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Built to last? The sustainability of health system improvements, interventions and change strategies: A study protocol for a systematic review.

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Built to last? The sustainability of health system improvements, interventions and change strategies: A study protocol for a systematic review.

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ABSTRACT (206 words)

Introduction: To conduct a systematic review and identify, synthesise and draw meaning from studies that measure the sustainability of interventions and change programs in the health system. Ultimately, the goal is to establish the academic base for sustainable *initiatives* to contribute to the sustainability of *health systems*.

Methods and analysis: The protocol outlines a method by which to execute a rigorous systematic review. The design includes applying primary and secondary data collection techniques, such as a comprehensive database search complimented by contact with experts, searching secondary databases and reference lists, including through snowballing. The review and analysis process will occur via an abstract review followed by a full-text screening process. The inclusion criteria include: English language, peer-reviewed, primary, empirical research articles published after 2011, in scholarly journals, for which the full text is available. No restrictions on location will be applied. The review that results from this protocol will synthesize and compare characteristics of the included studies. Ultimately, it is intended that this will make it easier to identify and design sustainable interventions.

Ethics and dissemination: As no primary data was collected, ethical approval was not required. Results will be disseminated in conference presentations, peer-reviewed publications and amongst policymaker bodies interested in creating sustainable health systems.

ARTICLE SUMMARY: STRENGTHS AND LIMITATIONS OF THE STUDY

- Defining sustainability is challenging, making it difficult to develop inclusion criteria.
- The protocol is multi-faceted, with pluralist methods being deployed to identify useful articles.
- An updated systematic review in this area is much-needed and will be a useful reference for clinicians, policymakers and researchers.
- The search strategy has been refined by building on the search strategies of previous systematic reviews.

Built to last? The sustainability of health system improvements, interventions and change strategies: A study protocol for a systematic review.

INTRODUCTION

Rationale

Health systems are facing a battery of formidable challenges. Populations are ageing;(1-4) there is a rising prevalence of chronic conditions;(5-8) complex patients have multiple co-morbidities;(9-12) new technologies are creating new models of care;(13, 14) 20% or more of healthcare spending is wasteful;(15) the role of the patient is changing with a growing 'consumer culture' and demand for patient-centred health care models;(16-19) there is pressure to increase standards of patient safety and quality of care;(20-23) the costs of care are rising;(24, 25) and there are increased fiscal pressures to pay for everything.(26, 27) Every health system is striving for solutions that find and deploy viable methods to meet growing demands whilst capitalising on new technologies and ensuring that core processes of care remain of high quality.(28) However, the problem is complex. Health system sustainability—the capacity to deliver affordable, cost-effective outcomes over time—requires numerous stakeholders, multiple approaches and coordinated actions undertaken across various system components.(29) Whilst there have been previous related reviews,(30-38) there is an absence of up-to-date evidence on how disparate programs and interventions are achieving sustainability and how they might contribute to, or help inform, system sustainability. We propose a review aiming to provide a comprehensive summary of the evidence for the sustainability of interventions, programs and improvement efforts undertaken in the health sector.

Defining sustainability

Health systems comprise "all the activities whose primary purpose is to promote, restore and maintain health"(39)(p5). Sustainable health systems have sufficient resources to meet their objectives and are able to adapt at a rate that is faster than that of the changing environment:(40) in short, they keep up with developments, or leapfrog them. What constitutes a sustainable health system has been poorly articulated in the literature.(37, 41) Scheirer and Dearing define sustainability as "the continued use of program components and activities for the continued achievement of desirable program and population outcomes".(42)(p2060) Scheirer describes three separate operational definitions of sustainability: 1) the continued health benefits for individuals beyond the initial funding period; 2) the continuation of program activities within an organisation; and 3) the continued ability of a community to develop and deliver health promotion programs.(43)

Wiltsey Stirman et al.(30) noted that the current body of sustainability research is limited by a lack of working definitions and models of sustainability to guide researchers. In their review of sustainable interventions, 65% of studies did not provide an operational definition of sustainability. Studies that provided one most frequently cited Scheirer's definition.(43)

This protocol recognises that sustainability, as a complex construct, can be defined and operationalised in multi-faceted ways. Rather than subscribe to a precise definition, a sustainable health system is broadly conceptualized as one that is resilient, that endures, and adapts to constant pressures.(4, 40) Ultimately, sustainable strategies are identified as those that last, and contribute to improvement, over

time.(30, 43)

