PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Conceptualising contexts, mechanisms and outcomes for implementing large-scale, multi-site hospital improvement initiatives: a realist synthesis
AUTHORS	Long, Janet; Sarkies, Mitchell N; Francis Auton, Emilie; Nguyen, Hoa Mi; Pomare, Chiara; Hardwick, Rebecca; Braithwaite, Jeffrey

VERSION 1 – REVIEW

REVIEWER	HASSIOTIS, ANGELA ROYAL FREEand UNIVERSITY COLLEGE MEDICAL SCHOOL, PSYCHIATRY and BEHAVIOURAL SCIENCES
REVIEW RETURNED	02-Nov-2021

GENERAL COMMENTS	The manuscript is quite interesting in its scope about the implementation of large scale hospital improvement initiatives. Whilst I found it very informative and well written I think it could be improved by adding a clearer context as to which initiatives the authors are talking about and which type of hospitals. As I understood it, the manuscript describes a project that is part of a wider investigation but not sufficiently contextualised. The realist methodology is broadly well defined but how does this sit within the wider programme would be very helpful to a reader. Also, I think that implementation may be patchy for certain interventions but where things are mandatory and could be linked to patient harm including death (as might be in surgical environments) the issues at play are probably different and potentially implementation of change is mandated. Another angle that seems to be missing is the impact of patient experience and how this is harnessed within the literature and in the initiative implementation. Not all initiatives are well tolerated or accepted by the patients who should benefit from them. I would welcome, as reviewer, and interested clinician some consideration of these points in the context of the work.

REVIEWER	Ward, Marie Trinity College Dublin, School of Psychology
REVIEW RETURNED	10-Dec-2021

GENERAL COMMENTS	This is a really interesting and important piece of work in relation to understanding the mechanisms for large-scale multi-site hospital improvements. Some minor suggestions for improvement are attached.

VERSION 1 – AUTHOR RESPONSE

	Reviewer's Comments	Author's Response	Page in mss
Reviewer #1 AH			
	The manuscript is quite interesting in its scope about the implementation of large scale hospital improvement initiatives. Whilst I found it very informative and well written I think it could be improved by adding a clearer context as to which initiatives the authors are talking about and which type of hospitals. As I understood it, the manuscript describes a project that is part of a wider investigation but not sufficiently contextualised. The realist methodology is broadly well defined but how does this sit within the wider programme would be very helpful to a reader.	Thank you for your careful reading of the paper. We have added in more detail about the type of improvement initiatives we mean (to complement the existing examples). *Large-scale hospital interventions, as discussed here, are projects that are typically intended to be implemented across multiple hospitals (e.g., all public hospitals in a region). They are usually "top down" in nature, in contrast to local, clinician-initiated "grass-roots" projects. The mandate to implement these initiatives is typically from the hospitals' funding or governing bodies (e.g., State Health Departments, or local health networks), or high level clinical agencies (e.g., a national Quality and Safety Commission). Such interventions may be supported by additional staff and resources, and align with other high-level health system priorities…* *The QUARISMA intervention in Quebec, Canada, for example, was implemented in 32 hospitals.(1) The intervention was based on best practice guidelines derived from recommendations of the Society of Obstetricians and Gynaecologists. The hospitals that implemented it, successfully and safely reduced the rates of clinically unwarranted caesarean sections in low risk mothers.(1) Another example of a large-scale hospital intervention is the World Health Organisation's surgical safety check-list(2) which was successfully adopted in six high performing hospitals in The Netherlands. This significantly reduced surgical complications and mortality.(3)*	P.6

		We have also clarified the context of the wider project to show this study's relevance: *Both parts of the synthesis are part of a larger project (4) examining seven Leading Better Value Care projects implemented in metropolitan, remote and regional-based hospitals (n=100) across New South Wales (NSW), Australia between 2016 and 2018.(4) These projects are based on a value-based care paradigm and address unwarranted clinical variation, and preventable hospitalisations across seven high impact conditions.(5) Early results from this project showed that implementation strategies accompanying the projects were variably successful across sites at eliciting buy-in and adoption of the interventions. This current study is informing a realist evaluation of the implementation strategies used to build a nuanced model to support future large-scale hospital implementations; specifically, by defining relevant concepts and proposing initial program theories.*	
	Also, I think that implementation may be patchy for certain interventions but where things are mandatory and could be linked to patient harm including death (as might be in surgical environments) the issues at play are probably different and potentially implementation of change is mandated.	You raise an interesting point about implementation and enforceability of clinician actions. Mandatory practices are not included in our definition. We focussed on improvement initiatives: reducing unwarranted variation (e.g., reducing treatments that were only poorly supported by evidence in favour of ones that were more strongly supported), or ensuring processes that may be missed were consistently incorporated into clinicians' workflow. We have added the following clarifying sentence: *The focus of these initiatives is improvement of care and did not include mandated, enforceable health orders.*	p.5
	Another angle that seems to be missing is the impact of patient experience and how this is harnessed within the literature and in the initiative implementation. Not all initiatives are well tolerated or accepted by the patients who should benefit from them.	This is a good point but we did not find any literature that reported on patient input. We have added this explicitly in the limitations. *Notable was the lack of accounts of patient involvement in implementation plans.*	P.20

