2022

PRODUCES+

Draft Evidence-based Co-Creation Guideline

HEALTH CASCADE

EVIDENCE BASED CO-CREATION FOR PUBLIC HEALTH

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v1.0 January 2022

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Version 1.0

Public

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1. Background

The use of co-creation in many fields of science has grown exponentially in recent years. It is also now expected, and often demanded by, funders, governments, and policymakers to democratise and accelerate the impact of research and projects. Many claims about the benefits of co-creation have been made and it is often heralded as a panacea, but surprisingly there is a total lack of research investigating the validity of these claims and quantifying the actual impact of co-creation on public health (Williams et al., 2020).

Health CASCADE is the first multidisciplinary expert network dedicated to researching the methodology of evidence-based co-creation for public health and health promotion. Health CASCADE aims to CASCADE co-creation skills and expertise by training a new community of professionals capable of working across disciplines, and public and private sectors. From 2021 to 2024, a coordinated effort by seven beneficiaries and 14 partner organisations from eight European countries will use a multidisciplinary approach in multi-environment and -sectoral contexts to define, test and finalise the concept of evidence-based co-creation for public health (Verloigne et al., 2022).

There is currently no "precise or systematic framework to plan or develop co-created public health interventions and evaluate their effectiveness and impact" (Leask et al., 2019). Furthermore, co-creation has been proposed as a suitable strategy to tackle wicked problems,[1] yet little information and no clear step-by-step guide exist on how to do this (van Woezik et al., 2016).

Therefore, to initiate the development of a methodology of evidence-based co-creation for public health, it is important to strategically set the foundations for building evidence-based co-creation. This will be done in an iterative process and this document represents the first stage of development: the generation of a draft guideline for the co-creation of public health interventions. This work has been executed in parallel to research into the appropriate theoretical lens for evidence-based co-creation, and ethical principles to consider when engaging in co-creation — which are captured in separate documents. In the future, these three pieces of work will be integrated and aligned together to become a complete, integrated, guideline.

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[1] *A wicked problem is a problem that is difficult or impossible to solve because of incomplete, contradictory, and changing requirements that are often difficult to recognize.*

2. Introduction

Purpose

This guideline aims to provide co-creators with step-by-step guidance for executing a co-creation process for public health.

The working definition of co-creation in public health:

"An evidence-based methodology for the development, implementation and evaluation of innovations through continuous, open collaboration, interactional knowledge production and shared decision-making among key stakeholders, directed at improving public health." (Messiha, 2021).

The objective of this guideline is to build further on Leask and colleagues' PRODUCES framework by providing relevant resources that can assist with each stage of the co-creation process: planning, conducting, evaluating, and reporting (Leask et al., 2019).

Scope of this Guideline

Guideline Structure. This draft guideline for evidence-based co-creation for public health interventions (PRODUCES+) is structured around the stages and principles of a recent seminal publication by Calum Leask and colleagues (Leask et al., 2019). These stages and principles were selected because they are overarching in nature, and further revisions will still follow a similar structure and order. Additionally, they are sourced from a recent, well-referenced paper, which focuses on applying co-creation to public health interventions. Therefore, the use of these stages and principles was determined as an appropriate and low-risk starting point for structuring this guideline. Consequently, these preliminary sets of stages and principles used in this version of the guideline are subject to change based on further research and testing.

Guideline Content. The content of this document is based on a literature review of evaluation, implementation, and a snowballing search for methods suitable for co-creation. This document represents the first version of the guideline, so it is important to note that the content references existing resources that can help execute a co-creation process for public health interventions, but it is not a comprehensive guide. The next stage of development of this guideline will include additional systematic reviews, expert consultations, and participatory workshops. You can see further details on the next stage of development of this guideline in Section 9, Next Steps.

While this document is not based on systematic reviews, it contains relevant information and resources to lead you in your co-creation process, and spark reflections on the further development of this guide.

3. Theoretical Principles for Co-creation

The following text is relevant excerpts pulled from the Health CASCADE document: *Deliverable D1.1 ESR1 Document — Preliminary Synthesis* (Messiha, 2021)**.**

"Health CASCADE is seeking to provide a methodology for the combination of an evidence-based approach ("mode 1") and co-creation (" mode 2"). Further, participatory typologies, like Arnstein's ladder [of participation], are very simplified conceptualisations of how participation (adult and child respectively) is seen in a project / research / programme, and so caution must be exercised." (Messiha, 2021**).**

"It became clear that co-creation / transdisciplinary knowledge claims are not referenced to a solely objective or subjective reality. Further, when exploring suitable lenses, an ontology called 'critical realism' emerged in the literature and the primary interviews, as a potentially suitable lens that may be worthwhile to investigate further. For instance, as the propositions of critical realism consider objective reality as well as the role of subjective interpretation in framing reality, it could provide the balance needed for allowing co-creation." (Messiha, 2021**).**

4. Values and Features of Co-creation

The lists below represent a preliminary set of values and features sourced from the International Collaboration for Participatory Research (ICPHR) and National Institute for Health Research (NIHR) websites. For more guidance in identifying and adhering to values and features of the co-creation process, including examples of values and features of co-creation and how they can apply to your work, please reference the Draft Health CASCADE document: *Ethics in co-creation for public health: a preliminary, multi-source perspective (Chrifou, 2022).*

Key Values of Co-creation

Extracted from the International Collaboration for Participatory Health Research (ICPHR) and The National Institute for Health and Care Research (NIHR) websites.

1. <u>Sharing of power</u> – the research is jointly owned, and people work together to achieve a joint understanding
2. <u>Including all perspectives and skills</u> – make sure the research team includes all those who can contribute
3. <u>Respecting and valuing the knowledge of all those working together on the research</u> – everyone is of equal importance
4. <u>Reciprocity</u> – everybody benefits from working together

5. <u>Building and maintaining relationships</u> – an emphasis on relationships is key to sharing power. There needs to be joint understanding and consensus and clarity over roles and responsibilities. It is also important to value people and unlock their potential.

Key Features of Co-creation

Extracted from the [ICPHR](#) and [NIHR](#) website.

