I. POLICY

It is the policy of UPMC to improve processes for delivering evidence-based treatments and to protect patients from risk and potentially harmful experimentation. The Wolff Center at UPMC has organizational responsibility for oversight of this process.

Links to policies referenced within this policy can be found in Section VII.

II. PURPOSE

Quality Improvement (QI) projects aim to use existing scientific knowledge to improve patient care processes and health care outcomes in local care institutions or settings. These projects are strongly encouraged within UPMC. Unlike QI, research is the “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” about human disease and healthcare” as defined in 45 CFR 46.102(d) of the Code of Federal Regulations, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. In some instances, there may be confusion between which projects are research studies and which constitute QI activity. The purpose of this policy is to define an enterprise-wide process and procedure for distinguishing between QI and research activity and evaluating projects submitted for approval as QI. The goal is to ensure that projects submitted as QI are not research or potentially harmful to patients and are compliant with UPMC’s HIPAA requirements (as well as UPMC privacy commitments to its patients) and federal research laws. Projects that are determined to be research will be referred to the University of Pittsburgh Institutional Review Board (IRB) for review, or in the case of UPMC Hamot, their local IRB. Conversely, projects that are determined by either of the IRBs to be QI studies will be reviewed pursuant to the procedures set forth in this policy.

III. SCOPE

This policy applies to all United States based business units of UPMC including hospitals, University of Pittsburgh Physicians, and the Health Plan. As such, the sponsors of studies must be employees or staff of a UPMC entity. Should a non-employed physician request to participate in an approved QI project, they must successfully complete all required conflict disclosures as defined in the current UPMC Conflict of Interest- General Obligations HS-EC1700 policy. Further, the non-employed...
physician understands and agrees that the UPMC Conflict of Interest policy governs and defines their participation in any approved QI project.

IV. RESPONSIBILITY

The responsibility for reviewing, referring, and approving submitted QI projects shall be overseen by the UPMC QI Review Committee (QRC). Two levels of review will guide the oversight. A core committee consisting of health system physicians and a representative from the Wolff Center will conduct the first level of review for all projects submitted systemwide. Certain projects involving external funding; product, device, medication/biologic, or technology evaluation; experimental methods; use of registry data; or disclosed conflicts of interest may be considered complex. These types of complex projects will require additional expert evaluation and will be referred to an expanded QRC consisting of representatives from the Office of Sponsored Programs and Research (OSPARS), the University of Pittsburgh or UPMC Hamot IRB, the appropriate Supply Chain Management (SCM) resource, the UPMC System Pharmacy and Therapeutics (P&T) Committee, Corporate Compliance, the New Technology Device Request Group, a registry review team, and/or other UPMC or University of Pittsburgh business units. Typically, reviews will be completed within 2 to 3 weeks of submission but may take longer for projects requiring a second level review.

V. PROCEDURE

All QI sponsors will complete the electronic QI or Research Checklist (Appendix A). The responses to these questions will serve as an initial screen and electronically direct the sponsor to submit the project to the QRC for QI activity, SCM for product or device evaluation (in accordance with existing guidelines detailed in the UPMC Value Analysis Program HS-MM0302, UPMC Vendor Management HS-MM0314, and Guidelines for Purchasing Materials, Goods and Services HS-MM0300 policies), the System P & T Committee for drug/biologic evaluation, the New Technology Device Request Group for technology evaluation, or the IRB in the case of possible research. Review of QI projects will follow the process outlined below.

The UPMC QRC will review all submitted QI projects as follows:

1. All QI projects proposed at UPMC should be reviewed. UPMC encourages sponsors to submit projects for review and strives to achieve full participation.

2. A section of the INFONET Quality site, Quality Improvement Projects, has been established for all aspects of this work.

3. The sponsor will electronically Submit a Project for Review through the link on the Quality Improvement Projects Infonet site. The submission process will first prompt the sponsor to complete the QI or Research Checklist. Based on checklist responses, the sponsor will automatically be directed to the QI Project Submission Form as appropriate (Appendix B). Sponsors will respond to specific questions and provide
project details including: Title of the Project; Sponsor Name, Title, and Department; Facility; Anticipated Start and End Date; Background of the Problem; Specific Aims; Sample and Setting; Methods (intervention, measures, data collection, security, and analysis plans); and Results.

Data must be accessed, collected and stored according to relevant UPMC policies [HS-RS0005 Research Using UPMC Electronic Protected Health Information (e- PHI)] governing data security and patient confidentiality. All patient identifiable data collected and stored for the project must comply with UPMC Policy HS-MR1000 Release of Protected Health Information regarding the privacy and security of clinical data.