Prior reviews of sustainable health systems

Several reviews have investigated the sustainability of interventions and programs and their effect on outcomes, each looking at different areas or levels of the health sector.(30-38) Some have focused on sustainability in specific regions, such as Canada and the United States,(31) or sub-Saharan Africa.(32) Others have looked at specific types of programs or interventions, such as chronic disease programs and interventions,(33, 34) medical professionals' adherence to clinical practice guidelines,(35) and the influence of interventions on sustaining culture change.(36) Approaches to achieving program sustainability have also been investigated, without examining outcomes.(37, 38)

Wiltsey Stirman et al.'s review took a more expansive approach to studying sustainable interventions. Without limiting their review by context, the authors examined a broad scope of studies to assess the sustainability of interventions, the outcomes they provided, and their influences in a variety of countries and health settings.(30) They revealed a "fragmented and underdeveloped" body of research.(30)(p13) Five years later, with growing pressure on our health systems, and increased interest in sustainable health care, there is a need to establish the current state of the evidence.

Objectives

Following Wiltsey Stirman et al.(30), the objective of our review is to provide an account of the sustainability of interventions, programs and improvement efforts in

health settings. We aim to analyse research conducted since Wiltsey Stirman et al.'s 2012 study and will be guided by the research questions outlined in their review: 1) How has sustainability been defined? 2) At what levels and units of analysis has it been studied? 3) What research methods have been used? 4) Over what time periods? 5) What outcomes have been reported in the empirical literature? 6) What were the findings? and, 7) What has research told us to date about influences on sustainability?

Synthesising the most relevant and up-to-date literature will provide important information for decision-makers, researchers, health professionals, clinicians, and patients interested in collaborating on sustainable interventions, programs and improvement efforts. Ultimately, the goal is for sustainable *initiatives* to contribute to the sustainability of *health systems*.

METHODS

Eligibility criteria

Guided by previous reviews(30, 32, 43-45), studies will be included if they report on either the status of an ongoing intervention, program or improvement, or the continued health benefits after the initial program period, or program funding, ends. Studies that provide evidence on the influence of program sustainability will be included regardless of whether this was the primary aim of the study.

Outcome measures

Outcome measures will include objective measures of sustainability, such as improved health and safety, or cost reduction with sustained quality over time. Indicators of sustainability are expected to be highly heterogeneous, and consequently multiple methods of measuring sustainability will be considered.

Report characteristics

Following earlier reviews(30, 32, 43-45), publications will be considered against the following inclusion criteria: English language, peer-reviewed, primary, empirical research articles published after 2011, in scholarly journals, for which the full text is available. No restrictions on location will be applied. In order to provide a comprehensive review of the peer-reviewed evidence, grey literature will be excluded.

Information sources

Our search terms, as detailed in the search strategy (Table 1), are intended to cover a wide range of terminology used to define, measure and study sustainability. Search terms will be applied to the databases CINAHL, EMBASE, and Ovid MEDLINE. These databases were selected due to their specific focus on biomedical, health system, allied health, and nursing research. Health care-related subject headings (i.e., Health care delivery, Delivery of health care) will be employed to limit the search to healthcare settings.

Table 1: Search strategy

Topic	**Search terms**
Sustainability	Sustainab* OR "sustainable development" OR continuation OR continual OR institutionali* OR resilien* OR durab* OR viab* OR stability OR stable OR persist* OR maintenance OR routin*
AND	
Improvement/	Improvement OR improve OR innovation OR reform* OR intervention OR program* OR strateg* OR project OR plan OR

intervention	"change management"

Additional search methods will be conducted to reduce the likelihood that relevant articles are overlooked. Applying a snowballing approach, a hand search of bibliographic references of key systematic reviews will be conducted, and experts in the field will be contacted for advice on potential studies for inclusion. Additionally, a title search will be conducted using the Scopus and Web of Science databases, which include articles from medicine and health sciences, in addition to the arts, humanities and social sciences.

Study records

Data management

Using the strategy specified in Table 1, and informed by the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) statement, the initial search will be carried out by three researchers (JHe, KL and EM). These researchers will also examine the reference lists of pertinent reviews and contact appropriate experts in the field for advice on potentially relevant articles. Data will be imported into an EndNote library by LT and duplicates will be deleted.