1. Establishing ground rules
2. Ongoing Dialogue Joint ownership of key decisions
3. A commitment to relationship building
4. Opportunities for personal growth and development
5. Flexibility
6. Continuous reflection
7. Valuing and evaluating the impact of co-creation research

5. Methods for Co-creation

The working definition used for methods is "*a strategy, process, or a collection of techniques that are utilized in the gathering of data or evidence for analysis, aiming to uncover new information or create a better understanding of a topic.*" (University of Newcastle Library, 2022). The methods represented throughout this guideline were sourced through a snowballing method using an Artificial Intelligence tool, called [Research Rabbit](#), starting from the Leask et.al. 2019 paper (Leask et al., 2019). A method was included if it was referenced as a tool or approach used in a co-creation process in any sector. This also created a basis for the type of details and descriptive information that can be sourced per method. Through this snowballing method, several methods were identified and mapped to the four stages of the co-creation process (Planning, Conducting, Evaluating and Reporting). When a method was identified, but there were insufficient details on the method, an additional search was conducted to identify a paper that contains more description information about the method. Finally, the sourced methods were grouped based on their similarities to each other, which are referred to as *Categories* throughout this guideline.

For ease of use, you will find the method category and suggested methods per stage and principle in the text below. It is important to note that the methods found throughout this guideline are a small sample of the total methods that are anticipated to be relevant for the co-creation process. Therefore, we encourage you to test out these methods, but you're also welcome to use other methods that you find relevant but are not mentioned in this version of the guideline. Finally, for more information on the next steps of the methods development process, please reference Section 9, Next Steps.

6. Implementation and Evaluation

The Current Landscape

Why do we need further research in implementation and evaluation for co-creation? The landscape of implementation science is extremely diverse in purposes, theoretical orientations and methods and has evolved critically in the past decades. Bringing conceptual clarity to the implementation elements of 1) the ground-enactment and/or participation by the end-users, 2) conditions and contexts that affect implementation, and 3) alignment of outcomes have been considered central to the purpose of bringing implementation science studies forward (Century and Cassata 2016).

> **Some current definitions of implementation frameworks**
>
> Implementation can be defined as the process of putting to use or integrating a policy within a setting or a system, or the process of maintaining the use and capacity of a policy (Moullin et al. 2015). Frameworks can be intended as models and theoretical approaches that are "a graphical or narrative representation of the key factors, concepts, or variables to explain the phenomenon of implementation, and as a minimum needed to include the steps, strategies, and factors for implementation" (Moullin et al. 2015, 3).
>
> An implementation framework can be intended as "strategic or action-planning models that provide a systematic way to develop, manage, and evaluate interventions" (Tabak et al., 2012).

When conducting a preliminary review of the literature into implementation purposes and characteristics, we realised that implementation in co-creation behaves differently than in classic, linear models of intervention. In traditional understandings of implementation research, the aim is to help intervention teams to understand what, why, and how interventions that were created in a controlled setting or ordinary practice, can work in real-world settings. Implementation science is therefore meant to help transfer created innovations into real-life contexts and to test approaches to improve their transfer and application.

Implementation and Evaluation in Co-creation

On the contrary, in co-creation, services, activities and interventions are intended to be designed together with, or to highly rely on, the intended users and participants. Unlike classic understandings, implementation research, in co-creation, aims to understand and work together with real-world conditions, rather than trying to control for these conditions or to remove their influence as causal effects. This implies working with populations that will be affected by an intervention, rather than selecting beneficiaries who may not represent the target population of an intervention (such as studying healthy volunteers or excluding patients who have comorbidities).

Therefore, if in co-creation, interventions are meant to be designed in a real-world setting and with participants from the very beginning, the relationship between intervention development and implementation begins to fade and to behave differently than in more linear settings of implementation.

So far, there is no "precise or systematic framework to plan or develop co-created public health interventions and evaluate their effectiveness and impact" (Leask et al., 2019). This highlights the need to look further into a potential redefinition of implementation science for co-creation, while also studying existing implementation and evaluation frameworks to assess whether they might, or not be, appropriate to the setting of co-creation.

While we are building a definition for implementation that circumscribes to co-creation settings for public health, Nielsen's work might be useful to help you navigate the complex world of implementation.

(Nilsen 2015) classification of implementation frameworks:

Process models: Frameworks that "specify steps (stages, phases) in the process of translating research into practice, including the implementation and use of research. Process models aim to describe and/or guide the process of translating research into practice. An action model is a type of process model that provides practical guidance in the planning and execution of implementation endeavours and/or implementation strategies to facilitate implementation" (Nilsen 2015, 3).

Determinant frameworks: Frameworks that "specify types (also known as classes or domains) of determinants and individual determinants, which function as barriers and enablers (independent variables) that influence implementation outcomes (dependent variables). Some frameworks also specify relationships between some types of determinants. The overarching aim is to understand and/or explain influences on implementation outcomes, e.g., predicting outcomes or interpreting outcomes retrospectively" (Nilsen 2015, 3).

Classic theories: "Theories that originate from fields external to implementation science, e.g., psychology, sociology, and organisational theory, which can be applied to provide the understanding and/or explanation of aspects of implementation frameworks" (Nilsen 2015, 3).

Implementation theories: "Theories that have been developed by implementation researchers (from scratch or by adapting existing theories and concepts) to provide the understanding and/or explanation of aspects of implementation" (Nilsen 2015, 3).

Evaluation frameworks: Frameworks that "specify aspects of implementation that could be evaluated to determine implementation success" (Nilsen 2015, 3).

Implementation and Evaluation in this Guideline

The implementation and evaluation frameworks included here have been sourced through a literature review. We have selected frameworks that preliminary seem to adhere best to the context of co-creation because taking highly into consideration multiple stakeholders' engagement, iteration, and

evaluation. Frameworks have then been placed within the various Leask's stages with the hope they would help you ask the right questions and consider new, relevant elements in each step.

7. Stages of the Co-creation Process

This section of the guideline goes through the (preliminary) stages of the co-creation process, which have been defined as described by Leask and colleagues (Leask et al., 2019). Each stage includes related principles, recommended evaluation and implementation frameworks, as well as suggested categories and types of methods.

Stage 1: Planning your Co-created Intervention

When academic researchers are initially planning the co-creation, two main principles require consideration: 1) Framing the aim of the Study; and 2) Sampling.

Principle 1: Framing the Aim of The Study

Framing the aim of the study systematically can help ensure the co-creation process generates trustworthy evidence (Leask et al., 2019).