If data collection is required from the paper medical chart or electronic charts, the sponsor must also submit a data collection form. The form should indicate the name of the party responsible for collecting data and where all data will be stored.

4. The core QRC will conduct a first level review of the project and, as appropriate, may:
   - Approve the project, assign it a QI Number and send electronic notification to the sponsor and the local site, or
   - Send complex projects to selected members of the expanded QRC for a second level of review.

5. After conducting a second level review, the expanded QRC may, in turn, recommend that the core QRC
   - Approve the project, assign it a QI Number and send electronic notification to the sponsor and the local site,
   - Notify the sponsor and corresponding IRB that the project may be research, according to the definition of research in 45 CFR 46.102(d) and suggest that it be submitted to the IRB for review.
   - Deny approval.

6. Projects referred to the QRC from the University of Pittsburgh or UPMC Hamot IRB will be reviewed to ensure that the submission is a QI project.

7. The QRC shall maintain an electronic database of all project submissions and approvals and prepare a quarterly report for the Chief Quality Officer. The approved projects in the database will also be housed on the Quality Improvement Projects Infonet site, allowing for querying and systemwide sharing via Search QI Projects at UPMC.
   - The Chief Quality Officer of UPMC reviews all system reports for concerns, patterns, or trends and will report to the Chief Medical Officer.
8. Sponsors are asked to update the “Project Results” field in the electronic form when projects have been completed and may be requested to present the outcomes to the hospital or business unit’s quality oversight body.

9. In most cases, project approval will be granted for one year but may be less as deemed necessary by the QRC. Decisions will be made on a case by case basis and approval time will be included in the approval letter.

10. Results of quality improvement projects must be reviewed by local quality directors and approved by the Chief Quality Officer prior to dissemination (via presentation or publication) outside of UPMC. The UPMC QRC has adopted reporting guidelines for QI studies (Appendix C). If the sponsor desires to publish project findings, the SQUIRE 2.0 Guidelines serve as the suggested reporting format.

11. The Wolff Center oversight team will facilitate shared learning across the enterprise.

VI. EVALUATION

Members of the QRC and appropriate members of the IRB and SCM will periodically evaluate this policy and recommend modifications to this policy or applicable procedures as appropriate.

VII. POLICIES REFERENCED WITHIN THIS POLICY

- HS-EC1700 Conflict of Interest-General Obligations
- HS-MM0302 Value Analysis Program
- HS-MM0314 Vendor Management
- HS-MM0300 Guidelines for Purchasing Materials, Goods and Services
- HS-RS0005 Research Using UPMC Electronic Protected Health Information (e-PHI)
- HS-MR1000 Release of Protected Health Information

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SIGNED: Steven Shapiro, MD.
Executive Vice President, UPMC
Chief Medical and Scientific Officer,
President, Health Services Division

Tami Minnier, RN, MSN
Chief Quality Officer

ORIGINAL: March 15, 2005
APPROVALS:
Executive Staff: April 1, 2016
PRECEDE: April 15, 2015 (effective May 29, 2015)
SPONSOR: Quality Improvement Review Committee

* With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.

Attachments – Appendices A, B, and C

REFERENCE

Appendix A

Quality Improvement or Research Checklist*

*Completed Electronically - In general, a QI project does not require Institutional Review Board (IRB) review and approval because it is not human subjects research that is subject to the federal human subjects protection regulations. The following questions may be helpful in determining if a proposed activity is research or QI activity, and if it might require review by Supply Chain Management, the System P & T Committee, or the New Technology Device Request Group.

<table>
<thead>
<tr>
<th>Project Description</th>
<th>Yes</th>
<th>NO</th>
</tr>
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<tbody>
<tr>
<td><strong>1. Purpose</strong></td>
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<tr>
<td>Is the activity primarily intended to improve patient care processes, outcomes, or system performance at UPMC?</td>
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<tr>
<td><strong>2. Scope/Evidence</strong></td>
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<tr>
<td>Does the activity aim to evaluate or improve current practice based upon existing knowledge and evidence that is generally accepted by UPMC clinicians?</td>
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<tr>
<td><strong>3. Risk</strong></td>
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<tr>
<td>Is the risk or burden to participants greater than what normally exists in the care they are already receiving?</td>
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<tr>
<td><strong>4. Methods</strong></td>
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<tr>
<td>Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?</td>
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<tr>
<td><strong>5. Consent</strong></td>
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<tr>
<td>Will the consent for treatment that is already obtained in clinical practice cover the planned activity?</td>
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<tr>
<td><strong>6. Benefits</strong></td>
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<tr>
<td>Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?</td>
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<tr>
<td><strong>7. New Use</strong></td>
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<td></td>
</tr>
<tr>
<td>Will the project involve new use of existing equipment, products, medications/biologics, or technology (e.g. apps, software or hardware upgrades) for a not yet approved purpose or group of patients at UPMC?</td>
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</tr>
</tbody>
</table>

