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Using experience-based co-design with patients, carers and healthcare professionals to develop theory-based interventions for safer medicines use

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ABSTRACT

Background: Experience-Based Co-Design (EBCD) is a participatory design method which was originally developed and is still primarily used as a healthcare quality improvement tool. Traditionally, EBCD has been sited within single services or settings and has yielded improvements grounded in the experiences of those delivering and receiving care.

Method: In this article we present how EBCD can be adapted to develop complex interventions, underpinned by theory, to be tested more widely within the healthcare system as part of a multi-phase, multi-site research study. We begin with an outline of co-design and the stages of EBCD. We then provide an overview of how EBCD can be assimilated into an intervention development and evaluation study, giving examples of the adaptations and research tools and methods that can be deployed. We also suggest how to appraise the resulting intervention so it is realistic and tractable in multiple sites. We describe how EBCD can be combined with different behaviour change theories and methods for intervention development and finally, we make suggestions about the skills needed for successful intervention development using EBCD.

Conclusion: EBCD has been recognised as being a collaborative approach to improving healthcare services that puts patients and healthcare staff at the heart of initiatives and potential changes. We have demonstrated how EBCD can be integrated into a research project and how existing research approaches can be assimilated into EBCD stages. We have also suggested where behaviour change theories can be used to better understand intervention change mechanisms.

Introduction

Experience-Based Co-Design (EBCD) is a participatory design method that was originally developed, and is still primarily used, as a healthcare quality improvement tool.[1] It is a multi-stage process involving patients, carers and staff in identifying how healthcare services can deliver enhanced experiences to improve care. As an improvement tool it has combined four main underpinning approaches:

i. participatory action research,
ii. user centred design,
iii. learning theory, and
iv. narrative-based approaches to change.[2]

The method has been mainly used in single sites to improve patient experiences of local services. However, EBCD can be integrated into projects to realise complex interventions, which can then be tested more widely within the healthcare system. Recently, the unrealised potential of EBCD to develop complex healthcare interventions as part of a wider, multi-phase research study has been highlighted.[3] To address this, we outline how EBCD can be integrated into an intervention design and evaluation project embedded within a multi-site research project. We use the example of developing complex interventions, underpinned by behaviour change theory, to increase the safety of medicines management. In doing so, we discuss the use potential use of EBCD in the context of medicines optimisation research and offer practical tips on how researchers can adapt this method to develop and evaluate interventions.

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Table 1
Potential areas that would benefit from co-designed medicines management interventions.

Area of focus	Co-design potential to make use of patients' medicines management expertise
Medicines self-management	Patient skills, strategies and tools to effectively and safely manage their own medicines, including error mitigation and error management, supply management, support that can be leveraged, support for communication with healthcare professionals.
Medicines optimisation at care transitions	Interventions to optimise how patients can prepare for moving from hospital to home, managing ongoing supply ordering and collection, adapting routines to take into account changes made in hospital, ongoing communication with healthcare professionals about management of medicines at care transitions, such as patient follow-up support with medicines by community pharmacy after discharge from hospital.
Managing medicines with regular dose changes	Interventions to support patients after doses have changed to understand how strategies and tools could help them check their prescriptions reflect those changes and manage their supplies.
Shared decision-making for prescribing	Interventions to support patients in their consultations with staff about prescribing decisions, for example in the choice of medicines or whether to discontinue a medicine, and ongoing management and support after a medicine has been changed.

Medicines are the most commonly used healthcare intervention worldwide and are fundamental in the management and prevention of health conditions. In the United Kingdom (UK), the National Health Service (NHS) spends approximately £16 billion a year on medicines across primary and secondary care. Yet whilst medicines are a frequently used intervention, they are managed through systems that are highly error prone, producing the potential for patient harm in the prescribing, dispensing and administering parts of the system.[4] Globally, each year an estimated US$42 billion is associated with medication errors.[5] Consequently, reducing avoidable harm associated with medicines errors by half by 2022 is the subject of a worldwide campaign by the World Health Organization (WHO).[5]

Numerous interventions to reduce harm from medicines have targeted different stages in the management process,[6,7] and many of which are aimed at patients' use of medicines, including the acquisition of skills to self-manage medicines.[7] However, it is difficult to discern if or how patients have been involved in intervention development. We also know that patients play a proactive and safety-critical role in managing their medicines, undertaking tasks independently of healthcare professionals and without their guidance or support.[8–10] Indeed, there is a demonstrated link between improved patient experiences and both patient safety and clinical effectiveness in healthcare.[10] As such, building on the skills that many patients clearly have is crucial, for example through understanding and building on their medicines management routines and experiences through involving them in developing interventions to enhance safety. Table 1 outlines areas of medicines management where co-design approaches could be used to develop interventions to improve care.