When planning your intervention, remember:

- To ensure transparency with the co-creators about the aim of the process (Leask et al., 2019);
- To frame the aim of your study or project in a systematic way to help ensure the process generates scientifically trustworthy evidence (Leask et al., 2019);
- To narrow your project aims to increase the success chance of your co-creation process (Leask et al., 2019);

- That the non-academic co-creators will influence what the intervention looks like (Leask et al., 2019);
- When addressing a complex problem, end-users and other stakeholders may collaborate with academic researchers to define the objectives (Leask et al., 2019);
- To narrow to specified health behaviour and population (Leask et al., 2019);
- To define what part of the problem the process will address by expressing the specific objective of the process (Leask et al., 2019); and

- To identify who the co-creators are, as this will be a combination of service providers and end-users.

Frameworks for Framing the Aim of the Study

Frameworks that can help you frame your study:

1. **PARIHS framework:** The PARIHS framework values and considers the "quality of the evidence." Grounding an intervention on evidence-based considerations is one of PARIHS' three key constructs. They argue evidence encompasses codified and uncodified sources of knowledge, including research evidence, practitioner experience, community preferences and experiences, and local information (Kitson et al., 2008). The original article from Kitson and colleagues, describing the framework can be found here. A useful, synthetic overview of the framework is offered by McMaster University here.

2. **The PICO framework:** The Cochrane (PICO) process, signifying the patient or problem (P), intervention (I), comparison (C) and outcome (O). This framework may help you describe it in one sentence (Schardt et al., 2007). A useful, online introduction to the PICO framework has been developed by Glasgow Caledonian University and is available here.

3. **The PRODUCES framework:** The framework developed by (Leask et al., 2019) suggests you consider the following elements and ask the following questions when planning your co-creation process:

   - **Pr**oblem: What is the reason for the process?
   - **O**bjective: What is the aim of the process?
   - **D**esign: What specific participatory methodology is used for co-creation?
   - (End-) **U**sers: Who will use the co-created intervention?
   - **C**o-creators: Who is engaging in the process?
   - **E**valuation: How is success measured?
   - **S**caling: How can the co-created intervention be scaled to other contexts?

Frameworks that can help you reflect upon your intervention context:

1. **The PROCEDE/PRECEED model:** The PRECEDE-PROCEED model is a comprehensive structure for assessing health needs for designing, implementing, and evaluating health promotion and other public health programs to meet those needs. PRECEDE provides the structure for planning a targeted and focused public health program. PROCEED provides the structure for implementing and evaluating the public health program. The framework can be consulted online here.

2. **TDF (Theoretical Domains Framework):** The TDF is a comprehensive framework a researcher can use to identify factors (i.e., barriers and facilitators) that may influence behaviours and

includes considerations around social and environmental factors. It is said to be able to serve as 1) a planning tool to help identify determinants (and appropriate techniques) to address previously identified barriers and facilitators to positively impact outcomes of an implementation strategy; and, 2) as an evaluation tool to assess how effective intervention was at targeting specific behaviour determinants and/or to retrospectively identify factors that contributed to the success and/or failure of an intervention (Nilsen 2015).

It is said to provide a useful and straightforward guideline on how the TDF framework can be used to assess implementation problems and support intervention design (Atkins et al., 2017). The article can be accessed via [this link.](#)

Frameworks that can help you choose your facilitation methods:

1. **The PARIHS diagnostic and evaluation grid:** The PARIHS framework emphasizes the need for appropriate facilitation to improve the likelihood of success and its diagnostic and evaluative grid has been argued to be useful for choosing the facilitation methods needed (Harvey and Kitson 2016). The framework has been argued to be useful "to identify critical evidentiary (e.g., patient experience, information from the local setting) and contextual (e.g., leadership, receptive context) elements that may impact EBP implementation" (Moullin et al., 2020, pg. 7). This framework is intended to support the development of implementation strategies, which heavily rely on facilitation. The PARISH diagnostic and evaluation grip might prove useful when reflecting upon the facilitation methods needed (Kitson et al., 2008). The PARISH diagnostic and evaluation grid can be found in Figure 1 of Kitson et al., (2008) paper [here](#).

Frameworks that can help you define your target behaviour:

1. **The COM-B model:** is part of the Behavioural Change Wheel so it closely aims to support design teams in understanding what will bring about the desired behaviour change in the target group's Capability, Opportunity and/or Motivation to engage in the behaviour. The framework is highly based on behavioural change theories and beliefs (Michie, van Stralen, and West 2011). Social Change UK has developed an introduction leaflet to the COM-B model available as a pdf [here](#).

Method Categories for Framing your study:

1. **Assessment:** These methods can be used to further assess your problem or the need for the co-creation process.

a. <u>Published evidence synthesis</u>: a method for identifying the existence of a problem. It can challenge assumptions and broaden discussions to include data and divergent perspectives. Sourced from (O'Cathain et al., 2019).

b. <u>Needs Assessment:</u> a method for identifying the existence of a problem, or what you will try to achieve with your project. Sourced from (O'Cathain et al., 2019).

2. **Establishing the co-creation Team:** These methods help you define the type of co-creation team you would like to establish, as well as identify the skills of the co-creators needed to finalize the task.

   a. <u>The 'editorial rights' team / Development team</u>: a group of co-creators that can make final decisions about the intervention. This group should include developers and members of the target population, and it is recommended to include a variety of disciplines and expertise in the team; all members should interact directly with members of the target population. Sourced from (O'Cathain et al., 2019).

   b. <u>Establish an action group:</u> this group should be comprised of stakeholders who can use their relevant expertise to build the solution to the problem identified. Sourced from (O'Cathain et al., 2019).

   c. <u>Establish a planning group:</u> this group should focus on bringing a variety of stakeholders together, and collaborative working with the target populations and those who will deliver the intervention. This is a method to ensure members of the target population have decision-making rights throughout the co-creation process. Sourced from (O'Cathain et al., 2019).

3. **Fieldwork:** A group of methods intended for gaining a deeper understanding of the problem; identify any other factors that can impact the performance of an intervention.

   a. <u>Media portrayal of the co-creation purpose</u>: a method for gathering printed media images, such as from newspapers and magazines, which convey the purpose of the process. Using visual aids as discussion tools in the co-creation process has been identified as an effective tool to enhance the effectiveness of co-creators. Sourced from (Leask et al., 2019).

   b. <u>Informal discussions w/ people outside the co-creation group</u>: a method to encourage co-creators to informally discuss process topics with non-co-creator stakeholders. It can provide a fresh perspective on the topic and enhance ideas and is an informal

form of snowball sampling that may increase the generalisability of findings. Sourced from (Leask et al., 2019).

