ACCEPTABILITY OF HEALTHCARE INTERVENTIONS: A THEORETICAL FRAMEWORK AND PROPOSED RESEARCH AGENDA

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The important role of service users in managing their own healthcare is widely recognised. The advent of person-centred care (Royen et al., 2010) has legitimised the views of people who receive health-related interventions. Evidence of this is seen in the growing focus on assessing the 'acceptability' of interventions to recipients as well as to those who deliver them (Sekhon, Cartwright & Francis, 2017). But is there consensus in the literature about the nature of acceptability and how best to assess it? In this editorial we argue that acceptability (of healthcare interventions) is ill-defined, under-theorised and poorly assessed. Health psychology has a long history of theorising and operationalising constructs used in applied health research, so we examine our discipline's efforts to define, theorise and assess acceptability. We conclude this editorial by proposing a definition of acceptability and a theoretical framework to guide empirical investigation (Sekhon et al., 2017).

Leading guidance in the health sciences (e.g., Craig et al., 2008; Eldridge et al., 2016; Moore et al., 2015) emphasises the importance of assessing acceptability. However, both guidance documents and empirical articles addressing acceptability typically omit any explicit definition of the construct. Dictionary definitions of acceptability include "pleasure to the receiver, satisfactory; capable of being endured; tolerable [and] bearable" (Dictionary.com 2017).

In a recent systematic overview of systematic reviews (Sekhon et al., 2017) we showed that, in the context of trials of a range of healthcare interventions (e.g. drug, screening, self-management, physical activity), acceptability is most often inferred from participants' behaviour, notably in the levels of consent to participate in a study; degree of uptake, adherence or engagement (with the intervention); extent of retention or drop-out. Authors of papers included in the overview made the assumption that low intervention acceptability explained low participation rates and high dropout rates in these trials. However, behavioural factors may not fully explain participant withdrawal and ignore the value of participant-reported

evaluations of acceptability. The overview also revealed that only a small number of primary studies included in the systematic reviews assessed acceptability using direct self-report measures, for example measures of satisfaction with treatment, measures assessing participants' attitudes towards the intervention, or completion of interviews to explore participant experiences and perceptions of the intervention.

This overview of reviews of the broader applied health literature found no clear conceptual definition of acceptability and no shared theoretical understanding of the nature of acceptability. We propose that acceptability research needs a theoretical framework and associated methods for assessing the cognitive and affective components of acceptability independently of the behaviours it proposes to predict or explain.

Conceptualising acceptability

Researchers have understood and explained acceptability in a range of ways, which may inform approaches to theorising acceptability. For example, Pechey, Burge, Mentzakis, Suhrcke, and Marteau (2014) propose that the 'public acceptability' of interventions is an *attitudinal* construct. In an interesting elaboration, Cohn (2016) proposes that public acceptability is a function of *sense-making* (reminiscent of *illness coherence* from the illness perceptions literature).

Yardley et al., (2015) propose the person–centred approach to enhancing intervention acceptability, which describes the use of qualitative methods to investigate the "*beliefs, attitudes, needs* and *situation"* (p. 1) of intervention recipients. Acceptability (of recommended health behaviours) has also been explored broadly in terms of perceptions and purpose (of the behaviour) and compatibility with personal identity (McGowan et al., 2017).

From these examples it is evident a range of psychological constructs have been proposed to be related to, or part of, acceptability, suggesting that acceptability can be considered as a multi – faceted construct.

Contribution of acceptability research published in the BJHP

To explore how research published in the British Journal of Health Psychology (BJHP) has contributed to investigating the acceptability of interventions, we searched for BJHP articles in the Wiley Online Library for the following terms: (*acceptab* in Abstract) AND (intervention OR treatment OR strategy OR policy in FullText).*

Nine papers met the criteria of reporting empirical research that includes some analysis or comment on acceptability (two quantitative, three qualitative, four mixed methods) (Appendix 1). We extracted data from the full text articles and examined their contribution to defining, theorising or proposing methods for assessing the acceptability of healthcare interventions.

