STUDY PROTOCOL

What are the mechanisms that enable the reciprocal involvement of seldom heard groups in health and social care research? A rapid realist review protocol [version 1; peer review: 3 approved]

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Abstract

Background: The University College Dublin (UCD) PPI Ignite Connect Network will fundamentally embed public and patient involvement (PPI) in health-related research, education and training, professional practice and administration in UCD’s institutional structures and procedures. A significant focus of the programme of work is on actively engaging and developing long-term reciprocal relationships with seldom heard groups, via our ten inaugural partners.
Methods: This rapid realist review will explore what are the mechanisms that are important in actively engaging seldom heard groups in health and social care research. The review process will follow five iterative steps: (1) clarify scope, (2) search for evidence, (3) appraise primary studies and extract data, (4) synthesise evidence and draw conclusions, and (5) disseminate findings. The reviewers will consult with expert and reference panels to focus the review, provide local contextual insights and develop a programme theory consisting of context–mechanism–outcome configurations. The expert panel will oversee the review process and agree, via consensus, the final programme theory. Review findings will follow the adopted RAMESES guideline and will be disseminated via a report, presentations and peer-reviewed publication.

Discussion: The review will update and consolidate evidence on the mechanisms that enable the reciprocal engagement and participation of 'seldom heard' groups in health and social care research. Via the expert and reference process, we will draw from a sizeable body of published and unpublished research and grey literature. The local contextual insights provided will aid the development of our programme theories. This new evidence will inform the design and development of the UCD PPI Ignite program focused on ensuring sustained reciprocal partnerships.

Keywords
Public and Patient Involvement, Co-design, engaged research, capacity building, rapid realist review, seldom heard groups, protocol study

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Competing interests: No competing interests were disclosed.

Grant information: Health Research Board Ireland [PPI-2017-004], HRB PPI Ignite Award.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Ni Shé É, Davies C, Blake C et al. What are the mechanisms that enable the reciprocal involvement of seldom heard groups in health and social care research? A rapid realist review protocol [version 1; peer review: 3 approved] HRB Open Research 2018, 1:7 (https://doi.org/10.12688/hrbopenres.12790.1)

First published: 28 Feb 2018, 1:7 (https://doi.org/10.12688/hrbopenres.12790.1)
Introduction

The rise of public and patient involvement

Both nationally and internationally, there continues to be a significant emphasis in the literature on advancing our understanding of what public and patient involvement (PPI) in health research involves and on mapping subsequent impacts\(^\text{1-5}\). This work builds on advances in the humanities and social sciences literature around community based applied research, focused on co-design, community capacity building, emancipatory and participatory action research\(^\text{6-10}\). As PPI, knowledge exchange and co-design become more generally entrenched in legislation, standards and linked with mandatory funding requirements\(^\text{11}\), focus has shifted onto what is required to sustain and embed these principles within university structures\(^\text{1}\). Whilst the policy and funding shifts are to be welcomed, there is also the awareness that the change has been slow, often manifesting at the lowest levels of engagements\(^\text{12}\). Occho and Matthews outline a range of reasons why achieving genuine patient involvement presents challenges, citing in particular a lack of diversity of those becoming involved\(^\text{13}\). The sustainability of PPI has become a more recent priority in the literature in tandem with an interest in advancing co-production/co-design\(^\text{14-17}\). These shifts brings new demands to support, develop and sustain long-term reciprocal partnerships. Key to this are efforts, initiatives, and strategies designed to enhance the collaborative capacity skills of researchers, the public and those working within the health system\(^\text{18}\). Also critical are refining the financial and ethical structures of universities and health organisations, providing on-going education and training and celebrating success by providing recognition built into career metrics\(^\text{19}\).