To realise such complex interventions, there is an established UK guideline – developed by the Medicines Research Council (MRC) – recommending the processes involved in their development and evaluation.[11] There is limited detail in the guidance about intervention development. However, O'Cathain et al. have developed (from systematic review) a taxonomy of approaches to doing this, the first being the 'partnership approach'. Here, people who will use the intervention participate equally with the research team throughout intervention development.[12] When well-designed and managed, EBCD offers exactly such an approach. Here we will outline how EBCD can be combined with the guidelines for intervention development and be underpinned by theory whilst still being grounded in and built from the experiences of the people it targets. First, we offer a brief introduction to co-design.

What is co-design?

Traditionally, industry has designed products for people or with people's needs in mind.[13] Methods where designers and end-users work together, as equal partners, to design new products, have been increasingly popular. Co-design, as one method of developing products and services, has been used for decades in the fields of business marketing, design, IT and architecture.[14] It goes beyond basic stakeholder consultation, or observation, to encourage joint working aiming to create solutions. It is participatory in nature, where the basic principle is to bring stakeholders (researchers, designers, end users etc.) together to work collectively during a design process.[15] The value of co-design is the sharing of varied perspectives in order to understand both 'demand' and 'supply' – in order to create successful outputs. Most importantly, by involving the end-user, more innovative ideas that better match users' needs are generated. In doing this, evidence demonstrates an overall improved customer satisfaction.[15]

The concept of co-design has been adopted within healthcare quality improvement practices. Here, staff and patients associated with a particular service work together to design different ways of working. Co-design has resulted in tangible improvements in, for example, breast services,[16] bedside handovers, and communication at hospital discharge.[17]

Co-design for healthcare involves engagement with, and empowerment of, those individuals (staff and patients) with lived experience. It aims to advance quality of life and health outcomes for all involved.[18] Whilst co-design has notable benefits, it also has limitations. For example, it is important to plan stakeholder engagement carefully to ensure involvement is meaningful and beyond the tokenistic.

Whilst co-design is increasing in popularity, its use has mainly been within quality or service improvement projects. There is, however, growing evidence of researchers using co-design within larger intervention development research projects. For example, Hahn-Goldberg et al. used participatory action research to inform the co-design of a patient-oriented discharge summary,[19] and Tsianakas et al. used EBCD to develop an intervention in a chemotherapy outpatients service to take forward to acceptability and feasibility research.[20] These approaches require different considerations than when designing an EBCD study for local service improvement.

What is experience-based co-design?

One method of co-design increasingly used in healthcare is EBCD, originally known as Experience-Based Design (EBD). Using EBCD, the experiences of those who use and deliver healthcare services are explored. Together, groups identify ways in which services can be adapted to improve those experiences. Traditionally, EBCD has been used as a service improvement technique focussing on the experiences and emotions of healthcare service users. It has done this through eliciting the points in the patient pathway where people's experiences of services are defined ('moments of truth' or 'touchpoints'). Those who developed the method emphasise its focus on designing experiences rather than processes.[21] EBCD was first developed and piloted in 2005–6 in a UK head and neck cancer service.[22] This work identified care touchpoints related to the physical environment in which care was experienced, for example a queuing system for clinical check-in confused and embarrassed patients. Other examples were weighing patients in a public place, and patients had problems reaching the bedside bell to attract attention when experiencing post-operative problems.[22] Since this first study, EBCD has been widely used: a 2013 survey found that 59 EBCD projects had been conducted or were underway in the UK, Australia, New Zealand, Canada, Sweden and the

Netherlands for a range of services and conditions. These included palliative care, neonatal care, orthopaedics, cancer, mental health, and diabetes.[23] At this time there were no EBCD studies focussing solely on the medicines management system. A 2020 systematic review of published studies included one study focussing on multi-morbid patients for whom managing polypharmacy was a priority.[24]