Of the nine papers, only Bradbury, Dennison, Little, and Yardley (2015) presented an explicit definition of acceptability, proposing that an acceptable intervention is one that is "*credible*, *comprehensible*, *usable*, and *engaging*" (p. 47).

Two studies compared the acceptability of different intervention components (Morrison et al., 2014) or of different ways to deliver the intervention (Nadarzynski et al., 2017). All studies concluded that the intervention under investigation was acceptable. However, of the six studies that included quantitative methods, only one explicitly linked a specific measure to their assessment of acceptability (Humphris & Ozakinci, 2008) and no studies presented a pre-defined threshold below which it would be deemed that the intervention was not acceptable. Some authors implied an operational definition by linking their conclusions (that the intervention was acceptable) to the following measures or concepts:

- Patients' views/perceptions/experiences/feedback about the intervention (Barlow, et al., 1997; Dennison, et al., 2010)
- Satisfaction with intervention delivery (Humphris & Ozakinci, 2008)
- Absence of harm linked to participating in the intervention (Smyth et al., 2008)
- Positive affect linked to participating in the intervention (Dennison et al., 2010)
- Behaviour (drop-out / failure to complete participation in the intervention) (Sharp et al., 2013)

- Perception of personal benefit from participating in the intervention (Morrison et al., 2014)
- Perception of usefulness of the intervention (Powell, et al., 2015)

In summary, in the literature identified, there was no consensual definition of acceptability and no shared theoretical understanding of the nature of acceptability. Furthermore, acceptability was often conflated with other key terms, for example, feasibility; enjoyment; satisfaction; uptake.

As a discipline, health psychology needs to determine whether acceptability is best understood as a mere synonym for other terms that describe recipients' or deliverers' views of an intervention (e.g. acceptability = attitude or satisfaction or feasibility etc.), or as a single distinct construct (e.g. acceptability ≠ attitude or satisfaction or feasibility etc.) or, indeed, as a constellation of related constructs (e.g. acceptability = attitude + satisfaction + feasibility etc.). Such a determination requires robust empirical and perhaps psychometric testing, but first requires careful work to define and theorise acceptability.

Theoretical Framework of Acceptability

We have argued that the scientific investigation of acceptability requires a clear conceptual definition that distinguishes it from, or specifies its relationship to, related concepts such as attitude or satisfaction and that does not conflate acceptability with behaviours such as uptake or engagement.

To advance acceptability research, we have recently developed a Theoretical Framework of Acceptability (TFA) by inductively synthesising the findings from the overview of reviews, and applying methods of deductive reasoning to theorise the concept of acceptability (Sekhon et al., 2017). We propose the following definition of acceptability (of a healthcare intervention):

> *"A multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention"* (Sekhon et al., 2017, P. 1).

The TFA consists of seven component constructs: Affective attitude, Burden, Intervention coherence, Ethicality, Opportunity costs, Perceived effectiveness and Self-efficacy (Sekhon et al., 2017) (Table 1).

Table 1: Definitions of the component constructs in the Theoretical Framework of Acceptability (Sekhon, Cartwright & Francis, 2017)

Affective Attitude	How an individual feels about the intervention
Burden	The perceived amount of effort that is required to participate in the intervention
Ethicality	The extent to which the intervention has good fit with an individual's value system
Intervention Coherence	The extent to which the participant understands the intervention and how it works
Opportunity Costs	The extent to which benefits, profits, or values must be given up to engage in the intervention
Perceived effectiveness	The extent to which the intervention is perceived to be likely to achieve its purpose
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention

The TFA is designed to facilitate assessment of intervention acceptability from the perspectives of people who receive healthcare interventions and people who deliver such interventions. Further, we propose that acceptability of an intervention can be assessed from three temporal perspectives (prospective, concurrent or retrospective) depending on the timing of assessment in relation to engagement with the intervention. This framework has a recognisable provenance

in health psychology, as it is based on a number of identifiable theoretical threads within the discipline.

