Evaluating the impact of investing in the industry of clinical practice guidelines for health systems

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Research Article

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Abstract

Rationale: This review has been conducted to facilitate evidence-informed policymaking and help healthcare policymakers in Saudi Arabia decide whether or not a sustainable investment in the CPG industry is socially and economically viable.

Objectives: To investigate whether the clinical practice guidelines help to improve clinical practice and save costs.

Methods: A literature review to evaluate the benefits of implementing clinical practice guidelines.

Results: The clinical practice guidelines help improve clinical practice, but the evidence about their impact on saving costs is insufficient in the literature.

Conclusion: Investing in CPGs industry seems socially and economically viable as there are many benefits health-care regulators, providers, and payers might gain. The unified national CPGs would enable health-care regulators to optimise the quality of care services, including by protecting patient safety and preventing malpractice, and to reduce the number of medical errors. While updating national unified clinical guidelines would represent a trustworthy peer-reviewed approach to health care and offer providers a reference for best practices in health care customised to the local context. Also, having a national reference for standardised medical practices would help healthcare payers improve value-based payments.

Introduction

Clinical practice guidelines (CPGs) relate to clinical matters, generally dealing with clinical conditions or symptoms, and are usually meant for use by health-care providers and other health-care actors such as health services managers, payers, patients, and their caregivers. Clinical guidelines are standardised recommendations for health-care practitioners on how to diagnose and treat medical conditions systematically to ensure that patients receive optimal health care. These clinical guidelines usually summarise the most updated medical knowledge and weigh the benefits and harms of diagnostic and treatment procedures to provide statements that include recommendations based on recent high-quality medical evidence or health technology assessment with a view to optimising patient care. Therefore, they should be reviewed and updated regularly. Clinical guidelines are not legally obligatory. They assist health-care practitioners and patients in deciding on appropriate health care for particular clinical circumstances, which means that health-care providers do not have to follow the recommendations if they believe they are not suitable for some patients based on their clinical judgments, but deviations from guidelines must be justified (1-3).

Clinical guidelines are meant to enhance the effectiveness and quality of care, decrease variations in clinical practice, and reduce the costs from unnecessary medical procedures, preventable mistakes, and adverse events. Quality improvement initiatives are associated with CPGs, as evidence-informed

recommendations constitute the basis for identifying core outcomes and measurable standards of care (2). Both health-care regulators and payers can use measurable standards of care. Health-care regulators can use measurable standards to assess the performance of health-care providers and to monitor patient safety, while health-care payers who adopt the strategy of performance-based pay or value-based health-care payment can use measurable standards to reward or penalise health-care providers. Furthermore, clinical guidelines can be used in local contexts as a reference for standardised medical procedures by health-care payers to estimate the local costs of health-care services.

In recent decades, several non-profit organisations have invested in the CPG industry worldwide, including the World Health Organization (WHO), the National Institute for Health and Care Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN), and the Australian National Health and Medical Research Council (NHMRC). The investment usually includes CPG development, reporting, adoption, contextualisation or adaptation, evaluation, and implementation (2). The continuing innovations in health-care technologies and the growing amount of medical evidence used in this field can be overwhelming and require consistent investment of more resources in the CPG industry.

However, investing in the CPG industry may have unintended consequences. First, they may fail to change practice. Dissemination strategies can be distinguished as being either active or passive. The active or dynamic dissemination approach, which is preferred among health-care practitioners, involves procedures such as proactive education of health-care practitioners, electronic reminder systems, and audit and feedback, while the passive dissemination approach is mainly based on publishing or mailing updated information (4-8). Taking diabetes CPGs as an example, the evidence shows that the level of diabetes CPG awareness among health-care providers, which is considered an indicator of greater adherence to the guidelines, ranges between 75% and 89% in Turkey, the United States, and China. In comparison, it is around 51% in Saudi Arabia (6). The low level of CPG awareness among health-care providers may lead to lowering the value that is supposed to be returned from investing in the CPG industry.

Second, CPGs may face professional resistance. Some health-care practitioners do not follow CPGs, as they argue that each patient has different needs, particularly in terms of medicine. These reasons and unsustainable resources for investment may lead health-care policymakers to be hesitant to commit to such investment. However, this can be addressed if health system policymakers use a more proactive strategy for dissemination and link the quality initiatives with the payment systems to health-care providers, which would increase the level of CPG awareness among health-care providers intuitively.

