PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Understanding how and why audits work: protocol for a realist review of audit programmes to improve hospital care
AUTHORS	Hut-Mossel, Lisanne; Welker, Gera; Ahaus, Kees; Gans, Rob

VERSION 1 - REVIEW

REVIEWER	Professor Angela Hassiotis UCL Division of Psychiatry UK
REVIEW RETURNED	05-Dec-2016

GENERAL COMMENTS	I have read the paper with interest and in fact it has made realist reviews easier to understand! The authors use accepted theoretical principles and reporting guidance which further reassures of the rigour of the work to be undertaken. Audits are such a mainstay of health care improvements that it is encouraging to see this investigation into how they work and why and under what circumstances. Knowing how best to carry them out it will improve not just the audit but also reduce unnecessary repetitions and failed audits, consequently limiting poor care delivery. I have very few comments as follows: 1. It is not clear why the inpatient/hospital setting has been chosen when the abstract discusses healthcare. It was not until I reached the inclusion criteria that I saw it which is puzzling. Surely safety is in the community too for health interventions-a rationale should be added 2. Dissemination should be more creative; not sure what a group of 12 can achieve. It is my view that they could act as advisory group to the research but not enough for dissemination purposes. I would recommend a dissemination event which can bring together practitioners and other stakeholders as well as targeted publications for a variety of audiences including policy briefings. 3. Although strengths and limitations are mentioned in a table on p3, these are not mentioned again in the text with further clarification. This section should be added 4. The area of investigation is quite extended as is all healthcare according to the authors. Would it be perhaps more focused if it were to deal with audits in surgery or a major/priority health issue as such an approach would provide both over-arching themes (e.g. applicable to other medical fields) as well as drill down into the specifics of audits in that particular topic.

REVIEWER	Dr Linda Patterson OBE FRCP Trustee Healthcare Quality Improvement Partnership HQIP Retired Consultant physician, East Lancs Hospitals NHS Trust Past clinical Vice President Royal Colleges of Physicians , London

	UK
REVIEW RETURNED	07-Dec-2016

GENERAL COMMENTS	The paper is a preliminary paper describing the methodology to do a realist review of publications of clinical audit It will need to be read with the final paper when the results are available. The term clinical audit needs to be better explained. The authors use the term to relate to peer review of clinical practice, accreditation, and formal audit programmes. Clinical audit is normally a term which applies to measurement of performance against preset standards . The audit cycle would then be completed by an improvement programme to improve that performance and then remeasure. More clarity about the terms is needed.

REVIEWER	Pamela Mazzocato Karolinska Institutet, Sweden
REVIEW RETURNED	12-Dec-2016

GENERAL COMMENTS	Thank you for the opportunity to review this interesting study protocol; the planned study is a realist review to understand how and why audits might, or might not, work in terms of delivering the intended outcome of improved quality of healthcare and to examine under what circumstances audits could potentially be effective by formulating and refining underlying programme theories. Overall, I find the purpose of the planned study important, the choice of a realist review interesting and appropriate, the design rigorous, and I look forward to reading the findings of this review. Below follow a list of minor and major changes to address: 1. Abstract: the aim in the abstract is formulated as: “to understand how and why audits might, or might not, work in terms of delivering the intended outcome of improved quality of healthcare and to examine under what circumstances audits could potentially be effective by formulating and refining underlying programme theories.” I suggest to remove the last part of the aim formulation “by formulating and refining underlying programme theories” because it requires specific knowledge in realist review, which has not been introduced yet. 2. Strengths and limitations: the limitation mentioned in the third bullet seems to be general for any type of review. Are there any limitations of expected challenges in conducting a realist review specifically? 3. In the introduction or methods section, please clarify the philosophical assumptions behind a realist approach, specifically in relation to the methods (claimed) ability to understand how and why interventions yield (or not) the expected outcomes. 4. Introduction: audit is described as a widely used strategy in QI. While audit may be seen as a QI strategy, the authors need to elaborate further on the origins of audit and how it relates to both quality assurance and quality improvement. Indeed, while audit can be seen as QI improvement strategy, it seems to be more anchored into the quality assurance focus on monitoring standards and thresholds, rather than a QI focus on using data to understand variation. Please clarify how audits are a QI strategy and how you view QI in relation to quality assurance. 5. The comment above has also implications for how quality is defined in the context of this review. Please clarify the definition of quality used in this review. In the methods, you may also consider

