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Commentary

To the bone: Comment on “I wanted a skeleton ... they brought a prince”: A qualitative investigation of factors mediating the implementation of a Performance Based Incentive program in Malawi

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ABSTRACT

Recently, McMahon and colleagues set out to build on a widely-used fidelity framework, assessing the role of moderating factors during the implementation of performance-based financing programs in Malawi. Their attempt draws again the attention to the importance of approaching real word implementation issues from a theoretical perspective. It also highlights the importance of fidelity assessment within process evaluation of health programs. In this comment we argue that theoretical developments in the field of implementation science in global health would benefit from an accurate understanding of existing conceptual frameworks as well as from taking into account all contemporary contributions.

The recent work of McMahon and colleagues on assessing the role of moderating factors while implementing performance-based financing (PBF) programs in Malawi (McMahon, Muula, & Allegri, 2018), draws again the attention on the importance of approaching real word implementation issues within a theoretical perspective. It responds to calls in the literature for the development of better quality and theoretically informed research to increase the understanding of how interventions are being implemented (Belle, Pas, & Marchal, 2016; Ridde, 2016).

As emphasized by McMahon et al. (2018), mainstream research on PBF has remained outcome-related; although more and more implementation studies are being published (Bodson et al. 2018; De Allegri, Bertone, McMahon, Mounpe Chare, & Robyn, 2018; Ridde, Yaogo, Zongo, Some, & Turcotte-Tremblay, 2018). While some outcome-related research on PBF has shown rather promising results, setbacks have also been observed as well as some PBF experiences leading to poor quality of services (McMahon et al., 2018; Zizien, Korachais, Compaore, Ridde, & De Brouwere, 2018) or unintended effects (Turcotte-Tremblay, Gali-Gali, De Allegri, & Ridde, 2017). In such situations apprehending implementation fidelity is crucial to help decision-makers, intervention developers and implementers to discriminate between intervention failure (i.e., lack of effectiveness) and implementation failure (i.e. incorrect deployment) (Proctor, Powell, &

McMillen, 2013; Proctor et al., 2011).

For PBF programs, this distinction is essential as more and more voices are being raised on the ineffectiveness, even counter productivity, of this type of interventions and the lack of validity of their underlying theories. A good example is recent work by Paul et al. (2018) in which the authors argue that PBF as it is currently implemented in many low and middle-income countries (LMICs) does not satisfy the promises; and reasons for intervention failure and/or implementation failure are still not clear. Theoretical frameworks for fidelity research can be useful in this debate which has also political and ideological implications.

Carroll et al.'s framework (Carroll et al., 2007) slightly modified by Hasson et al. who added two moderating factors (Hasson, 2010; Hasson, Blomberg, & Dunér, 2012) (i.e., context and participant recruitment), is the most comprehensive framework for implementation fidelity. The framework has been empirically tested and it proved to be a useful evaluation tool for assessing fidelity of complex interventions (Gagliardi, Straus, Shojania, & Urbach, 2014; von Thiele Schwarz, Hasson, & Lindfors, 2015). McMahon and colleagues (2018) made a most welcomed attempt “... to build on Carroll's - and then Hasson's - framework...” by expanding the potential moderators (i.e., intervention complexity and participant engagement, experiences and expectations)

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based on expectation theory and field data. Their empirical work is scientifically sound and interesting. It is a process evaluation that potentially provides grounds for concrete recommendations in order to improve implementation of this particular PBF program. However, we have some concerns with the authors' theoretical contribution; and we want to approach them in a constructive perspective for the collective development of fidelity research and implementation science.

Our first quibbles are related to the author's understanding of the core of Carroll et al.'s framework. Identifying potential sources of variability in implementation has been deemed essential in the literature (Arai, Roen, Roberts, & Popay, 2005; Belaid and Ridde, 2015; Roen, Arai, Roberts, & Popay, 2006). Indeed, Carroll et al. recognize that "a high level of adherence or fidelity to an intervention... is not achieved easily"; and that "several factors may influence or moderate the degree of fidelity with which an intervention is implemented" (Carroll et al. 2007). However, Carroll et al.'s framework does not primarily focus on moderating factors, as argued by McMahon et al. (2018). It aims at providing a comprehensive picture of "the vital elements of implementation fidelity and their relationship to one another": the four subcategories of adherence (i.e. details of content, coverage, frequency and duration), moderators and the identification of essential components (Carroll et al., 2007).

Indeed, Carroll et al. put into perspective the relation between fidelity assessment and outcome evaluation. Both are needed for determining the minimal requirements, i.e. essential components, for high implementation fidelity of an intervention. Carroll et al. argue that "identifying these essential components also provides scope for identifying adaptability to local conditions"; as "an intervention cannot always be implemented fully in the real world" (Carroll et al., 2007). This is particularly relevant for interventions that are more likely to be adapted. This seems to be the case for PBF programs in Malawi, as argued by McMahon et al. (2018) as well as elsewhere (Bodson et al., 2018).

