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Development and Psychometric Evaluation of the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool: A Study Protocol

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Abstract

Introduction

The need for quantitative criteria to appraise the quality of implementation research has recently been highlighted to improve methodological rigor. The Implementation Science Research development (ImpRes) tool and supplementary guide provide methodological guidance and recommendations on how to design high-quality implementation research. This protocol reports on the development of the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool, a quantitative appraisal tool, developed based on the structure and content of the ImpRes tool and supplementary guide, to evaluate the conceptual and methodological quality of implementation research.

Methods and analysis

This study employs a three-stage sequential mixed-methods design. During stage 1 the research team will map core domains of the ImpRes tool, guidance and recommendations contained in the supplementary guide and within the literature, to ImpResPAC. In stage 2, an international multi-disciplinary expert group, recruited through purposive sampling, will inform the refinement of ImpResPAC, including content, scoring system and user instructions. In stage 3, an extensive psychometric evaluation of ImpResPAC, that was created in stage 1 and refined in stage 2, will be conducted. The scaling assumptions (inter-item and item-total correlations), reliability (internal consistency, inter-rater) and validity (construct and convergent validity) will be investigated by applying ImpResPAC to 50 protocols published in *Implementation Science.* We envisage developing ImpResPAC in this way will provide implementation research stakeholders, primarily grant reviewers and educators, to undertake a comprehensive, transparent and fair appraisal of the conceptual and methodological quality of implementation research, increasing the likelihood of funding research that will generate knowledge and contribute to the advancement of the field.

Ethics and dissemination:

This study will involve human participants. This study has been registered and minimal risk ethical clearance granted by, The Research Ethics Office, King's College London (Reference number MRA-20/21-20807)

Strengths and limitations of this study:

- This research will advance the field by developing a quantitative appraisal tool to allow implementation research stakeholders, primarily grant reviewers and educators, to undertake a comprehensive, transparent and fair appraisal of the conceptual and methodological quality of implementation research, increasing the likelihood of funding research that will generate knowledge and contribute to the advancement of the field.
- Future studies should evaluate the value of ImpResPAC with implementation research stakeholders that have applied the tool.
- Although a broad range of implementation research protocols will be appraised, using ImpResPAC, limiting the appraisal to protocols published in *Implementation Science*, is likely to positively skew the results.

Keywords:

Implementation science; Implementation research; Research appraisal; Methodological quality; Psychometric evaluation.

Introduction:

High-quality research is critical to knowledge accumulation and the advancement of scientific fields. Over the past decade, Implementation Science (IS) has benefited from notable efforts to advance the conceptual clarity of fundamental IS concepts and methodological guidance and recommendations to support applied health researchers and practitioners working within the field to design high-quality implementation research (1) (2) (3) (4) (5). Such advances include, but are not limited to, the proposal of an effectiveness-implementation hybrid design typology (1), an implementation theory and framework comparison and selection tool (6), a working taxonomy of implementation outcomes (3), taxonomies of implementation strategies (4) (5) (7), guidance to identify, select and tailor implementation strategies (8), and repositories of implementation outcome instruments (9) (10) (11) (12) (13).

Despite these advances, however, practical guidance consolidating IS concepts and methodological guidelines and recommendations, (e.g., design decisions to inform the appropriate hybrid design selection) until recently was lacking. This gap, in part, is likely to have contributed to poor quality implementation research (14), (15).

Recently, the Implementation Science Research Development (ImpRes) tool and supplementary guide were developed, with the explicit aim to address this gap (15), ImpRes was intended to support applied health researchers and those working within the field to design high-quality implementation research, and consequently help educate the next generation of IS researchers and build capacity within the field (15). Based on key conceptual and methodological literature containing design guidance and recommendations, and an expert consensus-building brainstorming process, ImpRes incorporates core IS principles and concepts that researchers should consider when designing IS research – including application of appropriate theories and/or frameworks, selection of implementation and other types of outcomes, development of stakeholder informed implementation strategies, and evaluation of health economic elements of implementation efforts. Initial

usability testing with end-users (i.e., researchers with varying degrees of implementation science knowledge/expertise) showed that the ImpRes tool is useful for identifying project areas where implementation research is lacking and for improving the quality of implementation research (15).

Whilst ImpRes has the potential to contribute to filling a much-needed capacity-building gap, the need for a quantitative tool to appraise the quality of implementation research has recently been highlighted as a further area for development of the field (14). Research appraisal tools allow research stakeholders (e.g., research grant panels and educators) to undertake a standardized, transparent, objective, and fair appraisal (16).

A previous attempt to use the traditional National Institutes of Health (NIH) scoring criteria to evaluate grant applications for implementation and improvement sciences projects, identified the need for evaluation criteria capable of identifying specific strengths and weaknesses of implementation studies (14). An initial effort to address this gap has recently been reported by Crable et al, 2018 who developed a scoring system, '*ImplemeNtation and Improvement Science Proposals Evaluation CriTeria* (INSPECT)', based on Proctor's 10 key ingredients in high-quality implementation research grant proposals, to identify common deficiencies in implementation and improvement science research proposals from a grant application perspective (14).

Another example of prior efforts to quantify the quality of implementation research, by some of the authors of this paper (CS, LG, LH), reported the initial development of a quantitative appraisal tool, based on the ImpRes tool and supplementary guide (17) (18). This initial development work focused on five of the ten ImpRes domains: 1) Implementation research characteristics; 2) Implementation theories, frameworks and models; 3) Determinants of implementation; 4) Implementation strategies; 5) Implementation outcomes. This quantitative appraisal tool, structured as a rubric, applied analytic scoring to study protocols, published in *Implementation Science*, using a 4-point scale (ranging from '1' indicating that the protocol is lacking detail and of sub-optimal conceptual and methodological quality, to '4' indicating that

the protocol provides explicit descriptions, justifications and citations from the literature and is of excellent conceptual and methodological quality). Initial development included applying the appraisal criteria to 16 implementation research protocols, published in *Implementation Science*, where all cumulative scores were expressed as a percentage of the total achievable score for that protocol, to indicate and allow IS protocols to be compared based on conceptual and methodological strength. Intra-class correlation coefficient (ICC) tests indicated excellent inter-rater reliability (IRR).

Here we build upon this early-phase study by Sweetnam et al, 2018 (17) (18) and report a study that will develop a complete and comprehensive tool to appraise the conceptual and methodological quality of implementation research, termed the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool. The study aims to develop appraisal criteria for the remaining five ImpRes domains: 1) Service and patient outcomes; 2) Unintended consequences; 3) Economic evaluation; 4) Stakeholder involvement and engagement; 5) Patient and public involvement and engagement; and to refine the existing criteria developed by Sweetnam et al, 2018 (17) (18).

The specific objectives of the research are as follows:

1. To formulate an ImpResPAC expert advisory group to contribute to the refinement and content of ImpResPAC.
2. To develop a comprehensive and in-depth quantitative appraisal tool to be used by implementation research stakeholders to appraise the conceptual and methodological quality of IS research: ImpResPAC.
3. To evaluate the psychometric properties (reliability and validity) and usability, including the acceptability, feasibility, and appropriateness, of ImpResPAC.

ImpResPAC will complement but extend recent efforts by Crable et al (14) who developed and evaluated the 'INSPECT' tool. Whilst overlap between INSPECT and ImpResPAC will exist, the two appraisal systems will differ notably in focus, depth of appraisal, and the foundations upon which they are based. For example, INSPECT primarily focuses on fundability whereas ImpResPAC focuses on conceptual and methodological quality of implementation research. Furthermore, INSPECT operationalizes the "key ingredients" to writing implementation research grant proposals developed by Proctor et al. (19) which operates specifically within the National Institutes of Health (NIH) proposal scoring framework (20), whereas ImpResPAC will not be developed within the constraints of a single grant proposal scoring framework, thus its applicability will not be limited in this way.

Methods and analysis:

We will conduct a multi-stage, mixed-methods study to develop, refine, and evaluate the psychometric strength of ImpResPAC.

Stage 1: ImpResPAC development

ImpResPAC will map onto the ten domains of the ImpRes tool and supplementary guide (see Figure 1).

As part of a previous dissertation study, five of the ImpResPAC domains were developed and inter-rater reliability was assessed (17). Formal quantitative psychometric testing of the content validity and concurrent validity of ImpResPAC was beyond the scope of this previous work. In this research, the five previously developed domains will be subject to refinement within the tool development stage of this study, and the remaining five domains will be developed, by the ImpResPAC development/research team. Furthermore, more extensive and rigorous psychometric evaluation will be performed for all ten ImpResPAC domains.

Figure 1. ImpRes domains to be represented in ImpResPAC (15)

Stage 2: ImpResPAC Content Validation and Refinement

To ensure that ImpResPAC is face and content valid we will use purposive sampling to form an ImpResPAC expert advisory group, consisting of a number of eminent academics that have made a significant contribution to the conceptual and methodological advancement of one or more of the ImpResPAC domains. Experts will be asked to review and provide feedback, including modifications and suggestions for improvement, on the ImpResPAC domain(s) that they have expertise in.

We define an expert as 'someone widely recognized as a reliable source of knowledge, technique, or skill whose judgment is accorded authority and status by the public or his or her peers' (21). The ImpResPAC development/research team will generate a list of experts that meet the above criteria, based on our collective knowledge. Once experts have agreed to participate in the study, we will encourage them to nominate additional experts, i.e., snowballing technique, whose contribution would be valuable. Once experts agree to participate, they will have the option to be recognized as a contributor in the study or for their participant to remain anonymous.

