

## Adaptation of interventions for implementation and/or re-evaluation in new contexts: The ADAPT guidance (v1.0)

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## 1. Aims and overview of this document

A growing literature provides insights into which interventions work to improve population health. Using these beyond their original contexts may be more efficient than developing new interventions for each context. However, implementation and effects of interventions are often context dependent. Interventions transported without adaptation may be less effective than those adapted to achieve intervention-context fit. While the importance of appropriately adapting interventions is recognised, there is no overarching guidance for researchers, policymakers, practitioners, research funders and journal editors on how to adapt interventions. Where interventions fail to reproduce effects in a new context, it is hard to build understandings of why this was the case.

The ADAPT study has developed new guidance via 3 interconnected work packages, with advice and guidance from an international advisory group. We undertook i) a systematic review of guidance and a scoping review of how people undertake and report adaptations ii) qualitative interviews with researchers, funders, journal editors and policy and practice stakeholders involved in intervention adaptation; iii) a 3-round modified e-Delphi exercise. Findings were synthesised into a draft of this guidance document, discussed at a series of online workshops with participants in our Delphi exercise, prior to finalising the guidance.

In this document, after introducing the background for development of guidance in Section 2, we provide detail on how this guidance was produced (Section 3). We then discuss key terms and debates identified in developing the guidance (Section 4). In Section 5 we discuss distinctions between intervention development and adaptation, and circumstances in which adaptation may be preferable to development of a new intervention (and vice versa). Section 6 then presents our new guidance on: forming an adaptation team; assessing the rationale for intervention and considering intervention-context fit; planning and undertaking adaptations; evaluating adapted interventions; implementing and maintaining adapted interventions at scale. Finally, Section 7 provides recommendations for reporting adapted interventions. Adaptation is a rapidly growing area of inquiry. Hence, we signpost to emerging sources of guidance for specific issues covered here, much of which emerged alongside our study.

## 2. Background

Interest is growing in the adaptation of population health interventions for new contexts (Miller et al., 2020; Stirman et al., 2019; Escoffery et al., 2018). As evidence accumulates on which interventions work, implementing these in routine practice may ensure resource is invested in developing new interventions only where necessary. However, interventions commonly exhibit a degree of context-specificity (Pawson et al., 1997; Burchett et al., 2018; Bonell et al., 2012; Craig et al., 2018; Howarth et al., 2016; Pfadenhauer et al., 2017; Pfadenhauer et al., 2015). Population health problems are emergent products of interactions between human actors and institutions, whose interactions form ‘complex systems’ (i.e. sets of interconnected elements which form an indivisible whole and perform coherent functions). Complex systems include families, schools, and hospitals. These are in turn nested within higher-level community, health, and education systems. Interventions introduce change to these systems, such as altering how doctors interact with patients, or legislating a minimum alcohol price. In doing so, they attempt to disrupt interactions within and between systems, and produce better outcomes for individuals, and the population as a whole (Moore et al., 2019; Hawe et al., 2009; Bicket et al., 2020). Impacts of the same intervention may however differ according to system histories and starting points, at the time at which intervention is introduced.

Context-specificity is sometimes exaggerated; contextual contingencies for many interventions are relatively stable across time and space, meaning they do transfer well (Leijten et al., 2016). Overstating context-specificity can risk legitimising political decisions not to adopt evidence-informed actions, by allowing actors to appeal to doubt regarding whether they will work *here*. However, as Davey and colleague have argued, the extent to which evaluations have to date informed decision-making beyond their original context has generally been greatest for interventions that are relatively simple, and less context dependent (Davey et al., 2018). While some ‘transported’ interventions show good effects (Leijten et al., 2016), many have been infeasible (Griffin et al., 2019), or ineffective in new contexts (Robling et al., 2016; Gorman, 2017). A 2016 meta-analysis found that interventions adopted without adaptation tended to be less effective than contextually adapted or locally developed interventions (Sundell et al., 2016). Growing interest in intervention adaptation, paralleled by growing literature on the role of context in intervention effects (Craig et al., 2018; Howarth et al., 2016; Pfadenhauer et al., 2017; Pfadenhauer et al., 2015; Moore et al., 2013), reflects recognition that carefully considering intervention-context fit may increase the likelihood of successful transfer (Miller et al., 2020; Stirman et al., 2019; Escoffery et al., 2018).

Transferability is often considered particularly uncertain when interventions are used in a new location, such as moving from higher to lower income countries, or vice versa. Much adaptation research also focuses on using interventions with different populations, or population sub-groups, within the same location (Kanamori et al., 2019). In the context of the COVID-19 pandemic, ongoing as this guidance was written, the changed context imposed by social distancing measures meant many previously feasible interventions could no longer be delivered. Many stakeholders adapted interventions from face-to-face to online delivery to achieve fit with this changed context (Greenhalgh et al., 2020; Liu et al., 2020). Emphasis on history within systems perspectives draws attention to temporal dimensions of context (Hawe et al., 2009). For example, many interventions, if used today, will interact with a different technological context than in any evaluation only a few years ago (Michie et al., 2017). Given the well documented lag between generation of evidence and implementation in routine practice (Blair, 2014), intervention-context fit cannot always be taken for granted even where evidence was developed at an earlier point in the history of the same health, education or social care systems. As systems into which interventions are implemented continuously evolve, interventions may lose their impact unless they also continuously adapt (Kemp, 2020). As Horton and colleagues (2018) argue, reproducing interventions is not a passive process for local implementers, but involves distributed effort and substantial creativity and reinvention. Hence, adaptation is typically needed as interventions are introduced to a new context, or indeed, as they are maintained over time within ever changing contexts (Richard et al., 2015; Power et al., 2019; Horton et al., 2018). Decisions on the nature and extent of adaptation needed will likely be influenced by the extent and nature of differences and similarities between the context from which evidence of effectiveness was derived, and that in which the intervention is being considered (Escoffery et al., 2018).

A growing number of examples of efforts to use interventions in new contexts are emerging in the literature (Gorman, 2017; Hunt et al., 2020; Robling et al., 2016), and these commonly do undergo substantial adaptation prior to implementation and/or re-evaluation. These adaptations may be motivated by a range of considerations. The RE-AIM framework (Glasgow et al., 1999) posits that to achieve population health impact, interventions need to reach a sufficient proportion of their target population to be effective for those who participate in them, to achieve sufficient adoption by relevant organisations and institutions, to be adequately implemented, and become maintained within routine practice over time. Adaptations may represent attempts to maximise population health impact, or to reduce the risk of intervention generated health inequalities, perhaps via one or more of these dimensions. Examples include adaptations to smoking cessation interventions to improve effects among poorer smokers (Kock et al., 2019), or adaptations to health behaviour

interventions to improve reach among patients with physical disabilities (Betts et al., 2018). Interventions may be adapted to align with cultural norms, values, and preferences, in order to improve reach, and willingness of organisations to adopt interventions. For example, sexual health interventions for Latino seasonal workers in the United States require sensitivity to different cultural norms than in other sectors of the US population (Kanamori et al., 2019). Adaptations may be directed toward ensuring that an intervention is implementable within local resources, in ways which have potential to be maintained over time. When adapting interventions from higher to lower income contexts for example, this may include ‘task shifting’, distributing the work of intervention delivery to differing local workforces. For example, an intervention for pre-school children with autism was delivered by speech and language therapists in higher income countries, but effectively adapted for delivery by non-specialists in South Asian contexts where a similar workforce was not available (Divan et al., 2015; Rahman et al., 2016).

However, goals such as improving the likelihood of implementation and maintaining effectiveness can operate in tension (Barnes et al., 2017). In an ineffective Swedish replication of the US Strengthening Families Programme (SFP), adaptations included doubling class sizes to which children’s sessions were delivered (Skärstrand et al., 2013). While this reduced costs and made the intervention easier to implement, it likely altered the dynamics of the intervention (Segrott et al., 2014). As discussed, in the context of the COVID-19 pandemic, many stakeholders have moved face-to-face interventions to online modes of delivery (Greenhalgh et al., 2020; Liu et al., 2020). This may ensure these can still be implemented in a changed context but raises questions about whether changes to the nature of social interaction will impact on effectiveness, or whether the fact that intervention occurs in participants’ homes create new risks. Improving aspects of intervention context-fit by aligning interventions with current norms and practices can also result in an intervention becoming insufficiently distinct from usual practice to lead to better outcomes (Löfholm et al., 2013).

Hence, significant uncertainty remains on what aspects of interventions can be adapted, and how, while maintaining integrity to the principles of an intervention. Processes by which policy, practice and academic stakeholders and user communities make and implement decisions about adaptations remain unclear. While thinking around aspects of these processes is rapidly emerging (Aarons et al., 2017; Miller et al., 2020; Stirman et al., 2019; Kirk et al., 2020), there is limited consensus-informed guidance on issues such as when adaptations and/or contextual differences introduce sufficient uncertainty that investment in a new evaluation is justified prior to implementation, or on how to report adaptations. Hence, guidance is needed to improve consistency in the commissioning,

conduct and reporting of studies adapting population health interventions for new contexts, and to stimulate further thinking in undertaking high quality adaptations.

### 3. How has this guidance been developed?

The ADAPT Study, was funded by the UK MRC-NIHR from 2018-2021. It brought together an international team of public health, health services and health care researchers to develop guidance. The team also included members with experience in education, social care and global health research. An international advisory group of academics and policy representatives provided advice throughout. As detailed in our earlier publications (Evans et al., 2019) and depicted in Figure 1, the process of developing guidance centred around 3 interlinked work packages. These were:

1. a systematic review of existing guidance (Movsisyan et al., 2019) and scoping review of empirical examples of adaptation;
2. qualitative work with researchers, journal editors, funders and policy and practice stakeholders linked to cases of intervention adaptation and;
3. a Delphi consensus exercise (Campbell et al., 2020).

The systematic review synthesised 35 existing guidance papers on adaptation, developing a draft framework, and identifying key gaps in existing guidance (Movsisyan et al., 2019). The scoping review mapped 298 studies which reported on intervention adaptations and analysed in-depth the content of 28 studies randomly selected from that map; it further discussed consistency of practice with existing guidance. Parallel qualitative work used the same sampling strata used by the scoping review to identify examples of adaptation, and understand experiences of researchers, policy and practice stakeholders, funders, and journal editors. Mid-way through the project, a full day meeting among the study team and its international advisory group was convened to discuss emerging findings from the first two work packages, and plan for next stages (Evans et al., 2020). Informed by the reviews and qualitative work, and discussion at this meeting, we undertook a 3 stage Delphi exercise. The Delphi aimed to: examine the perceived clarity and usefulness of definitions used within the guidance; assess consensus with recommendations developed from the reviews and qualitative work; explore a range of perspectives on issues identified as areas of ongoing debate. This generated a set of statements on which stakeholders reached consensus<sup>1</sup>, which were discussed and further refined by the author group into recommendations.

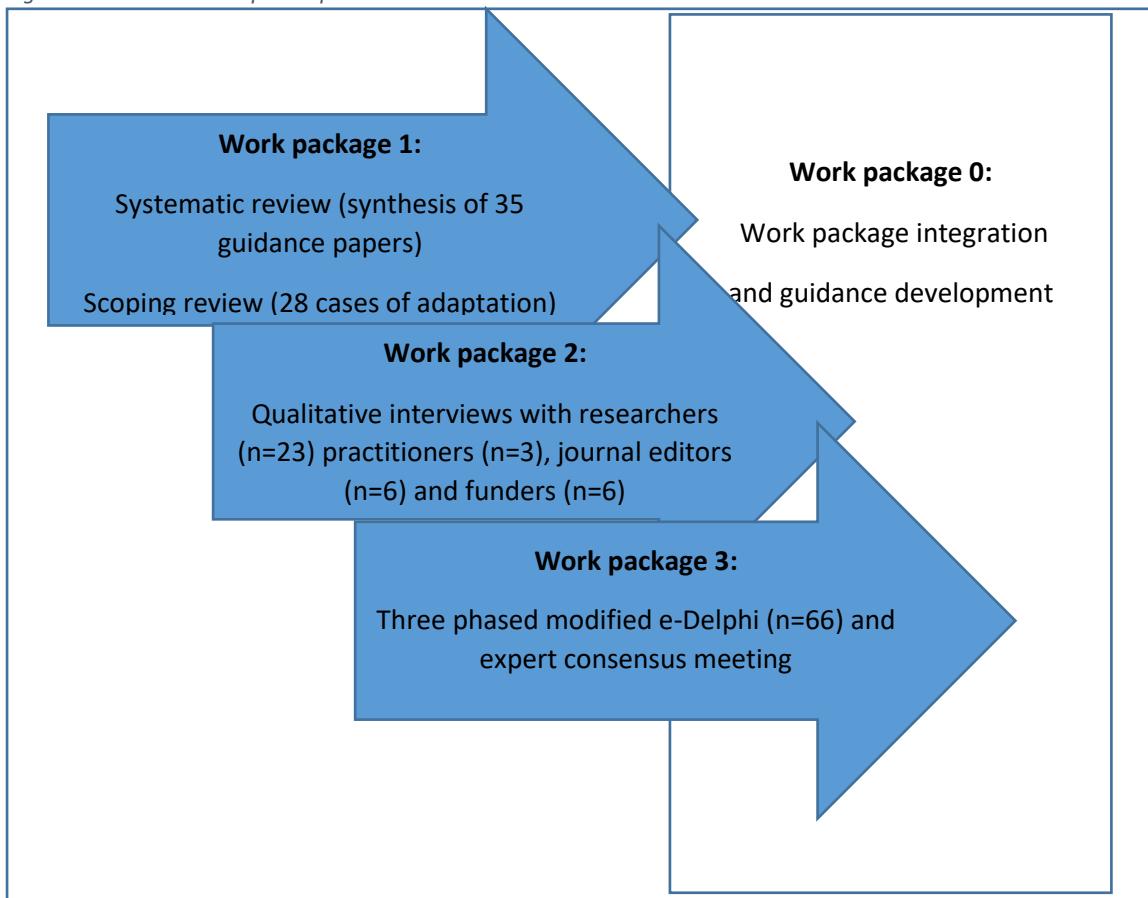
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<sup>1</sup> Where we refer to ‘consensus’, this relates to >70% of Delphi participants rating an issue or recommendation as highly important or valid. Consensus scores for each of the survey items asked in our Delphi surveys, and a summary of how each of these informed the final recommendations, are provided as appendices.

A first draft of full guidance was then produced by a core writing group including representation of each of the 3 underpinning work packages, before being refined by a wider group including the study investigators and members of our international advisory group. Consensus was reached on a large number of items in our Delphi surveys. Because some were not specific to adaptation and reflected good practice in intervention research more broadly, we cover these briefly with signposting to other guidance, and focus in more depth on recommendations specific to adapting interventions for new contexts. In drafting the guidance, a small number of additional recommendations were developed to address identified gaps. A draft of the full guidance then formed the basis for discussions at a series of online international expert workshops. These were conducted in place of a planned face-to-face meeting specified in our protocol (Campbell et al., 2020), but which was cancelled due to the COVID-19 outbreak. They included 18 UK, international and global health academics and policy and practice stakeholders. One invitee who was unable to attend submitted written comments. The guidance was revised and finalised considering discussions at workshops.

A diverse range of stakeholder perspectives was incorporated into the guidance informally via discussions at international workshops and international methods teaching by members of the team. Members of our team were involved in updating the MRC's overarching guidance on the development and evaluation of complex interventions (Skivington et al., Under review). Communication between teams aimed to maximise consistency and minimise contradiction. However, our guidance involves more recent stakeholder consultation, and more extensive focus on one specific aspect briefly covered within that guidance. Hence, our terminology and other considerations sometimes depart slightly from those in MRC guidance. Adaptation is a rapidly emerging field of enquiry in which new frameworks were emerging as the work progressed (Miller et al., 2020; Stirman et al., 2019). Hence, we signpost to other sources of guidance as appropriate, including some published after completion of our underpinning research (Bicket et al., 2020; Hopkins et al., 2020; Kirk et al., 2020).

Drawing upon our underpinning research, we first discuss issues which frame the scope of our guidance in Sections 4 and 5. Section 4 provides definitions of key terms and their evolution during our research, while Section 5 discusses motivations which may underpin a decision to adapt an existing intervention (rather than developing a new one). Section 6 presents our recommendations for adapting an intervention for implementation and/or re-evaluation in a new context, while Section 7 provides recommendations for reporting.