Besides, by including outcome evaluation within their framework for implementation fidelity, Carroll et al. provide researchers with an important reminder that should not be ignored. Evaluating implementation efforts, assessing moderators and measuring fidelity and adaptation has a meaning only in the context of outcomes (Backer, 2002; Pérez, Van der Stuyft, Zabala, Castro, & Lefevre, 2016). McMahon and colleagues themselves explicitly attempt to explain observed heterogeneity in PBF outcomes by looking closely at implementation processes (De Allegri et al., 2018; McMahon et al., 2016).

In this respect, the emphasis and importance given to moderators by McMahon and colleagues in Carroll et al.'s framework is problematic. It could lead, at best, to a reductionist use of the framework while examining implementation of complex PBF programs. At a broader level, it could also mislead researchers in other fields attempting to develop fidelity research based on the original and expanded Carroll et al.'s frameworks. Likewise, it may also have implications for the development of the theoretical foundations of implementation science by generating one-sided developments on fidelity.

Our second concern is that the authors proposed to add complexity of intervention as a standalone moderator. For them, complexity refers primarily to the manner in which PBF requires that those implementing the program have (specific) skills that are not often in the purview of a clinician's training and thus proved challenging (McMahon et al., 2018). Paraphrasing Hasson et al., for Carroll et al. "...complexity refers to both the description of the intervention and the real nature of the intervention." (Hasson, 2010). These ideas on intervention complexity are rooted in a broader literature on diffusion of innovations within organizations, within which it is defined not only in relation to field implementers' expertise and skills, but primarily as the degree to which an intervention is perceived as difficult to understand and use (Greenhalgh et al. 2004). This subjective component of intervention complexity is important when replicating interventions that are considered new by the users.

Last but not least, in the last years further contributions to Carroll et al.'s framework have been proposed that the authors did not use. Von Thiele Schwarz et al. (2015) suggested applying Carroll et al.'s subcategories of adherence to describe and categorize adaptations. More recently, Pérez et al. (2016) proposed a conceptual framework of implementation fidelity derived from Carroll et al. suitable to assess the fidelity-adaptation balance for adaptive and complex interventions. These authors support the idea that adaptations could either improve on or threaten the intervention's theory of action and thus impact positively or negatively on effectiveness.

Taking into account the above theoretical developments would have better informed the discussion on adaptations that affected the implementation fidelity of the PBF program in Malawi and, subsequently shed more light on the reasons for (lack of) effectiveness. For instance, McMahon et al., state that interviewees complained of the lack of flexibility for adjusting the PBF program at district and facility level. Following the authors ideas on the importance of participant engagement, experiences and expectations as a moderator, readers possibly would have learned more on how this issue might affect the expected outcome. Likewise, even in the absence of outcome data, it may be possible to differentiate between positive and negative adaptations. Interpreting the adaptations that actually occurred (e.g. changes in the training system and in the verification process) in the light of the entire Carroll et al.'s framework would have enhanced McMahon et al. (2018) analysis and assisted in inferring their potential effect on outcomes.

Pérez et al. (2016) also build on Carroll et al.'s and Hasson et al.'s ideas on moderating factors. They propose to maintain comprehensiveness of policy description, quality of delivery, and participant responsiveness as basic potential moderators. However, they do suggest including other setting- or situation-specific moderators if needed. This is in line with Hasson et al.'s ideas on the role of context (i.e., larger social, political, and economic environment that may influence implementation). It also suggests that certain moderators might emerge for specific interventions. Craig, Ruggiero, Frohlich, Mykhalovskiy, and Group (2018) further developed this idea by putting forward a broad understanding of context, which includes a comprehensive range of features (e.g. epidemiological, social and economic, cultural, historical, political; ethical; geographical, organizational). They recommend identifying casuistically the relevant features of context to minimize the risk of overlooking potentially significant dimensions.

Furthermore, Pérez et al. (2016) argue that facilitation strategies are a particular kind of moderators that could influence other moderators not only with the purpose to increase "strict adherence," but to contribute to achieve an adequate fidelity-adaptation balance. This issue is particularly relevant for interventions that are more likely to be adapted. Indeed, moderators are factors somewhat of different nature. While complexity is an intrinsic intervention feature, moderators such as participant responsiveness and expectations proposed by McMahon and colleagues might shape adherence, but can be also tuned by facilitation strategies.

We believe that the implementation framework adapted to PBF programs proposed by McMahon and colleagues would have benefited from taking into account the above theoretical developments on Carroll et al.'s and Hasson et al.'s frameworks. The field of implementation science is rapidly developing in global health and it must draw on all contemporary contributions and collective reflection in order to better comprehend the challenges of implementing complex effective interventions.

Ethical statement

The manuscript has been approved by all the authors. Declarations of interest: none.

Conflict of interest statement

The authors have declared that no competing interests exist.

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