Using surveys, the expert advisory group will review ImpResPAC domain(s) and items for content, style and comprehensiveness. Members of the expert advisory group will be presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC domain(s) that they are an expert in, survey instructions, and survey questions. The survey will be attached in an email to experts.

Experts will be asked to review the ImpResPAC domain(s) and associated items for the domain(s) that they agree they are 'experts' in. Members of the expert advisory group will have 4 weeks to complete the survey. A reminder email will be sent two weeks after the survey is first sent and one week before the 4-week deadline.

The development/research team will collate and review all comments and suggested refinements to ImpResPAC and refinements will be decided via group discussions until consensus is reached. Once ImpResPAC is finalized, we will quantitatively assess the acceptability, appropriateness and feasibility of ImpResPAC. All members of the ImpResPAC expert advisory group will be invited to review the refined version ImpResPAC and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC via a follow-up survey. See additional file 1 for survey questions.

Stage 3: Application and Psychometric Evaluation of ImpResPAC

ImpResPAC, developed in stage 1 and content validated and refined based on expert feedback in stage 2, will be applied to 50 research protocols published in *Implementation Science* to evaluate its psychometric strength.

Two of the study authors (CS and LH), with expertise and experience in implementation and improvement science research, will independently appraise the conceptual and methodological quality of the 50 most recently published research protocols published in *Implementation Science*, using ImpResPAC. We decided to appraise research protocols published in *Implementation Science* as it is the most well established (since 2006), highest impact factor (IF) journal in the field and regarded, by researchers, practitioners and funders as a key source for dissemination and implementation (D&I) research in health (22). Furthermore, *Implementation Science* publishes research covering a broad array of content areas and settings, making it an ideal test bed for ImpResPAC.

Inclusion Criteria:

Study protocols that describe:

1. Effectiveness-implementation hybrid design studies (i.e., "*a study design that takes a dual focus in assessing clinical effectiveness and implementation*") (1).
2. Implementation research studies (i.e., "*Research focused on the adoption or uptake of clinical interventions by providers and/or systems of care")* (1).

Exclusion criteria:

Study protocols/proposals that describe:

1. Theoretical or methodological research (e.g., theory development, measurement development), where implementation of an evidence-based intervention is not planned
2. De-implementation studies of interventions found to be of low value, wasteful or clinically ineffective. The field of de-implementation is expanding rapidly, and although there have been recent attempts to theorise the de-implementation process (23), and the field is still in infancy (24). As such consensus regarding de-implementation and research guidance is lacking and further methodological development is still necessary (25). For this very reason, this subsection of IS was not included in the ImpRes tool and guide and will also not be included in ImpResPAC.

Assessment of the validity and reliability of ImpResPAC

We will employ an item exploratory factor analysis (EFA) to the polychoric matrix of the 10 ImpResPAC domains to determine and confirm scale factor structures (construct validity). A varimax rotation will be applied to improve the interpretability of the factors obtained. We will use three criteria to select the final factors: i) The scree plot ii) eigenvalues >1 and iii) >90% of total variance explained by the factors. ImpResPAC will be applied to 50 protocols for pragmatic reasons, as this equates to the minimum number of observations (50), required when conducting EFA (26).

Convergent validity will be further examined by estimating the correlation between ImpResPAC dimension with the total scores of the INSPECT scale (14) as both scoring criteria rate the quality of proposed implementation science research. Spearman's correlation coefficients will be calculated and interpreted as follows: >0.90: excellent relationship, 0.71-0.90: good, 0.51-0.70: fair, 0.31-0.50: weak, and <0.30: none (28).

We are expecting fair to good correlations, as excellent correlations would indicate that ImpResPAC is a duplication of INSPECT. A comparison of ImpResPAC and INSPECT domains, presented in Table 1, indicates clear similarities between a number of domains (i.e., ImpResPAC domains 1 – 4), a degree of similarities between some domains (i.e., ImpResPAC domains 5 – 9), and no apparent similarities between some domains (i.e., ImpResPAC domain 10). Given the varying degrees of content overlap between ImpResPAC and INSPECT domains, as described in details above, we hypothesize that there will be a fair to good relationship (correlation coefficient r: 0.31-0.70) between global ImpResPAC and INSPECT scores.

Cronbach's alpha coefficient will be used to evaluate the reliability (internal consistency) of the ten domains of ImpResPAC, as it evaluates the extent to which the domains within a scale are inter-correlated with one another and thus seem to measure the same concept. It's value ranges from 0 to 1 and internal consistency is suggested to be acceptable when Cronbach's alpha is at least 0.70 (28). Inter-rater reliability will be assessed using Criterion of Lin's $\rho \geq 0.70$ to indicate acceptable reliability. A weighted kappa score will also be calculated for each ImpResPAC domain to provide details on the test–retest and inter-rater reliability. A criterion of weighted kappa ≥0.40 will be used to indicate acceptable domain level reliability. Precision will be assessed to test how well each domain fits within its proposed scale (28). Corrected domain-total correlations of < 30 will indicate poor fit of items within the ImpResPAC total score (30). Each ImpResPAC item will be correlated both with its own global domain score total and with the other global domain totals. Each component will require higher correlation with its own domain than other ImpResPAC domains to demonstrate precision.

Patient and Public Involvement:

Patients or the public were not involved in the design, conduct or reporting plans of this research.

Table 1. Comparison of domains included in INSPECT versus ImpResPAC

	ImpResPAC domains *(Informed by ImpRes tool and guide, Hull et al (15).*	INSPECT domains *(Informed by 'ten key ingredients', Proctor et al (19).*
ImpResPAC domains with clear overlap in domains (1 - 4).		
1	Implementation theories, frameworks and models	Conceptual model and theoretical justification
2	Stakeholder involvement and engagement	Stakeholder priorities and engagement in change
3	Patient and public involvement (PPI) and engagement	
4	Implementation strategies	Implementation strategy/process
ImpResPAC domains with some degree of overlap in domains (5 – 9).		
5	Implementation research characteristics	The care gap or quality gap
6	Determinants of implementation contextual factors	Setting's readiness to adopt new services/treatments/programs
7	Economic evaluation	Feasibility of proposed research design and methods
8	Service and patient outcomes	Measurement and analysis section
9	Implementation outcomes	
ImpResPAC domains with no apparent overlap in domains (10).		
10	Unintended consequences	*No comparable/similar domain*
	No comparable/similar domain	Policy/funding environment; leverage or support for sustaining change
	No comparable/similar domain	Team experience with setting
	No comparable/similar domain	The evidence-based treatment to be implemented

Key: ImpResPAC domain 1-4: clear overlap in domains; ImpResPAC domain 5-9: Some degree of overlap in domains; ImpResPAC domain 10: No apparent overlap in domains

Discussion

This study will develop, refine, content validate, and evaluate the psychometric strength (i.e., the reliability and validity) of an expert derived tool, ImpResPAC, to appraise the conceptual and methodological quality of implementation research. The proposed research will fill an important gap in our ability, as a field, to conduct a comprehensive, transparent, systematic and in-depth quantitative appraisal of implementation research. Purposively sampling experts to form an international ImpResPAC expert advisory group to refine and content validate ImpResPAC, will ensure appropriate appraisal criteria, relevant to the conceptual and methodological quality of implementation research, is developed, which will allow an in-depth, comprehensive appraisal of implementation research. Feedback on the acceptability, feasibility and appropriateness of ImpResPAC will also be sought from the ImpResPAC expert advisory group.

Previous research suggests that researchers seeking to design implementation research find it challenging to distinguish between implementation research and efficacy and effectiveness research and consequently fail to design high-quality implementation research (4). With the availability of the ImpRes tool and supplementary guide, consolidating methodological guidelines and recommendations, researchers are better equipped to design high-quality implementation research proposals. We envisage ImpResPAC will provide funding bodies with a standardized and transparent method to differentiate high and low-quality implementation research. In addition, we also anticipate that ImpResPAC could be incorporated into training materials and applied retrospectively by educators as a standardized appraisal tool across IS programs to quantitatively assess implementation research projects submitted by students.

Although INSPECT already exists as a standardized appraisal tool for implementation research proposals, we plan to develop a complementary, yet conceptually distinct tool that focuses exclusively on conceptual and methodological quality of IS research proposals. As such, ImpResPAC scoring domains will differ to INSPECT domains, as highlighted in Table 1. For example, *team experience with setting, treatment, and implementation process* is one of the ten *domains* of the INSPECT tool, however the ImpRes tool and supplementary guide, and consequently ImpResPAC, will not contain criteria measuring this domain as team experience is not a direct measure of conceptual or methodological quality of IS research. Similarly, ImpResPAC will contain criteria that INSPECT does not explicitly appraise. For example, ImpResPAC will appraise whether research teams plan to evaluate unintended consequences of implementation in addition to exploring and quantifying the anticipated benefits of implementation. Furthermore, the level of detail at which implementation research will be appraised using the two scoring systems will differ substantially. For example, INSPECT provides an overall appraisal of the *measurement and analysis* of IS research proposals, however the ImpRes guide, and consequently ImpResPAC, will contain three domains relating to measurement and analysis; 1) service and patient outcomes; 2) implementation outcomes; and 3) economic evaluation, providing a much more detailed and focused appraisal of the outcomes typically assessed in implementation research.

INSPECT operationalized grant proposal criteria proposed by Proctor's et al 'key ingredients', which were developed nearly a decade ago (i.e., 2012) (19), whereas ImpResPAC will identify conceptual and methodological strengths and weakness in IS projects taking account of the conceptual and methodological developments that have taken place in more recent years. As such, ImpResPAC will include and operationalize key methodological guidelines and recommendations that simply did not exist nearly a decade ago. ImpResPAC will operationalize, for example, the key methodological and conceptual guidelines and recommendations that have been described in the ImpRes tool and guide, as

well as guidelines suggested by our international expert advisory panel, and key literature published since the development of the ImpRes tool and guide.

