

Rapid Evidence Synthesis To Enable Innovation And Adoption in Health and Social Care

Gill Norman (✉ gill.norman@manchester.ac.uk)

University of Manchester

Paul Wilson

University of Manchester

Jo Dumville

University of Manchester

Peter Bower

University of Manchester

Nicky Cullum

University of Manchester

Research Article

Keywords: healthcare, Manchester, stakeholders , Academic Health Science Network

Posted Date: December 29th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-1135135/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background

The rapid identification and adoption of effective innovations in healthcare is a known challenge. The strongest evidence base for innovations can be provided by evidence synthesis, but this is frequently a lengthy process and even rapid versions of this can be time-consuming and complex. In the UK, the Accelerated Access Review and Academic Health Science Network (AHSN) have provided the impetus to develop a faster pathway for identification and adoption of high value innovations in the English NHS.

Methods

The Greater Manchester Applied Research Collaboration (ARC-GM) developed a framework for a rapid evidence synthesis (RES) process, which is highly integrated within the innovation pipeline of the Greater Manchester AHSN and the associated health care and research ecosystem. The RES uses evidence synthesis approaches and draws on the GRADE Evidence to Decision framework to provide rapid assessments of the existing evidence and its relevance for the decision-making process. We implemented this in a real-time context of decision-making around adoption of innovative health technologies.

Results

Key stakeholders in the Greater Manchester decision-making process for healthcare innovations have found that our approach is both timely and flexible, making it a useful input to considerations of innovation for adoption. The RES also identifies limitations of the evidence base for innovations subsequently adopted for roll-out, informing the evaluations planned subsequent to implementation. There is substantial interest from other ARCs and AHSNs in implementing a similar process.

Conclusions

The RES framework we have implemented aims to combine transparency and consistency with flexibility and rapidity, to maximise utility in a real-time decision-making context for healthcare innovations.

Introduction

Rapid evidence synthesis

Whilst evidence synthesis can represent the strongest evidence base for innovations, conventional systematic reviews may often take up to two years to produce,(1, 2) while even rapid reviews have a timeframe which may range up to a year.(3) Evidence summaries or evidence briefings are a form of rapid evidence synthesis which are usually produced on a shorter timescale driven by decision makers' needs,(4) and have been found useful in informing decision making, including by sub-national healthcare administrations.(5) Rapid evidence synthesis has been used to inform the commissioning of research,(6)

services,(7) and to inform policy making.(8) However, rapid evidence synthesis has not to date been widely used in decision making around innovation adoption, where timescales are shorter.

Background and context

Challenges in getting proven innovations rapidly adopted into systems, policies or practice have long been recognised. In the UK, the Accelerated Access Review provided fresh policy impetus to efforts to develop a faster pathway to identify and adopt high value innovations in the National Health Service (NHS) in England.(9) This set out recommendations to improve efficiency and outcomes for NHS patients by increasing the speed of access to innovative healthcare methods and technologies, including digital products. A key part of this has been to develop infrastructure like the Academic Health Science Networks (AHSNs) and the NHS Accelerated Access Collaborative (AAC) to support innovation in health and care. AHSNs are the agencies charged with supporting the introduction and diffusion of innovative products across the NHS.

In Greater Manchester, Health Innovation Manchester (HInM) is the AHSN with the remit to implement health innovations across the region. Our definition of innovation includes any technology, device, procedure, set of behaviours, routine, or way of working that is new to the Greater Manchester context. (10) Decisions about innovation adoption in Greater Manchester may need to be made rapidly, and for some novel technologies, the available evidence may be limited. It is important that decision making about healthcare innovation should be informed by evidence, and that there should be transparency about the evidence used and its reliability and relevance to the decision problem.

Rapid evidence synthesis in Greater Manchester

In order to ensure that decisions in Greater Manchester on innovation adoption and roll-out are informed by evidence, we developed a framework for the production of rapid evidence syntheses (RES) for innovations being considered for implementation in Greater Manchester. It has been made publicly available and registered,(11) and is provided here (see supplementary material). The framework builds on earlier work and experience in developing frameworks for briefings including those to directly inform decision-making by healthcare organisations.(12-14) It also has some similarities to other evidence briefing approaches which were identified in previous work.(15) However, we believe that the approach we have developed is unique in several important respects, and represents a development in combining the key considerations of speed, transparency, dual emphasis on robustness and relevance of evidence;(16, 17) and usability for stakeholders.

Speed and flexibility

The RES we produce are designed to be requested, undertaken and delivered in a time period of two weeks. We use a streamlined process to enable delivery in a considerably shorter timescale than other rapid evidence synthesis processes.(5-8) Our RES approach is also explicitly designed to take account of the fact that the evidence for innovations may be limited or of limited relevance, and incorporates

protocols for dealing with innovations which are complex interventions.(18, 19) Flexible question sets have provisions both for category level appraisal of the evidence or for component analysis of innovations.(20) This means that even where there is very limited evidence for an innovation *per se*, an RES can be produced which is capable of informing implementation decisions. We explore examples of this in the section below on “Flexibility in structuring the rapid evidence synthesis”.