4. **Observation:** Observation methods can be used for obtaining the views of the target population; to help articulate the problem fully or to understand the problem and the context in which the intervention will operate.

    a. <u>Participant observation</u>: a method for using observation of the direct target group is recommended as well as obtaining the views of the target population because people may not be able to articulate the problem fully. Sourced from (O'Cathain et al., 2019).

    b. <u>Non-participant observation</u>: a method for understanding the problem and the context in which the intervention will operate. The observation may be of service delivery where the intervention will occur. Sourced from (O'Cathain et al., 2019).

5. **Research**: The use of research methods can uncover more vital information about the target population, potential co-creators, past experiences with similar interventions, and needs that may affect the success of the co-creation process and / or the co-created intervention.

    a. <u>Primary Qualitative Research</u>: a method conducted with iterative qualitative research that uses diverse samples and open questions to explore people's experiences and needs. This method uses patients' narratives or archives of patient experiences and observation, consultation with stakeholders, and use of patient and public involvement. Sourced from (O'Cathain et al., 2019).

    b. <u>Asset Assessment:</u> a method to determine the strengths of the community in which an intervention will take place. Sourced from (O'Cathain et al., 2019).

    c. <u>A systematic review of quantitative evidence of effectiveness:</u> a method to identify what has worked or not worked for a particular intervention. It can be used to identify evidence of the effectiveness of interventions for these problems. Sourced from (O'Cathain et al., 2019).

Principle 2: Sampling

The sampling process of recruiting end-users and all necessary expertise as co-creators. The representation of relevant stakeholder groups is dynamic and there are different methods for sampling (Leask et al., 2019).

When planning for sampling for co-creators remember:

● Sampling in the co-creation process will be different in scope and nature from linear implementation models, as it selects beneficiaries who may not represent the target population of an intervention but instead intended to build a sampling that is representative of the populations that will be affected by an intervention.

● Leask and colleagues argue that the end-users may be defined specifically or broadly and this might impact the outcome. He explains that defining the end-users, for example, as "older adults" will imply that your co-creation is addressing many other sub-groups while defining them as "ambulatory, community-dwelling older adults" would narrow your target audience (Leask et al., 2019).

● Leask and colleagues suggest end-users' characteristics to take into consideration include: age, gender, physical condition, medical history, socioeconomic status, and ethnicity. He suggests that a representative sample from the end-user group should be recruited as co-creators during the development process and this may include sampling across different characteristics to ensure heterogeneity (Leask et al., 2019).

● Leask and colleagues describe the sampling for recruiting co-creators as a process with a dual purpose, 1) ensure a representative sample of end-users are recruited as co-creators so the co-created outcome can be utilised by that group or scaled to a population level; 2) ensure there is a representation of all necessary expertise from relevant stakeholder groups (Leask et al., 2019).

Method Categories for Sampling:

1. **Mapping:** These methods support gaining a better understanding of the system you may be working within, different relevant stakeholders, as well as tools for building a theory of change for your co-creation process.

   a. Whole system mapping / participatory systems mapping: this method was developed as a way to respond to complex systems by the production of a causal map of a system that is designed by a diverse set of stakeholders. This method also allows for network analysis with subjective information from stakeholders. Sourced from (Wilkinson et al., 2021) and (Barbrook-Johnson and Penn, 2021).

   b. Stakeholder mapping: this method can be used to identify the individuals, groups, or organisations affected by a project or who affect its outcomes. Sourced from (Skarlatidou et al., 2019)

2. **Sampling / Recruitment:** represents a different set of sampling methods for recruiting co-creators, end-users, or the target population. The selection of the specific sampling methods will depend on the aim of your co-creation process.

   a. Convenience sampling: a method to ensure the recruited co-creators are committed and will actively engage in the process. This method is a type of non-probability or non-random sampling where members of the target population that meet certain practical criteria, such as easy accessibility, geographical proximity, availability at a given time, or willingness to participate are included in the study. Sourced from (Leask et al., 2019) and (Alkassim et al., 2016).

   b. Maximum variation sampling: a method for finding end-users who cover the spectrum of perspectives, including typical and extreme cases. Sourced from (Leask et al., 2019).

   c. Opportunistic sampling: a method for recruiting additional stakeholders as co-creators throughout the co-creation process. When using the method, the representation of relevant stakeholder groups is dynamic. Sourced from (Leask et al., 2019).

   d. Purposeful or Judgement sampling: a method to ensure a representative sample of end-user and relevant stakeholder co-creators are recruited. It is the deliberate choice of a participant due to the qualities the participant possesses. This is a non-random method that does not need underlying theories or a set number of participants. It is typically used in qualitative studies. Sourced from (Leask et al., 2019) and (Ilker, 2016).

   e. Stratified sampling: a method for sampling across characteristics of interest to create a heterogeneous group with diverse experiences. Sourced from (Leask et al., 2019)

Stage 2: Conducting your intervention

When academic researchers conduct the co-created intervention, two main principles require consideration: 3) Manifesting Ownership and 4) Defining the Procedure.

Principle 3: Manifesting Ownership

Providing co-creators with a sense of ownership can improve creativity, practice, and knowledge production. Leask and colleagues recommend a set of recommendations for providing ownership, such as 'state of ownership,' 'Right of ownership,' and 'Act of Ownership' (Leask et al., 2019).

A Framework that can help you manifest ownership:

1. The PRODUCES framework. Leask and colleagues suggest conducting your intervention by considering the following: Stating your ownership by using the method of branding the group and setting out the status of each co-creator at the beginning. You might want to affirm for instance that all co-creators have equal standing in the group (Leask et al., 2019). They also suggest that ownership may be acquired incrementally over several workshops through an empowerment process of facilitating openness and perceived control of the process. Key concepts to remember: 1) Defining the right of ownership; and 2) Act upon ownership.

Methods for Manifesting Ownership:

Some methods can be used to manifest ownership throughout the conducting stage. This is clearly in alignment with Principle 3.

