Starting with the end in mind: Application of Implementation Science methods to enhance the operationalisation of pharma-sponsored patient support programmes

PCR161

Authors: Joanne Treacy,[a]* Selsebil Allani, and Jessica Walburn[a]

[a] IQVIA, Behavioural Science, Medical Communications, UK
* joanne.treacy@iqvia.com, corresponding author

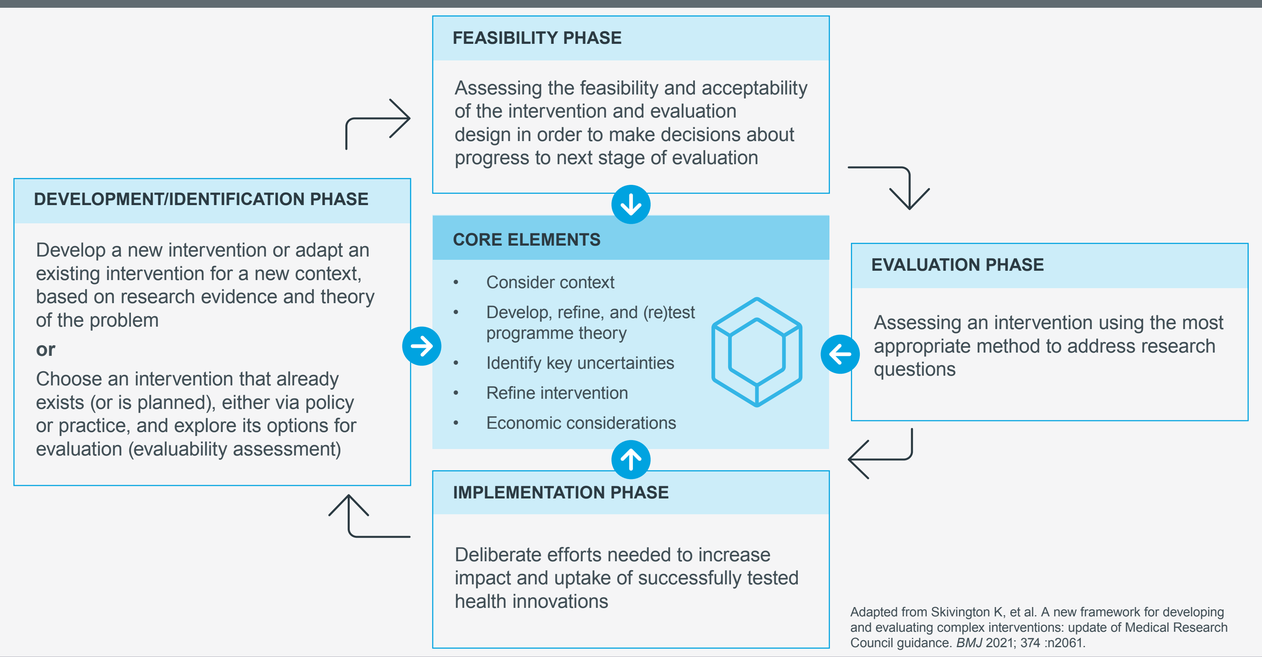
KEY TAKEAWAY

Proactive and systematic application of Implementation Science methodologies, together with complex intervention best practices, can be integrated early and throughout patient support programme (PSP) development to enhance implementation and impact.

BACKGROUND

- Pharma-sponsored PSPs aim to improve patient outcomes and enhance treatment experience by supporting holistic needs across the care journey, including adjustment to diagnosis, long-term management, and adherence to treatment.
- PSPs are complex interventions[1,2,3] with multiple interacting stakeholders and components. They are often designed at a global level but operationalised at the local level in the context of many practical local constraints and differences such as local resources, regulations, healthcare system nuances, and stakeholder perceptions.
- The effectiveness of PSPs can be impacted by loss of fidelity between the programme's design and implementation, which can result from poor consideration of these local contextual barriers.
- Best practice for development of complex interventions emphasises the need for proactive and holistic consideration of barriers to implementation early in design and throughout intervention development to allow refinement and adaptation as appropriate to context.[4] However, adequate and proactive investment to understanding these barriers is not always prioritised.
- Implementation Science (IS) methodologies explicitly and systematically integrated at intervention design i.e. starting with the end in mind, allows an opportunity to systematically understand and incorporate strategies to address.
- Our objective was to evaluate barriers to PSP implementation, with explicit consdieration of the application of IS methods, to guide recommendations to enhance the execution of PSPs, maximising efficiency and effectiveness.

FRAMEWORK FOR DEVELOPING AND EVALUATING COMPLEX INTERVENTIONS



Adapted from Skivington K, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021; 374 :n2061.

METHODS

- An inductive and deductive qualitative approach was used to explore perceptions of internal stakeholders experienced in the running of European PSPs. Leveraging behavioural science expertise and understanding of factors influencing PSP implementation, a discussion guide was informed by an IS framework, the Theoretical Domains Framework (TDF).[5]
- Participants were recruited using convenience sampling. Seven 1:1 semi-structured interviews and one focus group were conducted across six EU countries (UK/Ireland, Germany, Italy, and Spain/Portugal). Inclusion criteria-mandated PSP interventions included nurse-led education, psychological and medical support, or behaviour change content.
- Thematic analysis of data allowed identification of inductive themes, which were further translated and characterised using the COM-B (Capability, Opportunity, Motivation and Behaviour) framework[6] and TDF into actionable insights and proposed enhancement strategies.