Recently attention has focused on developing structures responding to the challenges identified in growing and sustaining PPI\(^\text{20-24}\). In Ireland this shift has started to commence. The work of the Campus Engage National Network, for example, has enabled a process of embedding civic engagement as a core function across the seven Irish universities and Dublin Institute of Technology (DIT). Their recent report points to a number of priorities centred on managing expectations, building infrastructure, implementing policies, leadership for innovation and streamlining funding. The Health Research Board’s (HRB) current strategy recognises and commits to embedding and strengthening PPI via their supported programs and projects. Following survey consultation with researchers and members of the public, by the HRB, a clear gap identified was in the need to support and guide researchers on how to approach PPI. It is within that context that the HRB launched the PPI Ignite Awards focused on institution wide responses. Currently, five universities have received funding under this scheme (UCD, DCU, TCD, UL, NUIG).

PPI Ignite and the University College Dublin context

The UCD PPI ignite connect team was successful in receiving funding to embed PPI in a variety of different ways across University College Dublin (UCD). Our working PPI definition stems from the UK National Institute for Health Research advisory group INVOLVE as “research being carried out “with” or “by” members of the public rather than “to,” “about” or “for” them”. University wide preliminary consultation commenced in 2016 to produce a “status report” of UCD’s existing PPI activity and supports. Approximately 20 submissions were collated by the UCD Research Office, followed by a facilitated interactive round table forum which, for the first time, brought together a wide range of internal PPI stakeholders. It was evident that there exists a diversity of PPI activity exists across the university and within affiliated Ireland East Hospital group (IEHG) partners. While some researchers were interested in incorporating PPI into their work but needed support to do it, there was also a significant body of expertise among those for whom PPI forms a core part of their research process. For example, within the health systems research team and researchers in social work group, PPI and co-design is integral to the research process with diverse stakeholder involvement throughout projects\(^\text{25-27}\). In the UCD Conway Institute, patient groups are being involved in research within the areas of oncology and blindness. These conversations formed the consensus that there is a diversity of PPI activities occurring across UCD, involving a breadth of PPI groups. However, these PPI activities are not joined up and following consultation several barriers were identified that need to be addressed to embed PPI as a core UCD activity, ensuring it aligns with the overall UCD strategy. The UCD PPI Ignite Connect program includes focusing on capacity and capability, embedding PPI within research and teaching, supporting knowledge mobilisation and network formations and developing PPI governance structures.

A significant focus of the UCD PPI Ignite Connect program is to overcome the often-identified challenges as noted by UCD researchers and within the literature of engaging ‘seldom heard groups’\(^\text{28}\). ‘Seldom heard’ a term defined by NHS involvement:

Describe groups who may experience barriers to accessing services or are under-represented in healthcare decision making. Traditionally, some of the groups identified in engagement activities include rural communities, black and minority ethnic (BME) groups, gypsies and travellers, lesbian, gay, bisexual and transgender, asylum seekers and refugees and young carers. However, in reality, teenagers, employees, people with mental health issues and many others may be considered as seldom heard, due to the fact engagement may not be straightforward.

Other population groups may also face marginalisation and exclusion from engagement, including people with disabilities, frail older people and people in institutional settings (e.g. care homes, prisons). Being ‘seldom heard’ indicates that existing structures, organisations and services that target their needs are not adequately enabling their voice to be heard via their current participation processes. The literature also uses an array of other terms in particular ‘hard-to-reach’, however, the utility of such a term has been questioned\(^\text{29-30}\). It is within this context that we will undertake a rapid realist review to answer the question; what are the mechanisms that enable the reciprocal involvement of seldom heard groups in health and social care research?
Why a rapid realist review of mechanisms?

Rapid realist reviews (RRR) are iteratively built on theoretical and empirical literature, enabling an unpacking of contexts and interrelated mechanisms underlying implementation activities. Significantly, they include the synthesis of a diversity of evidence types and actively involve diverse stakeholders in the co-production of the literature review process, ensuring increased clarity and awareness of the transferability of the review findings. In particular, RRRs are useful during the commencement phase of a multiphase project where findings need to be rapidly adapted to take account of emerging evidence and where there is limited time and resources. This is the case for the UCD PPI Ignite Connect program as the results of this RRR will be rapidly translated into action plan as part of the overall program.

The basic question of an RRR is ‘what is it about this intervention that works in this context and why’? A RRR works on understanding what are the contexts (C), mechanisms (M), and outcomes (O) that enable or constrain the implementation of an intervention (Figure 1).

