Published in final edited form as:

Int J Clin Pharm. 2016 June ; 38(3): 601–606. doi:10.1007/s11096-015-0180-6.

Development of a pharmacy practice intervention: lessons from the literature

Carmel M. Hughes, Cathal A. Cadogan, and Cristín A. Ryan

School of Pharmacy Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL, Northern Ireland

Abstract

The development of health interventions is receiving increasing attention within the scientific literature. In the past, interventions were often based on the ISLAGIATT principle: that is, 'It seemed like a good idea at the time'. However, such interventions were frequently ineffective because they were either delivered in part or not at all, demonstrating a lack of fidelity, or because little attention had been paid to their development, content, and mode of delivery. This commentary seeks to highlight the latest methodological advances in the field of intervention development, drawing on health psychology literature, together with guidance from key organisations and research consortia which are setting standards for development and reporting. Those working within pharmacy practice research can learn from the more systematic approach being advocated, and apply these methods to help generate evidence to support new services and professional roles.

Keywords

intervention; behaviour change; Theoretical Domains Framework

Introduction

Increasingly, evidence is being sought by policy makers to support the commissioning and delivery of new health services [1]. Therefore, such services need to be underpinned by rigorous research that has produced the required evidence. Very often, the evidence will be generated through intervention studies. In the case of pharmacy practice, such interventions may be developed and evaluated by researchers, with the goal of producing evidence to support wide-scale implementation by practitioners working in clinical practice, most commonly in a community or hospital pharmacy setting. This is contingent on the intervention proving effective. To date, the end result of pharmacy practice-based intervention development and evaluation has been highly variable; some studies have shown positive effects, while others have demonstrated negative effects or no effect at all. In order to address the lack of intervention effect across studies, it is increasingly recognised that more thought needs to be given to how interventions are developed and the manner by which they are likely to effect change in practice [2]. This commentary seeks to highlight important methodological advances in the development of interventions aimed at improving patient care, in the context of pharmacy practice research, and the broader health services arena.

A brief history of pharmacy practice interventions, successful or otherwise

The history of pharmacy practice interventions is somewhat chequered. The School of Pharmacy at Queen's University Belfast has undertaken several such studies and we have encountered problems and successes in equal measure [3–5]. We conducted studies that were targeted at patients with specific medical conditions e.g. heart failure, or specific populations e.g. older people living in the community. Even before the interventions were introduced, we experienced challenges with the recruitment of pharmacists, pharmacies, other health care professionals and indeed patients [3,5]. Invariably, many interventions were education-based and involved the provision of information by pharmacists to patients or other health care professionals. Pharmacists were trained on what they were expected to do in terms of recruiting patients, delivering the intervention and collecting data. The development of these interventions often involved a pragmatic approach based on available literature, as well as our own implicit assumptions of what we thought would likely work - or what Professor Martin Eccles has since described as the ISLAGIATT principle; that is 'It seemed like a good idea at the time' [6].

In retrospect, those interventions that appeared to be effective were largely delivered by highly experienced pharmacists, with excellent clinical knowledge and communication skills, as well as confidence in their actions [4]. Those interventions which did not appear to be effective were either delivered in part or not at all, demonstrating a lack of fidelity to the intervention. This was often attributed to lack of time on the part of the pharmacist [3,5]. When considered further, it was concluded that insufficient attention had been given to the content of the intervention, what we had expected pharmacists to do and how they would do it. We also had not consulted key stakeholders who would be delivering or receiving the intervention during the development stages. Indeed, these seem to be universal themes which arise when attempting to explain why interventions prove to be unsuccessful in healthcare research [7,8].

Development of interventions - a systematic approach

The Medical Research Council (MRC), one of the most important health-related research funding bodies in the United Kingdom (UK), has recognised the importance of intervention studies for advancing healthcare, as well as failings in how interventions have previously been developed, evaluated and implemented. In an attempt to address this, the MRC issued guidance in 2000 entitled 'A Framework for the Development and Evaluation of Randomised Controlled Trials (RCTs) for Complex Interventions to Improve Health' [9]. A 'complex intervention' was defined as one with several interacting components. In 2008, the guidance was updated and placed greater emphasis on the development and implementation phases, and how to evaluate the intervention [10]. Figure 1 outlines the main phases that the MRC recommends in the development and evaluation process.