Integration

The production of RES is embedded within, and integral to, the Greater Manchester AHSN innovation pipeline decision-making process, rather than representing an input from a separate organisation. The HInM innovation pipeline draws on ARC and AHSN expertise in implementation science, health care decision-making and lived experience, as well as evidence synthesis and evaluation. RES is recognised as one of the necessary components of the decision-making process alongside public patient involvement (PPI) input, business case assessment and local health and social care stakeholders. The RES does not include recommendations, but its findings contribute to the decisions reached. The assessment of evidence, its relevance and certainty, is therefore integrated into the considerations. The researcher responsible for the RES attends the pipeline qualification meetings before and after the RES is produced, enabling resolution of queries at each stage, supporting integration of the evidence appraisal.

Transparency and consistency:

The principles of the GRADE evidence to decision framework are central to our approach to RES; which makes the RES, and the decision process to which it contributes, more transparent, consistent, and reproducible.(16, 17) GRADE provides a clear set of considerations for the formation of judgements about the strength of the evidence base for each question addressed, and is central to the consideration of the certainty and relevance of the evidence, which are inter-related. The available GRADE frameworks have undergone substantive developments since our previous work on evidence briefings.(12)

Relevance

The RES uses GRADE approaches to consider the applicability of the evidence to the Greater Manchester context as well as its reliability. Context, both broadly and narrowly considered, can be key to the impact of introducing an intervention.(21) In the cases of complex or service-level interventions, in particular, it can be difficult to determine the boundary between the intervention and the context.(22) For example a test for poor prognosis in heart failure (23) has potential implications for an entire treatment pathway, (24) emphasising the importance of adopting a test-and-treat approach.(25) We are also mindful of the fact that many innovations may look superficially simple but are being considered for introduction into complex systems such as primary care.(26)

Although in the first instance our RES consider relevance in terms of a UK-wide NHS context, we also consider the local Greater Manchester context. We do not generally undertake RES where an innovation is already a nationally mandated priority, so local context is potentially important to all the innovations

assessed. Local context includes the existing service models, relevant infrastructure, area and population characteristics including urbanicity, relative deprivation etc. GRADE helps to ensure that relevance can be given equal prominence to certainty in evidence summaries. An example of identified limited relevance at the national level is where an RES of an innovation in asthma care identified only evidence from US trials. This is not directly relevant to asthma control in people with asthma in the UK, who at the population level have higher baseline control and use of preventative medication.(27) At the local level, an RES for an innovation improving connections between healthcare staff included evidence from a pilot project where one site was very rural.(28, 29) The evidence from that site was considered likely to be only indirectly relevant to Greater Manchester.

Methods

Process and stages of RES

We present a full example of an RES in supplementary material, a snapshot is shown in Figure 1.

The key elements of the completed RES are shown in Box 1.

BOX 1: Structure of RES

- A headline summary of the certainty and relevance of available evidence
- A bulleted summary for each question addressed
- A description of the innovation
- A set of key questions
- A summary of the search process
- Detailed answers to each question addressed in terms of available evidence and its certainty and relevance.
- Bibliography of sources used to answer the questions

Timeframe and personnel

The RES is designed to produce a “good-enough” answer to contribute to decision-making in a short timeframe, rather than a perfect answer. The methods described are implemented using a median of up to two days of time for an experienced researcher with a background in evidence synthesis. More complex innovations may entail more resource for RES production. More details are provided in the framework (see supplementary information).(11)

Describing the innovation

The first stage is to briefly describe the innovation in terms of its nature and purpose (Box 2). This establishes the type of innovation (e.g. intervention/test/service delivery mechanism); the population or system that is targeted and the outcomes which should be considered. A comparator will usually also be

identified through this process. This stage involves assessing and clarification of the information supplied by the sponsor.

Box 2. Example: Innovation description

Phagenyx is a device which is designed to reduce neurogenic dysphagia (dysfunction of eating).[1] This is dysphagia arising from the disruption of any of the neurological systems or processes involved in the execution of a coordinated safe swallow and occurs in people following stroke and in other conditions such as multiple sclerosis which impact muscle control. Dysphagia also occurs in people who have undergone sustained intubation for any reason. Phagenyx is classed as a pharyngeal electrical stimulation intervention and comprises a base station and a treatment catheter. It is applied over a period of days.

NICE guidance on the management of people with dysphagia following stroke states that they should be offered swallowing therapy at least three times a week, if they are able to participate, for as long as they continue to make functional gains. Therapy could include compensatory strategies, exercises and postural advice.[2]

Developing the questions

Using the description of the intervention, we formulate a series of questions based on the innovation description (Box 3). These begin with the most narrowly focused and move to wider category-based questions. These consider innovations in the same category and are key to production of a useful RES where evidence for the innovation is limited. Questions use the PICO(S) approach; defining the Population, Intervention (Innovation), Comparator, key Outcomes and Setting (where relevant).(30) The eligible study designs will always include existing evidence syntheses or, in their absence, the most relevant primary research design.

If the innovation is an intervention, then the questions will be ones of effectiveness and safety; where the innovation is (for example) a test or screening tool we consider accuracy as well as the impact on participants and health systems of implementing the technology. For complex interventions each core feature is described, and these are also taken into consideration in the question formation. When evaluating evidence for particular components of a complex intervention we are mindful of the fact that effectiveness in such an intervention may derive not solely from the additive effect of components but from their interaction with each other, as well as with the (often complex) system context.(31) We would therefore consider evidence relating to an individual component to be indirectly relevant to the innovation as a whole. There may be multiple questions of this form (to reflect different populations or comparators, for example).