Selection and data collection processes

To ensure consensus on the retained articles, abstracts from 5% of the Endnote library will be randomly assigned for assessment by pairs of reviewers (EM, JHe; KL, LT; GL and MC) against the inclusion criteria. Inter-rater agreement rates will be calculated for each pair using Cohen's Kappa. Any discrepancies between authors

concerning the inclusion or exclusion of articles will be discussed by all reviewers as a group, with JB as arbitrator, until a consensus is reached. Each researcher will then independently review 20% of the remaining abstracts against the inclusion criteria.

Following this process, included abstracts will be randomly assigned to the reviewers for a full text review against the inclusion criteria. A data extraction sheet will be used to record relevant information from included studies and reasons for exclusion for omitted studies (Supplementary file 1).

Data items and definitions

The concept of sustainability is ambiguously defined. As such, we define key terms used in the current systematic review protocol in Box 1. The data extraction sheet will record article details, context and setting, number of sites, type of study, details of improvement or intervention, assessment period, measures of sustainability, and key findings for individual studies.

Box 1

Definitions of variables

Sustainability: Continuation of interventions, programs and improvement efforts within health systems after initial implementation efforts or cessation of funding.(30)

Outcomes: The impact or benefits of interventions, programs and improvement efforts that continue after initial implementation efforts or cessation of funding.(30)

Outcomes and prioritization

Following Wiltsey Stirman et al.(30), and in line with Scheirer's definitions of sustainability,(43) sustainable outcomes may manifest as ongoing health benefits for individuals, the continuation of program activities, or the durability of community

capacity. Priority will be given to studies that address sustainability over a longer time frame. For example, studies assessing the sustainability of an improvement intervention over years, as opposed to months, will provide more valuable information about sustainability and its long-term effects. Other studies which will be prioritised include those that provide a working definition of sustainability, and those that report on multiple sustainability outcomes.

Risk of bias in individual studies

Where appropriate, study bias will be assessed using a Risk of Bias Template, specifically the Cochrane Collaboration's tool for assessing risk of bias, adapted from the Cochrane Handbook for Systematic Reviews.(46) Articles will be independently assessed and classified as 'high' or 'low' risk of bias. Consideration of bias will be given when interpreting the results of the review.

Data synthesis

Based on previous systematic reviews of this type(30, 41, 44, 47), a quantitative meta-analysis of data may not be feasible. In the event that it is possible, a random-effects model will be used.(48) Depending on the findings from the literature review, a scoping meta-review may also be undertaken.(47) Where meta-analysis is not appropriate, data will be summarised using a narrative synthesis approach.(49) The synthesis will focus on the overall evidence for sustained effectiveness of interventions, programs and improvement efforts.

Meta-biases

In publishing this protocol we aim to avoid publication bias or selective outcome reporting by detailing our search and inclusion criteria, and by employing a data extraction form.(50) Publication bias will also be limited by searching the reference lists of key systematic reviews and with the use of snowballing techniques to locate articles that may not have been detected in the database searches.(48)

Confidence in cumulative evidence

We will assess the quality of evidence using an appropriate assessment tool, such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.(51) Each study will be categorised by level of quality, in accordance with the chosen assessment tool.

CONCLUSION

The challenge of creating and maintaining a sustainable health system is an enduring problem faced by all health system stakeholders: politicians, funders, providers, insurers, policymakers and patients. Ageing populations and increasing demands for services present substantial challenges to the affordability of health care systems, making the need for an urgent solution all the more necessary. We do not know enough about how interventions, programs and improvement efforts, especially recent ones, are contributing to sustainability, nor the effect which they may have on system durability. The proposed review will provide a synthesis of the most current evidence on the sustainability of improvement interventions and will be of use to those interested in contributing to improved long-term health systems outcomes on a large scale.

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Amendments

Any deviations from this protocol will be reported in the final systematic review, accompanied by a justification of why these alterations are necessary.

Author's Contributions

JB conceptualized the study and leads the team's work. LT and GL drafted the initial manuscript and search strategy, assisted by KL and JHe. Important contributions to refine and improve the manuscript were provided by JB, KL, JHe, EM, JHo and MC.

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Competing Interests

There are no competing interests.