This study has a number of limitations. We acknowledge that in order to truly test the value of ImpResPAC, it will be preferable to seek feedback from implementation research stakeholders who have had the opportunity to apply the tool in practice, but this is beyond the scope of this research. Future studies should evaluate the value of ImpResPAC with implementation research stakeholders that have applied the tool. Secondly, although the implementation research protocols that will be appraised, using ImpResPAC, will cover a broad range of content areas and settings, appraising protocols published in *Implementation Science*, is likely to positively skew the results (i.e., it is fair to assume that only high-quality IS protocols will have been published in *Implementation Science*). This is a specific and inherent challenge with the planned research, as access to implementation research protocols rejected from journals and unsuccessful grant proposals submitted to funding bodies are not publicly available and unattainable for obvious reasons.

High-quality implementation research is key to advancing the field and improving the adoption, implementation, sustainment and scale-up of evidence-based interventions. This research will advance the field by developing a quantitative appraisal tool, which we believe will be of immediate use and value to IS research stakeholders (e.g., grant reviewers and educators), to undertake a comprehensive, transparent and fair appraisal of the conceptual and methodological quality of implementation research.

Ethics and dissemination:

This study will involve human participants. This study has been registered and minimal risk ethical clearance granted by, The Research Ethics Office, King's College London (Reference number MRA-20/21-20807)

Authors' contributions:

CS and LH initially conceptualized and designed this study. IB made significant contribution to the design of the psychometric evaluation section. NS, LG, RD, ZK, AB and AH all made significant contributions to the framing, editing, revisions, and content of the manuscript. All authors read and approved the final manuscript.

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Competing interests statement:

NS is the director of the London Safety and Training Solutions Ltd, which offers training in patient safety, implementation solutions and human factors to healthcare organisations. The other authors have no conflicts of interest to declare.

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List of abbreviations

EFA: Exploratory Factor Analysis

ICC: Intra-class Correlation Coefficient

ImpRes: Implementation Science Research development

ImpResPAC: Implementation Science Research Project Appraisal Criteria

INSPECT: ImplemeNtation and Improvement Science Proposals Evaluation CriTeria

IRR: Inter-Rater Reliability

IS: Implementation Science

NIH: National Institutes of Health

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Additional Files

Additional file 1: ImpResPAC Survey Questions (Stage 2: ImpResPAC Content Validation and Refinement Expert Advisory Group Survey Questions)

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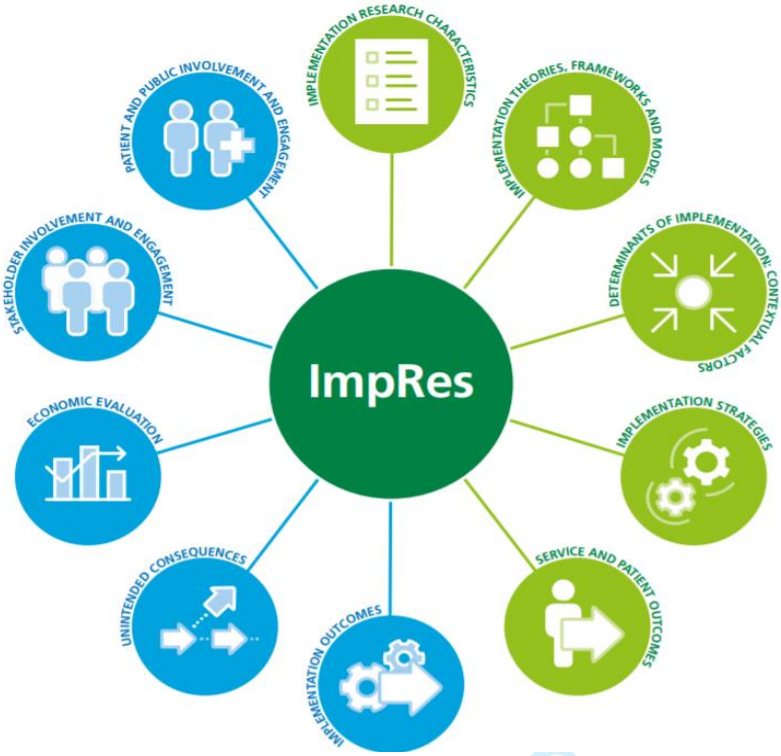
Table 1. Comparison of domains included in INSPECT versus ImpResPAC

	ImpResPAC domains *(Informed by ImpRes tool and guide, Hull et al (15).*	INSPECT domains *(Informed by 'ten key ingredients', Proctor et al (19).*
ImpResPAC domains with clear overlap in domains (1 - 4).		
1	Implementation theories, frameworks and models	Conceptual model and theoretical justification
2	Stakeholder involvement and engagement	Stakeholder priorities and engagement in change
3	Patient and public involvement (PPI) and engagement	
4	Implementation strategies	Implementation strategy/process
ImpResPAC domains with some degree of overlap in domains (5 – 9).		
5	Implementation research characteristics	The care gap or quality gap
6	Determinants of implementation contextual factors	Setting's readiness to adopt new services/treatments/programs
7	Economic evaluation	Feasibility of proposed research design and methods
8	Service and patient outcomes	Measurement and analysis section
9	Implementation outcomes	
ImpResPAC domains with no apparent overlap in domains (10).		
10	Unintended consequences	*No comparable/similar domain*
	No comparable/similar domain	Policy/funding environment; leverage or support for sustaining change
	No comparable/similar domain	Team experience with setting
	No comparable/similar domain	The evidence-based treatment to be implemented

Key: ImpResPAC domain 1-4: clear overlap in domains; ImpResPAC domain 5-9: Some degree of overlap in domains; ImpResPAC domain 10: No apparent overlap in domains

Figure 1. ImpRes domains to be represented in ImpResPAC (15)



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Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.
Each member of the expert advisory group will be presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC domain(s) that they are an expert in, survey instructions, and survey questions.

Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool.
The development/research team will collate and review all comments and suggested refinements to ImpResPAC and refinements will be decided via group discussions until consensus is reached. Once ImpResPAC is finalized, each member of the expert advisory group will be sent a survey and asked to review the refined version ImpResPAC and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC.

Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.

Based on the significant contribution you have made to the conceptual and methodological advancement of implementation research, in particular relating to the characteristics of implementation research, we would like your feedback on the ***Implementation Research Characteristics*** domain of ImpResPAC.

We would also like your feedback on the ***Unintended Consequences*** domain of ImpResPAC. Although a separate domain, it is very much linked to design of implementation research and the *Implementation Research Characteristics* domain. If, after reviewing the ***Unintended Consequences*** domain, you feel that you don't have the expertise to provide feedback, you can choose to provide feedback on the Implementation Research Characteristics domain only.

ImpResPAC contains 10 domains representing core implementation science principles and concepts, including:
(1) Implementation Research Characteristics
(2) Implementation Theories, Frameworks and Models
(3) Determinants of Implementation: Contextual Factors
(4) Implementation Strategies
(5) Service and Patient Outcomes
(6) Implementation Outcomes
(7) Unintended Consequences
(8) Economic Evaluation
(9) Stakeholder Involvement and Engagement
(10) Patient and Public Involvement and Engagement.

We appreciate that you may have expertise relating to other ImpResPAC domains, if you believe that you have expertise relating to any other ImpResPAC domain(s), please let us know and we will share these with you to enable you to provide feedback on these ImpResPAC domains.

Survey instructions

We would like you to review and provide feedback, including modifications and suggestions for improvement, on the 'Implementation Research Characteristics' ImpResPAC domain and associated items, presented in the table below. Following review of the domain items, you will then be asked to complete 5 questions regarding domain content, style and comprehensiveness. You will also be asked to

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provide feedback relating to the scoring scale and anchors and user instructions. We request your comments and suggestions for improvements to be made using the comment and track changes functions in word.

Overview of ImpResPAC

ImpResPAC aims to be a comprehensive and in-depth quantitative appraisal tool to evaluate the conceptual and methodological quality of implementation research. ImpResPAC contains 10 domains representing core implementation science principles and concepts (detailed above). For each domain, we have identified a number of items that we believe indicate high-quality implementation research.

We hope that ImpResPAC will advance the field of implementation science by providing a quantitative appraisal tool that can be used by a wide range of implementation research stakeholders, primarily grant reviewers and educators working within the field, to comprehensively appraise the conceptual and methodological quality of implementation research.

ImpResPAC user instructions

The ImpResPAC tool contains 10 domains representing core implementation science principles and concepts. Each domain contains a number of items that are indicative of high-quality implementation research. Each ImpResPAC domain, and associated items, should be considered in the context of the aims and objectives, scope and resources of the research project in question. As such, it is possible that one or more ImpResPAC domains, and associated items, will not be applicable. You are not expected to score each item within each domain, rather a single score for each applicable ImpResPAC domain should be provided.

For each applicable domain, the scores should be added together, to calculate a global score indicating the conceptual and methodological quality of the implementation project. For example, if 7 ImpResPAC domains are applicable, the global score would be out of a maximum score of 35 (7 domains x maximum domain score of 5 = 35).

Please note you are not expected to provide a score as part of completing this survey

Domain scoring scale and anchors

1 = Very poor: Proposed project fails to adequately address all items
2 = **Poor**: Proposed project fails to adequately address most items
3 = **Satisfactory**: Proposed project addresses some items adequately
4 = **Good:** Proposed project addresses most items adequately/fully
5 = **Excellent:** Proposed project fully addresses all items
N/A = domain considered not applicable given the aims, objectives, scope and resources of the project.