Whilst we first focus on effectiveness evidence for the specific innovation being assessed, where this limited, we will explore evidence for (2) the category of innovations (“innovations like this”), and then (3) wider categories of relevant innovation (e.g. “innovations with a similar aim”). Categories are sometimes

not obvious, particularly where the innovation is complex.(18-20, 22, 32) In the case of wider categories we may ultimately be looking at any intervention with a purpose similar to the index innovation or all interventions for the condition or issue under consideration (See Box 1) . These subsequent questions are designed to ensure that useful evidence can be provided where the evidence for the innovation itself is absent, limited or not directly relevant. They are also required when innovations are tests, where the evidence for available treatments should be considered as a whole in the absence of test-and-treat evaluations.(25) These additional questions are designed to be addressed only where the evidence for the first question(s) is considered insufficient. Implementation of the sequential question set is then flexible and sensitive to the nature of the identified evidence.

Box 3. Example: Key questions

1. **Focus on specific innovation:** What is the evidence for the impact of Phagenyx for key outcomes in people with neurogenic dysphagia compared to other interventions or to usual care?
2. **Focus on innovation category:** If there is limited evidence for Phagenyx, what is the evidence for the impact of similar interventions (pharyngeal electrical stimulation) for key outcomes in people with neurogenic dysphagia compared to other interventions or to usual care?
3. **Focus on wider relevant innovations:** If evidence for pharyngeal electrical stimulation is limited, what is the evidence for the impact of interventions for neurogenic dysphagia more generally?

Types of evidence

Our focus is always on those study designs best able to answer the questions we have developed. We focus on identification of existing evidence synthesis (systematic reviews) where possible; where this is not possible, we focus on the most informative primary evidence. In the case of most innovations this is from comparative studies, giving priority to randomised controlled trials. Where appropriate to the questions we also include diagnostic accuracy or prognostic studies. There are also questions, especially where the focus of an innovation is on patient experience, where mixed methods or qualitative studies will be the most appropriate form of primary evidence.

Identifying evidence

We adopt a pragmatic and iterative approach to identifying evidence. This uses an initially narrow focus to maximise relevance and progresses to a broader evidence base as necessary. We search key resources including NICE guidance;(33) PubMed; and the Cochrane Library, which includes both the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials.

We increasingly encourage sponsors to provide research evidence for the innovation, as would be the case with a submission to NICE; we routinely search the sponsor's website. Where appropriate we will use subject/domain-specific resources, such as the webpage of a particular Cochrane Group,(34) or the ORCHA database of health apps.(35) Where required we consult with an information specialist. We also use reference checking or forward citation searching of relevant evidence syntheses and primary studies.

Critical appraisal

We use appropriate methods to critically appraise the different types of evidence we identify.

Cochrane reviews are generally considered to represent reliable evidence and we use their summaries and assessments of evidence certainty rather than re-appraising the evidence, unless there are issues around relevance. Where possible with other high quality systematic reviews we will also use the existing assessments of evidence from the review. This approach maximises the use of existing high quality evidence while improving timeliness. We consider the quality of non-Cochrane systematic reviews, using the signalling questions from ROBIS as a guide.(36) We consider the possibility of duplication of evidence between multiple evidence syntheses.(37)

Where there is no existing evidence synthesis, or we have concerns about the robustness or relevance of a systematic review, we consider primary evidence for the question. We also move to assessing primary research where the existing synthesis has only partially addressed a question, for example because eligibility criteria were narrower. Conversely, where a review has a broader remit, we may look at the included primary studies relevant to our question. In the example of the Phagenyx RES we looked at the subgroup of RCTs assessing Phagenyx within the Cochrane review of interventions for dysphagia in stroke.(38)

Assessment of primary studies considers both the capacity of the study design(s) to answer the question, and an assessment of the risk of bias in the identified studies of the study to produce overall judgements of reliability. Because of our narrow timescale, we do not undertake full assessments but, as with ROBIS, are guided by the domains used. For example, for randomised controlled trials we are guided by the criteria and considerations of the Cochrane Risk of Bias tool,(39) for other study designs we consider questions posed by tools such as ROBINS-I; QUIPS etc.(40, 41)

Relationship with GRADE

In forming judgements about the certainty of the evidence we are guided by the principles of GRADE.(17, 42) GRADE assesses the certainty of evidence through evaluation of several domains in order to produce an assessment of high, moderate, low or very low certainty. The first domain is the risk of bias in the evidence, which we consider as outlined above. This is considered alongside questions of imprecision, inconsistency, and direct relevance of the evidence, and publication bias. There are adaptations of GRADE for non-effectiveness questions.(43, 44)

Apart from risk of bias the domains most relevant to our rapid evidence syntheses are usually imprecision (because of small sample sizes) and indirectness (often a function of context): there is often insufficient evidence to determine inconsistency between studies for the initial questions because there are usually only a small number of studies. The evidence for category-level questions is often of higher certainty than the evidence for the innovation itself; here the domains of inconsistency (and completeness of evidence (publication bias)) are more likely to be considerations.

We bear in mind that where inconsistency is present (as at the wider category level), this may be a consequence of either – or both – differences in the interventions or the systems in which they are evaluated as well as differences in participants or outcome measures. While some interventions are clearly complex, even simple interventions are frequently implemented into complex health systems and this is especially true of those which would represent changes in patient management.(26) This especially includes diagnostic and prognostics test, for which we always primarily ask about the effect of testing on the people involved and their management.(25)

Imprecision is usually the consequence of small studies with insufficient participants; this results in wide confidence intervals and effect estimates which would be highly likely to change with further evidence. Indirectness is also often an issue for some or all of the evidence. Because innovations assessed are novel there is often only a partial evidence base, where the evidence may be only indirectly relevant to many of the people in the question, although directly relevant to the group represented in the studies.