Third, insufficient investment in the CPG industry may also lead to unintended consequences related to using low-quality clinical guidelines not updated according to the most recent and high-quality evidence-based medicine or health technology assessment, which may lead to patients being prevented from receiving the most effective treatments available in the market or sometimes being over treated, which will in turn affect patients' health outcomes and the cost of care (2, 9-11).

Taking their promise and unintended consequences together, there are contradictory opinions among health-care policymakers about the importance of sustained investment in the CPG industry to providing unified national CPGs that can be used locally as a reference by health system actors, including health-care providers, regulators, and payers, and consequently whether such investment would have a significant impact on quality of care measures such as patients' health outcomes and the cost of care. In view of these tensions, this review has been conducted to facilitate evidence-informed policymaking and to help health-care policymakers in Saudi Arabia to decide whether or not sustainable investment in the CPG industry is socially and economically viable. This is done through answering the following question: Do CPGs improve clinical practice, and do they help save money?

Method

A literature review was carried out to summarise available evidence that evaluates the benefits of implementing CPGs, which include: improvement of clinical practices and reduction of the cost of care.

Information sources

A literature review was conducted by searching PubMed, Google Scholar, Cochrane library, and CPG providers' websites, where reviews could potentially be found about the impact of their clinical guidelines, in order to identify the most applicable English-language publications without time restriction (up to July 2020). The following key words were used in the search strategy for PubMed, Google Scholar, and Cochrane library: benefit analysis, impact analysis, effectiveness, cost-effectiveness, clinical guidelines, clinical practice guidelines, clinical pathways, quality, value, cost. Moreover, the reference lists of identified papers were reviewed to locate other relevant publications not identified in the database search.

Eligibility criteria

Study design

The literature review includes any report, review, or systematic review of empirical research that reviewed the impact of the implementation of CPGs for any health condition(s) on quality of care, patient outcomes, or cost of care.

Principal outcomes

The major outcomes of interest are the benefits, harms, or limitations that are reported as a result of implementing CPGs. Benefits could refer to improvements in quality performance metrics and patient outcomes after implementing CPGs. These might include, for example, a reduction in length of stay in hospitals, a reduction in the mortality rate among patients with a specific health condition, a decrease in the number of hospitals and emergency admissions or in the number of patients who developed health

complications from a particular disease. Also, benefits might refer to improvements in the status of health-care spending as a result of implementing clinical guidelines.

Analysis

All information that is collected from reports and papers were summarised and analysed thematically.

Results

Study selection

See Figure 1.

The Impact of Guideline Implementation on improving clinical practice and cost savings from academic published papers.

Ten academic studies were included in this review (Figure 1). Four studies reporting the impact of CPGs or clinical pathways for various health conditions (12-15), two for total hip and knee arthroplasties (16, 17), one for community-acquired pneumonia (18), one for oncology (19), one for mental health (20), and one for radical cystectomy (21).

Three out of four reviews examined reported improvements in clinical practice, including in health process, quality of care, and health outcomes. While only one of these four reviews examined the impact of CPGs on cost of care, it shows that reductions in cost ranged from 6% to 56%.

The two reviews that examined the impact of clinical pathways for hip and knee replacements generally revealed a reduction of complications and length of stay in hospital. But, before considering the effectiveness of implementing the clinical pathways for total hip and knee replacement therapies, the failure of accounting the length of stay in rehabilitation facilities should be considered because the cost of care would be shifted from acute care hospitals to rehabilitation facilities if patients were discharged earlier.

The one review that describes the impact of CPGs on oncology treatment revealed that compliance with the guidelines can lead to reducing the length of stay in hospital and complications, which should result in cost reduction without affecting patients' satisfaction. Another review assesses the impact of enhanced recovery after surgery protocols versus standard of care on preoperative outcomes of radical cystectomy and shows that the implementation of the protocols was associated with better quality of care and patient outcomes. However, the review that evaluates the impact of implementing guidelines for

mental care on improving clinical practice outcomes does not show any effect of treatment guidelines (Table 1).