Traditionally sited within single services or settings, EBCD has successfully yielded improvements through enhanced patient and staff involvement – grounded in the experiences of those delivering and receiving care in those places. Lately, however, the method has been adapted as part of a UK National Institute of Health Research Programme Grant for use in intervention development which is:

- embedded within a larger programme of research
- across multiple sites and
- across transitions of care which form structural gaps in the safety and continuity of care.[25]

In this research project, the team (including three of the authors of this work) adapted EBCD to provide a systematic way to prioritise the real-world problems experienced universally by patients in the management of their medicines, which were common across sites. It

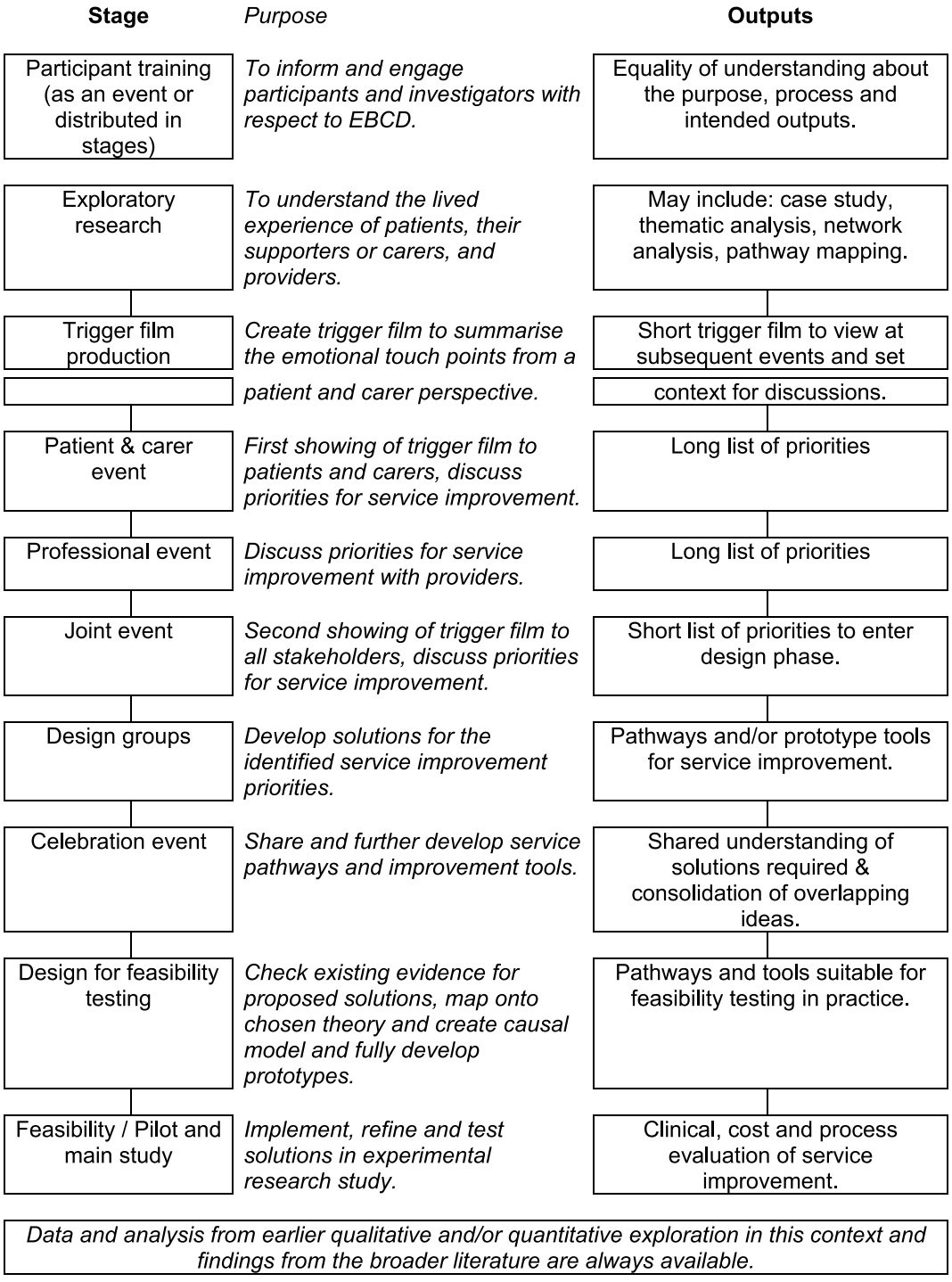

Fig. 1. Stages, purpose and outputs of multi-site complex intervention development using Experience Based Co-Design (EBCD).