Although the framework appears to be cyclical, starting with 'Development' and moving around to 'Implementation', it is recognised and accepted that the entire process is quite dynamic, and indeed refinements to the intervention content and mode of delivery may be required as researchers transition between the 'Development' and 'Feasibility/Piloting'

phases before progressing to the 'Evaluation' phase. What is important is that interventions should be developed systematically, 'using the best available evidence and appropriate theory', as summarised in the 'Development' phase [10]. The MRC recommends that, ideally, a systematic review should be consulted to identify the relevant evidence base and if one is not available, researchers should be prepared to undertake such a review. The steps required to either identify or undertake a systematic review are clear. However, what is much less clear is the aspect of identifying and/or developing appropriate theory.

The role and application of theory in intervention development

A theory can be defined as "a system of ideas or statements held as an explanation or account of a group of facts or phenomena" [11]. One of the key reasons for advocating the use of theory in the development phase is that it allows researchers to generate testable hypotheses and explore potential causal mechanisms underlying an intervention's effect [12]. This can help to overcome the inherent biases where researchers base their approach on their own implicit assumptions and personal beliefs [13] or the ISLAGIATT principle (It seemed like a good idea at the time) [6].

Very often in intervention studies, particularly in the context of pharmacy practice, we are interested in changing existing behaviour and this becomes the 'target' of the intervention. The target behaviour may be that of the pharmacist, a patient or indeed a carer. Eliciting behaviour change to achieve a desired outcome requires a clear understanding of the target behaviour that one is trying to change, which in turn requires knowledge of psychological theory underpinning behaviour. However, there are multiple theories of behaviour change [14], and for those developing interventions for use in pharmacy practice, the challenge lies in selecting the most appropriate theory. This overwhelming task has been somewhat simplified by the emergence of the Theoretical Domains Framework (TDF) which was derived from 33 psychological theories [11] and which can help to identify barriers and facilitators to behaviour change. The original TDF was compiled by a consensus group of health psychologists and health services researchers and included 12 theoretical domains relevant to changing health care professionals' behaviour. It was subsequently refined in 2012 to include 14 theoretical domains as follows: Knowledge; Skills; Social/professional role and identity; Beliefs about capabilities; Optimism; Beliefs about consequences; Reinforcement; Intentions; Goals; Memory, Attention and decision processes; Environmental context and resources; Social influences; Emotions; and Behavioural regulation (Table 1) [15,16]. It must be noted that the TDF is not in itself a theory, rather it is an integrated framework of behaviour change theories and, therefore, it does not specify relationships between the domains [16]. However, it serves to make behaviour change theory more accessible to researchers from non-health psychology backgrounds. Qualitative interviews based on the TDF provide an established method of incorporating a theory base into the intervention development phase. By exploring the target group's perceptions of each of the domains and how they impact on the target behaviour, one can begin to elucidate the mediators (i.e. barriers and facilitators) of behaviour change that will need to be targeted by the intervention.

For example, French *et al.* [17] conducted TDF-based focus groups with GPs to explore barriers and facilitators to the implementation of guidelines, specifically around diagnosis and management (the target behaviours) of lower back pain. Based on their analysis of the focus group data, the researchers were able to identify domains, such as 'Knowledge' that would need to be targeted as part of an intervention i.e. GPs did not know about the guidelines and how to use them.

Linking theoretical domains to intervention components

Having identified theoretical domains that are perceived as mediators of behaviour change, the next stage is to develop an intervention, based on the identified barriers and facilitators to change the target behaviour. This requires consideration of what will form the 'active ingredient' or the content of the intervention. Again, it is now recognised that there has been inadequate consideration of this aspect of intervention development, with poorly defined content and a lack of detail on implementation [18].

This absence of a standardised way of selecting, defining and reporting intervention content has led to a plethora of published studies which are difficult to replicate because of a lack of clarity of what the intervention involved and how it was delivered.

The advent of the Behavioural Change Technique (BCT) taxonomy may go some way to address this deficit [18]. This taxonomy provides a method of describing and characterising BCTs for inclusion in an intervention. A BCT had been defined as an 'observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour' [18]. Simply put, it is the active component of an intervention designed to change behaviour. The taxonomy consists of 93 BCTs which were developed through a series of consensus exercises involving a number of experts in delivering or developing behaviour change interventions. Examples of BCTs include Prompts and cues, Goal-setting, and Feedback on behaviour. Importantly, these BCTs have been defined and examples provided which should help in ensuring consistency in the manner in which BCTs are interpreted and operationalised across intervention studies. Table 2 provides definitions of the selected BCTs listed above and examples of how they can be operationalised as part of an intervention targeting adherence to medicines.