Table 1: summary of benefits of guidelines implementation on improving clinical practice and cost saving from academic papers

Reference	Review ID	Review objective	Intervention	Number of included studies	Degree of benefit	Comments
(12)	(Grimshaw, 1993)	Review the effect of CPGs on clinical practices in various health conditions	Various health conditions	59	<ul style="list-style-type: none"> - 4 studies show a significant improvement in health process - while others showed a substantial improvement in quality of care and health outcomes. 	The magnitude of the improvements in the performance was varied due to the successful introduction of CPGs which relies on several factors including: the health condition, the methods of developing the guidelines, and the dissemination approaches, and translating the guidelines to clinical pathways for implementation.
(13)	(Rotter, 2008)	Evaluate the impact of implementing clinical pathways on length of stay, hospital costs and patient outcomes	Various health conditions	17	<ul style="list-style-type: none"> - 12 out of 16 studies demonstrated a significant reduction in length of stay ranged between 0.8 and 2.5 days specifically in clinical pathways for invasive procedures while there was no significant differences in readmission rates to hospitals or complications. - 4 out 6 studies that assessed the impact of implementing clinical pathways on the cost of care shows a significant cost reduction with clinical pathways group 	the results should be contemplated cautiously because the heterogeneity between the included studies was high due to variation in health conditions and in the management of the places that implemented the clinical pathways.
(14)	(Kosimbei, 2011)	Summarises the evidence in developed and developing countries about the influence of CPGs on health care cost-saving.	Various health conditions	11	<ul style="list-style-type: none"> - 10 studies examined varied interventions show that CPGs increased cost-saving from 6-56% 	there are several determinants contributing in cost-saving include: reduce laboratory test, improve diagnostic specificity, generic prescribing, use cost-effective drugs, and increasing social financial responsibilities like enhancement the role of primary care groups in developed countries.

(15, 22)	(Rotter, 2012)	Assess the impact of implementing clinical pathway	Various health conditions	27	<ul style="list-style-type: none"> - This review shows a significant association between clinical pathway and reduction in hospital complications decreased around 36-94% such as pneumonia, wound infections, and bleeding. - Also, the implementation of clinical pathways improved documentation significantly by 5-30% 	<ul style="list-style-type: none"> - The methodological quality of included studies was poor, also, there is heterogeneities in terms of type of health conditions and clinical as the CPG can be translated to practice through various pathways. - Also, other confounding factors may affect the relation between a reduction in complications and improved documentation with implementing clinical pathways such as hospitals policies how they managed in different countries
(16)	(Kim, 2003)	Assess the effectiveness of clinical pathways for total hip and knee arthroplasties	Total hip and knee arthroplasties	11	<ul style="list-style-type: none"> - Eleven studies show a reduction in length of stay in acute hospitals during the implementation of clinical pathways with a remarkable variability was noticed in the reduction of length of stay ranged between 1.5-6.2 days for total knee replacement and 1.5-4.3 days for total hip replacement - Four out of nine studies measured the complications show a decrease of the number of complications with implementing the clinical pathway - Four studies only reported the functional status as a patient outcome but the results were varied due to inconsistency of type of measures used in these studies 	<ul style="list-style-type: none"> - Before considering the effectiveness of implementing the clinical pathways for total hip and knee replacement therapies, the failure of accounting the length of stay in rehabilitation facilities should be considered. As the cost of care would be shifted from acute care hospitals to rehabilitation facilities if patients were discharged earlier. - Another methodological limitation in the included studies that used historical controls (before and after the implementation of the clinical pathways), as the cost of health care might change due to changing in many factors related to health care markets such as health care technologies and regulations.
(17)	(Barbieri, 2009)	Evaluate the impact of implementing	Total hip and knee arthroplasties	22	<ul style="list-style-type: none"> - The groups who implemented the clinical pathways 	<ul style="list-style-type: none"> - This meta-analysis has some further limitations as most of included studies