Our considerations of relevance (which GRADE considers as (in)directness) are key to our assessments. In addition to the consideration of indirectness which informs our assessment of the certainty of the evidence we also consider the relevance of the evidence to the context and health system in which the innovation would be implemented – in this case Greater Manchester in the UK.

Results

Synthesis of the evidence

We use the identified evidence to produce narrative summaries of the evidence for the key questions in the RES. We always summarise evidence for core question(s) relating to the innovation, although we may identify little or no (useful) evidence. We provide a separate answer to each question addressed.

Where possible we summarise existing evidence syntheses, together with either their existing GRADE assessment or, if these are not available, a judgement based on our assessment of the GRADE considerations. We also provide an assessment of how relevant the evidence from the existing synthesis is to the question.

Where we have been unable to identify relevant existing evidence synthesis, we summarise the primary studies identified. We use a narrative summary to report effect estimates (with confidence intervals) and their certainty and relevance, very rarely would we seek to undertake meta-analysis.

We outline the certainty and relevance of the evidence for each outcome in the question, distinguishing where appropriate the population or subgroup to whom it is directly relevant. So in the Phagenyx population the evidence is directly relevant to people who have dysphagia following stroke, who represent a subgroup of people with dysphagia. We adopt the GRADE principle of assigning judgements around certainty to a particular outcome rather than at the study level. Where appropriate we report the evidence for each component of an intervention or intervention bundle (where there is no or very limited evidence

for the whole). We provide as nuanced a summary of the evidence as possible, clarifying where evidence has different levels of certainty for different populations, components or outcomes. An example of a full RES is provided in supplementary information.

Producing a summary

We provide two levels of summary information, written in non-technical language.

The first provides a single brief summary of the evidence picture and highlights its certainty and relevance (Box 4).

Box 4. Example: Headline summary

Phagenyx **may not change clinical outcomes** in people with dysphagia following stroke (low to moderate certainty evidence) but **probably increases the likelihood of decannulation** in people with tracheotomy and dysphagia following stroke (moderate certainty evidence). This is based on randomised controlled trials. Evidence in neurogenic dysphagia in other conditions is limited.

The second provides a bulleted summary of the certainty and relevance of the evidence for each key question, including (e.g.) nuances of the population to which the evidence is directly relevant (Box 5). This may include aspects of the evidence where relevance to the NHS, or to Greater Manchester, is limited. In both sections, summaries include questions for which we identified no evidence, very limited evidence or very uncertain evidence. The summary follows the approach of the whole evidence synthesis and does not make recommendations to the decision makers.

Box 5. Example: bulleted summary

- Most evidence relates to people with neurogenic dysphagia following stroke. In this population:
 - There is **low to moderate certainty evidence from RCTs**, including a moderately sized and methodologically strong trial, that Phagenyx **may not change clinical outcomes** in the general population of people with dysphagia following stroke. This is **directly relevant evidence to the UK NHS**.
 - In people with dysphagia and tracheotomy following stroke there is **moderate certainty evidence from small but well-conducted RCTs** that **decannulation is probably more likely** in people treated with Phagenyx. This evidence is limited by imprecision but **directly relevant to the UK NHS**.
 - There is **indirectly relevant evidence** from a **Cochrane systematic review** that, in people with dysphagia following stroke, swallowing therapy of any type probably has no effect on mortality but probably does reduce length of inpatient stay (moderate certainty evidence) and may reduce the proportion of people with dysphagia (low certainty evidence). Trials of Phagenyx contributed to this much wider review.
- There is **limited non-randomised evidence** assessing pharyngeal electrical stimulation in people with dysphagia due to causes other than stroke (people with multiple sclerosis and people in ICU).

- Further research may change the findings; the number of people involved is relatively low and new studies could substantially change the results.

Flexibility in structuring the rapid evidence synthesis

As described above, our question series has three possible levels: these relate to (1) evidence for the specific innovation, (2) evidence for innovation category and (3) evidence for wider relevant innovations. Our process involves addressing these questions sequentially, stopping at the point at which we have identified evidence of sufficient certainty and relevance. For the Phagenyx example, suitable innovation-specific (level 1) evidence was identified and no further evidence was required.(38, 45) In another example, a chatbot for mental health (46), there was limited innovation-specific evidence so the search was extended to evidence for the innovation type (level 2) question. (47, 48) For novel innovations that are not part of a wider innovation group only innovation-specific evidence will be relevant. (28)

The use of these questions sets allows us to be agile in our approach to RES. Where we consider a multicomponent or bundled innovation we can rapidly review evidence for the innovation as a whole and, where required, evidence for the innovation components. An example of this is the RES we carried out for RESTORE-2, a tool for care home staff which consists of three key components: identification of “soft signs” of possible physical decline; an early warning score and a structured communication plan. We identified limited evidence for the intervention as a whole,(49) so looked at level 1 and 2 questions, as required, for the different innovation components.(50-52)

The relevance of evidence reported in the RES is considered during subsequent decision making; with transparent and cautious extrapolation of indirect data where required. For example, in a RES for an innovation for both people with asthma and people with chronic obstructive pulmonary disease (COPD) we found only randomised evidence for people with asthma.(53, 54) and this was extrapolated to people with COPD in the absence of other suitable evidence, but we also considered a level 2 question for people with COPD.(55, 56)