	I would welcome, as reviewer, and interested clinician some consideration of these points in the context of the work.		
Reviewer #2 MW			
	This is a really interesting and important piece of work in relation to understanding the mechanisms for large-scale multi-site hospital improvements. Some minor suggestions for improvement are attached.	Thank you for your careful reading of the paper.	
	I would suggest 'multi-site' is added to the title.	Thanks for this suggestion. We agree it makes the term "large-scale" clearer. Title is now: *Conceptualising contexts, mechanisms and outcomes for implementing large-scale, multi-site hospital improvement initiatives: a realist synthesis*	P.1
	The literature on importance of local context could be added to with: Rogers L, De Brún A, McAuliffe E. Defining and assessing context in healthcare implementation studies: a systematic review. BMC Health Serv Res. 2020 Jun 29;20(1):591. doi: 10.1186/s12913-020-05212-7. PMID: 32600396; PMCID: PMC7322847.	We were aware of this relevant reference but see we have not explicitly referred to it. We have now added it in the introduction and mention it in Step 4 where we identify contextual factors from the literature. *Results suggest that those designing implementation strategies have failed to take into account local contextual features,(6) and that contextual features are poorly conceptualised and defined in reporting. (7) Moreover, the underlying mechanism of action, working within that context, is only rarely defined, implying that the way strategies work is poorly understood.* *At the same time as the CMO statements were being configured, articles that reported enough detail on these strategies were reviewed for evidence looking for specific contextual*	P.6 p.17

		factors (external, organisational or individual (7)) and mechanisms.	
	The work of Flynn et al would also be interesting to look at here: Flynn, R., Rotter, T., Hartfield, D. *et al.* A realist evaluation to identify contexts and mechanisms that enabled and hindered implementation and had an effect on sustainability of a lean intervention in pediatric healthcare. *BMC Health Serv Res* **19,** 912 (2019). https://doi.org/10.1186/s12913-019-4744-3	We have now included this paper in Step 4 as a source of evidence. From it we have added a CMO and used it to support other CMOs. *(C) When the proposed change does not align with personal or group priorities / do not make sense (M) the value of the change is discounted (O) resulting in poor engagement*	Table 6. p.44
	It is unclear why there is a need to redact the references to the larger study of which this realist synthesis is a part.	This was a journal requirement – part of the blinding process. Now removed.	p.8
	ERIC strategies are notes as 68 vs 73 in the ERIC paper.	This has been corrected.	p.11
	It needs to be made clearer who attended the fortnightly research team meetings and how many of these took place; what each person's input was and what their expertise in relation to implementation science or realist synthesis was.	We have expanded this section in the methods: *The research team (JL, MS, EFA, CP) were all experienced health services researchers, two with clinical backgrounds, one sociology and the other psychology, and a research assistant (H-MN). The team were actively mentored, and work validated by an experienced realist researcher (RH).* *In this next step, the research team held two, two-hour meetings to workshop ideas towards identifying potential initial program theories.(8)*	P.9 p.12

	Similarly it needs to be made clearer who took part in the research team workshop; their backgrounds and expertise in relation to implementation science or realist synthesis.	We have clarified: *This* [step 1] *was done by the research team in two one-hour meetings. This list was verified and expanded through ongoing discussions with partners involved in large-scale, multi-site initiatives at the NSW Ministry of Health (senior policy-makers), Agency for Clinical Innovation (senior implementation support strategists) and the Bureau of Health Information (senior data management and analysis professionals). Discussions occurred as one-on-one interactions (via email) or part of project meetings/updates.*	P.10
	It needs to be made clearer the process by which the 5 mid-range theories were chosen and why others were not. For example why was socio-technical system engineering not chosen; the only strategy that did not map to the ERIC taxonomy was alignment to strategic objectives – this is a key starting point (goal alignment) of STS engineering. McDonald N, McKenna L, Vining R, Doyle B, Liang J, Ward ME, Ulfvengren P, Geary U, Guilfoyle J, Shuhaiber A, Hernandez J, Fogarty M, Healy U, Tallon C, Brennan R. Evaluation of an Access-Risk-Knowledge (ARK) Platform for Governance of Risk and Change in Complex Socio-Technical Systems. *International Journal of Environmental Research and Public Health*. 2021; 18(23):12572. https://doi.org/10.3390/ijerph182312572	We thank you for this reference. We have expanded this section about theory selection and note that our short list of theories was to some extent pragmatic – time constraints being an issue on this funded research. We also have added this constraint to the limitations. *Many theories were proposed in the workshop, mainly from our prior research experience. We also read up on theories proposed by other realist researchers and added them for consideration. This work was being done in parallel with the realist evaluation of the actual state-wide initiative so this also guided our thinking. This resulted in a short list of promising theories….* *Theories were retained or excluded on their ability to broadly describe what was happening in one or more implementation strategies, how and why across a range of contexts, and a*	P.12

		range of levels (micro, meso and macro). *Limitations* *Another limitation was the need to constrain our search and inquiry to a subset of strategies and a single formal theory.*	
	On the RAMESES table – rather than 'yes' throughout the detail of where in the paper this point is addressed could be added.	These have now been added.	

VERSION 2 – REVIEW

REVIEWER	Ward, Marie Trinity College Dublin, School of Psychology
REVIEW RETURNED	16-Mar-2022

GENERAL COMMENTS	Well done on this really interesting and important piece of work in relation to understanding the mechanisms for large-scale multi-site hospital improvements.