		clinical pathways for hip and knee joints replacements when compared to standard medical care			show a significant reduction in postoperative complications and shorter length of stay compared to standard care groups - There is no significant differences noticed in the rates of discharge to home	were performed in academic hospitals and some studies used small sample sizes. - Pathways might have impact on the organisation of care if the care process is structured in a standardised way, teams critically analyse the actual organisation of the process and the multidisciplinary team is highly involved in the re-organisation. - Future studies should focus on evaluating pathways as complex interventions to help to understand which mechanisms within the clinical pathways really improve quality of care. With need for knee and hip joint replacement on the rise, use of clinical pathways might contribute to better quality of care and cost-effectiveness.
(18)	(Nathwani, 2001)	Review whether the guidelines for community-acquired pneumonia improve clinical practices or not	Community-acquired pneumonia	9	The implementation of CPGs and clinical pathways that developed locally helped health care providers to improve the quality of care and consequently reduce the cost of care - This review revealed that the implementation led to reducing the number of hospital admissions of patients with low risk of dying from community-acquired pneumonia - Four of nine studies that measured the complications reported a reduction in the number of complications when	- Variation in CPGs producers and setting of care, whether primary or secondary, led to variation in processes of care which resulted in inconsistent outcomes for patients who were hospitalised.

					implementing clinical pathways	
(19)	(Smith, 2001)	Describe the impact of CPGs on oncology treatment in the US, Canada, and France	Oncology	13	- The compliance of CPGs can contribute to reducing the length of stay and complications, which consequently lead to cost reduction without affecting patient satisfaction	This review is not sufficient evidence about the effectiveness of CPGs on oncology treatments as some program that implemented guidelines in this literature review were relied on a voluntary shift in healthcare providers practice behaviours without incentives or accountability component to shift
(20)	(Bighelli, 2016)	Evaluate the implementation of treatment guidelines for specialist mental health care on improving clinical practice outcomes	Mental health care	6	This review shows that there is no effect of treatment guidelines	All included studies were classified as low-quality evidence
(21)	(Giannarini, 2019)	Assess the impact of enhanced recovery after surgery protocols versus standard of care on perioperative outcomes of radical cystectomy	Radical cystectomy	27	Enhanced recovery after surgery protocols was associated with significantly faster recovery of bowel function, faster return to regular diet, and shorter length of stay in the hospital without increasing major complications, mortality, or readmission rates compared to standard of care	Radical cystectomy with enhanced recovery after surgical protocols should be considered the new standard of care.

The Impact of Guideline Implementation on improving clinical practice and cost savings from CPGs providers reports.

From a search of CPG providers, it was found that NICE is reviewing the impact of their guidelines.

NICE is a non-departmental public body in the United Kingdom, which is responsible for developing and providing national guidance and quality standards to improve health and social care. NICE has initiated resource impact analysis, which is also known as budget impact analysis, to assess financial changes in the use of resources as a result of implementing guidelines. NICE considers resource impact analysis for each guideline five years after the guideline’s publication and focuses on the costs or savings resulting from implementing the guideline during those five years; cost-saving estimates are not considered to be significant if they are less than £5 million for England (23). NICE has published several resource impact analysis reports for several guidelines that show significant annual cost savings as a result of implementing guidelines, ranging from £5.3 million to £17 million (Figure 1). These guidelines pertain to diagnosis and assessment of recent onset chest pain, the use of UrgoStart to treat diabetic foot ulcers and leg ulcers, the use of virtual chromoendoscopy to assess colorectal polyps during colonoscopy, the use of HeartFlow FFR_{CT} to estimate fractional flow reserve from coronary CT angiography, the use of Thopaz and portable digital systems to manage chest drains, diagnosis and management of chronic heart failure in adults, the use of the XprESS Multi-Sinus Dilation System to treat chronic sinusitis, abortion care, and diagnosis and management of diverticular disease (24) (Table 2).

Table 2: summary of resource impact analysis of NICE’s guidelines (24)