Discussion

The need for evidence-informed decision making is increasingly apparent for a wide range of healthcare organisations in a climate of increasing and competing demands for services. Decision-making is informed by multiple considerations, including costs and opportunity costs, acceptability and existing infrastructure. While it is critical that decisions are informed by evidence, it is also important that this process is both transparent and consistent. As with all rapid evaluation work, there is a necessary trade-off between rigour, speed and available research resources.(57)

The RES we undertake are not conducted as an alternative to a full systematic review – or even a more conventional rapid review. Rather they represent the introduction of some synthesis of existing research evidence so that it can be given due consideration in decision-making.

The framework presented here is grounded in the GRADE evidence to decision approach as well as previous work in evidence-briefing services.(12, 16) It utilises the principles of this approach to support researchers who need to rapidly identify, assess and synthesise evidence from existing evidence syntheses and other sources in order to support immediate, real-world, healthcare decision-making processes. These processes are multidimensional, taking account of evidence alongside stakeholder views, system constraints and financial considerations. We have found that developing and using this framework provides improved transparency about the evidence base for innovations, including the limitations and gaps, to inform pragmatic decisions about implementation and future evaluation needs. There is also transparency and consistency about the process used to generate the evidence synthesis and the limitations on this which are necessary for the rapidity obtained.

The framework is intended for use where there may be relatively limited evidence available for the innovation, as well as where more research is available. It is envisaged that this approach is used by researchers from organisations involved in decisions about innovation adoption, so that queries are rapidly resolved in the innovation description and question formulation stages. In our process researchers attend relevant meetings, enabling them to answer queries and discuss issues with stakeholders and decision-makers which arise from the RES. The RES does not therefore exist only as a stand-alone document but as part of a broader integration of relevant research evidence in the decision-making process. This may distinguish the process we present from other evidence briefing services which have tended to be externally commissioned.(5, 12)

Strengths and limitations of the process

The principal limitation of the process is the necessary trade-off between rapidity and both comprehensiveness and rigour which all rapid evaluation confronts. (57) This is the case both in evidence synthesis and in primary research.(58, 59) These trade-offs are sometimes explicit – as is the case with the NICE Digital Health Framework, which is particularly relevant to the significant proportion of our evaluations which relate to digital health innovations.(60) In this instance we use a transparent and structured process to make the trade-offs for rapidity of evidence synthesis explicit.

It is likely that we will not identify all relevant evidence for some questions; particularly broader category-level questions. This is particularly likely to be the case where we do not identify any relevant evidence syntheses and are summarising primary studies. The iterative process we use, which includes citation searching and a saturation-based approach, mitigates this risk, as does the focus on existing evidence syntheses. However, it is known that rapid review processes in general may produce different results to full systematic reviews. This is the case where processes are more complex than those employed in this rapid evidence synthesis process.(58, 61, 62) The fact that the RES is produced by a single researcher also makes it necessarily vulnerable to bias and error. The potential for error may be mitigated by the researcher being relatively experienced in evidence synthesis;(63) a possible adaptation to the process would be to incorporate checks by a second researcher, with a concomitant cost in time and resources.

This approach to rapid evidence synthesis has the advantage that it can be undertaken very rapidly – it is designed to be undertaken in the two weeks between the initial decision that an innovation has potential merit and a subsequent meeting, where an adoption decision will be made. This represents a very short timescale, even for evidence briefing production (6-8, 15) – and a much shorter timeframe even than most rapid reviews.(3) In maximising use of existing evidence synthesis wherever possible, it is an efficient process which minimises research waste.

The RES approach outlined is designed to be extremely flexible, both in terms of the questions which can be addressed and the process of answering those questions; it is an iterative and pragmatic process whereby researcher judgement can be used to refine the approach at every stage. This means it is easily adapted for the assessment of a wide range of innovations: those we have so far assessed include medical devices, screening and prognosis testing, bundled service process interventions and digital mHealth apps.

Implementation and evaluation

Our approach to rapid evidence synthesis has been developed and implemented in a real-time context of decision-making around adoption of innovative health technologies. Key stakeholders in this decision-making process have found that it is sufficiently timely and flexible to be a useful input, and have engaged actively with its production and interpretation. There is substantial interest from other ARCs and AHSNs in implementing a similar process; creating a common resource database of RES undertaken by any organisation would further minimise research waste and improve evidence-informed decision making. Although we consider local relevance, the RES first consider the relevance of evidence to the NHS in England, meaning that they are also relevant to other regional decision makers.

We track the progress of innovations for which we have undertaken RES; decisions to date have included adoption, requests for further information from the sponsor, and decisions not to progress. For innovations now adopted for roll-out, the RES can inform subsequent evaluation questions. Published evaluations of use of evidence briefings are limited,(15) and we are considering possible approaches to evaluating our use of RES.

Declarations

Ethics approval and consent to participate

Not applicable: this is a methods paper

Consent for publication

Not applicable: this is a methods paper

Availability of data and materials

The framework for this methodology is publicly available on OSF: <https://osf.io/hsxk5/>

It is also cited in the bibliography. Full copies of all rapid evidence syntheses produced are available on reasonable request to the corresponding author.

Competing interests

None of the authors have any competing interests to declare.