The recent literature has recognised that interventions are implemented through a process of evolving mechanisms, which speak to the reasoning and behaviour of the relevant personnel or collectives. However, these mechanisms are often not recognised in the reporting literature except in reference to general barriers and facilitators to implementation. Pawson and Tilley have conceptualised mechanism as a combination of resources offered by the programme of study and the stakeholders reasoning in response. Building on this earlier work, Lacour et al. (p.8) have extended this definition of mechanisms to include ‘an element of reasoning and reactions of (an) individual or collective agent(s) in regard to the resources available in a given context to bring about changes through the implementation of an intervention’. Resources are also relevant and will be included in this RRR as they interplay with the reasoning of health and social care researchers and seldom heard groups as to what is possible as well as desirable in practice. While the focus of this RRR will be on mechanisms, the realist elements of context and resources will be pertinent in as far as they interplay with the operationalising of mechanisms. Context in this study refers to the embedding of PPI within research structures and the subsequent establishment of the UCD PPI Ignite program.

Protocol

Aim of the review?

Our overarching RRR aim is to determine the mechanisms that enable the reciprocal involvement of seldom heard groups in health and social care research. This RRR will adhere to the RAMESES realist publication standards guide with adaptations to streamline and accelerate the process as advised in the literature.

Design

Key to the success of an RRR is the engagement of expert and reference panels. Reference panels are essentially sounding boards providing local contextual knowledge to ensure that the review and final conceptual model is inclusive to the experience of those ‘on the ground’. Previous work has involved site visits, workshops and a curated twitter chat to enable reference panel process. The expert panel includes content experts who must ensure that the review and the programme theory reflects current thinking. They are pivotal to the success of the overall RRR process. Expert panel members are also requested to contribute relevant documents to be included in the RRR review. Significantly, they are requested to include grey or operational docu-

**Figure 1. Rapid realist review of the evidence - What works, for who and in what circumstances?** This figure has been reproduced from under a CC-BY 4.0 license.

- **Context**: Something that can impact or even block, a Mechanism. The context may be provided by the intervention, or by a broader contextual ‘backdrop’ within which the programme (intervention) operates.
- **Resources**: Required to enable a mechanism.
- **Mechanism**: The generative force that results in an Outcome. It can be manifested as a reasoning and or response to the resources or capabilities offered by or embedded in a programme (intervention).
- **Outcome**: What happened intended or unexpected.
ments to the process, thus improving access to material not yet published. Secondly, the panel validates via consensus the final conceptual model. Expert panel involvement does not replace a literature search, rather it provides a way of quickly identifying relevant material for inclusion in the review and for tailoring a search strategy. Panellists draw on their expertise to ensure any interpretations of the literature fit with the experiences of those involved in the content area, as well as with the needs and realities of the local context. The expert panel will convene in March 2018 consisting of national and international members who have experience in health and social care systems, PPI, co-design, emancipatory research and UCD PPI Ignite Connect PPI organisations representing seldom heard groups. Membership of this group is currently being finalised.

Clarify the scope
The first inception meeting with expert panels members will clarify the scope of the RRR. Prior to the meeting ENS will undertake an initial scoping of the literature. The first meeting will clarify the research question, agree inclusion/exclusion criteria, search strategies and databases being used. Discussions at this initial meeting amongst the expert panel will also focus on how to ensure that local knowledge will be captured via the reference panel process. Previous work has involved site visits, workshops and a curated twitter chat to enable the reference panel process. Initial discussions in the development of this protocol suggested a number of roadshow workshops with some of our PPI partners as a reference panel process. This is an innovative approach that will enable the capturing of experiences from those seldom heard groups to be included in the programme theory. The reference panel process will be agreed upon by the expert panel at the initial expert panel inception meeting.

Search for evidence
The search for evidence in an RRR is iterative and will be progressively extended and refocused based on the identified sources as the review evolves. Data will be extracted over 14–16 weeks and weekly data sessions will be held to critically appraise, analyse and synthesise the data. Two members of the team, ENS and TK in consultation with a university faculty librarian, will undertake a search of the literature using PubMed, Cinahl and Web of Science databases. These databases are suggested as they offer extensive and complementary indexing of relevant literature. Added to this we will search grey literature data bases such as OpenGray and the INVOLVE evidence library. This search will also be supplemented with key articles and other documents as identified by the expert panel group.