1. <u>Branding the group</u>: this method aims to manifest ownership by branding the group. Sourced from (Leask et al., 2019).
2. <u>Identifying the rights and responsibilities of the group</u>: this method aims to manifest ownership by outlining group rights and responsibilities. All co-creators have the right and equal status within the group and their responsibility to contribute their ideas. Sourced from (Leask et al., 2019).

Principle 4: Defining the Procedure

Procedural components can be used to facilitate a co-creation process (Leask et al. 2019).

Method Categories for Defining the Procedure:

1. **Brainstorming / Mapping:** this currently contains one method that is also a mapping technique, *Concept Mapping*.

   a. <u>Concept Mapping</u>: This method uses a mixed-method approach to enable a group of people to articulate and depict graphically a coherent conceptual framework or model of any topic or issue of interest. It is a mixed method (structured process) designed to enable a group of people to map their ideas for a topic and designed to enable a group of people to articulate and depict graphically a coherent conceptual framework or model of any topic or issue of interest. Sourced from (Bruder et al., 2020) and (Trochim et al., 2017)

2. **Categorization Matrix:** this currently contains one method, the *Optimized Honeycomb Model for User Experience*.

   a. Optimized Honeycomb Model for User Experience: this method is a model, which is comprised of qualitative content analysis with a deductive-inductive approach. It's based on the UX Honeycomb model, which is a visualisation tool created by Peter Morville back in 2004. It is typically used as a teaching tool, to explain the basics of UX (User Experience), but it can also be used as a checklist for designers. Sourced from (Mansson et al., 2020).

3. **Dialogue:** This represents a group of methods used for generating fruitful and inclusive dialogue with the co-creators and /or target group.

   a. Dialogic Literary Gatherings (DLG): this method is an educational intervention for the collective creation of knowledge and meaning based on the reading of the best literary creations of humanity and the subsequent dialogue between all the participants. Additionally, reading quality literary works increases the capacity to better understand others, facilitating empathy and pro-social behaviour. Sourced from (Ruiz-Eugenio et al., 2021).

   b. Dialogue cafés: this method aims to engage the co-creators in discussions. This method generates new ideas, enables joint decision-making on key strategic issues, discovers new collaboration, and identifies steps for further exploration or implementation. It was created by taking elements from world cafés and dialogue conferences. Sourced from (Lund et al., 2021).

   c. Involvement Matrix: this method can be used prospectively to discuss possible roles of patients in different phases of projects, and retrospectively to discuss whether roles were carried out satisfactorily. This method was developed by a co-creation of experienced experts with researchers. Sourced from (Dirk-Wouter et al., 2020).

   d. World cafés: this method follows a principle of good conversation, where all co-creators are given the chance to talk about things that matter to them. This method follows 2 principles: 1) people want to talk together about things that matter to them; 2) if they do, they could create collective power. Sourced from (Lund et al., 2021).

4. **Fieldwork:** Some Fieldwork methods are used in the planning stage, but this category contains one method of the conducting stage, *Field Testing of the Prototype*.

a. <u>Field Testing of the Prototype</u>: This method is also a form of prototyping that allows the end-users to use the prototype in their typical real-world setting to identify any areas for improvement. Therefore, it can also be seen as a type of evaluation method during the conducting stage. The method provides co-creators with an example of what the final intervention may be like and allows them to use the prototype in their typical real-world setting and identify how it could be improved and will inform the implementation of the intervention itself. Sourced from (Leask et al., 2019).

5. **Interview:** These methods are mainly used for evaluating, but some methods can also be used in the conducting stage. These methods aim to source further input from the target group and/or co-creators. The specific type of interview and aim will vary based on the desired outcome.

   a. <u>Semi-structured interviews</u>: this method is an in-depth, qualitative interview where the co-creators are requested to answer pre-set open-ended questions and are utilized extensively in an interviewing format with an individual or sometimes even with a group. Sourced from (Popp et al., 2020) and (Jamshed, 2014).

   b. <u>Stakeholder interviews</u>: this method is for gathering input from stakeholders relevant to the study; usually open interviews without a particular framework. The interviewees should be treated as deliberative partners rather than research subjects, and rough causal theories about how co-creation was working. Sourced from (Sheriff et al., 2019).

   c. <u>Qualitative interviews</u>: qualitative research interviews are either unstructured, semi-structured, lightly structured, or in-depth. Unstructured interviews are generally suggested in conducting long-term fieldwork and allow respondents to let them express themselves in their ways and pace, with a minimal hold on respondents' responses. Sourced from (Jamshed, 2014).

6. **Observation:** Observation methods are mainly used for planning, but this category represents one method that can be used for observation in the conducting stage, *Participant Observation*.

   a. <u>Participant observation</u>: a method for using observation of the direct target group is recommended as well as obtaining the views of the target population because people may not be able to articulate the problem fully. Sourced from (O'Cathain et al., 2019).

7. **Prototyping:** This category represents a different type of prototyping method to test your concept and identify any areas for improvement. Prototyping is a complex development

task/process where a design teams implement ideas into tangible forms. It is important to note that prototypes can change rapidly after stakeholder feedback.

    a. <u>Concept prototyping:</u> this method develops potential concepts to be tested as a prototype. Prototyping is a complex development task/process where design teams implement ideas into tangible forms. Sourced from (Velazquez et al., 2021).

    b. <u>Product prototyping:</u> this is a method for prototyping a physical product or an intervention. Sourced from (Velazquez et al., 2021).

8. **Reflection:** Reflection has been used as a method for research processes and experiences, in ways that recognise the assumptions, frameworks and patterns of thought and behaviour that shape thinking and action. This category contains some methods that can be used for reflecting during the co-creation process.

    a. <u>Toxic River activity</u>: this method creates a process of critically reflecting on the team's success (or failure) to complete the activity/game. The group is asked to reflect on three key themes: 1) setting the agenda, 2) taking people along, and 3) doing it the right(s) way. Sourced from (Bilous et al., 2018).

    b. <u>Participatory drawing method</u>: this method aims to create a map of the issues that needed to be addressed. Participatory drawing can allow participants to express themselves in alternative ways that did not prioritise or privilege the written or spoken word. Sourced from (Bilous et al., 2018).

    c. <u>Video recordings</u>: this method provides an unstructured space where the co-creator can video record stories and ideas in response to the various module topics. Sourced from (Bilous et al., 2018).