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Part A: Survey questions

1. (a) Do the domain items represent and reflect high-quality conceptual and methodological elements of implementation research characteristics? Yes/no
(b) If no, please use track changes in the table above to provide amendments/suggestions for improvement.

2. (a) Are there any items missing from the domain? Yes/no
(b) If yes, please use track changes in the table above to suggest additional items for inclusion.

3. (a) Is the item wording clear? Yes/no
(b) If no, please use track changes in the table above to suggest amendments/improvements.

4. (a) Are the ImpResPAC user instructions (p.2) adequate and clear?
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.

5. (a) Is the scoring scale and associated anchors (p.2) appropriate and clear? Yes/no
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.

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Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool

Thank you for your initial feedback on Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool. After careful consideration of the feedback received from the expert advisory group, the ImpResPAC research/development group have refined the ImpResPAC tool.

On a scale of 1 – 5 please rate your level of agreement with the following statements on the acceptability, appropriateness and feasibility of the ImpResPAC tool.

Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory (Proctor et al, 2011). With this definition in mind, please rate the acceptability of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(i) The ImpResPAC Tool Acceptability						
	1	**2**	**3**	**4**	**5**	**6**
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an acceptable tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an acceptable tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an acceptable tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an acceptable tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising						

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implementation projects.						

Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not acceptable for use for this purpose.

_____

_____

_____

Appropriateness is the 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 to address a particular issue or problem (Proctor et al, 2011). With this definition in mind, please rate the appropriateness of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(ii) The ImpResPAC Tool Appropriateness						
	1	**2**	**3**	**4**	**5**	**6**
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an appropriate tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an appropriate tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an appropriate tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an appropriate tool to be used for educational purposes e.g.,						

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incorporating into training materials or quantitatively appraising implementation projects.						

Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not appropriate for use for this purpose.

_____

_____

_____

Feasibility is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting (Proctor et al, 2011). With this definition in mind, please rate the feasibility of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(iii) The ImpResPAC Tool Feasibility						
	1	**2**	**3**	**4**	**5**	**6**
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is a feasible tool to be used in the appraisal of grant applications.						
b) ImpResPAC is a feasible tool for researchers, to appraise the methodological and conceptual quality of their research						
c) ImpResPAC is a feasible tool for practitioners, to appraise the methodological and conceptual quality of their project.						

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d) ImpResPAC is a feasible tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising implementation projects.						

Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not feasible for use for this purpose.

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_____

Do you have any additional comments you will like to make about ImpResPAC?

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_____

_____

BMJ Open

Development and Psychometric Evaluation of the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool: A Study Protocol

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Development and Psychometric Evaluation of the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool: A Study Protocol

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Abstract

Introduction

The need for quantitative criteria to appraise the quality of implementation research has recently been highlighted to improve methodological rigor. The Implementation Science Research development (ImpRes) tool and supplementary guide provide methodological guidance and recommendations on how to design high-quality implementation research. This protocol reports on the development of the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool, a quantitative appraisal tool, developed based on the structure and content of the ImpRes tool and supplementary guide, to evaluate the conceptual and methodological quality of implementation research.

Methods and analysis

This study employs a three-stage sequential mixed-methods design. During stage 1 the research team will map core domains of the ImpRes tool, guidance and recommendations contained in the supplementary guide and within the literature, to ImpResPAC. In stage 2, an international multi-disciplinary expert group, recruited through purposive sampling, will inform the refinement of ImpResPAC, including content, scoring system and user instructions. In stage 3, an extensive psychometric evaluation of ImpResPAC, that was created in stage 1 and refined in stage 2, will be conducted. The scaling assumptions (inter-item and item-total correlations), reliability (internal consistency, inter-rater) and validity (construct and convergent validity) will be investigated by applying ImpResPAC to 50 protocols published in *Implementation Science.* We envisage developing ImpResPAC in this way will provide implementation research stakeholders, primarily grant reviewers and educators, to undertake a comprehensive, transparent and fair appraisal of the conceptual and methodological quality of implementation research, increasing the likelihood of funding research that will generate knowledge and contribute to the advancement of the field.

Ethics and dissemination:

This study will involve human participants. This study has been registered and minimal risk ethical clearance granted by, The Research Ethics Office, King's College London (Reference number MRA-20/21-20807). Participants will receive written information on the study via email and will provide e-consent if they wish to participate. We will use traditional academic modalities of dissemination (e.g., conferences, publications).

Strengths and limitations of this study:

- This study will develop and evaluate the psychometric properties of a quantitative appraisal tool, the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool, to evaluate the quality of implementation research.
- Input from a multi-disciplinary, international expert group will inform the development of ImpResPAC.
- Our definition of 'experts' in this study could exclude the perspectives of other stakeholder groups that could be useful and how the tool might be valued by groups excluded in the initial development process.
- ImpResPAC will enable users to undertake a comprehensive, transparent, and fair appraisal of the conceptual and methodological quality quality of implementation research.
- Some limitations to the study design include the lack of public and patient involvement, due to lack of funding to involve patient and the public in the research.

Keywords:

Implementation science; Implementation research; Research appraisal; Methodological quality; Psychometric evaluation.

Introduction:

High-quality research is critical to knowledge accumulation and the advancement of scientific fields. Over the past decade, Implementation Science (IS) has benefited from notable efforts to advance the conceptual clarity of fundamental IS concepts and methodological guidance and recommendations to support applied health researchers and practitioners working within the field to design high-quality implementation research (1) (2) (3) (4) (5). Such advances include, but are not limited to, the proposal of an effectiveness-implementation hybrid design typology (1), an implementation theory and framework comparison and selection tool (6), a working taxonomy of implementation outcomes (3), taxonomies of implementation strategies (4) (5) (7), guidance to identify, select and tailor implementation strategies (8), and repositories of implementation outcome instruments (9) (10) (11) (12) (13).

Despite these advances, however, practical guidance consolidating IS concepts and methodological guidelines and recommendations, (e.g., design decisions to inform the appropriate hybrid design selection) until recently was lacking. This gap, in part, is likely to have contributed to poor quality implementation research (14), (15).

Recently, the Implementation Science Research Development (ImpRes) tool and supplementary guide were developed, with the explicit aim to address this gap (15), ImpRes was intended to support applied health researchers and those working within the field to design high-quality implementation research, and consequently help educate the next generation of IS researchers and build capacity within the field (15). Based on key conceptual and methodological literature containing design guidance and recommendations, and an expert consensus-building brainstorming process, ImpRes incorporates core IS principles and concepts that researchers should consider when designing IS research – including application of appropriate theories and/or frameworks, selection of implementation and other types of outcomes, development of stakeholder informed implementation

strategies, and evaluation of health economic elements of implementation efforts. Initial usability testing with end-users (i.e., researchers with varying degrees of implementation science knowledge/expertise) showed that the ImpRes tool is useful for identifying project areas where implementation research is lacking and for improving the quality of implementation research (15).

Whilst ImpRes has the potential to contribute to filling a much-needed capacity-building gap, the need for a quantitative tool to appraise the quality of implementation research has recently been highlighted as a further area for development of the field (14).

Practical tools to improve the quality of reporting have been shown to improve research reporting (e.g., the development of the Consolidated Standards of Reporting Trials (CONSORT) checklist, for the reporting of randomised controlled trials (RCTs), (16) (17) (18). Research appraisal tools allow research stakeholders (e.g., research grant panels and educators) to undertake a standardized, transparent, objective, and fair appraisal (19).

A previous attempt to use the traditional National Institutes of Health (NIH) scoring criteria to evaluate grant applications for implementation and improvement sciences projects, identified the need for evaluation criteria capable of identifying specific strengths and weaknesses of implementation studies (14). An initial effort to address this gap has recently been reported by Crable et al, 2018 who developed a scoring system, '*ImplemeNtation and Improvement Science Proposals Evaluation CriTeria* (INSPECT)', based on Proctor's 10 key ingredients in high-quality implementation research grant proposals, to identify common deficiencies in implementation and improvement science research proposals from a grant application perspective (14).

Another example of prior efforts to quantify the quality of implementation research, by some of the authors of this paper (CS, LG, LH), reported the initial development of a quantitative appraisal tool, based on the ImpRes tool and supplementary guide (20) (21) as part of a master's dissertation project. Due to time constraints and scope of the master's dissertation

project, this initial development work focused on five of the ten ImpRes domains: 1) Implementation research characteristics; 2) Implementation theories, frameworks and models; 3) Determinants of implementation; 4) Implementation strategies; 5) Implementation outcomes. These domains were considered to be most relevant and specific to implementation research, whereas the other domains (e.g., service and patient outcome), while still relevant to implementation research, overlap over research types (e.g., effectiveness research).

This quantitative appraisal tool, structured as a rubric, applied analytic scoring to study protocols, published in *Implementation Science*, using a 4-point scale (ranging from '1' indicating that the protocol is lacking detail and of sub-optimal conceptual and methodological quality, to '4' indicating that the protocol provides explicit descriptions, justifications and citations from the literature and is of excellent conceptual and methodological quality). Initial development included applying the appraisal criteria to 16 implementation research protocols, published in *Implementation Science*, where all cumulative scores were expressed as a percentage of the total achievable score for that protocol, to indicate and allow IS protocols to be compared based on conceptual and methodological strength. The resulting Intra-class correlation coefficient (ICC) was in the excellent inter-rater reliability (IRR) range: ICC: 0.85 (22).