	the use of specific quality framework/definition that could help you to outline more specific CMO configurations. 6. Method: given the qualitative nature of the analysis that will be conducted, please add any relevant information about the team members performing the analysis. Any specific background that may influence the analysis? 7. Method/step 3: a. you mentioned that a full text screening of the articles were conducted to appraise if the articles retained relevant information, i.e. could provide relevant information on context and mechanisms. Why not outcomes? (the third element in CMO configurations)? What did you learn from this independent review and how was this translated into inclusion criteria for LH to screen the remaining 90% of the articles? Among other things, I expect the mechanisms not to (always) be explicitly described in the articles; therefore it would be helpful to understand how this component was treated. b. Was the search strategy piloted? If not, why? c. How are you planning to capture possible interactions between C-M-O? Please clarify if possible CMO configurations will be explored already in step 3, or if, as it sees, such interaction will be explored only in phase 4. The latter strategy may affect your ability to identify CMO configurations. d. Any software used to extract data? Please add if relevant.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

I have read the paper with interest and in fact it has made realist reviews easier to understand! The authors use accepted theoretical principles and reporting guidance which further reassures of the rigour of the work to be undertaken. Audits are such a mainstay of health care improvements that it is encouraging to see this investigation into how they work and why and under what circumstances. Knowing how best to carry them out it will improve not just the audit but also reduce unnecessary repetitions and failed audits, consequently limiting poor care delivery.

Authors' response:
We appreciate the positive feedback from the reviewer. We were pleased to hear that the reviewer thought this manuscript will make realist reviews more understandable. The reviewer rightly emphasises the relevance of audits for improving healthcare.

I have very few comments as follows:
1. It is not clear why the inpatient/hospital setting has been chosen when the abstract discusses healthcare. It was not until I reached the inclusion criteria that I saw it which is puzzling. Surely, safety is in the community too for health interventions-a rationale should be added

Authors' response:
Thank you for raising this point. We agree that safety is also an important issue for health interventions in other settings, such as in long-term care and care in the community. However, the audit programmes (in particular clinical audits) which we include in our realist review are currently only executed in hospital settings and we, therefore, restrict this realist review to the hospital setting. Accordingly, we have made changes in the text to emphasise this choice (p4).

2. Dissemination should be more creative; not sure what a group of 12 can achieve. It is my view that they could act as advisory group to the research but not enough for dissemination purposes. I would

recommend a dissemination event which can bring together practitioners and other stakeholders as well as targeted publications for a variety of audiences including policy briefings.

Authors' response:
Thank you for your helpful suggestion. We are planning to disseminate the outcomes of this realist review through events of The Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra) (NFU). Clinical audits are also used within the Netherlands in teaching hospitals, and hospitalists conduct clinical audits as part of their training. Once a year, a symposium is held for hospitalists and trainee hospitalists. We are planning to present the results of our realist review at one of these symposia. We now mention these dissemination activities in our manuscript:
"The outcomes of this realist review will be disseminated through events organised by The Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra) (NFU) and at a national symposium for hospitalists who conduct clinical audits as part of their training." (p18)

3. Although strengths and limitations are mentioned in a table on p3, these are not mentioned again in the text with further clarification. This section should be added.

Authors' response:
We have revised the text of third bullet point (also in line with reviewer 3, point 2) and added limitations to the "ethics and dissemination" paragraph.

