness management, current levels of support for self-management and behavioral change, and technology openness and acceptance (34). And as usual, we also gathered the demographic characteristics of patients and clinicians.

To make the necessary measurements in accordance with the eCCM's five building blocks, the research team used instruments they had applied to previous work. (62, 103-106). All questionnaires were adapted as appropriate to the allogeneic stem-cell transplant setting. In some cases, the researchers supplemented them with contextually relevant factors (e.g., patients' acceptance of symptom monitoring and data sharing) (37).

Second, to map setting-relevant factors and support our understanding of the quantitative results, we conducted focus groups with clinicians and individual interviews with patients. In both cases, our interview guides followed the eCCM's building blocks (34). In the center where we implemented the adapted version of the SMILe-ICM, as part of our focus group discussions, we explored factors facilitating or hindering the SMILe-ICM's implementation (37).

Quantitative and qualitative data were collected over a one-year period. Ongoing changes in context (e.g., changes in leadership) were noted by the SMILe project leaders and documented. The team also had regular contact with stakeholders via informal conversations and official stakeholder meetings. The data analysis followed three eCCM-guided steps: 1) analysis of quantitative (descriptive tables) and qualitative results (meta-maps); 2) mapping of quantitative and qualitative findings in a joint display; and 3) reflection on findings and their implications for intervention development and choices of implementation strategies (again in a joint display) (34, 37).

4.5.5 Step 5. Identifying and describing the relevance of contextual factors for intervention co-design, implementation strategies and outcomes

Whether a research team's goal is as immediate as the application of an implementation strategy or as far-reaching as the sustained implementation of an intervention into daily practice, their success depends heavily on how well they tailor their actions to the target context (8, 107-111).

4.5.5.1 Intervention development and selection of implementation/sustainability strategies

Numerous frameworks/guidelines help researchers develop interventions and select implementation strategies. One of these, is the Medical Research Council (MRC) guidance which describes four phases for the development and evaluation of complex interventions in healthcare: 1) developing a new intervention or identifying an already existing intervention; 2) assessing feasibility and acceptability of an intervention; 3) assessing an intervention (evaluation); and 4) implementing an intervention (111). Whereas context was previously considered mainly during process evaluation, i.e., retrospectively, this document recommends examining interactions between the intervention and context across all four of these phases (111).

Another guidance focusing on both intervention development and implementation strategies is Bartholomew, Parcel and Kok's "Intervention Mapping"—a five-step process, the foundation of which is a contextual analysis (112). Other methods that can be applied to match implementation strategies to contextual factors are concept mapping, group model building, and conjoint analysis (113).

Further, originally designed to facilitate implementation strategy choices, the CFIR–ERIC Implementation Strategy Matching Tool speeds identification of implementation strategies available in the Expert Recommendations for Implementing Change (ERIC) compilation. The ERIC compilation's strategies address specific constructs described in the CFIR framework (7). Just as with implementation strategies, specific sustainability strategies can also be selected to ensure that a successfully implemented intervention remains in clinical practice.

4.5.5.2 Adaption of interventions and implementation strategies

Even where proven intervention or implementation strategies are available, adaptions are usually required to ensure their effectiveness in a new context (107, 108, 114). However, before making changes, it is necessary to distinguish between core intervention components—which have to be implemented as they are to achieve a desired effect—and those adaptable to various contexts and settings (108). Building on the idea of Intervention Mapping, Implementation Mapping was developed for use with interventions that have already been developed and tested (25). To ensure that an adaptation is transparent and reproducible, a description should be given of which contextual details necessitate it and how the proposed adaption addresses those details (115).

Another source of guidance for adapting interventions is ADAPT, which consists of three steps: (1) assess the rationale for intervention, and consider the intervention-context fit of existing interventions; (2) plan and undertake piloting and evaluation; (3) implement and maintain the adapted intervention at scale (107). When adapting an intervention, it is always necessary to record which intervention components or implementation strategies were adapted, in which ways, and why. Frameworks such as FRAME (115) and FRAME-IS (116) can support this process.

4.5.5.3 Interpretation of implementation and effectiveness outcomes

An intervention's likely effects will vary across contexts and settings (117). The findings of the contextual analysis help to understand mechanisms that influence the implementation process (i.e., what was implemented and how well), and how these mechanisms will likely influence the intended intervention's effectiveness. Usually this step is part of a process evaluation (117).

To describe how and why a specific intervention leads to its expected effects, as well as to trace causal pathways between intervention components, implementation strategies and contextual factors, it will be necessary to development a program theory (111, 118).

Case example – Relevance of contextual analysis for development/adaption of the SMILe-ICM and implementation strategies

Contextual analysis guided the development/adaption of the SMILe-ICM and the selection of implementation strategies. All quantitative and qualitative findings were synthesized in a joint display and the intervention's implications summarized. Findings indicated gaps both in self-management (i.e., medication adherence, infection prevention, physical activity and symptom recognition) and in delivery system design (e.g., low levels of chronic illness management indicating gaps in chronic care delivery, continuity of care). Such gaps highlighted a need to re-engineer the current acute care model towards an ICM (34). Following the Behavior Change Wheel methodology, we considered the identified determinants to help us choose intervention functions and behavioral change techniques, (32, 119). As patients and clinicians were open to the use of an eHealth application, but expressed concerns that technology might replace human contact, the SMILe-ICM intervention includes both human- and technology-based components (32). The adaptions of the SMILe–ICM and its implementation strategies followed the FRAME-IS framework (37). The ERIC taxonomy was used to choose and describe context-specific implementation strategies. This process included conducting local consensus discussions, creating new clinical teams and accessing new funding (34, 37, 120). In addition, the contextual analysis itself represented a valuable implementation strategy: conducting a local needs assessment. Finally, as part of Phase B, the implementation pathway and outcomes (i.e., acceptability, appropriateness, feasibility, and fidelity) will be assessed from a patients' and healthcare providers' perspective and likely influences of context considered.

4.5.6 Step 6. Reporting of contextual analysis

As contextual analysis informs subsequent phases of an IS project—affecting, for example, intervention development—it is a critical component of that project and needs to be reported as such (121, 122). However, given the limited space available in journal articles, detailed findings of contextual analyses and their uses should be reported in separate papers. These are by no means restricted to dedicated IS journals but can also include journals with clinical focus (123). Further, a much more serious impediment to the reporting and dissemination of contextual findings is the lack of clear, comprehensive guidelines on how to report contextual analyses (121, 122). For instance, the Standards for Reporting Implementation Studies (StaRI Checklist) recommend the CFIR for reporting relevant contextual factors, however, information specifying which aspects of the contextual analysis to report are missing (20, 124, 125).

Case example – Reporting of the SMILe contextual analysis

The SMILe project's contextual analysis findings for its first study site were published in a separate paper. The same paper described the research team's implementation strategies and outlined their findings' implications for re-engineering stem cell transplant follow-up care (34). A second paper—this one on the SMILe-ICM's development—described how the research team had based their intervention components and mode-of delivery choices on information from their contextual analysis (32). Applying the BANANA approach to the SMILe project, we are focusing sharply on making our decision-making processes and results transparent and replicable. I.e., at each step, we are ensuring that both the results and the processes used to achieve them can be employed by other researchers (e.g., for scale-up).

4.6 Discussion

Contextual analysis is the foundation of every IS project. As noted above, its results inform all subsequent project phases, enhancing interventions' implementation and sustainability in real-world settings. However, few IS studies consider and report on context. Among other factors, this omission reflects conceptual inconsistencies, a lack of appropriate methodology, and shortfalls both of resources to guide contextual analyses and of reporting guidelines to consider contextual analyses (11, 26, 72, 73).

To fill these gaps, the BANANA approach provides guidance on conducting and reporting on contextual analyses in IS projects. Further, it describes how contextual information can be used to inform further project phases (e.g., intervention development). While we have described BANANA in terms of six individual steps, they do not always operate sequentially (Figure 4.2). Particularly the first three—choosing a TMF, identifying empirical evidence and involving stakeholders—are partly concurrent. Once in place, they form a firm foundation upon which first to identify relevant contextual factors, then, in the next steps, to assess context (step 4).

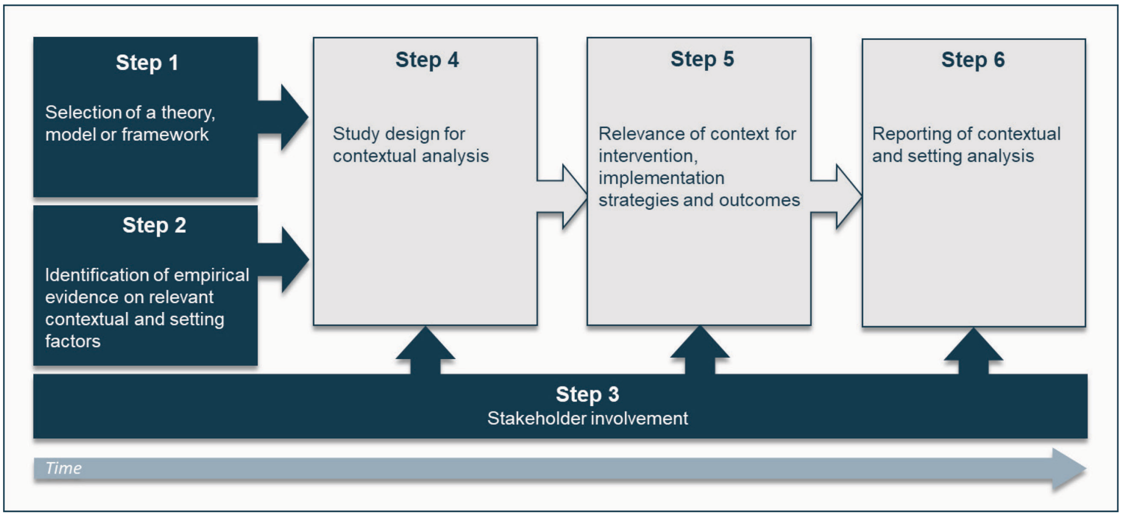

Figure 4.2. Overview of the six-step Basel Approach for coNtextual ANAlysis (BANANA)

When presenting BANANA at conferences or in workshops, participants often ask us for a checklist they can apply to their project's contextual analysis. However, we have deliberately avoided a “checklist or cookbook approach”: the aspects to be studied in context and the methods chosen always depend on the individual research project and its research questions. Applying a checklist risks oversimplifying the context and undervaluing the complex interconnections of contextual factors, many of which differ from one setting to the next (75, 126). In the worst cases, only superficial contextual knowledge would be generated, limiting the contextual analyses' capacity either to inform later phases of the IS project or to ensure the implementation's success (75, 127). Therefore, planning and conducting a contextual analysis usually requires a high degree of reflexivity and an experienced transdisciplinary research team covering experiences in the field of IS (e.g., knowledge and use of implementation TMFs, understanding of all implementation phases), and a broad knowledge of how to apply research methods.

In addition to the project and research questions, however, other considerations play roles in planning and conducting a contextual analysis. Soon after applying BANANA to the SMILe project, it became evident that the focus of our contextual analysis could change depending on who was conducting the analysis and their level of related experience. The SMILe project leaders (LL, SV) had both worked for several years in the SMILe-ICM's target setting. I.e., both have ample experience in the care of stem cell-transplanted patients as well as implicit knowledge of the target context and setting (e.g., work processes, resources available, leadership, organizational culture and legal aspects).

Second, although the importance of context in IS projects has been widely emphasized, donors remain hesitant to fund contextual analyses. A contextual analysis' rigor and thoroughness both reflect the available resources such as time, personnel, and especially funding (72, 73). These circumstances should be considered when evaluating contextual analysis and interpreting its results.

4.6.1 Strengths and limitations

BANANA was developed based on evidence and expert discussion and successfully applied within the SMILe project. However, additional testing will be necessary to ensure its reliability in other settings, for other interventions (e.g., in public health) and for other starting positions of a project (e.g., projects in which interventions or implementation strategies have already been developed). Further, we are considering methods of finding a broader consensus between implementation experts regarding BANANA's six steps, e.g., by applying a Delphi approach. Another limitation of BANANA is that interactions in context—particularly regarding how individuals are embedded within a context, and how they are influenced by and shape that context—require more consideration than was possible within the scope of this study. Therefore, we plan to further develop BANANA and complement it via a constructivist perspective.

4.6.2 Implications for research and funders

Improving researchers' consideration of context and their reporting of it in IS studies will clearly require conceptual and methodological developments; however, further measures are also required. First, coupled with the acknowledgment of contextual analysis as the foundational first phase of every IS project, its relevance to implementation success requires funding agencies to rethink how to support this phase. I.e., adequately resourcing contextual analyses will require specific funding schemes (75). Within reasonable tolerances, this will require a timeline for a thorough contextual analysis and further steps (e.g., intervention development) (75). Second, the reporting of context should be a condition for the publication of IS projects. Appropriate standards and guidelines must be developed to support researchers to meet this requirement.

4.7 Conclusions

Contextual analysis is a foundational first phase of every IS project, providing essential information to all subsequent phases. The BANANA approach successfully guided the SMILe project's contextual analysis. To help researchers make sense of their target contexts, and to strengthen every part of their work, this approach's principles can also be applied to other IS projects. However, it will first be necessary to adapt and test BANANA in other projects.

Equally importantly, considering the vast heterogeneity of the studies we reviewed, a coordinated campaign will be required to unify and enhance IS researchers' efforts to conduct and report on contextual analyses. As a first step, a common set of analysis and reporting guidelines will do much to improve the success and quality of implementation efforts.

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4.9 Supplementary Material

4.9.1 Additional file 4.1

Key resources for each step of the Basel Approach for coNtextual ANAlysis (BANANA)

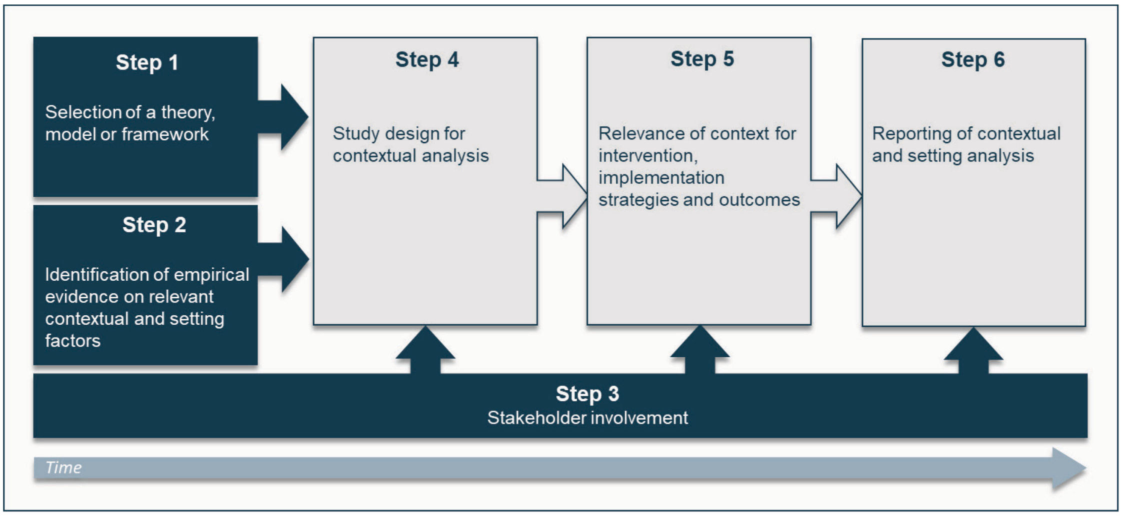

Figure 4.2. Overview of the six-step Basel Approach for coNtextual ANAlysis (BANANA)

Background information

Papers on context in general

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BANANA – STEP 1

Use of a theory, model or framework guiding contextual analysis

Reviews on TMFs - General

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Selecting TMFs

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BANANA – STEP 2

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BANANA – STEP3

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BANANA – STEP4

Choosing a study design for contextual analysis

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Measurement and data extraction tools for specific frameworks

CFIR (https://cfirguide.org/)

EPIS framework (https://episframework.com/)

CICI framework appendices; Pfadenhauer LM, Gerhardus A, Mozygemba K, Lysdahl KB, Booth A, Hofmann B, Wahlster P, Polus S, Burns J, Brereton L et al: Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. Implementation Science 2017, 12(1):21.

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BANANA – STEP 5

Identifying and describing relevance of contextual and setting factors for intervention co-design, implementation strategies and outcomes

Developing and adapting interventions

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Selecting and adapting implementation strategies

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BANANA – STEP 6

Reporting of contextual analysis

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4.9.2 Additional file 4.2

Overview of contextual factors most commonly reported in empirical evidence to influence implementation

	Rogers et al. (1)	Squires et al. (2)	Watson et al. (3)	Li et al. (4)
Micro-level	Self-efficacy	-	-	-
	Individual attitudes	-	-	-
	-	Patient characteristics	-	-
	-	Health care professional characteristics	-	-
Meso-level	Culture	Culture	-	Organizational culture
	Organizational climate	-	-	-
	Networks and communications	-	-	Networks and communication
	Organizational leadership engagement	Leadership	-	Leadership
	Available resources	Resource access	-	Resources
	Structural characteristics	Facility characteristics	-	-
	-	Evaluation	-	Evaluation, monitoring and feedback
	-	-	-	Champion
	Compatibility	-	-	-
	Organizational support	-	-	-
	-	System features	-	-
Macro-level	-	Professional role	Professional influences	-
	Political environment	-	Political support	-
	Social environment	Societal influences	Social climate	-
	-	-	Local infrastructure	-
	-	Regulatory or legislative standards	Policy and legal climate	-
	-	Collaboration	Relational climate	-
	-	-	Target population	-
	Economic environment	Financial	Economic and funding climate	-
Team level	Structural characteristics	Work structure	-	-
	Teamwork	-	-	-
	Culture	-	-	-
	Compatibility	-	-	-
	Available resources	-	-	-
	Local leadership engagement	-	-	-
	Team efficacy	-	-	-

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Chapter 5.

Methodological approaches to study context in intervention implementation studies: An evidence gap map

Juliane Mielke[1*], Thekla Brunkert[1,2*], Franziska Zúñiga[1], Michael Simon[1], Leah L. Zullig[3], Sabina De Geest[1,4]

[1] Institute of Nursing Science, Department Public Health, University of Basel, Basel, Switzerland

[2] University Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland

[3] Center for Innovation to Accelerate Discovery and Practice Transformation (ADAPT) Durham; Veterans Affairs Health Care and System; and Department of Population Health Sciences, School of Medicine, Duke University, Durham, NC USA

[4] Academic Center for Nursing and Midwifery, Department of Public Health and Primary Care, KU Leuven, Leuven, Belgium

**shared first authorship*

Submitted to Implementation Science

5.1 Abstract

Background

Within implementation science studies, contextual analysis is increasingly recognized as foundational to interventions' successful and sustainable implementation. However, inconsistencies between methodological approaches currently limit progress in studying context and guidance to standardize the use of those approaches is scant. Therefore, this study's objective was to systematically review and map current methodological approaches to contextual analysis in intervention implementation studies. The results would help us both to systematize the process of contextual analysis and identify gaps in the current evidence.

Methods

We conducted an evidence gap map (EGM) based on literature data via a stepwise approach. First, using an empirically developed search string, we randomly sampled 20% of all intervention implementation studies available from PubMed per year (2015–2020). Second, we assessed included studies that conducted a contextual analysis. Data extraction and evaluation followed the Basel Approach for CoNtextual ANAlysis (BANANA), using a color-coded rating scheme. Also based on BANANA and on the Context and Implementation of Complex Interventions (CICI) framework—an implementation framework that pays ample attention to context—we created visual maps of various approaches to contextual analysis.

Results

Of 15,286 identified intervention implementation studies and study protocols, 3017 were screened for inclusion. Of those, 110 warranted close examination, revealing 22% that reported on contextual analysis.

Only one study explicitly applied a framework for contextual analysis. Data were most commonly collected via surveys (n=15) and individual interviews (n=13). Ten studies reported mixed-methods analyses. Twenty-two assessed meso-level contextual and setting factors, with socio-cultural aspects most commonly studied. Eighteen described the use of contextual information for subsequent project phases (e.g., intervention development/adaption, selecting implementation strategies). Nine reported contextual factors' influences on implementation and/or effectiveness outcomes.

Conclusion

This study describes current approaches to contextual analysis in implementation science and provides a novel framework for evaluating and mapping it. By synthesizing our findings graphically in figures, we provide an initial evidence base framework that

can incorporate new findings as necessary. We strongly recommend further development of methodological approaches both to conduct contextual analysis and to systematize the reporting of it. These actions will increase the quality and consistency of implementation science research.

5.2 Contributions to the literature

- We provide a novel framework for mapping and evaluating methodological approaches to contextual analysis in terms of literature search and summarizing implementation science literature.
- This study provides an overview of existing approaches to contextual analysis while highlighting gaps in contextual analyses performed to date.
- The evidence-based map on contextual analysis can be used for summarizing other implementation science studies and points towards aspects of contextual analysis that need further development.

5.3 Background

Successful implementation of interventions in real-world settings depends on the dynamic, multi-dimensional, multi-level interplay between context, intervention and implementation strategies (1, 2). Therefore, a thorough understanding of the implementation context is critical. This is true not only for the initial implementation, but also for sustainability and scale-up (3-7). Filling this need is the role of contextual analysis, i.e., the mapping of multi-dimensional and multi-level contextual factors relevant for the implementation of an intervention in a specific setting.

Within an implementation science[1] project, we understand contextual analysis as a separate study. It starts well before implementation and continues throughout the project. The in-depth contextual knowledge informs subsequent phases of the project, especially the development or adaption of an intervention and choices of implementation strategies (8-10). Within that setting, contextual analysis helps to interpret the studied intervention's effectiveness and implementation outcomes and guides choices of sustainability strategies (11, 12).

Although the importance of context has been widely emphasized regarding implementation, little attention has been paid to its assessment in studies partly driven by funding frameworks that do not normally recognize this phase's importance (13-15). Yet, conceptual and methodological challenges hamper the assessment of context additionally. Even the concept of context is only partially mature (16-18): a recent systematic review revealed inconsistencies in current theoretical and operational definitions (18).

No unifying definition of context yet exists. Instead, we see terms including setting—sometimes divided into inner and outer setting—environment, or system characteristics, with each signifying a slightly different perspective (16, 19, 20). Further, no explicit methodological guidance yet describes how to assess, analyze or report context and setting.

Within a postpositivist paradigm, researchers tend to focus on single factors (commonly referred to as facilitators and barriers) to the exclusion of those occupying multiple levels and dimensions (18, 20, 21). These factors are often selected without theoretical support; and even where contextual analyses are conducted, the findings are rarely used to inform subsequent project phases (e.g., implementation strategy choices). Additionally, no specific methods to study contexts are described, the range of psychometrically sound measurement tools (particularly to assess macro-level factors) is limited, and

[1] Implementation science is a scientific study, promoting “the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care” (Eccles and Mittman, 2006)

reporting guidelines (e.g., Standards for Reporting implementation Studies (StaRI) (22, 23)) ambiguous regarding how contextual analysis to report (18, 24).

Based on a methodology reported by Stange and Glasgow (5) within a series of patient-centered medical home research for the US Agency for Healthcare Research and Quality (AHRQ), we developed the Basel Approach for CoNtextual ANAlysis (BANANA) and applied it successfully in two implementation science projects (25-27). This approach's theoretical grounding is the Context and Implementation of Complex Interventions (CICI) framework (2), a meta-framework incorporating insights from previous frameworks (e.g., the Consolidated Framework for Implementation Research (19)), but also filling previous gaps (e.g., differentiating between context and setting, focusing more on macro-level factors, considering how other interventions can affect implementation). Starting from an ecological perspective, the authors conceptualized context as a "set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded" (2), whereas setting refers to the physical location in which an intervention is to be implemented and interacts with both context and implementation (2). Context "is an overarching concept, comprising not only a physical location but also roles, interactions and relationships at multiple levels" (2). Contextual factors can be grouped into geographical, epidemiological, socio-cultural, socio-economic, political, legal or ethical domains, and include, e.g., the social structure, financial aspects, or the political climate.

To guide contextual analysis in implementation science projects, BANANA includes six steps: (1) choosing a theory, model or framework (TMF) to guide contextual analysis. (To enhance analytical granularity, the TMF can be complemented with one that is setting-specific.); (2) reviewing empirical evidence about relevant contextual factor(s), including facilitators and barriers, as well as practice patterns related to the implementation and intervention; (3) involving relevant stakeholders in the contextual analysis. This includes implementation agents, i.e., individuals (or organizations) targeted or affected by the implementation of an intervention (*target group*, e.g., patients, family caregivers), who implement an intervention (*implementers*, e.g., healthcare professionals) or who decide on the implementation of an intervention (*decision makers*, e.g., policy makers and funders) (2). Other stakeholders can include experts with advisory roles within the project (e.g., for intervention development); (4) collecting and analyzing data, combining qualitative and quantitative methods where appropriate; (5) identifying and describing the relevance of contextual factors for intervention co-design, implementation strategies and outcomes; and (6) reporting the contextual analysis (27). To strengthen the methodology for contextual analysis in implementation science, we recognized that it would be essential first to understand the key methods currently in use. Therefore, we set out to gather an evidence base. To identify gaps in that base we systematically reviewed and mapped the methodological approaches described. More specifically, we aimed (1) to determine the percentage of published intervention implementation studies reporting on contextual analysis; then (2) to assess, map and evaluate a) which methodological approaches were used for the identified studies' contextual analyses and identify gaps in current approaches and b) which results were used to inform subsequent phases of the associated studies.

5.4 Methods

To draft an evidence gap map (EGM) we reviewed and categorized the methodologies applied to contextual analyses in the identified studies. This process was basically a systematic search that included surveying the current state of methodological approaches to contextual analysis. As the name implies, this was very useful to identify gaps in those approaches (28-30). As for the mapping aspect, the results are presented in a user-friendly format, usually combining tables or visualizations and descriptive reports to summarize existing evidence and facilitate methodological improvements regarding the topic—in this case, contextual analysis (28-31). We reported our findings according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses–Scoping Reviews (PRISMA–ScR) Checklist (Additional file 1) (32).

5.4.1 Scope of the evidence gap map (EGM) and development of research questions

As a first step, to develop comprehensive, relevant research questions, this study's authors—all experienced implementation science researchers—discussed the boundaries and context of the EGM (31, 33). As noted, a stepwise approach helped us identify relevant literature and provide a comprehensive overview of the available evidence (Additional file 2): First, we aimed to identify intervention implementation studies and assessed whether they included contextual analyses (Step 1). Second, focusing exclusively on studies that reported contextual analyses, we mapped both the researchers' methods (Step 2a) and how they used the results to inform further phases of their projects (Step 2b).

5.4.2 Inclusion/ exclusion criteria

In step 1, we employed ten inclusion criteria to the prospective sample. We included (**a**) peer-reviewed articles or study protocols (**b**) concerning intervention implementation studies (**c**) if they employed experimental or quasi-experimental designs (**d**) to test intervention effectiveness (**e**) in real world settings. They also needed (**f**) to include at least one of Brown et al.'s "7 Ps" (34), i.e., programs, practices, principles, procedures, products, pills, and policies, and (**g**) to report on the evaluation of the implementation pathway. This included qualitative or quantitative information on the implementation process and/or on at least one implementation outcome as defined by Proctor et al. (35)

(Additional file 2). During the screening we identified a large number of feasibility studies that did not fit the scope of our study. Therefore, we decided only to include feasibility studies (**h**) if they assessed at least one additional implementation outcome (e.g., feasibility *and* acceptability). Further, only papers (**i**) written in English or German and (**j**) with available full texts were included. Because the level of detail of contextual analysis in study protocols is usually limited, we used the "cited by" function in PubMed to determine whether the intervention study had been already published and contained further information on contextual analysis. In cases where we identified the study protocol and related intervention implementation study, only the intervention study was included in the review. Further, we excluded studies reporting on context exclusively as part of the process evaluation or retrospectively.

5.4.3 Systematic searching – search strategy development

We applied Hausner et al.'s empirical-based approach (36) to develop our search strategy. Following a four-step process, we first used a precise search string to identify a subset of 163 articles in Pubmed that met our EGM's inclusion criteria (Additional file 3). Those articles were randomly assigned to a development (n = 81) or a validation set (n = 82). Second, using Pubmed ReMiner (https://hgserver2.amc.nl/cgi-bin/miner/miner2.cgi), we identified the search terms (keywords and MeSH terms) most commonly used in the development set articles. The identified search terms were used to develop a search string. In a third step, this string was tested against the validation set. The final search string consisted of 22 keywords (MeSH and free terms) and achieved a sensitivity of 95.1% (i.e., it identified 75 of the 81 development records). The fourth step consisted of documenting the search string development (Additional file 3).

As our main aim was to review and map a sample of papers reporting methodological approaches used for contextual analysis (not all existing literature), we searched only the PubMed electronic database. To maximize currency, we limited our search to the past six years (2015-2020). Using a random number generator, we then selected a random sample of 20% of the articles identified from each year. No further filters were applied.

5.4.4 Study selection

For step 1, using the web application Rayyan (https://rayyan.qcri.org), two reviewers (JM, TB) independently screened titles and abstracts of the randomly selected implementation science papers against the described inclusion criteria (37). Second, each reviewer (JM, TB) independently screened the full texts of all included papers. In case of disagreement between the two reviewers, a third reviewer (SDG) was consulted to reach consensus. For step 2, the first two reviewers (JM, TB) independently screened the full texts of previously included intervention implementation studies against the respective eligibility criteria. Again, the third reviewer (SDG) was consulted in case of disagreement.

5.4.5 Data extraction and analysis

We extracted the general data of all included intervention implementation studies (e.g., design, setting). Guided by BANANA, specific characteristics of studies including contextual analyses were extracted, including general information (e.g., whether context was analyzed at various timepoints, TMFs used), implementation agents involved in each analysis and methods applied to conduct contextual analysis (i.e., quantitative and qualitative methods). Further, we assessed the results of the contextual analyses, i.e., we noted how those results were used for subsequent study phases and whether the researchers had considered how contextual factors might influence implementation and summative outcomes (Additional file 2). As it quickly became clear that few studies explicitly reported the use of hybrid designs, we used Curran et al.'s description to categorize these in the remainder that we checked, i.e., as hybrid type 1/2/3[2] (38). All extracted data were charted in an Excel file. General study characteristics were analyzed descriptively, calculating frequencies and percentages.

5.4.6 Mapping of identified methodological approaches

To map the identified approaches for contextual analysis in a user-friendly format, we created color coded tables and depicted the information graphically (i.e., in an EGM). The structure of the tables follows the BANANA approach and provides a comprehensive overview of all relevant information. More detailed information on the assessed approaches can be found in the Additional files 4 and 5.

To provide an overview of contextual factors assessed, an EGM was developed using two software tools: EPPI-Reviewer Version 4.12.3.0 (39) and EPPI-Mapper Version 1.2.5 (40). As terminology and conceptualization of contextual factors varied widely across the identified studies, with none differentiating between context and setting, we used the CICI framework to categorize identified micro-, meso- und macro-level aspects (2). Contextual factors were grouped to the seven CICI context domains (i.e., geographical, epidemiological, socio-cultural, socio-economic, political, legal and ethical) and subcategories further specifying contextual domains (e.g., infrastructure, organization structure, leadership). Setting factors as part of the context (i.e., those referring to the physical location in which an intervention is implemented) were categorized into three domains: work environment, physical characteristics and practice

[2] Hybrid Type 1: Prime focus on testing intervention effectiveness, and second, studying implementation.
Hybrid Type 2: equal focus on testing intervention effectiveness and implementation strategies.
Hybrid Type 3: Prime focus on testing effectiveness of implementation strategies, and second, assessing the intervention (38).

patterns. Since included studies did not differentiated setting as a part of context, JM inductively categorized all identified setting factors for each domain (e.g., pertaining to work flow, capacity, availability of resources) to clearly structure and summarize them. These choices were then reviewed by TB. Inconsistencies were discussed with SDG and FZ. Using dots, the evidence map concisely depicts which aspects of context and setting were assessed in each implementation and at which level. Each dot's color indicates whether the method used was quantitative or qualitative; its size indicates how many studies investigated this aspect. I.e., the larger the dot, the more studies have considered this specific aspect. As the evidence map is interactive, categories can be shown or hidden to provide simpler or more complex views. The respective studies' references (including abstracts) can also be displayed.

5.4.7 Evaluation of identified methodological approaches

To critically evaluate the methodological approaches to contextual analysis reported in the included studies, we grouped the extracted data via five of the six steps described in the BANANA approach (27). The sixth step of BANANA was not evaluated as it refers to the reporting of the contextual analysis, which was an inclusion criterion for the assessed studies. We applied color-coding to indicate whether each study clearly addressed a component (green), only mentioned it partly (yellow), or failed to address it (red). The color coding was done independently by two researchers (JM, TB). In cases of disagreement, a third researcher (SDG) was consulted to decide on the rating.