If question numbers 1,2,4-6 are all answered as “Yes” and number 3 is answered as “No,” IRB review is likely not required and the project will be electronically directed to the QI project site for submission and review by the Quality Review Committee (QRC). If the answer to question #7 is also “Yes,” project inquiries will be directed to Supply Chain Management, the System P&T Committee, or the New Technology Device Request Group via email. If the answer to question numbers 1,2,4-6 is “No,” or if the answer to question number 3 is “Yes,” the project may be research, and the sponsor will be electronically directed to a choice of IRB emails (University of Pittsburgh or UPMC Hamot) for advisement.
Appendix B

UPMC Health System
Quality Improvement Project Submission Form*
*Completed Electronically

Project Description

Project Title:

Sponsor:

Sponsor Title:

Sponsor Department:

Co-Sponsor(s):

GME Involvement
Are any of the sponsors or co-sponsors residents or fellows? No ☐ Yes ☐ - provide names

Academic Requirement
Does this project fulfill an academic requirement? No ☐ Yes ☐ - specify institution/degree

UPMC Facility Where Project will be Implemented:

Anticipated Start Date:

Anticipated End Date:

Referred by IRB ☐ Yes ☐ No ☐

Project Summary

- Briefly summarize the background of the problem and aims of the project.
- Describe the sample and setting in which the project will be conducted.
- Describe the intervention and how it will be implemented.
- Identify process and outcome measures that will be used to evaluate the effectiveness of the intervention and how consistently it is implemented.
- Specify data collection methods—what data will be collected, how, and by whom.
- Outline plans to maintain data security and patient confidentiality.
- Describe methods for data analysis.
Project Results: Enter results after project is complete.

Key Words: Please list 3-4 key search terms/phrases (e.g., falls, hand hygiene, ICU family communication, noise).

Project Methodology

Corrective Plan
Is there a commitment to implementing a plan for follow-up based on the outcomes of the project? No □ Yes □-describe

Funding
Will this project be supported by funding or any in-kind donations such as equipment loan? No □ Yes □-select internal or external and specify funding source or agency (Flag for second level review by OSPARS for external funding)

Product, Device, Medication, Biologic, or Technology Evaluation
- Does the project involve the evaluation of a product, device, medication, or biologic?

□ Product/Device
   No □ Yes □ describe the evaluation and include manufacturer name and model (Flag for second level review by SCM)
   o Is it FDA approved? No □ Yes □
   o Does UPMC currently purchase it? No □ Yes □
   o Will the project involve new use of the product or equipment for a not yet approved purpose or group of patients at UPMC? No □ Yes □ -- describe
   o Has the product been assessed previously by a Value Analysis Committee, including the Technology and Innovative Practice Assessment Committee (TIPAC)? No □ Yes □ -- describe
   o Has the equipment or product been approved for purchase but with defined restrictions or expectations on its use? No □ Yes □ -- describe

□ Medication/Biologic
   No □ Yes □
   o Is the agent FDA-approved?
     ■ No □ Flag for second level review by IRB Yes □
   o Is the use being evaluated currently a labeled indication by the FDA?
     ■ No □ Flag for second level review by System P&T Yes □
   o Is there a current UPMC formulary decision on this agent?
     ■ No □ Flag for second level review by System P&T Yes □

□ New Technology
   No □ Yes □-describe (app, software, hardware upgrade) Flag for second level review by New Technology Device Request Group
External Participants
Are any entities external to UPMC participating in the project?
No ☐  Yes ☐ - list the entities and specify their role in the project

Research Association
Is this project associated with a University of Pittsburgh or UPMC research project or clinical trial or being conducted in order to collect pilot data that will be used as a basis for future funding proposals to external agencies or companies?
No ☐  Yes ☐ - explain

Patient Data Collection Methodology
- Will patient data be collected as part of this project? No ☐  Yes ☐

- If yes, please indicate how patient data will be collected:
  ☐ Chart review through hard copy medical records (i.e., Horizon Patient Folder (HPF) and hardcopy records)
  ☐ Chart review through electronic medical records (e.g., Cerner, Epic, Varian)
    *SharePoint email notification to Wolff Center Quality Analytics*
  ☐ Data collection from a UPMC registry or other database (specify)
    *SharePoint email notification to Wolff Center Quality Analytics*
  ☐ Data collection from other applications (MARS, Clinical Connect HIE, ClinicView, other Quality Data)
    *SharePoint email notification to Wolff Center Quality Analytics*
  ☐ Patient interviews/observations

- Will you be collecting protected health information (PHI) as part of this project?
  No ☐  Yes ☐

All patient identifiable data collected and stored for this study needs to comply with UPMC Policy HS-MR1000 Release of Protected Health Information regarding the privacy and security of clinical data.