Funding and Acknowledgements

This research was funded by the National Institute for Health Research Applied Research Collaboration Greater Manchester. The views expressed in this publication are those of the authors and not necessarily those of the National Institute for Health Research or the Department of Health and Social Care.

Authors' contributions

NC conceived the idea. GN, NC, JD, PW and PB developed the framework, which draws on previous work by PW. GN produced the rapid evidence syntheses with support from NC and JD. GN wrote the first draft of the paper with substantive contributions from PW, PB, JD and NC. All authors approved the submission for publication.

Acknowledgements

No additional acknowledgements

References

1. Borah R, Brown AW, Capers PL, Kaiser KA. Analysis of the time and workers needed to conduct systematic reviews of medical interventions using data from the PROSPERO registry. *BMJ Open*. 2017;7:e012545.
2. Cochrane. Proposing and registering new Cochrane Reviews <https://community.cochrane.org/review-production/production-resources/proposing-and-registering-new-cochrane-reviews>: Cochrane Community; [
3. Featherstone R, Dryden D, Foisy M, Guise J-M, Mitchell M, Paynter R, et al. Advancing knowledge of rapid reviews: an analysis of results, conclusions and recommendations from published review articles examining rapid reviews. *Systematic reviews*. 2015;4:50.
4. Khangura S, Konnyu K, Cushman R, Grimshaw J, Moher D. Evidence summaries: the evolution of a rapid review approach. *Systematic reviews*. 2012;1:10.
5. Hailey D, Corabian P, Harstall C, Schneider W. The use and impact of rapid health technology assessments. *International Journal of Technology Assessments in Health Care*. 2000;16(2):651–6.

6. Chambers D, Booth A, Rodgers M, Preston L, Dalton J, Goyder E, et al. Evidence to support delivery of effective health services: a responsive programme of rapid evidence synthesis. *Evidence and Policy*. 2021;17(1):173–87.
7. Wilson P, Farley K, Bickerdike L, Booth A, Chambers D, M L, et al. Does access to a demand-led evidence briefing service improve uptake and use of research evidence by health service commissioners? A controlled before and after study. *Implementation Science*. 2017;12:20.
8. Partridge A, Mansilla C, Randhawa H, Lavis J, El-Jardali F, Sewankambo N. Lessons learned from descriptions and evaluations of knowledge translation platforms supporting evidence-informed policy-making in low- and middle-income countries: a systematic review. *Health Research Policy and Systems*. 2020;18(1):127.
9. Trust W. Accelerated Access: review of innovative medicines and medical technologies supported by the Wellcome Trust. <https://www.gov.uk/government/publications/accelerated-access-review-final-report>; 2016.
10. Greenhalgh T, Robert G, MacFarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations *The Milbank Quarterly*. 2004;82(4):581–629.
11. Norman G. Rapid evidence synthesis to support health system decision making.. 2020.
12. Chambers D, Wilson P. A framework for production of systematic review based briefings to support evidence-informed decision-making. *Systematic reviews*. 2012;1:32.
13. CRD. EffectivenessMatters <https://www.york.ac.uk/crd/publications/effectiveness-matters>: Centre for Reviews and Dissemination; 2017 [
14. CRD. Effective Health Care <https://://>: Centre for Reviews and Dissemination; 2004 [
15. Chambers D, Wilson P, Thompson C, Hanbury A, Farley K, Light K. Maximising the impact of systematic review in health care decision making: a systematic scoping review of knowledge-translation resources. *The Milbank Quarterly*.89(1):131–56.
16. Alonso-Coello P, Schunemann H, Moberg J, Brignardello-Petersen R, Akl E, Davoli M, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. *BMJ*. 2016;353:i2016.
17. Guyatt G, Oxman A, Akl E, Kunz R, Vist G, Brozek J, et al. GRADE Guidelines: 1. Introduction-GRADE Evidence Profiles and Summary of Findings Tables. *Journal of Clinical Epidemiology*. 2011;64(4):383–94.
18. Petticrew M, Anderson L, Elder R, Grimshaw J, Hopkins D, Hahn R, et al. Complex interventions and their implications for systematic reviews: a pragmatic approach. *J Clin Epidemiol*. 2013;66:1209–14.
19. Petticrew M, Knai C, Thomas J, Rehfues E, Noyes J, Gerhardus A, et al. Implications of a complexity perspective for systematic reviews and guideline development in health decision making *BMJ Global Health*. 2019;4(S1):e000899.
20. Sutcliffe K, Thomas J, Stokes G, Hinds K, Bangpan M. Intervention Component Analysis (ICA): a pragmatic approach for identifying the critical features of complex interventions. *Systematic*