DISCUSSION

- This study identifies key barriers that impact implementation and highlights how proactive application of Implementation Science frameworks can easily integrate into intervention design and offer an opportunity to pre-empt implementation challenges.
- PSPs can be considered complex public health interventions, and therefore should follow best practice guidance, with attention given not only to the design of the intervention itself, but also to the conditions needed to realise its mechanisms of change and/or the resources required to support intervention reach and impact in real-world implementation.
- Explicit and proactive application of theory and evidence-based frameworks to identify and map, not just barriers to desired outcome behaviours such as adherence, but also barriers to implementation specific to each representative context, with appropriate local stakeholder involvement to co-create and validate solutions, allows assumptions to be challenged and issues to be anticipated and addressed. Providing appropriate guidance to support adaptation can empower confidence to adapt while maintaining fidelity.

RESULTS

Overall, participants perceived proactive understanding of the barriers to local service delivery, using more formal systematic approaches, as beneficial to optimisation.

PSP interventions: Designing with the end in mind

QUALITATIVE THEMES			
LOCAL CONTEXT IN DESIGN	**LOCAL STAKEHOLDERS AT CENTRE**	**DESIGN TO EVALUATE**	**PRESCRIBE FLEXIBILITY**
Detailed consideration of local context and implementation early in the design process	Identification and inclusion of local stakeholders early in design	Importance of collecting operational data and experiences of service delivery staff to inform programme evolution	Provision of guidance to support flexibility and adaptations, whilst maintaining fidelity

Analysis of the themes influencing implementation using the COM-B model allowed identification and categorisation of the determining factors impacting implementation. Applying TDF (which relates to COM-B) then allowed identification of the mechanisms of action to be targeted to drive change, informing future intervention design and implementation planning.

COM-B + TDF analysis

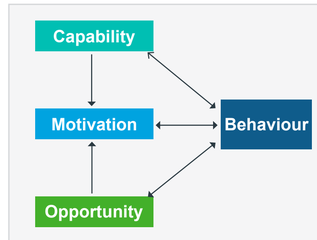
Capability Knowledge and skills	**Motivation** Perceptions, beliefs, and emotions	**Opportunity** Physical and social environment
• **Knowledge** – Awareness of local context nuances and regulations • **Knowledge** – Lack of clarity of roles and responsibilities between clinical and PSP HCPs • **Skills** – PSP HCP skills and experience with PSP intervention techniques, e.g., psychological or behaviour change strategies • **Skills** – Awareness to adapt PSP while holding fidelity	• **Perception** – Global design does not adequately account for a variety of contexts/differences of local markets • **Perception** – Global design doesn't permit personalisation or modification • **Perception** – Global design is overcomplicated and costly • **Belief** – Lack of confidence to adapt while maintaining fidelity • **Belief** – Clinical HCPs' lack of understanding/distrust in pharma-sponsored PSPs, which leads to poor engagement and patient enrolment	• Lack of inclusion of right stakeholders at right time • Limited investment to consult all stakeholders • Disconnect between global vs local client needs • Restrictive local regulations, e.g., ethics approval • PSP evaluation or modification being out of clients' scope/budget at design
Mechanisms of action • Knowledge; skills • Cognitive and interpersonal skills	**Mechanisms of action** • Beliefs about consequences • Beliefs about capabilities • Social and professional role and identity	**Mechanisms of action** • Environmental context and resources • Social influences

Applying TDF (an Implementation Science framework), allowed identification of key factors (mechanisms of action) that inform intervention design and implementation planning. Examples are included below.

Capability – Knowledge and skills
Knowledge of local market regulations and context is critical to incorporate as part of PSP design. For example, in Spain, PSPs with intervention are subject to ethical approval.

Motivation – Perceptions, beliefs, and emotions
Confidence and beliefs about the PSP's ability to adapt to local needs while holding fidelity to its design may be hampered if sufficient detailed guidance and empowerment is not provided as part of design and implementation planning.

Opportunity – Physical and social environment
Environmental factors, such as local affiliate resources, budget, and/or healthcare system nuances, need to be considered to ensure the feasibility of the design.



CONCLUSIONS AND IMPLICATIONS

PSP are costly programmes that are often designed at a global level, but implemented in local contexts, and thus can encounter many practical and motivational barriers at implementation.

Whilst iterative end-to-end programme planning (design to evaluation) is generally considered standard practice, limitations to explicit investment in understanding proactive implementation and evaluative planning at the design stage still exist.

This qualitive study highlights the opportunity for systematic application and integration of IS methods early in design and throughout development. Having a "starting with the end in mind" mindset at the design stage increases the potential of developing a PSP that can be accepted, adopted, evaluated, and refined across different contexts, ensuring pragmatic, flexible, and efficient operationalisation of the PSP.

REFERENCES:

1. Craig P, Dieppe P, Macintyre S, et al. *Developing and evaluating complex interventions*: new guidance. Medical Research Council, 2006.
2. Eccles MP, et al. *Implementation Sci.* 2006;1:1.
3. Bauer MS & Kirchner J. *Psych Res* 2020;283:112376.
4. Skivington K, Matthews L, Simpson S A, Craig P, Baird J, Blazeby J M, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021; 374 :n2061.
5. Atkins L, Francis J, Islam R, et al. A guide to using the Theoretical Domains Framework of behavior change to investigate implementation problems. *Implement Sci.* 2017;12:77.
6. Michie S, Van Stralen MM, West R. The behavior change wheel: a new method for characterising and designing behavior change interventions. *Implement Sci.* 2011;6:42.

ABBREVIATIONS: HCP = healthcare professional **COM-B =** capability, opportunity, motivation, and behaviour **TDF =** theoretical domains framework **BCT =** behaviour change techniques