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Developing and testing complex behaviour change interventions to support proactive deprescribing

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The nature of the problem

A culture of prescribing to treat long-term conditions, coupled with age-associated changes in the processes of metabolising medicine, have led to an 'overprescribing epidemic' amongst older adults (1). The World Health Organization recognises overprescribing as a serious problem yet deprescribing of medicines with more risks than benefits is not routine practice. Approximately half of older adults admitted to hospital are prescribed at least one medicine with more risks than benefits (2); however, only 1% have a medicine deprescribed during an admission (3).

Behaviour

Older adults and informal caregivers expect healthcare professionals to deprescribe medicines that are no longer appropriate (4). This requires behaviour change from healthcare professionals. Deprescribing is a complex and heterogenous process and the 'target behaviour', which is the *thing* we are asking healthcare professionals to do, varies depending on several factors. For example, asking healthcare professionals to 'reactively' deprescribe medicines that have already caused harm is a different behaviour to asking them to 'proactively' deprescribe medicines that may cause harm in the future. The first step in changing behaviour is to *define the target behaviour* .

Intervention components and behaviour change techniques (BCTs)

Behaviour change interventions should target and address the barriers and enablers (determinants) to the target behaviour. There are multiple determinants of behaviour and thus interventions require several components to address them. Behaviour change interventions are therefore complex interventions comprising of multiple interacting components (5). Behaviour change techniques (BCTs) are the irreducible 'active ingredients' of a behaviour change intervention that bring about behaviour change

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Selection and formulation of BCTs into tangible components that can be combined to form an intervention should be informed by evidence and behaviour change theory. Evidence provides a rich understanding of the behavioural determinants. Theory enables the behavioural mechanisms by which BCTs exert their effects to be defined. There are numerous behaviour change theories, many with overlapping constructs thus selecting any one theory to fully represent the potential determinants of a behaviour is challenging. The theoretical domains framework (TDF) is an integrative framework of behaviour change theories comprising 14 mechanisms of action domains such as *knowledge* , *beliefs about capabilities* and *emotion* (6) and has been successfully applied to define the behavioural mechanisms of action of deprescribing in hospital (7).

Interventions and how they are hypothesised to change behaviour and resultant outcomes can be visually depicted in a logic model. Logic models represent the causal theoretical assumptions of an intervention and moderating factors. They can also describe the context within which an intervention is implemented and how the two interact. Below we outline some of the key components of a logic model that should be tested and refined using learning from feasibility testing and evaluation processes.

Context

Understanding the context within which a behaviour change intervention is implemented helps explain why an intervention did or did not change behaviour (5). Contextual factors include the setting e.g. the size of a hospital and characteristics of its wards, and organisational arrangements of how staff work and interact with the intervention. Other contextual factors that may influence a deprescribing intervention include the characteristics of staff delivering or receiving the intervention such as their level of experience, views on deprescribing and other initiatives also occurring at the site e.g. other deprescribing research. An intervention may change behaviour in one setting but not another owing to contextual differences. Understanding these contextual factors is key to facilitating the intervention being adopted into the wider healthcare system after completing a definitive trial (5). This permits the implementation strategy for an intervention to be adapted according to local contextual factors.

Outputs and moderating factors

Outputs are the activities undertaken when implementing a behaviour change intervention (8, 9). Historically, evaluation has focussed on the intervention's effectiveness without evaluating fidelity (9). Fidelity is the degree to which an intervention is implemented as intended. It is essential for interpreting whether the observed outputs are a faithful measure of intervention effectiveness. Guidance for process evaluations of complex interventions emphasises the importance of evaluating fidelity, but does not provide recommendations regarding how to do it. Several frameworks are available to guide fidelity evaluation; however, they are frequently not adopted in trials of behaviour change interventions (9).