- Is participation in this project/program part of a national registry or database?
  No ☐  Yes ☐ - name the registry/database *(Flag for second level review by Registry Team)*

  *QI projects and/or programs that include the submission of local data to external partners and third parties (e.g. national registries & databases) require business associate agreements (BAA) and data usage agreements (DUA).*

- Please specify who will be accessing the data, including any individuals not employed by UPMC.
Please attach a sample data collection form.

**Blinding**
If the project involves a therapeutic intervention, is the intervention to be delivered in a blinded fashion? No ☐ Yes ☐ *(Flag for second level review by IRB)*

**Withdrawing Treatment**
Does the project involve “withdrawing” or holding back any needed and generally accepted treatments for the patients’ condition? No ☐ Yes ☐ *(Flag for second level review by IRB)*

**Randomization**
Does the project involve prospective assignment of patients to different procedures or therapies based on predetermined plans such as randomization?
No ☐ Yes ☐ *(Flag for second level review by IRB)*

**Conflict of Interest**
Please list all potentially relevant financial and non-financial conflicts of interest of individuals leading this project. *(Flag for second level review by Corporate Compliance)*

For illustrative purposes, potential conflicts of interest could arise from the following types of relationships, among others.

- consulting agreement between individual leading the proposed project and the manufacturer of the device or drug used or evaluated in connection with the project;
- participation by an individual involved in the proposed project on a scientific advisory board of the manufacturer of the device or drug used or evaluated in connection with the project;
- royalty arrangement between an individual involved in the proposed project on a scientific advisory board of the manufacturer of the device or drug used or evaluated in connection with the project;
- Individual leading the proposed project developed intellectual property being used or evaluated as part of the project, regardless of whether such intellectual property was sold, transferred or licensed to a third party.

**QI versus Research**
Briefly describe why you think this is a QI project and not a research study.

*Results of quality improvement projects must be reviewed by local quality directors and approved by the Chief Quality Officer prior to dissemination (via presentation or publication) outside of UPMC. The UPMC QRC has adopted reporting guidelines for QI studies (Appendix C). If the sponsor desires to publish project findings, the SQUIRE 2.0 Guidelines will serve as the required reporting format.*

Projects reviewed and approved by the UPMC QI Review Committee do not meet the federal definition of research according to 45 CFR 46.102(d) and do not require additional IRB oversight.
QI Review Committee (QRC)
For Committee Use Only

Based on responses to the questions above, this project request has been flagged for potential second level review by:
OSPARS Yes or No
SCM Yes or No
IRB Yes or No
System P & T Committee Yes or No
Registry Team Yes or No
Corporate Compliance Yes or No
New Technology Device Request Group Yes or No

QRC Comments (for internal comments between members of the QRC Committee):

Project Status:
New, Submitted, Approved, Declined, Withdrawn, Request for more information, Updated with more information by sponsor, Referred for second level review, Further review completed, In progress, Research, Incomplete, Approved from paper form

QRC Reviewer:

Date of Review:

Date of Decision:

Note to Sponsor:

QRC Project Summary

Project Follow-Up (for Projects that have an Anticipated End Date that is past):
Date of QRC Follow-up with Sponsor:

To execute spellcheck on any of the fields above, simply click with your mouse in the field you wish to check and then click on the "Spelling" button on the SharePoint ribbon at the top of the page. Any misspelled words will be marked in red.

You may need to click the "Submit" or "Save" button more than once. When your project has been successfully saved or submitted, this form will automatically close. Check your UPMC email for a message containing a link to your saved/submitted project.
# Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) 
publication guidelines

<table>
<thead>
<tr>
<th>Text section and item name</th>
<th>Section or item description</th>
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<tbody>
<tr>
<td>▶ The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare.</td>
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<tr>
<td>▶ The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s).</td>
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<td>▶ A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these.</td>
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<tr>
<td>▶ Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript.</td>
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<tr>
<td>▶ The SQUIRE glossary contains definitions of many of the key words in SQUIRE.</td>
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<td>▶ The explanation and elaboration document provides specific examples of well-written SQUIRE items and an in-depth explanation of each item.</td>
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<tr>
<td>▶ Please cite SQUIRE when it is used to write a manuscript.</td>
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</table>

## Notes to authors

**Title and abstract**

1. **Title**
   - Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency and equity of healthcare).