Supplementary file 1. Data extraction sheet

Article details (authors, title, endnote reference)			
Context; setting			
Number of sites			
Type of study: qualitative, quantitative, mixed method; cross-sectional, longitudinal			
Details of improvement/intervention			
Assessment period (or period of program/intervention)			
Measures of sustainability			
Key findings			

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ABSTRACT (241 words)

Introduction: The sustainability of health care interventions and change programs is of increasing importance to researchers and health care stakeholders interested in creating sustainable health systems to cope with mounting stressors. The aim of this protocol is to extend earlier work and describe a systematic review to identify, synthesise and draw meaning from studies published within the last five years which measure the sustainability of interventions, improvement efforts, and change strategies in the health system. **Methods and analysis:** The protocol outlines a method by which to execute a rigorous systematic review. The design includes applying primary and secondary data collection techniques, consisting of a comprehensive database search complemented by contact with experts, and searching secondary databases and reference lists, using snowballing techniques. The review and analysis process will occur via an abstract review followed by a full-text screening process. The inclusion criteria include: English language, peer-reviewed, primary, empirical research articles published after 2011, in scholarly journals, for which the full text is available. No restrictions on location will be applied. The review that results from this protocol will synthesize and compare characteristics of the included studies. Ultimately, it is intended that this will help make it easier to identify and design sustainable interventions, improvement efforts and change strategies.

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Rationale

Health systems are facing a battery of formidable challenges. Populations are ageing;(1-4) there is a rising prevalence of chronic conditions;(5-8) complex patients have multiple co-morbidities;(9-12) new technologies are creating new models of care;(13, 14) 20% or more of health care spending is wasteful;(15) the role of the patient is changing with a growing 'consumer culture' and demand for patient-centred health care models;(16-19) there is pressure to increase standards of patient safety and quality of care;(20-23) the costs of care are rising,(24, 25) driven in part by high prices for new cancer and orphan drugs;(26-28) and there are increased fiscal pressures to pay for everything medicine can do.(29, 30) Every health system is striving for solutions that find and deploy viable methods to meet growing demands whilst capitalising on new technologies and ensuring that core processes of care remain of high quality.(31) However, the problem is complex. Health system sustainability—the capacity to deliver affordable, cost-effective outcomes over time—requires numerous stakeholders, multiple approaches and coordinated actions undertaken across various system components.(32, 33) Sustainable health systems are ones that have sufficient resources to meet their objectives and are able to adapt to a changing environment;(34) in short, they keep up with developments, or leapfrog hurdles. One way in which policymakers, decision-makers, and health care management try to achieve the sustainability goal is through the implementation of

improvements, interventions, and change strategies.

Whilst older reviews have been conducted on this topic,(35-43) a synthesis of the more recent evidence, regarding how disparate programs and interventions are achieving sustainability and how they might contribute to or help inform system sustainability, is absent. Therefore, we propose a systematic review with an in-depth focus on the sustainability of such improvement programs.

Defining sustainability

Sustainability is poorly defined in the literature,(35, 42, 43) which has hindered the development of a consensus, evidence-based, operational paradigm for research and evaluation.(43, 44) A seminal report released by the World Commission on Environment and Development in 1987 articulated "sustainable development" as that which "meets the needs of the present without compromising the ability of future generations to meet their own needs" and as a "process of change in which the exploitation of resources, the direction of investments, the orientation of technological development, and institutional change are all in harmony and enhance both current and future potential to meet human needs and aspiration".(45) This trans-disciplinary conceptualisation of sustainability construes it as a multi-dimensional dynamic interplay of economic, social and ecological factors.(42)

Regarding the sustainability of improvement programs in health care, a focus on innovation and organisational development has led to the conceptualisation of sustainability as the "ongoing delivery of health programmes, which may be measured by the longevity of independent projects, or how well programmes become institutionalised in organisation or health and social systems".(44)(p1580) This

approach has been criticised for promoting the continuation and institutionalisation of health programs with insufficient prioritisation of enduring health outcomes. Gruen et al. (2008) argue that sustainability instead requires "ongoing cycles of reflection, planning, and action".(44)(p1587) Hudson and Vissing (2013) argue that health benefits may be better achieved through alternate programs or treatments, therefore requiring the constant evaluation and evolution of existing programs and interventions.(43) They contend that a blinkered adherence to program maintenance may fail to promote population health.

Envisaging sustainable interventions as static tools fails to take into account the complex adaptive nature of health care systems.(43, 44, 46) Within a complex adaptive system framework, sustainability interventions can be better seen as another variable(47) which act on the dynamic system. We can potentially refine and improve interventions over time, to sustainably meet contextual needs and maintain desirable patient outcomes.(33)