*Figure 1 Guidance development process*

#### 4. Definitions of terms and areas of ongoing debate

In this section, we introduce some key terms, including their evolution during our guidance development work, and areas of ongoing debate in relation to these. Definitions of a fuller range of terms used within the literature on adapting interventions are provided within our systematic review (Movsisyan et al., 2019). We acknowledge that stakeholders will hold different definitions of these terms. Hence, we do not make claims to these being 'true' definitions but focus on their perceived clarity and usefulness in defining our scope. Definitions as used in our guidance are provided in Box 1, with further suggested readings in Box 2. Given that, in our Delphi surveys and qualitative interviews, a key area of ongoing conceptual debate centred around how interventions are 'standardised', we conclude this section with discussion of perspectives on intervention fidelity and integrity, and their implications for adapting interventions. While stakeholders (and indeed members of our author group) adopted slightly different positions on some of these issues, we nevertheless reached consensus on recommendations which may be applied from a range of conceptual starting points.

*Box 1. Key terms, and how this guidance uses them*

**Adaptation:** Intentional modification(s) of an evidence-informed intervention, in order to achieve better fit with a new context. This includes planned adaptations (i.e. changes made prior to introducing a new intervention) and responsive adaptations (i.e. changes made intentionally, but in response to emerging contextual issues occurring during implementation). Adaptation of interventions is likely to be ongoing as contexts change over time.

**Population health intervention:** A spectrum of interventions, programmes, and policies in public health and health services that seek to change the population distribution of risk. This can include micro-level interventions delivered to individuals (e.g. smoking cessation support), but with the potential to achieve sufficiently widespread population reach to improve population health, through to interventions delivered at the macro-level (e.g. smoke-free legislation) (Craig et al., 2018).

**Evidence-informed intervention:** Interventions which have some prior evidence from use in another context. This may include evidence that it has ‘worked’ in changing outcomes of interest (or different outcomes), and/or evidence of feasibility, acceptability, delivery processes and/or cost-effectiveness.

**Implementation:** Refers to the delivery of ‘evidence-informed’ interventions in routine practice. Implementation considerations run through all stages of intervention research, for example, process evaluation studying delivery in order to understand how implementation in routine practice might be achieved or undermined.

**Context:** Any feature of the circumstances in which an intervention is implemented that may interact with the intervention to produce variation in outcomes. It may include, but is not limited to, geographical, organisational/service, cultural, economic, ethical, legal and political circumstances, and local practices (Craig et al., 2018). These features of context change to some extent over time, as well as varying between locations.

**System:** A set of interconnected elements whose interactions form a coherent whole. This can include micro-systems such as schools, families and hospitals. These are nested within larger systems such as the education system, and healthcare systems. Complex systems are distinguished from simple systems by their indivisibility into their component parts.

The **context** into which an intervention is delivered will include the **system** conditions at the point in the history of the system at which the intervention takes place.

**Stakeholders:** Any individual, organisation, community or other collective that has a direct interest and/or investment in an issue. For the purposes of the guidance stakeholders include those involved in delivering the intervention, participants, policy makers, and supporting partners such as funders and advocacy groups. They may also include those allocating budgets to delivery of interventions.

**Fidelity and integrity:** Fidelity is commonly defined as the extent to which an intervention is delivered ‘as intended’. ‘Integrity’ is used to describe the extent to which the function and processes of an evidence-informed intervention are maintained.

*Box 2. Sources of further guidance and discussion*

Advice on balancing adaptation and fidelity can be found in **Kemp 2016** and **Miller et al 2020**. Further information on how to define and consider context can be found in **Craig et al. 2018** and **Pfadenhauer et al. 2017**. For relevant discussion on different approaches to defining and operationalising fidelity and integrity see **Hawe et al. 2004** and **2009**, **Jolles et al. 2019** and **Kirk et al. 2019**. **Movsisyan et al. 2019** provide a fuller list of key terms and definitions in intervention adaptation.

#### 4.1. Adaptation

Based on our systematic review, the definition of **adaptation** used in our Delphi exercise was “intentional modification(s) of an evidence-informed intervention, in order to achieve better fit between an intervention and a new context”. There was consensus in our Delphi exercise that this definition was clear and useful in defining our scope. Other terms used within the literature to describe adaptation processes include tailoring and modification, but for consistency we use only adaptation throughout. Updated MRC guidance discusses adaptation as a form of intervention development. However, in line with INDEX guidance, we consider these to be distinct processes (O'Cathain et al., 2019a; O'Cathain et al., 2019b) (see Section 5 for further discussion of this distinction).

Qualitative comments within our Delphi identified a need to consider both **planned adaptations** (i.e. changes made prior to introducing a new intervention) and **responsive adaptations** (i.e. changes made in response to emerging contextual issues occurring as an intervention is delivered) in our guidance. ‘Responsive adaptation’ overlaps with ‘refinement’ which refers to ongoing improvements made to an intervention during feasibility studies and evaluation. ‘Refinement’ is a key concept for all stages of intervention development, evaluation, and implementation in new MRC guidance. For internal consistency throughout our guidance, we use the term responsive adaptation rather than refinement. While in our Delphi exercise, we used the term ‘reactive’ adaptation, we subsequently reflected that the term ‘reactive’ has unhelpful negative connotations. While we provide guidance for pre-planned and responsive adaptation, we acknowledge that continuous adaptation is a naturally occurring process when change is introduced into a complex system (Horton et al., 2018), and not all adaptation is intentional. However, carefully planning adaptations, and using systematic processes to document and classify responsive adaptations, may limit the extent to which spontaneous adaptations undermine intervention mechanisms (Marsiglia and Booth, 2015; Kemp, 2020).

#### 4.2. Population health intervention

Drawing on previous NIHR-CIHR funded guidance (Craig et al., 2018), we define population health interventions as a spectrum of interventions, programmes, and policies in public health and health services that seek to change the population distribution of risk. This can include interventions which operate at micro, meso- or macro- levels (or a combination of these).

*Box 3. Adapting micro-, meso- and macro-level interventions*

A key emerging theme from our systematic review, and subsequent scoping review, was that most guidance for, and case examples of, adaptation focus on micro-level or meso-level interventions. There were few examples focused on macro-level interventions (see definition in Section 4.2). This perhaps largely reflected our focus on academic literature and specifically health research, with much adaptation of macro-level interventions occurring and being reported outside of academia and/or perhaps within political and public policy literature. For example, shortly before our guidance began to be developed, Minimum Unit Pricing was introduced in Scotland with promising initial effects (Christie, 2019). In subsequent months, this was introduced in Wales. However, the Welsh Government did not simply copy Scotland's legislation but invited public consultation on issues such as whether the minimum price should match that in Scotland, and potential for unintended consequences.

Our engagement with policy and practice partners involved in adaptation of macro-level interventions was impacted by our guidance being drafted in the midst of the COVID-19 pandemic, during which, public health agencies and government bodies were focused on managing this crisis. However, COVID-19 itself presented a range of emerging case examples of the rapid adaptation of population health intervention approaches across contexts. For example, the UK government was heavily criticised for delays in legislating to enforce social distancing (Dalglish, 2020). A commonly cited reason was that British people would not accept these restrictions and would not comply (Hunter, 2020), attributed to notions of 'behavioural fatigue'. This concept was rejected by many behavioural scientists at the time (Sibony, 2020), and the idea that people would not comply was subsequently contradicted by widespread public support and compliance. However, it reflected a theory-based assumption that evidence from countries which had rapidly introduced restrictions could not be directly transferred to the UK context due to cultural differences. While UK governments introduced legislation restricting social interaction at the same time, these differed in strength between nations. For example, in more conservative England, government advice was to only exercise once per day. In Wales, where there is arguably more of a tradition of state intervention in public health, this was explicitly legislated. Restrictions were eased more rapidly in England than in the devolved nations despite higher case numbers.

While we drew predominantly on guidance for and examples of adaptations of micro- and meso-level adaptations in developing the guidance, we nevertheless anticipate that many of these principles will be transferable to macro-level policymaking. We draw on our experience with macro-level policy such as smoke free legislation in illustrating some of our recommendations.

For the purposes of our scoping review and sampling of case examples, we defined micro-, meso- and macro-level interventions as follows: Micro-level interventions were defined as those intervening with individuals and their immediate social network and relationships, such as the

family. Meso-level interventions were defined as those focusing on intervening with medium-level population groups, such as neighborhoods and schools. Here, intervention mechanisms typically focused on institutional or cultural change. Macro-level interventions were those that intervened with overarching social systems operating at the national or global level, such as through regulations, taxation, other government policies or mass media interventions.

#### 4.3. Evidence informed interventions

Our original focus was on '**evidence-informed**' interventions, by which we meant interventions which had been evaluated and have been shown to be effective elsewhere.

However, this remit was described as too narrow by many across our qualitative interviews and qualitative responses to Delphi items. Qualitative interviews suggested that interventions which show initial evidence of feasibility are often adapted for use elsewhere, and then evaluated. Further, interventions may have been evaluated, but in relation to inappropriate outcomes, or outcomes which are not the primary drivers for their use in a new study context. Hence, our use of the term '**evidence-informed**' includes interventions underpinned by a broader range of evidence, rather than just effectiveness data. The nature and quality of prior evidence will inform a range of decisions, which we discuss throughout our recommendations.

*Box 4. Types of evidence which might already exist for an '**evidence-informed**' intervention selected for adaptation*

Interventions which are being adapted from elsewhere will likely have some prior evidence base. A range of evaluation designs might have been used, which partly reflect differences in the research questions which have been asked of the intervention, or the perspectives and resources of the team who have undertaken evaluation(Petticrew and Roberts, 2003). Prior evidence may include the following, all of which may provide useful insights for adaptation studies:

- **Feasibility studies** – feasibility studies, including pilot evaluations, are often conducted to make a decision on whether to proceed to a larger scale evaluation. These often focus on issues such as whether the intervention can be delivered, and acceptability to the target population and intended delivery agents;
- **Effectiveness studies** – these may include randomised controlled trials, quasi/natural experimental studies, or before and after studies;
- **Process evaluations** – these are typically qualitative and mixed method studies, which focus on understanding a range of issues such as implementation processes, mechanisms and contextual influences on intervention. They may occur alongside outcomes evaluations or as stand-alone studies;
- **Cost-effectiveness evaluation** – economic studies are commonly embedded within effectiveness studies;
- **Implementation and maintenance studies** – a range of evidence may be available relating to post-evaluation scale up and monitoring of routine delivery;
- **Systematic reviews** – for some interventions which have been evaluated in multiple contexts, systematic reviews may exist which draw together lessons on what has been learned from these various evaluations.

*Box 4 continued*

Prior research may have focused on these issues purely at the population level, or in terms of **equity** (i.e. who does the intervention reach, for whom is the intervention effective?), both of which will be important considerations in informing adaptation decisions, and understanding what remaining evidence gaps need to be addressed in the new context.

The nature, and quality, of prior evidence for the intervention will inform decisions such as what uncertainties remain, and hence what new evidence is needed in the new context.

While interventions are often used elsewhere because they have ‘worked’, sometimes they are introduced to new contexts without robust prior evaluation of effectiveness. The Community Group Programme (Nolas et al., 2012) is a group based intervention for children exposed to domestic violence and abuse, originally developed in Canada. It is used in the UK and has good evidence of acceptability and feasibility, although its effects on child mental health have not having been robustly evaluated to date. Members of the author team are conducting a feasibility study with nested pilot randomised trial to address this evidence gap.

Drawing on the CICI framework (Pfadenhauer et al., 2017) and recent NIHR-CIHR funded guidance for taking account of context in intervention development and evaluation (Craig et al., 2018), we defined **context** within our Delphi exercise as ‘any feature of the circumstances in which an intervention is implemented that may interact with the intervention to produce variation in outcomes. It may include geographical, organisational/service, cultural, economic, ethical, legal, and political circumstances. There was consensus among our Delphi participants that this was a clear and useful definition.

However, there was also some concern regarding the need to consider more micro-level features of context, such as organisational cultures and usual practices, which form part of the NIHR definition of context. While our definition included *example* dimensions of context, these were not intended to be exhaustive. A range of frameworks for considering contextual similarity and difference is provided in Section 6.2.5. Some participants emphasised that intervention and context cannot be easily separated, with interventions representing attempts to change some aspect of a pre-existing context, and which may become a lasting part of that context. Nevertheless, it can be conceptually useful for the purposes of understanding how new ways of working interact with and alter prior contexts, to draw some boundaries between intervention and context (while remaining cognisant of the artificial nature of this separation). Many cases of adaptation identified within our scoping review involved adapting an intervention for different populations within the same country, and discussions at our expert workshops emphasised that targeting a different population within the same location can be considered to be working within a new set of contextual parameters.

#### 4.5. Complex system

We define a system as a set of interconnected elements whose interactions form a whole, to produce a coherent set of functions. Within this guidance, the focus is primarily on '**complex systems**', which are distinguished from simple systems by the fact that they cannot be divided into component parts without losing sight of the overall functioning of the system. Examples include systems such as schools, hospitals, or families, which are in turn nested within education, health care and community systems. Others will include the food system or the tobacco system, which would include all actors and institutions involved in the production, supply, regulation and use of these products. The *context* into which an intervention is delivered includes the system conditions which surround the intervention at the point in history at which that 'event' (i.e. the intervention) took place. This may then in turn be altered by the intervention, or for reasons unrelated to the intervention. Systems into which population health interventions are commonly introduced are also often referred to as 'complex adaptive systems' (Keshavarz et al., 2010), due to their ongoing adaptation and capacity for learning in response to feedback. However, consistent with new guidance on handling complexity in evaluation (Bicket et al., 2020), we use the term 'complex system' throughout.

#### 4.6. Implementation

We use the term **implementation** to describe the delivery of an intervention in routine practice.

We acknowledge that there are differences in the literature on how the word 'implementation' is used. It is often used interchangeably with intervention delivery (Glasgow et al., 1999; Moore et al., 2014; Moore et al., 2015a), but in other cases, is reserved in other cases specifically for the use of research findings in practice (O'Cathain et al., 2019a; O'Cathain et al., 2019b). Consistent with MRC guidance for developing and evaluating interventions, we emphasise the need for implementation to form a focus of all stages. Process evaluation at earlier stages for example, aims to understand how implementation in routine practice might be achieved or undermined, as well as enabling attribution of effects to an intervention 'as delivered'.

#### 4.7. Stakeholders

We define **stakeholders** as 'any individual, organisation, community or other collective that has a direct interest and/or investment in a particular issue. For the purposes of the guidance, stakeholders include those involved in delivering the intervention, participants, policy makers, and supporting partners such as funders and advocacy groups.' There was consensus in our Delphi exercise that this was a clear and useful definition.

For population health research, it can be difficult to define who are the relevant stakeholders, as all members of a population have a stake in population health. The population health decision space involves a large number of individuals, institutions and networks (Brownson et al., 2009), including researchers from a range of disciplines, the public, various civil society organisations, the media, practitioners and service providers as well as policy-makers and industry actors across multiple sectors at local, regional, national and international levels (Lavis et al., 2003). This may include those who will decide on the allocation of resource to interventions and their evaluations. Comments in our Delphi exercise on who to involve in adaptation were often grounded in the kinds of populations and settings with which participants worked. Decisions on who to involve in intervention adaptation will vary significantly according to the nature of intervention being adapted (see Section 6.1).

#### 4.8. Fidelity and integrity

In our reviews, adaptation was often discussed in relation to '**fidelity**', defined within MRC guidance for developing and evaluating interventions, as the degree to which an intervention is delivered as intended. An inconsistency was that adaptation was sometimes assumed to reduce fidelity (Lewis et al., 2019), though other times, positioned as necessary to maintain fidelity across contexts (Kemp, 2016). In our Delphi exercise, while marginally short of consensus, most agreed that adaptation is sometimes necessary to maintain fidelity in a new context. Qualitative comments indicated two main conceptualisations of fidelity, which related to how interventions are standardised, and hence how they can be adapted without compromising fidelity. Some emphasised that interventions have 'core' components, to be delivered intact; as long as core components are replicated, the intervention can be considered to retain fidelity despite adaptation of other components. This perspective was dominant within our systematic review (Movsisyan et al., 2019). Others emphasised the need to standardise overall functions of an intervention, rather than the form of its components. This latter perspective was less common in our systematic review, but is adopted within new MRC guidance which argues that in effectiveness evaluation and implementation, standardisation will often relate more to the functions of the intervention than the specific form of its components (Skivington et al., Under review). Rather than fidelity, some authors use the term '**integrity**', drawing attention not only to 'what' was intended for delivery, but 'why' it was intended. While often used interchangeably with fidelity (Richard et al., 2015), integrity draws attention to wholeness and indivisibility, consistent with systems perspectives. Hence, attention is placed upon maintaining functional integrity of the intervention *as a whole* when undertaking adaptation. Expanded discussion is presented in Box 5.