5.5 Results

We used a two-phase sampling process. In Phase 1, our PubMed search returned 15,286 records. After removing duplicates, we randomly sampled 20% of the remaining studies from each of the six selected publication years (2015–2020) (n=3017). In Phase 2, we screened this sample via the inclusion criteria noted above. Figure 5.1 presents a flow chart of the screening process. This left 110 intervention implementation studies for data extraction. For Phase 1, our inter-rater reliability was 76.7%; for Phase 2 it was 91.1%. As the included articles were both, original studies and study protocols, in the interests of readability, we will describe all results in the past tense

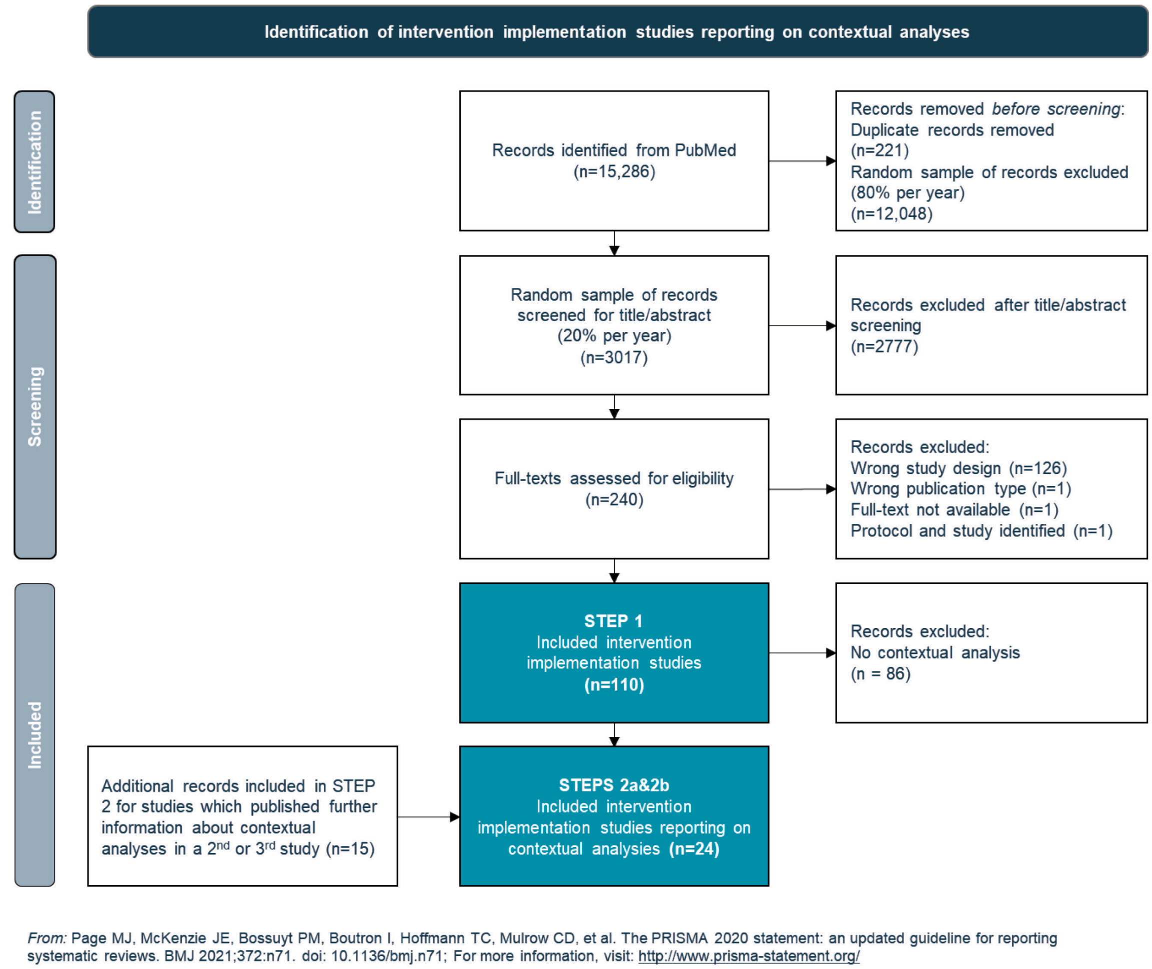

Figure 5.1. PRISMA flow chart presenting a stepwise approach to identify relevant studies

5.5.1 General characteristics of included studies (Step 1)

Of the 110 extracted articles the majority were study protocols (n=90); most (n=82) were either from North America (n=45) or Europe (n=37) (Table 5.1). The studies were conducted in a wide range of settings, the most common being primary care (n=20), community care (n=15), the health care system (n=13) and schools (n=12). Eighty-four of their designs were experimental; twenty-six were quasi-experimental. Further details of the studies are described in the additional file 4.

Table 5.1. Characteristics of intervention implementation studies included in step 1 and step 2 in n (%)[1]

		Studies step 1 (n = 110)	**Studies step 2** (n = 24)
Article type	Study protocol	90 (81.8)	22 (91.7)
	Original article	20 (18.2)	2 (8.3)
Continent	North America	45 (40.9)	11 (45.8)
	Europe	37 (33.6)	10 (41.7)
	Australia	14 (12.7)	2 (8.3)
	Africa	7 (6.4)	1 (4.2)
	Asia	5 (4.6)	-
	South America	2 (1.8)	-
Setting	Health care	72 (65.5)	16 (66.7)
	Primary care	20 (31.8)	5 (20.8)
	Health care system	13 (11.8)	4 (16.7)
	Hospitals	9 (8.2)	2 (8.3)
	Nursing homes	9 (8.2)	1 (4.2)
	Mental health care	7 (6.4)	-
	Outpatient care	5 (4.6)	1 (4.2)
	Emergency departments	4 (3.6)	2 (8.3)
	Rehabilitation services	3 (2.7)	1 (4.2)
	Veterans Health Administration	2 (1.8)	-
	Community settings	35 (31.8)	7 (29.2)
	Community care	15 (13.6)	1 (4.2)
	Schools	12 (10.9)	4 (16.7)
	Workplace	2 (1.8)	
	Churches	2 (1.8)	-
	Justice	2 (1.8)	2 (8.3)
	Kindergarten	2 (1.8)	-
	Other	3 (2.7)	1 (4.2)
	Family planning services	1 (0.9)	-
	Pharmacies	1 (0.9)	-
	Supermarkets	1 (0.9)	1 (4.2)
Study design testing clinical effectiveness	Experimental	84 (76.4)	17 (70.8)
	Quasi-experimental	26 (23.6)	7 (29.2)

Note. [1] Step 1 focusses on all identified intervention implementation studies, step 2 focusses only on studies that conducted a contextual analysis.

5.5.2 Characteristics of studies reporting on contextual analysis and methodological approaches applied (Step 2)

Of the sample's 110 studies, 24 (21.8%) reported conducting contextual analyses (Table 5.2). As authors of seven studies had released further information or results elsewhere, we located and extracted those records (n=15) as well. Based on Curran et al.'s definitions (38), we identified (or categorized if not described) 17 hybrid type 1, five hybrid type 2, and two hybrid type 3 designs. Seven of the 24 assessed context at one time point; 12 assessed it at two, and five at three timepoints during their projects (Additional file 5).

Table 5.2. Overview of included studies conducting a contextual analysis

Study	First author, ([1])	Year	Article type	Country	Design[2] (Outcomes see additional file 5)	Setting	Intervention	Intervention level: Micro	Meso	Macro	Process evaluation[3]
1	Apers et al. (81)	2020	Study protocol	Belgium	Hybrid Type 1 CE: Modified stepped wedge cluster design I: Mixed-methods	Primary care	HIV-testing intervention in primary care (general practitioners)		X		Y
2	Berhanu et al. (82)	2020	Study protocol	Ethiopia	Hybrid Type 1 CE: Pre-post randomized control group design I: Mixed-methods	Primary care	Optimizing Health Extension Program to increase the utilization of primary child health services		X		Y
3	Bidwell et al. (83)	2018	Study protocol	UK	Hybrid Type 2 CE: Randomized stepped-wedge design I: Mixed methods	Hospitals	Care bundle to reduce incidence of obstetric anal sphincter injuries	X	X		N
4	D'Onofrio et al. (84) (*(85)*)	2019	Study protocol	USA	Hybrid Type 3 CE: Modified stepped wedge design I: Mixed methods	Emergency departments	Emergency department-initiated buprenorphine for patients with opioid use disorder	X	X		N
5	Grazioli et al. (86) (*(87-89)*)	2019	Study protocol	Switzerland	Hybrid Type 2 CE: Randomized pre-post design I: Mixed methods	Emergency departments	Case management intervention for frequent users of the emergency department	X	X		Y
6	Hartzler et al. (90)	2017	Study protocol	USA	Hybrid Type 2 CE: Randomized controlled trial I: Mixed methods	Schools	Teen marijuana check-up in schools	X	X		N

Table 5.2. Overview of included studies conducting a contextual analysis

Study	First author, ([1])	Year	Article type	Country	Design[2] (Outcomes see additional file 5)	Setting	Intervention	Intervention level: Micro	Meso	Macro	Process evaluation[3]
7	Johnson et al. (91)	2018	Study protocol	USA	Hybrid Type 1 CE: Randomized controlled trial I: Mixed methods	Justice	Afrocentric, group-based, computerized HIV / sexually transmitted infection (STI) prevention intervention for controlled substance-using black women in community corrections settings	X			N
8	Knight et al. (92) (*(93)*)	2016	Study protocol	USA	Hybrid Type 3 CE: Cluster randomized interrupted time series I: Multi methods	Justice	Interventions for Adolescents in the Legal System for substance abuse		X	X	N
9	Kwan et al. (94)	2020	Study protocol	USA	Hybrid Type 1 CE: Cluster randomized controlled trial I: Mixed methods	Primary care	Patient-driven, shared medical appointments for providing diabetes self-management education and self-management support	X	X		N
10	Lakerveld et al. (95)	2018	Study protocol	Netherlands	Hybrid Type 1 CE: Randomized controlled trial I: Mixed methods	Supermarkets	Multi-level intervention using pricing and nudging strategies in the supermarket and context-specific mobile physical activity promotion app to impact on lifestyle behaviors and cardiometabolic health in adults with lower socio-economic status	X	X		N

Table 5.2. Overview of included studies conducting a contextual analysis

Study	First author, ([1])	Year	Article type	Country	Design[2] (Outcomes see additional file 5)	Setting	Intervention	Intervention level: Micro	Intervention level: Meso	Intervention level: Macro	Process evaluation[3]
11	Nahar et al. (96)	2020	Study protocol	UK	Hybrid Type 1 CE: Stepped wedge cluster randomized controlled trial I: Mixed methods	Health care system	Multi-component community engagement intervention for cardiovascular disease prevention in socially disadvantaged populations	X	X		Y
12	Osilla et al. (97)	2020	Study protocol	USA	Hybrid Type 1 CE: Randomized controlled trial I: Survey	Outpatient care	Group-based therapy for support persons of adults on buprenorphine/naloxone to engage treatment resistant persons into treatment through positive communication and other behavioral strategies	X	X		U
13	Quintiliani et al. (98)	2015	Study protocol	USA	Hybrid Type 1 CE: Randomized controlled trial I: Multi methods	Primary care	Smoking-cessation intervention that combines patient navigation and financial incentives	X	X		Y
14	Rahm et al. (99)	2018	Study protocol	USA	Hybrid Type 1 CE: Unclear I: Qualitative and configurational comparative methodology	Health care system	Organizational toolkit for Lynch syndrome screening			X	Y
15	Rotter et al. (100)	2017	Study protocol	Canada	Hybrid Type 2 CE: Interrupted time series design with control groups I: unclear	Health care system	Clinical pathways for treatment of COPD		X		N

Table 5.2. Overview of included studies conducting a contextual analysis

Study	First author, ([1])	Year	Article type	Country	Design[2] (Outcomes see additional file 5)	Setting	Intervention	Intervention level: Micro	Meso	Macro	Process evaluation[3]
16	Saevareid et al. (101) (*(102-104)*)	2018	Study protocol	Norway	Hybrid Type 1 CE: Cluster randomized controlled trial I: Mixed methods	Nursing homes	Advanced care planning intervention in nursing homes		X		Y
17	Shanley et al. (105)	2019	Study protocol	Australia	Hybrid Type 2 CE: Pre-post design I: Mixed methods	Health care system	Innovative, tiered, culturally sensitive, neurodevelopmental assessment process within remote geographic locations with limited professional expertise, that considers fetal alcohol spectrum disorders as a potential outcome		X	X	Y
18	Smeltzer et al. (106) (*(107)*)	2018	Original article	USA	Hybrid Type 1 CE: Pre-post control group design I: unclear	Community care	Multidisciplinary lung cancer care model	X	X		Y
19	Steele Gray et al. (108) *((109, 110))*	2016	Study protocol	Canada	Hybrid Type 1 CE: Cluster randomized controlled trial I: Mixed methods	Primary care	Electronic patient reported (ePRO) mobile app and portal to creating and monitoring goal-oriented patient-care plans to improve patient self-management and shared decision making between patients and health care providers as well as proactive patient monitoring by the patient, caregiver(s), and health care provider	X	X		Y

Table 5.2. Overview of included studies conducting a contextual analysis

Study	First author, (1)	Year	Article type	Country	Design[2] (Outcomes see additional file 5)	Setting	Intervention	Intervention level: Micro	Meso	Macro	Process evaluation[3]
20	Sutherland et al. (111) (*(112-114)*)	2019	Study protocol	Australia	Hybrid Type 1 CE: Cluster randomized controlled trial I: Mixed methods	Schools	Multi-component intervention that uses an existing school-based communication application to reduce kilojoule content from discretionary foods and drinks consumed by children from school lunch boxes whilst at school	X	X		N
21	Taylor et al. (115) *((116))*	2015	Original article	UK	Hybrid Type 1 CE: randomized controlled trial I: Multi methods	Rehabilitation services	Home-based self-care rehabilitation intervention in heart failure patients and caregivers	X	X		Y
22	van Delft et al. (117)	2019	Study protocol	Netherlands	Hybrid Type 1 CE: Pre-post design I: Mixed methods	Hospitals	Complex, multidimensional intervention to improve physical behavior during hospitalization, i.e., decrease patients` sedentary behavior and increase physical activity	X	X		Y
23	van Dongen et al. (118) (*(119)*)	2019	Study protocol	Netherlands	Hybrid Type 1 CE: Controlled time series design I: Mixed methods	Schools	Community based school intervention including four strategies for building the community capacity of students, school personnel, and parents	X	X		Y

Table 5.2. Overview of included studies conducting a contextual analysis

Study	First author, ([1])	Year	Article type	Country	Design[2] (Outcomes see additional file 5)	Setting	Intervention	Intervention level: Micro	Intervention level: Meso	Intervention level: Macro	Process evaluation[3]
24	Verjans-Janssen et al. (120)	2018	Study protocol	Netherlands	Hybrid Type 1 CE: Pre-post control group design I: Mixed methods	Schools	School-based physical activity and nutrition intervention including family-based lifestyle parenting program	X	X		N

Note: [1]reference of further paper(s) in which results of the contextual analysis were published in italics; [2]CE = study design clinical effectiveness, I = study design implementation, RCT = randomized controlled trial; Hybrid Type 1 = prime focus on testing intervention effectiveness, and second, studying implementation. Hybrid Type 2 = equal focus on testing intervention effectiveness and implementation strategies; Hybrid Type 3 = prime focus on testing effectiveness of implementation strategies, and second, assessing the intervention; [3]Process evaluation planned or results described as part of the intervention implementation study: Y = yes, N = not reported, U = unclear

5.5.3 TMFs used and empirical evidence considered for contextual analysis

The included studies used eleven distinct TMFs. Those used can be broadly categorized into process models (e.g., Knowledge-to-Action Models), determinant frameworks (e.g., CFIR), or classic theories (e.g., social cognitive theory) (41). One, the RE-AIM (reach, effectiveness, adoption, implementation, maintenance) Planning and Evaluation Framework is a process and evaluation framework that includes a determinant component (42). Only one study specifically described how it used a TMF (CFIR) for contextual analysis and how that TMF guided it (43). The others (n=15) referred more generally to their TMFs guiding their overall implementation process, with RE-AIM (n=7) and the Consolidated Framework for Implementation Research (CFIR) (n=3), cited most often. Four studies reported combining two TMFs, e.g., CFIR and RE-AIM. In addition, seven considered empirical evidence about relevant contextual factors (Figure 5.2).

5.5.4 Consideration of implementation agents

Only nine studies collected data of all three types of implementation agents, with implementers most often being involved in the assessment of context (n=19) (Figure 5.2). In some cases, stakeholder groups who functioned as expert panels or advisory boards throughout the project (n=11) were established. These included, e.g., health care providers from various medical fields, people affected by specific illnesses or health conditions, leaders and administrators, and delegates for non-profit organizations or government departments (Additional file 5).

5.5.5 Methods applied for data collection and analysis

Of the 24 studies that reported using contextual analyses, 23 clearly described their methods. Of these 23, while ten explicitly reported using mixed-methods analysis, we found that 13 applied combinations of quantitative and qualitative methods. The remaining ten applied either quantitative (n=2) or qualitative (n=8) methods alone (Figure 5.2). Quantitative data collection methods included purpose-designed surveys (n=15), behavior mapping (n=1), and retrospective use of national survey (n=1) and surveillance (n=1) data. Seven qualitative data collection methods were used: individual interviews (n=13), focus groups (n=13), observations (n=2), as well as photovoice methodology[3] (n=2), telephone interviews (n=1), yarning[4] (n=1) and site visits (n=1).

[3] Photovoice is a participatory research methodology, that allows study participants to record and reflect on their experiences (e.g., quit smoking) by taking photos and discussing those in guided discussion sessions (78, 79)

[4] Yarning: Yarning is a highly structured qualitative research methodology, to gain knowledge from indigenous people by storytelling (80)

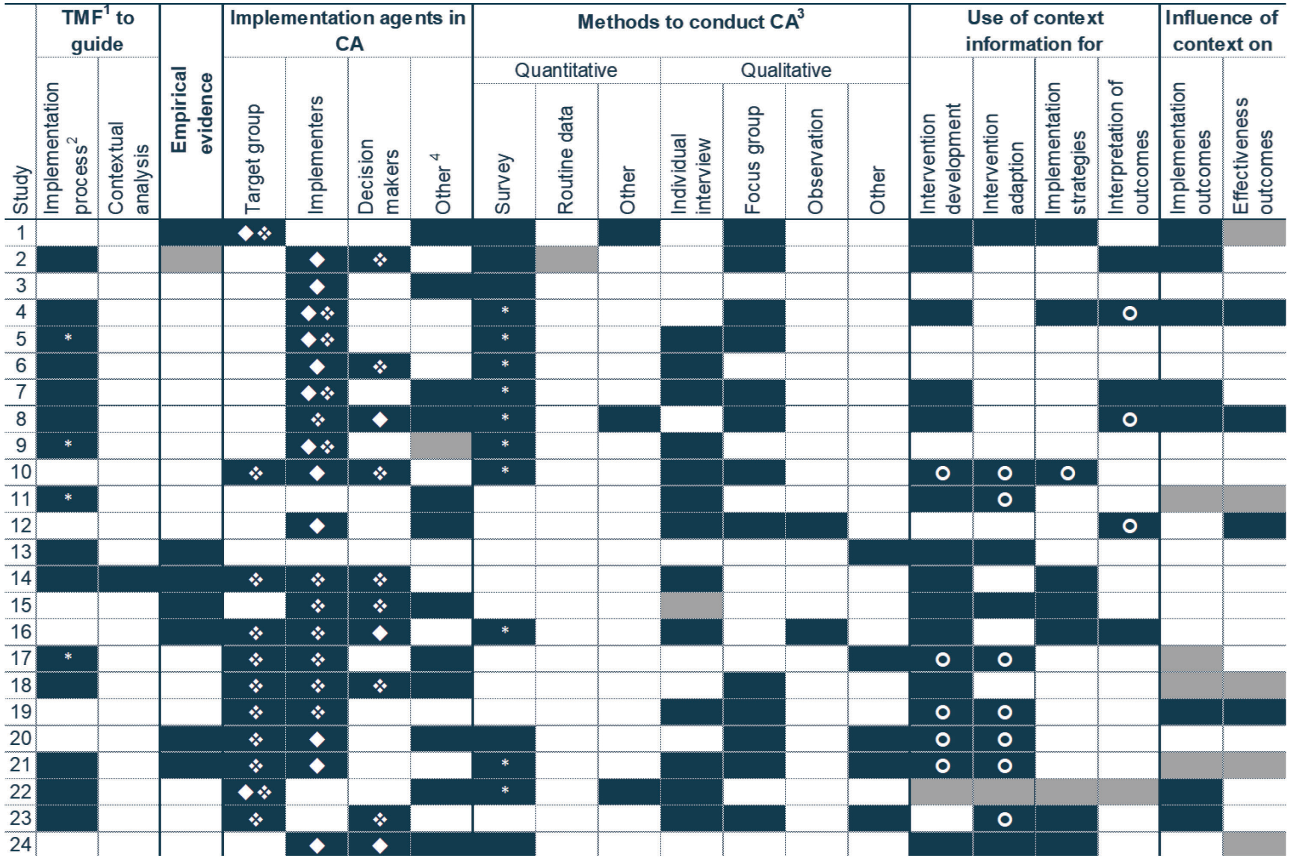

Figure 5.2. Characteristics of studies that performed contextual analyses (CAs)
Color coding: ■ dark blue = reported, □ white = not reported, ■ grey = unclear;
[1] TMF = theory, model, frameworks; [2] IP = overall implementation process in the assessed study, asterisk indicates combination of two TMFs; [3] asterisk indicates mixed methods analysis; [4] expert group / advisory panel;
◆ quantitative, ❖ qualitative; **O** authors described the process how contextual information were used

5.5.6 Contextual and setting factors assessed

We identified 43 separate factors. Following the CICI framework, we first categorized these as either context (n= 30) or setting factors (n=13), then mapped them on an evidence gap map (Additional file 6) (2). In general, meso-level factors (n=22) were most commonly assessed, accounting for almost half of all mentions. The remainder were roughly equally divided between macro- (n=13) and micro-level factors (n=12). Fifteen studies considered context on at least two levels. We report a detailed overview of all assessed factors in Additional file 7.

Contextual factors. Within context, socio-cultural factors were most commonly assessed (e.g., knowledge and perceptions, lifestyle, social structure) (n= 20); no studies reported on legal aspects. In descending order of frequency, other contextual domains included political (e.g., policies, leadership) (n=12), geographic (e.g., larger infrastructure) (n=5), epidemiological (e.g., incidence and prevalence of disease) (n=5), socio-economic (occupational aspects, living conditions) and ethical (ethical principles (n=2), conflicts of interest (n=2)). Seven studies described their assessment of inner or outer context or of facilitators and barriers, but did not further specify contextual factors in detail.

Setting factors. In view of setting, most studies assessments focused on the work environment (e.g., availability and accessibility of resources) (n=15). Other setting aspects assessed included practice patterns (e.g., service delivery, care planning) (n=11) as well as the setting's physical characteristics (e.g., study site, physical environment) (n=7).

5.5.7 Use of contextual information for subsequent project phases

Eighteen study protocols described further uses of contextual information to develop (n=17) and/or adapt interventions (n=11), eight used contextual information to choose implementation strategies, and six used it to interpret study outcomes. Of these, ten described their processes for doing that. Both original study papers described the further use of contextual information; however, only one reported how it was used.

5.5.8 Influences of contextual factors on outcomes

Twelve study protocols and both original studies reported process evaluations. We identified nine studies that explicitly reported contextual factors' influences on implementation outcomes and/or effectiveness outcomes (Figure 5.2). Various terms were used to signify similar implementation outcomes; and even where studies labeled these outcomes similarly, their definitions varied. In five protocol papers, as well as in both original studies, it was unclear whether any association had been considered

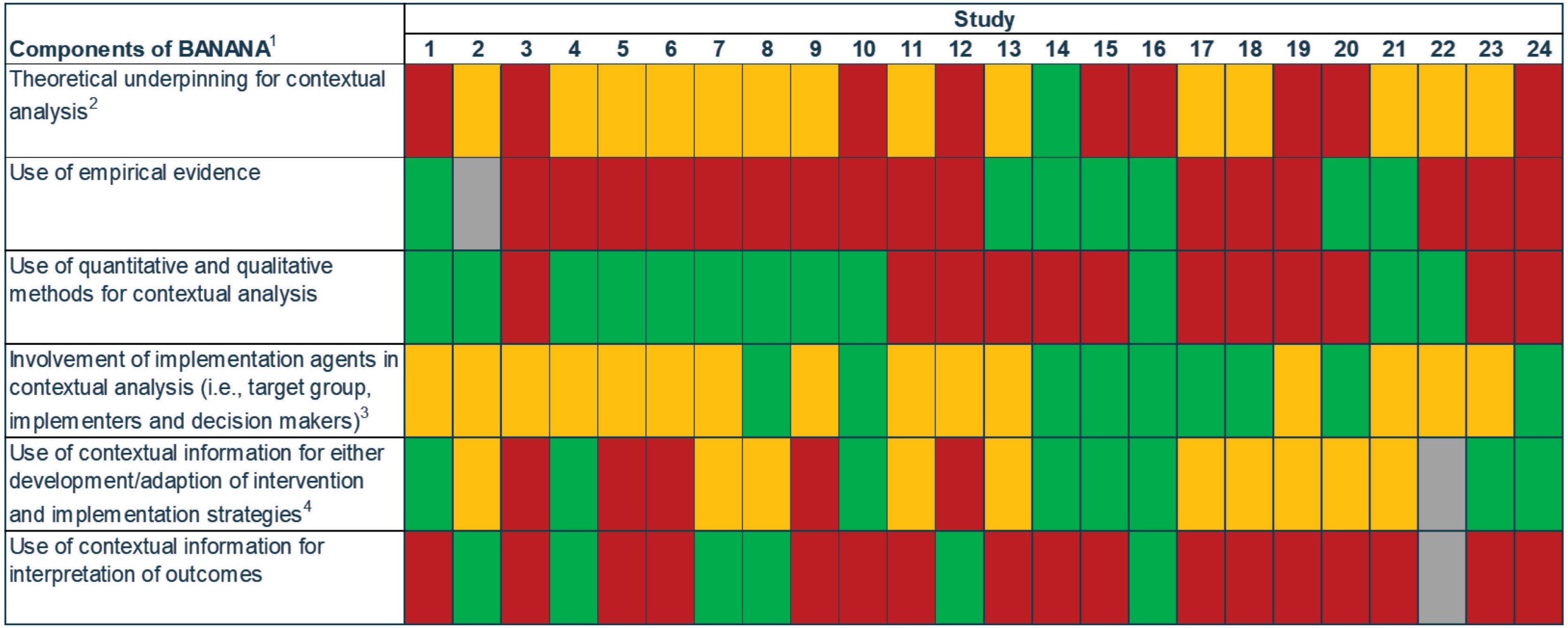

Figure 5.3. Evaluation of contextual analyses according to the Basel Approach for Contextual Analysis (BANANA). Colors indicate, whether each study clearly addressed a component (■ green), only mentioned it partly (■ yellow), failed to address it (■ red), or if it is unclear whether the component is addressed (grey). [1] including steps 1-5, whereas step five was divided into intervention/implementation strategies and implementation outcomes; as step six refers to the reporting of contextual analysis it is not included in this figure

Further explanations on color codes of specific components:

[2] ■ green = TMF indicated to specifically guide contextual analysis, ■ yellow = TMF indicated to guide overall implementation process, ■ red = no TMF indicated;

[3] ■ green = all types of implementation agents were involved (i.e., target group, implementers, and decision makers), ■ yellow = at least two types of implementation agents were involved, ■ red = no involvement of implementation agents described;

[4] ■ green = use of contextual information for intervention and implementation strategy development/adaption, ■ yellow = use for either intervention or implementation strategy development/adaption, ■ red = use of contextual information not described;

We have checked the colors used with the Chromatic Vision Simulator Web Edition 1.3 for their blind-friendliness.

between contextual factors and either implementation outcomes or effectiveness outcomes.

5.5.9 Evaluation of methodological approaches for contextual analysis

Our evaluation of the identified approaches to contextual analysis revealed that few studies addressed the key components of contextual analysis that are described in detail within BANANA (Figure 5.3). The components that most studies clearly described were *the use of quantitative and qualitative methods* (n=12) and *the involvement of implementation agents* (n=9). The latter was also described *partly* within most of the remaining studies (n=15). The two least addressed components were *the use of contextual information to interpret outcomes* (n=7) and *the use of empirical evidence* (n=7).

5.6 Discussion

This study provides an overview of the current methodological approaches to contextual analysis in intervention implementation studies and indicates gaps. Using EGM methodology, we applied a novel approach for summarizing and evaluating available evidence on contextual analysis to develop an initial evidence gap map on contextual analysis methodology. Based on a random sample drawn from 110 intervention implementation studies, we found that fewer than one-quarter of those studies (21.8%) reported on analyses of their projects' contexts and settings. The studies that did report on contextual analyses showed high variability in the methodological approaches they used. This was true for both, the analyses and of how they were reported.

Using the BANANA approach—one of the first frameworks for evaluating CAs—we found widespread significant methodological gaps. For example, few contextual analyses were theory based: only one study explicitly reported the use of a TMF for its contextual analysis; and fewer than half (8/22) provided information how they used findings from their CA to inform their project's subsequent steps.

5.6.1 Lack of TMFs guiding contextual analysis

Building our understanding of context demands a stable theoretical basis. In addition to guiding our selection of multilevel contextual factors, this will enable operationalization both of context and of setting. Still, of the 24 studies we reviewed, only one provided both a specific description of its authors' use of a TMF to guide their contextual analysis and their rationale for using the one they did (43, 44). Congruent with our findings, research shows that 22.5 – 48% of implementation science studies typically use TMFs; and of those that do, few explicitly explain their choices (44-47).

The phenomenon of “underuse, superficial use or misuse” (48) of TMFs has been described elsewhere in implementation science literature (47, 49-51). All of the identified TMFs consider context, but differ widely regarding their focus and conceptualization of context (18, 20). Lacking clear theoretical underpinnings, their assessments of contextual factors appear arbitrary. While limiting both the comparability and the generalizability of their results, this gives the impression of a lack of rigor concerning the contextual analysis. And as this analysis provides the data for further fine-tuning of the project, any such deficiencies will reduce the credibility of all subsequent study phases. This includes also the emerging focus of differentiating setting from context, which was not reflected in includes studies and complicated data analysis (2, 16).

5.6.2 Variability in conceptualization and assessment of context

Consistent with other reviews' findings, the assessed studies' conceptualizations of context tended to be vague. For example, while a diverse range of factors were assessed at numerous levels, no definitions accompanied them. The resulting vagueness (e.g., documentation of inner and outer context, local contextual determinants, environmental-level characteristics, facilitators and barriers), hampered our efforts either to understand, to summarize and to compare those factors (13, 17, 18).

We noted considerable differences regarding which levels' and domains' contextual factors were appropriate targets for investigation. In contrast to Rogers et al.'s review (18) of studies from 2008-2018, which found that micro-level factors were most often assessed, our results regarding reports published over the last six years (2015-2020) showed a significant focus on the meso level, with socio-cultural contextual factors (e.g., social structure, community structure) most frequently captured. Macro-level factors (including political, legal and socio-economic aspects) were less commonly studied.

This scarcity might also reflect a shortage of tools and frameworks focusing on the macro level (20, 24, 52, 53). However, evidence points to the importance of macro-level factors for adoption and successful implementation of interventions. For example, policy dynamics—or rather, competing policy agendas—can create major macro-level barriers to implementation (52, 54, 55). Further, when reviewing research on projects that resulted in mis-implementation of interventions, it quickly becomes clear that the most common causes of premature termination of effective interventions or programs are all funding-related (86-87.6%) (56, 57). This observation drives home the point that, to maximize the chances of a project's success (e.g., by recognizing changes in funding priorities at an early stage acquiring additional funding), its contextual analyses has to consider and closely monitor factors at every level. However, the choice of which contextual factors to study and which stakeholders to involve at which phases depends largely on the type of intervention. This may also explain why the recorded contextual factors differed so widely between studies.

Furthermore, both the assessment of context and the reporting of contextual analysis might be biased by their analysts' level of pre-existing knowledge, i.e., researchers' inside knowledge may influence the quality or impartiality of their results. For example, researchers working in a specific setting may already be aware of certain contextual determinants (e.g., processes and practice patterns) or may gather important information informally (e.g., via chance meetings with implementation agents, observation of practice). While this information is not explicitly collected for the contextual analysis, it can lead to confirmation bias. I.e., it can leave "blind spots" in contextual analysis, exerting subtle pressure on analysis or interpretation to favor factors that support pre-existing hypotheses or beliefs (58).

5.6.3 Limited involvement of various implementation agents

Both to enhance the quality of a project's research and to ensure appropriateness of intervention and implementation strategies through co-design, it is crucial to involve implementation agents in diverse positions (59, 60). This is true throughout the implementation project but especially so in the contextual analysis. Also, in the reviewed studies, the most commonly considered implementation agents were implementers; however, persons affected by the intervention and decision makers often went unrepresented. Implementation science guidelines generally recommend the most representative possible range of implementation agents' and other stakeholders' voices—the clear assumption being that this improves the likelihood of a successful and sustainable implementation (61). In order to benefit fully from implementation agents' views, a stakeholder involvement strategy should be developed, specifying both, the tasks performed by the involved implementation agents and the methods used to involve them (62).