Earlier this decade, Wiltsey Stirman et al. (2012) noted that the current body of sustainability research is limited by a lack of working definitions and models of sustainability to guide researchers.(35) In their review of sustainable interventions, 65% of studies did not provide an operational definition of sustainability, whereas those that did, frequently cited Scheirer's (2005) definitions, which are based on earlier work of Shediac-Rizkallah and Bone (1998).(48, 49) Scheirer (2005) describes three separate operational definitions for interventions which promote sustainability: 1) the continued health benefits for individuals beyond the initial funding period; 2) the continuation of program activities within an organisation; and 3) the continued ability of a community to develop and deliver health promotion programs.(48) In a later paper on sustainability, Scheirer and Dearing (2011) defined sustainability as

"the continued use of program components and activities for the continued achievement of desirable program and population outcomes".(47)(p2060) In our review we will consider an amalgam of Scheirer (2005) and Scheirer and Dearing's (2011) definitions.(47, 48) We have selected these definitions of sustainability based on an understanding of health systems as complex adaptive systems and the prioritisation of health outcomes alongside the maintenance of programs, or program elements.

Prior reviews of sustainable health interventions and programs

Several reviews have investigated the sustainability of interventions and programs and their effects on outcomes, typically looking at different areas or levels of the health sector.(35-44) Some have focused on sustainability in specific regions, such as Canada and the United States,(36) or sub-Saharan Africa.(37) Others have looked at specific types of programs or interventions, such as chronic disease programs and interventions,(38, 39) medical professionals' adherence to clinical practice guidelines,(40) and the influence of interventions on sustaining culture change.(41) Approaches to achieving program sustainability have also been investigated, without examining outcomes.(42, 43)

Gruen et al. (2008) conducted a broader systematic review looking at both empirical studies and conceptual frameworks of health program sustainability.(44) They focused on health programs assessed over a defined period. The authors then identified factors they believed to be associated with the programs' sustainability. The authors developed a conceptual framework for sustainability planning grounded in sustainability science, which regards health programs as complex systems.

Likewise, Wiltsey Stirman et al.'s (2012) review took a more expansive approach to studying sustainable interventions, whilst maintaining a focus on empirical studies.(35) Without limiting their review by context, the authors examined a broad scope of studies to assess the sustainability of interventions, the outcomes they provided, and their influences in a variety of countries and health settings.(35) They revealed a "fragmented and underdeveloped" body of research, suffering from a lack of methodological rigor and definitional consensus.(35)(p13) The authors note that the absence of validated measures, of program monitoring post implementation and of real-time observations have also affected the evidence-base. Five years later, with growing pressure on our health systems, and increased interest in sustainable health care, there is a need to establish the current state of the evidence.

Objectives

Following Wiltsey Stirman and colleagues,(35) the objective of our review is to provide an account of the sustainability of interventions, improvement efforts, and change strategies in health settings. We aim to analyse research conducted since Wiltsey Stirman et al.'s 2012 review in order to provide an updated synthesis of the literature on health and sustainability the past five years. As Figure 1 shows, considerable growth in publications focused on sustainability in health care has occurred between 2013-2016, supporting the need for an updated review of the evidence.

<Insert Figure 1 here>

Figure 1: Publication titles containing the words "health" and "sustainability", 1978-present. Adapted from Hudson and Vissing (2013), using data from Google Scholar.

Following Wiltsey Stirman et al. (2012), the review will be guided by the following research questions: 1) How has sustainability been defined? 2) At what levels and units of analysis has it been studied? 3) What research methods have been used? 4) Over what time periods? 5) What outcomes have been reported in the empirical literature? 6) What were the findings? 7) What has research told us to date about influences on sustainability? and, 8) How is sustainability conceptualized in a complex adaptive system?

This systematic review will provide an essential contribution by synthesising the most relevant and up-to-date literature in this area. It seeks to provide important information for decision-makers, researchers, health professionals, clinicians, and patients interested in collaborating on sustainable interventions, programs and improvement efforts.

METHODS

Eligibility criteria

Guided by previous reviews,(35, 37, 46, 48, 50) studies will be included if they report on either the status of an ongoing intervention, program or improvement, or the continued health benefits after the initial program period, or program funding, ends. Similar to Wiltsey Stirman and colleagues, there is no specified time frame between program or funding completion, and assessment of outcomes, but rather, each study

with be evaluated on a case-by-case basis. Studies that provide evidence on the influence of program sustainability will be included regardless of whether this was the primary aim of the study.

Outcome measures

Outcome measures will include objective measures of sustainability, such as improved health and safety,(35, 44) or cost reduction with sustained quality over time.(38) Indicators of sustainability are expected to be highly heterogeneous, and consequently multiple methods of measuring sustainability will be considered.