These approaches to standardisation may be equally valid in different scenarios, as reflected within Glasgow and colleagues' (1999) definition of implementation, which refers to 'fidelity to the various

elements of an intervention's key *functions or components*' (<http://www.re-aim.org/about/what-is-re-aim/implementation/> our emphasis). It is useful for an adaptation team to be upfront in agreeing and articulating what approach they are adopting to standardisation. In either case, adequate theorisation of *how* the intervention works is critical. Unless earlier evaluations have delved into the intervention's 'black box', assumptions about which components matter, or which functions to replicate, remain hypothetical. Without a deep understanding of *how* the intervention worked (Kirk et al., 2019), altering components considered optional may inadvertently undermine effectiveness, or a team may focus on reproducing functions which were not responsible for effects. Human judgement is always present in articulating how interventions worked and seeking to replicate these mechanisms across contexts. Guidance will not eliminate this judgement or remove uncertainty in these processes, but aims to provide tools for managing these challenges, and reporting them transparently.

*Box 5. Fidelity, integrity and adaptation: an extended discussion*

In our Delphi surveys, stakeholders highlighted two conceptualisations of fidelity which shaped how potential for adaptation of an intervention was conceived. Some emphasised that interventions have 'core' components, which must be delivered intact, with other components open to adaptation. This perspective was also reflected within many frameworks within our systematic review. Flexibility may for example be built into how an intervention is implemented to enable fit with local processes, while maintaining attention to ensuring a standardised intervention can be delivered to participants as a result (Hoddinott et al., 2012).

However, some participants emphasised that the relationship between adaptation and fidelity depends on how standardisation, and by extension, fidelity, is conceived. If an intervention is to be standardised in terms of the form of its components, adaptation may render this a different intervention. If the aim is to standardise in terms of overall process and functions, an intervention might look different from one context to another, while maintaining consistency to its theoretical principles (Hawe et al., 2004). For example, within standardised national education curricula, rather than all schools being expected to provide children with the same lessons, teachers are given guidance on learning objectives for students to achieve and principles to be followed in achieving them. Each school and teacher will tailor methods to achieve fit with their practice and needs of individual classes and pupils. So long as locally developed teaching approaches fulfil the functions set out in the curriculum, the intervention is standardised.

Arguments regarding how interventions ought to be standardised have been discussed within the behavioural counselling literature, where some argue that standardisation could be achieved by providing counsellors a script and set series of questions, but that this would deviate from theoretical patient-centred principles (Miller and Rollnick, 2009). Hence, maintaining fidelity requires skilled adaptations of form, while maintaining consistency with process and function. Defining standardisation this way might be particularly useful for interventions which involve introducing change in communities or organisations, where substantial tailoring may be needed for interventions to be accommodated into the practices of systems with differing starting points (Jolles et al., 2019; Villeval et al., 2019).

*Box 5. Continued*

For some interventions, the distinction between standardising by function or form may be minimal. However, for interventions with greater degrees of complexity in terms of their interactions with context, standardisation by process and function may lead to differing forms in each context. In these cases, defining protocols too rigidly will most likely lead implementers to make spontaneous changes to fit local practice which depart from the principles of the intervention (Marsiglia and Booth, 2015). In adapting an intervention for a new context, attention needs to be paid to maintaining integrity to its overall functioning. Isolating individual components for adaptation or otherwise potentially has unintended consequences for interactions between the elements of the intervention, and hence the functioning of the intervention.

Rather than ‘fidelity’, some favour the term ‘integrity’. This draws attention not just to ‘what’ is intended to be delivered but also ‘why’, in terms of the functions interventions serve. Consistent with systems perspectives, integrity also draws attention to wholeness and indivisibility, with interventions greater than the sum of their parts.

Regardless of how standardisation has been defined, **a deep theorisation of how the intervention actually works (and data providing empirical verification of that theory), will be central to transferring an intervention to a new context.** Without this, assumptions regarding which components are critical to maintain, or what functions to strive to replicate, remain hypothetical. Removal or alteration of components considered non-core may undermine the effectiveness of the intervention. Efforts may be directed to reproducing functions which were not responsible for change.

As Howarth and colleagues argue “attempts to replicate successful programmes risk disappointment that may be blamed on context, when the true culprit is that only the superficial outer appearance of the intervention has been reproduced” (p107 )(Howarth et al., 2016). Programme theories are often not singular, precisely described, or adequately empirically examined within evaluation studies. Hence, human judgement is always present in articulating how interventions, and their components, brought about change and seeking to replicate them across contexts.

## 5. Motivations for adapting an intervention rather than developing a new one

Recent guidance on development of health interventions led by members of the author team, proposed that adapting an intervention may sometimes be a helpful alternative to developing a new intervention, defining adaptation as distinct from intervention development (O'Cathain et al., 2019a; O'Cathain et al., 2019b). Our Delphi exercise indicated consensus that the choice to adapt an intervention *rather than* developing a new intervention may be driven by i) Higher expectation of effectiveness associated with adapting an evidence-informed intervention rather than developing a new intervention and ii) Resources saved by adapting an intervention rather than developing a new intervention. There was no consensus on a 3<sup>rd</sup> item that adaptation saved time relative to intervention development.

There can however be a fine line between intervention development and adaptation. Sometimes a new intervention might be formed through combining elements of multiple evidence-informed interventions. For the purposes of this guidance and consistent with INDEX guidance for developing complex interventions (O'Cathain et al., 2019a; O'Cathain et al., 2019b), we distinguish between intervention adaptation (which focuses on adapting a single defined intervention for a new context), and intervention development (which involves formation of a new intervention, but nevertheless, will sometimes involve drawing upon previous interventions). In some cases, a team may be undertaking a hybrid of intervention development and adaptation, adapting a single intervention from elsewhere, but augmenting this with new locally developed components. A team may also begin with an intention to adapt an intervention, but over time realise that the intervention has undergone so much adaptation that it essentially becomes a new intervention. Informed by our qualitative interviews, where an intervention is changed to the extent that its mechanisms are altered, our guidance conceives this as a new intervention. Hence, guidance on intervention development may be useful in these cases.

We highlight throughout our recommendations in Section 6, key decision points at which a team might move away from adaptation and toward intervention development or may use intervention development guidance in conjunction with this guidance. In these cases, INDEX guidance (O'Cathain et al., 2019a; O'Cathain et al., 2019b) offers a useful source of additional guidance.

*Box 6. A case example of intervention development based on adaptation of multiple interventions*

- Bonell and colleagues conducted an evaluation of the Learning Together intervention in South East England, a school based intervention to reduce bullying (Bonell et al., 2018). This was informed by two previous evidence-informed interventions (Bonell et al., 2014) (the Gatehouse and Aban Aya interventions) and also integrated restorative practices into school policy and practice. While adapting principles of existing interventions, these elements are combined to form a new programme theory. Hence, our guidance would consider this to be intervention development rather than adaptation of an intervention for a new context.

As discussed throughout Section 6, a key practical distinction between adaptation and intervention development relates to how equipoise is likely to be handled in plans for evaluation and implementation. For a new intervention with no prior evidence base, the default assumption is likely to be sufficient equipoise that rigorous controlled evaluation is needed prior to implementation. For adaptations of existing, and well-evidenced interventions, this default is less clear. In many cases, equipoise will be negligible and postponing full scale implementation may not be warranted.

## 6. Recommendations for adapting interventions for new contexts

Our recommendations in this section are presented in a staged form in both our process model ([Figure 2](#)) and step-by-step guide (Box 7), from forming an adaptation team, to full implementation and maintenance. In line with recent expert consultations on the usefulness of existing adaptation guidance (Yoong et al., 2020), and concerns expressed in our qualitative interviews that overly prescriptive guidance can stifle innovation, we provide evidence and consensus informed recommendations which allow flexibility to fit unique situations each team will be operating within. Consensus scores for all Delphi items which informed recommendations introduced in this section are presented in Appendix 1, and mapped onto final recommendations in Appendix 2.

While presented sequentially for ease of reading, the stages we present are not always linear, and may involve iteration within and between stages. Adaptation may be initiated at differing stages, and stakeholders may use this guidance from differing starting points. For example, stakeholders may begin with a population health ‘problem’ and then aim to identify an intervention. In other instances, an intervention may have been identified whose suitability for a new context is being considered. We have endeavoured to ensure that the guidance will be useful to stakeholders entering the adaptation process at any of these various starting points. Further suggested readings mapped to each sub-section are presented in Box 8.

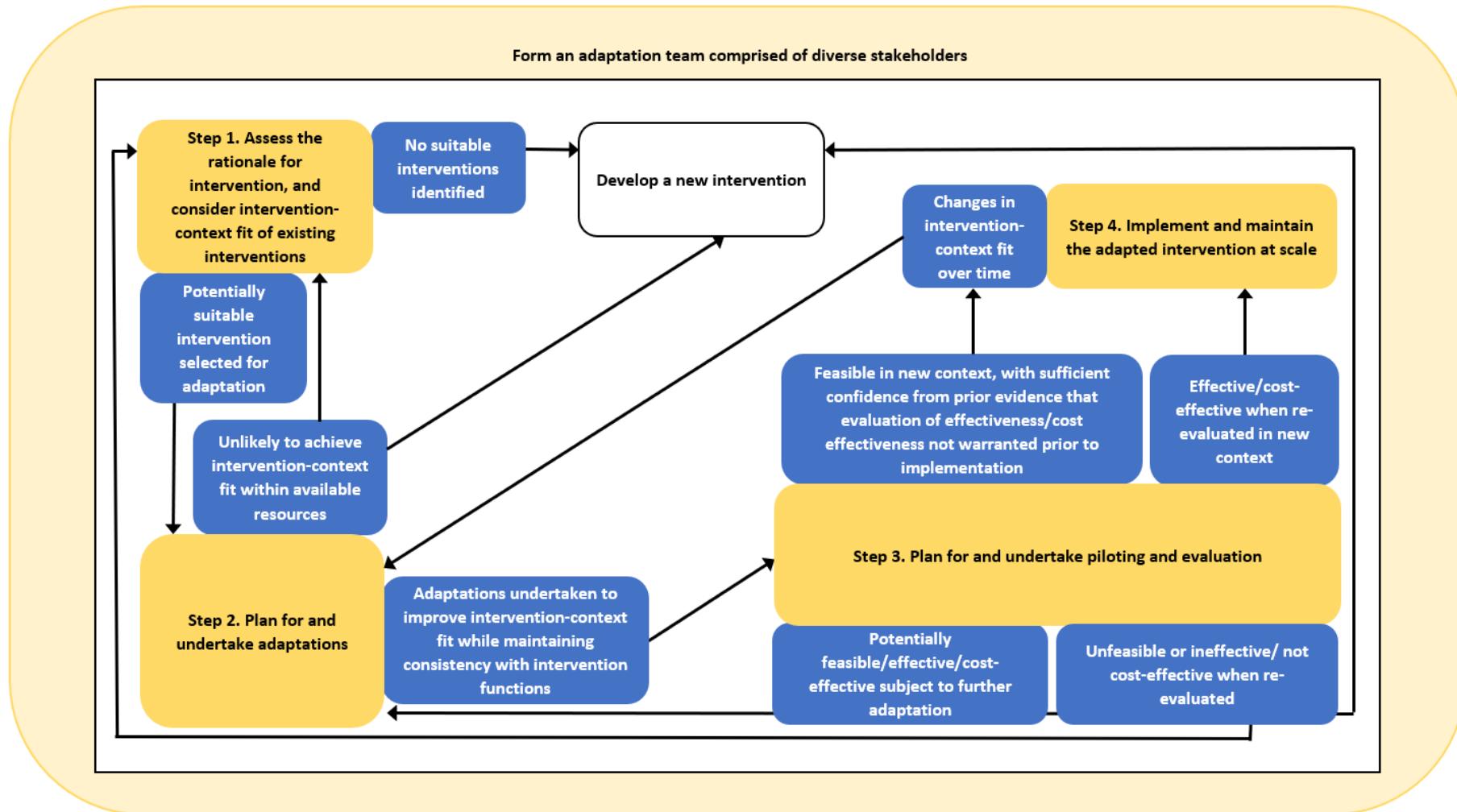
Whatever the starting point, we recommend **forming an adaptation team** with the expertise and experience to oversee adaptation process, and agreeing principles for their involvement throughout, including careful management of conflicts of interest (Section 6.1).

Our guidance stages and associated framework ([Figure 2](#)) then move to **assessing the rationale for intervention and considering intervention context fit** (section 6.2). Following this stage a team may i) decide there are no suitable interventions, and move to intervention development instead; ii) identify an existing evidence-informed intervention which is considered likely to achieve intervention-context fit subject to adaptation.

Having selected an intervention, a team may move forward to **planning and undertaking adaptation** (Section 6.3). At this stage, a decision may be made following further consideration i) that the intervention is unlikely to achieve fit within available resources, in which case a team might terminate adaptation and move to intervention development (or selection of a different intervention if multiple candidate interventions are available), ii) that the intervention can be adapted to achieve intervention-context fit, while retaining consistency with intended functions.

In the latter instance, attention turns to **planning for and undertaking evaluation** (Section 6.4), as warranted by the degree and nature of uncertainty posed by the intervention. This will likely include piloting, and beginning to develop principles for documenting and classifying responsive adaptations. This stage may include evaluation of effectiveness and cost effectiveness if there is significant uncertainty. Where an intervention shows promise but significant further adaptation is needed, a team may rotate back to undertaking adaptations. If found to be effective and cost-effective (or if on the basis of prior evidence, further evaluation is not deemed to be warranted prior to implementation) then a team may move forward to **implement and maintain the adapted intervention at scale (Section 0)**. In many cases, adaptation will not end here. As context changes over time with potential knock-on effects for intervention context fit, there may be an ongoing need to iterate back to undertaking and evaluating adaptations as an intervention is maintained at scale.

*Figure 2 ADAPT process model for adapting interventions for a new context. Yellow boxes=stages of ADAPT step-by-step guidance (see Box 3). Blue boxes=categories of potential conclusion from each stage. Directional arrows=recommendations for moving, forward or backward through ADAPT stages (or exiting), on the basis of stage conclusions.*



*Box 7. The ADAPT step-by-step guidance for adapting interventions for a new context*

<p><b>Form an adaptation team comprised of diverse stakeholders</b></p> <ul style="list-style-type: none"> <li>a. Involve stakeholders early and throughout the adaptation process</li> <li>b. Agree principles for decision-making and involvement of members</li> <li>c. Consider the pros and cons of working with original intervention developers</li> <li>d. Review and update membership of adaptation team as adaptation progresses</li> </ul>	<p><b>Step 1. Assess the rationale for intervention, and consider intervention-context fit</b></p> <ul style="list-style-type: none"> <li>a. Define the problem in the target population</li> <li>b. Identify candidate interventions</li> <li>c. Obtain detailed information on the selected intervention and its context</li> <li>d. Consider the robustness of effectiveness claims</li> <li>e. Map similarity and difference between original and new contexts</li> <li>f. Consider intellectual property issues</li> </ul> <p><b>Step 2. Plan for and undertake adaptations</b></p> <ul style="list-style-type: none"> <li>a. Identify and respond to constraints and facilitators</li> <li>b. Adapt intervention materials</li> <li>c. Consider potential for unintended consequences</li> <li>d. Consider costs and resources needed for the adapted intervention</li> <li>e. Recruit individuals and groups to deliver the intervention</li> </ul> <p><b>Step 3. Plan for and undertake piloting and evaluation</b></p> <ul style="list-style-type: none"> <li>a. Consider the extent and type of evaluation warranted</li> <li>b. Consider the value of new information to policymakers, practitioners and other stakeholders</li> <li>c. Consider resources available for evaluation</li> <li>d. Evaluate feasibility and consider further adaptations based on feedback</li> <li>e. Document and classify responsive adaptations</li> <li>f. Undertake evaluation of effectiveness, cost-effectiveness and/or process (if warranted)</li> </ul> <p><b>Step 4. Implement and maintain the adapted intervention at scale</b></p> <ul style="list-style-type: none"> <li>a. Build sustainable partnerships, capacity and plans for maintenance</li> <li>b. Establish data monitoring systems</li> </ul>
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*Box 8. Sources of additional reading relating to each guidance section***Form an adaptation team of stakeholders**

For guidance on co-production which will be relevant where adapting interventions see **NIHR Involve 2018** and **Hawkins et al. 2017**. For a critical overview of some key challenges in co-producing research, see **Oliver et al. 2018**.