Conclusions and Recommendations

Health psychology is well placed in the applied health sciences to lead on theorising and assessing intervention acceptability. Whilst the TFA is still in its early days and its usefulness is yet to be established, we would argue that there are at least three important benefits of using the health psychology-informed TFA to assess acceptability. First, as a multi-component framework, it can be used to identify the source of specific problems with acceptability, thereby suggesting intervention refinements that may address these problems to enhance acceptability. Second, a framework comprising cognitions, affect and values but not behaviour makes it possible to conduct empirical investigations of potential acceptability-behaviour gaps. Third, by offering a definition, a theoretical framework and proposed assessment approaches, the TFA enables on-going monitoring of acceptability over time, and facilitates comparisons of acceptability between alternative or competing interventions.

We have drawn on research literature and existing health psychology theory to propose a theoretical framework to guide the assessment of acceptability (Sekhon et al., 2017). This framework is a starting point for research on the conceptual integrity of our understanding of acceptability composed of multiple constructs, and for further development of qualitative and quantitative strategies to assess, compare and enhance the acceptability of interventions. For example, further research in required to assess whether acceptability is conceptually distinct from related constructs (e.g. satisfaction, feasibility, engagement, tolerability) or whether related constructs would make useful additions to the proposed TFA. In our on-going work we have applied the TFA to develop qualitative (topic guides) and quantitative (questionnaire) materials to assess the acceptability of two complex interventions (to be published separately). These materials require further development and formal validation.

We offer the TFA to the health psychology community for use in empirical research, to establish an evidence base for its usefulness, for further debate and to advance the science and practice of assessing the acceptability of healthcare interventions.

References

Appendix 1: Papers published in the British Journal of Health Psychology (presented in chronological order of publication) that investigated or described the acceptability of a healthcare intervention.

Authors, date, title	Study design (quantitative, qualitative or mixed)	Sample, intervention, theoretical basis	Key quotations that refer to acceptability	Acceptability explicitly defined?	Contribution to theorising or assessing acceptability
Barlow, Williams, Wright (1997). Improving arthritis self-management among older adults: 'Just what the doctor didn't order'.	Mixed/ unclear	62 older people (> 55 years); Arthritis Self-Management Programmes (involving health education) delivered in community settings; Cognitive-behavioural intervention drawing on self-efficacy theory	*This form of health [education] intervention is not only acceptable to older people in the UK, but can offer … benefits in terms of arthritis self-efficacy* (p. 175, p. 185)	No	Reported outcomes were arthritis self-efficacy, positive affect, cognitive symptom management, communication with doctors, exercise, relaxation, pain, depression, and visits to GPs. An open question … at follow-up, invited participants to "report their views" about the programme (p. 179).
Humphris, Ozakinci. (2008). The AFTER intervention: A structured psychological approach to reduce fears of recurrence in patients with head and neck cancer.	Quantitative	Survivors of head and neck cancer; Intervention included "structured sessions, manualized delivery by a specialist nurse, invitation to caregiver, expression of fears, examination and change of	*Initial testing showed acceptability (nurse satisfaction ratings by patient) of the intervention* (p. 223) Acceptability mentioned in abstract but not in main text.	No	Acceptability was operationalised as self-reported satisfaction with nurse who delivered the intervention.

		beliefs, and checking behaviour. Initial testing showed acceptability (nurse satisfaction)" (p. 223) Theoretical basis: "self-regulation model (SRM) of Leventhal, Nerenz, and Steele (1984)" (p. 223)			
Smyth, Hockemeyer, & Tulloch. (2008). Expressive writing and post-traumatic stress disorder: Effects on trauma symptoms, mood states, and cortisol reactivity.	Unclear / mixed	25 volunteers with a verified diagnosis of PTSD; Expressive writing about their traumatic experience; Empirical, but no theoretical basis, described.	*Expressive writing was acceptable to patients with PTSD* (p. 85) *Our data suggests that the intervention did not cause unacceptable distress, although some risk was noted. One experimental participant self-selected out of the study after the first writing session for iatrogenic reasons, indicating an unwillingness to continue writing due to distress* (p. 92). *It appears that, if administered under highly controlled circumstances, even participants with severe*	No	The authors imply that acceptability of an intervention equates to the absence of harm linked to participation. In this case, distress to one participant (out of 25) was considered by the authors to be acceptable.