9. **Storytelling:** This category of methods aims to capture different voices and empower participants, as well as document and reflect reality. It is also a way of representing individual narratives.

    a. <u>Digital story-making / stories</u>: this is a method for representing individual narratives. It uses a 3-5 minute visual narrative synthesizing images, video, and audio recordings of voice, music, and text to create compelling accounts of experience. Sourced from (Parsons et al., 2015).

    b. <u>Photovoice</u>: this method aims to empower co-creators, who are often from socially marginalized groups and are unable to articulate their thoughts appropriately into words. By utilising photographs taken and selected by participants, respondents can

reflect upon and explore the reasons, emotions and experiences that have guided their chosen images. This is one of the most published methods. Sourced from (Haffejee, 2021).

Stage 3: Evaluating Co-Creation

When academic researchers are evaluating a co-created intervention, two main principles require consideration: 5) Evaluating the co-creation process; and 6) Evaluating the co-created intervention (Leask et al., 2019).

Principle 5: Evaluating the co-creation process

What is Evaluation and What are We Evaluating?

When looking into evaluation frameworks, we found a considerable difference in the objects of evaluation. While authors in the past have seen evaluation mostly as an impact evaluation to undertake after the programme, recent authors are also making a call for process evaluation (Carroll et al., 2007; Leask et al., 2019; Moore et al., 2015).

Evaluating the process can enable you to:

- Assess fidelity: Whether the intervention was delivered as intended (Craig et al., 2008)
- Assess dose: The quantity of intervention implemented (Moore et al., 2015).
- The reach of intervention: Whether the intended audience encounters the intervention and how (Moore et al. 2015).
- Understand the mechanisms of impact: how the intervention produced change (Moore et al., 2015).
- Enable scaling (Leask et al., 2019): When the developed solution is used to target a wider population to achieve greater impact.

The need for formative evaluation in co-creation has been argued to be crucial to co-creation processes. Van Dijk-de Vries (2019) argues that "to ensure that the end user's perception is continuously captured, researchers should assess stakeholders' needs and involvement in the process throughout the implementation so that, in case of adjustment is needed, implementation mechanisms and ways can be undertaken. If an evaluation is not conducted from an earlier stage, it becomes complex to potentially adapt interventions".

An evaluation is intended to be formative when "data are fed back to the implementation team and/or staff in the target system during the study to adapt and improve the process of implementation during the protocol" (Bauer et al., 2015).

Continuous reflection and iteration:

As highlighted by Leask et al., 2019, 'iteration' is defined as a cyclical process, which happens at all stages of the co-creation, starting at the very beginning, from your pre-planning stages until your last stage of the process. Understanding the evaluation as iterative breaks the linearity of the process with the scope to ensure participants' needs and beliefs are represented.

Moore and colleagues similarly argue that "as co-creation is an iterative process, evaluation may be embedded throughout the process to ensure the process results in an outcome that is representative of co-creators opinion and suitable, tailored and valid for end-users" (Moore et al., 2015, pg. 8).

Therefore, **when evaluating the co-creation process** remember to consider evaluating the process by assessing the co-creator's satisfaction and ensuring the developed intervention is representative of the co-creators needs (Leask et al., 2019).

Frameworks that can help you evaluate your interventions:

- **The APEASE evaluate framework:** The Behaviour Change Wheel (BCW) lists criteria to apply when making evaluation judgements under the acronym, APEASE: Acceptability, Practicability, Effectiveness, Affordability, Side-effects, and Equity (Michie, van Stralen, and West 2011). A description of each criterion can be found in the guideline developed by Public Health England on how to achieve Behaviour Change (West, R. et al., 2019, pg. 16). An informative one-page factsheet on the APEASE evaluation framework produced by Unlocking Behavioural Change can be found here.

Principle 6: Evaluating the co-created intervention

Leask includes this principle about the assessment of the effectiveness of the co-created intervention. Some projects evaluate the effectiveness of the intervention by measuring the outcomes, however, these measurements do not control for community operating factors (Leask et al., 2019).

When evaluating the co-creation intervention Leask and colleagues also suggest you may want to consider evaluating your outcomes by including them in a clinical trial (Leask et al., 2019).

Finally, empowerment and capacity building might be important elements for you to consider when evaluating the co-created interventions.

Methods for Evaluation:

<u>What type of evaluation data?</u>

In formative evaluation "data are fed back to the implementation team and/or staff in the target system during the study to adapt and improve the process of implementation during the course of the protocol" (Bauer 2015). Data for formative evaluation can include qualitative and quantitative data and the choice of preferred methods for co-creation would depend on developed theories and principles for co-creation settings.

The following are suggested methods categories for evaluation of the intervention or process:

1. **Assessment:** These methods are mainly used in the Planning Stage, but this category represents one method that can be used for evaluation.

    a. <u>Respondent Validation</u>: This method aims to validate responses from respondents of interviews or surveys — to ensure the interpretation by the facilitator was correct. This can be done using extended focus group discussions where co-creators are presented with interpretations of the data as preliminary findings, and this functioned as a basis for discussion. It was very important to check that what I was inferring [was] what people were meaning to say. These were also recorded and transcribed. Sourced from (Leask et al., 2019) and (Holland, 2018).

2. **Interviews:** This category represents different types of interview methods that can be used to evaluate written, verbal, or visual communication material to assess the co-creation process, or the co-created intervention.

    a. <u>Qualitative interviews</u>: qualitative research interviews are either unstructured, semi-structured, lightly structured, or in-depth. Unstructured interviews are suggested in conducting long-term fieldwork and allow respondents to let them express themselves in their ways and pace, with a minimal hold on respondents' responses. Sourced from (Jamshed, 2014).

    b. <u>Qualitative content analysis:</u> this method is for systematically evaluating written, verbal, or visual communication material - to keep the systematic nature of the content analysis without quantification. Raw data from transcripts of an audio recording of sessions or interviews.

3. **Reflection:** Reflection has been used as a method for research processes and experiences, in ways that recognise the assumptions, frameworks and patterns of thought and behaviour that

shape thinking and action. This category contains some methods that can be used for evaluating the co-creation process.

    a. <u>Co-created River</u>: this is a method used in establishing the co-creation principles and a way for the co-creators to evaluate the co-creation process. Participants are first asked to record on red and yellow sticky notes their challenges (red) and successes (yellow). These were placed in chronological order on a long piece of paper on the workshop space floor, with participants allowed to read and respond to each other's notes. Sourced from (Bilous et al., 2018).

    b. <u>Graffiti wall</u>: this is a method for asking co-creators to respond to particular questions or ideas, as well as providing more flexible space. Sourced from (Bilous et al., 2018).