However, a critical step involves linking theoretical domains with effective techniques to elicit desired changes in the target behaviour. Michie *et al.* [19] published an early method for linking BCTs to the TDF, which involved up to four researchers independently rating their level of agreement as to whether or not a BCT would target a particular domain from the TDF and coming to a consensus agreement. A more recent publication has developed the method further and more efficiently. Cane *et al.* [20] reported that 59 of the 93 BCTs can be reliably mapped to 12 of the 14 domains in the TDF (Social/professional role and identity and Memory, attention and decision processes were not included). A number of BCTs were allocated predominantly to three domains: Beliefs about consequences, Reinforcement and Social influences, suggesting that these are the domains where there is the greatest consensus as to how to bring about behaviour change. Furthermore, some domains were associated with very few BCTs, which is important when considering the development of an

intervention. It is important to have agreement about a few BCTs rather than to have a large range of BCTs to choose from [20]. For example, the domain Behavioural Regulation was associated with only one BCT, Self-monitoring of behaviour, while the domain Goals was associated with five BCTs: Goal setting (outcomes), Goal setting (behaviour), Review of outcome goals, Review of behaviour goals, and Action planning.

Theory-based interventions: are they effective?

There have been very few studies which have followed a rigorous and systematic approach from theory-based intervention development using BCTs through to evaluation. One study which has adopted this approach and alluded to above, is that by French *et al.* [17], which focused on lower back pain. The research team selected 10 BCTs which they had mapped to the TDF domains which were found to be important to the target behaviours. These BCTs were then incorporated into a 'cohesive intervention', which was delivered to GPs through interactive workshops consisting of lectures, group discussions and activities, and evaluated in a cluster randomised controlled trial [21]. Adherence to guidelines for lower back pain was found to increase in those GPs who had received the intervention, but the researchers were unable to recruit sufficient patient participants and consequently, were unable to measure GPs' clinical behaviour, patient-related outcomes in terms of health, behaviour and health service utilisation. Therefore, no studies to date have definitively demonstrated that a theory-based approach involving the TDF leads to a more effective healthcare intervention.

Pharmacy practice is beginning to embrace this approach in moving "...to theory-based intervention development using established BCTs. Recent work by Cadogan *et al.* [22] used the TDF to undertake interviews with general practitioners (GPs) exploring approaches to prescribing polypharmacy to older people and to identify the key TDF domains which acted as barriers and facilitators to prescribing appropriate polypharmacy. 'Knowledge', 'Skills', 'Beliefs about consequences', 'Social influences' and 'Social/professional role and identity' were identified as key theoretical domains that facilitated the prescribing of appropriate polypharmacy to older patients. GPs reported that their clinical knowledge and skills facilitated them in making the necessary prescribing changes to ensure that older people receive appropriate polypharmacy. 'Environmental context and resources' was the main theoretical domain that prevented GPs from prescribing appropriate polypharmacy to older people in primary care, particularly time needed to address polypharmacy [22]. Complementary interviews have taken place with community pharmacists, focus groups have been conducted with patients who have been exposed to polypharmacy, and analysis is ongoing. This multi-stakeholder perspective will enable a more holistic overview of how an intervention which will incorporate BCTs may be developed that will focus on improving appropriate polypharmacy in primary care.

The future of intervention development

Until further rigorous evaluations of theory-based interventions are completed, some commentators [e.g. 23,24] are likely to remain sceptical as to the proclaimed benefits of a theory-based approach to intervention development. We would contend that this type of approach serves to advance the process of intervention development by providing a

systematic method that encourages detailed investigation of the target behaviour and the likely mediators of behaviour change. It also encourages the use of clearly defined intervention components from an established taxonomy, which could ultimately enhance the replication of interventions across different healthcare settings.