**Assess the rationale for intervention, and select a suitable intervention**

For further information on the approaches to map the system around the problem in the target population, see **Rutter et al. 2019**, to model the transportability of the intervention effects, see and **Westreich et al. 2017**, and agent based modelling see **Badham et al. 2018**. **Escoffery et al. 2018** provide an overview of how different guidance papers conduct needs assessment to inform intervention adaptation. The TRANSFER approach is described in detail in **Munthe-Kaas et al. 2020**. Further guidance on how to develop complex interventions can be found in **O'Cathain et al. 2019a,b**. For more details on how to describe and assess key features of context, see the CICI framework by **Pfadenhauer et al. 2017** (and additional frameworks in Box 12).

**Plan for and undertake adaptations**

New guidance on considering the impact of adaptations on intervention functioning is available in the MADI framework (**Kirk et al. 2020**). **Bonell et al. (2013)** article on dark logic models discusses a means of considering unintended consequences and may be useful in considering potential unintended consequences of adaptations. INDEX guidance on how to develop complex interventions which may often be useful in conjunction with this guidance, can be found in **O'Cathain et al. 2019a,b**.

**Plan for and undertake evaluation**

For further guidance on how to define, conduct and report pilot studies, see **Hallingberg et al. 2018** and **Eldridge et al. 2016**. See **Skivington et al.** for the **updated MRC guidance** on how to develop and evaluate complex interventions and **Moore et al. 2015** for the MRC guidance on the process evaluation of complex interventions. **Aarons et al. 2017** provide more details on intervention re-evaluation in a new context. See **Bicket et al. 2020** for guidance on handling complexity in evaluation and **Hopkins et al 2020** for guidance on types of outcomes evaluation design. The IDEA decision tool by **Miller et al 2020** discusses processes for iteratively undertaking and evaluating adaptations. Bayesian thinking about uncertainty is discussed by **Befani & Stedman-Bryce 2017** and **Heino et al 2018**.

**Implement and maintain the adapted intervention**

For further guidance on ‘scaling out’ interventions (i.e. implementing them in new contexts) see **Aarons et al. 2017**. Where an intervention has been evaluated in the new context, differences between scale-out and scale-up are minimal. Hence, other sources of guidance on scale-up (e.g. **Koorts et al. 2018**) are useful.

**Report the adapted intervention**

Guidance on how to report interventions can be found in **Hoffman et al. 2014** and its extension for population health and policy interventions – in **Campbell et al. 2018**. **Booth et al. 2019** describe how context can be considered in the evaluation of complex interventions. For further details and guidance on the reporting of intervention adaptations, see **Stirman et al. 2019**.

## 6.1 Form an adaptation team group comprised of diverse stakeholders

### 6.1.1 Involve stakeholders early and throughout adaptation processes

There was consensus in our Delphi exercise on the importance of including the following stakeholders in adaptation research: i) members of the target population, ii) researchers with experience of adaptation, evaluation, and working with the target population, iv) individuals and organisations responsible for delivery and v) individuals and organisations responsible for decisions about post evaluation scale up. We recommend forming adaptation teams comprising these stakeholders as early as possible, with ongoing collaboration needed as a team moves from identifying suitable interventions through to implementation. For example, stakeholders will work together in identifying which interventions, and which aspects of context warrant adaptation (Section 6.2). Following piloting, collaboration to consider feedback from those implementing and taking part in the intervention may inform a concrete intervention model and plans for its implementation and/or evaluation. As described in Section 6.4.5, capturing responsive adaptations and classifying these in terms of their fit with or departure from programme theory will require ongoing partnerships. Further, as described in Section 6.5.1, building partnerships throughout will facilitate wider implementation where this is warranted. Teams will likely include a core group of members comprised of the above groups throughout all stages, although some individuals with expertise on specific issues may be consulted on a more ad-hoc basis. Forming teams whose members are respectful of one another's perspectives, but who nevertheless hold diverse views and experiences and are able to challenge one another's assumptions, is likely to be helpful in preventing groupthink and premature consensus (Hoddinott, 2015). There may sometimes be good reasons to exclude some groups due to conflicts of interest. For example, where intervention aims to reduce harms related to unhealthy commodities such as tobacco, alcohol, soft drinks, collaborating with industries which produce those commodities may undermine the credibility of the team's work (Petticrew et al., 2018). PPI is likely to play an important role in contextualising research to the everyday realities of a new context, and an increasing body of guidance and case examples describes principles for patient and public involvement (PPI) in research (Kaisler and Missbach, 2020; Bedwell and Lavender, 2020).

### 6.1.2 Agree principles for decision making and involvement of members

Some adaptation processes will be researcher-led, others will be policy-practice led. Others might be community-led. Hence, some teams will operate in a more top-down way, while others may be formed in more bottom-up way, being more community-led from the outset. Top down approaches, involving decision making by a small number of individuals in positions of authority, may achieve adoption more rapidly due to their being led by agents with power and resources to deploy.

However, they may also be less likely to achieve contextual fit and longer term sustainability than approaches which involve collective decision making (Rogers, 2010). In practice, many interventions involve a combination of top-down and bottom-up elements. Co-production, is likely to be valuable in successful adaptation, given that the overarching goal of adaptation is to achieve intervention-context fit, which requires detailed knowledge of both evidence and local context. Co-production is defined by NIHR Involve as “an approach in which researchers, practitioners and the public work together, sharing power and responsibility from the start to the end of the project, including the generation of knowledge” (NIHR Involve, 2018). It can be challenging, and requires careful consideration of who will be involved in which decisions and how, and clarity on expected outcomes of the co-production process for all of those involved (Oliver et al., 2019). Some stakeholders may work together in equal partnership, while others may be involved in an advisory capacity without decision-making power. Clarity on leadership, and who among the group will make decisions and take responsibility for them is important. It might be that decisions will be made by majority vote among the group with each member holding equal power. Alternatively, one group may have more decision-making power than others. Ultimately, decisions on whether an intervention can be taken to scale may be taken largely by individuals or groups such as policymakers, who make decisions regarding resource allocation at regional and national levels.

**6.1.3 Consider pros and cons of working with original intervention developers**

There was no consensus in our Delphi exercise on whether it was important to involve the developers of the original intervention (see Section 6.2.6 for discussion of intellectual property issues). Involvement of developers may be beneficial in providing additional detail on the intervention beyond published materials, to aid replication of its mechanisms in the new context. Indeed, while in some cases it may not be possible to involve developers who have moved onto other roles or have other commitments, franchise models may sometimes mandate their involvement. However, our discussions at expert workshops highlighted several challenges. Some spoke of experiences that those who developed an intervention often have narrowly defined ideas of what it means to replicate it, which might inhibit the scope for adaptation and ability to achieve intervention-context fit. In situations such as where introducing an intervention to a lower income setting, power imbalances may occur where a developer from a higher income context is given substantial influence in decision-making on what is right for people in a lower-income context. As in pharmaceutical trials where financial conflicts of interest tend to increase the likelihood of concluding that an intervention works (Liss, 2006), developers will often have a range of financial and non-financial interests. Emotional investment in a body of work, or pressures from employers and funders to demonstrate wider impact of the original research, may represent important non-

financial conflicts of interest. Hence, where working with intervention developers, interests will need to be transparently managed throughout. It may be appropriate that individuals with a clear vested interest in demonstrating wider impacts of an intervention are excluded from certain aspects of decision making, or at least that their influence is reported transparently, with parameters around the role developers will play made clear to all parties from the outset.

**6.1.4 Review and update membership of adaptation team as adaptation progresses**  
The composition of teams will often need to be somewhat fluid, with membership and roles reviewed and updated as stakeholders move through the stages described below. For example, there was strong consensus among our Delphi participants that engaging those who will deliver the intervention in adaptation decisions was important. However, if a group is beginning from a position of defining the problem with no intervention in mind, it may be difficult to anticipate who the implementers might be. Hence, it may only be once candidate interventions have been identified that stakeholders who would have responsibility for implementation can be identified.

*Box 9 Case examples relating to involvement of stakeholders in intervention adaptation*

- **Co-production can be important in adapting interventions to new contexts, as it requires in depth understanding of the theory and evidence base of the intervention and of the new context.** Hawkins and colleagues (2017) developed a framework for adapting an evidence-informed peer-led smoking intervention to a different topic area (substance use). During stage 1, focus groups, consultations, interviews, and observations of delivery were conducted with key stakeholders. Stage 2 brought together an inter-disciplinary intervention development group consisting of academics and practice representatives to jointly adapt existing, and produce new, intervention activities. In stage 3, intervention training and content were iteratively prototyped using process data on fidelity and acceptability to key stakeholders.
- **Clarity on the objectives of adaptation teams, the roles of each stakeholder group, and who will take responsibility for which decisions, is important.** Some adaptation processes will be researcher led and others policy led. Power will not always be equally distributed. During the COVID-19 pandemic, the UK government assembled scientific groups to advise on issues including which interventions to adopt to manage the outbreak, and how. A number of options were available from countries who had experienced earlier outbreaks, or from previous outbreaks. However, these groups were advisory. Government ministers ultimately made decisions, some of which were publicly opposed by members of these groups. Government claims to be following the science (The Economist, 2020) led to some concerns that scientists were being framed as decision-makers and would take the blame for any negative consequences.
- **It can be useful to involve original intervention developers in adapting an intervention, but vested interests need careful management.** An intervention's developers are likely to have financial and/or non-financial interests in that intervention. A recent overview of reviews of the Functional Family Therapy intervention, for example, concluded that there was some uncertainty over the effectiveness of the intervention due to the quality of reviews on which this conclusion was based, and recommended further assessment of effects if scale-up was to continue (Weisman and Montgomery, 2019). This was met with calls for retraction and revision by authors linked to the development and dissemination of the intervention (Robbins and Turner, 2019). The journal stood by the publication in its original form.

## 6.2 Assess the rationale for intervention and consider intervention-context fit

### 6.2.1 Define the problem in the target population

Defining the problem is an important stage in selecting an intervention for adaptation. This includes setting out the rationale for intervention, in terms of population-level needs and assets, as well as inequalities in their distribution, and considering potential settings for intervention. In practice, a group may be responding to a problem which has already been identified by another group of stakeholders. This may include cases where health research funders issue commissioned calls for intervention research relating to identified priority areas. Nevertheless, engagement with a range of stakeholders to understand the rationale for intervention from multiple perspectives may help shape intervention selection processes within pre-specified parameters. Approaches such as systems mapping can be helpful at this stage. These can allow stakeholders to surface and reconcile differing assumptions about how the problem is sustained by current system dynamics, and how an intervention might alter interactions between components of the system to improve outcomes (Rutter et al., 2019).

### 6.2.2 Identify candidate interventions

In our reviews and qualitative interviews, we found a range of ways in which interventions had been identified and selected for adaptation. Selection may be based on a systematic assessment of available evidence and comparison of existing interventions. In some cases, organisations who developed and/or evaluated an intervention may pro-actively seek implementation elsewhere by promoting it to stakeholders in other contexts, or a team may become aware of promising interventions via conferences or their networks or other mechanisms. Hence, the starting point may be a consideration of whether to use an intervention which has already been identified. In either scenario, it is useful to think critically about whether the intervention (or candidate interventions) meets a clear need, in a manner likely to achieve contextual fit. For some problems and intervention settings, up to date reviews will be available which compare effects of different interventions across a range of contexts. If there are none, it may be useful to conduct a new review or evidence map (Snilstveit et al., 2016). These will provide a starting point for generating a list of candidate interventions for consideration. It may be that no suitable interventions are identified, or that a team decides that combining elements from more than one intervention to form a new intervention would be appropriate. In these cases, recent guidance on intervention development may be useful (O'Cathain et al., 2019a; O'Cathain et al., 2019b).

### 6.2.3 Obtain detailed information on selection intervention and the contexts in which it has been evaluated

All publications relating to previous evaluations or their component parts are likely to provide useful insights for adaptation. Publications relating to overall effectiveness will be useful in providing a

starting point for considering how confident a team are that an intervention has worked previously (see Section 6.2.4 for discussion of evaluating the robustness of effectiveness claims). Interventions which are effective at the population level can nevertheless generate inequalities through differential effects in particular sub-groups (Moore et al., 2015b). Hence, sub-group analyses focused on differential effects can be important in understanding for whom the intervention worked (Petticrew et al., 2012). This may inform decisions on where adaptations may be needed to enhance effects for sub-groups of interest and minimise the risk of generating inequalities.

Publications describing and empirically investigating programme theory are likely to be important in enabling the kind of deep understanding of mechanisms which will be needed to maintain integrity in a new context. In some cases, programme theory will be described in a separate publication from any evaluation (Sidani et al., 2020). As many interventions are under-theorised, the process of building a programme theory may need to be undertaken retrospectively to guide adaptation processes. Process evaluation is increasingly integral to evaluation of population health interventions, and 2015 MRC guidance (Moore et al., 2014; Moore et al., 2015a) emphasised a major role for process evaluation as being enabling better judgements on how an intervention might be used beyond its original context. However, much historical evidence will be based solely on outcomes data. In some cases therefore, additional research in the original context (or other contexts where the intervention is in use), may be useful in order to fill in gaps in the understanding of the intervention prior to adapting it for a new context (Devlin and Wight, 2020; Duggleby et al., 2020).

Where an intervention has been used in several contexts, bringing together details of how other teams have adapted it, including process and outcomes publications from all of these studies, will help to form a clearer picture of its likely suitability, and need for adaptation. Where systematic and complete (Campbell et al., 2018), published information on interventions may be sufficient to enable judgements about which intervention, or interventions, are likely to be most suitable and form a basis for considering the need for adaptation. However, reporting of interventions is often incomplete. Hence, gaps may need to be filled by obtaining intervention manuals, and/or through contact with developers.

#### 6.2.4 Consider the robustness of effectiveness claims

As described in Section 5, prior evidence that an intervention has ‘worked’ elsewhere is often a key motivation for adapting an existing intervention rather than developing a new one, as this may increase confidence in likelihood of effectiveness. Where an intervention is explicitly being selected on the basis that it has ‘worked’ elsewhere, it is important to critically consider the evidence for that

claim. Claims to effectiveness may be based on poor quality studies with high risk of bias. If an intervention has only been shown to work when tested by its developers, by others with significant conflicts of interest, or in evaluations with high risk of bias, claims of effectiveness ought to be treated with caution. Where a single good quality, independently conducted and peer reviewed evaluation using a robust design is available, a positive outcome may still be due to chance. Replication of scientific findings, rather than considering a single study to have provided definitive evidence that an intervention worked, is a key cornerstone of science (Maxwell et al., 2015). Where an intervention has been robustly tested in several high-quality evaluations in differing contexts, including by teams independent from the original developers, there may be greater confidence in claims it has been effective.

However, some attendees at our expert workshops also emphasised a need to remain critical of claims that interventions have been *ineffective*. Automatically disregarding interventions which have not met the threshold for a conclusion of effectiveness may be wasteful. For example, while spurious sub-group analyses are sometimes used as a post-hoc means of finding an intervention effect (Axford et al., 2020), a priori defined secondary analyses may indicate that an intervention was effective for sub-groups which are like the populations for which intervention is being considered. While poor implementation is also sometimes used as a post-hoc ‘excuse’ for null effects (Axford et al., 2020), process data might legitimately support a hypothesis that effectiveness could be improved through addressing fixable weaknesses in implementation. Further, conclusions that interventions have not worked are usually based on frequentist logic, with primary analysis having failed to achieve a p-value of  $<0.05$ . Conflation of failure to reach a threshold for concluding presence of an effect with evidence of no effect is increasingly criticised (Amrhein et al., 2019). Bayesian perspectives (Heino et al., 2018) can enable researchers to distinguish between evidence of ineffectiveness, or evidence that data are simply too insensitive to inform a conclusion either way. Reanalysis of trial data finds that in most cases where null findings are reported, more data are needed to reach a firm conclusion; in relatively few cases do Bayes Factors support a hypothesis of no effect (Beard et al., 2016). Hence, where considering interventions whose previous evaluations have not concluded that the intervention was effective, use of Bayes Factors can be a useful means of assessing whether there is evidence that the intervention did not work, or whether previous evaluations were inconclusive. Coupled with careful consideration of process evaluation evidence, a team may conclude that an intervention is sufficiently likely to work in the new context that it merits further consideration and re-evaluation, with adaptations building on learning from earlier work. Further discussion of Bayesian approaches to uncertainty is provided in Section 6.4.1.

Judgements on the robustness and nature of existing evidence will feed into later considerations regarding the benefits of maintaining fidelity to the original model, and the extent of re-evaluation warranted. If an intervention has not been tested for effectiveness, but is considered to have potential, it will most likely warrant evaluation of effectiveness as if it were a new intervention, such as a new randomised trial or other robust outcomes evaluation.