Ref.	Guidance	Year of released/ Update	Degree of improving clinical practice	Estimated saving per 100,000 population	Estimated saving for England
(25)	“Chest pain of recent onset: assessment and diagnosis (CG95)”	2016	The savings are expected to be the result of a change in diagnostic imaging because an increase in the number of people receiving CT coronary angiography leads to savings by reducing the number of people undergoing invasive coronary angiography and other diagnostic tests.	£31,500	£17.0 million
(26)	“UrgoStart for treating diabetic foot ulcers and leg ulcers (MTG42)”	2019	The cost savings mainly result from better healing with UrgoStart dressing, which leads to a decrease in the number of amputations.	£22,200	12.2 million
(27)	“Virtual chromoendoscopy to assess colorectal polyps during colonoscopy (DG28)”	2017	The cost savings for this guideline result from the avoidance of unnecessary histopathology assessments when assessing colorectal polyps.	£18,800	£10.3 million
(28)	“HeartFlow FFR_{CT} for estimating fractional flow reserve from coronary CT angiography (MTG32)”	2017	The expected cost savings from implementing this guideline may result from avoiding unnecessary procedures, including invasive coronary angiography and percutaneous coronary interventions.	£16,800	£9.1 million
(29)	“Thopaz+ portable digital system for managing chest drains (MTG37)”	2018	The cost savings mainly result from minimising the length of stay in the hospital.	£14,500	£7.9 million
(30)	“Chronic heart failure in adults: diagnosis and management (NG106)”	2018	The investment in cardiac rehabilitation services leads to cost savings from decreased readmission to the hospital for patients with chronic heart failure.	£13,900	£7.7 million
(31)	“XprESS multi sinus dilation system for treating chronic sinusitis (MTG30)”	2016	The expected cost savings may result from minimising inpatient procedures, minimising revision operations, and decreasing readmissions following treatment with XprESS. Further benefits are expected to include a reduction in the number of inpatient bed days needed and, on the other hand, an increase in day cases and operating theatre capacity. However, the level of cost savings is expected to vary depending on the cost of the XprESS device and how many XprESS procedures are carried out in an outpatient setting.	£13,600	£7.4 million
(32)	“Abortion care (NG140)”	2019	The estimated cost savings are anticipated to result from reduced waiting times, reduced rhesus status testing, reduced anti-d prophylaxis, and a reduced number of ultrasound scans.	£11,800	£6.6 million

(33)	“Diverticular disease: diagnosis and management (NG147)”	2019	The cost savings are expected to result from earlier discharge from hospital for patients with uncomplicated acute diverticulitis, a decrease in the use of IV antibiotics, a decrease in the number of patients having re-sectional surgery, and a decrease in first-line and subsequent stoma care.	£9,500	£5.3 million
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Discussion

The literature review shows there is a significant impact of implementing CPGs on improving clinical practice, including clinical process, quality of care, and patient outcomes, which ultimately lead to improved cost-efficiency or a reduction in the cost of care, but the impact on cost of care was not examined sufficiently. However, the achievement of cost savings from implementing the guidelines five years after publication are subject to several factors, including health-care provider training and adherence to CPGs, the affordability for local health-care resources to adopt new clinical pathways or new technology, and the availability and supply chain of health-care technology in the local market, which is influenced by health-technology producer capacities and their capabilities of negotiation with the providers and buyers of care services regarding price. In addition, adherence to guidelines when lacking sufficient local resources may lead to inequity issues and put care providers and payers under pressure because this may prevent all eligible patients with certain health conditions from having equal access to optimal care services. Other factors related to hospital management may be related to estimates of cost saving, such as quality improvement initiatives or policy changes in hospitals, the method used to translate CPGs into practice clinical pathways, and the introduction of case mix. Furthermore, considering pre- and post-implementation of guidance in the study design may result in overestimating the cost savings.

Although some health-care providers may disagree about having national unified CPGs—claiming that guidelines could be beneficial in terms of optimising quality but that every case is a unique experience in terms of medicine—the literature shows that when considering the practice improvement methods, all are harmonious with the complementary paradigms of both evidence-based practice as well as practice-based evidence. These include starting the process guidance, process monitoring, and outcome management, which aim to improve clinical practice by changing the behaviour of health care practitioners. It was claimed that mainly psychological, surgical, and physiotherapy interventions are different in this respect from health technology interventions, including pharmacological and medical device interventions where, following choice of medication or medical device to prescribe, there is little or no need for calibration (34). However, there are similarities. Both need calibration, especially considering that continuing innovations in health-care technologies and the growing amount of medical evidence used in this field can be overwhelming and require consistent investment of more resources for calibration, and also considering the six dimensions of quality that include accessibility, acceptability to patients, appropriateness to patients need, equity, effectiveness and efficiency (2, 35). Moreover, many have argued that the physicians should not only be the agent of the patient, but they should also be the steward of society’s limited resources available for health care. If medical associations or groups who

produce or develop guidelines consider a criterion of clinical effectiveness and cost-effectiveness, they could be taking a societal economic perspective. If guidelines are based only on clinical effectiveness and do not consider cost-effectiveness this would make physicians poor stewards of societal resources. In the United Kingdom, this dual role is recognised with the clinical practice groups incorporated into contracts between purchasers and providers (36). Elsewhere, health-care payers may play a role in limiting access to the optimal care services, for example, by applying co-payment policies for certain medicines or medical procedures (37).