Revised third bullet point:
• "The main limitation is that realist reviews are dependent upon the transparency and adequacy of the reporting of data on the context, the mechanisms and their relationship to the produced outcomes of individual studies by the original authors. The potential lack of adequate data in this regard might hamper developing a full understanding of how and why audits are effective and might restrict the full development of the programme theory." (p3)

Text added:
"It has been argued that the theory and emerging evidence about how best to design audits (and what should be avoided) should be incorporated in the development and reporting of audits [12, 41]. However, such theoretical underpinnings are rarely reported in articles about audits, and this might hamper a full understanding of how and why audits are effective, and further impose restrictions on the ability to fully develop the programme theory and the applicability of the programme theory." (p18)

4. The area of investigation is quite extended as is all healthcare according to the authors. Would it be perhaps more focused if it were to deal with audits in surgery or a major/priority health issue as such an approach would provide both over-arching themes (e.g. applicable to other medical fields) as well as drill down into the specifics of audits in that particular topic.

Authors' response:
The reviewer is correct in that the included articles focus on a wide range of audit programmes in hospital care that address several issues. We would argue that the range of literature included in this realist review enables an understanding of the broader context of hospital care and can provide more information on contextual factors, mechanisms and their relationship to the produced outcomes. Therefore, we decided not to narrow the focus of our planned realist review.

Reviewer: 2

The paper is a preliminary paper describing the methodology to do a realist review of publications of clinical audit It will need to be read with the final paper when the results are available.

The term clinical audit needs to be better explained. The authors use the term to relate to peer review of clinical practice, accreditation, and formal audit programmes. Clinical audit is normally a term which applies to measurement of performance against preset standards . The audit cycle would then be completed by an improvement programme to improve that performance and then remeasure. More clarity about the terms is needed.

Authors' response:

Thank you for reviewing our manuscript and for your helpful suggestion. In our manuscript, we aim to recognise the differences and make a distinction between clinical audits and other audits, such as external audits (e.g. accreditation, certification, external peer reviews) and internal audits (see also our response to reviewer 3, point 4). We have revised the description of a clinical audit, which is now more in line with the reviewer's comment:
"Clinical audits differ from other types of audits in that they are mostly undertaken and initiated by healthcare professionals. As such, healthcare professionals work together to collect data and evaluate their own practices. Following this, they develop and apply improvements in their daily practices, and then the audit cycle is repeated to demonstrate improved and sustained improvements [7]. As such, clinical audits do not necessarily use external criteria and are not carried out in response to external demands as the initiative comes from the healthcare professionals themselves [10]."(p5)

Reviewer: 3

Thank you for the opportunity to review this interesting study protocol; the planned study is a realist review to understand how and why audits might, or might not, work in terms of delivering the intended outcome of improved quality of healthcare and to examine under what circumstances audits could potentially be effective by formulating and refining underlying programme theories.

Overall, I find the purpose of the planned study important, the choice of a realist review interesting and appropriate, the design rigorous, and I look forward to reading the findings of this review.

Authors' response:
We are pleased that the reviewer sees the purpose of our study as important, the opting for a realist review as interesting and appropriate, and the design rigorous. We have revised the manuscript as outlined below in response to this reviewer's specific points.

Below follow a list of minor and major changes to address:
1. Abstract: the aim in the abstract is formulated as: "to understand how and why audits might, or might not, work in terms of delivering the intended outcome of improved quality of healthcare and to examine under what circumstances audits could potentially be effective by formulating and refining underlying programme theories." I suggest to remove the last part of the aim formulation "by formulating and refining underlying programme theories" because it requires specific knowledge in realist review, which has not been introduced yet.

Authors' response:

Thank you for your suggestion. We agreed and removed the last part of the sentence (p2).

2. Strengths and limitations: the limitation mentioned in the third bullet seems to be general for any type of review. Are there any limitations of expected challenges in conducting a realist review specifically?

Authors' response:
The revised limitations are now more focused on the realist review method, and the text of the third bullet point now reads:
"The main limitation is that realist reviews are dependent upon the transparency and adequacy of the reporting of data on the context, the mechanisms and their relationship to the produced outcomes of individual studies by the original authors. The potential lack of adequate data in this regard might hamper developing a full understanding of how and why audits are effective and might restrict the full development of the programme theory." (p3)
Additionally, in line with the feedback of reviewer 1, we have also added limitations to the paragraph "ethics and dissemination" (p18).