included a range of stakeholders in intervention design – focussing on the parts of the system where change could help improve both patient experience and safety. The resulting co-designed interventions were deconstructed into individual components and each component was mapped onto the taxonomy of behaviour change techniques (BCTs)[26] to understand how those components could effect change, whether it be through helping patients understand changes to their medicines, how they could identify problems such as incorrect prescriptions or if they started to become unwell, or to provide practical support in managing medicines. After stakeholder consensus determined which components were likely to be deliverable, acceptable and effective the intervention (the Medicines at Transitions Intervention) then underwent feasibility testing,[27] and is now the subject of a national clinical cluster randomised control trial and process evaluation in 42 healthcare trusts.[28] The outcome measures of interest were all cause mortality and readmission to hospital, along with secondary outcomes including knowledge of medicines and satisfaction with medicines-related care.

What are the stages of EBCD?

There are several, well-documented stages to delivering EBCD which usually take up to one year to complete.[29] However, an accelerated version of EBCD exists to facilitate completing the process within a shorter timeframe.[30] Importantly, patients should be full partners in this process and be represented on the project steering group, and not just participants in the co-design stages. A full EBCD toolkit, is available online, which takes users through how EBCD works as a quality improvement tool.[31]

In short, the main full EBCD stages comprise:

- Project set-up, including establishing a steering group and training of staff and patient representatives.
- Observations of service delivery and interviews with patients and staff. Observations can be conducted in different settings, for example in hospital, ward observations can shed light on the way care is delivered to patients. This could include the degree of patient involvement in conversations about medicines, or how medicines supplies are obtained by patients. In the community, observations could take place in clinics, in community pharmacies, or in GP practices.
- Staff and patient interviews to understand experiences of giving and receiving care and to identify emotional touchpoints.
- Patient interviews are filmed and a short (20–30 min) trigger film is produced that communicates their experiences and the impacts of the emotional touchpoints on them. The trigger film is particularly effective at communicating aspects of the patient experience that are invisible to staff. For example, hospital staff may not be aware of how confused patients can be about their medicines once they are at home after being discharged, or the errors that patients experience, such as mistakes in repeat prescriptions following a spell in hospital.
- Group meetings with staff to review the evidence from observations and interviews and suggest priorities for change.
- Group meetings with patients to view the trigger film, create an emotional map for their care experiences and suggest priorities for change.
- A joint event during which staff and patients watch and discuss the trigger film and then agree priorities for service improvement.
- Facilitated, co-design groups including patients and staff work on creating tools or redesign services to address the agreed priorities
- A celebration event to reflect on the EBCD process and recognise the achievements of staff and patients who took part.

Adapting EBCD for complex intervention development and testing as part of a multiphase project

The MRC guideline intervention development, evaluation and implementation process in healthcare comprises five main stages:

1. development,
2. piloting and feasibility,
3. evaluation,
4. reporting and
5. implementation.[32,33]

EBCD sits well within the development phase of the process, although it should be combined with essential steps of:

- identifying the evidence base in the relevant area (through conducting or identifying a systematic review), and
- conducting empirical research to inform the theory of change for the resulting intervention.

EBCD is easily adaptable here as its early stages involve interviews with patients and healthcare staff. For example, in the early stages of our project to develop an intervention to support safe medicines management at transitions of care for older people with frailty, Tomlinson et al. conducted a systematic review to establish the characteristics of effective interventions.[34] We then used the interview stage of EBCD to conduct qualitative research in two healthcare areas with older people after discharge from hospital, analysed using the Framework method.[35] Interviews generated the EBCD trigger film as well as a robust evidence base to support the process of change, which could then be mapped on to existing change theories (see *Combining EBCD with different theories and methods for complex intervention development*).