#### 6.2.5 Map similarity and difference between original and new contexts

In our systematic review, we found that most guidance for adapting interventions encourages researchers to look for differences between the context(s) in which the intervention has previously been evaluated, and the new context into which it is planned. However, participants in our qualitative work emphasised that focusing purely on *difference* between contexts may lead to an assumption that extensive adaptation is always needed, as all contexts are different. Many contextual differences will be irrelevant; interventions may transfer well to seemingly very different contexts, while failing to transfer to more similar ones. Hence, we recommend attending not just to differences between contexts, but also to similarity, in terms of whether contextual contingencies needed to make the intervention implementable and effective are present.

Our Delphi exercise reached consensus on a number of reasons why an intervention might be adapted for a new context, which mapped closely onto the domains of the RE-AIM framework (Glasgow et al., 1999) (see Box 10 below). Emphasis in assessing contextual similarities and differences may usefully be anchored around considerations of whether these differences are likely to act upon these RE-AIM dimensions (reach, effectiveness, adoption, implementation and maintenance). It is important to consider these not only in terms of overall population impact, but also in terms of equity, to increase the likelihood of interventions being inequality-reducing. Participants at our expert workshops emphasised the importance of considering whether an intervention is likely to be adopted by organisations serving disadvantaged communities, and achieve reach and effectiveness among disadvantaged groups, rather than just whether it will achieve these goals at the population level.

*Box 10. Considerations in adapting an intervention for new context on which Delphi participants reached consensus:*

- achieving adequate retention of participants in the adapted intervention;
- expected effectiveness of the adapted intervention in the new context;
- engaging practitioners or others involved in delivery of the adapted intervention,
- ensuring the adapted intervention can be delivered in the new context,
- the likelihood of the intervention being sustained in the new context.

While the importance of context is well recognised (Howarth et al., 2016), major challenges lie in operationalising it in useful and tractable ways. Stakeholders involved in adapting an intervention will often hold differing views on what aspects of context matter, which will need to be considered and balanced within adaptation teams. For example, local implementers may focus on fine grained detail of their local context, while those with a national remit may take a more macro-view on context. In some cases, additional qualitative research may be needed to better characterise the new context to inform comparisons with previous contexts (Duggleby et al., 2020).

Drawing on an established framework or theory can be helpful in guiding thinking on how the above dimensions might be supported or undermined by context, and subsequent adaptation. A growing body of conceptual frameworks (Pfadenhauer et al., 2017; Pfadenhauer et al., 2015; Craig et al., 2018; Munthe-Kaas et al., 2020) and theories from sociology (May, 2013) and community psychology (O'Donnell et al., 1993) offer approaches to operationalising context and considering how it might impact on these factors. Box 11 provides an overview of potential frameworks identified by the author group or through our expert consultations. This is not an exhaustive review, but adaptation teams may decide that one of these, or elements of several of them, will help in achieving their aims.

Important considerations commonly reflected across frameworks include presence of resources to deliver an intervention, the roles into which intervention delivery would be embedded, acceptability (to the target population, intervention delivery agents and wider publics), the willingness and ability of local implementers to adopt the intervention, potential fit with local norms and existing systems, and the relative prevalence and distribution of the problem in the target population. An important contextual consideration which is not explicitly captured in these frameworks includes characterising 'usual care' in the original and new contexts. Effect sizes from other evaluations represent estimates of effectiveness relative to a control condition (Freedland et al., 2019). An intervention introduced into a context in which it is only marginally different from usual care may be more likely to be normalised into practice, but may make little difference to outcomes (Löfholm et al., 2013).

*Box 11. Some theories and frameworks for guiding thinking about similarity and difference in context*

- **May's (2013) general theory of implementation** specifies conditions for an intervention to be implementable which may form part of assessments of whether a new intervention can be introduced. These include i) capability (whether the intervention is workable and can be integrated into existing routines in a new context); ii) capacity (the availability of local norms, roles and resources needed to support the intervention) iii) potential (whether stakeholders are willing and able to deliver the intervention, and value the change which its implementation will bring about); iv) contribution (ability of local providers to work together and commit to delivery, investing in the operationalisation of the intervention in practice);

*Box 11. Continued*

- **Activity settings theory** (O'Donnell et al., 1993) derived from community psychology understands many interventions as being introduced into dynamic 'activity settings'. These are time and space bound patterns of social interaction, such as classrooms, or a GP consultation. These form units through which culture and community are shaped and spread over time. Hence, when for example, introducing an intervention to hospitals or schools within different education or health systems, stakeholders might analyse the activity settings within schools or hospitals, and differences and similarity between original and new contexts in terms of roles, funds, physical resources, symbols, people (McLaren and Hawe, 2005) and how the interaction of these elements create experiences for people within and across these settings. The goal of this would be to understand the dynamics of the settings into which interventions will be introduced.
- Wang, Moss and Hiller (2005) present a **framework for applicability** (whether an intervention can be implemented in a new context, which they describe as synonymous with 'feasibility') and **transferability** (whether if implemented, it will work in the same way). Considerations for the former include). Considerations for applicability include fit with political environment, acceptability to the public, cultural fit (with or without adaptation), availability of resources, ability of target population to understand and engage with the intervention, ability of organisations to deliver the intervention. Considerations for transferability include, the prevalence of the problem in the new context relative to the original context, characteristics of the target population and capacity to implement the intervention.
- The **CICI framework** (Pfadenhauer et al. 2017) defines key domains of context whose similarity and difference may be of relevance when considering intervention-context fit. These cover geographical (the physical environment, landscapes and resources available in a given setting), epidemiological (the distribution of diseases or conditions, the attributable burden of disease, as well as determinants of needs in populations), socio-cultural (historically derived and selected ideas and values that are shared among members of a group), socio-economic (the social and economic resources of a community and the access of a population to these resources), ethical (reflections of morality, which encompasses norms, rules, standards of conduct and principles that guide the decisions and behaviour of individuals and institutions), legal (the rules and regulations that have been established to protect a population's rights and societal interests) and political (distribution of power, assets and interests within a population, as well as the range of organisations involved, their interests and the formal and informal rules that govern interactions between them) aspects.
- **TRANSFER guidelines** (Munthe-Kaas et al., 2020) for systematic reviews emphasise collaborative decision making processes in understanding the transferability of systematic review findings to a new context. The authors state that a review team may i) identify a priori contextual considerations for transferability and conduct a subgroup, or regression, analysis for each transferability factor ii) interpret the results of the subgroup or regression analysis for each transferability factor and record whether they have no, minor, moderate or serious concerns regarding the transferability iii) make an overall assessment (no, minor, moderate or serious concerns) regarding the transferability of the review finding based on the concerns identified for each individual transferability factor. As this guidance is new at the time of writing, the authors state that they are generating case examples to illustrate the guidance.

*Box 11. Continued*

- The **Consolidated Framework for Intervention Research** (Damschroder et al., 2009) emphasises the need for interventions to be adapted in order to achieve fit with new contexts and comprises 5 core interacting domains for framing thinking and decision making. These are intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. The outer setting includes more macro-level characteristics of context (i.e. the economic, political, and social context within which an organization resides), and the inner setting includes features such as networks and communication, implementation climate and organisational cultures through which the implementation process will proceed.
- The **WHO-INTEGRATE framework** (Rehfuss et al., 2019) aids with evidence to decision making processes and takes complexity in the intervention and its interaction with the system (e.g. health system, society) in which it is to be implemented into account. It specifies criteria and considerations for teams using evidence to inform decisions on health interventions, which influence whether an intervention is likely to work in a given context. These include i) the *balance of health benefits and harms*, ii) *human rights and sociocultural acceptability*, iii) *health equity, equality and non-discrimination*, iv) *societal implications*, v) *financial and economic considerations*, and *feasibility and health system considerations*, as well as the meta-criterion of *quality of evidence*.
- **Realist evaluation** (Pawson and Tilley 1997) has been highly influential in thinking about context. From this perspective, interventions ‘work’ by introducing mechanisms which are sufficiently suited to their contexts to produce change. Hence, attention is placed on understanding context-mechanism-outcome configurations. The presence or absence of the contextual conditions necessary for intervention mechanisms to activate change becomes a key focus in understanding transferability of effects. Bonell and colleagues (2020) have proposed a realist framework for local decisions on whether to implement interventions evaluated as effective elsewhere.

A range of quantitative methods are emerging for modelling context and transferability. These include methods based on weighting original study data to the characteristics of a new population (Westreich et al., 2017). These may be useful in data-rich environments, where contextual effect modifiers are known and data on their population distribution are available in the new context. Methods such as agent-based modelling are increasingly used to build hypothetical models of the effects of interventions under varying assumptions regarding context (Badham et al., 2018). These might usefully be applied to simulating effects for the intervention, varying key parameters of the intervention and/or context, to simulate how outcomes might differ. This may enable estimation of how effects of the intervention might vary with context, and how making different adaptations might amplify or mitigate this, enabling fuller theorisation around intervention-context fit. Though offering promise, simulation based methods make a large number of assumptions, and require empirical verification (Sridhar and Majumder, 2020).

### 6.2.6 Consider intellectual property issues

Defined interventions may sometimes be franchised as a branded product, which may in some cases include constraints on the degree of adaptation allowed. This may be as simple as mandating use of a brand name which is not well received in a new context, or deeper aspects of the composition of the intervention. If constraints are likely to make intervention-context fit unachievable, selection of a different intervention may be necessary. However, evaluations typically generate insights into the kind of mechanisms which work to solve population health problems rather than being entirely specific to the product evaluated. Hence, it may be that a new, locally branded intervention can build on the insights from similar interventions elsewhere, without being constrained by limits placed on adaptation of the specific branded programme by its developers. Hence, what is being transported to a new context is not the intervention as a defined ‘product’, but its programme theory. Where the developer of the intervention, or holder of any intellectual property rights, is not a partner in adaptation, legal advice may be needed on whether plans avoid contraventions of intellectual property rights to avoid later legal challenges. Development of open-source, rather than proprietary interventions, is increasingly encouraged as license fees may act as a major barrier to their use by other groups, particularly in lower resource contexts (Gomide et al., 2016). Where choosing between two potentially suitable interventions, all else being equal, if one is open-source and the other is not, selecting the open-source intervention is likely to be preferable.

*Box 12. Illustrative case examples for issues to think through in selecting an intervention for a new context*

- **Where selecting an intervention on the basis it has worked elsewhere, it is important to critically consider the robustness effectiveness claims.** The Strengthening Families Programme demonstrated good effects on child outcomes in US studies, but numerous attempts to replicate these in European studies have failed. Potential reasons may include adaptations which undermine the functioning of the intervention. For example, in an ineffective Swedish replication of the Strengthening Families Programme (SFP), adaptations included doubling class sizes to which children’s sessions were delivered (Skärstrand et al., 2013), which may have altered the dynamics of the intervention, making it more feasible to implement but less effective. Others have argued that possible explanations include selective outcome reporting by the original study team, which casts some doubt on whether the intervention worked prior to its being transferred to new contexts (Gorman, 2017).

*Box 12. Continued*

- **In considering contextual similarities and differences, some contextual differences are more important than others.** The school based smoking prevention intervention ASSIST showed good population-level impacts on smoking uptake (Campbell et al., 2008). Sub-group analyses indicated that effects were greater in Welsh valleys contexts. These are areas characterised by high rates of smoking, strong social ties and relatively stable social networks, with limited inward and outward migration of pupils between schools. Hence, insights on contextual variability within the original study suggest that confidence in transferability may be greatest where a new context is also characterised by high smoking and strong, relatively stable, social ties. A recent study of the ASSIST intervention in Scotland found challenges using this in a contemporary Scottish context where smoking rates had become very low (Dobbie et al., 2019). Ongoing work is exploring the transferability of ASSIST to lower- and middle-income contexts. Intuitively, one may assume that differences between these new contexts and the original study context will be substantial. It may however be that these contexts are similar in ways which are important for intervention mechanisms to be activated, such as contextual contingencies of high smoking rates and strong community ties. While some adaptation to form may be essential in order to work within very different education systems, the functions may therefore be transferable.
- **Differences in an intervention's effect sizes may be driven by differences in usual care.** Löfholm and colleagues (2013) conducted a review of trials of 'multi-systemic therapy', an intervention to address anti-social behaviour in at-risk young people. This identified substantial variation in effect sizes between contexts. The authors characterised 'treatment as usual' comparison conditions in each of the studies, finding that in contexts such as Sweden the intervention was only marginally different to usual care. Outcomes for participants in 'treatment as usual' groups differed more across contexts than did outcomes in the 'intervention' group. Selection of an intervention which is similar to usual practice may ensure feasibility, but may sometimes add little to improving outcomes.
- **Existing interventions may have proprietary restrictions which limit their usefulness for new contexts.** Gomide and colleagues (2016) identified that web based smoking cessation interventions in the Portuguese language did not follow evidence-based principles. However, those which did, but were not available in Portuguese, were hosted on proprietary platforms whose costs were considered prohibitive for lower- and middle-income countries. Hence, the team built a new local intervention informed by the principles of evidence-based platforms, rather than paying to use and adapt existing proprietary interventions.

## 6.3 Plan for and undertake adaptations

### 6.3.1 Identify and respond to contextual constraints and facilitators

Consideration of intervention-context fit will likely have identified a range of constraints and facilitators to the use of the intervention in the new context. Considering these together, decisions need to be made on whether they can be addressed, and what adaptations might be undertaken to achieve this. It may be concluded that constraints are insurmountable, in which case termination of the adaptation process and movement back to intervention development (or selection of a different intervention) may be recommended. However, adaptations to address contextual constraints and

draw upon local facilitators will often be possible. An adaptation team may begin by brainstorming ideas for how adaptations might respond to these constraints and draw upon local facilitators. Sometimes, adaptations to make an intervention easier to implement can however undermine effectiveness. Hence, for proposed adaptations (individually and as a whole), consideration needs to be given to how these are likely to impact on effectiveness. The Model for Adaptation Design and Impact (MADI) framework (Kirk et al., 2020), provides one useful tool for considering these issues, and classifying adaptations in terms of hypothesised impacts on the causal logic of an intervention (Proctor et al., 2011) (see Figure 3).

Adaptation commonly involves addition of new actions to address contextual constraints. However, streamlining an intervention might sometimes improve feasibility while still fulfilling intended functions at lower cost. Approaches such as network meta-analyses might usefully inform identification of aspects of an intervention which are critical to maintaining functioning, and conversely, which could be removed to improve feasibility without undermining the functioning of the intervention (Molloy et al., 2018). Process evaluation data may also provide evidence that some aspects of the intervention were poorly delivered in the original evaluation, and/or appeared to make little or no contribution to intervention effects.

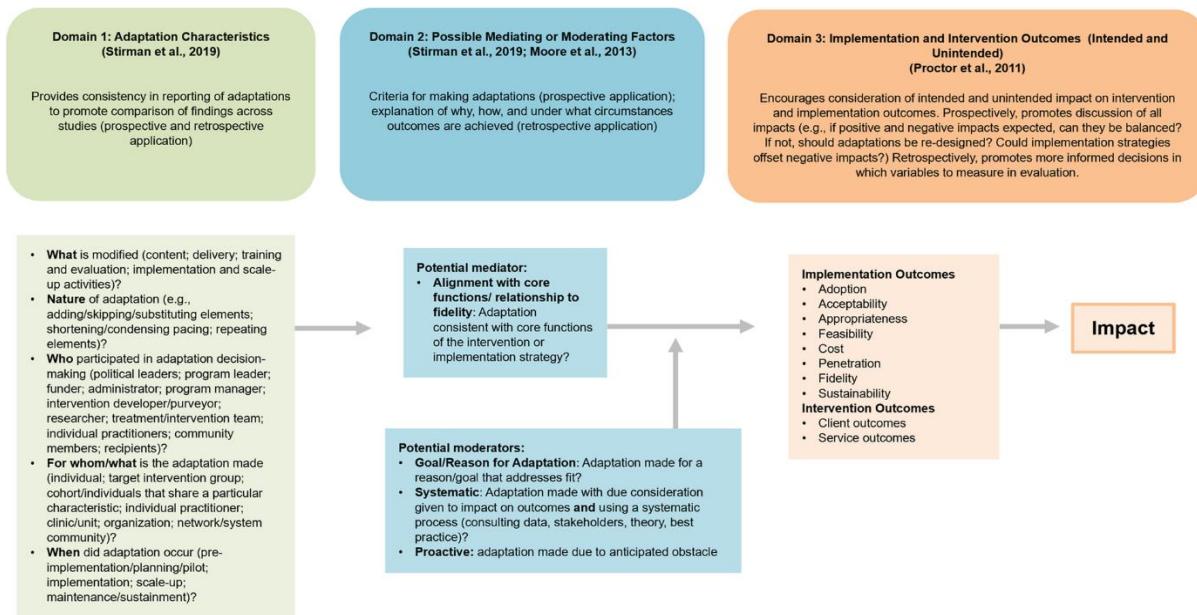
There was majority agreement, though not consensus, within our Delphi exercise that addressing constraints to intervention-context fit sometimes requires changes to both the intervention and the context. For example, a period of engagement may be needed to enhance buy-in and create a fertile context for implementation. It can sometimes be difficult to distinguish whether an adaptation represents a change to the intervention or to the context. Indeed, from a systems perspective, boundaries placed around ‘intervention’ and ‘context’ are somewhat artificial. One distinction lies in whether the adaptation is offered specifically for the benefit of intervention participants or reflects a change with wider anticipated benefits beyond the intervention population.