- Reviews. 2015;4:140.
21. Robert G, Fulop N. The role of context in successful improvement. 2014. In: Perspectives on context A selection of essays considering the role of context in successful quality improvement [Internet]. https://www.health.org.uk/sites/default/files/PerspectivesOnContext_fullversion.pdf: The Health Foundation.
 22. Wells M, Williams B, Treweek S, Coyle J, Taylor J. Intervention description is not enough: evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials*. 2012;13:95.
 23. Cuvelliez M, Vandewalle V, Brunin M, Beseme O, Hulot A, de Groote P, et al. Circulating proteomic signature of early death in heart failure patients with reduced ejection fraction. *Scientific Reports*. 2019;9:19202.
 24. NICE. Chronic heart failure in adults: diagnosis and management <https://www.nice.org.uk/guidance/ng106>: National Institute for Health and Care Excellence; 2018 [
 25. Ferrante di Ruffano L, Hyde C, McCaffery K, Bossuyt P, Deeks J. Assessing the value of diagnostic tests: a framework for designing and evaluating trials. *BMJ*. 2012;344:e686.
 26. Shiel A, Hawe P, Gold L. Complex interventions or complex systems? Implications for health economic evaluation. *BMJ*. 2008;336(7656):1281–3.
 27. Fuhlbrigge A, Reed ML, Stempel DA, Ortega HO, Fanning K, Stanford RH. The status of asthma control in the U.S. adult population. *Allergy and Asthma Proceedings*. 2009;30(5):29-33.
 28. NHS. Innovation: S12 Solutions <https://nhsaccelerator.com/innovation/s12-solutions/> NHS; 2020 [
 29. S12. S12 solutions <https://www.s12solutions.com/about-us> S12 solutions; 2020 [
 30. NICE. Developing review questions and planning the systematic review. National Institute for Health and Care Excellence. 2012 Accessed April 2021. In: The guidelines manual Process and methods [PMG6] [Internet]. <https://www.nice.org.uk/process/pmg6/chapter/developing-review-questions-and-planning-the-systematic-review>
 31. Campbell N, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. *BMJ*. 2007;334:445.
 32. JPT H, Lopez-Lopez J, Becker B, Davies S, Dawson S, Grimshaw J. Synthesising quantitative evidence in systematic reviews of complex health interventions. *BMJ Global health*. 2019;4:e000858.
 33. NICE. National Institute for Health and Care Excellence. <https://www.nice.org.uk/guidance> [
 34. Cochrane. Cochrane Review Groups. <https://www.cochranelibrary.com/about/cochrane-review-groups> [
 35. ORCHA. <https://orchahealth.com/> [
 36. Whiting P, Savović J, Higgins J, Caldwell D, Reeves B, Shea B, et al. ROBIS: a new tool to assess risk of bias in systematic reviews was developed. *Journal of Clinical Epidemiology*. 2016;69(9):225–34.
 37. Pollock M, Fernandes R, Newton A, Scott S, Hartling L. A decision tool to help researchers make decisions about including systematic reviews in overviews of reviews of healthcare interventions.

- Systematic Reviews 2019;8:29.
38. Bath PM, Lee H, Everton LF. Swallowing therapy for dysphagia in acute and subacute stroke. *Cochrane Database of Systematic Reviews*. 2018(10):CD000323.
 39. Higgins J, Savović J, Paget M, Elbers R, Sterne J. Chapter 8: Assessing risk of bias in a randomized trial. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al., editors. *Cochrane Handbook for Systematic Reviews of Interventions Version 6*. <https://training.cochrane.org/handbook/current/chapter-08>.2019.
 40. Sterne J, Hernan M, Reeves B, Savović J, Berkman N, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*. 2016;355:i4919.
 41. Hayden J, van der Windt D, Cartwright J, Côté P, Bombardier C. Assessing Bias in Studies of Prognostic Factors. *Annals of Internal Medicine* 158(4).
 42. Schünemann H, Cuello C, Akl E, Mustafa R, Meerpohl J, K T, et al. GRADE guidelines: 18. How ROBINS-I and other tools to assess risk of bias in nonrandomized studies should be used to rate the certainty of a body of evidence. *J Clin Epidemiol*. 2019;111:105–14.
 43. Iorio A, Spencer F, Falavigna M, Alba C, Lang E, Burnand B, et al. Use of GRADE for assessment of evidence about prognosis: rating confidence in estimates of event rates in broad categories of patients. *BMJ*. 2015;350:h870.
 44. Schunemann H, Mustafa R, Brozek J, Santesso N, Alonso-Coello P, Guyatt G. GRADE Guidelines: 16. GRADE evidence to decision frameworks for tests in clinical practice and public health. *J Clin Epidemiol*. 2016;76:89–98.
 45. Scutt P, Lee HS, Hamdy S, Bath PM. Pharyngeal Electrical Stimulation for Treatment of Poststroke Dysphagia: Individual Patient Data Meta-Analysis of Randomised Controlled Trials. *Stroke Research and Treatment*. 2015;2015:429053.
 46. Inkster B, Sarda S, Subramanian V. An Empathy-Driven, Conversational Artificial Intelligence Agent (Wysa) for Digital Mental Well-Being: Real-World Data Evaluation Mixed-Methods Study. *JMIR Mhealth Uhealth* 2018;6(11):e12106.
 47. Fitzpatrick KK, Darcy A, Vierhile M. Delivering Cognitive Behavior Therapy to Young Adults With Symptoms of Depression and Anxiety Using a Fully Automated Conversational Agent (Woebot): A Randomized Controlled Trial. *JMIR Mental Health*. 2017;4(2):e19.
 48. Ly KH, Ly AM, Andersson G. A fully automated conversational agent for promoting mental well-being: A pilot RCT using mixed methods. *Internet Interventions*. 2017;10:39–46.
 49. AHSN. Improving safety in care homes: A summary of Academic Health Science Network projects and innovations https://www.ahsnnetwork.com/app/uploads/2019/09/Care_Homes_Report_WEB.pdf2019 [
 50. Müller M, Jürgens J, Redaelli M, al. e. Impact of the communication and patient hand-off tool SBAR on patient safety: a systematic review. *BMJ Open*. 2018;8:e022202.
 51. Fang AHS, Lim WT, Balakrishnan T. Early warning score validation methodologies and performance metrics: a systematic review. *BMC Medical Information Decision Making*. 2020;20(1):111.