Here we build upon this early-phase study by Sweetnam et al, 2018 (20) (21) and report a study that will develop a complete and comprehensive tool to appraise the conceptual and methodological quality of implementation research, termed the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool. The study aims to develop appraisal criteria for the remaining five ImpRes domains: 1) Service and patient outcomes; 2) Unintended consequences; 3) Economic evaluation; 4) Stakeholder involvement and engagement; 5) Patient and public involvement and engagement; and to refine the existing criteria developed by Sweetnam et al, 2018 (20) (21).

The specific objectives of the research are as follows:

1. To formulate an ImpResPAC expert advisory group to contribute to the refinement and content of ImpResPAC.
2. To develop a comprehensive and in-depth quantitative appraisal tool to be used by implementation research funders to appraise the conceptual and methodological quality of IS research: ImpResPAC.
3. To evaluate the psychometric properties (reliability and validity) and usability, including the acceptability, feasibility, and appropriateness, of ImpResPAC.

ImpResPAC will complement but extend recent efforts by Crable et al (14) who developed and evaluated the 'INSPECT' tool. Whilst overlap between INSPECT and ImpResPAC will exist, the two appraisal systems will differ notably in focus, depth of appraisal, and the foundations upon which they are based. For example, INSPECT primarily focuses on fundability because it is based on grant proposal criteria whereas ImpResPAC, based on the ImpRes tool and guide, focuses on conceptual and methodological quality of implementation research. Furthermore, INSPECT operationalizes the "key ingredients" to writing implementation research grant proposals developed by Proctor et al. (19) which operates specifically within the National Institutes of Health (NIH) proposal scoring framework (23), whereas ImpResPAC will not be developed within the constraints of a single grant proposal scoring framework, thus its applicability will not be limited in this way.

Methods and analysis:

We will conduct a multi-stage, mixed-methods study to develop, refine, and evaluate the psychometric strength of ImpResPAC.

Stage 1: ImpResPAC development (September 2021 – November 2021)

ImpResPAC will map onto the ten domains of the ImpRes tool and supplementary guide (see Figure 1).

As part of a previous study, five of the ImpResPAC domains were developed and inter-rater reliability was assessed (20). Formal quantitative psychometric testing of the content validity and concurrent validity of ImpResPAC was beyond the scope of this previous work. In this research, the five previously developed domains will be subject to refinement within the tool development stage of this study, and the remaining five domains will be developed, by the ImpResPAC development/research team.

Figure 1. ImpRes domains to be represented in ImpResPAC (15)

Stage 2: ImpResPAC Content Validation and Refinement (December 2021 – December 2022)

To ensure that ImpResPAC is face and content valid we will use purposive sampling to form an ImpResPAC expert advisory group, consisting of a number of eminent academics across the world that have made a significant contribution to the conceptual and methodological advancement of one or more of the ImpResPAC domains. Experts in each domain will be asked to review and provide feedback, including modifications and suggestions for improvement, on the ImpResPAC domain(s) that they have expertise in.

We define an expert as 'someone widely recognized as a reliable source of knowledge, technique, or skill whose judgment is accorded authority and status by the public or his or her peers' (24). The ImpResPAC development/research team will generate a list of experts that meet the above criteria, based on our collective knowledge. Once experts have agreed

to participate in the study, we will encourage them to nominate additional experts, i.e., snowballing technique, whose contribution would be valuable. Once experts agree to participate, they will have the option to be recognized as a contributor in the study or for their participant to remain anonymous. We expect to identify 70 - 100 experts globally in the field of implementation science. We hope experts, both academics and practitioners, working in high-, middle- and low-income countries will participate.

Using surveys, the expert advisory group will review ImpResPAC domain(s) and items for content, style and comprehensiveness. Members of the expert advisory group will be presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC domain(s) that they are an expert in, survey instructions, and survey questions. The survey will be attached in an email to experts.

Experts will be asked to review the overview of ImpResPAC, ImpResPAC user instructions and ImpResPAC domain(s) and associated items for the domain(s) that they agree they are 'experts' in. Members of the expert advisory group will have 4 weeks to complete the survey. A reminder email will be sent two weeks after the survey is first sent and one week before the 4-week deadline.

The development/research team will collate and review all comments and suggested refinements to ImpResPAC and refinements will be decided via group discussions until consensus is reached. Once ImpResPAC is finalized, we will quantitatively assess the acceptability, appropriateness and feasibility of ImpResPAC. All members of the ImpResPAC expert advisory group will be invited to review the refined version ImpResPAC and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC (all domains) via a follow-up survey. Experts will be given the option of providing feedback on the domains that they provided feedback on in Stage 1 (survey A) or if they wish, providing feedback on the entire tool. See additional file 1 for survey questions.

Stage 3: Application and Psychometric Evaluation of ImpResPAC (January 2023 – July 2023)

ImpResPAC, developed in stage 1 and content validated and refined based on expert feedback in stage 2, will be applied to 50 research protocols published in *Implementation Science* to evaluate its psychometric strength.

Two of the study authors (CS and LH), with expertise and experience in implementation and improvement science research, will independently appraise the conceptual and methodological quality of the 50 most recently published research protocols published in *Implementation Science*, using ImpResPAC. We decided to appraise research protocols published in *Implementation Science* as it is the most well established (since 2006), highest impact factor journal in the field and regarded, by researchers, practitioners and funders as a key source for dissemination and implementation research in health (25). Furthermore, *Implementation Science* publishes research covering a broad array of content areas and settings, making it an ideal test bed for ImpResPAC.

Inclusion Criteria:

Study protocols that describe:

1. Effectiveness-implementation hybrid design studies (i.e., "*a study design that takes a dual focus in assessing clinical effectiveness and implementation*") (1).
2. Implementation research studies (i.e., "*Research focused on the adoption or uptake of clinical interventions by providers and/or systems of care")* (1).

Exclusion criteria:

Study protocols/proposals that describe:

1. Theoretical or methodological research (e.g., theory development, measurement development), where implementation of an evidence-based intervention is not planned
2. De-implementation studies of interventions found to be of low value, wasteful or clinically ineffective. The field of de-implementation is expanding rapidly, and although there have been recent attempts to theorise the de-implementation process (26), and the field is still in infancy (27). As such consensus regarding de-implementation and research guidance is lacking and further methodological development is still necessary (28). For this very reason, this subsection of IS was not included in the ImpRes tool and guide and will also not be included in ImpResPAC.

Assessment of the validity and reliability of ImpResPAC

We will employ an item exploratory factor analysis (EFA) to the polychoric matrix of the 10 ImpResPAC domains to determine and confirm scale factor structures (construct validity). A varimax rotation will be applied to improve the interpretability of the factors obtained. We will use three criteria to select the final factors: i) The scree plot ii) eigenvalues >1 and iii) >90% of total variance explained by the factors. ImpResPAC will be applied to 50 protocols for pragmatic reasons, as this equates to the minimum number of observations (50), required when conducting EFA (29).

Convergent validity will be further examined by estimating the correlation between the global ImpResPAC dimension with the global scores of INSPECT (14) as both scoring criteria rate the quality of proposed implementation science research. Spearman's correlation coefficients will be calculated and interpreted as follows: >0.90: excellent relationship, 0.71-0.90: good, 0.51-0.70: fair, 0.31-0.50: weak, and <0.30: none (30).

We are expecting fair to good correlations, as excellent correlations would indicate that ImpResPAC is a duplication of INSPECT. A comparison of ImpResPAC and INSPECT domains, presented in supplementary material indicates clear similarities between a number of domains (e.g., 'Theories, frameworks and models' domain of ImpResPAC and 'Conceptual model and theoretical justification' element of INSPECT), a degree of similarities between some domains (e.g., Determinants of implementation: contextual factors' domain of ImpResPAC and 'Feasibility of proposed research design and methods' element of INSPECT), and no apparent similarities between some domains (e.g., 'Patient and Public Involvement' domain of ImpResPAC, which has no similarities to INSPECT elements). Given the varying degrees of content overlap between ImpResPAC and INSPECT domains, as described in detail above, we hypothesize that there will be a fair to good relationship (correlation coefficient r: 0.31-0.70) between global ImpResPAC and INSPECT scores.

Cronbach's alpha coefficient will be used to evaluate the reliability (internal consistency) of the ten domains of ImpResPAC, as it evaluates the extent to which the domains within a scale are inter-correlated with one another and thus seem to measure the same concept. It's value ranges from 0 to 1 and internal consistency is suggested to be acceptable when Cronbach's alpha is at least 0.70 (30). Inter-rater reliability will be assessed using Criterion of Lin's $\rho \geq 0.70$ to indicate acceptable reliability. A weighted kappa score will also be calculated for each ImpResPAC domain to provide details on the test–retest and inter-rater reliability. A criterion of weighted kappa ≥0.40 will be used to indicate acceptable domain level reliability. Precision will be assessed to test how well each domain fits within its proposed scale (30). Corrected domain-total correlations of < 30 will indicate poor fit of items within the ImpResPAC total score (30). Each ImpResPAC item will be correlated both with its own global domain score total and with the other global domain totals. Each component

will require higher correlation with its own domain than other ImpResPAC domains to demonstrate precision.

Patient and Public Involvement:

Patients or the public were not involved in the design, conduct or reporting plans of this research.

Discussion

This study will develop, refine, content validate, and evaluate the psychometric strength (i.e., the reliability and validity) of an expert derived tool, ImpResPAC, to appraise the conceptual and methodological quality of implementation research. The proposed research will fill an important gap in our ability, as a field, to conduct a comprehensive, transparent, systematic and in-depth quantitative appraisal of implementation research. Purposively sampling experts to form an international ImpResPAC expert advisory group to refine and content validate ImpResPAC, will ensure appropriate appraisal criteria, relevant to the conceptual and methodological quality of implementation research, is developed, which will allow an in-depth, comprehensive appraisal of implementation research. Feedback on the acceptability, feasibility and appropriateness of ImpResPAC will also be sought from the ImpResPAC expert advisory group.