4. **Questionnaires / Surveys:** This category represents different survey types you can use to assess your target population and/or your co-creators experience of the co-creation process or the co-created intervention.

    a. <u>Online survey</u>: this is a quantitative or qualitative surveying method. Various online surveying tools can be used to execute this method. Sourced from (Chen et al., 2018).

    b. <u>Process evaluation questionnaire</u>: this method is for the evaluation of individual, collective or management perceptions and actions in implementing any intervention and their influence on the overall result of the intervention. Sourced from (Abildgarrd et al., 2016).

Stage 4: Reporting

Reporting Template

There are currently no related principles for the reporting stage. However, this is subject to change based on further research. Consequently, the PRODUCES Framework has been identified as the most suitable way to report back on your co-created intervention and the co-creation process. In the same way, PRISMA is used as a model to report on systematic reviews, the PRODUCES framework can serve a similar purpose in co-creation.

You can find the PRODUCES+ Reporting Template adapted from Leask and colleagues' paper in Annexe 1. This template can serve as a starting point for reporting on your co-creation process, intervention, and this guideline. Therefore, we encourage you to use this template to report on your experience

with using this guideline in your co-creation process, so we can also use your report to improve this guideline and expand its content and structure.

Method for Reporting:

One example of a reporting method is *Our Voice* from citizen science used as a citizen science-based community activation and engagement model. However, methods for reporting are currently limited, so at this stage, it is recommended to follow the PRODUCES+ reporting template mentioned above.

Scaling a co-created intervention

Following the four stages of the co-creation process, it is important to consider how the co-created intervention can be scaled. For this guideline, scaling has been defined as the intention to transfer a developed solution to a wider and/or different target population to achieve a greater impact.

How Might Scaling Look?

Scaling might prove particularly challenging in co-creation as the intervention is intended to be designed locally and with individual stakeholders. This "tailored" intervention process might be more difficult to replicate when it provides a highly contextual solution. Scaling and scaling methods is an aspect that has been understudied in co-creation literature and few resources exist on the topic. Therefore, this will be investigated further, with potential findings included in the next iteration of this guideline. For now, we recommend considering the following three models from scaling proposed by Leask and colleagues.

Leask and colleagues define three types of scaling models:

1. <u>Distributed model:</u> "In the distributed model, the design and implementation of each intervention are developed and initiated locally in collaboration with or by local actors specifically for this local group and setting. In this model, local solutions from multiple locations are developed independently and clustered to reach a larger population. Here, the actual co-creation process can be used as an intervention itself to assess whether engaging in the development process has influenced the end-users targeted health behaviour" (Leask et al., 2019, pg. 12).

2. <u>Generalisable model:</u> "The generalisable model is to develop, in collaboration with a sample of stakeholders and representative end-users of a larger population, a tailored intervention that can be scaled and implemented in a larger group" (Leask et al., 2019, pg. 12).

3. CASCADE Model: In Leask and colleagues' description of the cascade model, "one local intervention is designed and implemented locally in collaboration with or by local stakeholders and end-users specifically for this local group and settings. This solution is then transported and adapted in collaboration with or by a new group of local stakeholders and end-users for the same purpose, in different settings" (Leask et al., 2019, pg. 12).

Frameworks that can help you consider the scaling of your intervention:

The ADAPT Framework: is used for reporting adaptations and modifications to evidence-based interventions (Moore et al., 2021). The article can be found here.

8. Conclusion

This first iteration of a guideline offers a mapping of some existing resources, frameworks, and methods that we believe are relevant for executing the co-creation process. Furthermore, this draft guideline begins the important process of identifying gaps, indicating where future research and development are required. Finally, this guideline should be considered a prototype to be assessed in the field by the end-users, and co-creators. In this way, this guideline is being designed and developed in a way that mirrors its structure, co-creating a co-creation guideline.

9. Next Steps

Co-creation Methods Research

Since this guideline contains methods that were identified through a snowballing method, beginning with Leask and colleagues' paper, the first next step to further develop the methods provided in this guideline is conducting a systematic inventory of methods appropriate for use throughout the co-creation. This will be done using the recently established Health CASCADE Co-creation Database (Loisel & Agnello et al., 2022).

Furthermore, once this online systematic inventory is completed. A crowd-sourcing approach will be executed using Health CASCADE's social media channels and networks, and with co-creation practitioners, to source their methods, and to evaluate and source any missing or new methods.

Co-creation Implementation and Evaluation Research

Implementation research – A systematic review

We will register a protocol for a systematic review "Protocol of a meta-narrative systematic review of implementation and evaluation frameworks for public health interventions" into PROSPERO and aim to complete the systematic review in December 2022. You can read the protocol here.

Through this meta-narrative systematic review, we seek to understand the attributes of relevant implementation and evaluation frameworks as a first step to developing a framework to guide the implementation and evaluation of co-creation in public health. The review will allow us to clarify whether, within our research project, we would need to: 1) work towards a redefinition of implementation science in the context of co-creation; and 2) confirm or confute the need for the design of a new implementation framework for co-creation in public health.

If the need for a new implementation and evaluation framework emerges, synthesising and analysing existing frameworks would help us assess and select relevant components, such as key steps and key constructs, appropriate for the implementation and evaluation of co-created public interventions.

Evaluation Research

While existing evaluation frameworks will be identified through the systematic review, we will aim to shape and define evaluation for co-creation in its principles.

By consulting teams that have already conducted co-created interventions and in a co-creative way, we aim to 1) reflect upon the nature of evaluation, by assessing the dichotomy between process and impact evaluation and qualitative and quantitative assessment; 2) understand how iteration and formative evaluation would look like in co-created interventions; 3) give a preliminary indication of how an impact and a process evaluation would be performed; 4) look further at how the concepts of capacity building, empowerment and ownership contribute to the evaluation of a co-created intervention. In terms of the adaptation of co-created interventions, we are planning to conduct a study on the usability of the ADAPT framework for assessing the context of the transferred solution.