			psychiatric conditions (that self-select into such treatment) are generally not harmed by expressive writing Interventions (p. 92)		
Dennison, Stanbrook, Moss-Morris, Yardley, Chalder (2010). Cognitive behavioural therapy and psycho-education for chronic fatigue syndrome in young people: Reflections from the families' perspective.	Qualitative	16 young people with Chronic Fatigue Syndrome and 16 parents; CBT vs psycho-education;	*Participants found both CBT and psycho-education acceptable and helpful* (p. 167) *Most young people found the therapy sessions acceptable or even enjoyable* (p. 174). *…most participants appeared to find the extent of improvement acceptable* (p. 177).	No	Acceptability was assessed through semi-structured interviews to elicit "views and experiences". In reporting that the intervention was "acceptable or even enjoyable" (Column 3) implies that acceptability is related to participants' positive affect while experiencing the intervention.
Sharp, Holly, Broomfield. (2013). Computerized cognitive behaviour therapy for depression in people with a chronic physical illness. REVIEW / QUANT	Quantitative (Review)	(Review of a single study) People who have a chronic physical health problem; Computerized cognitive behaviour therapy	*The study reported considerable attrition suggesting the intervention might not have been acceptable to many participants* (p. 729) *The secondary outcomes were the acceptability of treatment, assessed indirectly*	No	By implication, acceptability identified through behaviour (study attrition rate)

			by the number of people who failed to complete the intervention (p. 733)		
Morrison, Moss-Morris, Michie, Yardley. (2014). Optimizing engagement with Internet-based health behaviour change interventions: Comparison of self-assessment with and without tailored feedback using a mixed methods approach.	Qualitative	Participants in study on self-care of mild bowel problems; Internet-based health behaviour change intervention (with and without tailored feedback);	*Self-assessment without tailored feedback appeared to be less acceptable to participants because it was viewed as offering no personal benefit in the absence of personalized advice* (p. 839) *The acceptability of self-assessment or monitoring components may be optimized by also providing tailored feedback* (p. 839)	No	Authors infer a link between acceptability and perception of personal benefit. Three subscales of the Positive Intervention Perception Scale were "perceptions of personal relevance", "Perceptions of self-assessment and goal setting" and "Engagement" (p. 850), but none of these were explicitly linked with acceptability. One of only two identified studies to report a comparison of the acceptability of different versions of an intervention. Offered suggestions for improving acceptability

Bradbury, Dennison, Little, Yardley (2015). Using mixed methods to develop and evaluate an online weight management intervention.	Mixed	Patients (various samples in various studies during intervention development and refinement); Positive Online Weight Reduction (POWeR) programme	*POWeR [an e-health intervention] is acceptable and potentially effective* (p. 45)	Yes, based on the research question: "What features appear to be important for patient acceptability, that is make the intervention credible, comprehensible, usable, and engaging?"	Examined strategies for improving acceptability
Powell, Ahmad, Gilbert, Brian, Johnston. (2015). Improving magnetic resonance imaging (MRI) examinations: Development and evaluation of an intervention to reduce movement in scanners and facilitate scan completion.	Mixed/ unclear	100 patients undergoing a magnetic resonance imaging scanning procedure; Range of behaviour change techniques delivered in video clips in a DVD; Intervention targeted self-efficacy	*Only one participant reported not finding the DVD useful* (abstract)*The intervention was acceptable and efficacious in improving scan behaviour* (under What this study adds) *All 40 participants reported that the DVD instruction leaflet was clear. Thirty-six participants (90%) reported that viewing the DVD made them better informed about the scan, and 39/40 (98%) agreed that the experience of having the scan was what they expected. (p. 459)*		By implication, acceptability operationally defined as self-reported usefulness.