5.6.4 Variability in methods used for contextual analysis

For contextual analysis, either a combination of quantitative and qualitative methods, or, if possible, a mixed-methods approach is recommended. Merging, connecting or embedding data obtained via various means increases both the breadth and the depth of the analysis (63, 64). It also improves our practical understanding of how interventions can work and of which implementation strategies are needed to successfully implement them (63, 65). Congruent with Rogers et al.'s findings (18), we found that only 37.5% of the studies used mixed-methods approaches (66, 67). Overall, while Rogers et al.'s sample included a smaller proportion of these approaches (19%), the tendency was the same. Like them, our sample also used more qualitative than quantitative methods (respectively 75% and 25% compared to Rogers et al.'s respective findings of 53% and 28%).

Likewise, surveys or interviews (with individuals or focus groups) were our sample's most common methods of capturing contextual details. However, recent studies increasingly emphasize the relevance of direct (e.g., ethnographic) observations in implementation research. These allow insider perspectives, including, for example, records of contextual aspects that implementation agents may take for granted and omit to mention, or tasks performed differently than generally reported (68-70).

Problematically, as contextual analysis in implementation science is primarily done within a postpositivist paradigm, researchers' understandings of context are often mechanistic and reductionistic. Therefore, we recommend that they also consider constructivist perspectives, particularly rapid ethnographic methods. In addition to probing more deeply into the context (e.g., to uncover hidden processes), these require fewer resources than traditional methods. This efficiency makes them particularly useful for contextual analyses, which are rarely well-resourced (70-72).

5.6.5 Gaps in reporting and use of contextual information

As noted above, the reviewed studies showed significant gaps in their descriptions of how contextual information was later used. The results mainly informed intervention development. However, reporting gaps may have resulted from the fact that we assessed study protocols almost exclusively.

Another factor influencing the reporting of contextual analyses in study protocols or journal articles is lack of space: a 5000-word article can adequately develop and describe its central topic, but very little more. Therefore, implementation scientists should consider publishing their contextual analyses as separate papers. This would allow detailed descriptions of their methods and results, as well as of how they used those results for further study phases. Detailed reporting guidelines for contextual analysis could help researchers to structure their findings and avoid the types of “blind spots” noted above.

5.6.6 Strengths and weaknesses

The current study's objective is to systematically review and map methodological approaches currently in use for contextual analyses, as well as to identify gaps in the identified approaches. In this regard, this paper's most notable strength is the empirical search string development. Given the reported challenges in finding implementation science literature, the string provides both high sensitivity and high specificity (73-75).

Furthermore, we provide a novel framework for evaluating existing CA-related evidence by applying the BANANA approach (27). This framework can be used as a monitoring system for literature on contextual analysis, while providing quality criteria to evaluate contextual analysis. Moreover, the developed EGM offers a concise and informative overview of the reviewed studies' results, thereby facilitating comparison between them. The map is a “living document” designed to be updatable by future researchers.

However, as we included primarily study protocols, the descriptions given of contextual analysis lacked adequate detail in some cases. This affects our analysis of how contextual information informed the studied projects' later phases. Although we searched study papers related to the protocol, we were unable to verify in every case the extent to which the planned approaches to contextual analysis were carried out in the project, or whether adaptations were made. We suspect that one major reason for the high number of identified study protocols was publishing bias. Considering that we only included articles reporting contextual analyses as part of intervention implementation studies, it is possible that many contextual analyses were reported in study protocols, then conducted as part of implementation projects but not published.

One possible weakness is that our strict inclusion criteria might have influenced our results. We focused on contextual analysis as a foundation for further study phases, i.e., prospective assessment of context and setting factors. As studies that conducted their contextual analyses retrospectively (e.g., as part of their process evaluation) would not enhance our understanding of contextual analysis in implementation science, we excluded them. For further research, it would be useful to adapt BANANA by planning a more comprehensive analysis—one that differentiates between the different implementation project phases (e.g., exploration, preparation, implementation and sustainment phase (76))—and to study differences between those phases' methodological approaches to contextual analysis.

5.7 Conclusions

To the best of our knowledge, this is the first study to provide a novel framework for evaluating and mapping methodological approaches to contextual analysis. Our evidence map provides a broad overview of methodologies applied in contextual analysis and shows which aspects of those studies can serve as models for other implementation science projects. The map is dynamic and can be updated as the literature on contextual analysis evolves.

We found wide variation regarding which methods were used for contextual analysis, which contextual factors were assessed, and how the results were applied in later study phases. Such a high level of heterogeneity is a major barrier to inter-study comparison or to later scale-up efforts. To reduce it, we recommend conducting contextual analyses according to TMFs. In addition to providing clear, proven and repeatable methodologies, these both support stronger conceptualization of the assessed context and enhance the rigor of the entire analytical process. If the described gaps are left open, contextual analysis will become a "black box" in many cases, greatly reducing its contribution over the course of implementation projects. Therefore, the implementation science community needs to take concerted action to develop, test and improve straightforward, robust methodologies for contextual analysis and reporting.

Across health care, researchers need to embrace contextual analysis as an essential element of every implementation science project; funding agencies need to develop specific opportunities to improve it; and journals need to demand full reporting on it. And every implementation science research team needs not only practical guidance on how to carry out contextual analysis, but also special guidelines on how to report their findings. Above all, we need to understand that, to achieve the quality and success that implementation science research promises, we will first need to break open the “black box” of contextual analysis.

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5.9 Supplementary Material

5.9.1 Additional file 1

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as an evidence gap map review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	3-4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	7
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	7-8
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	n.a.
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	8-9
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	9-10
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	9-10, additional file 3
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	10-11
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	10-12

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	11-12, additional file 3
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	n.a.
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	11-12
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	12, figure 1
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	13
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	n.a.
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	13-16
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	13-16
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	16-20
Limitations	20	Discuss the limitations of the scoping review process.	20-21
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	22
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	24

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.
* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to

systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

5.9.2 Additional file 2

Research questions and screening tool inclusion-/exclusion criteria

Research questions

Step 1 – Research questions with focus on all identified implementation intervention studies (limited to general data on the manuscript)
- What are the general characteristics of the studies regarding publication year, publishing journal, first author, research sector, geographical locations (country) of the research sites and design published journal? - What are the geographical locations (country) of the research sites where the implementation intervention studies were conducted? - Which hybrid designs were applied in the implementation intervention studies? - What is the total number of implementation intervention studies conducting a contextual analysis?
Step 2a - Research questions with focus on implementation intervention studies that performed a contextual analysis
- In which phase of the implementation project were contextual factors assessed (preparatory phase, baseline, midpoint, post) and how was information gathered through contextual analysis used? - Which theory, model or theoretical framework(s) according to Nilsen (1) guided the contextual analysis? - Which contextual factors were assessed at which level(s) (micro, meso, macro) in the contextual analysis and does the level correspond to the level the intervention targets? - Which domains of context were assessed in the contextual analysis according to the Context and Implementation of Complex interventions (CICI) framework (2)? - Which methods were applied to conduct the contextual analysis? - Was existing evidence from other empirical studies about relevant contextual factors considered in the contextual analysis? - Were implementation agents or other stakeholders involved during the contextual analysis?
Step 2b - Research questions that go beyond methods for conducting context analysis, but focus on the results of context analysis
- For which further study phases (e.g. intervention development, choice of implementation strategies) were contextual information used and how? - Which influences of contextual factors on implementation and effectiveness outcomes were reported?

Screening tool inclusion-/exclusion criteria

(All criteria needed to apply!)

Step 1		
Inclusion criteria		
	Criterion	**Explanation**
1	**Article type** Peer-reviewed article or study protocol	Editorials, letters to the editor, commentaries, guidelines, conference abstracts, case reports and dissertation will be excluded.
2	**Study design** Implementation intervention study	- Study tests effectiveness of an intervention (experimental or quasi-experimental design). - Intervention tested entails one of the 7 Ps (programs, practices, principles, procedures, products, pills, and policies) (3). - Intervention tested will be implemented in daily (clinical) practice. - Study reports on evaluation of implementation pathway (gathering information on implementation process qualitatively or quantitatively) and/or assessing implementation outcomes as defined by outcomes of Proctor et al. (4). If feasibility is reported as implementation outcome, at least one further implementation outcome (e.g., acceptability) needs to be reported.
3	**Language**	Paper is written in English or German.
4	**Full text**	Full text is available.
Exclusion criteria		
5	**Process evaluation**	Article is clearly labeled as process evaluation (title/abstract).
6	**Study protocol of an included study**	If study protocol: The study belonging to the protocol has already been included.

Step 2		
Inclusion criteria		
7	**Reports on contextual analysis**	- Contextual analysis entails **quantitative, qualitative, or mixed-methods** information about the context and the setting, in which the intervention will be implemented. - **Context** is defined as "a set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded. As such, context is not a backdrop for implementation, but interacts, influences, modifies and facilitates or constrains the intervention and its implementation. Context is usually considered in relation to an intervention, with which it actively interacts. It is an overarching concept, comprising not only a physical location but also roles, interactions and relationships at multiple levels" (2). - Contextual analysis is a separate step in an implementation intervention study (active data collection), which entails assessment of contextual information, e.g., **practice patterns, facilitators and barriers.** - Contextual analysis was done **prior to the start or throughout of the implementation intervention study** to inform, for example, intervention development or choice of implementation strategies.
Exclusion criteria		
	Process evaluation	- Contextual analysis conducted only part of a **process evaluation** will be excluded

Definitions of implementation outcomes

Implementation outcomes defined by Proctor et al. (4)

Implementation outcome	Definition (5)	Related terms
Acceptability	Extent to which implementation stakeholders perceive a treatment, service, practice, or innovation to be agreeable, palatable, or satisfactory.	Satisfaction with various aspects of the innovation (e.g., content, complexity, comfort, delivery, and credibility)
Adoption	Intention, initial decision, or action to try or employ an innovation or evidence-based practice.	Uptake, utilization, initial implementation, intention to try
Appropriateness	Perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation or evidence-based practice to address a particular issue or problem.	Perceived fit, relevance. Compatibility, suitability, usefulness, practicability
Feasibility	Extent to which a new innovation or practice can be successfully used or carried out within a given agency or setting. Reach + fidelity + dose = feasibility	Actual fit or utility, suitability for everyday use, practicability
Fidelity	Degree to which an intervention or implementation strategy was delivered as prescribed in the original protocol or as intended by program developers. May include multiple dimensions such as content, process, exposure, and dosage.	Delivered as intended, adherence, integrity, quality of program delivery
Implementation cost	Financial impact of an implementation effort. May include costs of treatment delivery, costs of the implementation strategy, and cost of using the service setting.	Marginal cost, cost-effectiveness, cost-benefit
Penetration	Extent to which an innovation or practice is integrated	Level of institutionalization, spread, service access
Sustainability	Extent to which a recently implemented practice is maintained and / or institutionalized within a service setting`s ongoing, stable operations.	Maintenance, continuation, durability; incorporation, integration, institutionalization, sustained use, routinization

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Data extraction tool

Step 1

	Variable	Explanation	Extracted data
General information article	**First author**	Record name of 1st author	
	Year	Record year of publication	
	Study title	Record article title	
	Journal	Record name of the journal in which the article was published	
	Article type	Record type of included article	☐ Study protocol ☐ Original article
	Country	Geographical location of study setting	
	Setting	Setting in which research was conducted	
Design	**Hybrid Design**	Which hybrid design was applied for the overall intervention study?	☐ Hybrid Type 1 ☐ Hybrid Type 2 ☐ Hybrid Type 3 ☐ Unclear
	Design clinical effectiveness	Which design was applied to evaluate effectiveness?	☐ Experimental ☐ Quasi-experimental ☐ Unclear
	Design implementation	Which design was applied to evaluate implementation?	
Outcomes	**Primary effectiveness outcome**	Record primary effectiveness outcome assessed	
	Implementation outcome	Record implementation outcome assessed	
Contextual analysis	**Contextual analysis**	Does the study report on a contextual analysis?	☐ Yes ☐ No
	Information about contextual analysis published in a further article	Is further information about the contextual analysis provided in a 2nd article? If yes record author, year and title	☐ Yes ☐ No ☐ Unclear Further information:

Step 2

	Variable	Explanation	Extracted data
Intervention	**Intervention**	Provide a brief description of the intervention	
	Intervention level	Indicate the level(s) the intervention targets	☐ Micro ☐ Meso ☐ Macro
Contextual analysis	**Timepoint contextual analysis**	Record timepoint(s) at which contextual analysis was conducted	☐ Preparatory phase Implementation phase ☐ Baseline ☐ Midpoint ☐ Post ☐ Process evaluation
	Theory, model or framework	Indicate theory, model or framework (TMF) applied to guide implementation process.	
		Indicate which theory, model or framework (TMF) was applied for contextual analysis.	
	Levels of context assessed	Indicate the level(s) at which context was studied	☐ Micro ☐ Meso ☐ Macro
	Empirical evidence	Was existing evidence from other empirical studies about relevant contextual factors considered in the contextual analysis?	☐ Yes ☐ No ☐ Unclear
	Design	Which study design was applied for contextual analysis?	☐ Quantitative ☐ Qualitative ☐ Quantitative & qualitative ☐ Unclear

Variable	Explanation	Extracted data
Mixed methods	Were data triangulated?	☐ Yes ☐ No ☐ Unclear
Methods (quantitative)	Report which contextual factors were assessed quantitatively and indicate at which level factors were assessed (micro, meso, macro)	☐ Unclear ☐ Not reported
	Specify quantitative methods applied to assess contextual factors	☐ Survey ☐ Routine data ☐ Other: ☐ Unclear ☐ Not reported
	Please indicate the measurement tool(s) used to assess contextual factors.	☐ Tool validated ☐ Tool self-developed ☐ Both ☐ Unclear ☐ Not reported
Methods (qualitative)	Report which aspects of context were explored qualitatively and indicate level at which aspect were assessed (micro, meso, macro)	☐ Unclear ☐ Not reported
	Specify qualitative data collection methods used for exploring context.	☐ Individual interviews ☐ Focus group interviews ☐ Observation ☐ Other:

Variable	Explanation	Extracted data
Implementation agents and other stakeholders	Indicate which implementation agents were included to assess contextual factors quantitatively?	Target group: Implementers: Decision makers: Other:
	Indicate which implementation agents were included to assess contextual factors qualitatively?	Target group: Implementers: Decision makers: Other:
	Was there a group of experts or an advisory board involved during the implementation study? If yes, report participants.	☐ Yes ☐ No ☐ Unclear Participants:
Funding	Indicate whether funding was received for the study.	☐ Yes, for overall project ☐ Yes, specifically for contextual analysis ☐ No ☐ Unclear

	Variable	Explanation	Extracted data
Use of context information	**Use of context information**	For which further study phase did authors used results from contextual analysis?	Intervention development ☐ Yes ☐ No ☐ Unclear Intervention adaption ☐ Yes ☐ No ☐ Unclear Implementation strategies ☐ Yes ☐ No ☐ Unclear Interpretation of outcomes ☐ Yes ☐ No ☐ Unclear
	How context information was used	Is there any description of the process how results were used to inform next study phase?	Intervention development ☐ Yes ☐ No ☐ Unclear Intervention adaption ☐ Yes ☐ No ☐ Unclear Implementation strategies ☐ Yes ☐ No ☐ Unclear Interpretation of outcomes ☐ Yes ☐ No ☐ Unclear

	Variable	Explanation	Extracted data
Evaluation implementation pathway	**Process evaluation**	Was a process evaluation planned or results of a process evaluation described as part of the implementation intervention study?	☐ Described ☐ Planned ☐ Unclear ☐ Not reported
	Influence on outcomes assessed	Was an association between contextual factors and implementation outcomes assessed?	☐ Yes ☐ Planned ☐ Unclear ☐ Not reported
		Was an association between contextual factors and summative outcomes assessed?	☐ Yes ☐ Planned ☐ Unclear ☐ Not reported

5.9.3 Additional file 3

Empirical search string development

Search string in Pubmed to identify relevant articles for development- and validation set (18.01.2021):

implementation[Title/Abstract] OR adoption[Title/Abstract] OR dissemination[Title/Abstract] OR implementation research[Title/Abstract] OR complex intervention[Title/Abstract]

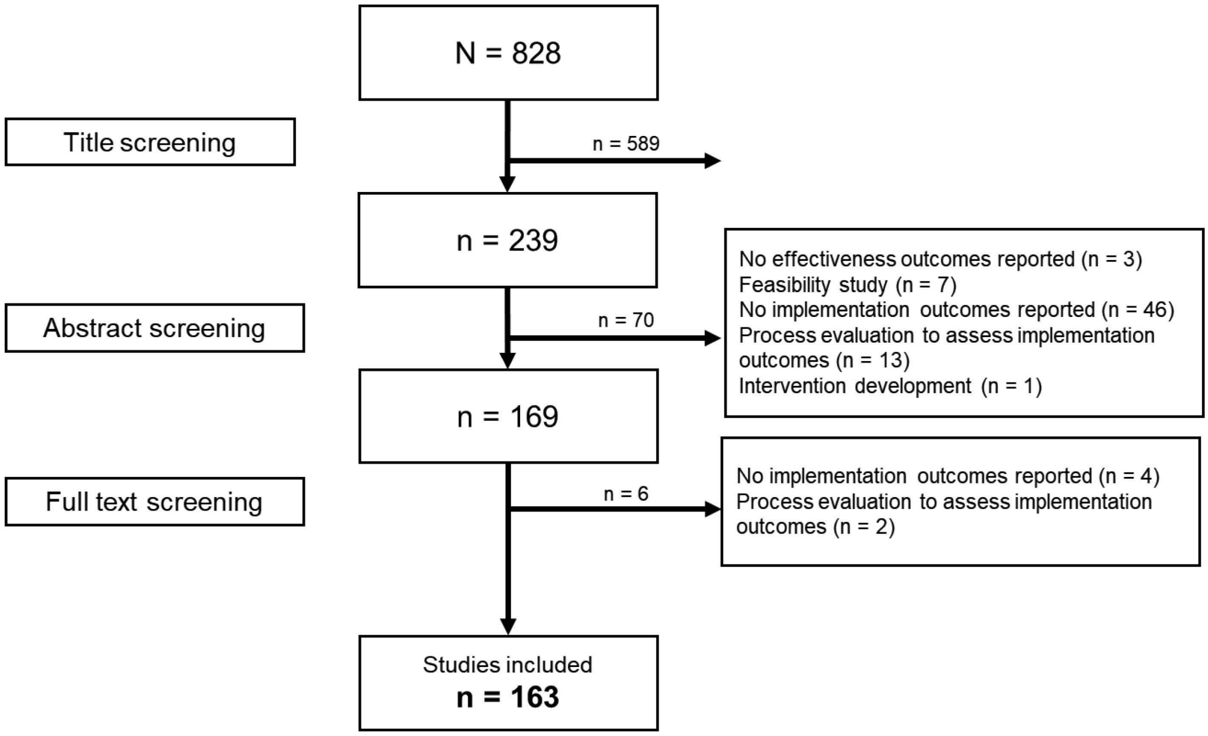
AND

acceptability[Title/Abstract] OR adoption[Title/Abstract] OR uptake[Title/Abstract] OR utilization[Title/Abstract] OR initial implementation[Title/Abstract] OR intention to try[Title/Abstract] OR appropriateness[Title/Abstract] OR perceived fit[Title/Abstract] OR relevance[Title/Abstract] OR compatibility[Title/Abstract] OR suitability[Title/Abstract] OR usefulness[Title/Abstract] OR practicability[Title/Abstract] OR feasibility OR utility[Title/Abstract] OR fidelity[Title/Abstract] OR adherence[Title/Abstract] OR integrity[Title/Abstract] OR implementation cost[Title/Abstract] OR penetration[Title/Abstract] OR sustainability[Title/Abstract] OR maintenance[Title/Abstract] OR continuation[Title/Abstract] OR durability[Title/Abstract] OR incorporation[Title/Abstract] OR integration[Title/Abstract] OR institutionalization[Title/Abstract] OR sustained use[Title/Abstract] OR routinization[Title/Abstract]

AND

study protocol[Title/Abstract] OR Clinical Trial Protocol[Publication Type] Filters: Clinical Trial, Clinical Trial Protocol, from 2006 - 2021 Sort by: Publication Date

Screening of relevant articles to be included in the development and validation set:



Articles included in the development and validation set:

Development Set (n = 81)

32552833 [PMID] OR 32160891 [PMID] OR 32075677 [PMID] OR 31996189 [PMID] OR 31907017 [PMID] OR 31882012 [PMID] OR 31842963 [PMID] OR 31791285 [PMID] OR 31753004 [PMID] OR 31712337 [PMID] OR 31678952 [PMID] OR 31594892 [PMID] OR 31500661 [PMID] OR 31477140 [PMID] OR 31310353 [PMID] OR 31409421 [PMID] OR 31326936 [PMID] OR 31307535 [PMID] OR 31289075 [PMID] OR 31248932 [PMID] OR 31233859 [PMID] OR 31196137 [PMID] OR 31092643 [PMID] OR 31046695 [PMID] OR 30951837 [PMID] OR 30904839 [PMID] OR 30872550 [PMID] OR 30798294 [PMID] OR 30772862 [PMID] OR 30683155 [PMID] OR 30634955 [PMID] OR 30782696 [PMID] OR 30604208 [PMID] OR 30594236 [PMID] OR 30576842 [PMID] OR 30552244 [PMID] OR 30514378 [PMID] OR 30290276 [PMID] OR 30103776 [PMID] OR 30075806 [PMID] OR 30055336 [PMID] OR 30021547 [PMID] OR 30005705 [PMID] OR 29895651 [PMID] OR 29880047 [PMID] OR 29866729 [PMID] OR 29788996 [PMID] OR 29764876 [PMID] OR 29739384 [PMID] OR 29661178 [PMID] OR 29606129 [PMID] OR 29522897 [PMID] OR 29374672 [PMID] OR 29370829 [PMID] OR 29288172 [PMID] OR 29157275 [PMID] OR 28821264 [PMID] OR 28630086 [PMID] OR 28166816 [PMID] OR 28109247 [PMID] OR 27884169 [PMID] OR 27798024 [PMID] OR 27756281 [PMID] OR 27592122 [PMID] OR 27553492 [PMID] OR 27473180 [PMID] OR 27400657 [PMID] OR 27130272 [PMID] OR 26936623 [PMID] OR 26831332 [PMID] OR 26353825 [PMID] OR 26268221 [PMID] OR 26297321 [PMID] OR 26100026 [PMID] OR 25873044 [PMID] OR 25527071 [PMID] OR 25273854 [PMID] OR 24950708 [PMID] OR 24559178 [PMID] OR 23758974 [PMID] OR 21851643 [PMID]

Validation Set (n = 82)

33419461 [PMID] OR 32375741 [PMID] OR 32084445 [PMID] OR 32005137 [PMID] OR 31907074 [PMID] OR 31888941 [PMID] OR 31874872 [PMID] OR 31829186 [PMID] OR 31784436 [PMID] OR 31727650 [PMID] OR 31699046 [PMID] OR 31619250 [PMID] OR 31525489 [PMID] OR 31481370 [PMID] OR 31462477 [PMID] OR 31416439 [PMID] OR 31345971 [PMID] OR 31324682 [PMID] OR 31300028 [PMID] OR 31289060 [PMID] OR 31248921 [PMID] OR 31215468 [PMID] OR 31138165 [PMID] OR 31063870 [PMID] OR 30992293 [PMID] OR 30928927 [PMID] OR 30898129 [PMID] OR 30808379 [PMID] OR 30777122 [PMID] OR 30696686 [PMID] OR 30782719 [PMID] OR 30782749 [PMID] OR 30630108 [PMID] OR 30598489 [PMID] OR 30587235 [PMID] OR 30576841 [PMID] OR 30547745 [PMID] OR 30383672 [PMID] OR 30208344 [PMID] OR 30081967 [PMID] OR 30071866 [PMID] OR 30041598 [PMID] OR 30007924 [PMID] OR 30146493 [PMID] OR 29884164 [PMID] OR 29866736 [PMID] OR 29858405 [PMID] OR 29769080 [PMID] OR 29739358 [PMID] OR 29716605 [PMID] OR 29625599 [PMID] OR 29602847 [PMID] OR 29506563 [PMID] OR 29373993 [PMID] OR 29334983 [PMID] OR 29202867 [PMID] OR 29078810 [PMID] OR 28720140 [PMID] OR 28532439 [PMID] OR 28115006 [PMID] OR 28003294 [PMID] OR 27842539 [PMID] OR 27770819 [PMID] OR 27707836 [PMID] OR 27557641 [PMID] OR 27473371 [PMID] OR 27417199 [PMID] OR 27354070 [PMID] OR 27084667 [PMID] OR 26845030 [PMID] OR 27015913 [PMID] OR 26345270 [PMID] OR 26223232 [PMID] OR 26112224 [PMID] OR 26018048 [PMID] OR 25887849 [PMID] OR 25443043 [PMID] OR 25224756 [PMID] OR 24719431 [PMID] OR 23924263 [PMID] OR 23731594 [PMID] OR 17274807 [PMID]

PMID: PubMed IDentifier

Final search string

implementation science[MeSH Terms] OR implement[Title/Abstract] OR implementation[Title/Abstract] OR introduce[Title/Abstract] OR introduced[Title/Abstract] OR introducing[Title/Abstract] OR introduction[Title/Abstract]

AND

sustainable[Title/Abstract] OR sustainability[Title/Abstract] OR dissemine[Title/Abstract] OR dissemination[Title/Abstract] OR adherent[Title/Abstract] OR adherence[Title/Abstract] OR acceptable[Title/Abstract] OR acceptability[Title/Abstract] OR feasible[Title/Abstract] OR feasibility[Title/Abstract] OR feasibly[Title/Abstract] OR effectiveness[Title/Abstract]

AND

trial[Title/Abstract] OR trialing[Title/Abstract] OR trials[Title/Abstract]

Sensitivity development set: 95.1% (n=77)

Sensitivity validation set: 91.5% (n=75)

5.9.4 Additional file 4

STEP 1 - General characteristics of identified implementation intervention studies (n = 110)

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
1	Apers H	2020	Development and Evaluation of an HIV-Testing Intervention for Primary Care: Protocol for a Mixed Methods Study	JMIR Res Protoc	Study protocol	Belgium	Primary care	*Hybrid type 1*
2	Berhanu D	2020	Protocol for the evaluation of a complex intervention aiming at increased utilisation of primary child health services in Ethiopia: a before and after study in intervention and comparison areas	BMC Health Services Research	Study protocol	Ethiopia	Primary care	*Hybrid type 1*
3	Bidwell P	2018	A multi-centre quality improvement project to reduce the incidence of obstetric anal sphincter injury (OASI): study protocol	BMC Pregnancy Childbirth	Study protocol	UK	Hospitals	*Hybrid type 2*
4	D'Onofrio G	2019	Implementation facilitation to promote emergency department-initiated buprenorphine for opioid use disorder: protocol for a hybrid type III effectiveness-implementation study (Project ED HEALTH)	Implementation Sci	Study protocol	USA	Emergency departments	Hybrid type 3
5	Grazioli VS	2019	Implementing a case management intervention for frequent users of the emergency department (I-CaM): an effectiveness-implementation hybrid trial study protocol	BMC Health Serv Res	Study protocol	Switzerland	Emergency departments	Hybrid type 2
6	Hartzler B	2017	Implementing the teen marijuana check-up in schools-a study protocol	Implement Sci	Study protocol	US	Schools	Hybrid type 2
7	Johnson K	2018	The effectiveness of a group-based computerized HIV/STI prevention intervention for black women who use drugs in the criminal justice system: study protocol for E-WORTH (Empowering African-American Women on the Road to Health): a Hybrid Type 1 randomized controlled trial	Trials	Study protocol	US	Justice	Hybrid type 1
8	Knight DK	2016	Juvenile Justice-Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS): a cluster randomized trial targeting system-wide improvement in substance use services	Implementation Sci	Study protocol	US	Justice	*Hybrid type 3*
9	Kwan BM	2020	The Invested in Diabetes Study Protocol: a cluster randomized pragmatic trial comparing standardized and patient-driven diabetes shared medical appointments	Trials	Study protocol	US	Primary care	*Hybrid type 1*
10	Lakerveld J	2018	Improving cardiometabolic health through nudging dietary behaviours and physical activity in low SES adults: design of the Supreme Nudge project	BMC Public Health	Study protocol	Netherlands	Supermarkets	*Hybrid type 1*

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
11	Nahar P	2020	A protocol paper: community engagement interventions for cardiovascular disease prevention in socially disadvantaged populations in the UK: an implementation research study	Glob Health Res Policy	Study protocol	UK	Health care system	*Hybrid type 1*
12	Osilla KC	2020	Study design to evaluate a group-based therapy for support persons of adults on buprenorphine/naloxone	Addict Sci Clin Pract	Study protocol	US	Outpatient care	*Hybrid type 1*
13	Quintiliani LM	2015	Patient navigation and financial incentives to promote smoking cessation in an underserved primary care population: A randomized controlled trial protocol	Contemp Clin Trials	Study protocol	US	Primary care	*Hybrid type 1*
14	Rahm AK	2018	Implementing universal Lynch syndrome screening (IMPULSS): protocol for a multi-site study to identify strategies to implement adapt and sustain genomic medicine programs in different organizational contexts	BMC Health Serv Res	Study protocol	US	Health care system	*Hybrid type 1*
15	Rotter T	2017	The development implementation and evaluation of clinical pathways for chronic obstructive pulmonary disease (COPD) in Saskatchewan: protocol for an interrupted times series evaluation	BMC Health Serv Res	Study protocol	Canada	Health care system	*Hybrid type 2*
16	Saevareid TJL	2018	Implementing advance care planning in nursing homes - study protocol of a cluster-randomized clinical trial	BMC Geriatr	Study protocol	Norway	Nursing homes	*Hybrid type 1*
17	Shanley DC	2019	Protocol for the Yapatjarrathati project: a mixed-method implementation trial of a tiered assessment process for identifying fetal alcohol spectrum disorders in a remote Australian community	BMC Health Serv Res	Study protocol	Australia	Health care system	*Hybrid type 2*
18	Smeltzer MP	2018	Pragmatic trial of a multidisciplinary lung cancer care model in a community healthcare setting: study design implementation evaluation and baseline clinical results	Transl Lung Cancer Res	Original article	US	Community care	*Hybrid type 1*
19	Steele Gray C	2016	Supporting Goal-Oriented Primary Health Care for Seniors with Complex Care Needs Using Mobile Technology: Evaluation and Implementation of the Health System Performance Research Network, Bridgepoint Electronic Patient Reported Outcome Tool	JMIR Res Protoc	Study protocol	Canada	Primary care	*Hybrid type 1*
20	Sutherland R	2019	Protocol for an effectiveness- implementation hybrid trial to assess the effectiveness and cost-effectiveness of an m-health intervention to decrease the consumption of discretionary foods packed in school lunchboxes: the 'SWAP IT' trial	BMC Public Health	Study protocol	Australia	Schools	Hybrid type 1
21	Taylor R	2015	Clinical effectiveness and cost-effectiveness of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) facilitated self-care rehabilitation intervention in heart failure patients and caregivers: rationale and protocol for a multicentre randomised controlled trial	Pilot and Feasibility Studies	Original article	UK	Rehabilitation services	*Hybrid type 1*

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
22	van Delft LMM	2019	Hospital in Motion a Multidimensional Implementation Project to Improve Patients' Physical Behavior During Hospitalization: Protocol for a Mixed-Methods Study	JMIR Res Protoc	Study protocol	Netherlands	Hospitals	*Hybrid type 1*
23	van Dongen BM	2019	Background and evaluation design of a community-based health-promoting school intervention: Fit Lifestyle at School and at Home (FLASH)	BMC Public Health	Study protocol	Netherlands	Schools	*Hybrid type 1*
24	Verjans-Janssen SRB	2018	Study protocol of the quasi-experimental evaluation of "KEIGAAF": a context-based physical activity and nutrition intervention for primary school children	BMC Public Health	Study protocol	Netherlands	Schools	*Hybrid type 1*
25	Abdelaziz TS	2016	Acute Kidney Outreach to Reduce Deterioration and Death (AKORDD) trial: the protocol for a large pilot study	BMJ Open	Study protocol	UK	Health care system	-
26	Abraham J	2019	Implementation of a multicomponent intervention to prevent physical restraints in Nursing homes (IMPRINT): A pragmatic cluster randomized controlled trial	Int J Nurs Stud	Original article	Germany	Nursing homes	-
27	Agar M	2015	Pragmatic cluster randomised controlled trial of facilitated family case conferencing compared with usual care for improving end of life care and outcomes in nursing home residents with advanced dementia and their families: the IDEAL study protocol	BMC Palliative Care	Study protocol	Australia	Nursing homes	-
28	Amaefule CE	2020	Effectiveness and acceptability of metformin in preventing the onset of type 2 diabetes after gestational diabetes in postnatal women: a protocol for a randomised, placebo-controlled, double-blind feasibility trial-Optimising health outcomes with Metformin to prevent diAbetes After pregnancy (OMAhA)	BMJ Open	Study protocol	UK	Nursing homes	-
29	Andersen S	2015	Shaping the Social: design of a settings-based intervention study to improve well-being and reduce smoking and dropout in Danish vocational schools	BMC Public Health	Study protocol	Denmark	Schools	-
30	Atanda O	2020	Evaluation of Mental Health First Aid from the Perspective Of Workplace End UseRs-EMPOWER: protocol of cluster randomised trial phase	Trials	Study protocol	UK	Workplace	-
31	Aziz Z	2018	A group-based lifestyle intervention for diabetes prevention in low- and middle-income country: implementation evaluation of the Kerala Diabetes Prevention Program	Implement Sci	Original article	India	Health care system	-
32	Baba CT	2017	Evaluating the impact of a walking program in a disadvantaged area: using the RE-AIM framework by mixed methods	BMC Public Health	Original article	Brazil	Primary health care	-