Evidence synthesis and program theory consensus
A modified version of the template for Intervention Description and Replication (TIDieR) checklist will be used for data extraction. The method of moving from data extractions to developed programme theories is iterative and takes place in parallel with ongoing consideration of the literature. This will be carried out by ENS and TK and emergent C(context)-M(mechanisms)R(Resources) and O (Outcomes) will also be discussed with others in the expert panel to obtain multiple perspectives. A final consensus meeting will be convened with the expert panel, once synthesis of the literature is complete, to validate and prioritise the conceptual model.

Dissemination of findings
Findings will be translated into evidence-based, practical knowledge, action plans and recommendations that will be shared with and applied by the UCD PPI connect team in their work. They will be disseminated in the form of a final short synthesis report, presentations to UCD PPI Connect stakeholders and via a peer reviewed publication.

Discussion
The UCD PPI Ignite Connect will seek to firmly embed PPI in UCD’s research learning and teaching activities and in its academic processes. With the implementation of UCD PPI Ignite Connect there is a clear institutional commitment to firmly embed PPI in academic and administrative structures and processes. We envisage innovative, co-designed research and teaching programmes that will contribute to improving pathways of care. Significantly the research program includes the active participation of seldom heard organisations. This RRR will synthesise and reinforce the evidence on the mechanisms that enable the reciprocal engagement and participation of seldom heard groups in health and social care research. Via the expert and reference process we draw from a sizeable body of published and unpublished research and grey literature. The local contextual insights provided will aid the development of our programme theories. This approach will ensure that the identified mechanisms will be included in the UCD PPI ignite connect program of work to enable the active inclusion of seldom heard groups in our PPI activities to enable their reciprocal participation.

Data availability
No data is associated with this article.

Competing interests
No competing interests were disclosed.

Grant information
Health Research Board Ireland [PPI-2017-004], HRB PPI Ignite Award.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.
References


Open Peer Review

Current Peer Review Status: ✔️ ✔️ ✔️

Version 1

Reviewer Report 14 March 2018

https://doi.org/10.21956/hrbopenres.13850.r26066

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Compared to clinical interventions, healthcare management and policy interventions are complex –as is the intervention underlying this proposed realist review, the UCD PPI Ignite Connect programme. Clinical interventions are often evaluated in randomised controlled trials (RCTs) that seek to establish whether intervention X has an effect Y under controlled conditions. The realist approach to evidence synthesis offers the potential for insights that go beyond this narrowly experimental paradigm of the randomized controlled trial, seeking to understand the mechanisms, context and outcomes that support or hinder the implementation of a programme (or complex intervention) - asking what is it that works (or fails) for whom in what circumstances? Adopting a realist approach for this review is an appropriate choice by the authors, with a clearly stated focus on understanding the mechanisms that enable the reciprocal involvement of seldom heard groups in health and social care research. The authors acknowledge that consideration of both resources (what is available to facilitate involvement?) and context (embedding of PPI within research structures and the establishment of the UCD PPI Ignite Connect programme) will be an important part of the review, given their influence over how the mechanisms will actually work.

Perhaps some clarity would be gained by adding an explanation of what resources will be considered in the review – those provided by the PPI Ignite programme? Provided through other channels in UCD? Provided by the programme partners?

A realist review by its nature is iterative and does not lend itself to strict definition of design and process in a published protocol, in the way that a systematic review of a clinical intervention does. The expert panel process is well described, the authors have previous experience of this process and it will play a key role in refining the scope of the review. The potential addition of one or more reference panels would add real strength to the review and is perhaps an essential pre-requisite for success. User participation facilitates the acquisition of unpublished contextual information from the seldom heard groups who are at the centre of the review question and will be the people who will embody and enact the theories that will be developed –so hearing directly from these people, rather than only from experts working with and on their behalf, would add real value and be very appropriate in the context of PPI.
Given the current stage of the review process, sufficient information on the search strategy is presented, allowing for iterative searching as the review progresses – presumably some snowball searching will be introduced if appropriate. If dates defining the extent of the database search are known, they should be added to the protocol. Presumably, if adhering to the RAMESES guidelines, details of the articles found and subsequently included will be reported in the review – reference to this could be included in the protocol.