Evaluating fidelity has historically focussed on *dose* and*reach,* whereas fidelity of delivery, receipt and enactment are now recognised as important (9). The Conceptual Framework for Implementation Fidelity (8) measures four components of fidelity: content, coverage, frequency and duration of the intervention. It also captures four moderators of fidelity: intervention complexity, facilitation strategies, quality of intervention delivery and responsiveness of participants (8). By comprehensively capturing fidelity of each intervention component, it can also be determined which are essential to achieving the desired change in behaviour. Any adaptation or flexibility of intervention delivery should also be captured to understand how sites implement an intervention component(s) and how this variation impacts the intervention's effectiveness.

Evaluation

Trials commonly include both outcome measures and process measures. Outcome measures indicate whether or not the intervention has worked. For example, the intended outcome of a deprescribing trial may be an improvement in quality of life or reduction in hospital readmissions. The outcome measure is used to inform the required sample size of a trial. The larger the difference that is anticipated between intervention and control, the smaller the required sample size to detect this difference with adequate precision. Researchers may choose a non-inferiority study; however, in most cases the required sample size prohibits such studies.

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In order to prove that the outcome from the intervention is 'no worse' than the control, the study requires a sample size that can detect a difference that is deemed negligible in clinical significance. This means that the study has to be powered to detect a very small difference unlike superiority studies when the research has to prove that the intervention is better than the control and choose a sample size accordingly.

Process measures represent intermediate steps to achieving an outcome. An example of a process measure to help explain the observed outcome is the number of medicines stopped. For example, in a trial powered to detect a difference in quality of life, if intervention participants have a significantly higher quality of life than control participants then we might assume that the intervention is effective. If, however, we find that the average number of medicines stopped is the same in both intervention and control arms, then we know that something other than stopping medicines is attributable to the difference.

Given that deprescribing is a complex behaviour with multiple determinants, effective interventions will also be complex as they need to comprise multiple components to address the target determinants. For example, the practitioner behaviour change intervention being tested in the CompreHensive geriAtRician-led MEdication Review (CHARMER) trial, aims to address five determinants of proactive deprescribing in hospital and thus comprises five intervention components. It is essential to evaluate the intervention's mechanism of action in order to understand how the intervention leads to any changes in deprescribing activities and how this then impacts on the primary outcome measure. Understanding mechanisms of actions can be achieved by developing questionnaires or surveys (6). To understand how the CHARMER deprescribing intervention changes the behaviours of pharmacists and geriatricians, we developed a questionnaire to identify changes in the five target determinants. This will enable identification of any targeted determinants that the intervention does not address and help explain how the intervention works (or does not work) in changing proactive deprescribing.

The role of condition-orientated measures in evaluating trials is unclear. For some research funders, condition-orientated measures such as blood pressure or lipid profile are acceptable trial outcome measures whilst for other research funders, these are deemed process outcomes. This disparity in expectations generates variation in practice and therefore reduces opportunity for the results from deprescribing trials to be compared, and trial data to be aggregated to increase the power and thus precision of the estimated effect of deprescribing. A Core Outcome Set (COS) is an agreed, standardised set of outcomes to be measured and reported in all clinical trials of a particular health condition or specific area of healthcare. Research teams can measure*additional* outcomes in their deprescribing trials, in addition to the COS, to suit their context and particular focus. A COS for hospital deprescribing trials for older people under the care of a geriatrician was recently reported (10). Consistent use of this COS by deprescribing trials will enhance uniformity of reporting; there is also a need for funders to align expectations on acceptable outcome measures.

Conclusion

There is a clearly defined pathway to developing and evaluating complex interventions; however, significant variation exists in the extent to which the pathway is followed. Within the pathway, there are inconsistencies of interpretation, for example the definition of an acceptable primary outcome. There is a need for the deprescribing community to address the inconsistencies and then follow the agreed pathway from defining the target deprescribing behaviour through to evaluating intervention fidelity alongside effectiveness.

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Conflict of interest statement

The authors declare that they do not have any conflict of interest.