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
33	Babughirana G	2020	Effects of Implementing the Timed and Targeted Counselling Model on Pregnancy Outcomes and Newborn Survival in Rural Uganda: Protocol for a Quasi-Experimental Study	Methods Protoc	Study protocol	Uganda	Health care system	-
34	Banfield M	2020	Contextual influences on the impact of a peer worker-led self-stigma program for people with mental health issues: protocol for an interventional implementation science study	Implement Sci Commun	Study protocol	Australia	Mental health care	-
35	Bast LS	2019	Implementation fidelity and adolescent smoking: The X:IT study-A school randomized smoking prevention trial	Eval Program Plann	Original article	Denmark	Schools	-
36	Benedetti TRB	2020	Re-thinking Physical Activity Programs for Older Brazilians and the Role of Public Health Centers: A Randomized Controlled Trial Using the RE-AIM Model	Frontiers in Public Health	Original article	Brazil	Community care	-
37	Betancourt TS	2020	Youth Functioning and Organizational Success for West African Regional Development (Youth FORWARD): Study Protocol	Psychiatr Serv	Study protocol	Sierra Leone	Mental health care	Hybrid type 2
38	Bettger JP	2020	Comparative implementation-effectiveness of three strategies to perform hearing screening among older adults in primary care clinics: study design and protocol	BMC Geriatrics	Study protocol	US	Primary care	Hybrid type 1
39	Boersma P	2017	Study protocol Implementation of the Veder contact method (VCM) in daily nursing home care for people with dementia: an evaluation based on the RE-AIM framework	Aging Ment Health	Study protocol	Netherlands	Nursing homes	-
40	Bower P	2015	A cluster randomised controlled trial and process evaluation of a training programme for mental health professionals to enhance user involvement in care planning in service users with severe mental health issues (EQUIP): study protocol for a randomised controlled trial	Trials	Study protocol	UK	Mental health care	-
41	Brain D	2020	Protocol for a randomised trial testing a community fibrosis assessment service for patients with suspected non-alcoholic fatty liver disease: LOCal assessment and triage evaluation of non-alcoholic fatty liver disease (LOCATE-NAFLD)	BMC Health Serv Res	Study protocol	Australia	Primary care	-
42	Brett L	2019	Ageing well: evaluation of social participation and quality of life tools to enhance community aged care (study protocol)	BMC Geriatr	Study protocol	Australia	Community care	-
43	Cassarino M	2019	A randomised controlled trial exploring the impact of a dedicated health and social care professionals team in the emergency department on the quality, safety, clinical and cost-effectiveness of care for older adults: a study protocol	Trials	Study protocol	Ireland	Emergency departments	-
44	Chewning B	2020	Disseminating Tai Chi in the Community: Promoting Home Practice and Improving Balance	Gerontologist	Original article	US	Community care	-

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
45	Chirwa E	2020	An effectiveness-implementation hybrid type 1 trial assessing the impact of group versus individual antenatal care on maternal and infant outcomes in Malawi	BMC Public Health	Study protocol	Malawi	Hospitals	Hybrid type 1
46	Correard F	2020	Impact of medication review via tele-expertise on unplanned hospitalizations at 3 months of nursing homes patients (TEM-EHPAD): study protocol for a randomized controlled trial	BMC Geriatrics	Study protocol	French	Nursing homes	-
47	Damschroder LJ	2017	Implementation findings from a hybrid III implementation-effectiveness trial of the Diabetes Prevention Program (DPP) in the Veterans Health Administration (VHA)	Implement Sci	Study protocol	US	Veterans Health Administration	Hybrid type 3
48	Dixit A	2019	A gender synchronized family planning intervention for married couples in rural India: study protocol for the CHARM2 cluster randomized controlled trial evaluation	Reprod Health	Study protocol	India	Family planning services	-
49	Filippopulos FM	2020	Computerized clinical decision system and mobile application with expert support to optimize management of vertigo in primary care: study protocol for a pragmatic cluster-randomized controlled trial	J Neurol	Study protocol	Germany	Primary care	-
50	Finney Rutten LJ	2020	Pragmatic cluster randomized trial to evaluate effectiveness and implementation of enhanced EHR-facilitated cancer symptom control (E2C2)	Trials	Study protocol	US	Hospitals	-
51	Gavalda-Espelta E	2020	Effectiveness of the integrated care model Salut+Social in patients with chronic conditions: A mixed methods study protocol	Medicine (Baltimore)	Study protocol	Spain	Health care system	-
52	Gelli A	2017	Improving diets and nutrition through an integrated poultry value chain and nutrition intervention (SELEVER) in Burkina Faso: study protocol for a randomized trial	Trials	Study protocol	Burkina Faso	Community care	-
53	Goldstein KM	2019	An electronic family health history tool to identify and manage patients at increased risk for colorectal cancer: protocol for a randomized controlled trial	Trials	Study protocol	US	Primary care	-
54	Gonzalez JS	2020	Design and methods of NYC care calls: An effectiveness trial of telephone-delivered type 2 diabetes self-management support	Contemp Clin Trials	Study protocol	US	Primary care	-
55	Hannon PA	2016	HealthLinks randomized controlled trial: Design and baseline results	Contemp Clin Trials	Study protocol	US	Workplace	-
56	Hawk M	2017	Using a Mixed Methods Approach to Examine Practice Characteristics Associated With Implementation of an Adult Immunization Intervention Using the 4 Pillars Practice Transformation Program	Journal for Healthcare Quality	Original article	US	Primary care	-
57	Haynes T	2018	Reducing depressive symptoms through behavioral activation in churches: A Hybrid-2 randomized effectiveness-implementation design	Contemporary Clinical Trials	Study protocol	US	Churches	Hybrid type 2

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
58	Heazell AEP	2017	Can promoting awareness of fetal movements and focusing interventions reduce fetal mortality? A stepped-wedge cluster randomised trial (AFFIRM)	BMJ Open	Study protocol	UK/Ireland	Hospitals	-
59	Heisler M	2019	Study protocol for a Community Health Worker (CHW)-led comprehensive neighborhood-focused program for medicaid enrollees in detroit	Contemp Clin Trials Commun	Study protocol	US	Community health care	-
60	Hensel JM	2016	A pragmatic randomized control trial and realist evaluation on the implementation and effectiveness of an internet application to support self-management among individuals seeking specialized mental health care: a study protocol	BMC Psychiatry	Study protocol	Canada	Mental health care	-
61	Hilbink M	2016	Effectiveness of a medication-adherence tool: study protocol for a randomized controlled trial	Trials	Study protocol	Netherlands	Pharmacies	-
62	Husebo BS	2015	COSMOS-improving the quality of life in nursing home patients: protocol for an effectiveness-implementation cluster randomized clinical hybrid trial	Implementation Sci	Study protocol	Norway	Nursing homes	Hybrid type 2
63	Huybregts L	2017	The impact of integrated prevention and treatment on child malnutrition and health: the PROMIS project, a randomized control trial in Burkina Faso and Mali	BMC Public Health	Study protocol	Burkina Faso/Mali	Community care	-
64	Islam N	2018	Protocol for the CHORD project (community health outreach to reduce diabetes): a cluster-randomized community health worker trial to prevent diabetes	BMC Public Health	Study protocol	US	Primary care	-
65	Jussila AM	2015	KIDS OUT! Protocol of a brief school-based intervention to promote physical activity and to reduce screen time in a sub-cohort of Finnish eighth graders	BMC Public Health	Study protocol	Finnland	Schools	-
66	Kilbourne AM	2018	Adaptive School-based Implementation of CBT (ASIC): clustered-SMART for building an optimized adaptive implementation intervention to improve uptake of mental health interventions in schools	Implement Sci	Study protocol	US	Schools	-
67	Kirkevold M	2018	Promoting psychosocial well-being following stroke: study protocol for a randomized, controlled trial	BMC Psychol	Study protocol	Norway	Rehabilitation services	-
68	Kobel S	2017	Design, Implementation, and Study Protocol of a Kindergarten-Based Health Promotion Intervention	Biomed Res Int	Study protocol	Germany	Kindergarten	-
69	Lane HG	2018	"Wellness Champions for Change," a multi-level intervention to improve school-level implementation of local wellness policies: Study protocol for a cluster randomized trial	Contemporary Clinical Trials	Study protocol	US	Schools	-
70	Lander N	2020	Embedding Active Pedagogies within Pre-Service Teacher Education: Implementation Considerations and Recommendations	Children	Original article	Australia	Schools	-

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
71	Legare F	2016	Implementing shared decision-making in interprofessional home care teams (the IPSDM-SW study): protocol for a stepped wedge cluster randomised trial	BMJ Open	Study protocol	Canada	Nursing homes	-
72	LeLaurin JH	2020	An Implementation Trial to Improve Tobacco Treatment for Cancer Patients: Patient Preferences, Treatment Acceptability and Effectiveness	Int J Environ Res Public Health	Original article	US	Outpatient clinic	-
73	Leyenaar JK	2020	Comparative effectiveness of direct admission and admission through emergency departments for children: a randomized stepped wedge study protocol	Trials	Study protocol	US	Emergency departments	-
74	Lim S	2019	The DREAM Initiative: study protocol for a randomized controlled trial testing an integrated electronic health record and community health worker intervention to promote weight loss among South Asian patients at risk for diabetes	Trials	Study protocol	US	Community care	-
75	Mangin D	2020	Health TAPESTRY Ontario: protocol for a randomized controlled trial to test reproducibility and implementation	Trials	Study protocol	Australia	Primary health care	Hybrid type 2
76	Margolis KL	2020	Design of a pragmatic cluster-randomized trial comparing telehealth care and best practice clinic-based care for uncontrolled high blood pressure	Contemp Clin Trials	Study protocol	US	Primary care	-
77	Markle-Reid M	2020	Study protocol for a hospital-to-home transitional care intervention for older adults with multiple chronic conditions and depressive symptoms: a pragmatic effectiveness-implementation trial	BMC Geriatr	Study protocol	Australia	Hospitals	Hybrid type 2
78	Martin RS	2017	Implementation of 'Goals of Patient Care' medical treatment orders in residential aged care facilities: protocol for a randomised controlled trial	BMJ Open	Study protocol	Australia	Nursing homes	-
79	Martino S	2016	The Effectiveness and Cost of Clinical Supervision for Motivational Interviewing: A Randomized Controlled Trial	J Subst Abuse Treat	Original article	US	Outpatient care	Hybrid type 2
80	Matthews L	2017	Study protocol for the 'HelpMeDoIt!' randomised controlled feasibility trial: an app, web and social support-based weight loss intervention for adults with obesity	BMJ Open	Study protocol	Scotland	Community care	-
81	Maxwell AE	2016	Implementation of an evidence-based intervention to promote colorectal cancer screening in community organizations: a cluster randomized trial	Transl Behav Med	Original article	US	Community care	-
82	McCreight MS	2019	Improving anti-platelet therapy adherence in the Veterans Health Administration: A randomized multi-site hybrid effectiveness-implementation study protocol	Contemp Clin Trials	Study protocol	US	Veterans Health Administration	Hybrid type 1
83	McKay H	2018	Implementation of a co-designed physical activity program for older adults: positive impact when delivered at scale	BMC Public Health	Original article	Canada	Community care	Hybrid type 2

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
84	McIlvennan CK	2016	A Multicenter Trial of a Shared Decision Support Intervention for Patients and Their Caregivers Offered Destination Therapy for Advanced Heart Failure: DECIDE-LVAD Rationale, Design, and Pilot Data	Journal of Cardiovascular Nursing	Study protocol	US	Health care system	-
85	Muller C	2020	Effects of strategies to improve general practitioner-nurse collaboration and communication in regard to hospital admissions of nursing home residents (interprof ACT): study protocol for a cluster randomised controlled trial	Trials	Study protocol	Germany	Nursing homes	-
86	Nelson LA	2018	Mobile Phone Support for Diabetes Self-Care Among Diverse Adults: Protocol for a Three-Arm Randomized Controlled Trial	JMIR Research Protocols	Study protocol	US	Primary care	Hybrid type 1
87	Packel L	2020	Optimizing the efficiency and implementation of cash transfers to improve adherence to antiretroviral therapy: study protocol for a cluster randomized controlled trial	Trials	Study protocol	Tanzania	Health care system	Hybrid type 1
88	Pitpitan EV	2018	Factors associated with program effectiveness in the implementation of a sexual risk reduction intervention for female sex workers across Mexico: Results from a randomized trial	PLoS One	Original article	Mexico	Community care	Hybrid type 1
89	Price-Haywood EG	2021	Depression, anxiety, pain and chronic opioid management in primary care: Type II effectiveness-implementation hybrid stepped wedge cluster randomized trial	Contemp Clin Trials	Study protocol	US	Primary care	Hybrid type 2
90	Rasmussen CDN	2020	App-Delivered Self-Management Intervention Trial selfBACK for People With Low Back Pain: Protocol for Implementation and Process Evaluation	JMIR Res Protoc	Study protocol	Denmark/Norway	Health care system	-
91	Rathod S	2016	Protocol for a multicentre study to assess feasibility, acceptability, effectiveness and direct costs of TRIumPH (Treatment and Recovery In PsycHosis): integrated care pathway for psychosis	BMJ Open	Study protocol	UK	Mental health care	-
92	Ray-Barruel G	2018	Implementing the I-DECIDED clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: protocol for an interrupted time-series study	BMJ Open	Study protocol	Australia	Hospitals	-
93	Reaven J	2018	Training clinicians to deliver group CBT to manage anxiety in youth with ASD: Results of a multisite trial	J Consult Clin Psychol	Original article	US	Mental health care	-
94	Ribbink ME	2020	Investigating the effectiveness of care delivery at an acute geriatric community hospital for older adults in the Netherlands: a protocol for a prospective controlled observational study	BMJ Open	Study protocol	Netherlands	Hospitals	-
95	Richter S	2020	People with multimorbidity in outpatient care: patient-focused and needs-oriented healthcare management (MamBo) - protocol for a multiperspective evaluation study	BMC Health Serv Res	Study protocol	Germany	Outpatient care	-
96	Ruble LA	2018	Randomized Control Trial of COMPASS for Improving Transition Outcomes of Students with Autism Spectrum Disorder	J Autism Dev Disord	Original article	US	Schools	-

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
97	Scheffers-van Schayck T	2018	Evaluation and Implementation of a Proactive Telephone Smoking Cessation Counseling for Parents: A Study Protocol of an Effectiveness Implementation Hybrid Design	Int J Environ Res Public Health	Study protocol	Netherlands	Community care	Hybrid type 2
98	Smith JD	2018	An individually tailored family-centered intervention for pediatric obesity in primary care: study protocol of a randomized type II hybrid effectiveness-implementation trial (Raising Healthy Children study)	Implement Sci	Study protocol	US	Primary care	Hybrid type 2
99	Straßner C	2019	Holistic care program for elderly patients to integrate spiritual needs, social activity, and self-care into disease management in primary care (HoPES3): study protocol for a cluster-randomized trial	Trials	Study protocol	Germany	Primary care	-
100	Sud A	2020	Sahaj Samadhi Meditation versus a Health Enhancement Program for depression in chronic pain: protocol for a randomized controlled trial and implementation evaluation	Trials	Study protocol	Canada	Health care system	Hybrid type 1
101	Sutherland R	2019	A cluster randomised trial of an intervention to increase the implementation of physical activity practices in secondary schools: study protocol for scaling up the Physical Activity 4 Everyone (PA4E1) program	BMC Public Health	Study protocol	Australia	Schools	Hybrid type 3
102	Thapa P	2019	The power of peers: an effectiveness evaluation of a cluster-controlled trial of group antenatal care in rural Nepal	Reprod Health	Original article	Nepal	Community care	Hybrid type 1
103	Toovey R	2018	Bike skills training for children with cerebral palsy: protocol for a randomised controlled trial	BMJ Open	Study protocol	Australia	Rehabilitation services	-
104	Varas-Doval R	2020	Evaluating an implementation programme for medication review with follow-up in community pharmacy using a hybrid effectiveness study design: translating evidence into practice	BMJ Open	Original article	Spain	Outpatient care	Hybrid type 2
105	Wallace BC	2020	A multicenter trial of a shared DECision Support Intervention for Patients offered implantable Cardioverter-DEfibrillators: DECIDE-ICD rationale, design, Medicare changes, and pilot data	Am Heart J	Study protocol	US	Health care system	Hybrid type 2
106	Wilcox S	2018	Faith, Activity, and Nutrition Randomized Dissemination and Implementation Study: Countywide Adoption, Reach, and Effectiveness	Am J Prev Med	Study protocol	US	Churches	-
107	Williams KE	2020	Rhythm and Movement for Self-Regulation (RAMSR) intervention for preschool self-regulation development in disadvantaged communities: a clustered randomised controlled trial study protocol	BMJ Open	Study protocol	Australia	Kindergarten	-
108	Wiltsey Stirman S	2017	Improving and sustaining delivery of CPT for PTSD in mental health systems: a cluster randomized trial	Implement Sci	Study protocol	Canada	Mental health care	Hybrid type 3
109	Wu Q	2017	Monitoring and evaluating the adherence to a complementary food supplement (Ying Yang Bao) among young children in rural Qinghai, China: a mixed methods evaluation study	Journal of Global Health	Original article	China	Community care	-

#	First author	Year	Title	Journal	Article type	Country	Setting	Hybrid type
110	Xu DR	2020	NUrse-led COntinuum of care for people with Diabetes and prediabetes (NUCOD) in Nepal: study protocol for a cluster randomized controlled trial	Trials	Study protocol	Nepal	Primary care	-

#	First author	Year	Design clinical effectiveness	Design implementation	Contextual analysis	Information about contextual analysis published in a further article (first author, year, title)		
1	Apers H	2020	Modified stepped wedge cluster design	Mixed methods process evaluation	**Yes**	-		
2	Berhanu D	2020	Pre-post randomized control group design	Mixed methods process evaluation	**Yes**	-		
3	Bidwell P	2018	randomized stepped-wedge design	Mixed methods	**Yes**	-		
4	D'Onofrio G	2019	Modified stepped wedge design	Mixed methods	**Yes**	Hawk KF, 2020, Barriers and Facilitators to Clinician Readiness to Provide Emergency Department-Initiated Buprenophine		
5	Grazioli VS	2019	randomized pre-post design	Mixed methods	**Yes**	von Allmen M, 2021, Does Case Management Provide Support for Staff Facing Frequent Users of Emergency Departments? A Comparative Mixed-Method Evaluation of ED Staff Perception	Chastonay OJ, 2021, Health care providers' perception of the frequent emergency department user issue and of targeted case management interventions: a cross-sectional national survey in Switzerland	Bodenmann P, 2021, Healthcare Providers' Perceptions of Challenges with Frequent Users of Emergency Department Care in Switzerland: A Qualitative Study
6	Hartzler B	2017	RCT	Mixed methods	**Yes**	-	-	-
7	Johnson K	2018	RCT	Mixed methods	**Yes**	-	-	-
8	Knight DK	2016	Cluster randomized interrupted time series	Multi methods	**Yes**	Knight DK, 2019, Organizational Context and Individual Adaptability in Promoting Perceived Importance and Use of Best Practices for Substance Use		
9	Kwan BM	2020	cluster RCT	Mixed methods	**Yes**	-	-	-
10	Lakerveld J	2018	RCT	Mixed methods	**Yes**	-	-	-
11	Nahar P	2020	Stepped wedge cluster RCT	Mixed methods process evaluation	**Yes**	-	-	-
12	Osilla KC	2020	RCT	Survey	**Yes**	-	-	-
13	Quintiliani LM	2015	RCT	Multi methods process evaluation	**Yes**	-	-	-

#	First author	Year	Design clinical effectiveness	Design implementation	Contextual analysis	Information about contextual analysis published in a further article (first author, year, title)		
14	Rahm AK	2018	Quasi-experimental	Process evaluation qualitative and configurational comparative methodology	**Yes**	-	-	-
15	Rotter T	2017	Quasi-experimental	Unclear	**Yes**	-	-	-
16	Saevareid TJL	2018	cluster RCT	Mixed methods process evaluation	**Yes**	Gjerberg E, 2017, Advance care planning in Norwegian nursing homes	Thoresen L, 2016, Advance Care Planning in Norwegian nursing homes-Who is it for?	Thoresen L, 2016, "I just think that we should be informed" a qualitative study of family involvement in advance care planning in nursing homes
17	Shanley DC	2019	Quasi-experimental	Mixed methods process evaluation	**Yes**	-	-	-
18	Smeltzer MP	2018	Quasi-experimental	Unclear	**Yes**	Kedia SK, 2015, "One-stop shop": lung caner patients`and caregivers`perceptions of multidisciplinary care in a community healthcare setting		
19	Steele Gray C	2016	cluster RCT	Mixed methods process evaluation	**Yes**	Steele Gray C, 2014, Tying eHealth Tools to Patient Needs: Exploring the Use of eHealth for Community-Dwelling Patients With Complex Chronic Disease and Disability	Steele Gray C, 2016, Improving Patient Experience and Primary Care Quality for Patients With Complex Chronic Disease Using the Electronic Patient-Reported Outcomes Tool: Adopting Qualitative Methods Into a User-Centered Design Approach	
20	Sutherland R	2019	cluster RCT	Mixed methods process evaluation	**Yes**	L Janssen, unpublished data, Parent acceptability of using a mobile phone application to promote healthy lunchboxes for childcare- and school-aged children	Reynolds R, 2019, Feasibility and principal acceptability of school-based mobile communication applications to disseminate healthy lunchbox messages to parents	Sutherland R, 2021, A Multicomponent mHealth-Based Intervention (SWAP IT) to Decrease the Consumption of Discretionary Foods Packed in School Lunchboxes: Type I Effectiveness–Implementation Hybrid Cluster Randomized Controlled Trial

#	First author	Year	Design clinical effectiveness	Design implementation	Contextual analysis	Information about contextual analysis published in a further article (first author, year, title)
21	Taylor R	2015	RCT	Multi methods process evaluataion	**Yes**	Greaves CJ, 2016, Optimising self-care support for people with heart failure and their caregivers: development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping
22	van Delft LMM	2019	Quasi-experimental	Mixed methods process evaluation	**Yes**	- - -
23	van Dongen BM	2019	Quasi-experimental	Mixed methods process evaluation	**Yes**	van Dongen, 2021, Opportunities for Capacity Building to Create Healthy School Communities in the Netherlands: Focus Group Discussions With Dutch Pupils
24	Verjans-Janssen SRB	2018	Quasi-experimental	Mixed methods process evaluation	**Yes**	- - -

#	First author	Year	Design clinical effectiveness	Contextual analysis
25	Abdelaziz TS	2016	Quasi-experimental	No
26	Abraham J	2019	cluster RCT	No
27	Agar M	2015	cluster RCT	No
28	Amaefule CE	2020	RCT	No
29	Andersen S	2015	Quasi-experimental	No
30	Atanda O	2020	cluster RCT	No
31	Aziz Z	2018	RCT	No
32	Baba CT	2017	Quasi-experimental	No
33	Babughirana G	2020	cluster randomized pre-post design controlled	No
34	Banfield M	2020	Quasi-experimental	No
35	Bast LS	2019	cluster RCT	No
36	Benedetti TRB	2020	cluster RCT	No
37	Betancourt TS	2020	cluster RCT	No
38	Bettger JP	2020	RCT	No
39	Boersma P	2017	Quasi-experimental	No
40	Bower P	2015	cluster RCT	No
41	Brain D	2020	RCT	No
42	Brett L	2019	Quasi-experimental	No
43	Cassarino M	2019	RCT	No
44	Chewning B	2020	RCT	No
45	Chirwa E	2020	RCT	No
46	Correard F	2020	RCT	No
47	Damschroder LJ	2017	Quasi-experimental	No
48	Dixit A	2019	cluster RCT	No
49	Filippopulos FM	2020	cluster RCT	No
50	Finney Rutten LJ	2020	cluster RCT	No
51	Gavalda-Espelta E	2020	Quasi-experimental	No
52	Gelli A	2017	cluster RCT	No
53	Goldstein KM	2019	RCT	No
54	Gonzalez JS	2020	RCT	No
55	Hannon PA	2016	cluster RCT	No
56	Hawk M	2017	cluster RCT	No
57	Haynes T	2018	cluster RCT	No
58	Heazell AEP	2017	Stepped wedge cluster RCT	No
59	Heisler M	2019	cluster RCT	No
60	Hensel JM	2016	RCT	No
61	Hilbink M	2016	cluster RCT	No
62	Husebo BS	2015	cluster RCT	No
63	Huybregts L	2017	cluster RCT	No
64	Islam N	2018	cluster RCT	No
65	Jussila AM	2015	cluster RCT	No
66	Kilbourne AM	2018	cluster RCT	No
67	Kirkevold M	2018	RCT	No
68	Kobel S	2017	cluster RCT	No
69	Lane HG	2018	cluster RCT	No
70	Lander N	2020	Quasi-experimental	No
71	Legare F	2016	Stepped wedge design cluster RCT	No
72	LeLaurin JH	2020	Quasi-experimental	No
73	Leyenaar JK	2020	randomized stepped wedge design	No
74	Lim S	2019	RCT	No
75	Mangin D	2020	RCT	No
76	Margolis KL	2020	cluster RCT	No
77	Markle-Reid M	2020	cluster RCT	No
78	Martin RS	2017	cluster RCT	No
79	Martino S	2016	RCT	No
80	Matthews L	2017	RCT	No
81	Maxwell AE	2016	cluster RCT	No
82	McCreight MS	2019	randomized stepped wedge trial	No
83	McKay H	2018	stepped wedge design	No
84	McIlvennan CK	2016	stepped wedge RCT	No
85	Muller C	2020	cluster RCT	No
86	Nelson LA	2018	RCT	No
87	Packel L	2020	cluster RCT	No
88	Pitpitan EV	2018	cluster RCT	No

#	First author	Year	Design clinical effectiveness	Contextual analysis
89	Price-Haywood EG	2021	stepped wedge cluster RCT	No
90	Rasmussen CDN	2020	RCT	No
91	Rathod S	2016	Quasi-experimental	No
92	Ray-Barruel G	2018	Quasi-experimental	No
93	Reaven J	2018	cluster RCT	No
94	Ribbink ME	2020	Quasi-experimental	No
95	Richter S	2020	Quasi-experimental	No
96	Ruble LA	2018	cluster RCT	No
97	Scheffers-van Schayck T	2018	RCT	No
98	Smith JD	2018	RCT	No
99	Straßner C	2019	cluster RCT	No
100	Sud A	2020	RCT	No
101	Sutherland R	2019	cluster RCT	No
102	Thapa P	2019	non-randomized, cluster controlled with nested cohort	No
103	Toovey R	2018	cluster RCT	No
104	Varas-Doval R	2020	cluster RCT	No
105	Wallace BC	2020	stepped wedge RCT	No
106	Wilcox S	2018	RCT	No
107	Williams KE	2020	cluster RCT	No
108	Wiltsey Stirman S	2017	cluster RCT	No
109	Wu Q	2017	Quasi-experimental	No
110	Xu DR	2020	cluster RCT	No

5.9.5 Additional file 5

STEP 2 - Study characteristics of implementation intervention studies that performed contextual analyses

x = reported, - = not reported, ? = unclear, QUAN = quantitative, QUAL = qualitative

#	Author	Year	Intervention	Intervention			Timepoint contextual analysis					Theory, model, or framework		Levels of			Empirical evidence
				Micro	Meso	Macro	Preparatory phase	Baseline	Midpoint	Post	Process evaluation	Overal implementation study	Contextual analysis	Micro	Meso	Macro	
1	Apers H	2020	HIV-testing intervention in primary care (general practitioners)		x		x				x	-	-	x	x	x	Yes
2	Berhanu D	2020	Optimizing Health Extension Program to increase the utilization of primary child health services		x		x			x		MRC Framework	-	x	x	x	Unclear
3	Bidwell P	2018	Care bundle to reduce incidence of obstetric anal sphincter injuries	x	x				x	x		-	-		x		No
4	D'Onofrio G	2019	Emergency department-initiated buprenorphine for patients with opioid use disorder	x	x			x	x	x		PARIHS	-		x	x	No
5	Grazioli VS	2019	Case management intervention for frequent users of the emergency department	x	x		x		x	x		Generic Implementation Framework, RE-AIM	-		x		No
6	Hartzler B	2017	Teen marijuana check-up in schools	x	x		x			x		EPIS	-		x		No
7	Johnson K	2018	Afrocentric, group-based, computerized HIV / sexually transmitted infection (STI) prevention intervention for controlled substance-using black women in community corrections settings	x				x	x			CFIR	CFIR	x	x	x	No
8	Knight DK	2016	Interventions for Adolescents in the Legal System for substance abuse		x	x		x		x		EPIS	-		x	x	No
9	Kwan BM	2020	Patient-driven, shared medical appointments for providing diabetes self-management education and self-management support	x	x			x	x	x		Replicating Effective Programs (REP) framework, RE-AIM	-		x		No

#	Author	Year	Intervention	Intervention			Timepoint contextual analysis phase					Theory, model, or framework		Levels of			Empirical evidence
				Micro	Meso	Macro	Preparatory phase	Baseline	Midpoint	Post	Process evaluation	Overal implementation study	Contextual analysis	Micro	Meso	Macro	
10	Lakerveld J	2018	Multi-level intervention using pricing and nudging strategies in the supermarket and context-specific mobile physical activity promotion app to impact on lifestyle behaviors and cardiometabolic health in adults with lower socio-economic status	x	x		x					-	-	x	x	x	No
11	Nahar P	2020	Multi-component community engagement intervention for cardiovascular disease prevention in socially disadvantaged populations	x	x		x				x	CFIR, RE-AIM	-			x	No
12	Osilla KC	2020	Group-based therapy for support persons of adults on buprenorphine/naloxone to engage treatment resistant persons into treatment through positive communication and other behavioral strategies	x	x		x			x		-	-		x		No
13	Quintiliani LM	2015	Smoking-cessation intervention that combines patient navigation and financial incentives	x	x		x		x			RE-AIM, Social Contextual Model including constructs from Social Cognitive Theory, Theory of Reasoned Action and Transtheoretical model of Behavior Change	-	x			Yes
14	Rahm AK	2018	Organizational toolkit for Lynch syndrome screening			x	x					CFIR	CFIR	x	x	x	Yes
15	Rotter T	2017	Clinical pathways for treatment of COPD		x		x					-	-		x	x	Yes
16	Saevareid TJL	2018	Advanced care planning intervention in nursing homes		x		x		x		x	-	-		x		Yes
17	Shanley DC	2019	Innovative, tiered, culturally sensitive, neurodevelopmental assessment process within remote geographic locations with limited professional expertise, that considers fetal alcohol spectrum disorders as a potential outcome		x	x			x			Knowledge-to-Action (KTA) framwork, RE-AIM	-		x	x	No
18	Smeltzer MP	2018	Multidisciplinary lung cancer care model	x	x		x					RE-AIM	-		x		No

#	Author	Year	Intervention	Intervention			Timepoint contextual analysis phase					Theory, model, or framework		Levels of			Empirical evidence
				Micro	Meso	Macro	Preparatory phase	Baseline	Midpoint	Post	Process evaluation	Overal implementation study	Contextual analysis	Micro	Meso	Macro	
19	Steele Gray C	2016	Electronic patient reported (ePRO) mobile app and portal to creating and monitoring goal-oriented patient-care plans to improve patient self-management and shared decision making between patients and health care providers as well as proactive patient monitoring by the patient, caregiver(s), and health care provider	x	x			x	x	x		-	-	x	x	x	No
20	Sutherland R	2019	Multi-component intervention that uses an existing school-based communication application to reduce kilojoule content from discretionary foods and drinks consumed by children from school lunch boxes whilst at school	x	x		x					-	-	x	x		Yes
21	Taylor R	2015	Home-based self-care rehabilitation intervention in heart failure patients and caregivers	x	x		x					MRC Framework	-	x	x		Yes
22	van Delft LMM	2019	Complex, multidimensional intervention to improve physical behavior during hospitalization, i.e., decrease patients` sedentary behavior and increase physical activity	x	x		x				x	Implementation model based on the study by Grol and Wensing	-	x	x		No
23	van Dongen BM	2019	Community based school intervention including four strategies for building the community capacity of students, school personnel, and parents	x	x		x		x			RE-AIM	-	x	x	x	No
24	Verjans-Janssen SRB	2018	School-based physical activity and nutrition intervention including family-based lifestyle parenting program	x	x		x				x	-	-	x	x	x	No