Indeed, there is an increasing expectation that much greater attention should be given to how interventions are described in scientific papers. This was originally advocated by the Consolidated Standards of Reporting Trials (CONSORT) statement which highlighted that authors should report on 'interventions for each group with sufficient details to allow replication, including how and when they were actually administered' [25]. This has been taken one step further through the publication of two complementary sets of guidelines: TIDieR (Template for intervention description and replication; [26]) and WIDER (Workgroup for Intervention Development and Evaluation Research; [27,28]). The primary purpose of TIDieR is to prompt authors to describe interventions in sufficient detail to allow others to replicate such interventions. Briefly, TIDieR consists of 12 items contained within a checklist that should be used to assess the quality of intervention reporting. Examples of the items include: a phrase that describes the intervention, the rationale, theory or goal of the elements essential to the intervention, the procedures, activities and processes used in the intervention and the modes of delivery (e.g. face-to-face, internet, telephone). Of particular relevance to this commentary are the WIDER recommendations which are an established framework to identify and describe the essential components for detailed reporting of behaviour change interventions [28]. Although there is some degree of overlap with TIDieR, WIDER requires a description of the intervention development (including theory considerations), the change techniques used in the intervention (the 'active' ingredients of the intervention) and the proposed causal processes targeted by the change techniques.

Conclusion

Increasingly, health care practice and delivery is expected to be based on high quality evidence obtained from rigorously conducted studies. Equally, these studies must be rigorously developed, and incorporate the latest advances in methods and reporting. This commentary has highlighted the latest methodological advances and current thinking in the rapidly evolving field of intervention development. Researchers in pharmacy practice should give due consideration to adopting such approaches as they strive to generate evidence that supports the role of pharmacists in patient care. Resultant studies will be more robust, easier to replicate and provide the evidence base upon which the value of pharmacy practice can be objectively judged.

Acknowledgements

CA Cadogan is currently being supported by a project grant from the Dunhill Medical Trust [grant number: R298/0513] focusing on the development of an intervention to improve appropriate polypharmacy in older people in primary care.

References

1. Godlee F. We need to put the evidence to work. *BMJ*. 2009; 339:b5236.

2. Michie S, Fixsen D, Grimshaw JM, Eccles MP. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implement Sci.* 2009; 4:40. [PubMed: 19607700]
3. Bernsten C, Bjorkman I, Caramona M, Crealey G, Frokjaer B, Grundberger E, et al. Improving the well-being of elderly patients via community pharmacy based provision of pharmaceutical care. *Drugs Aging.* 2001; 18:63–77. [PubMed: 11232739]
4. Patterson SM, Hughes CM, Crealey G, Cardwell C, Lapane K. An evaluation of an adapted United States model of pharmaceutical care to improve psychoactive prescribing for nursing home residents in Northern Ireland (Fleetwood NI Study). *J Am Geriatr Soc.* 2010; 58:44–53. [PubMed: 20002510]
5. Wazaify M, Hughes CM, McElnay JC. The implementation of a harm minimization model for the identification and treatment of over-the-counter drug misuse and abuse in community pharmacies in Northern Ireland. *Patient Educ Couns.* 2006; 64:136–141. [PubMed: 16431072]
6. Michie, S., Atkins, L., West, R. *The Behaviour Change Wheel: A Guide to Designing Interventions.* 1st ed. Silverback Publishing; London: 2014.
7. Page MJ, French SD, McKenzie JE, O'Connor DA, Green SE. Recruitment difficulties in a primary care cluster randomised trial: investigating factors contributing to general practitioners' recruitment of patients. *BMC Med Res Method.* 2011; 11:35.
8. Peters-Klimm F, Campbell S, Muller-Tasch T, Schellberg D, Gelbrich G, Herzog W, et al. Primary care-based multifaceted, interdisciplinary medical educational intervention for patients with systolic heart failure: lessons learned from a cluster randomised controlled trial. *Trials.* 2009; 10:68. [PubMed: 19678944]
9. Medical Research Council. *A framework for the development and evaluation of RCTs for complex interventions to improve health.* 2000.
10. Medical Research Council. *Developing and evaluating complex interventions: new guidance.* 2008.
11. Michie SM, Johnston C, Abraham R, Lawton D, Parker D Walker A. Making psychological theory useful for implementing evidence based practice: A consensus approach. *Quality and Safety in Health Care.* 2005; 14:26–33. [PubMed: 15692000]
12. Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG). Designing theoretically-informed implementation interventions. *Implement Sci.* 2006; 1:4. [PubMed: 16722571]
13. Grol R, Bosch MC, Hulscher MEJL, Eccles MP, Wensin M. Planning and studying improvement in patient care: The use of theoretical perspectives. *Milbank Quart.* 2007; 85:93–138.
14. Michie, S., West, R., Campbell, R., Brown, J., Gaisforth, H. *ABC of Behaviour Change Theories.* 1st ed. Silverback Publishing; London: 2014.
15. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci.* 2012; 7:37. [PubMed: 22530986]
16. Francis JJ, O'Connor D, Curran J. Theories of behaviour change synthesised into a set of theoretical groupings: introducing a thematic series on the theoretical domains framework. *Implement Sci.* 2012; 7:35. [PubMed: 22531601]
17. French SD, Green SE, O'Connor DA, McKenzie JE, Francis JJ, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implement Sci.* 2012; 7:38. [PubMed: 22531013]
18. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The Behavior Change Technique Taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behaviour change interventions. *Ann Behav Med.* 2013; 46:81–95. [PubMed: 23512568]
19. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From theory to intervention: mapping theoretically derived behavioural determinants to behavior change techniques. *Appl Psychol.* 2008; 57:660–680.
20. Cane J, Richardson M, Johnston M, Ladha R, Michie S. From lists of behaviour change techniques (BCTs) to structured hierarchies: comparison of two methods of developing a hierarchies of BCTs. *Br J Health Psychol.* 2015; 20:130–150. [PubMed: 24815766]
21. French SD, McKenzie JE, O'Connor DA, Grimshaw JM, Mortimer D, Francis JJ, et al. Evaluation of a theory-informed implementation intervention for the management of acute lower back pain in