Health CASCADE Feedback

Most importantly, your feedback on the usability and content of this guideline is paramount for its success of this guideline. Therefore, in 2022, we will engage the wider Health CASCADE network to further develop this guideline through the execution of participatory workshops, expert interviews,

and review of your Reporting Templates (accessible in Annexe 1). If you have further reflections that are not captured in these different platforms, then please reach out directly to Danielle Agnello (about methods) at danielle.agnello@gcu.ac.uk or Giuliana R. Longworth (about implementation and evaluation) at giulianaraffaellal@blanquerna.url.edu.

Annexe 1: PRODUCES+ Reporting Template

The following reporting template is adapted from Leask and colleagues' publication, Reporting Checklist — Table 6. This will serve as a starting point for further development of a reportable template for this Guideline. Future iterations of this template may include details on the proposed frameworks and methods per stage, reporting on the use of methods, well as any additional or revised stages that may arise. Your use and feedback on this template are very valuable for the evolution of this guideline. Therefore, we encourage you to use this adapted checklist to report on your experience with using this guideline in your co-creation process, so we can also use your report to improve this guideline and expand its content.

Stage	Checklist Item	Response	Example
Stage 1: Planning			
How was the aim of the study framed?	Use each element of the PRODUCES framework (PRoblem, Objective, Design, (end-) Users, Co-creators, Evaluation and Scalability) Which frameworks did you use?		Utilising PAAR (Design) to develop (Objective) and test (Evaluation), with academic researchers and older adults (Co-creators), a generalisable (Scalability) intervention to reduce sedentary behaviour (PRoblem) in community-dwelling older adults (end-Users).
Planning Methods	Which methods did you use? Why?		Example method: Opportunistic sampling or Asset Assessment.
	Were there any methods you used that are not mentioned in this guideline? If yes, please list them:		
Planning Frameworks	Which frameworks did you use? Why?		Example frameworks: PARIHS or PICO framework

	Were there any frameworks or models you used that are not mentioned in this guideline? If yes, please list them:		
Explain the sampling procedure	Explain the criteria used for sampling:		Convenience sampling and maximum variation sampling. End-users were 65+ years of age, community-dwelling, able to ambulate independently, able to give informed consent, able to attend a minimum of 5 meetings
	In what settings did sampling occur?		End-user co-creators were recruited from the university older adult database
	How many individuals engaged as co-creators (academic/non-academic stakeholders)?		Four university researchers and 11 community-dwelling older adults
	Describe the co-creators (demographics/groups/ other characteristics of interest)		Of the end-user co-creators, 11 participants (5 men), average age = 74 years. Average medications = 5.
Stage 2: Conducting			
How was ownership manifested?	Explain the methods used to manifest ownership (for example, branding the group, identifying the rights and responsibilities of the group):		Co-creators branded as GrandStand Research Group. Co-creators provided t-shirts, lab books, bags, and pens with the GrandStand logo. All co-creators told of their right to equal status within the group and their responsibility to contribute their ideas.
Procedure Components	What level of participation was there		Academic researchers and end-users strove

	from the co-creators?		to have equal participation. All co-creators asked for their input on each discussion point.
	How was the overall aim presented?		The overall aim is highlighted at the beginning of the process and the beginning of each workshop.
	How was the purpose of each meeting presented?		The purpose of each meeting is identified at the beginning of the meeting.
	What were the rules and responsibilities of participation agreed upon?		Individuals are told of their right to equal status within the group and to contribute their ideas.
Conducting Methods	Which methods did you use? Why?		Example methods: Concept Mapping or Dialogic Literary Gatherings.
	Were there any methods you used that are not mentioned in this guideline? If yes, please list them:		
Procedure Methods	Which areas did the co-creators require upskilling?		End-users were up-skilled regarding behaviour change theory and research methods. Academic researchers were upskilled regarding older adults' reasons and preferences for interrupting SB.
	What previous evidence was reviewed, and how?		Presentations of the context of older adults' SB [93], behavioural assets which can be used to interrupt sedentary periods [94] and behaviour change theories
	If a prototype was developed, describe		A full intervention prototype was created

	the prototype and the prototyping process:		from several key components which were individually prototyped, tested by co-creators, and then refined.
	Describe the frequency and duration of meetings:		Meetings occurred every 10–14 days and lasted approximately 2 h.
	Give examples of how iteration occurred during the process:		Prototypes were initially developed, tested externally and after discussions, refined and then tested again.
Conducting Frameworks	Which frameworks did you use? Why?		Example Framework: PRODUCES framework
	Were there any frameworks or models you used that are not mentioned in this guideline? If yes, please list them:		
Stage 3: Evaluating			
Evaluating Methods	Which methods did you use? Why?		Example Method: Qualitative Content Analysis
	Were there any methods you used that are not mentioned in this guideline? If yes, please list them:		
Evaluating Frameworks	Which frameworks did you use? Why?		Example Framework: The APEASE evaluation framework
	Were there any frameworks or models you used that are not mentioned in this guideline? If yes, please list them:		

Process	Explain how co-creator satisfaction and contribution are evaluated (for example reporting on attendance rates, questionnaires, and interviews).		Retention rates measured (100% retention, 0% dropout)
	How are results reported back to stakeholders and the public?		
Outcome	Explain how the validity of the outcome and the process were evaluated (for example, face validation, and member checking):		Face validation and member checking occurred throughout, including each developed prototype component and a summary of the information gathered from the previous meeting
	Explain plans for formal testing of the effectiveness/ scalability of the co-created outcome:		Plan to embed the intervention into a multi-centre RCT vs. a top-down, theory-driven intervention and standard care (control group) to assess the effectiveness of the intervention.
	Explain the outcome of the evaluation (if tested):		If you plan for form testing, outcomes which will be measured will include changes in sedentary time, changes in sedentary time fragmentation, participants' experience of using the intervention and the effect on function (noted as important by the end-user co-creators.
Reflections on this Guideline			
Guideline Structure	Did you find this guideline useful? (Y/N)		
	Please explain your response further:		

	Please explain your response further:		
This Reporting Template	Do you find this reporting template useful? (Y/N)		
	Please explain your response further:		
Recommendations	Do you have any recommendations on areas or sections that can be improved?		
	Did you feel like there was any information or details that were missing from this guideline?		
Final Comments	Do you have any final comments or reflections to share?		

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