### 6.3.2 Adapt intervention materials

Having considered candidate adaptations to achieve intervention-context fit, these can be brought together into a detailed set of intervention materials, including all proposed adaptations, and their rationale. This may include as an updated programme theory, manual, protocols and delivery plan. Our Delphi exercise reached consensus that it was important to consider whether programme theory would need adaptation to achieve intervention-context fit. Changes may include specifying different inputs and resources which will be used to deliver intervention activities in the new contexts, tailored intervention activities, and differences in anticipated interactions with context. However, in our qualitative work, many emphasised that the goal of adaptation was to maintain

consistency with intervention mechanisms in a different context. Interviewees argued that if intervention mechanisms were significantly modified, this can be considered a new intervention. Hence, consistent with the MADI framework described in Section 6.3.1, an adapted manual might specify how the package of adaptations as a whole is expected to both achieve intervention-context fit, and ensure activation of intended mechanisms. Clearly documenting processes through which proposed adaptations were considered and accepted as appropriate, or rejected as inappropriate, will provide a useful basis for subsequent iterative efforts to capture and classify responsive adaptations (see Section 6.4.5). Where a team consider an intervention to have undergone sufficient adaptation as to have become a ‘new’ intervention, we recommend using our guidance in conjunction with INDEX guidance (O’Cathain et al., 2019a; O’Cathain et al., 2019b).

*Figure 3 MADI framework reproduced from Kirk et al (2020)*



### 6.3.3 Consider potential for unintended consequences

Key characteristics of the complex systems into which interventions are delivered include unpredictability and emergence, which includes potential to give rise to unanticipated consequences (Bicket et al., 2020). An intervention may replicate the same benefits in a new context because contextual contingencies necessary for the intervention to work are present, and the intervention is feasible to implement. However, interactions with other features of a new context may mean it has unintended consequences not observed in the original evaluation. It may be possible to anticipate some unintended consequences in advance, through theorising interactions with the new context, and how these might cause unintended consequences (Bonell et al., 2015). However, ongoing qualitative work throughout subsequent stages of piloting, evaluation and implementation may be useful to capture emergence of unintended ‘side effects’ in the new context and develop plans to

mitigate them. Guidance for handling complexity in intervention research published after completion of our Delphi exercise, places strong emphasises the importance of developing protocols with a degree of flexibility to respond to emerging issues as they arise (Bicket et al., 2020).

#### 6.3.4 Consider costs and resources needed for the adapted intervention

Consideration of resources is likely to form part of earlier assessments of differences and similarities between contexts, and to feed into adaptation decisions. However, once a concrete adapted intervention model has been developed, revisiting the impact of context and adaptations on costs and resources can be useful. As discussed in Section 5, our Delphi exercises reached consensus that the likelihood of saving resources by adapting an existing intervention was a key motivation for doing so rather than developing a new one. However, because interventions will work with differing local resources, and costs of delivering an intervention may differ substantially between contexts, this assumption may not be upheld if costs in the new context are much higher. Hence, where analysis of costs has been conducted within a previous evaluation, these can be compared with estimated costs in the new context, considering whether the cost of the adapted intervention is likely to be substantially lower or higher in the new context. If the intervention is likely to be too resource intensive, a team may decide to move back to further adapt the intervention model, to selection of another intervention, or to development of a new intervention. Where estimated costs in the new context differ substantially to those in the original context, economic modelling may be helpful in informing a decision on whether, if as effective, it would be likely to remain cost effective.

#### 6.3.5 Recruit individuals and groups to deliver the intervention

Once a firm decision is made to proceed with an adapted intervention, beginning to identify and recruit a network of individuals and groups who are likely to be involved in delivery, and building expertise in delivering the intervention, are important prior to moving forward to piloting. This may involve recruiting community organisations, public, private and charitable sector organisations. It may involve providing training and support to a workforce similar to the group who delivered the original intervention. For example, while roles will vary across contexts, most societies will include groups such as teachers, general practitioners and law enforcement officers, who may be delivery agents for a range of interventions. However, interventions developed in higher income contexts which are being adapted for lower income contexts will often be embedded into the roles of workforces which do not exist in the same form in the new context. Where this is the case, a key focus for adaptation may be ‘task shifting’, focused on identifying whether the intervention can be accommodated into the roles of another group of practitioners, while maintaining its effectiveness (Divan et al., 2015).

*Box 13. Illustrative case examples for issues to think through in planning and undertaking adaptations*

- **Sometimes an intervention will need to be adapted to overcome contextual constraints.** In adapting a health behaviour intervention for people with impaired mobility, Betts and colleague (Betts et al., 2018) made a number of adaptations to reduce barriers, such as combining in-person sessions with conference calls and providing arm-based activity trackers.
- **Aspects of the context itself may need to be addressed before an intervention can be introduced.** A high profile example of a population health intervention where changes to the context were needed prior to implementation is smoke-free legislation. Concerted efforts were made to change public attitudes and increase public acceptability prior to implementation, to maximise the likelihood of successful implementation. These efforts achieved varying success across a range of contexts, with compliance very high in the UK but lower in nations such as Greece (Melonashi, 2017).
- **In theorising how an adapted intervention will work in the new context, it is useful to consider potential for unintended consequences.** Minimum unit pricing has shown good initial effects in Scotland (Christie, 2019), and has recently been implemented in Wales. As England has not introduced this, some concerns have been raised about cross-border sales. Scotland has a narrow border with England and most of its population live some distance from it, making cross-border sales unlikely to occur on a large scale. Some argue that with Wales' lengthier border, cross-border sales may be more of a problem, with large grocery shopping trips moving outside of Wales. Evaluation may need to focus on whether this contextually contingent unintended consequence occurs to confirm or counter these concerns.
- **Interventions will work with different financial and human resources in a different context.** An intervention for pre-school children diagnosed with autism was delivered by speech and language therapists in higher income countries, but was adapted to enable delivery by non-specialists in South Asian contexts where a similar trained workforce was not available (Divan et al., 2015). Positive effects of the original intervention were replicated in a new RCT (Rahman et al. 2016).

## 6.4 Plan for and undertake piloting and evaluation

### 6.4.1 Consider the extent and type of evaluation warranted

Our Delphi surveys indicated consensus that decisions on whether to proceed with implementing an adapted intervention, adapt further, or terminate, ought to be informed by evidence of i) feasibility, ii) acceptability (to participants and implementers), iii) effectiveness and iv) cost effectiveness. However, for interventions with a prior evidence base, much of this evidence may be ‘borrowed’ from prior evaluations rather than needing to be undertaken in full again prior to implementation. Reflecting this view, the only guidance our systematic review identified for deciding on the extent of re-evaluation emphasised notions of ‘borrowing strength’ (Aarons et al., 2017) from prior evidence, with re-evaluations depending on the degree and nature of similarity and difference in contexts. The type and extent of re-evaluation warranted is a qualitative judgement for an adaptation team to make, based on many of the same considerations which are likely to have shaped decisions on intervention selection and the degree of adaptation needed. These will include i) the quality and nature of prior evidence (see Section 6.2.4), and ii) (un)certainty regarding the applicability of this

evidence to the new context (see Section 6.2.5). While it is usually a good idea to undertake some form of evaluation, where prior evidence is robust and uncertainty minimal, evaluation might be embedded within implementation, using routine data and natural experimental designs rather than being conducted as a discrete phase prior to an implementation decision. This is consistent with principles of MRC guidance for developing and evaluating interventions, and MRC guidance for process evaluation (Moore et al., 2014; Moore et al., 2015a), which emphasise the importance of focusing evaluation on uncertainties posed by introducing a new intervention into a complex system. The team will also need to consider the extent to which evaluation will aim to primarily inform decision making in the specific new context (in which case, a less controlled evaluation of effects may be sufficient), or to build additional review-level evidence on how an intervention functions in different contexts.

Discussions at our expert workshops and with our advisory group identified Bayesian logic as a potentially useful approach for adaptation teams to consider in structuring thinking about uncertainty. Bayesian analyses focus on the relative likelihood of two competing conclusions (e.g. no effect or a pre-specified effect size). Bayesian logic has been applied to both quantitative (Heino et al., 2018) and qualitative approaches (Befani and Stedman-Bryce, 2017), and may be particularly relevant to adaptation research, given emphasis on the impact of prior knowledge on relative likelihood. Where there is no prior reason to believe success is more likely than failure, probability estimates of one outcome or the other will be 0.5, just like the flip of a coin. For interventions which do have a prior evidence base, a team may make a qualitatively driven decision to adjust confidence estimates based on this prior information (Befani and Stedman-Bryce, 2017). Estimates of confidence in achieving the desired outcome may be increased where an intervention has prior good quality evidence, and intervention-context fit is considered good. It may be down-rated where there are significant uncertainties regarding underpinning evidence and/or intervention-context fit. Plans to collect new evidence can then be formed which explicitly focus on updating a group's estimates of likelihood, through seeking confirming and disconfirming information. This might involve specifying associations short of another full effectiveness evaluation whose presence or absence would increase or reduce confidence that effects do transfer. For example, Heino and colleagues (2018) argue that Bayesian approaches function well with small sample sizes, and use within small scale pilot work might give investigators important signals on whether mechanisms necessary for intervention effects to occur are activated. Where the primary uncertainty relates to whether these mechanisms will be activated in the new context, this may update likelihood estimates sufficiently for a decision on implementation to be reached.

#### 6.4.2 Consider the value of information to policymakers, practitioners, and other stakeholders

In our meeting with our advisory group prior to our Delphi exercise, discussions suggested that combining Aarons and colleagues' ideas of 'borrowing strength' from previous evaluations with a value of information perspective could be helpful. Subsequently, there was consensus among our Delphi exercises that the value of new information to decision-makers was an important consideration at this stage. New information comes at a financial cost. While research is likely to be motivated by more than its instrumental role in informing a specific decision at a single point in time, considering what value this will add to decision-making can be helpful (Bindels et al., 2016). Formal value of information (VOI) analyses involves modelling, which weighs up the value of information against the cost of obtaining it (Fenwick et al., 2020). For adaptation studies, the principal decision for which a VOI analysis may be useful might be whether to commit to implementation, or to postpone a decision until new evaluation can be undertaken. Hence, VOI analyses may involve modelling whether the opportunity cost of delaying a decision to implement is outweighed by benefits of waiting for new evidence, leading to an "implement now, research later" recommendation, or vice versa (Tuffaha et al., 2015).

#### 6.4.3 Consider resources available for evaluation

Many interventions are introduced in contexts where there are limited resources available to undertake a large expensive evaluation. This may be the case in Lower- and Middle-Income Countries (LMICs) or other lower resource contexts, where stakeholders are interested in importing effective interventions from elsewhere into their setting. Nevertheless, some of the largest evaluations take place in resource poor settings, funded by international development or philanthropic organisations. There are an increasing number of funding streams which aim to link researchers across low- and high-income contexts to build expertise and capacity for evaluation research across both. Within high income settings, political actors may nevertheless choose to allocate limited resources to evaluation research, in which case resource availability may still be limited. Hence, resource considerations will play a major role in determining what evaluation work is undertaken. Where resource is limited, this needs to be targeted strategically toward understanding the most important uncertainties that are feasible to address. For example, where there is good evidence an intervention has worked elsewhere, simpler monitoring of changes in the intended outcomes, and qualitative exploration of potential novel unintended consequences, may be prioritised.

#### 6.4.4 Evaluate feasibility and consider further adaptations based on feedback

Once an adapted intervention model has been agreed in principle, small scale testing is useful to understand feasibility, practicalities of implementation, to troubleshoot issues with stakeholders and further adapt the intervention if warranted. Consistent with Eldridge and colleagues, we consider a ‘pilot’ to be one form of feasibility study, in which elements of an intervention are tested in miniature (Eldridge et al., 2016a; Eldridge et al., 2016b). The extent of feasibility testing will depend on the degree and nature of uncertainty regarding whether the adapted intervention can be successfully delivered. Where uncertainty is minimal regarding effectiveness, piloting may be embedded within a move straight to full implementation. In these instances, piloting of data monitoring structures which will be integrated into the roll out of the intervention may be helpful. Where another full evaluation of effectiveness and cost-effectiveness is warranted, testing aspects of the evaluation design for which there is uncertainty is important at this stage.

#### 6.4.5 Document and classify responsive adaptations

Our qualitative interviews, and responses within our Delphi exercise, emphasised that while adaptations can usefully be pre-planned where issues with intervention-context fit are identified in advance, adaptation will usually continue as an intervention is delivered. While 2008 MRC guidance acknowledged the degree of adaptation ‘allowed’ as a dimension of complexity (Craig and Petticrew, 2013), from complexity science perspectives, adaptation inevitably occurs as a consequence of introducing change into a complex system, rather than being allowed. Interventions often take on the characteristics of complex systems (Shiell et al., 2008). One of these is that systems self-organise through the collective actions of agents forming them, rather than being hierarchically controlled. Introduction of change into a system generates feedback, which will lead delivery agents to use local knowledge and expertise to adjust their practices in an ongoing way. Delivering an intervention is an active and creative process (Horton et al., 2018), and ongoing responsive adaptation can be considered as an intrinsic part of this. This becomes problematic only when it causes delivery to stray from the theoretical principles of the intervention or undermine its mechanisms (Bumbarger and Perkins, 2008). Spontaneous changes which compromise intervention functioning may be most likely where intervention protocols are defined in a manner which offers insufficient flexibility (Richard et al., 2015). Qualitative responses within our Delphi surveys emphasised that responsive adaptation was important, but that it was important to have systematic processes in place to document adaptations and agree how these would be classified in terms of whether they fit with, or contradicted, the underlying programme theory. Developing an agreed framework for categorising adaptations as (in)consistent with programme theory, which draws upon both academic and practitioner knowledge and experience, can enable guidance for intervention delivery to be

continuously updated with the kinds of responsive adaptations which are, or are not, considered likely to undermine the overall functioning of an intervention (Holliday et al., 2009). As described in Section 6.3.2, a team will ideally have undertaken a systematic process for considering the likely impact of pre-planned adaptations on the integrity of the intervention. This stage will involve extending these principles to assessment of the suitability or unsuitability of responsive adaptations. Documenting and classifying adaptations is likely to be an ongoing and iterative process as an intervention moves forward to full implementation, and indeed as it is maintained at scale. Box 14 provides discussion of emerging guidance on documenting and classifying adaptations and a case example.

*Box 14. Capturing and classifying responsive adaptations*

Miller and colleagues (2020) article on Iterative Decision-making on Evaluation of Adaptations was published shortly after our systematic review was complete, and draws attention to the iterative nature of intervention adaptation processes.

Where data or stakeholder feedback indicate adaptations are necessary, and core functions and processes of the intervention are known, a team can consider whether adaptations can be made which enable barriers to be addressed in a manner which remains consistent with core functions. Using FRAME (see Figure 4), the authors discuss classifying adaptations using the following questions: When did adaptation occur? Were adaptations planned? Who participated in the decision to adapt? What was the goal? What was modified? What is the nature of the content modification? Reflections on whether adaptations enhance intervention-context fit while maintaining integrity to process and functions, and analysis of programme data on the impacts of introducing the adaptation on proxy indicators such as participant engagement, may then inform decisions on whether adaptations are integrated in future iterations of the intervention, or adapt in alternative ways.

While the authors present uses of the framework at the programme level, they present discussion of how its principles might also be applied to more responsive micro-level adaptations occurring in local practice.

An illustrative case example of classifying emerging adaptations is a study by Betts and colleague (2018), who undertook a community-based participatory research study adapting an intervention to reduce barriers to accessing a health behaviour intervention among people with impaired mobility. While some changes were pre-planned, several additional barriers came to light leading to further **responsive** adaptations. These included offering make up sessions, and adding content and activities on goal setting, problem solving, planning, peer support, reflection, and motivation. During delivery, monthly meetings were held between researchers and intervention staff to discuss emerging challenges and responsive adaptations. Responsive adaptations agreed by this group were then carried forward as planned adaptations in future iterations.