The protocol makes no explicit reference to the criteria that will be used to appraise the quality of the evidence – some explanation of how this will be addressed would be helpful for those not familiar with the realist review process, if only to say that it will be based primarily on the judgement of the authors. Finally, implementation of the findings of a realist review are dependent on many different actors and multiple processes, and in this case, across multiple organisations. The Dissemination section shows that the authors are aware of these challenges and have good plans in place to aid dissemination and action based on the final review.

We look forward to hearing the outcome of this important review, which has implications across all health and social care research organisations.

Specific points:
1. Aim of review; the correct reference to RAMESES realist publication standards is https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-11-21

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

We have read this submission. We believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 12 March 2018
https://doi.org/10.21956/hrbopenres.13850.r26063

© 2018 Lambert V et al. This is an open access peer review report distributed under the terms of the Creative Commons Attribution Licence, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.
This manuscript describes a protocol for a rapid realist review to explore the mechanisms that enable the reciprocal involvement of ‘seldom heard’ groups in health and social care research. It is set within the context of the HRB funded public and patient involvement Ignite Awards, and as outlined in the background of this protocol will offer a valuable contribution to understanding the often-identified challenges of ensuring diversity of representation of public and patient members, including ‘seldom heard’ populations as the authors define. In this context, the design proposed i.e. a rapid realist review seems appropriate for the research question to allow for the active involvement of diverse stakeholders in the process and the synthesis of a diversity of evidence types. The protocol clearly describes the rationale and objectives of the study and provides sufficient details on the methods to allow for replication. As this is a protocol no data sets are presented.

This manuscript was well written and organized and there are no concerns about the scientific soundness of the article. There are some minor comments to be considered:

- In the abstract it states that the review process will follow five iterative steps; it could potentially be useful if these headings/steps could be followed through in the manuscript; step three (appraising primary studies and data extraction) seems to be amalgamated under search for evidence with data extraction also mentioned under evidence synthesis; perhaps these specific five steps could be made distinct within the manuscript and/or headings reviewed as it just appears that there is step missing

- Be consistent throughout the manuscript in terms of following through on using the terms ‘health and social care research’ (as used in the title of the manuscript)

- Until you define ‘seldom heard’ perhaps use inverted commas around this term (including in title)

- As a minor typographical issue be consistent throughout the manuscript in use of capitals, for example, for PPI Ignite Connect etc.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

We have read this submission. We believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
This report describes a protocol for research involving seldom heard groups in health care. As such it outlines the background to participant involvement and inclusion in health care research, defines 'seldom heard' and, in so doing, highlights the methodological issues and challenges of ensuring authentic representation. Relevant and current evidence is used to support the background details and justification of the approach to be used.

The method proposed for the protocol is usefully described and justified, using relevant and current theoretical evidence. The overall study design is clear and appears appropriate to the aims of the study being proposed. As this is only the protocol for a proposed study, there are no findings to be reported, however a sound plan is in place to conduct the analysis in an inclusive methodology which will add to the evidence for inclusive research. The details of the protocol are described to allow replicability, and there is a clear plan for dissemination of findings.

This protocol is innovative and and conforms to the ethos of inclusive evidence production, at the same time suggesting a way forward in engaging seldom heard participants. In this, it is a welcome addition to the resources available to researchers in this field.

Some minor proof-reading to correct occasional typographical or grammatical errors will improve the presentation of the work.

**Is the rationale for, and objectives of, the study clearly described?**
Yes

**Is the study design appropriate for the research question?**
Yes

**Are sufficient details of the methods provided to allow replication by others?**
Yes

**Are the datasets clearly presented in a useable and accessible format?**
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Co-production methodologies in substance use and addictive behaviour
I have read this submission. I believe that I have an appropriate level of expertise to confirm that
it is of an acceptable scientific standard.