When designing research incorporating EBCD, methodological considerations need to be considered which hallmark the project as research. As a research project, the research settings need to be chosen so that they represent a wider population, which is different to focussing on a local problem to initiate a quality improvement programme. In this way the transferability of the qualitative results can be optimised. To develop a medicines management complex intervention that has the potential to be implementable for a wider population, selecting multiple sites so that different site characteristics that may influence service delivery and patient experiences can be explored. For example, in our recent study four different acute secondary care sites were selected to conduct the qualitative phase to capture variations in practice, local pathways and in the patient population.[9] Further to this, patient and staff sampling frames will need to represent the wider population of interest, rather than just patients in one single setting.

The stages, purpose and outputs of complex intervention development using EBCD are outlined in Fig. 1. As adapted for use in research – rather than directly as a service quality improvement tool – the interviews that feed into the production of the trigger film are analysed qualitatively to produce a research evidence base. As the project is research, rather than local quality improvement, the necessary ethical opinions and approval must be sought.

Analysis of the interview data can be supported by appropriate methods, for example, Framework[35] or thematic analysis.[36] A review of EBCD projects has found that the majority systematically analysed interview data using a range of methods.[3] The interview data can also be combined and synthesised with data from observational research and routine data sources, such a local and national policies. This can be done across multiple settings to create a more robust research project and an intervention that can implemented in diverse environments. All the available data might be considered as forming a bounded case-study.[37] What range of data types are used and how it is combined will reflect the purpose of the research project and the ontological or epistemological assumptions of the various stakeholders.

The separate patient, staff and joint events can bring together individuals associated with multiple healthcare organisations within larger care systems.[38] This is beneficial when considering healthcare at transitions and the patient pathway is complex.[39] However, the priorities agreed and potential solutions designed may reflect a particular context and local processes. In other words, the solutions designed may

Table 2
Differences in flexibility of interventions developed through EBCD for local improvement and for multi-site evaluation.

EBCD for local quality improvement	EBCD for complex interventions for multi-site evaluation
Changes can be made quickly, and differences observed.	An intervention must be defined and once the trial study protocol is set and patients are recruited, interventions cannot easily be changed.
Implementation can be managed locally	The intervention may need to be flexible to adapt to local contexts, such as the type of staff involved in delivery. A multi-site feasibility study can help understand the flexibility needed to implement the intervention more widely.
Local testing/feedback can offer an assessment of whether the intervention improves experiences.[43]	No assumptions are made about whether the intervention is effective in advance of the trial results.
The site may continue to deliver the improved service.	Clear outcome measures need to be established. No sites will continue to deliver the intervention once trial data is collected.

require further adaptation for implementation across a system of care or in different geographies.

Users and carers who experience the whole care pathway may easily appreciate the usefulness of multi-site EBCD that brings together different parts of a system. However, some may be more interested in local service improvement. Moreover, healthcare staff may be less invested in discussions that do not directly influence their immediate working environment or the parts of the pathway that they usually see. When adapting for a multi-site research project with plans for a future large-scale evaluation, the scope to make local improvements as a result of EBCD should be agreed with each site. Changes to local practice may be deemed necessary after staff and patients view the trigger film and take part in co-design activities, however and changes made might preclude those sites from participating in future evaluations because their model of usual care may change to be too close to the intervention being trialled.

The success of multi-site EBCD depends on the identification of willing volunteers with the time and experience to work for the common good. Clearly, some incentives and adaptations are required to cover stakeholder expenses and provide universal access to meeting locations. However, this philosophy fits with the concept of integrated care systems,[38] and the smoothing out of transitions between levels of care.

Table 3
Stages to integrate EBCD into an intervention development and evaluation research project.