Report characteristics

Following earlier reviews,(35, 37, 46, 48, 50) publications will be considered against the following inclusion criteria: English language, peer-reviewed, primary, empirical research articles published after 2011, in scholarly journals, for which the full text is available. No restrictions on location will be applied. In order to provide a comprehensive review of the peer-reviewed evidence, grey literature will be excluded.

Information sources and search strategy

Our search terms, as detailed in the search strategy (Table 1), are intended to cover a wide range of terminology used to define, measure and study sustainability. Search terms will be applied to the databases CINAHL, EMBASE, and Ovid MEDLINE. These databases were selected due to their specific focus on biomedical, health system, allied health, and nursing research. Health care-related subject headings (i.e., Health care delivery, Delivery of health care) will be employed to limit the search to health care settings.

Table 1: Search strategy

Topic	Search terms
Sustainability	Sustainab* OR "sustainable development" OR continuation OR continual OR institutionali* OR resilien* OR durab* OR viab* OR stability OR stable OR persist* OR maintenance OR routin*
AND	
Improvement/ intervention	Improvement OR improve OR innovation OR reform* OR intervention OR program* OR strateg* OR project OR plan OR "change management"

Additional search methods will be conducted to reduce the likelihood that relevant articles are overlooked. Applying a snowballing approach, a hand search of bibliographic references of key systematic reviews will be conducted, and experts in the field will be contacted for advice on potential studies for inclusion. Additionally, a title search will be conducted using the Scopus and Web of Science databases, which include articles from medicine and health sciences, in addition to the arts, humanities and social sciences.

Study records

Data management

Using the strategy specified in Table 1, and informed by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement, the initial search will be carried out by three researchers (JHe, KL and EM). These researchers will also examine the reference lists of pertinent reviews and contact

appropriate experts in the field for advice on potentially relevant articles. Data will be imported into an EndNote library by LT and duplicates will be deleted.

Selection and data collection processes

To ensure consensus on the retained articles, abstracts from 5% of the EndNote library will be randomly assigned for assessment by pairs of reviewers (EM, JHe; KL, LT; GL, JH) against the inclusion criteria. Inter-rater agreement rates will be calculated for each pair using Cohen's Kappa. Any discrepancies between authors concerning the inclusion or exclusion of articles will be discussed by all reviewers as a group, with JB as arbitrator, until a consensus is reached. Each researcher will then independently review the remaining abstracts against the inclusion criteria.

Following this process, included abstracts will be randomly assigned to the reviewers for a full text review against the inclusion criteria. A data extraction sheet will be used to record relevant information from included studies and reasons for exclusion for omitted studies (Supplementary file 1). It is expected that this process will begin soon after publication of the protocol, and we are scheduling to complete by mid-2018.

Data items

The data extraction sheet will record article details, definition of sustainability (if provided), context and setting, number of sites, type of study, details of improvement or intervention, assessment period, measures of sustainability, and key findings for individual studies.

Outcomes and prioritization

Following Wiltsey Stirman et al.,(35) and in line with Scheirer's, and Scheirer's and Dearing's definitions of sustainability,(47, 48) outcomes refer to the ongoing impact or health benefits of interventions, programs, change strategies, and improvement efforts that continue after initial implementation efforts or cessation of funding. Priority will be given to studies that address sustainability over a longer time frame. For example, studies assessing the sustainability of an improvement intervention over years, as opposed to months, will provide more valuable information about sustainability and its long-term effects. Other studies which will be prioritised include those that provide a working definition of sustainability, and those that report on multiple sustainability outcomes.

Risk of bias in individual studies

Where appropriate, study bias will be assessed using a Risk of Bias Template, specifically the Cochrane Collaboration's tool for assessing risk of bias, adapted from the Cochrane Handbook for Systematic Reviews.(51) Articles will be independently assessed and classified as 'high' or 'low' risk of bias. Consideration of bias will be given when interpreting the results of the review.