52. Douw G, Schoonhoven L, Holwerds T, al. e. Nurses' worry or concern and early recognition of deteriorating patients on general wards in acute care hospitals: a systematic review. *Critical Care*. 2015;19(1):230.
53. Van Sickle D, Barrett M, Humblet O, Henderson K, Hogg C. Randomized, controlled study of the impact of a mobile health tool on asthma SABA use, control and adherence. *European Respiratory Journal*. 2016;48:PA1018.
54. Merchant RK. Effectiveness of population health management using the Propeller health asthma platform: A randomized clinical trial. *The Journal of Allergy and Clinical Immunology: In Practice*. 2016;4(3):455–63.
55. McCabe C, McCann M, Brady AM. Computer and mobile technology interventions for self-management in chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews*. 2017(5):CD011425.
56. Zwerink M, Brusse-Keizer M, van der Valk PDLPM, Zielhuis GA, Monninkhof EM, van der Palen J, et al. Self management for patients with chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews*. 2014(3):CD002990.
57. BRACE. The trade off between rigour and real world evidence needs <https://www.birmingham.ac.uk/research/brace/blogs/.aspx>: University of Birmingham; 2021 [
58. Marshall IJ, Marshall R, Wallace BC, Brassey J, Thomas J. Rapid reviews may produce different results to systematic reviews: a meta-epidemiological study. *Journal of Clinical Epidemiology*. 2019;109:30–41.
59. Vindrola-Padros C. Can We Re-Imagine Research So It Is Timely, Relevant and Responsive? Comment on "Experience of Health Leadership in Partnering with University-Based Researchers in Canada: A Call to 'Re-Imagine' Research". *International Journal of Health Policy and Management*. 2021;10(3):172–5.
60. NICE. Evidence standards framework for digital health technologies <https://>: National Institute for Health and Care Excellence; 2021 [
61. Reynen E, Robson R, Ivory J, Hwee J, Straus SE, Pham B, et al. A retrospective comparison of systematic reviews with same-topic rapid reviews. *Journal of Clinical Epidemiology*. 2018;96:23–34.
62. Taylor-Phillips S, Geppert J, Stinton C, Freeman K, Johnson S, Fraseer H, et al. Comparison of a full systematic review versus rapid review approaches to assess a newborn screening test for tyrosinemia type 1. *Research Synthesis Methods*. 2017;8(4):475–84.
63. Waffenschmidt S, Knelangen M, Sieben W, al. e. Single screening versus conventional double screening for study selection in systematic reviews: a methodological systematic review. *BMC Medical Research Methodology*. 2019;19:132.

Figures

Rapid evidence synthesis: RESTORE2

There is no comparative evidence and very limited evidence evaluating the impact of RESTORE2 on patient or service outcomes for people in residential care. There is evidence which varies in strength and relevance for use of each of the components of RESTORE2, or similar interventions.

Summary

- We did not identify comparative evidence evaluating the use of RESTORE2 for residential care settings. Very limited descriptive information is available for the impact on outcomes.
- There is some reasonably relevant evidence from primary non-comparative observational studies that soft signs observed by nursing assistants may be predictive of acute illness in older people being cared for in residential settings; impact on patient outcomes is less clear and may be dependent on the involvement of healthcare professionals.
- Evidence for pre-hospital triage using NEWS 2 is limited; evidence from cohort studies of use in hospital and paramedic settings supports its predictive value but does not address impact on patient outcomes. There is evidence from systematic reviews that early warning systems generally, when used in hospital and prehospital settings, have predictive value; but evidence for impact on outcomes is more mixed. Use of early warning systems shows limitations in adherence when implemented by healthcare professionals; this may be relevant to residential settings.
- There is moderate certainty evidence from a systematic review that use of the SBAR structured communication tool improves patient outcomes. This includes directly relevant evidence from nursing homes looking at outcomes related to hospitalisation.

Description of the intervention

RESTORE2 (Recognise Early Soft Signs, Take Observations, Respond, Escalate)[1] is a tool designed to enable care home staff to recognise and respond to signs of possible physical deterioration in care home residents. It identifies "soft signs", supports observation taking and incorporates calculation of a National Early Warning Score (NEWS2).[2] It includes an escalation tool and a structured communication plan (SBAR).[3] It is a downloadable, printable paper-based form.[4] There is a RESTORE2 mini (Soft signs) version available which only uses the soft signs approach. It's use, or that of an equivalent tool, was recommended by the British Geriatric Society in their guidance on managing the COVID-19 pandemic in British care homes.[5]

Key questions

1. What is the effect of using RESTORE2 on outcomes for care home residents? Evidence for components may need to be considered in addition to the "bundle". Outcomes include unplanned health service use as well as patient morbidity and mortality.
2. What is the effect of tools like RESTORE2 (or those like the key components of RESTORE2) on outcomes for care home residents?
3. What is the reliability of the RESTORE2 and its relevant components in identifying care home residents who are at risk of deterioration compared to other methods or routine care?

Figure 1

Example of completed RES

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [FrameworkforARCrapiidevidencesynthesisJuly2020.pdf](#)

- [phagenyrapidevidencesynthesis.pdf](#)