- general medical practice: The IMPLEMENT cluster randomised trial. *PLoS One*. 2013; 8:e65471. [PubMed: 23785427]
22. Cadogan CA, Ryan C, Gormley GJ, Passmore P, Francis J, Kerse N, et al. Prescribing appropriate polypharmacy for older people in primary care: a qualitative study of general practitioners' perceptions and experiences. *Int J Pharm Pract*. 2015; 23:9–10.
 23. Oxman AD, Fretheim A, Flottorp S. The OFF theory of research utilization. *J Clin Epidemiol*. 2005; 58:113–6. [PubMed: 15680741]
 24. Bhattacharyya O, Reeves S, Garfinkel S, Zwarenstein M. Designing theoretically-informed implementation interventions: fine in theory, but evidence of effectiveness in practice is needed. *Implement Sci*. 2006; 1:5. [PubMed: 16722583]
 25. Schultz K, Altman D, Moher D, CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010; 340:c332. [PubMed: 20332509]
 26. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014; 348:g1687. [PubMed: 24609605]
 27. Workgroup for Intervention Development and Evaluation Reporting (WIDER). Improving reporting of behavioural interventions: WIDER consensus statement. 2009. at <<http://interventiondesign.co.uk/wp-content/uploads/2009/02/wider-recommendations.pdf>>
 28. Albrecht L, Archibald M, Arseneau D, Scott SD. Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implement Sci*. 2013; 8:52. [PubMed: 23680355]

Figure 1. Adapted from the MRC framework for the development of a complex intervention [10]

Table 1
The Theoretical Domains Framework (adapted from [15])

Domain	Definition
Knowledge	An awareness of the existence of something
Skills	An ability or proficiency acquired through practice
Social/professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting
Beliefs about capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use
Optimism	The confidence that things will happen for the best or that desired goals will be attained
Beliefs about Consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus
Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way
Goals	Mental representations of outcomes or end states than an individual wants to achieve
Memory, attention and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives
Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour
Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours
Emotions	A complex reaction pattern, involving experiential, behavioural, and psychological elements, by which the individual attempts to deal with a personally significant matter or event
Behavioural Regulation	Anything aimed at managing or changing objectively observed or measured actions

Table 2
Selected BCTs, their definitions and a linked example relating to adherence to medicines
(adapted from [6])

BCT	Definition	Example
Goal-setting	Set or agree a goal defined in terms of the behaviour to be achieved	Set a goal of taking all medicines as prescribed with patients
Prompts and cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance	Place a post-it note on the door to remind patients to take medicines before leaving the house in the morning
Self-monitoring	Instruct self-recording of specified behaviour	Request patients to note each time they take their medicines in a diary