3. In the introduction or methods section, please clarify the philosophical assumptions behind a realist approach, specifically in relation to the methods (claimed) ability to understand how and why interventions yield (or not) the expected outcomes.

Authors' response:
We now emphasise the philosophical underpinnings of a realist review in the manuscript:
"A realist review aims to clarify, from observed data, the outcomes (O) of particular interventions in relation to context (C) and mechanisms (M). This 'CMO' configuration is based on the philosophical assumption that an intervention in a specific context (C) evokes mechanisms (M) that generate an outcome (O). Consequently, the underlying mechanisms can be expected to produce a broad range of outcomes (O) when performed in different contexts (C) [19, 20, 23]. The philosophical basis is realism, which is positioned between positivism and constructivism and assumes the existence of an external reality (a 'real world') that is 'filtered' (i.e. perceived, interpreted and responded to) through the inputs of individuals. Consequently, it is not the intervention in and of itself that causes outcomes but the individuals who initiate a process of change and as such have an effect on whether and how the intervention works [20]." (p7)

4. Introduction: audit is described as a widely used strategy in QI. While audit may be seen as a QI strategy, the authors need to elaborate further on the origins of audit and how it relates to both quality assurance and quality improvement. Indeed, while audit can be seen as QI improvement strategy, it seems to be more anchored into the quality assurance focus on monitoring standards and thresholds, rather than a QI focus on using data to understand variation. Please clarify how audits are a QI strategy and how you view QI in relation to quality assurance.

Authors' response:
Thank you for your alertness and this insightful comment. We think that this is an interesting viewpoint. Quality Assurance (QA) refers to initiatives designed to assure minimum standards of (existing) care, and the mechanisms created to identify and deal with performance that does not meet these standards (Klazinga, 2000; ISO, 2015). On the other hand, Quality Improvement (QI) focuses on approaches that seek to improve care, and prevent poor care, on a continuous basis as part of everyday routines (ISO, 2015; Dixon, 2014; Balding, 2008). Both approaches seek to safeguard standards and improve care quality. In our view, QA has been perceived as largely externally driven

and seems to be related to externally driven audits (i.e. accreditation, certification, external peer reviews and internal audits often in preparation for an external audit). Conversely, clinical audits, which are not necessarily externally driven, seem to be more focused and anchored in QI. As the realist review proceeds, this might well form an addition to our programme theory. We have added text to the introduction to emphasise this apparent contradiction:
"Externally driven audits (i.e. accreditation, certification, external peer reviews and preparatory internal audits) seem to be more strongly anchored in Quality Assurance (QA), referring to initiatives designed to assure compliance with minimum quality standards [5, 6]. Clinical audits, on the other hand, represent a from QA to a Quality Improvement (QI) process, with a focus on seeking to improve care, and prevent poor care. This process takes place continuously as part of everyday routines [6-8]." (p4)

5. The comment above has also implications for how quality is defined in the context of this review. Please clarify the definition of quality used in this review. In the methods, you may also consider the use of specific quality framework/definition that could help you to outline more specific CMO configurations.

Authors' response:
We have added the definition of quality used by the World Health Organisation (WHO):
"The World Health Organisation (WHO) describes the quality of healthcare quality as follows: 'quality of care means that a health system should seek to make improvements in six areas or dimensions of quality' [30]. These dimensions are: effectiveness, efficiency, accessibility, acceptability, equity and safety." (p9)

6. Method: given the qualitative nature of the analysis that will be conducted, please add any relevant information about the team members performing the analysis. Any specific background that may influence the analysis?