Data synthesis

Based on previous systematic reviews of this type,(35, 44, 52) a quantitative meta-analysis of data may not be feasible. In the event that it is possible, a random-effects model will be used.(53) Depending on the findings from the literature review, a scoping meta-review may also be undertaken.(54)

Where meta-analysis is not appropriate, data will be summarised using a narrative

synthesis approach.(55) The synthesis will focus on the overall evidence for sustained effectiveness of interventions, programs and change strategies, including barriers and facilitators to their sustainability and the outcomes they produce. Articles will be grouped and discussed according to similarities and differences in their setting, participants, the research methods (e.g., quantitative, qualitative or mixed-method; cross-sectional versus longitudinal), and results obtained. Possible areas of comparison include differences between; micro and macro interventions, short-term and long-term programs, and between low-, middle- and high- countries. Results will be used to determine factors associated with sustainability.(35, 44)

Meta-biases

In publishing this protocol we aim to avoid publication bias or selective outcome reporting by detailing our search and inclusion criteria, and by employing a data extraction form.(56) Publication bias will also be limited by searching the reference lists of key systematic reviews and with the use of snowballing techniques to locate articles that may not have been detected in the database searches.(53)

Confidence in cumulative evidence

We will assess the quality of evidence using an appropriate assessment tool, such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.(57) Each study will be categorised by level of quality, in accordance with the chosen assessment tool.

CONCLUSION

The challenge of creating and maintaining a sustainable health system is an enduring problem faced by all health system stakeholders, including politicians, funders, providers, insurers, policymakers and patients. Ageing populations and increasing demands for services present substantial challenges to the affordability of health care systems, making the need for an urgent solution all the more necessary. We do not know enough about how interventions, programs and improvement efforts, especially recent ones, are contributing to sustainability, nor the effect which they may have on system durability. The proposed review will provide a synthesis of the most current evidence on the sustainability of improvement interventions and will be of use to those interested in contributing to improved long-term health systems outcomes on a large scale.

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Amendments

Any deviations from this protocol will be reported in the final systematic review, accompanied by a justification of why these alterations are necessary.

Author's Contributions

JB conceptualized the study and leads the team's work. LT and GL drafted the initial manuscript and search strategy, assisted by KL and JHe. Important contributions to refine and improve the manuscript were provided by JB, KL, JHe, EM, JHo and MC.

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Competing Interests

There are no competing interests.

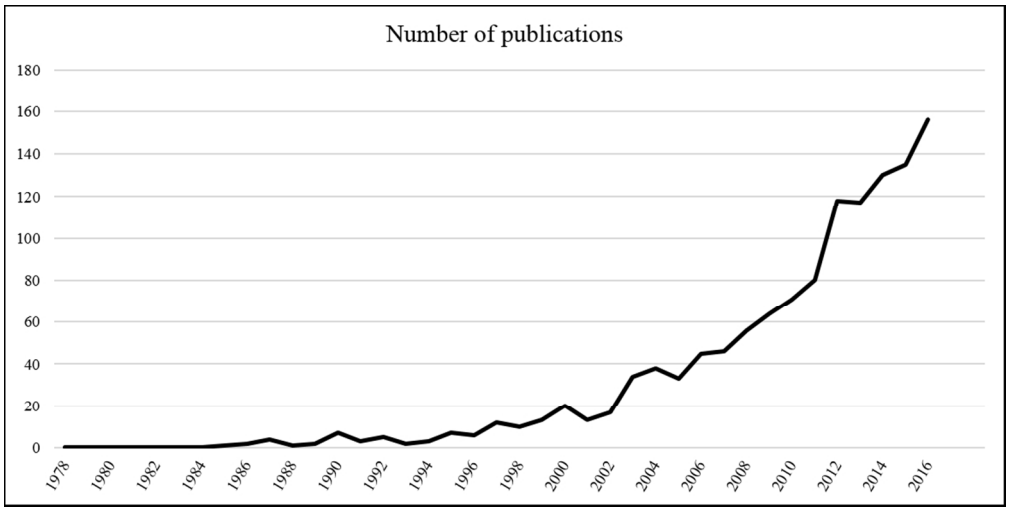

Figure 1: Publication titles containing the words "health" and "sustainability", 1978-present. Adapted from Hudson and Vissing (2013), using data from Google Scholar.

99x49mm (300 x 300 DPI)

Supplementary file 1. Data extraction sheet

Article details (authors, title, endnote reference)			
Definition of sustainability			
Context; setting			
Number of sites			
Type of study: qualitative, quantitative, mixed method; cross-sectional, longitudinal			
Details of improvement/intervention			
Assessment period (or period of program/intervention)			
Measures of sustainability			
Key findings			

BMJ Open

Built to last? The sustainability of health system improvements, interventions and change strategies: A study protocol for a systematic review.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018568.R2
Article Type:	Protocol
Date Submitted by the Author:	12-Oct-2017
Complete List of Authors:	Braithwaite, Jeffrey; Macquarie University, Australian Institute of Health Innovation Testa, Luke; Macquarie University, Australian Institute of Health Innovation Lamprell, Gina; Macquarie University, Australian Institute of Health Innovation Herkes, Jessica; Macquarie University, Australian Institute of Health Innovation Ludlow, Kristiana; Macquarie University, Australian Institute of Health Innovation McPherson, Elise; Macquarie University, Australian Institute of Health Innovation Campbell, Margie; Macquarie University, Australian Institute of Health Innovation Holt, Joanna; Macquarie University, Australian Institute of Health Innovation
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health policy, Public health
Keywords:	sustainability, health systems improvement, interventions, complex systems, systematic review, study protocol

Built to last? The sustainability of health system improvements, interventions and change strategies: A study protocol for a systematic review.