#	Author	Design	Mixed methods	Methods (QUAN)					Methods (QUAL)				Implementation agents		Expert panel / advisory board
							Tool								
				Survey	Routine data	Other	validated	developed	Individual	Focus group interviews	Observation	Other	QUAN	QUAL	
1	Apers H	QUAN & QUAL	Yes	x		National surveillance data	?	?		x			General practitioners	General practitioners	Advisory board consisting of general practitioners (GPs), representatives of GP umbrella organizations, policy makers, HIV care specialists, public health specialists, prevention specialists, lab specialists
2	Berhanu D	QUAN & QUAL	Unclear	x	?		?	?		x			Primary care workers	Governmental and non-governmental stakeholders in the field of maternal, newborn and child health services	-
3	Bidwell P	QUAN	No	x			x						Clinicians, champions	-	Clinical and methodological experts with representatives from the Royal College of Obstetricians and Gynaecologists (RCOG), the London School of Hygiene and Tropical Medicine (LSHTM), College of Midwives (RCM) & independent advisory board
4	D'Onofrio G	QUAN & QUAL	Yes	x			x	x		x			Emergency deoartment providers: physicians and residents, advanced practice providers (physician assistants, advanced nurse practitioners), nurses, counselors, social workers, pharmacists, and administrators; community providers: physicians, advanced practice providers, administrative leaders, counselors, and social workers	-	-

#	Author	Design	Mixed methods	Methods (QUAN) Survey	Methods (QUAN) Routine data	Methods (QUAN) Other	Methods (QUAN) Tool validated	Methods (QUAN) Tool developed	Methods (QUAL) Individual	Methods (QUAL) Focus group interviews	Methods (QUAL) Observation	Methods (QUAL) Other	Implementation agents QUAN	Implementation agents QUAL	Expert panel / advisory board
5	Grazioli VS	QUAN & QUAL	Yes	x				x	x	x			Emergency department staff	Champions, nurses and physicians	-
6	Hartzler B	QUAN & QUAL	Yes	x			x		x				School staff members	Principals, other leaders	-
7	Johnson K	QUAN & QUAL	Yes	x			?	?	x	x			NGO community reentry facilitators	NGO community reentry facilitators	Formerly incarcerated and other justice involved men and women, New York City Department of Probation representatives, New York City Department of Health representatives, NGO community leadership personnel, and not-for-profit service providers from a variety of settings who serve justice-involved individuals
8	Knight DK	QUAN & QUAL	Yes	x		JJ-TRIALS National Survey items	x	x		x			Agency leadership (juvenile justice/ behavioral health)	Staff of juvenile justice & behavioral health	National Institute on Drug Abuse, researchers, and Juvenile Justice partners
9	Kwan BM	QUAN & QUAL	Yes	x			x		x				Practice members involved in self-management appointments	Practice members involved in self-management appointments	Stakeholder input (not further specified)
10	Lakerveld J	QUAN & QUAL	Yes	x				x	x	x	x		Supermarket staff	Actors from all levels of the supermarket chain, target population	-
11	Nahar P	QUAL	No						x				-	Stakeholders (not further specified)	-
12	Osilla KC	QUAN	No	x				?					Medical assistants, nurses, psychologists, physicians from primary care, physicians from buprenorphine clinics	-	Patient and support peron panel; clinic stakeholder panel composed of medical and behavioral health providers at each participating clinic, community health care clinic administrators

#	Author	Design	Mixed methods	Methods (QUAN) Survey	Methods (QUAN) Routine data	Methods (QUAN) Other	Methods (QUAN) Tool validated	Methods (QUAN) Tool developed	Methods (QUAL) Individual	Methods (QUAL) Focus group interviews	Methods (QUAL) Observation	Methods (QUAL) Other	Implementation agents QUAN	Implementation agents QUAL	Expert panel / advisory board
13	Quintiliani LM	QUAL	No									Photovoice methodology	-	Tobacco users	-
14	Rahm AK	QUAL	No						x				-	Pathologists, oncologists, surgeons, genetic counsellors, gastroenterologist, health care administrators, health plan leaders, patients newly diagnosed with cololateral cancer, patients who have been notified of a positive lynch syndrome screen result and were recommended for additional genetic counseling and testing to confirm diagnosis	-
15	Rotter T	QUAL	Unclear						?				-	Senior leadership, front-line leadership, clinical/technical expertise	Quality improvement teams from each health care region, Saskatchewan Health Quality Council, Leaders of a COPD program, members of the ministry of health, Lung association, telehealth services, primary care providers, respirologists, pharmacists, nurses
16	Saevareid TJL	QUAN & QUAL	Yes	x					x		x		Nursing home	Nursing home staff, patients, relatives	-
17	Shanley DC	QUAL	No									Yarning	-	Primary, secondary and end users	Representation from local Elders, First Nations health practitioners, and community members

#	Author	Design	Mixed methods	Methods (QUAN) Survey	Routine data	Other	Tool validated	Tool developed	Methods (QUAL) Individual	Focus group interviews	Observation	Other	Implementation agents QUAN	Implementation agents QUAL	Expert panel / advisory board
18	Smeltzer MP	QUAL	No							x			-	Patients, caregivers, primary care physicians, nurses, hospital, administrators, senior executives of national health insurance companies, pulmonologists, thoracic surgeons, medical oncologists, radiation oncologists	Pre-planning: a patient, caregiver, medical oncologist, thoracic surgeon, nurse navigator, hospital administrators, corporate attorny Later: steering committee consisting of additional patients, caregivers, epidemiologists, clinical psychologist, implementation scienctist, medical anthropologist, representative from the American Cancer Society, palliative care nurse, representative of a local Federally Qualified Health Center
19	Steele Gray C	QUAL	No						x	x			-	Community-dwelling patients with compley chronic disease and disability, caregivers, content experts, primary care providers, patient advocate	-
20	Sutherland R	QUAN & QUAL	No	x						x		Telephone interviews	-	Parents, school principals	Multidisciplinary team of academic and end-user stakeholders from government health agencies, educational systems employees, universities and technology partners and parent representatives with expertise in nutrition, school based health intervention, behavior change, implementation science and technology based interventions

#	Author	Design	Mixed methods	Methods (QUAN)					Methods (QUAL)				Implementation agents		Expert panel / advisory board
							Tool								
				Survey	Routine data	Other	validated	developed	Individual	Focus group interviews	Observation	Other	QUAN	QUAL	
21	Taylor R	QUAN & QUAL	Yes	x			?	?	x	x		Site visit	Specialist nurses, cardiologists, general practitioners, exercise physiologists, pharmacists, health professionals	Patients, family caregivers	-
22	van Delft LMM	QUAN & QUAL	Yes	x		Behavior mapping	?	?	x				Patients, caregivers	Patients, caregivers	Multidisciplinary project team on each ward including a program manager, a nurse, a physiotherapist, and a physician
23	van Dongen BM	QUAL	No						x	x		Photovoice	-	Students, parents, school personnel	-
24	Verjans-Janssen SRB	QUAN	No	x			x	x					School principals, teachers, physical exercise teachers	-	Working group consisting of school staff (teachers, school principal, physical exercise teacher, local health or sport professionals, social worker, health promotor, school doctor), parents

#	Author	Funding	**Funding agency** (award number)	**Use of context**				**How contextual information were used**				**Process evaluation**	**Outcomes assessed**		**Influence on**		
				Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes	Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes		Primary effectiveness outcome(s)	Implementation outcome(s)	Implementation outcomes	Effectiveness outcomes	**PIMID** (PubMed ID)
1	Apers H	For overall project	European HIV-ERA JTC 2014; Belgian Funding Agency IWT 140922	x	x	x						Planned	No. HIV diagnoses	Fidelity, Feasibility, Acceptability	Assessed	Unclear	32497016
2	Berhanu D	For overall project	Bill & Melinda Gates Foundation (OPP1132551)	x			x					Planned	Care seeking	Fidelity, Reach, Dose, Adaptions	Planned	-	32316969
3	Bidwell P	For overall project	Health Foundation (7674)									-	Reduce obstetric anal sphincter injuries rates	Feasibility, Coverage, Sustainability, Acceptability	-	-	30103734
4	D'Onofrio G	For overall project	National Institute on Drug Abuse (NIDA) Clinical Trials Network (UG1DA015831); Opioid Use Disorder in the Emergency Department (CTN 0069)	x		x	x				x	-	Rates of patient engagement in	Adoption formal addiction treatment (on 30th Fidelity day after emergency department visit)	Assessed	Planned	31064390
5	Grazioli VS	For overall project	Swiss National Science Foundation (FNS 407440_167341)									Planned	Emergency department use Quality of life	Adoption, Reach, Fidelity, Integration & normalization	-	-	30634955
6	Hartzler B	For overall project	National Institute on Drug Abuse (R01DA040650)									-	School costs for technical assistance, Frequency of marijuana use	Fidelity	-	-	28797270

#	Author	Funding	**Funding agency** (award number)	**Use of context**				**How contextual information were used**				**Process evaluation**	**Outcomes assessed**		**Influence on**		**PIMID** (PubMed ID)
				Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes	Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes		Primary effectiveness outcome(s)	Implementation outcome(s)	Implementation outcomes	Effectiveness outcomes	
7	Johnson K	For overall project	NIDA grant (R01DA025878)	x			x				?	-	Reduced incidence of biologically confirmed sexually transmitted infections	Fidelity	Planned	-	30201039
8	Knight DK	For overall project	Chestnut Health Systems (U01DA036221); Columbia University (U01DA036226); Emory University (U01DA036233); Mississippi State University (U01DA036176); Temple University (U01DA036225); Texas Christian University (U01DA036224); University of Kentucky (U01DA036158)	x			x	x			x	-	Improvements in evidence-based screening, assessment and linkage to substance use treatment	Fidelity	Assessed	Planned	27130175

#	Author	Funding	**Funding agency** (award number)	Use of context: Intervention development	Use of context: Intervention adaption	Use of context: Implementati on strategies	Use of context: Interpretation of outcomes	How contextual information were used: Intervention development	How contextual information were used: Intervention adaption	How contextual information were used: Implementati on strategies	How contextual information were used: Interpretation of outcomes	Process evaluation	Outcomes assessed: Primary effectiveness outcome(s)	Outcomes assessed: Implementation outcome(s)	Influence on: Implementation outcomes	Influence on: Effectiveness outcomes	**PIMID** (PubMed ID)
9	Kwan BM	For overall project	Patient-Centered Outcomes Research Institute (PCORI) Award (IHS-1609-36322)									-	Diabetes distress	Reach, Fidelity and adaptions, Practice motivations for adoption, Perceived value and sustainability shared medical appointments (SMAs), Implementation cost of SMAs	-	-	31924249
10	Lakerveld J	For overall project	Netherlands Heart Foundation; Netherlands Organization for Health Research and Development (ZonMw)	x	x	x		x	x	x		-	Changes in parameters of metabolic health (blood pressure, cholesterol values, HbA1c or glucose, and waist circumference at 6 and 12 months)	Feasibility, Reach Adoption, Implementation, Maintanace	-	-	30029600
11	Nahar P	For overall project	Horizon 2020 Research and Innovation Action Grant Agreement (733356)	x	x				x			Planned	Change in the cardiovascular disease risk score	Fidelity, Feasibility, Acceptabiliy, Uptake, Scalability	Unclear	Unclear	32190745
12	Osilla KC	For overall project	Patient-Centered Outcomes Research Institute (PCORI) Project Program Award (OBOT-2018C2-12876)				x				x	Unclear	Buprenorphine retention	Acceptability Ease of use, Fit with current paractices, Provider motivation and willingness to implement new practices, and attitudes	-	Planned	32653029

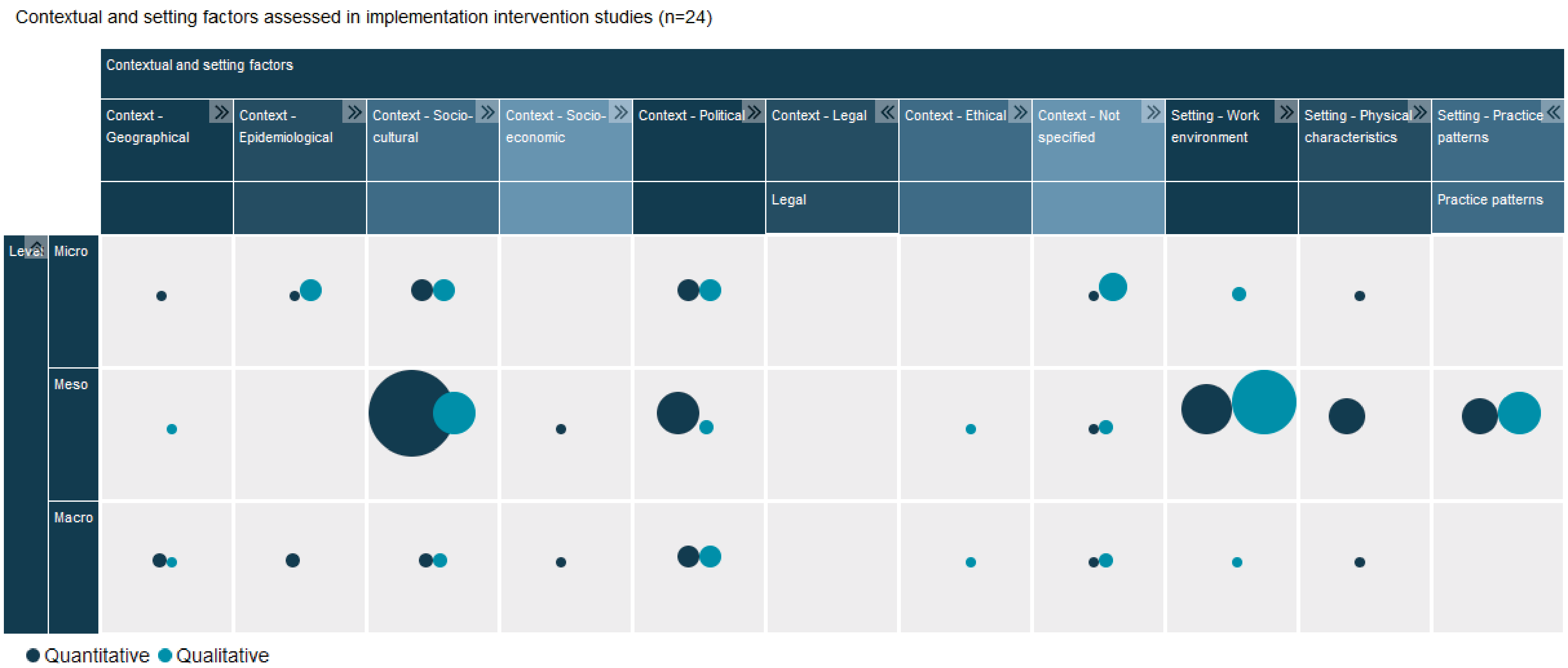
#	Author	Funding	Funding agency (award number)	Use of context				How contextual information were used				Process evaluation	Outcomes assessed		Influence on		PIMID (PubMed ID)
				Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes	Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes		Primary effectiveness outcome(s)	Implementation outcome(s)	Implementation outcomes	Effectiveness outcomes	
13	Quintiliani LM	For overall project	American Cancer Society (125785-RSG-14-034-01CPPB.)	x	x							Planned	Biochemically confirmed smoking cessation	Reach, Adoption, Implementation, Maintanance	-	-	26362691
14	Rahm AK	For overall project	National Cancer Institute (NCI) twenty-first Century Cures Act - Beau Biden Cancer Moonshot (R01CA211723)	x		x						Planned	Annual incident colorectal cancer and endometrial cancer cases by age strata Lynch sydrome prevalence or the assumption of an equivalent rate for all populations, Intervention cost	Implementation or maintanance of any systematic Lynch syndrome screening, Quality tracking of screening	-	-	30376847
15	Rotter T	For overall project	Lung Health Institute of Canada; Saskatchewan Ministry of Health; Novartis	x	x	x						-	Quality of care (hospital readmission rate, emergency department presentation rate)	Guideline adherence (scheduled primary care provider an specialists visits)	-	-	29183318
16	Saevareid TJL	For overall project	Research Council of Norway	x		x	x					Results described	Patients who participated in a conversation on end-of-life treatment	Fidelity	-	-	30103692

#	Author	Funding	Funding agency (award number)	Use of context: Intervention development	Use of context: Intervention adaption	Use of context: Implementati on strategies	Use of context: Interpretation of outcomes	How contextual information were used: Intervention development	How contextual information were used: Intervention adaption	How contextual information were used: Implementati on strategies	How contextual information were used: Interpretation of outcomes	Process evaluation	Outcomes assessed: Primary effectiveness outcome(s)	Outcomes assessed: Implementation outcome(s)	Influence on: Implementation outcomes	Influence on: Effectiveness outcomes	**PIMID** (PubMed ID)
17	Shanley DC	For overall project	Australian Government Department of Health, Drug and Alcohol Program (H1617G038)	x	x			x	x			Planned	No primary outcome defined, effectiveness assessed according to RE-AIM (e.g., practitioner knowledge, condfidence and proportion doing assessment)	Reach, Adoption, Implementation, Maintanance	Unclear	-	31500612
18	Smeltzer MP	For overall project	Patient Center Outcomes Research Institute (PCORI) (IH-1304-6147)	x								Planned	Effectiveness of services (timeliness of care, thoroughness of staging, stage-appropriate treatment, patient reported outcomes, caregiver reported outcomes, and survival), Overall survival, Progression free survival	Reach¸ Implementation	Unclear	Unclear	29535915
19	Steele Gray C	For overall project	Ontario Ministry of Health and Long-term Care's Health Research Fund (06034); CIHR Planning and Dissemination Grant (CIHR-137200)	x	x			x	x			Planned	Health-related quality of life	Use, Tool experience, Coverage, Range, Sustainability	Planned	Planned	27341765

#	Author	Funding	Funding agency (award number)	Use of context				How contextual information were used				Process evaluation	Outcomes assessed		Influence on		PIMID (PubMed ID)
				Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes	Intervention development	Intervention adaption	Implementati on strategies	Interpretation of outcomes		Primary effectiveness outcome(s)	Implementation outcome(s)	Implementation outcomes	Effectiveness outcomes	
20	Sutherland R	For overall project	NSW Ministry of Health, Translational Research Grant Scheme	x	x			x	x			-	Mean energy (kJ) content of discretionary lunchbox foods and drinks packed in lunchboxes	Acceptability, Feasibility, Adoption Appropriateness, School engagement	-	-	31718597
21	Taylor R	For overall project	National Institute for Health Research (NIHR) (RP-PG-1210-12004)	x	x			x	x			Planned	Patient disease-specific health care related quality of life	Fidelity	Unclear	Unclear	26700291
22	van Delft LMM	Unclear		?	?	?	?	?		?	?	Planned	Physical behavior	Adaption, Dose Reach, Implementation success	Planned	-	30964442
23	van Dongen BM	For overall project	Netherlands Organization for Health Research and Development (ZonMw) (50–53105–98-033)		x	x			x			Planned	Change in community capacity	Adoption, Maintanance, Fidelity	Planned	-	31221106
24	Verjans-Jansen SRD	For overall project	Fonds NutsOhra (101.253)	x	x		x					Planned	BMI z-score	What is implemented and how is it implemented	-	Unclear	29980235

5.9.6 Additional file 6

Evidence gap map – Screenshot of the interactive online evidence gap map



Download link for .html file evidence gap map: https://zenodo.org/record/6580953#.YpACBVTP3b0
Note: Please save the file to your computer to ensure that the file can be opened properly.

5.9.7 Additional file 7

Overview of contextual factors identified in implementation intervention studies

(mapped according to the Context and Implementation of Complex Interventions (CICI) framework (1))

CONTEXT												
	Level											
	Micro-level				Meso-level				Macro-level			
Domain	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref
Geographical	Infrastructure	Active transportation		(2)	Infrastructure	Relevant health services available		(3)	Infra-structure	District resources and infrastructure		(4)
										Range and number of treatment services in the emergency department catchment area		(5)
									General	Questions that focus on the external environment of all recruitment and intervention locations		(6)
Epidemiological	Determinants of needs	Patient needs and resources Caregiver needs Support needs Current situation needs and desires on themes of community and family involvement Support needs		(7) (8) (8) (9) (8)	-				Demo-graphic	Demography		(4)
									Incidence/prevalence of disease and severity of disease	Number of undiagnosed HIV infections		(10)
										Prevalence of HIV		(10)
										Time distribution between HIV infection and diagnosis		(10)
										Changes over time	Recent epidemics and natural disasters	(4)

CONTEX												
Domain	Level											
	Micro-level				Meso-level				Macro-level			
	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref
Socio-cultural	Knowledge and perceptions; beliefs	Lynch syndrome knowledge and beliefs, perceptions of evidence		(7)	Social structure	Networks	Organization structure	(7)	Know-ledge & perceptions	Current community understanding of fetal alcohol spectrum disorder		(13)
		Opinion of exercise in general		(11)			Relational coordination and relationships in particular work processes in primary care teams	(12)				
		Individual readiness to implement screening		(7)			Networks	(6)				
		Coming to terms with heart failure (incl. problems associated with the condition and how they were resolved)		(8)								
		GP`s perception of target group-based HIV testing		(10)								
		Knowledge of disease and danger signs		(4)								
		Knowledge and beliefs of the intervention, that might influence adoption		(6)								
		Information needs		(8)								
		Sources of knowledge		(4)								
	Family structures	Members of the household		(4)					Lifestyle	The extent to which an unhealthy lifestyle as a risk factor for cardiometabolic health presents a societal problem		(14)
										Lifestyle context of the community		(15)
						Supervision and mentorship	Supportive supervision and mentorship from health centers to health posts	(4)	Social capital	Community engagement		(4)
										Community strengths and needs		(13)
						Communication	Communication	(6, 12)				
						Climate	Attitudes towards their workplace (organizational climate)	(16)	Social structure	Networks	Systems map of case-processing in their jurisdiction depicting "linkages" with community behavioral health partners	(16)
							Provider motivation	(17)				
							Commitment to work	(4)				
							Climate	(6)				
						Culture	School culture	(9)			Relationships between JJ and BH agencies in providing services	(16)
							Practice culture	(12)				
							Work culture	(4)				
							Culture	(6)				

CONTEX												
	Level											
	Micro-level				Meso-level				Macro-level			
Domain	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref
Socio-cultural					Community characteristic and level of coordination/ involvement with community	Readiness for change	Organizational readiness for change	(5, 18, 19)				
							Whether they would consider changing app providers and what would encourage such a change	(20)				
						Implementation climate	Willingness to implement new practices	(17)				
							Implementation climate in organization	(7)				
							Implementation climate	(19, 21)				
							Perceived organizational priority to implement	(7)				
							How likely they were to implement such an app in future	(20)				
						Other	Individual identification with organization	(6)				
					Knowledge and perceptions	Perceived value and use of substance use services and perceived value of HIV-STI and substance use prevention		(16)				
						Knowledge on newborn and child health care		(4)				
						Current opinion about physical behavior during hospital stay		(11)				
						Attitudes towards their workplace (support, functioning)		(16)				
						Value of ongoing monitoring of symptoms and functional status as part of usual care		(22)				
						Underlying mental structures, and resulting practices and perceptions of systemic leverage points and barriers		(14)				
						Value of educational tools		(13)				
						Attitudes about technology		(6)				
						Importance and interest in the upcoming SAMs, factors thought to affect adoption of the SMAs, and anticipated patient response to the SMAs		(12)				

CONTEX												
Domain	Level											
	Micro-level				Meso-level				Macro-level			
	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref
Socio-cultural					Knowledge and perceptions	Opinion on the most feasible HIV-testing intervention for primary care		(10)				
						Organizational providers` attitudes towards the intervention and features of the intervention itself that might facilitate or compromise implementation		(6)				
						Awareness, perceptions and knowledge of the (5 or more ED visits/year) FUED problematic as well as specific needs and interests regarding case management		(19)				
Socio-economic	-				Occupational aspects	Informal payment		(4)	Living conditions	Healthy-nutrition promoting environment		(2)
						Working conditions		(4)		Physical activity friendliness of the neighborhood		(2)
Political	Health care system	Service delivery	Use of maternal and perinatal health services	(4)	Health care system	Leadership	Implementation leadership	(21)	Public policies	Policy and environment		(9)
			Care seeking and treatment for child`s illness	(4)			Leadership and roles	(9)	Health care system	Integration of patient`s needs and perspective	Experiences with the health care system: things that are important as a receiver of care	(22)
							Leadership	(4)				

CONTEX												
Domain	Level											
	Micro-level				Meso-level				Macro-level			
	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref
		Integration of patient`s needs and perspective	The role of patients accessing appropriate educational materials Information needs User experience, and preferences for app features What types of information should be shared about those symptoms (i.e., indicators, scales, and contextual information) Whether a eHealth tool might meet patients` needs (example eHealth tool was presented) Self-behaviors that should be targeted What outcomes are important for people with heart failure They were read a list of statements pertaining to the communication of lunchbox messages to parents and to what extent they agreed with the statements	(22) (8) (14) (22) (22) (8) (8) (20)							Opinions from stakeholders in need for an intervention Experiences with the health care system: what can be done to improve things	(3) (22)
						Integration of patient`s needs and perspective	Teacher and parental involvement in PA promotion at school Teacher and parental involvement in nutrition at school Suggested content and delivery formats Opinions from stakeholders in need for an intervention	(2) (2) (8) (3)		Service delivery	ED, hospital, and community treatment programs Maternal, newborn and child health programs	(5) (4)
						Service delivery	Services provided to newborns and children Services their agency provides Current service provision Strengths and weaknesses of existing heart failure services	(4) (16) (8) (8)	Relevant changes over time	Policies	Impact of external policies on organization	(7)
Legal	-				-				-			
Ethical	-				Ethical principles and code of conduct	Responsibility of supermarket and other food retrial actors in promoting a healthier lifestyle Competitive pressure to implement screening		(14) (7)	-			

CONTEX												
Domain	Level											
	Micro-level				Meso-level				Macro-level			
	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref	Factor according CICI	Category defined	Factor identified	Ref
Ethical					Conflicting interests	Competitive pressure to implement screening		(7)				
Not specified	Facilitators and barriers		Facilitators and barriers to smoking cessation Benefits of and barriers to exercise/physical activity	(23) (8)	Context	Inner context	Documentation of inner context Local contextual determinant	(16) (20)	Context	Outer context	Environmental level characteristics Documentation of outer context	(6) (16)
			Challenges and barriers patients experience using eHealth Perceived demand- and supply-side barriers to CBNC and iCCM service utilization	(22) (4)	Facilitators and barriers	Perceived demand- and supply-side barriers to CBNC and iCCM service utilization Community reentry facilitators that might facilitate or compromise implementation		(4) (6)	Facilitators and barriers	Perceived demand- and supply-side barriers to CBNC and iCCM service utilization		(4)

Chapter 6.

Understanding dynamic complexity in context – Enriching contextual analysis in implementation science by a constructivist perspective

Juliane Mielke[1], Sabina De Geest[1,2], Franziska Zúñiga[1], Thekla Brunkert[1,3], Leah L. Zullig[4], Lisa M. Pfadenhauer[5], Sandra Staudacher[1,6]

[1] Institute of Nursing Science, Department Public Health, University of Basel, Basel, Switzerland

[2] Academic Center for Nursing and Midwifery, Department of Public Health and Primary Care,

KU Leuven, Leuven, Belgium

[3] University Department of Geriatric Medicine FELIX PLATTER, Basel, Switzerland

[4] Center for Innovation to Accelerate Discovery and Practice Transformation (ADAPT), Durham Veterans Affairs Health Care System and Department of Population Health Sciences, School of Medicine, Duke University, Durham, NC USA

[5] Institute for Medical Information Processing, Biometry and Epidemiology, LMU Munich, Germany; Pettenkofer School of Public Health, LMU Munich, Germany

[6] Department of Health Services Research, Care and Public Health Research Institute, Maastricht University, 6229 GT Maastricht, The Netherlands

Manuscript will be submitted to Implementation Science

6.1 Abstract

Background

Contextual analysis is recognized as an indispensable part of implementation science methodology: it provides the foundation for successful and sustainable implementation projects. Yet, driven by the prevailing post-positivist understanding of context, contextual analysis typically focusses on individual characteristics of context. I.e., contextual dynamics and interactions go unnoticed. Conducting contextual analysis from a constructivist perspective promotes a multilayered approach, building a more comprehensive understanding of context, and thus facilitating successful implementation. In this debate, we highlight the limitations of prevailing perspectives on context and approaches to contextual analysis. We then describe how contextual analysis can be enriched by working from a constructivist perspective. We finish with a discussion of the methodological and practical implications the proposed changes would entail.

Main text

Emerging literature attempts to address both the concept of context and methods for contextual analysis. Various theories, models and frameworks consider context (e.g., the Consolidated Framework for Integrated Research (CFIR)); however, many of these are reductionistic and do not acknowledge the dynamic nature of context or interactions within it. Most also fall short regarding their guidance on assessing context: in fact, few validated measures for such assessments are available anywhere. To complement recent conceptualizations of context, we suggest integrating the following five constructivist concepts: 1) social space; 2) social place; 3) agency; 4) sensation; and 5) embodiment in the *Context and Implementation of Complex Interventions (CICI) framework*. We demonstrate the value of these concepts using COVID-19 (corona virus disease 2019) vaccination uptake as an example. To study context from a constructivist perspective, we also suggest additional considerations in view of methodologies for data collection and analysis, e.g., rapid ethnographic methods.

Conclusion

A constructivist perspective contributes to a stronger conceptualization of contextual analysis. Considering the five constructivist concepts helps to overcome contextual analysis' current shortcomings, while revealing complex dynamics that usually go unnoticed. Thus, more comprehensive understanding of context can be developed to inform subsequent phases of an implementation project, thereby maximizing an intervention's uptake and sustainability.

6.2 Contributions to the literature

- We highlight the importance of understanding context's dynamics and complexities both to successfully implement interventions and to articulate shortcomings in current approaches for contextual analysis.
- As well as describing how contextual analysis can be enriched by approaching it from a constructivist perspective, we propose five key constructivist concepts to consider during contextual analyses.
- We illustrate how these concepts can be integrated into existing conceptualizations of context and provide a case example to demonstrate the value the constructivist perspective adds to contextual analysis.

6.3 Background

Contextual analysis has been recognized as an essential element of implementation science (IS) methodology: it lays the foundation of successful and sustainable implementation projects (1, 2). However, no standard definition of contextual analysis exists in IS. For the purposes of this article, then, we define contextual analysis as a distinct part of an IS project that starts before an intervention is developed or adapted for implementation. It typically includes a theory-supported mapping of a range of relevant factors (often labelled as barriers/facilitators). Given that context evolves over time, repeated assessments of context should be conducted throughout the project. Its results are crucial to inform every subsequent phase of an implementation study, i.e., intervention development or adaption (1, 3-5), choices of implementation strategies (6-8), interpretation of implementation and effectiveness outcomes (5, 8-10), choice of sustainability strategies (10), and scale-up (11, 12).

While an increasing number of researchers are reporting on how they map facilitators and barriers to their projects' success—often not theory based—(2, 8, 13-16), contextual analyses are often performed isolated from their IS projects' next phases. This reflects the implicit post-positivist assumption that context is a static background. Based on this assumption, contextual analysis focuses on individual characteristics of context without considering dynamic interactions (13, 17). This mindset hampers both the tailoring of interventions to target contexts and the selection of contextually adapted implementation strategies. If it does occasionally contribute to the IS goal of enhancing implementation success, such contributions are accidental and sub-optimal (18, 19)

Shaped by research fields including public health, education, social work, environmental science, and political science, among others, IS has gained traction over the past two decades with researchers in evidence-based medicine and public health (20, 21). As a field of research, IS achieved considerable theoretical and methodological advances, developed a variety of theories, models and frameworks (TMFs) (21-24) and applied rigorous methods e.g., to assess implementation processes, mechanisms and outcomes (7, 25-32). Similarly, studies have been undertaken to identify relevant contextual factors in IS and to develop measurement tools to analyze context (8, 9, 33-35). A number of these advancements are strongly connected with a causal/linear (post-positivist) understanding of context.

The post-positivist paradigm is cause-and-effect oriented, recognizing “all cause and effect [as] a probability that may or may not occur” (36, p. 59). Therefore, only artifacts of context are studied; their relationships to each other, their underlying structures, values, beliefs and culture, are usually dismissed—all of which limits a holistic understanding of context as a complex and dynamic system. Further, this view neglects the fact that implementation takes place in social contexts where implementation agents, the context, intervention and implementation all interact continuously (13). Implementation agents include three main groups of individuals or organizations: those directly targeted or affected by an intervention (e.g., patients and their relatives); those that decide on that intervention's implementation (e.g., leaders, politicians, funders); and those that implement the intervention (e.g., health care providers) (37). These agents' actions are based on their beliefs, norms, values, and identities, all of which are shaped by the contexts in which they are located. Likewise, through their actions, implementation agents can shape and alter their context. Therefore, as part of the context analysis, it is crucial to understand how the agents are embedded in a context, how the context influences their actions, and how they can shape and reshape the context.

Naturally, any changes to the context also influence the implementation. This is even more important if implementation researchers not embedded in the context want to understand the relationships and interactions within it. In such cases, based on a constructivist perspective context can be seen as a subjective construct based on interactions and social processes of individuals at a specific place and time.

We assert that enriching the prevailing post-positivist view on context via a constructivist perspective and stronger methodological guidance will support improved use of continuous contextual analysis for all subsequent phases of IS projects.