Previous research suggests that researchers seeking to design implementation research find it challenging to distinguish between implementation research and efficacy and effectiveness research and consequently fail to design high-quality implementation research (4). With the availability of the ImpRes tool and supplementary guide, consolidating methodological guidelines and recommendations, researchers, practitioners and students are better

equipped to design high-quality implementation research proposals. We envisage ImpResPAC primarily being used by funding bodies as a standardized and transparent method to differentiate high and low-quality implementation research and identify areas for improvement before funding decisions are made. In addition, we also envisage that ImpResPAC will be useful to educators that are tasked with appraising implementation projects submitted by students/learners, especially in educational settings where the ImpRes tool and guide informed the curriculum. We plan to explore whether another potential application of ImpResPAC would be for implementation researchers, practitioners and students/learners to use ImpResPAC as a quality assurance step, to self-assess a funding application or implementation project, prior to submission.

Although INSPECT already exists as a standardized appraisal tool for implementation research proposals, we plan to develop a complementary, yet conceptually distinct tool that focuses exclusively on conceptual and methodological quality of IS research proposals. As such, ImpResPAC scoring domains will differ to INSPECT domains, as highlighted in supplementary material (additional file 2). For example, *team experience with setting, treatment, and implementation process* is one of the ten elements of the INSPECT tool, however the ImpRes tool and supplementary guide, and consequently ImpResPAC, will not contain criteria measuring this domain as team experience is not a direct measure of conceptual or methodological quality of IS research. Similarly, ImpResPAC will contain criteria that INSPECT does not explicitly appraise. For example, ImpResPAC will appraise whether research teams plan to evaluate unintended consequences of implementation in addition to exploring and quantifying the anticipated benefits of implementation. Furthermore, the level of detail at which implementation research will be appraised using the two scoring systems will differ substantially. For example, INSPECT provides an overall appraisal of the *measurement and analysis* of IS research proposals, however the ImpRes guide, and consequently ImpResPAC, will contain three domains relating to measurement and analysis; 1) service and patient outcomes; 2) implementation outcomes; and 3)

economic evaluation, providing a much more detailed and focused appraisal of the outcomes typically assessed in implementation research. The initial mapping of the ImpRes tool and supplementation guide to develop the ImpResPAC tool (stage 1) and a detailed comparison of ImpResPAC tool domain items (initial mapping) and the INSPECT tool element items can be found in supplementary material (additional file 2).

INSPECT operationalized grant proposal criteria proposed by Proctor's et al 'key ingredients', which were developed nearly a decade ago (i.e., 2012) (19), whereas ImpResPAC will identify conceptual and methodological strengths and weakness in IS projects taking account of the conceptual and methodological developments that have taken place in more recent years. As such, ImpResPAC will include and operationalize key methodological guidelines and recommendations that simply did not exist nearly a decade ago (1) (8) (10) (31) (32) (33) (34) (35) (36) (37). ImpResPAC will operationalize, for example, the key methodological and conceptual guidelines and recommendations that have been described in the ImpRes tool and guide, as well as guidelines suggested by our international expert advisory panel, and key literature published since the development of the ImpRes tool and guide.

This study has a number of limitations. We acknowledge the importance of public and patient involvement in the design of implementation research, but the study we report here is not funded and did not have the funds to involve patient and the public in the research. We strongly recommend that any future ImpResPAC research, including further validation and utilisation, includes patient and public involvement. Secondly, we acknowledge that in order to truly test the value of ImpResPAC, it will be preferable to seek feedback from implementation research stakeholders who have had the opportunity to apply the tool in practice, but this is beyond the scope of this research. Future studies should evaluate the

value of ImpResPAC with implementation research stakeholders that have applied the tool. Thirdly, our definition of 'experts' (someone widely recognized as a reliable source of knowledge, technique, or skill whose judgment is accorded authority and status by the public or his or her peers) could exclude useful perspectives of stakeholder groups. Lastly, although the implementation research protocols that will be appraised, using ImpResPAC, will cover a broad range of content areas and settings, appraising protocols published in *Implementation Science*, is likely to positively skew the results (i.e., it is fair to assume that only high-quality IS protocols will have been published in *Implementation Science*). This is a specific and inherent challenge with the planned research, as access to implementation research protocols rejected from journals and unsuccessful grant proposals submitted to funding bodies are not publicly available and unattainable for obvious reasons.

High-quality implementation research is key to advancing the field and improving the adoption, implementation, sustainment and scale-up of evidence-based interventions. This research will advance the field by developing a quantitative appraisal tool, which we believe will be of immediate use and value to IS research stakeholders (e.g., grant reviewers and educators), to undertake a comprehensive, transparent and fair appraisal of the conceptual and methodological quality of implementation research.

Ethics and dissemination:

This study will involve human participants. This study has been registered and minimal risk ethical clearance granted by, The Research Ethics Office, King's College London (Reference number MRA-20/21-20807). Participants will receive written information on the study via email and will provide e-consent if they wish to participate. We will use traditional academic modalities of dissemination (e.g., conferences, publications).

Authors' contributions:

CS and LH initially conceptualized and designed this study. IB made significant contribution to the design of the psychometric evaluation section. NS, LG, RD, ZK, AB and AH all made significant contributions to the framing, editing, revisions, and content of the manuscript. All authors read and approved the final manuscript.

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Competing interests statement:

NS is the director of the London Safety and Training Solutions Ltd, which offers training in patient safety, implementation solutions and human factors to healthcare organisations. The other authors have no conflicts of interest to declare.

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List of abbreviations

EFA: Exploratory Factor Analysis

ICC: Intra-class Correlation Coefficient

ImpRes: Implementation Science Research development

ImpResPAC: Implementation Science Research Project Appraisal Criteria

INSPECT: ImplemeNtation and Improvement Science Proposals Evaluation CriTeria

IRR: Inter-Rater Reliability

IS: Implementation Science

NIH: National Institutes of Health

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Additional Files

Additional file 1: ImpResPAC Survey Questions (Stage 2: ImpResPAC Content Validation and Refinement Expert Advisory Group Survey Questions)

Additional file 2: Comparison of ImpResPAC tool (initial version developed in stage 1) and the INSPECT tool.

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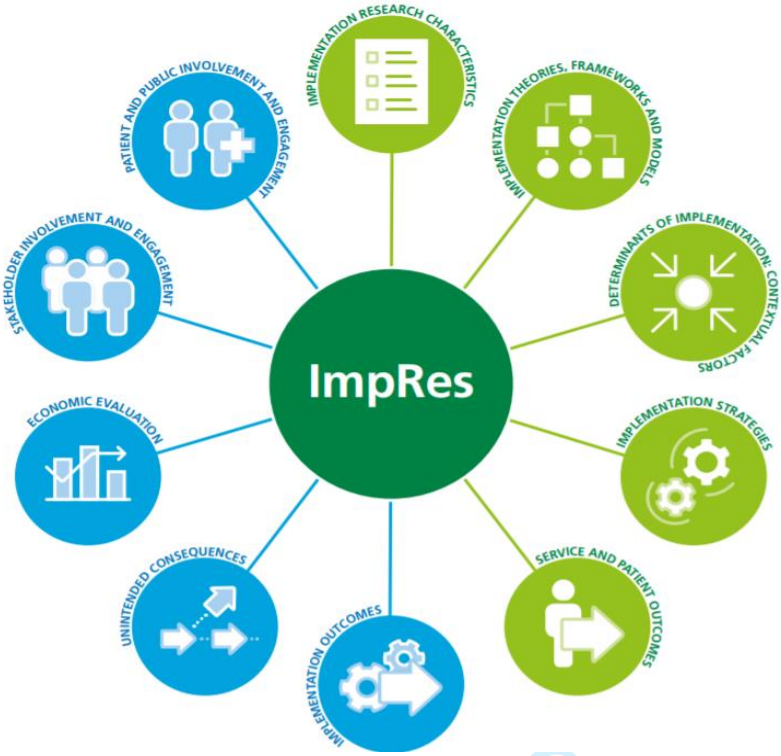
Figure 1. ImpRes domains to be represented in ImpResPAC (15)



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Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.
Each member of the expert advisory group will be presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC domain(s) that they are an expert in, survey instructions, and survey questions.

Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool.
The development/research team will collate and review all comments and suggested refinements to ImpResPAC and refinements will be decided via group discussions until consensus is reached. Once ImpResPAC is finalized, each member of the expert advisory group will be sent a survey and asked to review the refined version ImpResPAC and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC.

Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.

Based on the significant contribution you have made to the conceptual and methodological advancement of implementation research, in particular relating to the characteristics of implementation research, we would like your feedback on the ***Implementation Research Characteristics*** domain of ImpResPAC.

We would also like your feedback on the ***Unintended Consequences*** domain of ImpResPAC. Although a separate domain, it is very much linked to design of implementation research and the *Implementation Research Characteristics* domain. If, after reviewing the ***Unintended Consequences*** domain, you feel that you don't have the expertise to provide feedback, you can choose to provide feedback on the Implementation Research Characteristics domain only.

ImpResPAC contains 10 domains representing core implementation science principles and concepts, including:
(1) Implementation Research Characteristics
(2) Implementation Theories, Frameworks and Models
(3) Determinants of Implementation: Contextual Factors
(4) Implementation Strategies
(5) Service and Patient Outcomes
(6) Implementation Outcomes
(7) Unintended Consequences
(8) Economic Evaluation
(9) Stakeholder Involvement and Engagement
(10) Patient and Public Involvement and Engagement.