Authors' response:
We have added a paragraph providing information on the background of the team members:
"The review team represents a range of disciplines and professions, which enables us to consider multiple perspectives and insights on the data gathered within this realist review. LH has a nursing background and is a PhD candidate. GW is an implementation fellow and has several years of experience as a quality manager. KA has a background in economics and business, is a professor of healthcare management and has numerous publications related to quality and patient safety. RG is a medical specialist, professor of internal medicine, chair of the Dutch Training Program of Internal Medicine and President of the Dutch Society of Hospital Medicine. He is also involved in the training of hospitalists, who are conducting clinical audits as part of their training. Further, all the members of the review team are experienced in qualitative research." (p8)

7. Method/step 3:
a. you mentioned that a full text screening of the articles were conducted to appraise if the articles retained relevant information, i.e. could provide relevant information on context and mechanisms. Why not outcomes? (the third element in CMO configurations)? What did you learn from this independent review and how was this translated into inclusion criteria for LH to screen the remaining 90% of the articles? Among other things, I expect the mechanisms not to (always) be explicitly described in the articles; therefore it would be helpful to understand how this component was treated.

Authors' response:

Thank you for spotting that we had failed to mention the appraisal of articles on the outcomes, which we of course plan to do, and we have added the outcomes to the text (p11). Independent reviews of the full text by two reviewers were conducted to ensure consistency of judgement. The inclusion criteria for the remaining 90% of the articles were unchanged following this screening. We have made some minor changes to the text to add clarity:
"Second, to ensure consistency of judgement, the full texts of a random ten percent of the articles were independently reviewed by LH and GW and retained if they were deemed relevant (i.e. the article could provide data on the context, mechanisms or outcomes of an audit). One reviewer (LH) reviewed the remaining 90% for their relevancy." (p11)
Indeed, we also expect that mechanisms may be hidden within the included articles. We have added text to explain how we plan to handle this challenge:
"First, in order to support and formulate such chains of inference, patterns of similar mechanisms will be sought across different contexts to see if emerging patterns of outcomes ('demi-regularities') are identified. Second, since we expect context-outcome regularities to be easier to identify than mechanisms, because mechanisms are underlying and hence often unobservable or 'hidden', context-outcome regularities will be used as a basis for uncovering mechanisms [20, 39]. Cases in which the contexts are restrictive or supportive will be identified and this will help in formulating the chains of inference and in recognising and explaining interactions between context, mechanisms and outcomes. Third, we will not overlook the possibility that there may be more than one mechanism in play at the same time. The chains of inference so formulated will function as a basis for the CMO configurations to be developed." (pp15-16)

b. Was the search strategy piloted? If not, why?

Authors' response:
Yes, after piloting the search in MEDLINE, the search was adapted for searching other databases. We have revised the text to emphasise this piloting process:
"The search strategy was piloted first in MEDLINE and later adapted for searching the other databases (see Supplementary File 2)."(p10)

c. How are you planning to capture possible interactions between C-M-O? Please clarify if possible CMO configurations will be explored already in step 3, or if, as it sees, such interaction will be explored only in phase 4. The latter strategy may affect your ability to identify CMO configurations.

Authors' response:
Thank you for this raising this point. In our view, step 3 (4.3 formulating chains of inference from the identified themes) will serve as an exploratory step before we formulate CMO configurations. The chains of inference will function as a basis for the CMO configurations to be developed. We have the text to better illustrate the functions of steps 4.3 and 4.4:
"Cases in which the contexts are restrictive or supportive will be identified and this will help in formulating the chains of inference and in recognising and explaining interactions between context, mechanisms and outcomes. (…)The chains of inference so formulated will function as a basis for the CMO configurations to be developed." (p16)

d. Any software used to extract data? Please add if relevant.

Authors' response:
Although no software will be used within the data extraction phase, we have developed speadsheets in Excel to assist in data extraction. This has been clarified in the text:

“Quality appraisal and data extraction will be undertaken using pre-specified Excel spreadsheets (available on request from the first author). As the aim of the data extraction process is to evaluate and refine the initial programme theory, the contents of the data extraction sheets will be developed by the review team based on the content of the initial programme theory. To test the usability of the data extraction sheets, the file will be pretested on two purposefully selected articles [33]. For each study, the quality will be appraised and general characteristics extracted concerning the study’s setting, the unit of analysis (including type of organisation) along with sections of the text that relate to context, mechanisms and their relationship to the produced outcomes.” (p12)

VERSION 2 – REVIEW

REVIEWER	Professor Angela Hassiotis UCL Division of Psychiatry, UK
REVIEW RETURNED	29-Jan-2017

GENERAL COMMENTS	I am satisfied that the authors have addressed the reviewers' comments adequately. Therefore, the paper should be accepted from my point of view.