Therefore, this paper's aims are threefold. First, we will reflect on and note the limitations of the current conceptualization of context in IS and current approaches for studying context. Second, we will describe how IS methodology can be strengthened by a more comprehensive conceptualization of contextual analysis. To this end, we will endorse a constructivist perspective to contextual analysis specifically to inform all subsequent IS project phases. Using COVID-19 vaccination program implementation as an example, we will reflect upon what contextual analysis in IS can gain from integrating a constructivist view. Third, we will stimulate a discussion on the methodological and practical implications of conducting a contextual analysis.

6.4 Main text

We conducted a narrative review of articles in electronic data bases including PubMed, EMBASE and Web of Science to identify the concepts and theoretical foundations of context in IS. Backward searches of identified papers' reference lists led to related IS studies. Important sources regarding social sciences include Emirbayer and Mische (38), Cresswell (39, 40), Lefebvre and Nicholson-Smith (41), Bourdieu (42, 43), Massey (44), and May (45, 46).

6.4.1 Current conceptualization of context

Given the high variability of terminology and conceptualization concerning context across IS literature, TMFs, combined with a lack of well-worked-out methodology, concept analyses and other research suggest that the concept of context in IS is only partially mature (47-50).

One IS framework that gives most attention to the context's multilevel and dynamic nature is the Context and Implementation of Complex Interventions (CICI) framework (a development and evaluation framework) (37). CICI is a meta-theoretical framework derived from empirical evidence. It takes an ecological perspective on context, i.e., it views context as multi-level, multi-dimensional and interactive. Based on a concept analysis, the CICI authors distinguish between setting and context. For them, context refers to

> “a set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded. As such, context is not a backdrop for implementation, but interacts, influences, modifies and facilitates or constrains the intervention and its implementation. [...] It is an overarching concept, comprising not only the physical location but also roles, interactions and relationships at multiple levels” (37).

As a construct within the health care system, context applies to the three levels of that system (micro-, meso-, macro-level). According to CICI, it also extends across the seven context domains (geographical, epidemiological, socio-cultural, socio-economic, political, legal, and ethical), each of which includes its unique set of contextual factors. For the CICI framework, context is dynamic, interacting within the setting with the intervention and implementation (i.e., implementation theory, processes, strategies, outcomes and agents) over time (37).

The CICI specifies that setting is part of the context. Its description should provide a more granular depiction of the physical location in which the intervention or evidence-based practice will be implemented (e.g., ward, hospital, country) (37). Therefore, setting focuses on aspects such as physical characteristics, work environment and practice patterns (37). However, current IS TMFs afford setting minor importance and provide little or no guidance on how to operationalize it.

6.4.2 Current approaches to contextual analysis

Although context's importance to implementation has been emphasized, only a fraction of IS studies (9%) report on it; and of those, only a minority show thorough contextual analyses (51-53). This might reflect the fact that contextual analysis tends to be poorly described, leading to huge variability in methodological approaches to it (34, 54, 55).

Contextual analyses are commonly neither theory-based nor linked to further study phases. A recently conducted evidence gap map of 24 implementation intervention studies revealed that only one study specifically reported that its contextual analysis had been guided by a TMF (51). To be clear, many TMFs do address context. However, they do not provide concrete descriptions of how to assess their specific contextual constructs.

Further, there was enormous variability regarding which aspects of context were considered and most studies failed to convey a dynamic and interactive understanding of context (34, 51). Instead, they tend to focus on distinct characteristics of context that can be measured and controlled (e.g., resources, leadership) (2, 17, 56-59). Rather than building an understanding of their complex context, they tend to quantify and generalize implementation determinants (i.e., assess the influence of X on Y) that directly affect implementation. This linear-thinking, mechanistic approach is based on a post-positivist understanding—one that is also reflected in the implementation frameworks currently available to guide contextual analysis (60).

6.4.3 Limitations of contextual analysis grounded in a post-positivist perspective

As an instrument through which first to understand the interplay of factors within a given context, then to apply that understanding to IS projects' later phases, the post-positivist perspective exploits only a fraction of a contextual analysis' potential. Thus, many implementation strategies still fail to achieve maximum potency (e.g., COVID-19 vaccination rates remain low despite incentives); others can even lead to counter-intuitive effects, such as nudging using restrictions on other areas of public life, which may have led to increased anti-vaccination sentiment (13, 61-63). On common result is that, while some aspects of context seem favorable (e.g., committed leadership, sufficient resources available), implementations fail or cannot be sustained (64). Such examples highlight the need not only to consider the quantifiable aspects of context, but to develop a broader understanding of context, i.e., to understand which structures, individual views, values, and motivations underlie the implementation agents' actions and can influence a successful implementation (13)

This limited, post-positivist view's potential consequences become very clear in light of implementation challenges during the current COVID-19 pandemic. Although sufficient doses of vaccine are now available, regulatory frameworks in place (vaccine approval, recommendations available from the responsible commissions), and the infrastructure prepared (vaccination centers, primary care practices, mobile vaccination teams), vaccination coverage is increasing only slowly in some industrialized countries. Why then, with easy access to safe, highly-effective vaccines, are large numbers of people not yet vaccinated? Research shows that reasons are complex and influenced by social processes (65).

6.4.4 Embracing a constructivist perspective regarding contextual analysis

The constructivist paradigm acknowledges the dynamic nature of context, as well as the presence of multiple, subjective realities based on individuals' lived experiences and constructed through interactions with others (Table 6.1) (36, p.60). Interacting with and within a system such as a social group or an organization (e.g., a hospital), implementation agents tacitly agree on ideas, norms and rules that shape their actions. These same unspoken agreements make it clear when someone not strictly adheres to these norms. Since they are not verbalized and communicated actively, but adopted based on habitual everyday practices in specific settings, norms are not typically obvious to individuals.

In hospitals, one example of an unwritten rule is that only healthcare professionals can measure and record the blood pressure of chronically ill patients with hypertension (67). However, when implementing a self-management intervention that makes patients responsible for taking and recording their own blood pressure, this rule needs to be understood and strategies developed to overcome it.

Integrating a constructivist perspective in contextual analysis offers an additional source of knowledge: by helping to open the “black box” of the context in which people act and interact, it also illustrates their social relationships, and how context shapes their behavior and actions in day-to-day practice and vice-versa (68-70). Via a knowledge of that underlying structure, researchers can identify and describe values and beliefs and track their evolution over time. Within that specific context, this allows them to expose potential problems and increases their understanding of why and how this context influences implementation success (14, 60, 61).

Building on the current state of IS research, we identified five relevant concepts from sociology and social anthropology, i.e., 1) *social place and* 2) *social space;* 3) *agency;* 4) *sensation; and* 5) *embodiment*. Below, we explain each concept in a separate paragraph, indicating how it can enrich the current view of contextual analysis, thereby strengthening the basis for all later implementation phases. However, as these five concepts overlap with and influence one another, they cannot be considered independently.

Table 6.1. Comparison of post-positivist and constructivist perspectives in regard to contextual analysis in implementation science (based on Creswell et al. (36, 66)

	Post-positivist perspective	**Constructivist perspective**
Interpretive framework		
Possible Researcher Goals	To discover potential facilitators and barriers which might impact the implementation of an intervention	To understand the complex context and setting in which the intervention will be implemented, including e.g., social, cultural, behavioral aspects and relationships
Potential Researcher Influences	Implementation researcher has training in quantitative and/or qualitative research	Implementation researcher has training in ethnographic methods
Examples of Researcher Practice	To ensure rigor, facilitators and barriers to intervention implementation are systematically assessed and analyzed	(Multiple) realities constructed by implementation agents are interpreted by the research team
Philosophical questions		
Ontology *(What is the nature of reality?)*	There exists a single, generalizable reality: Implementation of the intervention is affected by identified facilitators and barriers	Based on their lived experiences and interactions with other individuals, multiple realities are constructed by implementation agents in view of the intervention
Epistemology *(What is the relationship between the researcher and that being researched?)*	Relevant facilitators and barriers to implementation are objectively assessed using instruments and structured assessments	The implementation researcher collects subjective information in collaboration with implementation agents (co-construction)
Axiology *(What is the role of values?)*	Implementation researcher bias are minimized e.g. by using validated measurement scales	Implementation researcher uses personal interpretation, individual values of implementation agents are desirable
Methodology *(What is the process of research?)*	Deductive methods are applied, e.g., testing hypotheses or theories; results are compared among participants	Inductive methods are applied, i.e., based on implementation agents' perspectives, patterns, theories and interpretations are built up

To illustrate the individual concepts, we used the CICI framework as a starting point, then expanded it to encompass our five concepts (37). We also reported on healthcare system-level challenges to COVID-19 vaccine programs during the ongoing pandemic. These examples reflect several types of insights and ways in which a constructivist perspective could have helped public health officials anticipate and avoid certain problems regarding vaccination programs (Table 6.2).

6.4.4.1 Place and social space

Within the concept of context, place refers to the physical setting, whereas social space represents the abstract dimension in which relationships and interactions of individual implementation agents occur (40).

Place. The concept of place helps to operationalize the setting. It combines the three elements of *location, locale, and sense of place* (39). Location and locale are usually assessed by default in IS.

According to Creswell, *location* is an ‘absolute point in space‘, which has a certain distance from other locations, i.e., it defines where a place is, e.g., via coordinates. Characteristics of the location can affect individuals` behavior. Considering the example of COVID-19 vaccination campaigns, location can refer to the individual vaccination centers that administer the COVID-19 vaccination. At the beginning of the pandemic, most of these were centralized in larger cities. While they were easily reachable by individuals living nearby or using public transport, those with limited mobility or in rural areas struggled, e.g., to access the vaccination center or were burdened by travel expenses. These factors limited the utilization of such centers (71). When establishing vaccine distribution networks and supply chains, particularly in areas where decentralized centers later emerged, the distance between vaccination centers can affect both the supply and uptake of vaccines (72).

Locale includes a combination of physical and social aspects in which individuals' social relations unfold (39, 40). Physical aspects refer to “the landscape of a place—its physical manifestation as a unique assemblage of buildings, parks, roads and infrastructure” (40). Social aspects identify locale as "a setting for particular practices that mark it out from other places” (40). In our example, physical aspects can refer to the physical existence of buildings or vacant land where vaccination centers can be established. They also include available infrastructure, e.g., public transport, that allows individuals to access the centers or otherwise supports vaccine uptake. Social aspects of locale include places that are well-frequented during pandemic times, such as supermarket parking lots. The deployment of mobile vaccination teams in these areas offers an efficient way to increase vaccinations' reach and adoption.

Table 6.2. Overview of concepts to integrate a constructivist perspective in contextual analysis exemplified by COVID-19 vaccination uptake (cf. Table 2) and questions that can be applied to inform subsequent phases of an implementation project.

Concept	Definition	Example COVID-19	Questions informing next phases of an IS project
Place			
Location	Defines where a place is (e.g., indicated with coordinates).	The vaccination centers are centralized in larger cities.	– What is the exact location of the setting in which the intervention will be implemented? – How does the location impact, for example, the reach of implementation agents?
Locale	Physical and social aspects of a place in which social relations unfold.	Availability of public transport to access the vaccination center.	– Which aspects of the setting influence the agents' actions? – What physical and social resources are available in a setting that can support implementation? – What other resources might be needed?
Sense of place	Individual or shared meanings or emotions associated with a place.	Primary care physician offices are associated with trusting relationships.	– How do individual meanings of a setting influence implementation agents' actions in terms of the intervention?
Social space	Social space is produced by interactions of agents, depended, e.g., of social status or economic capital.	Individuals with different social and cultural backgrounds share a common space.	– Which networks of implementation agents exist, how do they interact in daily practice (e.g., team dynamics) and what might be their potential influence on the implementation process? – How can these networks or agents within them be involved within the implementation project?
Agency	Capacity of agents to shape the context in which they are situated at a given point in time based on their experience, personality, knowledge, skills, beliefs, attitudes or their structural social position.	Given their trustworthiness, religious leaders can exert a considerable influence on members of their community to get vaccinated.	– Which agents have a higher level of agency and might act as gatekeepers for implementation? – Which implementation strategies will be appropriate to enhance the agency of implementation agents to support implementation in practice?
Sensation and embodiment	Lived experiences agents perceive with their bodies in social and ecological contexts, that shape their actions.	The place where the vaccines are administered makes individuals feel uncomfortable.	– How do embodied experiences of implementation agents shapes their action, e.g., to adopt an intervention? – Which intervention components or implementation strategies are more appropriate for these agents?

While locale refers to the observable and tangible aspects of a place and its uses, *sense of place* refers to its subjective aspects. These include the meanings individuals or groups associate with a place, particularly the feelings and emotions it evokes (39, 40). For example, many people think of their primary care physicians' offices as places where they can go with all of their health concerns. This perception is based on long-standing trustful relationship with their primary care providers. For such people, receiving vaccinations from their primary care physicians rather than from healthcare professionals in a vaccination center can enhance vaccine uptake (73, 74). Further, there are several places that play important roles for individuals and where social interactions can take place. For example, a unit's nurses might perceive their nurse station as an important place where they come together, exchanging information, having conversations or team meetings. Regarding vaccine hesitancy among nurses, this could be a good place to provide implementation strategies, e.g., to discuss their concerns about side effects or the vaccines' rapid development process (75).

For contextual analysis, the concept of place helps clarify our understanding of setting and context, and to specify aspects of a setting that require analysis. Exploring place in implementation studies will foster an understanding of the structures, values, beliefs and shared meanings, feelings or emotions that affect agents' actions. In particular, understanding the sense of place stakeholders associate with a particular locale will add a useful perspective. This will both enhance the granularity of the IS researchers' contextual data and deepen their understanding of which aspects of a setting influence implementation agents' actions.

For COVID-19 vaccination campaigns, the concept of place could inform multiple implementation strategies to enhance and address barriers to vaccine uptake. These strategies could include, e.g., providing free transportation to vaccination centers. For low-income individuals, this would overcome cost barriers; and for those with limited mobility, either special-needs transportation, offering vaccinations in high-traffic, easily-accessible areas or involving primary care physicians in vaccination campaigns (76).

Social space. The concept of social space implies multilevel interactions driven by characteristics of place and social relationships between agents (77). Exploring social spaces informs our understanding of how social interactions influence agents' decisions and behaviors in practice (77, 78). Social space is never static; it is continuously shaped and reshaped through lived experience of everyday practices (44, p.283, 79). Social space depends on social milieus and on agents' positions within their society. Societal positioning results from interactions between the specific rules of the field (a setting in which agents and their social positions are located), each agent's habitus (ingrained habits, skills and dispositions) and each agent's social, economic and cultural capital (43, 80).

Between individual agents within a group, strong boundaries can exist (80). The more closely agents, groups or organizations are located within a space, the more properties they will have in common (42, 80). Social spaces exist across national borders or within societies, families, workspaces (e.g., hospital wards), or cities (e.g., hospital networks or national programs) (59).

During the COVID-19 pandemic, vaccination hesitancy varied considerably among social groups that share common spaces, e.g., younger individuals, low-income communities, rural residents, or migrant populations (81, 82). When identifying such spaces, it is important to reflect on how they affect implementation and to consider their implications for intervention and implementation strategies.

When considering younger adults' vaccine hesitancy, their concerns vary from those in other social groups, e.g., their doubts about the safety or side/adverse effects of vaccines may focus more on fertility/pregnancy (71). Addressing such concerns and enhancing vaccine uptake will require targeted education, outreach programs or mass media disseminated via channels popular among younger adults (e.g., social media platforms and internet) (82). Also, very well-networked individuals can act effectively as role models/influencers. Being aware of such central roles can be extremely useful, for example, for improving communication processes or facilitating implementation.

All countries and cultures have their social spaces, which show varying degrees of willingness to be vaccinated; they also have diverse vaccine-supply chains and—particularly in low-income countries—unequal access to vaccines. All of these factors must be considered when selecting targeted measures to increase vaccine uptake (83).

As part of context, social space influences context and daily practice routines and helps to explain changes in both (84). To understand social space, it is important first to know the place, affiliations, relationships between agents, including their relative power, social backgrounds including culture, and economic capital (78, 80). It is important to identify agents that share a social space as this space impacts their decisions and behaviors (78). Each space includes its own combination of implementation-relevant factors, any of which might influence a proposed implementation strategy's effectiveness. Therefore, an awareness of a context's main social spaces might help to improve the fit of implementation strategies.

6.4.4.2 Agency

Agency refers to agents' capacity to shape the context in which they are situated at a given moment (38). Agents can be individuals, groups or organizations who respond interactively and dynamically to changes in the context. These responses depend on their past experiences (habits), their underlying mental models (e.g., norms, attitudes), and their structural social positions (37, 38, 45, 85, 86).

Implementation processes depend on agency, whereas variations or changes in context (e.g., an interventions' implementation) affect individuals' agency (87). Thus, within implementation projects, it is important to understand how the various agents are embedded within their context, how their actions affect the context and, based on that, what value each agent can add to a successful implementation (45).

Some agents are assumed to have a higher level of agency. In Rogers' theory of diffusion, these are known as innovators and early adopters (88). Other agents, e.g., the late majority, have lower levels of agency (45). As well as power structures, variations or changes in context (e.g., social, cultural, economic, relational) affect individuals' agency (87, 89, p.29-30). Rogers et al. identified power dynamics as significant factors regarding their impacts on intervention implementation (90).

Regarding COVID vaccine uptake, agency becomes apparent not only when individuals are vaccinated but also when they refuse vaccination. Several factors can lead to an agent's refusal: religious reasons, beliefs, attitudes with healthcare practice, distrust of government (65, 71). As described by Wiysonge et al., individual worldviews, such as the neoliberal belief that each person is individually responsibility for his or her health—in contrast to a collective responsibility—affect vaccine uptake (91). However, some factors might also shape individuals' agency. For example, education, language skills or health literacy might all affect access to healthcare services, influence the agent's ability to detect misinformation or interpret conflicting or changing information (71, 92, 93). Other individuals perceived as powerful might act as a ‘gatekeeper for implementation’, e.g., encouraging others to get vaccinated. These are often religious leaders, specific family members, or community leaders (71).

However, as noted, besides responding to context, individuals can change context either through acting or through refraining from action. For example, after vaccination certificates became necessary to enter restaurants some individuals counterfeited them or banded together in political groups to stoke anti-vaccine beliefs (94). When choosing implementation strategies to increase vaccine uptake, such capacities need to be considered.

Relative to contextual analysis as a whole, the concept of agency acknowledges not only how agents mutually constitute and influence one another, but also how they interact with their context (38, 85, 86). Early identification of agents with high levels of agency will help implementation scientists facilitate the adoption and sustainability of their target interventions. Specific implementation strategies are also available to enlist implementation agents with lower levels of agency (e.g., providing multilingual reading or mass media campaigning for those with limited language skills (76)).

6.4.4.3 Sensation and Embodiment

As concepts, sensation and embodiment have often gone unnoticed in IS. Embodiment reflects the lived experiences—those agents perceive directly via their corporal and lived bodies in social and ecological contexts—that shape agents' actions, and thus also, whether they choose to support interventions' adoption and implementation (95, p.28, 96-100).

The corporal body can be distinguished from the lived body (101). Whereas the corporal body is substantive and measurable (i.e., it has a mass, occupies space, and performs diverse physical functions), the lived body refers to the subjective, lived experience based on sensation, i.e., “touch, proprioceptive sensations, kinesthetic sensations” (102). Thus, as it relates to contextual analysis, the body can be viewed as a tangible resource that produces outputs, but that also embodies lived experiences agents gain throughout their daily lives (e.g., stress, burnout, discrimination) and affecting their actions (96-98, 100, 103).

Negative experiences are particularly relevant to members of marginalized social groups, whose experiences of social exclusion have eroded their trust in government and, by extension, vaccines (91). They may habitually express those lived experiences in everyday life, for example in “gestures, tone of voice, emotions, body posture, bodily contact and language” (104) that convey meaning, but that they find difficult to articulate in words (105). For example, individuals with pre-existing conditions or who are concerned about contracting COVID for other reasons unconsciously stay further away from people who may not be vaccinated.

Both sensation and embodiment are essential to human agency. After COVID–19 vaccines were widely available, for example, it quickly became apparent that young healthy people, or those with few healthcare contacts, perceived their risk for severe COVID infection as very low and thus refused vaccination. Some, having experienced side effects from their first dose, refused a second dose or booster.

Also, when thinking about the setting where vaccines are administered, some people might feel uncomfortable traveling to or within larger cities for their vaccinations. While being processed through a vaccination center, others might be overwhelmed at being treated by care staff they have never met. Whether positive or negative, underlying experiences and attitudes are implicit in individuals' behavior and can influence the implementation. Considering embodiment within an implementation context and helping individuals articulate their lived experiences facilitates understanding of the contextual mechanisms that shape agents' actions, while exposing leverage points for contextually adapted implementation strategies (e.g., tailored measures for increasing marginalized groups' trust in vaccines) (105).

6.4.5 Methodological implications: Use of rapid qualitative methods and rapid ethnographies

Studying context from a constructivist perspective requires additional methodological considerations for data collection, data analysis and reporting.

6.4.5.1 Data collection

To qualitatively study context, most commonly interview methods are used (34). However, in their case study, Long et al., (59) noted that, as not all participants are equally available for the interviews or express themselves openly, interviews only provide initial qualitative information, e.g., about participants' levels of agency, their relationships, mental models and expectations. To understand the interactions in a context-affecting implementation, a range of qualitative methods including various forms of interviews, direct observation and document analysis is recommended (30, 59).

Regarding the five constructivist concepts introduced above, observations have the potential to provide a holistic view by exploring the agents' processes (implicit or habitual), interactions and behaviors that might otherwise be considered commonplace or unintentional, or simply not accepted, leaving them unaddressed (69, 106, 107). Further, informal knowledge, shared formal practice as well as mismatches between recommended practice and actual practice can be uncovered (69). For instance, as part of the Facilitating Implementation of Research Evidence (FIRE) study (108, 109), non-participant observation revealed that three interacting concepts were interacting and influencing implementation: place (resources in a setting, standards, physical nursing environment), social space and agency (e.g., formal and informal leadership, teamwork and professional autonomy) (107).

Alongside observation, document or archival analysis can be utilized to develop an understanding of historical or policy-related context influencing agents' actions (106). Interviews with key implementation agents support ongoing longitudinal assessment of context. The structures of key informant interviews can range from informal conversations to semi-structured interviews (110). Additionally, fieldnotes can be taken to record changes in context, e.g., during regular team meetings or discussions with key agents (106).

Further, ethnographic approaches seem to be well-suited to the complex and dynamic interactions between context, implementation and intervention (68, 106, 107, 111, 112). Ethnography is a theory-driven approach, providing a detailed description of diverse implementation agents, their behaviors and interactions in everyday practice, as well as how agents make sense of the context based on their norms, values, beliefs and roles (36, p.148, 110, 111, 113). In comparison to other qualitative approaches, ethnography specializes in the study of larger groups of agents interacting over time. This suits it well to multisite research, which might be interesting for larger IS projects targeting multiple settings (36, p.143, 111).

However, for contextual analysis, qualitative and particularly ethnographic approaches have been criticized as costly and time consuming, generating large volumes of data (2). As the resources for a contextual analysis are usually limited, we argue that to inform later phases optimally, it is important to generate as much information as our resources will allow.

This is especially true for the COVID-19 situation, where in a relatively short time, a comprehensive understanding of context had to be acquired. This need has led to the current focus on rapid qualitative and ethnographic methods within contextual analysis (2, 114-116). Those methods allow researchers to reliably, efficiently and affordably gather more information about context and setting in a shorter time (115). To help capture “relevant social, cultural and behavioral information, and focus on human experiences and practices” (117, p.6), rapid ethnographies exploit diverse sources including interviews, observations, focus groups and mapping processes (116). We offer one caveat regarding rapid methods. In addition to strong familiarity with the methods themselves, applying them requires at least a basic understanding of the setting in which an intervention will be implemented. Otherwise, a deep-dive contextual analysis is needed.

Another evidence source that is less resource intensive than primary research but still useful for concise research questions is secondary research. As a starting point, reviews and studies provide overviews of relevant contextual factors influencing implementation. Findings from secondary research can streamline a contextual analysis and help decide which contextual factors to focus on. However, since findings from one setting are not directly transferable to another, secondary research cannot fully replace the collection of primary data.

6.4.5.2 Analysis and reporting

Context is situational and continuously shaped and reshaped. Constructed by various agents, its characteristics depend on situational aspects and prevailing conditions at the time of observation (118). To recognize changes in context and enable adaptions of intervention and implementation strategies to fit the evolving context, context should be assessed longitudinally (119). For instance, regular stakeholder meetings or informal exchanges with implementation agents can highlight early signs of changes that require adaption. However in-depth up-to-date contextual knowledge is acquired, it is an essential prerequisite to addressing contextual changes in ways that sustain interventions in daily practice (10). When reporting the findings of a contextual analysis, in addition to descriptive data and narratives, case studies, vignettes or typologies can be employed.

6.4.6 Implications for practice: Considering the position of the researcher studying context

The concepts of social space and place, agency, sensation and embodiment enrich contextual analysis in IS. While providing a rigorous way to reveal otherwise overlooked contextual aspects, they increase the understanding of the complex and dynamic interactions in context that need to be targeted (112, 120). These insights allow researchers to identify practices or aspects that might impact their intervention and implementation processes, as well as key implementation agents that need to be closely monitored throughout the implementation process (112, 120).

Gaining this thorough understanding of context is particularly important depending on who is conducting the contextual analysis and with what intentions. Implementation researchers may actually be part of the setting, i.e., they may be analyzing part of an academic institution with which they are associated (cf. embedded implementation research (121, 122)). Compared to external observers, these researchers start with inside knowledge of the context and setting. This will give them a different perspective during the contextual analysis, i.e., internal analysts will focus on different contextual factors than their external counterparts.

In fact, using embedded researchers to perform contextual analysis is recognized as an implementation strategy in itself. One advantage such researchers offer is that, if they have experience from previous projects in the same setting, they will likely have a working knowledge of the structures, processes, practice patterns and culture. By helping them to focus on relevant contextual factors, such knowledge helps them first select target factors, then conduct their contextual analysis. It also supports the involvement of implementation agents within the setting, and may even promote the proposed intervention's implementation and sustainability (122).

One obvious risk is that notable choices (e.g., of intervention components and implementation strategies) will be based on implicit knowledge, making them opaque to external researchers. Moreover, experience within a setting may bias researchers' observations both of context and of setting (e.g., confirmation bias), thereby limiting their findings' generalizability. Therefore, in addition to ensuring that the perspectives they consider are representative of all agents within the setting, embedded researchers need to reflect carefully on their own positions and how this might affect how they interpret their findings (122). In contrast, external researchers or practitioners conducting a contextual analysis must first develop a working understanding of how the context and setting work. Particularly for those researchers, taking a constructivist perspective will increase the depth of their contextual analysis and help to make otherwise invisible aspects of context visible.

6.5 Conclusions

6.5.1 Value of the constructivist perspective for contextual analysis and implications in defining context

Contextual analysis is an indispensable part of the IS methodology, providing a firm foundation for successful and sustainable implementation projects. Yet, driven by the prevailing post-positivist understanding of context, contextual analysis generally focusses on individual characteristics of context and setting. This means the dynamism and complexity of context go unstudied. By endorsing contextual analysis from a constructivist perspective, this paper promotes a multi-layered approach to contextual analysis. By offering a far more comprehensive understanding of context, we believe that this new paradigm will facilitate successful and sustainable implementation.

Implementation depends on social processes and interactions between agents and context within the target setting. In IS, contextual analyses usually focus on what people say or what they say they do (characteristics of context and setting), e.g., their comments on resource availability, practice patterns, or readiness for change; however, they rarely observe and assess what people actually do in daily practice.

Therefore, both to provide a solid basis for intervention development or adaption and to inform choices of contextually adapted implementation strategies, we suggest using the five constructivist concepts of place, social space, agency, sensation and embodiment to complement previous conceptualizations of context.

Exemplified via the case of COVID-19 vaccine uptake, we describe how the concept of *social space* helps to understand how implementation agents are embedded in their context and how they relate to one another. The concept of *place* complements earlier views of setting, specifically regarding the point where interaction between implementation agents occurs, the meaning of setting, and how this affects our interpretations of agents' actions. The concept of *agency* allows us to consider what abilities implementation agents possess to change their context. *Sensation* and *embodiment* help define what subjective experiences implementation agents had or are having, and how those experiences influence their actions. In IS, applying these concepts to contextual analysis both helps to overcome several of its current shortcomings and deepens our understanding of the complexities of everyday context.

From a constructivist perspective (Figure 6.1), we understand context as an overarching, multidimensional, multilevel concept. It consists of a set of interrelated characteristics and patterns, and is both enabled and driven by its various agents' social structures and underlying values and beliefs. Within a context, multiple social spaces generally exist. These are essential for social interactions between the agents who shape the context and setting. Intertwined with context, setting combines the three perspectives of place: location, locale and sense of place. The setting is where an intervention is implemented and where it then interacts with implemented implementation strategies, agents and/or any concurrent interventions. Those interactions mutually shape and reshape the context. Agents have the capacity to change context and setting (agency), but also to respond to changes in context and setting. Thus, context is situational, dynamic and continuously evolving.

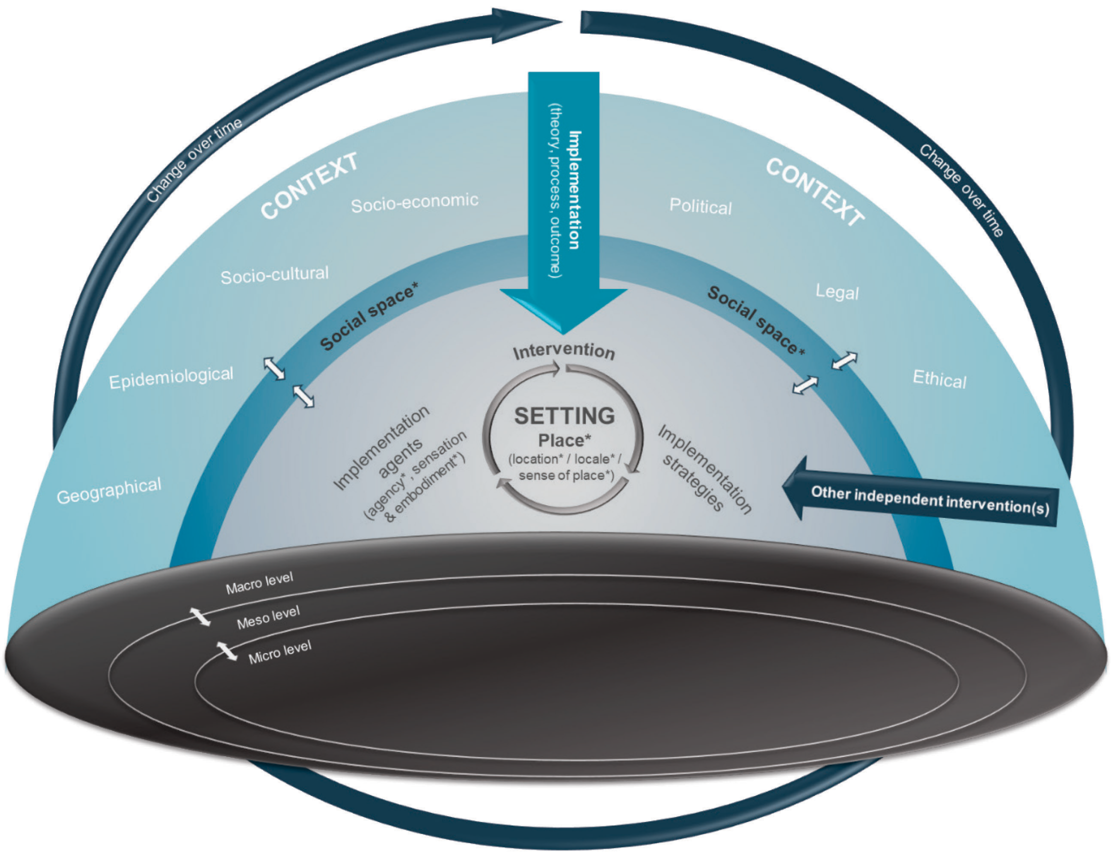


Figure 6.1. Context is multidimensional, including seven context domains (geographical, epidemiological, socio-cultural, socio-economic, political, legal, ethical) and multilevel (micro-, meso-, macro-level). Within a context several social spaces exist, providing a condition for social interactions between agents that shape context and setting. Setting is intertwined with context and combines the three perspectives of place: location, locale and sense of place. The implementation (including implementation theory, process and outcomes) of an intervention takes place in the setting. During and after implementation, the intervention interacts with implemented implementation strategies and agents or other independent interventions implemented at the same time in the setting. Those interactions mutually shape and reshape the context. Agents have the capacity (agency) to change context and setting, but also to respond to changes in context and setting. Thus, context is situational, dynamic and continually evolving.
This figure has been adapted from Pfadenhauer et al. (37) with the permission of the first author Lisa Pfadenhauer.

For research teams conducting contextual analyses, a constructivist perspective enables a more detailed view of context and reveals complex dynamics that would otherwise remain invisible. In doing so, the constructivist perspective exceeds that of the frequently used realist methodology (123). While the realist methodology focuses on context-mechanism-outcome configurations to understand what needs to happen for a successful implementation, a constructivist perspective helps to understand agents' actions regarding implementation (29, 30, 124, 125). To understand what agents do, it is necessary first to identify the social structures, norms, values and beliefs that drive their actions, and to explore how context and agents interact and mutually influence one another (70). Thus, we hope that this paper contributes to a stronger conceptualization of contextual analysis. And finally, we strongly believe that approaching contextual analysis from a constructivist viewpoint broadens and deepens the contextual knowledge available to inform IS projects' subsequent phases, thereby maximizing both uptake and sustainability (6, 7, 63, 120).