We appreciate that you may have expertise relating to other ImpResPAC domains, if you believe that you have expertise relating to any other ImpResPAC domain(s), please let us know and we will share these with you to enable you to provide feedback on these ImpResPAC domains.

Survey instructions

We would like you to review and provide feedback, including modifications and suggestions for improvement, on the 'Implementation Research Characteristics' ImpResPAC domain and associated items, presented in the table below. Following review of the domain items, you will then be asked to complete 5 questions regarding domain content, style and comprehensiveness. You will also be asked to

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provide feedback relating to the scoring scale and anchors and user instructions. We request your comments and suggestions for improvements to be made using the comment and track changes functions in word.

Overview of ImpResPAC

ImpResPAC aims to be a comprehensive and in-depth quantitative appraisal tool to evaluate the conceptual and methodological quality of implementation research. ImpResPAC contains 10 domains representing core implementation science principles and concepts (detailed above). For each domain, we have identified a number of items that we believe indicate high-quality implementation research.

We hope that ImpResPAC will advance the field of implementation science by providing a quantitative appraisal tool that can be used by a wide range of implementation research stakeholders, primarily grant reviewers and educators working within the field, to comprehensively appraise the conceptual and methodological quality of implementation research.

ImpResPAC user instructions

The ImpResPAC tool contains 10 domains representing core implementation science principles and concepts. Each domain contains a number of items that are indicative of high-quality implementation research. Each ImpResPAC domain, and associated items, should be considered in the context of the aims and objectives, scope and resources of the research project in question. As such, it is possible that one or more ImpResPAC domains, and associated items, will not be applicable. You are not expected to score each item within each domain, rather a single score for each applicable ImpResPAC domain should be provided.

For each applicable domain, the scores should be added together, to calculate a global score indicating the conceptual and methodological quality of the implementation project. For example, if 7 ImpResPAC domains are applicable, the global score would be out of a maximum score of 35 (7 domains x maximum domain score of 5 = 35).

Please note you are not expected to provide a score as part of completing this survey

Domain scoring scale and anchors

1 = Very poor: Proposed project fails to adequately address all items
2 = **Poor**: Proposed project fails to adequately address most items
3 = **Satisfactory**: Proposed project addresses some items adequately
4 = **Good:** Proposed project addresses most items adequately/fully
5 = **Excellent:** Proposed project fully addresses all items
N/A = domain considered not applicable given the aims, objectives, scope and resources of the project.

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Part A: Survey questions

1. (a) Do the domain items represent and reflect high-quality conceptual and methodological elements of implementation research characteristics? Yes/no
(b) If no, please use track changes in the table above to provide amendments/suggestions for improvement.

2. (a) Are there any items missing from the domain? Yes/no
(b) If yes, please use track changes in the table above to suggest additional items for inclusion.

3. (a) Is the item wording clear? Yes/no
(b) If no, please use track changes in the table above to suggest amendments/improvements.

4. (a) Are the ImpResPAC user instructions (p.2) adequate and clear?
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.

5. (a) Is the scoring scale and associated anchors (p.2) appropriate and clear? Yes/no
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.

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Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool

Thank you for your initial feedback on Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool. After careful consideration of the feedback received from the expert advisory group, the ImpResPAC research/development group have refined the ImpResPAC tool.

On a scale of 1 – 5 please rate your level of agreement with the following statements on the acceptability, appropriateness and feasibility of the ImpResPAC tool.

Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory (Proctor et al, 2011). With this definition in mind, please rate the acceptability of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(i) The ImpResPAC Tool Acceptability						
	1	**2**	**3**	**4**	**5**	**6**
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an acceptable tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an acceptable tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an acceptable tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an acceptable tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising						

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implementation projects.						

Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not acceptable for use for this purpose.

_____

_____

_____

Appropriateness is the 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 to address a particular issue or problem (Proctor et al, 2011). With this definition in mind, please rate the appropriateness of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(ii) The ImpResPAC Tool Appropriateness						
	1	**2**	**3**	**4**	**5**	**6**
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an appropriate tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an appropriate tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an appropriate tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an appropriate tool to be used for educational purposes e.g.,						

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incorporating into training materials or quantitatively appraising implementation projects.						

Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not appropriate for use for this purpose.

_____

_____

_____

Feasibility is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting (Proctor et al, 2011). With this definition in mind, please rate the feasibility of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(iii) The ImpResPAC Tool Feasibility						
	1	**2**	**3**	**4**	**5**	**6**
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is a feasible tool to be used in the appraisal of grant applications.						
b) ImpResPAC is a feasible tool for researchers, to appraise the methodological and conceptual quality of their research						
c) ImpResPAC is a feasible tool for practitioners, to appraise the methodological and conceptual quality of their project.						

KING'S COLLEGE LONDON
CENTRE FOR IMPLEMENTATION SCIENCE
IMPRESPAC SURVEY QUESTIONS

Study ID: MRM-21/22-20807 **Form Version Date: 28/11/2021**

d) ImpResPAC is a feasible tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising implementation projects.						

Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not feasible for use for this purpose.

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Do you have any additional comments you will like to make about ImpResPAC?

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ImpResPAC stage 1 Results: Initial mapping of ImpRes tool and guide to develop ImpResPAC, compared with INSPECT element items

- Below is a comparison of ImpResPAC domain items and INPECT element items.
- Rows with bolded font, have some level of overlap (high, medium or low).
- Rows with non-bolded font and grey cells in one column have no overlap between tools.
- Key:
    - **High level of overlap:** the ImpResPAC domain items overlap directly with the INSPECT element item, covering the same principles.
    - **Medium level of overlap**: the ImpResPAC domain item covers a similar principle as the INSPECT element item, but not the same.
    - **Low level of overlap:** the ImpResPAC domain items does not directly overlap with the INSPECT element item, but the domain and element has principles in common.

Additional File 2: ImpResPAC and INSPECT comparison (initial mapping completed as stage 1 of the study)

ImpResPAC (initial mapping)		*INSPECT (14)*		*Level of overlap:*
Domain:	**Item wording (score of 5 – given if the proposed project fully addresses all items):**	**Element:**	**Item wording (score of 3 – highest score available, given for an element if all of the criteria requirements are met):**	
Implementation research characteristics	**The project explicitly seeks to address an implementation problem; it clearly describes the associated quality of care gap and evidence-based intervention identified to address the problem.**	**The care or quality gap**	**Explicit, well thought out description of the potential for improvement.**	**High**
Implementation research characteristics	**Clear, detailed, and strong justification provided to support the proposed project, supported by appropriate literature, and/or local data. If literature has been used to support the proposed project, this is up-to-date and has been critically appraised.**	**The care or quality gap**	**Clearly defined quality gap is supported by local setting data (i.e., evidence of chart review or other preliminary data) and appropriate citations from the literature.**	**High**
		The care or quality gap	Proposed implementation and/or improvement study is clearly linked to a safety net setting.	*None*
Implementation research characteristics	Implementation aims and objectives are explicitly and clearly articulated and align with the proposed project design, methods, and measures.			*None*

Implementation research characteristics	Implementation stage(s) of the proposed project and the associated activities planned at each stage are described in detail.			*None*
Implementation research characteristics	Design of the proposed project is clearly and comprehensively described and positioned along the effectiveness-implementation research continuum (e.g., hybrid type 1, 2, 3, or pure implementation) and aligns appropriately to the aims and objectives of the project.			*None*
Implementation research characteristics	**Clear rationale is provided for choice of research design supported by literature and/or local data (e.g., hybrid type 1 design will provide data justifying that the clinical intervention has strong face validity supporting applicability in a new setting, population, or delivery method).**	**Feasibility of proposed research design and methods**	**The proposed study includes appropriate methods, interventions, and other components that are achievable as a pilot study and are justified against potential alternatives.**	**Low**
Theories, Frameworks, Models Domain	**Clear, detailed, and strong justification is provided to support the selection of implementation theories, models and/or frameworks (framework hereafter), supported by appropriate literature, and/or data from implementation site(s)**	**Conceptual model and theoretical justification**	**An implementation and/or improvement science-specific conceptual model or framework is clearly described, with theoretical constructions explicitly described within the proposed setting, population, and intervention contexts.**	**High**
Theories, Frameworks, Models Domain	**The chosen implementation framework(s) inform and structure all aspects of the proposed project (i.e., project design, aims and objectives, data collection, including measures, and data analysis, where relevant).**	**Conceptual model and theoretical justification**	**The implementation and/or improvement science-specific conceptual model or framework is used to frame the proposed study in all aspects including the study questions, aims/objectives, hypotheses, process, and outcome measures.**	**High**
		Conceptual model and theoretical justification	Some discussion may refer and describe how study findings would build upon or otherwise contribute to theory or the larger implementation and/or improvement science fields.	None
Theories, Frameworks, Models Domain	Constructs/elements/domains of implementation framework(s) are measured using psychometrically robust and/or pragmatic instruments.			*None*
Theories, Frameworks, Models Domain	If frameworks are applied pragmatically (i.e., not in its entirety), clear and strong justification is provided.			*None*
Theories, Frameworks, Models Domain	Proposed adaptations (above and beyond pragmatic application) to chosen frameworks are clearly and comprehensively described and strong justification is provided.			*None*