2. **Abstract**
   - a. Provide adequate information to aid in searching and indexing.
   - b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions.

## Introduction

**Why did you start?**

3. **Problem description**
   - Nature and significance of the local problem.
<table>
<thead>
<tr>
<th>Text section and item name</th>
<th>Section or item description</th>
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</thead>
<tbody>
<tr>
<td>4. Available knowledge</td>
<td>Summary of what is currently known about the problem, including relevant previous studies.</td>
</tr>
<tr>
<td>5. Rationale</td>
<td>Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work.</td>
</tr>
<tr>
<td>6. Specific aims</td>
<td>Purpose of the project and of this report.</td>
</tr>
<tr>
<td>Methods</td>
<td>What did you do?</td>
</tr>
<tr>
<td>7. Context</td>
<td>Contextual elements considered important at the outset of introducing the intervention(s).</td>
</tr>
<tr>
<td>8. Intervention(s)</td>
<td>a. Description of the intervention(s) in sufficient detail that others could reproduce it.</td>
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<tr>
<td></td>
<td>b. Specifics of the team involved in the work.</td>
</tr>
<tr>
<td>9. Study of the intervention(s)</td>
<td>a. Approach chosen for assessing the impact of the intervention(s).</td>
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<td></td>
<td>b. Approach used to establish whether the observed outcomes were due to the intervention(s).</td>
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<tr>
<td>10. Measures</td>
<td>a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions and their validity and reliability.</td>
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<tr>
<td></td>
<td>b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost.</td>
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<tr>
<td></td>
<td>c. Methods employed for assessing completeness and accuracy of data.</td>
</tr>
<tr>
<td>11. Analysis</td>
<td>a. Qualitative and quantitative methods used to draw inferences from the data.</td>
</tr>
<tr>
<td></td>
<td>b. Methods for understanding variation within the data, including the effects of time as a variable.</td>
</tr>
<tr>
<td>12. Ethical considerations</td>
<td>Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest.</td>
</tr>
<tr>
<td>Results</td>
<td>What did you find?</td>
</tr>
<tr>
<td>13. Results</td>
<td>a. Initial steps of the intervention(s) and their evolution over time (eg, time-line diagram, flow chart or table), including modifications made...</td>
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<td>Text section and item name</td>
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<td>to the intervention during the project.</td>
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<td></td>
<td>b. Details of the process measures and outcomes.</td>
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<td></td>
<td>c. Contextual elements that interacted with the intervention(s).</td>
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<tr>
<td></td>
<td>d. Observed associations between outcomes, interventions and relevant contextual elements.</td>
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<td></td>
<td>e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s).</td>
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<tr>
<td></td>
<td>f. Details about missing data.</td>
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<tr>
<td>Discussion</td>
<td><strong>What does it mean?</strong></td>
</tr>
<tr>
<td>14. Summary</td>
<td>a. Key findings, including relevance to the rationale and specific aims.</td>
</tr>
<tr>
<td></td>
<td>b. Particular strengths of the project.</td>
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<tr>
<td>15. Interpretation</td>
<td>a. Nature of the association between the intervention(s) and the outcomes.</td>
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<td></td>
<td>b. Comparison of results with findings from other publications.</td>
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<td></td>
<td>c. Impact of the project on people and systems.</td>
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<td></td>
<td>d. Reasons for any differences between observed and anticipated outcomes, including the influence of context.</td>
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<td></td>
<td>e. Costs and strategic trade-offs, including opportunity costs.</td>
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<tr>
<td>16. Limitations</td>
<td>a. Limits to the generalizability of the work.</td>
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<td></td>
<td>b. Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement or analysis.</td>
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<tr>
<td></td>
<td>c. Efforts made to minimize and adjust for limitations.</td>
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<tr>
<td>17. Conclusions</td>
<td>a. Usefulness of the work.</td>
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<td>b. Sustainability.</td>
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<td>Text section and item name</td>
<td>Section or item description</td>
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<td></td>
<td>c. Potential for spread to other contexts.</td>
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<tr>
<td></td>
<td>d. Implications for practice and for further study in the field.</td>
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<tr>
<td></td>
<td>e. Suggested next steps.</td>
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</tbody>
</table>

Other information

| 18. Funding | Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation and reporting. |