Stage	Adaptations and research methods needed
Research design phase	• Identify or conduct literature review • Specify your research questions and objectives. • Empirical research design including selecting the underpinning theories, selection of research sites to represent populations of interest and to capture different models of care deliver, sample design, data collection plan and analysis methods. • Ethical and governance approvals
Non-participant observations	• Observations are performed by researcher rather than service providers. • Information sheets and consent forms for observations • Observation schedule (based on the theoretical approach taken) • Field note booklets
Staff qualitative interviews	• Interview guide (informed by the theoretical approach taken). Information sheets and consent forms • Audio recording devices
Patient/carer qualitative interviews	• Interview guide (informed by the theoretical approach taken) • Information sheets and consent forms • Audio and video recording devices
Synthesis and qualitative analysis	• Data collected from observations and interviews are analysed using qualitative methods, such as Framework analysis,[38] or narrative analysis which can elicit meaning from patient and staff stories.[48] • Fylan et al.[6] and Tomlinson et al.[7] are examples of medicines safety and continuity research programmes using qualitative research as the first stage of EBCD.
Trigger film editing	• The trigger film is edited from the video recordings of patient interviews focussing on emotional touch points. • A patient representative should be involved in helping identify the relevant parts of the footage. • This stage is managed separately from the synthesis and qualitative analysis of observations and patient and staff interviews. The film should tell the story of how patients experience the care they receive rather than the story of the data analysis.
Patient feedback event	• This event supports patients in an emotional mapping of their care journey and setting priorities for change. • Taking careful notes of the emotional maps and priorities is essential. • You may run more than one of these events depending on the number of sites
Staff feedback event	• This event offers feedback on research findings and support priority setting. You should document the priorities for change generated by staff.
Joint event	• Document the agreed priorities and how they have been allocated.
Co-design groups	• Participants are facilitated to develop prototypes or plans for change, which can be mapped onto the priorities generated. Teams can use a range of creative methods, such as character vignettes to aid their thinking, and craft materials or props can be used to help realise prototype interventions. We have witnessed how patients really want to be listened to and enjoy being practical, hands on, and seeing the results of their work. • Prototypes from different groups can be broken down into components and compared against the evidence-base generated from qualitative research and systematic review.
Building the intervention	• Components that will form the intervention can be agreed through stakeholder consensus, for example through an expert panel of patients and healthcare staff. Each component can be rated against specific criteria agreed by the wider research team and patient advisers. One such set of criteria to assess the components are the APEASE criteria: affordability; practicability; effectiveness and cost-effectiveness; acceptability; side-effects and safety; equity.[40]
Intervention mapping	• Logic models[44] or a theory of change[45] can be developed using frameworks such as the Behaviour Change Technique Taxonomy.[26]
User-testing, feasibility study and intervention refinement	• User-testing of patient-facing tools such a medicines information and a feasibility-testing phase will explore how your intervention will operate in a clinical environment. • Sites should be chosen to reflect diversity in population and models of care delivery so that necessary adaptations can be identified for a multi-site trial. • Observations and qualitative research with patient and healthcare staff will uncover important barriers and facilitators to successful intervention implementation. • A TIDieR checklist[46] can be used to describe the refined intervention and a user guide developed for implementation.

As is shown in Fig. 1, EBCD is an sequential process. Each step has defined outputs which are reviewed and built on in the subsequent steps. EBCD is to an extent 'self-healing' and incorporates reflection.

- This means participants have ample opportunities to suggest, create and refine ideas; whether these relate to problems (priorities) or solutions.
- It also carefully builds stakeholder consensus whilst privileging the views and experience of service users.
- It has the capacity to 'bring along' divergent viewpoints and individuals.
- The entire process is conducted transparently, and participants can readily see if their suggestions influence the deliverables at each step.

In our experience, the trigger film is the key that unlocks common purpose and joint effort. This model of intervention development ensures that the overall objective of change (improved care for patients) is not lost and that, if needed, focus can easily be restored.

When using EBCD as part of the process of developing complex interventions, some care is necessary to ensure that proposed solutions are realistic and tractable in multiple locations where they may need to adapt to local requirements. For example, the APEASE criteria (affordability, practicability, effectiveness and cost-effectiveness, acceptability, side-effects and safety, equity)[40] can be applied using consensus methods[41] and/or expert judgement. EBCD allows creative solutions to flow from service participants, however, research considerations require that these solutions are screened and validated. When EBCD is used for quality improvement in a single location any implementation issues can be easily resolved in the next rapid iteration, for example using Plan, Do, Study Act cycles.[42] However, when a complex intervention is being developed for trial, the proposed interventions arising from EBCD will be fixed within the evaluation study protocol and fidelity to the intervention will be assessed during the trial phase. The intervention developed may, however, need to be flexible enough to be delivered in different sites and to allow for contextual factors and here an implementation framework would be useful. We have found with our interventions the feasibility study stage consolidates knowledge of how the intervention can accommodate local variation. Sites that are involved in development of EBCD locally may implement the intervention for local improvement, but we cannot assume that the intervention will bring about improvement in new sites trialling it as part of a multi-site evaluation. Consequently, once evaluation data collection is complete, those trial sites should stop delivering the intervention until the results are available. These differences are highlighted in Table 2.