Theories, Frameworks, Models Domain	If more than one framework is proposed, the unique contribution of each is described.			*None*
Determinants of implementation: contextual factors	The project aims to prospectively identify factors likely to hinder or facilitate implementation efforts.			*None*
Determinants of implementation: contextual factors	Detailed and strong justification is provided to support the identification and selection of the chosen implementation framework, supported by appropriate literature.			*None*
Determinants of implementation: contextual factors	Clear and detailed description and justification is provided of suggested adaptations to the intervention and/or implementation strategy (if applicable). Adaptations are based on implementation determinants and maintain the core features of the intervention.			*None*
Determinants of implementation: contextual factors	**Clear and detailed description of how implementation determinants will be identified.**	**Feasibility of proposed research design and methods**	**Potential barriers to implementation are clearly identified with potential plans to overcome those barriers.**	**High**
Determinants of implementation: contextual factors	**An appropriate theory, framework, or model (framework hereafter) has been selected to identify and understand the factors affecting implementation success or failure.**			**Medium**
Determinants of implementation: contextual factors	**The project aims to prospectively identify factors likely to hinder or facilitate implementation efforts.**	**Feasibility of proposed research design and methods**	**Explicitly describes preliminary data on the assessed organizational and political capacity and readiness for implementation (assessment completed prior to application/pilot).**	**Low**
Determinants of implementation: contextual factors	**Clear and detailed description of how implementation determinants will be identified.**	**Feasibility of proposed research design and methods**	**Preliminary capacity and readiness assessments were completed using a scale with established validity and reliability, or a scale that has undergone some validity and reliability testing.**	**Low**
			May include strategies for how those opposed to change in the study setting will be involved with or have their concerns addressed by study processes or components.	*None*

			Evidence of support (e.g., letters from the study setting that address how the proposed study aligns with the organization's priorities/policies.	*None*
Implementation Strategies	**Implementation strategies are described in sufficient detail to allow replication.**	**Implementation strategy/process**	**Explicitly describes how implementation strategies will be observed or empirically tested.**	**Medium**
Implementation Strategies	Implementation strategies will be (or have been) selected and tailored to overcome identified barriers to implementation and/or harness identified facilitators.			*None*
Implementation Strategies	Clear description of the methods used to select implementation strategies.			*None*
Implementation Strategies	Explicitly states the implementation outcome(s) that are targeted for improvement by the implementation strategy.			*None*
Implementation Strategies	**Implementation strategy selection is theoretically and/or empirically justified, supported by relevant literature.**	**Implementation strategy/process**	**Explicitly describes and theoretically justifies the implementation strategies.**	**High**
Implementation Strategies	Intention to involve patients and the public in the identification and selection of implementation strategies.			*None*
Implementation Strategies	Intention to involve stakeholders in the identification and selection of implementation strategies.			*None*
		Implementation strategy/process	Explicitly describes how implementation strategies link to the stated aims/setting/outcome measures of the proposed study.	*None*
		Implementation strategy/process	Implementation strategies are feasible given the pilot study timeline and budget constraints.	*None*
Service and Patient Outcomes	The degree of focus placed on measuring service and/or patient outcomes is guided by the strength of the evidence for the intervention in question.			*None*
Service and Patient Outcomes	Explicit alignment between service and/or patient outcomes to be collected and the proposed project aims and objectives.			*None*
Service and Patient Outcomes	Clear and explicit evidence that stakeholders were involved or will be involved in the selection of service and/or patient outcomes to be evaluated.			*None*
Service and Patient Outcomes	Explicit awareness that service and/or patient outcomes are not sufficient for understanding implementation success or failure.			*None*

Service and Patient Outcomes	A clear and detailed description of service and/or patient outcome data analysis plan is presented and is linked to implementation outcome data analysis plans.			*None*
Implementation outcomes	**The proposed project includes the evaluation of implementation outcome(s).**	**Measurement and analysis section**	**Outcomes described are implementation and/or improvement science-related.**	High
Implementation outcomes	**The implementation outcomes of interest align with the project aims and objectives.**	**Measurement and analysis section**	**Outcomes are clearly linked to the proposed study aims.**	High
Implementation outcomes	**Where quantitative implementation outcome instrument(s) are proposed to be used to assess implementation outcome(s), evidence of its psychometric strength is provided.**	**Measurement and analysis section**	**Measurement and data analytic plans robustly describe how all variables and outcomes will be measured and are appropriate for the proposed study through a clear theoretical justification.**	High
Implementation outcomes	Clear and explicit evidence that stakeholders were involved, or will be involved, in the identification and selection of relevant and important implementation outcomes to be evaluated.			*None*
Implementation outcomes	Clear and explicit evidence that patients/public were involved, or will be involved, in the identification selection of relevant and important implementation outcomes to be evaluated.			*None*
Implementation outcomes	**The measurement method, unit of analysis and time point(s) of implementation outcome data collection are appropriate for the proposed project's aims and objectives.**	***Measurement and analysis section***	**The unit of analysis is appropriate for the proposed study.**	**High**
Implementation outcomes	A clear and detailed description of implementation outcome data analysis plan is presented and is linked to service and patient outcomes data analysis, if applicable.			*None*
Unintended Consequences	Discussion of the intention to explore unintended consequences (including unexpected benefits, unexpected drawbacks and perverse results) that might occur as a result of implementation efforts.			*None*
	Project is designed to allow for the identification and effective management of unintended consequences.			*None*
Economic Evaluation	The type of economic evaluation and the economic project question has been clearly articulated.			*None*

Economic Evaluation	The perspective of the economic evaluation is clearly stated and justified in relation to the context of the research and the time horizon over which resource impacts and patient/population outcomes are to be evaluated is clearly indicated.			*None*
Economic Evaluation	There is a clear statement of how patient/population health outcomes are to be quantified.			*None*
Economic Evaluation	**The approach to measurement of resource use (including resources used in implementation) and to costing resource use is clearly stated, including data sources.**	***Feasibility of proposed research design and methods***	**The budget and timeline are appropriate.**	**Low**
Economic Evaluation	The methodological approach to evaluation and the approach to measurement of resource use (including resources used in implementation) and to costing resource use (including data sources) is clearly stated.			*None*
Economic Evaluation	The approach to sensitivity analysis to evaluate the robustness of conclusions to uncertainty around the value of key implementation, clinical, epidemiological and economic parameters is indicated.			*None*
Economic Evaluation	Clear and explicit recognition of implementation strategy cost during implementation phase and beyond initial implementation phase (scale up phase).			*None*
Stakeholder Involvement and Engagement		Stakeholder priorities, engagement in change	Comprehensive description of who all of the identifiable stakeholders are.	*None*
Stakeholder Involvement and Engagement		Stakeholder priorities, engagement in change	Clear understanding of stakeholder concerns related to the intervention as evidenced by a stakeholder analysis plan that describes how the applicant will collect comprehensive information on stakeholders' interests, interrelations, influences, preferences, and priorities.	*None*
Stakeholder Involvement and Engagement	**Evidence that stakeholders were engaged and/or involved in developing the project proposal and are part of the research team.**	**Stakeholder priorities, engagement in change**	**Detailed description of how stakeholders were involved in the conceptual design of the intervention and in considering the implementation strategies, process, and outcomes.**	**High**

Stakeholder Involvement and Engagement	Clear and explicit evidence of intention to engage and/or involve stakeholders in all relevant later stages of the project.			*None*
Stakeholder Involvement and Engagement	Clear and explicit rationale/purpose of engagement and/or involvement provided.			*None*
Stakeholder Involvement and Engagement	**Informed by stakeholder preferences and priorities, the project proposes to be a partnership between researchers and relevant stakeholder(s) based upon shared power.**	**Stakeholder priorities, engagement in change**	**An explicit agreement (such as a memorandum of understanding) or evidence of collaboration between the stakeholders and the applicant that is explained with relevance to the proposed study process and how findings will be communicated.**	**Medium**
Stakeholder Involvement and Engagement	Engagement and/or involvement methods are well described and appropriate.			*None*
Patient and Public Involvement	Evidence that patient, service users and the public were engaged and/or involved in developing the project proposal and are part of the research team.			*None*
Patient and Public Involvement	Clear and explicit evidence of intention to engage and/or involve patient, service users and the public in all relevant later stages of the project.			*None*
Patient and Public Involvement	Clear and explicit rationale/purpose of engagement and/or involvement provided.			*None*
Patient and Public Involvement	Informed by patient, service users and the public preferences and priorities, the project proposes to be a partnership between researchers and relevant patient, service users and the public based upon shared power.			*None*
Patient and Public Involvement	Engagement and/or involvement methods are well described and appropriate.			*None*
		Team experience with setting, treatment, and implementation process	Clearly describes how team experience relates to the study setting, treatment, and processes	*None*

		Team experience with setting, treatment, and implementation process	Team description, biographical sketches, resumes/CVs depict a multidisciplinary skillset relevant to the proposed study setting, treatment, processes, and other needs.	*None*
		Team experience with setting, treatment, and implementation process	Staffing plan facilitates successful study completion without necessitating CIIS support.	*None*
		Team experience with setting, treatment, and implementation process	Clearly describes strengths of the research environment including resources and infrastructure.	*None*
		Team experience with setting, treatment, and implementation process	If principal investigator is considered junior or early career or novice to implementation science, senior leadership outside of CIIS has been identified to support study completion with mentoring and/or consultation.	*None*
		Policy/funding environment; leverage of support for sustaining change	The internal/external policy trends and/or funding environment are clearly described.	*None*
		Policy/funding environment; leverage of support for sustaining change	Potential impact of the intervention is explicitly linked to relevant policies and funding issues associated with a safety net setting.	*None*

		Policy/funding environment; leverage of support for sustaining change	The dissemination plan for study findings indicates what and how a contribution will be made to the broader policy level and safety net setting.	*None*