Conclusion

From the summarised evidence above, it can be concluded that investing in the CPGs industry seems socially and economically viable as there are many benefits health-care regulators, providers, and payers might gain.

The benefits health-care regulators might gain

The unified national CPGs would enable health-care regulators to optimise the quality of care services, including by protecting patient safety and preventing malpractice, and to reduce the number of medical errors by:

- Helping regulators to identify core outcomes and measurable standards of care and collect meaningful data to monitor the quality of care, allowing the regulators to intervene and modify when needed to enhance health-care services. Furthermore, transparency and publishing these data to the public would help patients to choose better-performing health-care providers, and it would provoke positive competition between health-care providers to improve their standards of care. Also, these data would help health-care payers to reward or penalise health-care providers, mainly if the health-care payment system is connected to the quality initiative.
- Providing a reliable, accountable, efficient reference to support regulators in creating standards for health-care-accredited training centres. Consequently, this would help in reducing unwarranted care practice variation and would improve the quality and safety of health care.
- Supporting the development of national policies, in particular health benefits packages, to minimise the gap in treatment plans through including the best health-care practices, and the most cost-effective medical procedures and treatments.

The benefits health-care providers might gain

The updated national unified clinical guidelines would represent a trustworthy peer-reviewed approach to health care and offer providers a reference for best practices in health care customised to the local context. This could help providers to:

- Standardise treatment plans for safer practice that would minimise the number of patient complaints and enable correct management of expectations and avoid confusion, thereby protecting health-care providers against lawsuits. Furthermore, standardised medical practice would help providers to unify drug purchases and justify medical billings and claims.
- Set the bar high among all local health-care providers so that patients benefit from additional services and competition among health-care providers.

The benefits health-care payers might gain

Having a national reference for standardised medical practices would help health-care payers' to:

- Unify drug purchases, standardise medical billing, and justify medical claims, which would make getting approval for treatment plans and cost tracking consistent
- Improve value and minimise inefficient costs to avoid financial risks by excluding unnecessary care services and preventing waste and abuse that might be practised by health-care providers
- Use the core outcomes and measurable standards to compare providers' performance, which would create a better negotiation tool for comparing health-care service prices.

Policy Implications

For efficient investment in CPGs, it is recommended that, rather than reinventing the wheel, policymakers could create a strategic partnership with one of the well-known organisations in the CPG industry such as NICE. Also, the strategic partnership could be with higher education institutes and medical associations in the country to support the new national body in providing evidence-based medicine and conducting health technology assessment to review and update clinical guidelines consistently. The CPGs should be adopted or developed locally, if possible, to best consider issues like value judgements, resource use, local context characteristics, and feasibility, which are aspects that may differ depending on the sector (public or private) or country contexts (38). In Canada, family physicians develop their own guidelines, which leads to greater compliance than when they receive guidelines developed by others (36). In Saudi Arabia, there are three entities with a role in improving clinical practices and the value of health care

through evidence-based practice. These are the national centre for evidence-based health practice, which is part of the Saudi Health Council, the scientific health societies which are part of the Saudi Commission for Health Specialities, and various health societies that come under the education institutions umbrella. However, their efforts are not completely coordinated nor perfectly integrated with a lack of sufficient resources to provide unified national CPGs that can serve all local beneficiaries including health care providers either in public or private sectors, health care payers, health sector regulators, patients, and medical schools. Nevertheless, this review has shown that there is value in developing a set of CPGs for Saudi Arabia, and that many health policy and professional leaders are receptive to the idea. The next challenge will be to build a consensus among the three entities to drive this agenda forward.

Declarations

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Competing Interests:

No competing interests

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Figures

Figure 1

literature review flow chart diagram