#### 6.4.6 Undertake evaluation of effectiveness, cost-effectiveness and process (if warranted)

If feasible, but a significant degree of uncertainty remains about whether it will work in the new context, a full evaluation of effectiveness, cost-effectiveness and process may be needed. A number of resources exist for deciding on the most appropriate design for evaluating effectiveness (Hopkins et al., 2020). Where a randomised controlled trial is feasible, this will be the most robust of estimating effects, but for many population health interventions, natural experiment designs may be more appropriate (Craig et al., 2012). In cases, where there is only modest uncertainty on whether effects will be replicated, and the ‘equipoise’ necessary to form the ethical basis for randomisation is not present, alternative methods such as designs with matched comparisons may be favoured. These may be embedded within a full implementation rather than forming a discrete prior phase if delaying implementation is not deemed to be warranted. It is often difficult to generate conclusive evidence on the contribution that adapting an intervention has made to maintaining (or reducing) effectiveness. Some studies have tried to isolate impacts of adaptation by directly comparing standard delivery of an evidence based intervention with a culturally adapted version of the same intervention (Burrow-Sánchez et al., 2015). There are limited scenarios in which this might be possible; where adaptation is undertaken because an intervention is simply not feasible without it, any such comparison will be with a poorly delivered version of the original intervention. Process evaluations (Moore et al., 2014; Moore et al., 2015a) of adapted interventions might usefully pay attention to understanding perceived impacts of adaptations on intervention-context fit, as well as exploring unintended harms and mechanisms. These may build on aspects of prior process evaluations within the original evaluation, for example to allow between study comparisons on measures of implementation. They may further the evidence base for the intervention by extending understandings of implementation, mechanisms and context generated by earlier evaluation.

*Box 15 Case examples relating to evaluating interventions in a new context*

- **Decisions on what kind of evaluation is needed will be driven by where uncertainties lie, and how significant they are.** The Football Fans in Training intervention was an effective weight loss intervention for male football fans, delivered via sports clubs in Scotland (Hunt et al., 2020). It was scaled out to football and other sporting contexts in Australia, Canada, New Zealand, England and elsewhere in Europe. In some cases, where adaptations were deemed minor, light touch pre-post evaluation or feasibility studies was undertaken. Where adaptations were deemed moderate or substantial, another RCT was undertaken.
- **Value of information assessments can aid decisions on whether a full evaluation is warranted prior to implementation.** Evidence from a systematic review and meta-analysis of nutritional support for preventing pressure ulcers in high-risk patients formed the basis of a decision model on whether to implement the intervention now or evaluate prior to implementation. This informed a decision that the opportunity cost of delaying outweighed the value of new evaluation. Hence, this informed a recommendation to implement now, and research later (Tuffaha et al., 2015)

*Box 15. Continued*

- **Some feasibility testing prior to a new evaluation, or wider implementation can be useful.** The Nutrition And Physical Activity Self-Assessment for Child Care (NAP SACC) intervention showed positive impacts in the US, and was adapted for the UK (Kipping et al., 2019). Adaptations included revision of self-assessment tools to context-specific local concerns, as well as changing the labelling of these as a self-assessment forms to ‘review and reflect’ forms to avoid evoking language associated with that used by government inspectors. The number of action planning goals due to concerns with capacity and workload of implementing staff. The team undertook a substantial feasibility study with nested pilot RCT testing the intervention in full in 5 nurseries. A full scale RCT is in progress.
- **Feasibility testing may indicate that progression is not warranted.** Healthy Dads Healthy Kids is a weight management programme for fathers of primary school-aged children and their children, with 90-minute training sessions over 9 weeks. It showed effects on weight loss in Australia, and was adapted to increase cultural acceptability to a multi-ethnic UK population (Griffin et al., 2019). However, in piloting, the team were unable to meet their recruitment targets and identifying appropriately skilled programme facilitators proved challenging. A decision was made not to proceed with the intervention without further adaptation.
- **Responsive adaptations will occur as interventions are implemented.** In delivering the National Exercise Referral Scheme in Wales, some local area coordinators highlighted a shortage of community-based low intensity physical activity opportunities for patients to move onto after the scheme as a major barrier to continued exercise after the scheme. Some began to build low intensity classes into schedules for their centres. Coordinators commented that offering a wider range of lower intensity classes, which were not initiated specifically for scheme patients, changed the culture of leisure centres and availability of classes for users beyond scheme patients (Moore, 2010).
- **In some cases, it might be possible to compare an intervention with or without adaptation to test whether adaptation maintains or enhances effectiveness; adaptations may not enhance population impacts but might still reduce inequalities.** Burrow-Sanchez and colleagues (2015) evaluated an evidence-based cognitive behavioural therapy-based intervention for reducing adolescent substance use, delivered as per original manuals. This was compared against a culturally adapted form of the same intervention, tailored for Latino populations. Both were found to have similar population level impacts. However, the culturally tailored version had better impacts for participants with a greater commitment to their ethnic identity.

## 6.5 Implement and maintain the adapted intervention at scale

### 6.5.1 Build sustainable partnerships, capacity and plans for maintenance

There was consensus within our Delphi exercises that building partnerships and capacity, for maintenance was important in effectively scaling out adapted interventions. Ideally, interventions will only have been selected for adaptation where there is good reason to believe that they are likely to be effective, and are likely to achieve sufficient fit to be scalable (Zamboni et al., 2019). Further, the collaborative processes described throughout will be directed toward achieving consensus on whether full implementation is warranted based on the combination of prior evidence and any new evidence generated in the new context. These will also focus on building plans for who will provide

what resources to support implementation. Hence, this stage will represent a continuation of the work initiated through stakeholder groups from piloting stages onwards, including recruiting an expanded network of individuals and groups, creating and maintaining a fertile context for implementation (Ellis et al., 2020). Where moving rapidly to scale without a need for a large evaluation, a dedicated period may be needed to build these networks and wider support for the intervention. Our Delphi exercises indicated consensus that establishing a plan for maintenance is important in scaling out a new intervention. While many effective interventions are not subsequently implemented in routine practice, where adapting an intervention which has previously been found effective, there may be teams who have implemented the intervention at scale previously or are currently doing so. Engagement with these teams throughout adaptation may provide important information on challenges and solutions in taking the intervention to scale.

#### 6.5.2 Establish data monitoring systems

Embedding systems to monitor long-term implementation and effects is useful in understanding how the intervention maintained over time, and for maintaining high quality delivery and effects at scale. Evaluations are often conducted in samples which are not representative of the intended population, and implementation can sometimes weaken as interventions move to scale. Sophisticated infrastructures are increasingly being developed for linking intervention monitoring data to routine health, education and social care data (Clarke et al., 2019), which can provide valuable mechanisms for examining intervention maintenance. For the National Exercise Referral Scheme in Wales for example, routine data linked to health care records indicates that scheme uptake dropped, and became substantially more unequal by socioeconomic status in the 10 years following positive RCT findings (Morgan et al., 2020). From a systems perspective, many evaluations are not long enough to capture non-linear intervention effects which build over time through reinforcing feedback loops. For example, improving cycling safety may increase numbers of cyclists, which may further increase safety through ‘safety in numbers’ effects, which may further increase cycling and so on. Hence, observational data embedded into implementation can enable ongoing analysis of whether effects increase or diminish over time. If interventions have been taken to scale elsewhere with monitoring systems built in, it may be useful to consult with teams responsible for this to harmonise monitoring systems. Where the intervention has been accompanied by high quality monitoring systems elsewhere at scale, replicating these may open potential for cross-context comparisons and sharing of lessons regarding maintenance over time. Building in mechanisms for capturing ongoing responsive adaptations (and continuously refining the categorisation framework for defining these as consistent or inconsistent with intervention theory) is helpful in understanding if adaptations maintain coherence with intention over time.

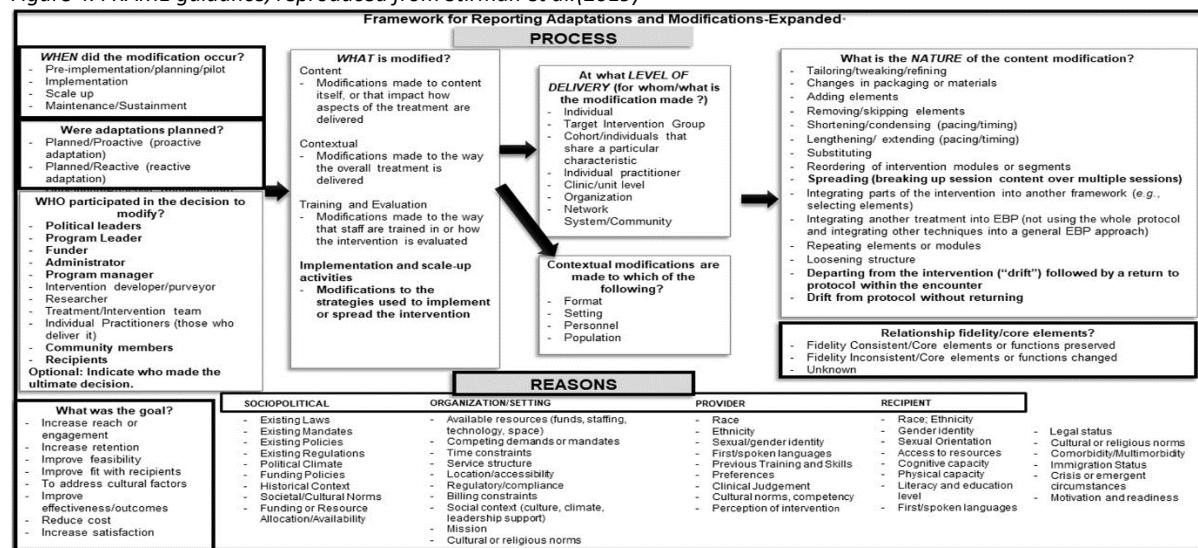
## 7. Report the adapted intervention

Transparent reporting is important for future replication efforts, and for later syntheses which pool together studies in order to understand when adaptations may or may not be necessary in new contexts (Booth et al., 2019). Systematic reviews of the effects of transported interventions have cited an absence of detail on adaptation within primary studies as limiting the ability to analyse the impacts of adaptation on intervention effectiveness (Leijten et al., 2016). This echoes a tendency for often limited reporting of how interventions were developed in the first place, which new guidance from the INDEX team aims to address (Duncan et al., 2020).

### 7.1 Use existing guidelines

Qualitative responses to our Delphi surveys emphasised the importance of drawing upon existing guidance for reporting interventions. There are a number of sources of existing guidance which can be drawn upon for reporting, such as the TIDIER framework (Hoffmann et al., 2014), and its recent extension to population health and policy interventions, TIDieR-PHP (Campbell et al., 2018). The latter includes a number of pertinent recommendations on reporting both planned and unplanned variations in delivery. While our systematic review identified few reporting guidance specifically for adaptations of interventions, Stirman and colleagues published the updated FRAME guidance on this topic shortly after our review was complete (Stirman et al., 2019). Hence, use of these existing guidelines is recommended as a starting point. Below, we describe a number of additional reporting considerations rated as important within our Delphi surveys, or identified through subsequent expert workshops.

*Figure 4. FRAME guidance, reproduced from Stirman et al.(2019)*



## 7.2 Describe the population health problem being addressed

Selection of an intervention to be adapted for a new context represents an implicit or explicit statement that there is a problem which requires intervention, and that the proposed intervention represents a potential solution to this. Hence, articulating the rationale for intervention is crucial. This may involve referring to up-to-date studies reporting the prevalence and patterning of the population health problem (e.g. smoking, obesity) and how this ‘epidemiological context’ compares to the original intervention context, or other contexts in which the intervention has been successfully evaluated.

## 7.3 Describe the original intervention and its context and report its evidence base

In many cases, an intervention selected for adaptation will already be described in a number of evaluation articles and grey literature. There may be a publicly available intervention manual including a logic model and programme theory. Other groups who have since used the intervention elsewhere may have further adapted these materials. Hence, reporting clear linkage to the provenance of the original intervention via referencing and signposting to other sources may reduce the need to dedicate space to describe these issues in detail. Where this is not available, constructing a clear description of the original intervention and programme theory, perhaps from information obtained by contacting developers, structured according to existing intervention reporting frameworks is a useful starting point. This will include providing details of the programme theory.

## 7.4 Describe the new context, and important similarities and differences to the original context

Decisions on what is adapted and how adaptations are made are likely to be driven in large part by considerations relating to the similarity and difference of previous and new, and hence intervention-context fit. Hence, reporting on aspects of context which were considered in making these assessments will add transparency to these processes, and support evolution of a wider evidence base on what kinds of contextual considerations matter in adapting interventions for new contexts. This will include reporting any frameworks used to decide on which aspects of context mattered for transferability and adaptation.

## 7.5 Describe the rationale, type and processes undertaken to adapt the intervention, including which stakeholders were involved

In our audit of published studies, we found that it is often unclear why decisions were made to undertake certain adaptations (and not others). Further, understanding the extent to which the intervention is the same as, or different to, the original intervention requires clear reporting of the type and extent of adaptation. Reporting on the processes followed in undertaking adaptations,

including who were the key decision makers, and how decisions were taken, and how wider publics were involved, represents an important means of building an evidence base regarding how best to undertake adaptations. This may include reference to sources of guidance drawn upon in making decisions and implementing and evaluating adaptations. Describing the process of adaptation will also include describing which stakeholders were involved, at which stages and how, including decision-making processes and how any conflicts of interest were managed (see Section 6.1).

#### **7.6 Describe the adapted intervention in detail to enable replication**

As with any intervention study, it is important that the adapted intervention is described in sufficient detail to enable replication. Existing guidance such as TIDieR (Hoffmann et al., 2014) and TIDieR-PHP (Campbell et al., 2018) are particularly useful here. This may focus in particular on describing what was different about the adapted intervention relative to the original intervention, paying attention to TIDieR-PHP items in reporting planned and unplanned variations in delivery (Campbell et al., 2018). This will include a focus both on variation between the original and adapted intervention, and variation in delivery within the new context.

#### **7.7 Describe how well the adapted intervention was delivered in the new context**

Frameworks for reporting interventions such as TIDieR and TIDieR-PHP emphasise the importance of capturing the fidelity of the intervention. It may be useful to base fidelity assessments on tools used for any earlier evaluation in order to enable comparability of fidelity between contexts. These tools may themselves need adapting to capture how well adapted aspects of the intervention are delivered. However, as described in Section 3, fidelity is an area of ongoing conceptual development, and fidelity assessment tools from older studies may not be considered fit for purpose, in which case bespoke assessment tools may be needed to capture and report these. Description of how an intervention was delivered may draw on a combination of quantitative assessments and qualitative process evaluation data. Describing participants' engagement with the intervention, including socio-demographic patterning, is important in understanding both the likely population level impact of the intervention and its equity impacts.

#### **7.8 Describe the rationale for the type of re-evaluation undertaken in the new context**

As described in Section 6.4, we found very limited guidance for decision-making regarding what type of evaluation was needed in the new context. Hence, describing the rationale for these choices, based on a clear articulation of the uncertainties posed by the intervention in the new context, may be helpful in both encouraging teams to systematically think through these decisions, and enabling understandings of how these decisions are made to inform this area of guidance.

### 7.9 Describe the role of original intervention developers in the adaptation

As discussed in Section 6.1, involvement of intervention developers is likely to be helpful in terms of providing nuanced information on the intervention, but also brings potential conflicts of interest.

Describing the role of developers in the adaptation of the intervention for the new context if applicable, including how conflicts of interest were managed, was highlighted by our expert panel as an additional reporting recommendation.

## 8. Conclusions

We have presented a new framework for key issues to think through in adapting an intervention for a new context. We hope that this will help decision-making by researchers, funders, journal editors and policy and practice stakeholders when adapting interventions for a new context. As we have seen with iterative revisions of the MRC guidance for development and evaluation of interventions, such guidance can be an event within evidence production systems, which influences the behaviour of key actors, with the goal of producing better and more appropriately used evidence. Guidance is therefore not a definitive conclusion to the conversation in developing emerging methodologies, but a starting point for ongoing innovation and methodological development. We hope that the application of our guidance over time will generate feedback which might reinforce its recommendations, and lead to further refinement. Hence, we welcome feedback from users of the guidance on how it might be improved in future iterations.