6.6 References

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Chapter 7.

Synthesis and Discussion

Despite recent progress in overcoming research-to-practice lags, slow or incomplete translation of evidence into practice still contributes to massive resource and research waste. The burdens of these failures and delays are borne by society, health care systems and patients (1-3). As implementation scientists have shown, one of the major barriers to the adoption of proven interventions is the mistaken assumption that an intervention that fits one context will fit others without adaptions. As indicated in the two case examples in **Chapter 1**, contextual tailoring is a major determinant for successful and sustainable implementation initiatives; therefore, context needs to be considered very early in the implementation process (4, 5).

Unfortunately, one problem currently facing implementation scientists is that concepts and methods for studying context are only partially mature; and little methodological guidance is available for contextual analysis. In fact, the degree to which an intervention matches the target context—whether because of its original design or via adaption—may be the key determinant of whether it can be sustainably implemented. And ensuring a close fit demands in-depth contextual understanding. This informs not only intervention development and choices of implementation and sustainability strategies but also interpretation of outcomes and later, scale-up efforts. Therefore, contextual information is the foundation of an implementation science project.

In order to speed up the translational pipeline, i.e., to accelerate and enhance the translation of interventions into real-world settings, context needs to be considered from the very start of an implementation science project. However, for this process to follow transferable principles, a coherent methodology for contextual analysis is needed.

In response to this need, the current dissertation focusses on contextual analysis, treating it as a foundational phase of an implementation science project and making them more powerful in real-world settings. Overall, our aim was to strengthen the theoretical and methodological foundations of contextual analysis in implementation science. In the following, we synthesize and discuss key findings with reference to existing evidence, the strengths and limitations of current concepts. We conclude with a summary of these findings' implications for research and practice and suggestions to support capacity building for contextual analysis and implementation science.

7.1 Key findings

While searching for articles relevant to describe the state of science in view of contextual analysis, inconsistencies and heterogeneity regarding terminology were major barriers to identifying and accessing implementation science evidence (**Chapter 3**). To develop a well-targeted and reproducible search strategy, we surveyed 56 implementation science experts asking them to identify and prioritize journals that publish implementation science relevant content and that can be included in search strategies, i.e., that support and facilitate the identification of implementation science evidence. The journals *Implementation Science* and *BMC Health Services and Research* were perceived as most relevant by 97.1% of the experts.

Subsequent steps in the dissertation focused on strengthening the theoretical and methodological foundations for contextual analysis in implementation science. First, within the implementation science project SMILe (SteM cell transplantatIon faciLitated by eHealth), we developed the Basel Approach for coNtextual ANAlysis (BANANA) (**Chapter 4**). BANANA builds on a previous publication by Stange and Glasgow (6) and includes a six step-process to study context and inform subsequent phases of an implementation science project. BANANA successfully guided the contextual analysis in the SMILe project and might be valuable for other implementation science projects as well.

Second, regarding methodological approaches to contextual analysis, our evidence gap map (EGM) provided an overview both of those applied in the reviewed implementation intervention studies, and of those approaches' limitations (**Chapter 5**). We found that slightly more than one-fifth (22%) of the included studies reported on context. Those that conducted contextual analyses, showed broad variability in their conceptualizations of context and in the methods they used. Fewer than half of the reviewed studies (42%) were theory-based; the most showed only limited stakeholder involvement.

Third, as part of the EGM (**Chapter 5**), we propose a novel framework for mapping and evaluating methodological approaches to contextual analysis in view of literature searches (i.e., empirically developed search string) and visualizations of summarized evidence (color-coded evidence-based maps).

Fourth, reflecting on the shortcomings of current approaches to contextual analysis, particularly those driven by the prevailing post-positivist understanding of context, we present five constructivist concepts (i.e., social space, place, agency, sensation and embodiment). These complement recent conceptualizations of context and promote a more comprehensive and multilayered understanding of context (**Chapter 6**). Further, we discussed methodological and practical considerations, e.g., in view of data collection and analysis.

7.2 Contextual analysis as a foundational phase in implementation science projects

Implementation science lacks a unified term and definition for contextual analysis. Among other names, contextual analysis has been referred to as a "pre-implementation phase", "contextual inquiry", or "assessment of facilitators and barriers". To the best of our knowledge, we are the first to refer to it explicitly as *a separate essential foundational* *phase in implementation science projects,* as in the studies we included in our EGM (**Chapter 5**) (7-9).

Better known, on the other hand, are activities referred to as *Designing for Dissemination, Implementation, and Sustainability* (D4DIS) (10, p.29). In order to improve implementation and speed interventions' translation into real-world settings, D4DIS aims to integrate implementation- and dissemination-related considerations (10, p.22) as early as projects' planning and development, or even the evaluation of an intervention (effectiveness research) (11, 12). Hybrid designs support combining elements of clinical effectiveness trials with those of implementation trials. While hybrid 1 designs focus primarily on testing the effectiveness of clinical interventions and secondarily on exploring implementation-related factors (e.g., facilitators and barriers to implementation), context is often only considered retrospectively or as part of a process evaluation (13, 14). One activity within D4DIS, is the pre-implementation assessment (15). Designed to guide quality improvement programs, this pre-implementation assessment “identifies a high-priority need, selects effective practices to address the need, engages stakeholders to build implementation capacity, specifies needed practice adaptations and evaluation goals, and activates leadership support” (16).

Going beyond this idea, the Basel Approach for coNtextual ANAlysis (BANANA) (**Chapter 4**) focusses not only on the identification of implementation determinants (i.e., facilitators and barriers), but provides a novel methodology for studying implementation context. We define contextual analysis as the mapping of quantitative and qualitative contextual information (e.g., implementation determinants, practice patterns) in ways relevant to an intervention's implementation into real-world practice. BANANA treats contextual analysis as a separate phase conducted at the beginning of an implementation project (i.e., prospective assessment of context) that includes specific research questions and TMFs (Figure 7.1). Contextual analysis builds the fundament for all subsequent phases of an implementation science project (i.e., intervention co-creation, choice of implementation and sustainability strategies, interpretation of effectiveness and implementation outcomes) and should already be included as a separate phase within efficacy research

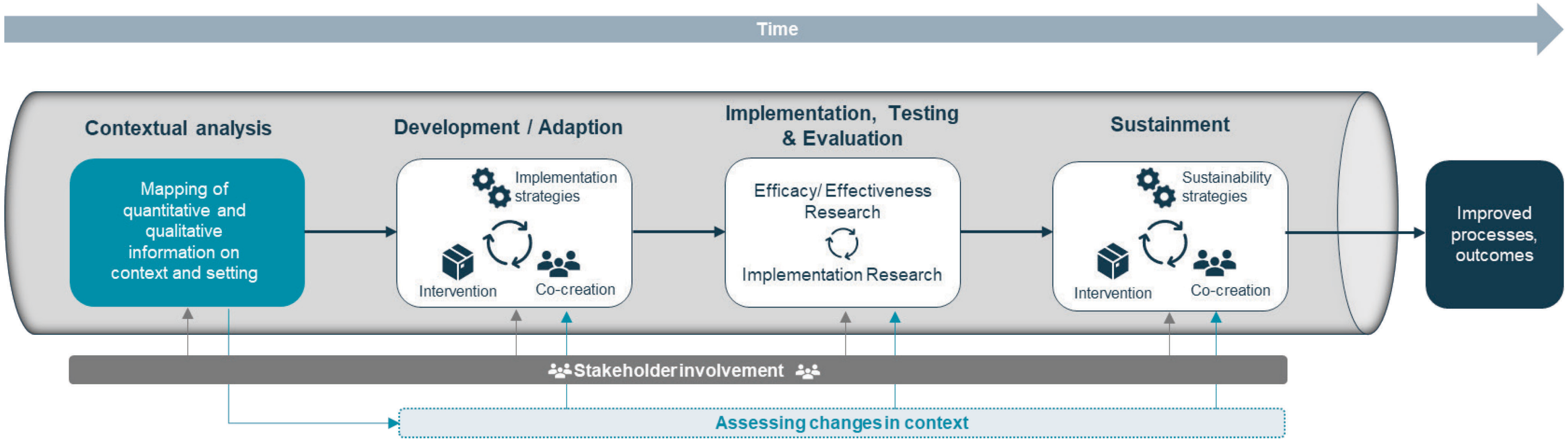

Figure 7.1. Contextual analysis as foundational phase in implementation science projects to speed up the translation pipeline (14)

When considering Case Example 2 (**Chapter 1**)—implementation of inclisiran (a cholesterol-lowering medication) into primary care—this might include as part of efficacy research to start thinking (together with stakeholders) on how to organize and deliver the new treatment and on appropriate implementation strategies supporting implementation. In addition, considerations for sustainability in practice can already be made (e.g., financing the administration of inclisiran in primary care). These are initial considerations that will become more concrete as the intervention progresses and evidence of its effectiveness grows, and will also be adapted to changes in context as needed.

The value of this approach—i.e., treating contextual analysis as a foundational first phase—becomes evident in three of our institute's ongoing/completed implementation science projects (INTERCARE, SMILe, and INSPIRE) (17-25). All are either already planned or could be completed within a timeframe of three to four years, starting with a contextual analysis as foundational phase that varied from 12 to 22 months (*O. Yip, written communication, January 16, 2022; S. Valenta, personal communication, January 17, 2022*) (17, 20). The projects' experiences provide initial indications that this approach valuably enhances implementation in real-world settings and speeds the translational pipeline (17-25).

An overview of the three projects' aims can be found in Table 7.1. Each included two Phases. The contextual analysis was positioned as *Phase A.* In addition to contextual analysis, Phase A also comprised subsequent intervention development/adaption and choice of implementation strategies. Additionally, stakeholder involvement was planned and integrated in Phase A and continued in *Phase B*, which focusses on the implementation, testing and evaluation of the developed care models using hybrid designs.

In all projects, the comprehensive foundation of Phase A, provided a solid 'take off' for Phase B. Despite extensive time and resources invested to conduct Phase A, the ease of implementation of INTERCARE and SMILe, as well as the initial smooth experience of implementing INSPIRE (*O. Yip, written communication, January 16, 2022*), suggest a methodologically valuable approach when real impact in real-world settings is the driving force of the research efforts. Moreover, for SMILe and INTERCARE, not only implementation went smoothly, but there is also initial evidence of sustainability and scale-up (26).

In INTERCARE ten of the eleven participating nursing homes persisted in the further use of the care model. Given the considerable interest from other nursing homes, the INTERCARE team is also preparing INTERSCALE, a hybrid 3-effectiveness implementation study, to test the most efficient implementation strategy for the INTERCARE intervention.

Within SMILe, the two participating university hospitals have already decided to sustain the SMILe integrated care model beyond the project period, i.e., funding will be provided for the care coordinator, despite the fact that its effectiveness results will be expected in the fall of 2022, the earliest. Similarly, SMILe project leaders receive requests from other international stem cell transplant centers to participate in the SMILe project.

Table 7.1 Aims of the three implementation science projects at the Institute of Nursing Science, Basel, Switzerland, which conducted a contextual analyses as its foundational phase—INTERCARE (17, 18), SMILe (19-22), and INSPIRE (23-25)

Project 1 (completed) The **INTERCARE Study** (improving INTERprofessional CARE for better resident outcomes) aims to reduce avoidable hospitalizations in Swiss nursing homes via an interprofessional nurse-led model of care. Results of Phase B (i.e., evaluation of implementation effectiveness outcomes) revealed a statistically significant decrease of unplanned transfers from nursing homes to hospitals after implementation of INTERCARE (27). Those decrease was associated with the high fidelity to specific tools that were developed as part of the care model (i.e., ISBAR and STOP and WATCH) (26).
Project 2 (ongoing) The **SMILe project** (SteM cell transplantatIon facIlitated by eHealth) aims to develop/adapt, implement, test and evaluate an integrated care model (ICM) for stem cell transplantation facilitated by eHealth (SMILe-ICM).
Project 3 (ongoing) The **INSPIRE Project** (Implementation of a nurse-led community care program for senior citizens in Baselland, Switzerland) aims to develop, implement and evaluate a care model for older people including a nurse-led assessment and care advice center on the levels of patient, provider and system.

However, besides the described strengths, the definition we provide for contextual analysis also has limitations. For example, as the definition evolved iteratively based on evidence and experience, it only focusses on the assessment of context at the beginning of an implementation science project. Given that contextual analysis is also used for other purposes and during other phases of an implementation project (e.g., process evaluation), a concept analysis at the beginning of the dissertation could have helped to further explore and define contextual analysis and to distinguish it from other concepts (28).

Implications for research

Contextual analysis needs to be recognized as a foundational phase in implementation science projects. Current implementation science study designs (e.g., hybrid designs) do not consider contextual analysis as a separate phase.

Given our promising experience with investing in a solid Phase A, the Basel Implementation Science research team will therefore collaborate with Geoffrey Curran, who has published the first paper in implementation science on hybrid designs (14). Working together, our goal is to publish a paper that reports on and discusses this methodological approach in order to strengthen the discussion of methodological design in implementation science internationally.

Moreover, further research is needed to understand whether the focus of a contextual analysis changes depending on the research phase it is conducted (e.g., efficacy research or effectiveness research) and on its purpose (e.g., to inform sustainment or scale-up of interventions).

7.3 Finding implementation science evidence

Literature searches are the basis of each research project and also in contextual analyses. They support the identification of empirical evidence on contextual factors relevant to an intervention's implementation and sustainability. However, in implementation science, inconsistencies in terminology and fragmentation of implementation science-relevant literature across multiple disciplines complicate the development of well-targeted and reproducible searches, reduce related research quality and hinder the development of implementation science as a field of study (29-31).

To overcome those challenges and to identify the state of science on contextual analyses in the implementation science literature, we conducted a survey asking 56 implementation science experts to identify journals for inclusion in search strings in addition to text words and MeSH terms (**Chapter 3**). Based on their responses, we presented a basic selection of journals publishing implementation science-relevant content and implementation science special issues over the last 20 years. However, we recognized, that expert`s rankings of the journals varied geographically and by discipline, limiting generalizability of findings. This finding is closely linked to the fact, that implementation science is inherently a multidisciplinary research field. I.e., research is therefore published not only in implementation science specific journals, but also in a wide range of subject-specific journals. This diversity was reflected in the special issues we identified. While the inclusion of journals in search strategies is a pragmatic way to access the implementation science literature, it is very likely that gaps in identifying implementation science evidence will remain due to the variability in expert ratings and the large number of journals identified.

To develop a more comprehensive overview of journals publishing implementation science relevant content—including subject-specific journals as well— a social network analysis, such as those conducted by Polites et al. in the field of information systems might facilitate the identification and evaluation of implementation science journals' relationships and influences (32). Originally, social network analysis is a methodology focusing on networks of individuals and relationships between these individuals (33). However, in regard to journals, social network analysis allows the mapping of relationships between different journals. This helps researchers both to analyze each journal's role in a network structure and to identify subgroups of journals related to a specific research focus (32). The disadvantage of network analysis is that it would require a subset of all possible journals publishing implementation science-relevant content. Yet, the field of implementation science rapidly develops, with new implementation science journals being launched. Since 2016, *Implementation Science Communications*, the *Journal of Clinical and Translational Science*, *Implementation Research and Practice*, *JBI Evidence Implementation,* and *Global Implementation Research and Applications* have all started publishing. In addition, several non-implementation-specific journals, e.g., *Frontiers in Health Services,* now offer special sections on implementation science. Such rapid expansion and diversification enlarge the list of relevant journals and increases the complexity in accessing implementation science evidence from outside the most accessible sources.

As described by Hausner et al., empirically guided search approaches (34) present an alternative method of developing efficient and reliable search strategies, and have the potential to improve searches regarding both sensitivity and specificity. For example, the empirically developed search string we used to finding intervention implementation studies for our evidence gap map achieved a sensitivity of 95.1 % (**Chapter 5**). However, high sensitivity often comes at the expense of specificity: our search returned 15,286 records for screening (30).

Therefore, in addition to innovative search strategies (e.g., use of text mining tools to identify search terms), methods are also needed to simplify the screening of literature (35). Already, several software tools make it faster and easier (36, 37). For example for our evidence gap map, we used the Rayyan and EPPI-Reviewer tools (**Chapter 5**), both of which also employ machine learning and data/text mining features that (semi-) automate screening processes (38, 39). These tools are especially useful when screening data sets with more than 2500 records; however, as their accuracy still varies greatly, they should only be used no complement manual screening, not to replace it (38, 40).

Implications for research

As an important step to improve implementation science research quality, further investment is required to develop reproducible search strings, both to access implementation science evidence (cf. search strings for PubMed and Cochrane Library databases) and to enhance the algorithms of software tools supporting the screening of identified evidence.

7.4 Current state of science regarding contextual analysis including gaps and limitations

To assess the state of science regarding methodological approaches to contextual analysis, we constructed an evidence gap map (EGM) of implementation intervention studies (2015-2020) (**Chapter 5**). Of the 110 studies we included, only 24 (22%) reported on contextual analysis. Those 24 showed high variability in their conceptualizations of context, the methodological approaches they applied for contextual analysis and their reporting.

7.4.1 Lack of theoretical underpinning guiding contextual analysis

In contextual analyses, theories, models and frameworks (TMFs) can provide guidance in the selection of relevant contextual factors and operationalization of concepts, while promoting the use of common language and increasing study findings' generalizability (41-45). In general, our EGM showed that the studied implementation intervention studies' TMF use was sub-optimal. Overall, only ten of the 24 studies used a TMF.

These findings are consistent with those of several previous studies in implementation science. Those reported that 22.5%–48% of their reviewed studies used TMFs (46-49). Furthermore, the TMFs named in our EGM were more likely to be applied in later phases of the implementation process. Only one study's authors explained explicitly both their purpose for using a TMF (i.e., contextual analysis) and how they applied it. In implementation projects in general, many study authors either fail to justify their choice of framework, or mention a framework but use it only superficially, incorrectly, or not at all (13, 44, 50). This is problematic because, while TMFs can clearly support translation of evidence into practice, their incorrect application can lead to misinterpretation, misguided decisions and poor outcomes (44, 45). Also, that only 22% of the studies in our EGM performed contextual analysis may be related to the underutilization of TMFs for the overall project.

Reasons for the non-use or incorrect use of TMFs include difficulties in identifying, selecting and combining TMFs. The multitude of TMFs that now exist—150 in Strifler's review (51)—make these steps even more challenging. Further only few guidance for the selection and combination of TMFs exist (44, 50, 52, 53). Therefore, the selection of a TMF is often not based on scientific reasons, but simply because the TMF is already known or used, or for political reasons (42). This also results in the continued use of outdated TMFs, such as the Promoting Action on Research Implementation in Health Services (PARiHS) framework, instead of its updated version, the integrated PARiHS (i-PARIHS) (54).

Implications for Research

There is a general need to increase researchers' awareness of TMFs' relevance for the overall implementation science project but also for contextual analysis. The latter assumes, that researchers consider contextual analysis foundational for an implementation science project. Details of any TMFs used, the rationale for their selection, and explanations of how they were applied are all essential and should be considered standard components of reporting. And naturally, reporting guidelines need to specify how these details should be included (55).

When selecting frameworks, the suitability of the framework for a specific purpose (i.e., contextual analysis) should be the primary consideration. To test a framework, users should also check whether any useful adaptations or enhancements to it are available and familiarize themselves with the TMF they judge most suitable.

Perhaps most importantly, TMF developers can also contribute to and enhance the use of TMFs, e.g., by publishing scholarly documents providing guidance and possibly explaining useful modifications (45). Further, for example, websites such as those of the Consolidated Framework for Implementation Research (CFIR) (56) or the EPIS framework (Exploration, Preparation, Implementation, Sustainment) (57) research groups can help ensure that all current and relevant information on a framework is available in one place. Such website might also thrive the use of the Context and Implementation of Complex Interventions (CICI) framework in implementation science for contextual analyses, an important meta-framework that pays ample attention to the interactive and dynamic context (58).

7.4.2 Limited use of empirical evidence for contextual analysis

While a TMF provides information on developing a comprehensive overview of contextual factors that are relevant to intervention implementation and that can be captured in a contextual analysis, they cannot guide decisions about which factors to examine in a particular project. First, not all contextual factors are relevant to every implementation science project (59). Second, the available resources for a contextual analysis are often scarce; so priorities have to be set for the analysis (60). Third, factors that may not have been mentioned in the framework may also play important roles.

Regarding this third point, empirical evidence can help to identify contextual factors relevant to a particular implementation project (58, 61, 62). However, our EGM showed that only seven of the 24 reviewed studies reported explicitly the use of empirical evidence for contextual analysis. Several reasons may contribute to limited use of empirical evidence. First, as noted in **Chapter 3**, identifying and accessing empirical evidence in implementation science is challenging by reason of the above. These challenges are magnified, when searches additionally entail other implementation science concepts, which are as poorly conceptualized (e.g., context). Second, the use of other empirical sources (e.g., professional knowledge, patient experiences or local data) is often not reported, resulting in reporting bias (63). Third, due to the general under-recognition of context as a source of evidence—one that uncovers not only factors that influence many or all implementation projects, but also those unique to one specific intervention in one specific setting (**Chapter 5**).

Aiming to address this issue, Ariadne Labs' Atlas initiative developed The Atlas Context Data Repository (60, 64). That initiative's primary goal is to identify and rank contextual factors according to their impact on implementation. The dataset will eventually be extended to serve increasingly broader ranges of interventions and settings. It will also investigate whether contextual factors vary at different points in time (60). However, Atlas is initially only examining individual determinants independently of one another. Contextual factors are interrelated, often interacting dynamically to influence implementation success. A failure to consider such interactions threatens not only to limit an intervention's success, but to produce unexpected, possibly undesirable effects.

7.4.3 Variability in conceptualization and assessment of contextual factors

In addition to the issues named above (**Chapter 3**), the evidence on contextual factors is limited and sometimes inconclusive due to various reasons (**Chapter 4**) (61, 65-67). In the sample of implementation intervention studies included in our EGM, we found that context is often not defined and factors studied (e.g., environmental level characteristics) not sufficiently operationalized (68). By developing the EGM, we were able to visualize which contextual and setting factors the included studies had explored and to what degree (**Chapter 5**). We identified 43 distinct factors, which we mapped using the categories of the Context and Implementation of Complex Interventions (CICI) framework which operationalizes context and setting (58). While the use of theory for mapping is usually a strength, in turn, this posed challenges regarding data extraction for the EGM. Those challenges arose not from weaknesses in our methodology, but because none of the included studies distinguished between context and setting. Therefore, the classification must be interpreted with caution: otherwise, both synonymy (i.e., the use of identical terms to describe non-identical constructs/factors) and homonymy (i.e., the use of non-identical terms to describe identical constructs/factors) can lead to conceptual inconsistencies including the misclassification of identified factors (69, 70).

Overall, our analysis revealed imbalances in reporting contextual factors that may indicate reporting bias. For instance, the selected studies focused predominantly on meso-level factors (e.g., socio-cultural aspects or practice patterns); macro-level factors were less frequently studied. These findings are unsurprising: while TMFs focusing on organizational-level factors are abundant, there is a lack of macro-level measurement tools (58, 66, 71-73). Further, as described in **Chapter 6**, the researcher's perspective may also influence both analysis and reporting. A research familiar with a setting may focus on different aspects of context or not that extensively as someone from outside. This emphasized again, that no cook-book-approach will work for contextual analysis (**Chapter 4**). The choice of contextual factors to be studied requires intellectual work based on the specific project.

One limitation of this map is that, when classifying contextual factors, we did not distinguish the point in time at which each was studied. Such data would help explain whether—and if so, how—the relative relevance of contextual factors differs across the study period. Nevertheless, the evidence map provides a useful overview of all contextual factors studied in the implementation intervention studies, and of the levels at which they were assessed. Thus, the evidence map provides an initial evidence base that can be both expanded and deepened across the course of further studies.

7.4.4 Variability in methods applied and measurement tools available for context

To increase the breadth and depth of a contextual analysis, either a combination of qualitative and quantitative methods, or if possible an actual mixed-methods design, is usually recommended (74, 75). Echoing the results of Rogers et al's systematic review, our EGM (**Chapter 5**) showed considerable variability in the methodology employed for contextual analysis. Overall, where only one method was used, it was more often qualitative than quantitative, with surveys, individual interviews, and focus group discussions were most often applied. One-third of the reviewed studies used a mixed-methods design.

The choice of methods for contextual analysis always depends on the research questions to be answered in the contextual analysis. Apart from that, notable considerations include resource availability (e.g., funding, personnel), the time frame in which a contextual analysis has to be carried out, or the number of settings to be studied (e.g., international multisite implementation projects) (76). And as the onset of the COVID-19 pandemic showed, external circumstances can also play major roles in regard to methods. In that case, effective measures had to be chosen or developed, then implemented extremely quickly (77).

One more point that varied considerably between studies was the number of timepoints for data collection. Of the 24 reviewed studies, seventeen measured context at two or three points (i.e., at the beginning, middle and end of the implementation, or as part of a process evaluation); seven assessed context only once. This once again demonstrates that the planning and execution of a contextual analysis requires a lot of reflection for which there is no standard procedure. For this reason, the early and close collaboration of experienced implementation researchers and practitioners is key (78). This will aid generating synergies in terms of methodological skills and practical experience to maximize the value of contextual analyses.

One topic not yet explored in detail in this dissertation is that of measurement tools usable to assess multilevel contextual factors quantitatively. To assist implementation researchers and practitioners in their selection of measurement instruments, the Society for Implementation Research Collaboration (SIRC) Instrument Review Project is compiling a repository of such instruments (70). Their Instrument Review Project aims to identify quantitative measurement tools that assess constructs of CFIR (79) and/or the Implementation Outcomes Framework (80), and show strong psychometric and pragmatic evidence (i.e., acceptability, compatibility, ease of use, and usefulness (81)) (70). To date, over 420 instruments have been identified, 94 of which focus on context. While various instruments are available to assess context, their focus is very heterogenous (outer setting n=4, inner setting n=94) (82). While no measures of *external policy and incentives*, *tension for change*, or *goals and feedback* have been identified, numerous measures are available to assess *readiness for implementation* (n=16), *implementation climate* (n=15), and *learning climate* (n=14). As seen in similar projects, though, the preliminary results raise questions regarding quality. While the first results regarding the identified measures' pragmatic evidence have yet to be reported, this suggests psychometric weaknesses in the project's measurement instruments (82).

Implications for research

In general. The development and use of a consensus definition for contextual factors is important not only for the development of valid and reliable measurement instruments, but also for the generalizability and interpretation of the results.

Methods. The described complexity not only of contextual analyses but of implementation science projects in general, demands collaboration of experienced transdisciplinary implementation science research teams with both, expertise in various quantitative and qualitative research methods, as well as implementation science practitioners.

Measurement tools. For quantitative assessment of contextual factors, measurement instruments showing sound psychometric properties and supported by pragmatic evidence should be used wherever possible. To identify appropriate measurement instruments, the resources of the SIRC or other reviews are valuable resources. Regarding the uneven availability of measurement instruments, attention should focus on the use of existing measurement instruments before developing new (possibly redundant) ones, as well as on the validation, where necessary, of the chosen instruments' psychometric properties and pragmatic evidence. (81, 82). In the case of contextual factors for which no measurement tools can be located, such tools should be developed.

Data collection and analysis. Increased insight and detail are needed regarding 1) how frequently and at what points context should be studied during implementation science projects; 2) whether the relevance of contextual factors varies between measurement points in the contextual analysis; and 3) which methods are most appropriate at different measurement points or over longer periods of time.

7.4.5 Limited involvement of various types of stakeholders

Stakeholder involvement is essential to the quality and success of an implementation project and can also enhance dissemination (83-85). In our EGM (**Chapter 5**), we examined whether and which stakeholders were involved in the mapped studies' contextual analyses. Compared to two previous reviews of medication adherence intervention trials, in which four of 21 (86) and ten of 24 (87) either fully or partially reported stakeholder involvement, all of our EGM's studies reported stakeholder involvement. The differences may be related either to increasing recognition of the importance of stakeholder involvement (Zullig et al. examined studies from 2007–2014 (86)), or to the settings and foci of the reported interventions. However, one limitation of our study is that, due to the included studies' sparse descriptions, we were able neither to distinguish whether their references to stakeholder involvement applied specifically to the contextual analysis (versus the entire implementation project), nor to extract more precise information about their stakeholders' involvement (e.g., timepoints for stakeholder analysis, tasks, and methods for involvement).

In order to ensure the success and maximize the impact of stakeholder involvement on the contextual analysis as foundational phase (and thus on the entire implementation project), it is useful to involve stakeholders with diverse perspectives, i.e., they should represent the target group, implementers, decision makers and, if necessary, groups such as experts. Nevertheless, as our EGM shows, only nine of the 24 reviewed studies involved a full range of stakeholders.

For successful and sustainable implementation, of course, not only the intervention's implementers matter, but also its target group and decision makers (e.g., funders). While the selection of stakeholders always depends on the individual intervention, it was striking that in nineteen of 24 (79%) of our implementation intervention studies involved implementers, while the target group and decision makers were included respectively in eleven (41%) and ten (41.6%).

Implications for research

Overall, little guidance is yet available regarding stakeholder involvement in implementation science, either in general or specifically for contextual analysis. Further research is urgently needed, e.g., concerning how stakeholders' roles may differ at different stages of an implementation science project (e.g. contextual analysis, process evaluation), and which methods are most useful for involvement. In order both to increase the efficiency of stakeholder involvement and to avoid tokenism, a stakeholder strategy should be developed for each implementation project. This would specify exactly which stakeholders should be involved and possible strategies for recruiting them. Standardizing the reporting of stakeholder involvement (including any implementation science-specific vocabulary) will require the development of focused guidelines. These can be based on existing resources such as INVOLVE (88) and PARADIGM (89).

7.4.6 Gaps in reporting and use of contextual information

Clear reporting of contextual analyses' findings is vital to shed light on factors that may influence an intervention's implementation and effectiveness and to inform subsequent project phases. Such an analysis' aim is not to create generalizable knowledge, but to indicate how, based on the described findings, the research team chose, developed and adapted the necessary intervention and implementation strategies to fit this particular study (90).

Of the 24 studies depicted in our EGM, seventeen (71%) used their contextual analyses' findings as bases for intervention development (n=13) and/or adaptation (n=10), and/or choice of implementation strategies (n=6). Nine (37.5%) of the included studies used contextual information to interpret implementation outcomes (n=8) and/or to explain effectiveness outcomes (n=4). Such interpretations allow this study's readers some direct evidence of its external validity, i.e., the extent to which the study's target context is comparable to what they see in theirs, and, e.g., what types of adaptions they might need to consider in terms of scaling up the intervention (91, 92).

Overall, however, we noted major reporting gaps. Seven (29.2%) of the studies contained no mention whether or how contextual information was used. Within the context of our study, such gaps can be partially explained by the fact that we included only protocol papers. However, in the cases of nine papers, we were able to use the online databases' "cited by" functions to identify original studies linked to those protocols and thus to complete the missing information. Furthermore, one additional published paper may describe in greater detail how the results of the contextual analysis were used to develop an intervention that was the focus of one or our selected protocol papers.

More generally, however, the reporting of contextual analysis poses three major challenges. First, there is a lack of guidance for the reporting of contextual factors. Many reporting guidelines refer to the relevance of context, but provide little advice on which of its aspects to report (90). In these terms, the Standards for Reporting Implementation Studies (StaRI) are the most elaborate available, as they approach context as a distinct item regarding both methods ("describing the context in which the intervention was implemented") and results ("contextual changes (if any) which may have affected outcomes") sections (91). In an extra explanation and exploration document, the StaRI authors both recommend using the CFIR framework (79) to report contextual dimensions and provide useful examples of how context should be reported (93). However, this raises the question of whether the use of CFIR is appropriate for reporting of context in all projects, or whether project-specific frameworks should rather be used for reporting.

Second, more important than the lack of guidance concerning contextual aspects to report, no reporting guideline covers the contextual analysis itself. Reporting guidelines can improve the reliability, utility, and value of research through complete, transparent, and accurate reporting (94). For example, the BANANA approach could serve as a starting point from which to develop a reporting guideline. For the reporting of contextual analyses, BANANA would complement any of a group of effective reporting guidelines. Depending on a given study's purpose and design, appropriate choices would include

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement (95), Consolidated criteria for reporting qualitative research (COREQ) (96), Standards for Reporting Implementation Studies (StaRI) Statement (91) or the Template for Intervention Description and Replication (TIDieR) checklist (97). Also, as in our mapping review, BANANA would be useful to evaluate the reporting of a contextual analysis (**Chapter 5**).

Third, the majority of journals' limits on word counts preclude full reporting of both implementation intervention studies' and the contextual analyses upon which they are based (6, 90, 91). However, some allow the inclusion of additional information such as tables, figures, or online supplementary files (6, 91, 93). To ensure that enough information on context and contextual analysis is available to inform other projects, it can also be useful to consider publishing contextual analyses as separate papers (90, 91).