A useful step is the production of logic models[44,45] for all elements of the complex intervention and completion of a TIDieR checklist.[46] The logic model(s) will relate the practical aspects of the intervention to underpinning theories or mechanisms and outcomes that have previously been achieved. Intervention development will usually conclude with the production of an intervention manual to instruct those responsible for implementation.[47]

An overview of the materials necessary for implementing EBCD as a research project is shown in Table 3.

Combining EBCD with behaviour change theories and methods for complex intervention development

Different theories have been used in the literature to guide intervention design and implementation,[49–51] aiming to improve effectiveness and uptake. In this article, we acknowledge there are many theoretical lenses that could underpin intervention design, but we focus our attention on the example of behaviour change theory. This is because an understanding of the likely behavioural mechanisms that will bring about change are instrumental when designing our intervention to improve medication safety. There is also a recognition that behaviours and systems, such as medicines management, are complex.

Researchers will often use underpinning theories to help them design their studies, interpret the data, and to help them understand phenomena.[48] Intervention development should be underpinned by a sound theoretical basis as this is more likely to result in effective design and implementation.[33] Many studies have used theory in this way to inform the design of their interventions by considering all influential factors. Some studies may choose to underpin their intervention design by implementation theory (for example, the Consolidated Framework for Implementation Research),[52] which looks at system wide factors that can help with the uptake of new interventions. Others, such as ours, may choose to use behaviour change theory to identify the behavioural barriers and enablers which the intervention can be designed to target.

Kok et al. state that effective interventions will:

- target key determinants that predict the behaviour that needs to change,
- use techniques that are able to modify key determinants, and
- fit the target population, culture and context.[53]

Clearly, co-design with patients and healthcare staff is beneficial and useful in achieving these ideals. EBCD, used as a research method for intervention design, rather than service improvement, is different as it will often first require the identification or development of appropriate theory. This can somewhat complicate the EBCD process as the researcher needs to find methods of synthesising their chosen theory with EBCD output. The theory needs to underpin the methods of EBCD, as well as inform the design of the intervention. Suggestions of how we have thoughtfully combined theory and EBCD and used them synergistically are displayed in Table 4.

There are many theories that can be used to help make sense of intervention design and a discussion of them all is outside the scope of this article. We shall instead focus on our application of behaviour change theory, with EBCD, through the use of:

- the Theoretical Domains Framework (TDF),[54]
- the Behaviour Change Technique Taxonomy (BCTT),[26] and
- the COM-B system.[40]

We have chosen to underpin our intervention development of a care transition intervention for older people living with frailty with behaviour change theory, namely because we want someone (a patient, family carer or healthcare professional) to do something differently to promote medicines safety. Here, we have applied behaviour change theory to help identify the barriers and facilitators to performing the chosen behaviour (for example, medicines adherence, safe prescribing habits

Table 4
Synergistic use of EBCD and theories of behaviour change.

Step of behaviour change theory-informed intervention design	How EBCD can be utilised
Identify the key determinants of behaviour	• EBCD participants review the trigger film and generate emotional touchpoints, which can also come from their own experiences. • Priorities for improvement are identified from the touchpoints that the researcher needs to then consider in terms of behaviour.
Identify the techniques that target these determinants	• EBCD participants can select techniques (from validated lists, literature search, etc.) they feel would be most efficacious in the given context, based on their personal experiences.
Model to fit the target population, culture and context	• Design of the intervention content closely involves those that will deliver (healthcare staff) and receive the service (staff or patients). • Event activities designed to elicit perspectives on acceptability, practicality and cost-effectiveness.

Table 5
Combining EBCD with behaviour change theories to underpin intervention design.