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## APPENDIX 1 - The ADAPT guidance Delphi exercise rounds 1 and 3 summary of item ratings

**Response rate:** Round 1 had 49% response rate (n=68/140). Round 3 had 47% response rate (n=31/66).

Tables presenting self-reported information provided by participants about their: role/expertise, country of institution, and place of employment

Self-reported role/expertise	n*
Member of research funding board	12
Representative of research funder	4
Journal editor	5
Intervention researcher	50
Quantitative researcher	39
Qualitative researcher	32
Practitioner	7
Clinician	11
Other	7

\*many participants reported more than one role

Country/continent of institution	n
UK	30
USA	17
Europe	8
Canada	3
South America	3
Australia	1

Place(s) of employment	n**
University	53
Public sector organisation	11
Non-profit organisation	7
For-profit organisation	1

\*\*some reported more than one institution

Experience of adaptation of interventions for implementation in new contexts was provided by 50 participants: 30 reported extensive experience, 11 reported more limited experience.

The Delphi exercise explained to participants the numerical rating categories:

- Rating 7-to-9 = **high** clarity/usefulness/validity/importance
- Rating 4-to-6 = **uncertain** clarity/usefulness/validity/importance
- Rating 1-to-3 = **low** clarity/usefulness/validity/importance

*To prevent deductive disclosure, tables report % rating items as 'high', and cell counts of <=5 (or (>=(total sample-5)) are suppressed*

## Key terms

Adaptation	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
To what extent is this understanding of adaptation <b>clear</b> for defining the scope of the guidance?	1	68	8	76% (52)
	3	31	8	81% (25)
To what extent is this understanding of adaptation <b>useful</b> for defining the scope of the guidance?	1	68	8	76% (52)
	3	30	7.5	70% (21)
Context				
To what extent is this understanding of context <b>clear</b> for defining the scope of the guidance?	1	68	8	84% (57)
	3	28	8	79% (22)
To what extent is this understanding of context <b>useful</b> for defining the scope of the guidance?	1	68	8	74% (49)
	3	27	8	78% (21)
Stakeholders				
To what extent is this understanding of stakeholders <b>clear</b> for defining the scope of the guidance?	1	67	8	91% (61)
	3	26	8	>=21
To what extent this understanding of stakeholders <b>useful</b> for defining the scope of the guidance?	1	66	8	86% (57)
	3	26	8	>=21

## Key debates

	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
<b>Fidelity and adaptation</b>				
Adapting an evidence-informed intervention always reduces intervention fidelity.	1	67	3	<=5
	3	27	3	<=5
Adapting an evidence-informed intervention can increase fidelity, by allowing an intervention to function as intended in the new context.	1	66	7	64% (42)
	3	25	7	68% (17)
<b>Proactive and reactive adaptation</b>				
Adaptation should be proactive, i.e. the intervention should be deliberately changed prior to implementation in a new context	1	68	6	46% (31)
	3	25	6	36% (9)
Adaptation may be reactive, i.e. changes may be allowed to occur during implementation in a new context rather than being pre-planned	1	67	7	69% (46)
	3	24	8	88% (21)
Adaptation may be undertaken by any stakeholders	1	66	5	30% (20)
	3	25	5	28% (7)
<b>Adaptation and context</b>				
Adaptation should be proactive, i.e. the intervention should be deliberately changed prior to implementation in a new context	1	67	7	63% (42)
	3	24	7	58% (14)

## Deciding whether adaptation is required

How important are the following considerations when deciding between adapting an existing intervention or developing a new intervention?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Time saved by adapting an intervention rather than developing a new intervention	1	63	7	54% (34)
	3	26	6	42% (11)
Resources saved by adapting an intervention rather than developing a new intervention	1	60	7	72% (43)
	3	25	7	68% (17)
Higher expectation of effectiveness associated with adapting an evidence-informed intervention rather than developing a new intervention	1	63	8	76% (48)
	3	23	8	78% (18)

How important is it to do the following when selecting an evidence-informed intervention and deciding whether it needs to be adapted?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Define the health problem in the target population, including its prevalence, determinants and modifiable risk factors	1	64	8	89% (57)
	3	23	8	>=18
Assess what resources are available to address the problem in the new context	1	64	8	89% (56)
	3	23	8	>=18
Assess preferences of stakeholders in the new context	1	63	8	84% (53)
	3	22	8	>=18
Compare existing interventions to select the best match to the new context	1	64	8	77% (46)
	3	23	8	>=18

How important is it to include the following **stakeholders** in the adaptation of an intervention for a new context?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Members of the target population	1	62	9	97% (60) >=18
	3	23	9	
Researchers with experience of intervention adaption	1	61	8	82% (50) >=17
	3	22	8	
Researchers with experience of intervention evaluation	1	62	8	84% (52) >=17
	3	22	8	
Researchers with experience of working with the target population	1	62	8	77% (48) >=17
	3	22	8	
Individuals/organisations responsible for developing the intervention in the original context	1	62	6.5	51% (31)
	3	21	6	50% (10)
Individuals/organisations responsible for delivering the intervention in the new context	1	63	9	100% (63)
	3	22	9	95% (20)
Individuals/organisations responsible for decisions about large scale implementation post evaluation	1	63	7	81% (51)
	3	21	7	85% (17)

## Preparing to adapt an intervention

How important are each of the following when preparing to adapt an intervention?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Ensuring the adapted intervention can be delivered in the new context	1	64	9	98% (58)
	3	21	9	>=16
Engaging practitioners or others involved in the delivery of the adapted intervention	1	64	8	92% (59)
	3	21	9	>=16
Achieving adequate levels of participation in the adapted intervention	1	63	8	68% (43)
	3	19	7	63% (12)
Achieving adequate levels of diversity among participants in the adapted intervention	1	63	7	52% (33)
	3	19	6	42% (8)
Achieving adequate retention of participants in the adapted intervention	1	61	7	74% (45)
	3	20	7	70% (14)
The expected effectiveness of the adapted intervention in the new context	1	62	8	76% (47)
	3	20	8	85% (17)
The sustainability of the adapted intervention in the new context	1	61	8	90% (54)
	3	19	8	100% (19)

How important are the following processes when preparing an adaptation of an intervention?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Identify similarities and differences between the original and new context	1	59	8	80% (47)
	3	20	9	>=15
Assess whether aspects of the intervention theory of change need to be modified to fit the new context	1	58	8	74% (43)
	3	20	8	75% (15)
Identify potential facilitators of delivery in the new context	1	59	8	95% (56)
	3	20	8	>=15

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Identify potential barriers to delivery in the new context	1	58	9	>=53
	3	20	9	>=15
Develop an adapted intervention model (e.g., draft manuals, intervention protocols, delivery plan)	1	58	9	88% (51)
	3	20	9	>=15
Review the new model with stakeholders and revise based on feedback	1	58	9	93% (54)
	3	20	9	>=15
Recruit individuals and organisations involved in the delivery of the intervention in the new context	1	56	8	84% (47)
	3	20	8	70% (14)
Build expertise in delivering the intervention (e.g., training of community-based organisations, intervention implementers)	1	56	9	88% (47)
	3	20	8	80% (16)

## How to deliver the adapted intervention

How important are the following processes when planning how to deliver the adapted intervention in the new context?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Assess the feasibility of delivering the adapted intervention	1	62	8.5	>=57
	3	20	9	>=15
Revise the intervention model as necessary based on the results of the feasibility study	1	61	9	>=56
	3	19	8	>=14
Provide ongoing support and feedback to those delivering the intervention	1	61	8	90% (55)
	3	19	8	>=14
Obtain stakeholder feedback and finalise the intervention model and the delivery plan	1	62	8	89% (55)
	3	19	8	>=14
Document "reactive" adaptations during delivery	1	62	9	90% (56)
	3	19	9	>=14

## Evaluating the effectiveness of the adapted intervention

How important are the following criteria in deciding the type and extent of evaluation (e.g. fully –powered effectiveness evaluation, feasibility evaluation, process evaluation, implementation evaluation) needed once the intervention has been adapted?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Applicability of existing effectiveness evidence to the new context	1	62	8	74% (46)
	3	20	8	>=15
Extent to which the intervention has been adapted in the new context	1	62	8.5	92% (57)
	3	19	9	>=15
Availability of resource in the new context (e.g. time, finance, evaluation expertise)	1	63	8	86% (54)
	3	19	8	>=14
The value of new evaluation evidence to decision-makers in the new context	1	63	8	73% (46)
	3	19	8	>=14

How important are the following criteria for deciding whether to implement, undertake a further cycle of adaptation and testing, or abandon an adapted intervention?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Acceptability of the adapted intervention to participants	1	64	9	>=59
	3	19	9	>=14
Acceptability of the adapted intervention to deliverers	1	63	8	84% (53)
	3	19	8	>=14
Feasibility of delivering the adapted intervention in the new context	1	63	8	>=58
	3	19	9	>=14
Effectiveness of the adapted intervention in the new context	1	64	8	>=58
	3	19	9	>=14
Cost effectiveness of the adapted intervention in the new context	1	63	7	78% (49)
	3	19	8	>=14

How important are the following processes when planning for post-evaluation implementation of an adapted intervention?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Establish a plan to maintain delivery of the adapted intervention in the new context	1	62	8	87% (54)
	3	19	8	>=14
Secure agreement from stakeholders	1	62	8	79% (49)
	3	19	8	>=14
Develop capacity to support long term implementation	1	61	8	89% (54)
	3	19	8	>=14
Establish a data monitoring system	1	62	8	85% (53)
	3	19	8	>=14

## Adaptation Reporting

How important is it to do the following when reporting the adaptation and/or evaluation of an intervention?

Item	Round	Responses (n)	Median rating	Rated high (7-9) % (n)
Describe the population health problem being addressed	1	61	9	90% (55)
	3	20	9	>=15
Explain the perspective of the research team (e.g. disciplinary backgrounds and theoretical perspective of the research team)	1	63	7	51% (32)
	3	20	7	70% (14)
Explain why the intervention was adapted	1	62	9	>=57
	3	20	9	>=15
Describe the original intervention and context and report its evidence-base	1	61	8	85% (52)
	3	20	8	>=15
Describe the new context, and key similarities and differences to the original context	1	62	9	85% (53)
	3	20	9	>=15
Describe the type and extent of adaptation undertaken	1	61	9	>=56
	3	20	9	>=15
Describe the processes undertaken to adapt the intervention, including which stakeholders were involved	1	62	9	>=56
	3	20	9	>=15
Describe the adapted intervention in detail to enable replication	1	62	9	90% (56)
	3	20	9	>=15
Describe how well the adapted intervention was delivered in the new context	1	61	8	>=56
	3	20	8	>=15

## APPENDIX 2 – Mapping of Delphi consensus items onto final recommendations

This appendix provides an overview of the linkage between Delphi survey items (which were informed by our systematic review and qualitative research) and our final recommendations. Consensus (and disagreement) on items was discussed among the study team and international advisory group, alongside findings from other work packages, in order to construct draft recommendations (which were shared and further discussed with a subset of Delphi participants at a series of online expert workshops).

Recommendations in **Section 6.1** are informed by consensus in our Delphi surveys that it was important to involve members of the following populations throughout intervention adaptation processes:

- Members of the target population
- Researchers with experience of intervention adaptation
- Researchers with experience of intervention evaluation
- Researchers with experience of working with the target population
- Individuals/organisations responsible for delivering the intervention in the new context
- Individuals/organisations responsible for decisions about large scale implementation post evaluation

Discussion of stakeholder involvement at our expert workshops centred around key issues relating to ‘how’ to involve these stakeholders. These included a focus on involving a diverse range of stakeholders in a meaningful way at all stages of adaptation process, power and distribution of roles in decision making, pros and cons of working with intervention developers, and the dynamic nature of stakeholder involvement.

Recommendations in **Section 6.2** are informed by the following items, on which consensus was reached in our DELPHI surveys:

Item	Recommendation
• Define the health problem in the target population, including its prevalence, determinants and modifiable risk factors	6.2.1
• Compare existing interventions to select the best match to the new context	6.2.2 to 6.2.4
• Assess preferences of stakeholders in the new context	6.2.2 (& 6.1)
• Identify similarities and differences between the original and new context	6.2.5

In addition, following discussion among the author group (and reflecting the lack of consensus on the importance of involving intervention developers), we included recommendations relating to considering intellectual property issues. Given that as discussed in Section 5, a key rationale for adapting an existing intervention is a higher perceived likelihood of an intervention working if it has previously worked elsewhere, we also recommend considering the robustness of claims to effectiveness, as well as obtaining detailed information on selected interventions and their contexts.

Recommendations in Section 6.3 are informed by the following items which our Delphi exercises reached consensus were important:

Recommendation
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- Identify potential facilitators of delivery in the new context 6.3.1
- Identify potential barriers to delivery in the new context 6.3.1
- Assess what resources are available to address the problem in the new context 6.3.5
- Develop an adapted intervention model (e.g., draft manuals, intervention protocols, delivery plan) 6.3.2
- Review the new model with stakeholders and revise based on feedback 6.3.2 (& 6.1)
- Recruit individuals and organisations involved in the delivery of the intervention in the new context 6.3.5
- Assess whether aspects of the intervention theory of change need to be modified to fit the new context 6.3.2 & 6.3.3

For the last item, while we used ‘theory of change’, we subsequently revised this to ‘programme theory’ for consistency with new MRC guidance for developing and evaluating complex interventions. Following discussion among the author group, we expanded consideration of programme theory to include unintended consequences due to interaction with a new context.

Recommendations in **Section 6.4** are informed by two clusters of items on which our Delphi surveys reached consensus. The first set of items below were considered important in decision making regarding what form of evaluation is likely to be required prior to full implementation.

Item	Recommendation
• Applicability of existing effectiveness evidence to the new context	6.4.1
• Extent to which the intervention has been adapted in the new context	6.4.1
• The value of new evaluation evidence to decision-makers in the new context	6.4.2
• Availability of resource in the new context (e.g. time, finance, evaluation expertise)	6.4.3

The second set of statements focus on the process of piloting and preparing for movement to evaluation (or straight to full implementation).

Item	Recommendation
• Assess the feasibility of delivering the adapted intervention	6.4.4
• Revise the intervention model as necessary based on the results of the feasibility study	6.4.4
• Obtain stakeholder feedback and finalise the intervention model and the delivery plan	6.4.4
• Provide ongoing support and feedback to those delivering the intervention	6.4.5
• Document “reactive” adaptations during delivery	6.4.5

In addition, we include a recommendation regarding undertaking the evaluation identified as necessary via the above processes, with signposting to sources of guidance rather than providing detail on evaluation designs. While sequentially, feasibility testing will come prior to evaluation it is helpful to first develop a good understanding of what future evaluation is warranted, and what design this would take, so that uncertainties can be identified to focus on in feasibility testing. Hence, we begin with considerations of what kind of evaluation is needed, prior to discussing feasibility testing.

Recommendations in **Section 6.5.** are informed by the following statements on which our expert panel reached consensus.

	<b>Recommendations</b>
• Establish a plan to maintain delivery of the adapted intervention in the new context	6.5.1
• Secure agreement from stakeholders	6.5.1 (& 6.1)
• Develop capacity to support long term implementation	6.5.1
• Establish a data monitoring system	6.5.2

Some distinguish between ‘scale-up’ (i.e. taking an intervention to scale in the context where it was implemented) and ‘scale-out’ (i.e. taking an intervention to scale in a context other than where it was implemented). Once an intervention has been adapted and evaluated in the new context, distinction between scale out and scale up diminishes, and hence guidance on scale-up is relevant here (Koorts et al., 2018; Kirk et al., 2015). However, as described in Section 6.4, interventions may be implemented at scale without the need for prior evaluation where uncertainty is low. Many of the statements on which our Delphi surveys reached consensus apply as much to situations where an intervention is being implemented in its original context, or a new context. However, we highlight throughout our discussion of these considerations for interventions which have a prior evidence base to draw upon, or which may currently be in use at scale in other contexts.

Recommendations in **Section 7** are informed by the following reporting items:

- Describe the population health problem being addressed
- Describe the original intervention and context and report its evidence-base
- Describe the new context, and key similarities and differences to the original context
- Explain why the intervention was adapted
- Describe the type and extent of adaptation undertaken
- Describe the processes undertaken to adapt the intervention, including which stakeholders were involved
- Describe the adapted intervention in detail to enable replication
- Describe how well the adapted intervention was delivered in the new context

There was not consensus on the need to report the background of the research team. In addition, following discussion among the research team, reflecting the limited guidance regarding how to make decisions about what type and extent of re-evaluation to undertake, we include an additional item on describing the rationale for undertaking another evaluation study (or not) prior to implementation. In addition, following our online workshops, we added a recommendation to report the role of original intervention developers within decision-making. A key additional theme within qualitative comments from our Delphi panel was the need to use existing reporting frameworks rather than starting from scratch. Before focusing on our new recommendations, we discuss existing guidance which researchers may use in reporting adaptation of interventions.