Implications for research

Before we can enhance the reporting of contextual analyses, we must increase implementation science researchers' awareness of these analyses' value as foundational phase. As a later step, journals might consider making a contextual analysis report a prerequisite for implementation science studies' publication.

In the meantime, to ensure the accurate, transparent and complete reporting of contextual analysis in implementation science studies, a dedicated reporting guideline should be developed for use in combination with existing reporting guidelines. Furthermore, we must reflect on whether current word restrictions allow for the additional requirements of reporting implementation science studies' contextual analyses. If not, it will be necessary to develop solutions to this problem (e.g., increasing word count). For the moment, though, implementation scientists should consider publishing their contextual analyses as separate papers or adding them as supplementary materials.

7.5 The Basel Approach for coNtextual ANAlysis

In order to guide contextual analysis as a foundational phase of implementation science projects, we developed the Basel Approach for coNtextual ANAlysis (BANANA), a six-step approach to conducting and reporting contextual analysis (**Chapter 4**). These steps are 1) selection of a TMF to guide contextual analysis; 2) identification of empirical evidence on relevant contextual and setting factors; 3) involvement of stakeholders; 4) choice of a study design for contextual analysis; 5) determining relevance of context/setting to intervention, implementation strategies and outcomes; 6) reporting of contextual analysis. As noted in **Chapter 4**, steps 1-3 can proceed simultaneously and build the basis for data collection and analysis. Regarding the existing evidence on this topic, BANANA includes an initial definition of contextual analysis and provides further detail, particularly on combining context- and setting-specific TMFs to guide contextual analysis, suitable methods to study context, and using the findings of a contextual analysis to inform subsequent phases of an implementation science project.

One notable strength of BANANA is that it is grounded on theoretical and empirical evidence and has been developed by a multidisciplinary research team with extensive expertise in implementation, data, and social sciences combined with deep knowledge of qualitative, quantitative, and mixed-methods research. Also, as BANANA grew out of the SteM cell transplantation facilitated by eHealth (SMILe) project (19, 98), it facilitated not only easy exchanges within the multidisciplinary SMILe project team, but also a first application and testing in an ongoing implementation science project.

At the same time, this also represents a limitation of BANANA. As SMILe focuses primarily on the development (and adaptation) of an integrated care model (the SMILe-ICM) and its specific selection of implementation strategies BANANA is focused on guiding contextual analysis in projects developing and testing new interventions (e.g., Hybrid 1 designs). To know the extent to which it can also guide contextual analysis foundational to Hybrid 2 or Hybrid 3 designs we will need to investigate it in further studies and adapt it as necessary. Further, the SMILe project's unique feature is that the project leaders belonged to the clinical team in the setting where the intervention was to be implemented. Thus, project leaders already implicitly understood much about the context, including major relationships and interactions between contextual factors that might affect implementation. Therefore, knowing whether BANANA can guide contextual analysis in other settings or for other interventions as successfully as in SMILe will require further testing.

However, considering that the methods and focus of a contextual analysis always need to fit the intervention to be implemented, every project requires careful reflection and planning. Therefore, we explicitly decided not to provide a ‘checklist approach’, as that would imply a reductionist understanding of context, thereby limiting contextual analysis' value to subsequent phases of an implementation science project. Instead, we describe each step in detail as we applied it to the SMILe project. Researchers can then shape and apply it as appropriate to their needs. This approach assumes a far-sighted plan: BANANA provides not just a series of stepping stones but a foundation for later project phases, including the development/adaption of intervention and implementation strategies. Since these aspects represent a field of research in themselves, we only explain key elements. These include a comprehensive list of resources for each step that requires more detailed information (e.g., guidance for stakeholder involvement, methods particularly applicable to contextual analysis, frameworks for developing interventions).

Another limitation concerns the use of contextual information for an implementation project's evaluation and testing phase. BANANA addresses only ways to use contextual information to explain implementation outcomes or interpret effectiveness outcomes. Further uses of contextual information for designing this evaluation and testing phase, e.g., informing data collection approaches in (hybrid) effectiveness studies, facilitating selection of outcomes, determining eligibility criteria and sampling participants have not been considered. Such uses should be examined regarding reducing research waste 1 and described in a next version of the BANANA approach (1, 99-101).

While BANANA's main focus is on contextual analysis, it can also be useful elsewhere. In producing our EGM (**Chapter 5**), for example, we used it to structure the visual maps and evaluate the methodological approaches applied within the included studies for their contextual analyses. To do so, we evaluated the extent to which those studies had considered points that were also recommended in BANANA. A color-coding system was used to illustrate whether authors had clearly addressed a component (green), mentioned it only partly (yellow), or failed to address it (red). This method of review provides a concise overview of the current state of the evidence and its limitations.

7.6 Endorsing a constructivist perspective in contextual analysis

As noted in **Chapter 6** and described in the BANANA approach, one limitation of contextual analysis is that, if driven entirely by a post-positivist understanding of context, it fails to consider social interactions in context, including those between implementation agents (stakeholders), context, and intervention (102). Consequently, the understanding of context is limited to inform subsequent phases and support successful implementation. Thus, while a context appears promising, implementation strategies may not achieve their maximum potency, or may even lead to counteractive effects. In such cases, an implementation may fail outright or not achieve sustainability (103-107). In **Chapter 6** (above) we described how this problem affected COVID-19 vaccine uptake. After vaccines became available, we quickly saw that the critical barriers went beyond establishing their effectiveness and safety, or providing access to them. In fact, the most resilient barriers involve complex social interactions. However, even a full contextual analysis could not have anticipated such interactions, as the post-positivist perspective is not equipped to discern them.

To bridge this gap, a constructivist perspective allows researchers to explore both contextual dynamics and the implementation agents' subjective perspectives. These capacities enable a multi-layered, finely-hued approach to contextual analysis. Therefore, within BANANA, we have proposed that contextual analysis should consider the five key concepts: 1) social space; 2) social place; 3) agency; 4) sensation; and 5) embodiment. To illustrate how these concepts can complement existing conceptualizations of context, using the COVID-19 vaccination example, we integrated the concepts into the CICI framework and described their value. In addition, we reflected on methodological implications, e.g., in terms of data collection and analysis. Key findings included 1) longitudinal assessment of context to capture ongoing developments; 2) use of rapid ethnographies and rapid qualitative methods; 3) additional use of case studies, vignettes or typologies to report descriptive data.

The value added by the constructivist perspective becomes particularly evident when the researchers conducting a contextual analysis are not embedded in that setting/context. In the case of the SMILe project, for example, both SMILe project leaders had worked for years in the study setting and were completely familiar with, e.g., the Swiss health care system, the clinic's organizational culture, structures, processes and procedures, as well as clinical experience with the group for which the SMILe intervention was developed. In that case, their awareness of many social processes affecting the patients, clinicians and managers was clearly an asset to the contextual analysis. If the same project leaders were commissioned to implement SMILe, e.g., in a Chinese hospital, they would need to gain most or all of the relevant information for its implementation via contextual analysis. This said, pre-existing knowledge about the context and setting can also lead to disadvantages. The most obvious of these is confirmation bias, i.e., the principle that existing hypotheses or beliefs can influence analysis or interpretation of contextual findings (108).

Implications for research

Based on the findings recounted in **Chapter 6**, BANANA should be further developed to include a constructivist perspective. I.e., contextual analysis should integrate the five constructivist concepts—social space, social place, agency, sensation and embodiment—into the current conceptualizations of context and setting, and methodological considerations need to be included. In addition, the value of the constructivist perspective in contextual analyses should be thoroughly explored, for example, by comparing different approaches to contextual analysis.

7.7 Reflections on the applied theoretical framework

Our understanding and conceptualization of context in this dissertation are based on the CICI framework. As outlined in the introduction, CICI is a meta-framework that pays ample attention to context. For our purposes, its most important characteristics include its acknowledgment of a distinction between context and setting and its consideration of the complex interactions that transpire between context, intervention and implementation in the setting (58). While several other frameworks concentrate mainly on micro- and meso-level factors, CICI focuses more on the macro level. It also outlines seven contextual domains: geographic, epidemiological, socio-cultural, socio-economic, political, legal, and ethical. These encompass contextual factors that can interact across levels (micro-, meso-, macro-level) and domains.

Although CICI was initially developed to support systematic reviews and health technology assessments, we successfully applied it to primary research (i.e., the SMILe project). One of CICI's particularly useful features is its provision of formal definitions for all concepts, based not only on theoretical but also on empirical evidence (109). Regarding contextual analysis, its differentiation between context and setting both allows a more holistic view of context and increases granularity of the contextual analysis. This strength becomes obvious when comparing CICI with other implementation science frameworks such as the CFIR (79). While the CFIR's developers also mention differences between context ("the set of circumstances and unique factors that surround a particular implementation effort") and setting ("the environmental characteristics in which implementation occurs") (79), this difference is not discernable in the CFIR framework. Working with CICI, that distinction is strong, i.e., the factors of the setting, e.g., the organization in which an intervention is implemented matter, stand out clearly from the wider context in which that setting (organization) is located. Context includes, for example, the society that shapes the norms and values of individuals working within an organization, the infrastructure that surrounds an organization (e.g., transport), the political system and climate or socio-economic factors such as education or income. Likewise, when considering public health or eHealth interventions, the setting is not necessarily an organization; nor are individuals implementing or affected by an intervention necessarily part of one (58).

However, the CICI framework also has certain limitations. As noted above, CICI explicitly emphasizes the complexity of context—its interactions with the implementation and intervention, as well as the need to consider changes over time. Yet, it fails to consider interactions among contextual factors. Further, compared to context, setting is only weakly operationalized. To overcome these shortcomings' effects on contextual analysis, we suggested combining CICI with a setting-specific TMF (**Chapter 4**). However, further research is needed in regard to the concept of setting. Adding the overtly constructivist concept of place (location, locale, sense of place) was only a first attempt to further operationalize setting and to complement our understanding regarding which aspects of a setting are relevant for implementation (**Chapter 6**).

7.8 Moving towards methodological innovation in implementation science with contextual analysis as the fundamental phase

The current version of BANANA provides limited guidance on how to address complex interactions in context and to assess changes over time. Further, the current design of contextual analysis is time and cost intensive. Therefore, the following section will discuss additional considerations regarding the methodology and design of approaches to contextual analysis.

7.8.1 Methodological approaches to address complexity of context

Implementation science aims to bridge the gap between trials and real-world use, i.e., it supports the translation of evidence into practice (110). However, dynamic complexity in real world settings, such as delays between cause and effect, non-linearity of interactions, and unpredictability of system behavior, challenge implementation scientists' efforts (103, 107, 111-113). Contexts in which interventions are implemented are complex adaptive systems (112, 114). And regardless of whether the intervention being implemented is simple or complex, the implementation of an intervention always changes the context and vice versa (context - intervention dyad (102)) (107, 112).

Complex adaptive systems can be characterized according to four properties: 1) they are made up of agents; 2) these agents interact with each other; 3) interactions produce effects that were not directly intended (emergence); 4) these effects persist and evolve over time, responding to changes in context (115-117). Accounting for systems' complexity requires specialized research designs and methods. For example, designs can be in-depth, mixed-method case studies including ethnographic narratives (112), or social science-informed approaches (103). Furthermore, systems science methods can be used to understand system's complex interconnections that are relevant for example, to the adoption and implementation of an intervention and its performance over time (111, 118).

Three commonly used methods that are applicable within implementation science projects are Social Network Analysis, Agent-based modeling and Systems dynamics modeling (111, 115, 119). These methods can contribute valuably not only to contextual analysis, but also to other implementation project phases (104, 118).

Social network analysis uses graphic methods to visualize, describe and model social relationships and structures to understand how they impact for example implementation. In terms of implementation, social processes include, for example, partnerships between implementation agents who support or carry out implementation, but also the social context of the target group. In regard to implementers the following aspect can be studied: e.g., silo-working, poor communication, professional isolation, social processes

(120). Valente et al. demonstrated the use of social network analysis for each implementation science project phase (i.e., exploration, adoption, implementation, and sustainment (121)) to understand, monitor, influence or evaluate implementation (118). For the first phase of a project (i.e., exploration), social network analysis can provide valuable insights e.g., to determine if networks exist, whether they are related to implementation agents' attributes, and to identify isolated or marginalized individuals or sub-groups within a network (118).

Agent-based modeling uses computer simulations to study agents' interactions with one another and with the environment. For example, Huang et al. used agent-based model building to model interactions between patients, providers and site administrators to inform development of a smoking cessation intervention and appropriate implementation strategies for its implementation (122).

Systems dynamics modeling uses various tools (e.g., causal loop diagrams, stock and flow diagrams), to frame, understand and discuss behavior of a complex system over time (111, 115, 119). For example, Powell et al. promoted group model building as a method for selecting contextually-fitting implementation strategies (123) Based on systems dynamic modeling, group model building is a participative approach that develops systems dynamics models in collaboration with stakeholders (123).

Systems science methods can help researchers and stakeholders such as target groups, decision makers, and implementers to understand complex contextual interconnections. These are relevant because they might influence the success and sustainability of implementations and the scaling-up of interventions (111, 114, 124). Therefore, to strengthen contextual analysis as the basis of every implementation science project, we call on researchers to embrace the complexity of contextual analysis and develop a *“system-mindset”* (102).

7.8.2 Design considerations to speed-up contextual analysis

As the first phase of any implementation science project, contextual analysis commonly faces three challenges that require specific design considerations: 1) limited resources (e.g., funding, personnel); 2) time constraints (e.g., time frame in which a contextual analysis has to be carried out); 3) multiple settings to study (e.g., multi-site international implementation projects); other external circumstances (e.g., the COVID-19 pandemic requires quick implementation of measures) (76, 77).

In this regard, we have pointed in **Chapter 4** to the use of rapid qualitative research methods either as an alternative or a complement to traditional research methods (104). Rapid research methods produce timely and actionable insights, as the studies are conducted over relatively short periods of weeks or months and data collection and analysis usually take place in parallel. Participatory approaches are often used and multiple methods combined. Their findings are then triangulated (125, 126).

Rapid research methods have also been used in contextual analyses, but pursuing different objectives. 1) Parmar et al. used a qualitative systematic rapid review to identify *empirical evidence on relevant facilitators and barriers* for the implementation of competency-based education for health providers (127); 2) Guided by the CFIR framework, Lewinski et al. used rapid qualitative analysis (79) to inform the *development of an intervention* to improve care coordination (128); and 3) Guided by the CFIR framework, Taylor et al. conducted a rapid evaluation of stakeholder-perceived facilitators and barriers. Their object was to inform the *development of targeted implementation strategies* supporting the implementation of family engagement navigator program models (129); 4) Cohn et al. also conducted a CFIR-guided rapid evaluation. However, their study focused on an interim analysis of facilitators and barriers to mobile health use in HIV care settings. They intended to use the results to inform *adaptions of an implementation strategy* for that intervention (130).

While these studies all reported success with the rapid research methods they used, none provided any comparison to traditional research approaches. Elsewhere, though, initial studies comparing traditional and rapid approaches in implementation science projects have shown the rapid methods to be as effective and rigorous but more time and cost effective (125, 131, 132). Still, when deciding whether to use such methods, their potential limitations should also be carefully considered (131). For example, rigorous and efficient realization of projects using rapid methods can imply a high workload and logistic burden for their researchers. Their reliability may also require research teams with wide-ranging competencies and research skills (125, 131, 133, 134). Therefore, the feasibility and reliability of rapid research methods for contextual analysis should be further explored.

In cases where resources are scarce, where especially large sets of data must be collected on contextual factors (e.g., multi-site projects) or where longitudinal assessment of contextual factors is necessary, routine data (e.g., general population, community service, or hospital data), can often effectively complement traditional methods (135). The main advantages of routine data are that, compared to traditional survey data, they allow researchers to collect large amounts of regularly-updated data on large and diverse populations over long periods at low cost (136).

One particularly interesting use for routine data would be for national-level public health interventions. In such cases, they could provide quick macro-level overviews both of factors relevant to epidemiological (e.g., demographics, population density, incidence/prevalence of disease, mortality), socio-cultural (e.g., structural social inequalities) or socio-economic concerns (e.g., socio-economic status, income) and to how data were changing over time (136, 137). Further insights are needed concerning the use of routine data in contextual analysis, particularly regarding which data are most suitable for observing long-term contextual changes. In this regard, also limitations of routine data need to be considered, e.g., limited focus on certain variables, lack of completeness, limited data quality, lack of sensitivity and specificity for specific analyses (135).

7.9 Building capacity for contextual analysis and implementation science

In recent years, even as implementation science has become increasingly relevant, the adoption of implementation science methodologies (including contextual analysis) into practice has only been moderate (138-141). A useful framework that has been applied in several implementation science studies to illustrate factors for bridging the gap between research and practice, and improving, for example, adoption, implementation, or dissemination, is the push-pull capacity model (142-146). The model points to the necessity of connecting *push factors* from science (e.g., research, knowledge generation) with *pull factors* from practice (e.g., demands in clinical practice) via *capacity factors* (143, 144). In the following we will use the model's structure to describes factors that synergistically support capacity-building for both, implementation science and contextual analysis (Figure 7.2).

7.9.1 Push of science

7.9.1.1 Applying transdisciplinary research approaches

Implementation science is a team sport. By connecting researchers across disciplines, organizations and cultural boundaries, transdisciplinary research approaches are key to overcome "silo thinking" to tackle complex challenges (147). Such approaches appear to be succeeding. Researchers working in transdisciplinary teams show higher scientific impact: compared to their monodisciplinary counterparts, they produce more publications and are more often cited (148-150).

7.9.1.2 Involving stakeholders in all phases of implementation science including contextual analysis

While stakeholder involvement (also known as patient and public involvement) is a rather new research paradigm, it is already considered best practice in research (151). In some countries (e.g., UK, the Netherlands, Canada, Australia, USA), it is now a prerequisite for obtaining funding (151, 152). Stakeholder involvement is essential to the quality and success of an implementation project and can contribute to better implementation and

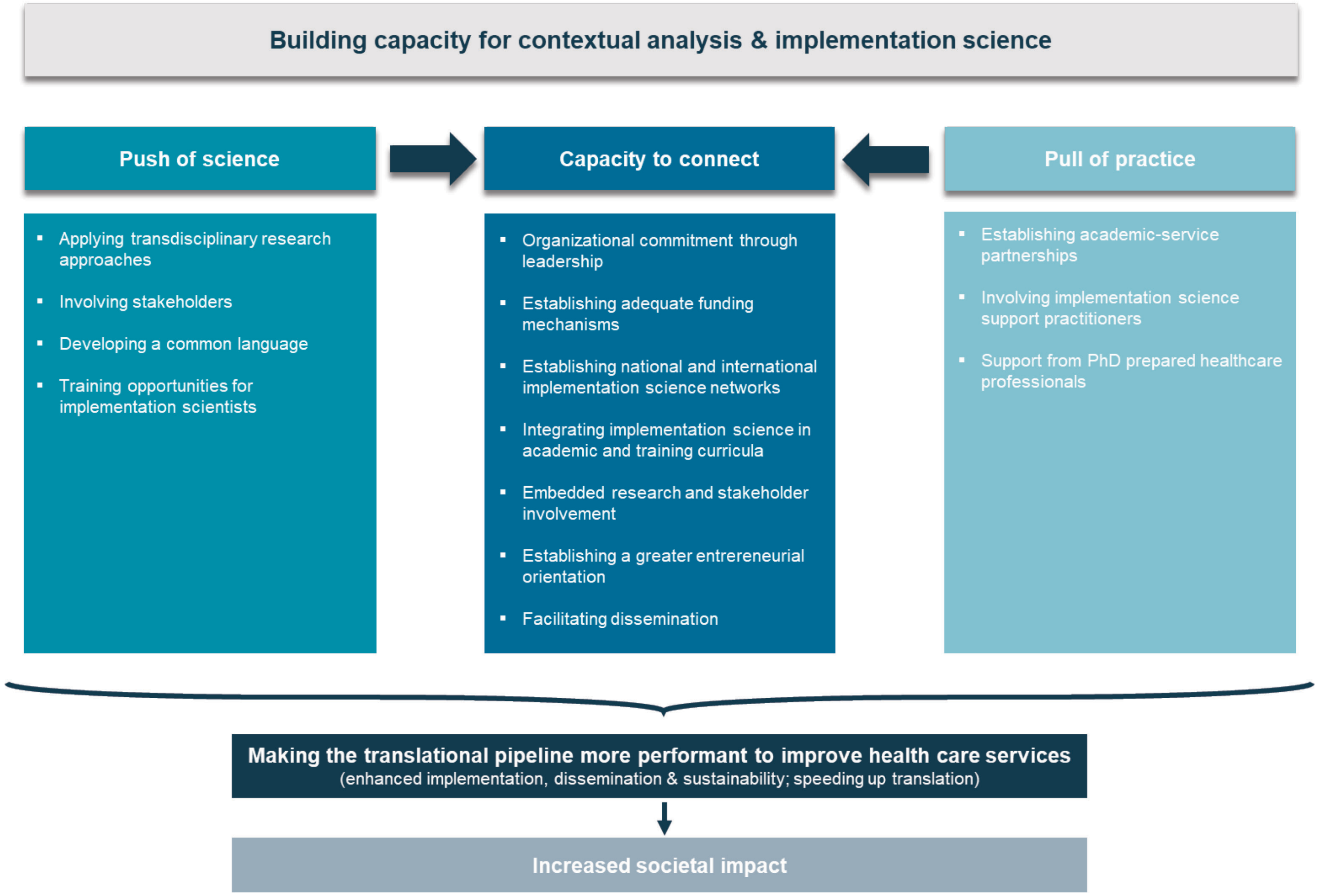

Figure 7.2. Push-pull-capacity model indicating factors to build capacity for contextual analysis and implementation science. Adapted from Chest, 118 /2 Suppl, Curry S, Organizational interventions to encourage guideline implementation, 40S-46S., Copyright (2020), with permission from Elsevier. The Creative Commons license does not apply to this content.

dissemination (83-85). Still, while existing frameworks such as INVOLVE (88) or instruments from PARADIGM (89) can be applied to implementation science projects, no implementation science specific guidance yet exists on this topic.

Stakeholders who should be involved in contextual analysis include the target group (e.g., patients and their families), implementers (e.g., healthcare professionals), decision makers (e.g., leadership) and intermediaries (e.g., policy makers, funders, health insurers). These groups' input can inform all phases of a contextual analysis, including selecting a TMF, evaluating empirical evidence, deciding which aspects of context to study. Even after the analysis is complete, they can assist with the interpretation and dissemination of findings (85, 153). Collaborative approaches, e.g., using group model building to identify relevant contextual factors, increase the results' relevance to practice (154, 155). Finally, outcomes of stakeholder involvement need to be further evaluated. For example, Bombard et al. reviewed strategies for stakeholder involvement, as well as outcomes and patients' experiences with involvement (83).

7.9.1.3 Developing a common language

In order to overcome inconsistencies and heterogeneity in terminology and labeling, a common language needs to be developed for implementation science (e.g., concepts of implementation science and context). Defining and operationalizing important constructs, will considerably increase development of tools, generalizability of findings and especially access to implementation science evidence. In this context, the MeSH term "implementation science" introduced by the National Library of Medicine in 2019 will facilitate the search for implementation science evidence, but further investment is needed.

7.9.1.4 Training opportunities for implementation scientists

Conducting a contextual analysis requires skills related not only to implementation science, but also to other fields (e.g., qualitative, mixed-methods data collection). However, some of these skills may not be immediately transferable to implementation science contexts. In a national survey of US health research, Stevens et al. found that attending an implementation science training seminar was associated with engagement in implementation science research (aOR[5] 3.77, 95%CI 2.96–4.81, $p < .001$) (156). This result suggests a common assumption that such seminars will prepare their participants to choose and adequately perform contextual analysis tasks relevant to their implementation projects (156, 157).

However, to achieve maximum impact, implementation science training programs must be adapted to the researchers' specific needs (158). Recognizing this need, a growing number of institutional and national training opportunities have emerged in

[5] Adjusted odds ratio (aOR)

implementation science. These include summer schools and master classes, webinars and online learning, and academic graduate programs (159, 160). Additionally, phase- or topic- specific toolkits and repositories, commonly covering various themes such as identification and use of theories, models, and frameworks, have been developed. Themes include implementation research and practice (53, 161-163), selecting implementation strategies (161, 164), choosing measurement tools (162), implementation outcomes (163, 165), conducting evaluations and disseminating findings (159, 162, 163, 166).

As context applies to all aspects of implementation science projects, it is commonly addressed in general training courses; however, concrete training opportunities—e.g., dealing specifically with conducting contextual analyses—are rather rare and should be more widely developed. Furthermore, mentoring or exchange programs can let participants learn and spread the best practices of the international implementation science community. While sustaining the growth and consistency of implementation science methodology such programs will enhance research productivity (138, 159, 167, 168).

7.9.2 Pull of practice

7.9.2.1 Establishing academic-service partnerships

Another way to strengthen implementation practice is through academic and service partnerships (169, 170). I.e., research institutions and service providers work together to improve the uptake of interventions into routine practice. Although several such collaborations exist, evaluation of this approach is still not widespread in implementation science (169, 170).

7.9.2.2 Involving implementation science support practitioners

For practice settings struggling to implement interventions into their specific settings, implementation science support practitioners are an empowering resource. Researchers from the National Implementation Research Network (NIRN), the University of North Carolina, the European Implementation Collaborative (EIC) and the Centre for Effective Services (Ireland) developed a profile and practice guide that describes core competencies of implementation science support practitioners. Accordingly, these are professionals who work directly with the practice and assist “organizations, leaders, and staff in their implementation of evidence-informed practices and policies” (171). They also build implementation capacity among practitioners and organizations (171). Regarding contextual analysis, then, it is critically important to consider what roles implementation science support practitioners can play to support practice and whether or how those roles could be expanded (158, 172).

7.9.2.3 PhD prepared healthcare professionals supporting implementation practice

For proven contextual analysis-related research to influence current practice, usefulness and relevance are not enough. It also requires close exchange and collaboration between implementation scientists and practitioners (138, 139, 167). For example, working alongside clinicians within healthcare teams, PhD- and DNP- (Doctor of Nursing Practice) level nurses can apply and advance implementation science approaches such as contextual analysis (173, 174).

7.9.3 Capacity to connect push and pull

7.9.3.1 Organizational commitment through leadership

An organizational climate that is open to and supports evidence-based improvement reflects competent, informed and committed leadership (139, 175). Beyond understanding the links between implementation science methodology (e.g., contextual analysis) and improved clinical outcomes, leaders—whether in clinical practice or university research—are positioned to shape missions, visions and agendas that place implementation science activities at their core (159). For example, the Swiss Academy of Medical Sciences (SAMS) now recommends that public calls for research proposals explicitly include implementation science principles among their selection criteria (176). More than any other group, leaders have both the responsible and the ability to provide necessary infrastructure to conduct implementation studies including human, financial, material resources.

7.9.3.2 Establishing adequate funding mechanisms

Depending on the study design used, contextual analyses are resource-intensive. This requires specific funding mechanisms at local, state, federal and national levels that adequately resource contextual analysis alongside implementation intervention studies (59, 139, 177).

To ensure sufficient research quality, the timeframe for a contextual analysis must be set realistically (59). However, as funders tend to prioritize projects designed for broad use and reproducibility rather than implementation, pre-developmental work is often not funded separately (156, 178). Therefore, further efforts are needed to ensure that contextual analysis is recognized as essential to implementation science methodology. While contextual analysis requires a considerable initial investment, it greatly increases an intervention's chances of successful, sustainable and timely implementation, i.e., a healthy societal return on investment (78). Before funding agencies can base resource allocations on societal impacts, though, economic evaluations will be necessary to determine both contextual analysis' normal cost and its potential long-term value (179).

7.9.3.3 Establishing national and international implementation science networks

National and international implementation science networks, are critical to building capacity in implementation science research and practice (159, 180). The European Implementation Collaborative (EIC) provides such an infrastructure to promote both, awareness of implementation science and practice, and common understanding and language within Europe (181). Furthermore, EIC links individuals and national groups for example, at the European Implementation Event, a conference held every 2 years to stimulate exchange within the implementation science community. One network at a national level, is the Swiss Implementation Science Network (IMPACT). Launched in 2019, IMPACT aims to strengthen implementation research capacity in Switzerland by 1) showcasing Swiss implementation research projects, 2) providing networking and training opportunities for researchers and other stakeholders, and 3) leveraging funding opportunities in Switzerland (180, 182). To this end, IMPACT organizes yearly conferences and webinar series covering a wide range of implementation science topics in diverse research fields (e.g., health policy, systems science, environmental science). To ensure that networks on national and international level drive implementation science and practice, their priorities need to be aligned with the needs of the implementation science community (180, 183).

7.9.3.4 Integrating implementation science in academic and training curricula

To build broad awareness, understanding, and skills in implementation science, an initial foundation can be laid in the education and training of researchers and practitioners. Specific training opportunities can be integrated into academic and training curricula (184-186). For example, the Gillings School of Global Public Health at the University of North Carolina (UNC) at Chapel Hill has developed an interdisciplinary course program to enhance the practical skills of public health professionals and master's students in implementation science (184). Studies on competencies required for implementation science research and practice can guide the development of such programs (157, 187). Further tailoring to the different needs of diverse professionals and various settings, is essential (186).

7.9.3.5 Embedded research and stakeholder involvement

Effectively planning and conducting implementation science projects—including contextual analyses—requires embedded research (159, 160, 188). As a collaborative and adaptive approach, embedded research involves multidisciplinary collaboration between research experts (in implementation science, sociology, epidemiology, economics, etc.) and implementers (e.g., healthcare professionals) through every phase of an implementation science project (co-designed research) (138, 188, 189). For example, implementation researchers can be integrated into healthcare teams to plan and conduct contextual analysis, and vice versa. Implementers who are well-embedded in a setting typically show a clear understanding of that setting's implementation-relevant principles and processes (174, 189).

7.9.3.6 Establishing a greater entrepreneurial orientation

To enhance uptake and adoption of implementation science innovations, recent studies have considered that implementation science innovators may need to a more entrepreneurial orientation (144, 190). Proctor et al. suggests investing in specific entrepreneurship tools such as market viability assessments (190). As a research instrument, these help suppliers answer questions relevant to the launch of an innovative product, i.e., who are the target users, will they be willing to pay for it, how large is the target user group, will it be adopted into real-world use, and will its use be sustainable (190). We agree that such information is extremely valuable. In fact, some aspects of contextual analysis overlap with market viability assessment which provides essential information to develop effective interventions and implementation strategies. Building public-private partnerships between research institutions and small businesses will allow combining skills and knowledge related to entrepreneurship and implementation science to achieve synergistic effects and support translation of innovation in real-world (190).

7.9.3.7 Facilitating dissemination

To promote implementation science and contextual analysis, both should be presented at conferences and workshops (167). Additionally, journals need to tie their publication of an implementation science study report to the inclusion of a full contextual analysis. Accordingly, journals also need to adjust their word count restrictions to allow inclusion of both as elements of a single report. Further, to increase implementation science awareness and expand its community, other content related to implementation science projects can be shared and discussed via social networks or other communication channels (156, 180). In any case, however, it is important to conceive a dissemination strategy that meets the needs, requirements and interests of the end users.

7.10 Conclusions

Although implementation science has advanced tremendously over the past two decades, health research still faces the challenge that translating interventions into practice is slow and failing. To bridge or even close this research-to-practice gap and reduce research waste, implementation science researchers need to rethink their current approaches. Specifically, they need to recognize that any intervention's successful and sustainable implementation into a real-world setting depends on how well it fits the target context. And yet, if researchers even study context, they often do so very late in the course of an implementation project. Then, with no guidance to conduct a contextual analysis, they may find the process both dauntingly complex.

In response to these challenges, this dissertation`s contribution is threefold. First, we highlight the need to include contextual analysis not only as a *"must have"* for an implementation science study, but as its foundation. A contextual analysis needs to start at the beginning of an implementation project. Its findings are the basis of all subsequent phases. While conducting a contextual analysis requires considerable investments of time and financial resources, it has both short- and long-term benefits. In the short term, it increases the quality of each subsequent study phase. And in the long term, it greatly increases the success and speed of an intervention's translation to real-world settings. I.e., it helps close the research-to-practice gap and thus enhances societal impact.

Second, we have developed a methodology that provides guidance on how to perform a contextual analysis (BANANA). As an example of the BANANA approach's application, it is guiding an ongoing implementation project (the SMILe project).

Third, we provide suggestions on how contextual analysis can be enhanced to overcome its current limitations, many of which arise from gaps in the currently prevalent post-positivist perspective. These gaps apply not only to the concept of context but also to methodological and design considerations. Our suggestions include complementing the current view by adding a constructivist viewpoint.

In addition to presenting a case for using contextual analysis as the foundation for every future implementation study, this dissertation strengthens implementation science methodology in ways that will affect the overall quality and success not only of implementation science projects, but of implementation science itself as a field of study. To focus for a moment on one of this field's central goals, though, narrowing the current chasm between research and practice will require innovative collaboration that involve not only researchers and practitioners, but also patients and their families, unit nurses, hospital administrators, policy makers, funding agencies and all other stakeholders at every level. As a first step, the most reliable way to make the translational pipeline more performant is to invest in contextual analysis as a foundational phase in implementation science projects in every way possible, thereby improving healthcare services and achieving societal impact.

7.11 References

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