Tool	Brief description	Suggestions for application	Considerations
Theoretical Domains Framework[54]	A validated, broad framework of 14 (originally 12) theoretical constructs (for example, skills, knowledge, emotion etc.) relevant to behaviour change determinants, identified from 33 theories.	• Researchers map the determinants of behaviour arising from the qualitative interviews to the constructs of the TDF. • This is validated by EBCD participants, giving an understanding of the barriers and enablers to behaviour change which can help prioritise the intervention mode of action and content.	EBCD participants may need some training to help support this level of analysis. Using the TDF allows participants to consider a wide range of factors that can affect behaviour.
Behaviour Change Technique Taxonomy[26]	A list of 93 behaviour change techniques, categorised into 16 clusters, linked to each theoretical construct of the TDF.	• Key determinants of behaviour can be transparently and systematically mapped (via the TDF) to appropriate behaviour change techniques that are likely to result in behaviour change. • EBCD participants can then develop the intervention using these as a starting point.	The taxonomy is developed from public health interventions so some will not be relevant in your context. Some BCTs might be challenging to operationalise in real-life practice.
COM-B model[40]	Framework that considers the capability, opportunity and motivation that drives behaviour. This is positioned within nine intervention functions and seven policy categories that could enable the intervention to occur.	• Participants can offer unique insights into capability, opportunity and motivation factors. • They are prompted to consider which functions and policy categories would be useful to promote behaviour change based on their experiences of care.	A broad model that considers the concepts and contexts necessary for intervention design. Can be considered reductionist however, and therefore nuanced meaning can be lost.

etc) and prioritise suitable evidence-based intervention components that will promote your target behaviour by overcoming the barriers and enhancing the facilitators. The TDF, BCTT and COM-B are all potential tools that can be used to underpin EBCD methods. How we have applied these theories to our EBCD work is demonstrated in Table 5. By bringing theory into the EBCD process, participants are provided with an opportunity to interrogate academic processes of intervention design, and cognitively challenge what the theory tells us is the right course of action.

Skills needed for successful complex intervention development using EBCD

First, a highly collaborative, multi-disciplinary team that includes patients and carers is necessary. Research skills are crucial to the interview and observation stage, for example, qualitative interviewing skills, non-participant observation skills and the ability to manage, analyse and synthesise data. Second, the ability to tell a story of the experience of care is crucial, this is done through translating patient stories to the trigger film, exploring the emotional map of care with patients and through presentations at the EBCD joint event.

Increasingly, we are convinced that bringing on board an expert design team to help bring co-design groups' ideas to life is an essential step. We have found that both patients and staff can be bounded by the horizons of what they feel the health service can achieve and by their own experiences of receiving and delivering care, for example we have found that co-design groups have favoured developing information booklets to support use of medicines because they are used to giving or being given information. To help break though this, designers can bring ideas to life in unexpected ways, for example through helping co-design groups visualise solutions for medicines management differently by using character vignettes. We have witnessed how patients and staff really enjoy being hands-on in creating physical prototypes, and seeing the results of their work.

Engaging patients from the planning stage helps guide the study towards issues that are important to patients. Patients can also support developing study materials, offer advice about recruitment, co-edit the trigger film, and advise about interpretation of results. Patients have supported us throughout the lifecycle of several EBCD projects, one of which has developed an intervention for clinical trial. Patients in this group, all heart failure patients, or carers, have also been co-analysts of data collected during the trial's qualitative process evaluation.[55]

Finally, it is important to ensure the research team has access to collaborators with the appropriate skills to map the intervention onto the chosen theory or framework, understand the mechanisms with which it will effect change and how that change can be evaluated. Having a clearly documented and measurable outcome derived from the early empirical research, literature review and stakeholder conversations will aid this process.

Summary

EBCD has been recognised as being a collaborative approach to improving healthcare services that puts patients and healthcare staff at the heart of initiatives and potential changes and, as such, it is preferable to top-down service re-organization approaches. We have demonstrated how EBCD can be integrated into a research project that aims to develop and test an intervention supported by behaviour change theory to enhance the safety and continuity of medicines and suggested how existing research approaches can be assimilated into EBCD stages. We have also suggested where behaviour change theories can be used to inform EBCD and to better understand intervention change mechanisms.

Author statement

Beth Fylan: conceptualisation, writing original draft preparation and editing; Justine Tomlinson: conceptualisation, writing and editing; David K Raynor: conceptualisation, editing; Jonathan Silcock: conceptualisation, writing and editing.

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