REVIEWER	Dr Linda Patterson OBE FRCP Board Member Healthcare Quality Improvement Partnership uK (oversees and commission national clinical audit) non Executive Director Calderdale and Huddersfield NHS tRust uK Previous Consultant Physician, Burnley Lancashire UK.
REVIEW RETURNED	31-Jan-2017

GENERAL COMMENTS	You have answered the comments made by the reviewers. I am still troubled by the definition of internal audit not using external standards. The term audit should be used when measuring against a predetermined standard -either internal or external . however, you have also emphasised the quality improvement aspect of "closing the sudit cycle", which is useful. it may be that the literature you will be reviewing will also have differing definitions and understanding of the term audit -sometimes used to describe any review of practice . A purist definition would be measurement against a standard.

REVIEWER	Pamela Mazzocato Karolinska Institutet, Sweden
REVIEW RETURNED	07-Feb-2017

GENERAL COMMENTS	All the issues I mentioned in my previous review have been successfully addressed. One very minor comment: please check the structure of the paragraphs in the introduction, i.e. the sentence that starts with "externally driven audits (i.e....., should be moved to a separate paragraph and combined with the paragraph that starts with "external audits are used to...". I look forward to read the findings of this review!

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
I am satisfied that the authors have addressed the reviewers' comments adequately. Therefore, the paper should be accepted from my point of view.

Authors' response:
Thank you for reviewing our manuscript. We are pleased to hear that you find the paper should be accepted.

Reviewer: 2
You have answered the comments made by the reviewers. I am still troubled by the definition of internal audit not using external standards. The term audit should be used when measuring against a predetermined standard -either internal or external.
However, you have also emphasised the quality improvement aspect of "closing the audit cycle", which is useful. It may be that the literature you will be reviewing will also have differing definitions and understanding of the term audit -sometimes used to describe any review of practice. A purist definition would be measurement against a standard.

Authors' response:
Thank you for your suggestion. We agree that measuring against standards is an important element of all types of audits. We have clarified this in our manuscript and revised text within the introduction to emphasise this:
"Such audits are commonly used within hospital care aiming to promote quality improvements by evaluating the delivered care against standards, controlling and/or changing healthcare processes and healthcare providers' performance [3]." (p 4)

And

"Internal audits are used to evaluate the delivered care against standards with different purposes." (p 5)

Reviewer: 3
Dear Editor and authors,

All the issues I mentioned in my previous review have been successfully addressed. One very minor comment: please check the structure of the paragraphs in the introduction, i.e. the sentence that starts with "externally driven audits (i.e....., should be moved to a separate paragraph and combined with the paragraph that starts with "external audits are used to...".

I look forward to read the findings of this review!
Kind regards,
Pamela Mazzocato

Authors' response:
Thank you for your helpful remark. We agree that the structure of these paragraphs could be improved. We decided to restructure these paragraphs:
"Externally driven audits (i.e. accreditation, certification, external peer reviews and preparatory internal audits) seem to be more strongly anchored in Quality Assurance (QA), referring to initiatives designed to assure compliance with minimum quality standards [5, 6]. These external audits are used to assess certain dimensions or characteristics of a healthcare providing organisation against specified standards [9]. (…)
Clinical audits differ from other types of audits in that they are mostly undertaken and initiated by

healthcare professionals. Moreover, clinical audits represent a shift from QA to a Quality Improvement (QI) process, with a focus on seeking to improve care, and prevent poor care. This process takes place continuously as part of everyday routines [6-8]. As such, healthcare professionals work together to collect data and evaluate their own practices. Following this, they develop and apply improvements in their daily practices, and then the audit cycle is repeated to demonstrate improved and sustained improvements [7]". (p 4-5)