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Keywords

sustainability, health systems improvement, interventions, complex systems, systematic review, study protocol

ABSTRACT (241 words)

Introduction: The sustainability of health care interventions and change programs is of increasing importance to researchers and health care stakeholders interested in creating sustainable health systems to cope with mounting stressors. The aim of this protocol is to extend earlier work and describe a systematic review to identify, synthesise and draw meaning from studies published within the last five years which measure the sustainability of interventions, improvement efforts, and change strategies in the health system. **Methods and analysis:** The protocol outlines a method by which to execute a rigorous systematic review. The design includes applying primary and secondary data collection techniques, consisting of a comprehensive database search complemented by contact with experts, and searching secondary databases and reference lists, using snowballing techniques. The review and analysis process will occur via an abstract review followed by a full-text screening process. The inclusion criteria include: English language, peer-reviewed, primary, empirical research articles published after 2011, in scholarly journals, for which the full text is available. No restrictions on location will be applied. The review that results from this protocol will synthesize and compare characteristics of the included studies. Ultimately, it is intended that this will help make it easier to identify and design sustainable interventions, improvement efforts and change strategies.

Ethics and dissemination: As no primary data was collected, ethical approval was not required. Results will be disseminated in conference presentations, peer-reviewed publications and amongst policymaker bodies interested in creating sustainable health systems.

ARTICLE SUMMARY: STRENGTHS AND LIMITATIONS OF THE STUDY

- Defining sustainability is challenging, making it difficult to develop inclusion criteria.
- The protocol is multi-faceted, with pluralist methods being deployed to identify useful articles.
- An updated systematic review in this area is much-needed and will be a useful reference for clinicians, policymakers and researchers.
- The search strategy has been refined by building on the search strategies of previous systematic reviews.

Built to last? The sustainability of health system improvements, interventions and change strategies: A study protocol for a systematic review.

INTRODUCTION

Rationale

Health systems are facing a battery of formidable challenges. Populations are ageing;(1-4) there is a rising prevalence of chronic conditions;(5-8) complex patients have multiple co-morbidities;(9-12) new technologies are creating new models of care;(13, 14) 20% or more of health care spending is wasteful;(15) the role of the patient is changing with a growing 'consumer culture' and demand for patient-centred health care models;(16-19) there is pressure to increase standards of patient safety and quality of care;(20-23) the costs of care are rising,(24, 25) driven in part by high prices for new cancer and orphan drugs;(26-28) and there are increased fiscal pressures to pay for everything medicine can do.(29, 30) Every health system is striving for solutions that find and deploy viable methods to meet growing demands whilst capitalising on new technologies and ensuring that core processes of care remain of high quality.(31) However, the problem is complex. Health system sustainability—the capacity to deliver affordable, cost-effective outcomes over time—requires numerous stakeholders, multiple approaches and coordinated actions undertaken across various system components.(32, 33) Sustainable health systems are ones that have sufficient resources to meet their objectives and are able to adapt to a changing environment;(34) in short, they keep up with developments, or leapfrog hurdles. One way in which policymakers, decision-makers, and health care management try to achieve the sustainability goal is through the implementation of

improvements, interventions, and change strategies.

Whilst older reviews have been conducted on this topic,(35-43) a synthesis of the more recent evidence, regarding how disparate programs and interventions are achieving sustainability and how they might contribute to or help inform system sustainability, is absent. Therefore, we propose a systematic review with an in-depth focus on the sustainability of such improvement programs.

Defining sustainability

Sustainability is poorly defined in the literature,(35, 42, 43) which has hindered the development of a consensus, evidence-based, operational paradigm for research and evaluation.(43, 44) A seminal report released by the World Commission on Environment and Development in 1987 articulated "sustainable development" as that which "meets the needs of the present without compromising the ability of future generations to meet their own needs" and as a "process of change in which the exploitation of resources, the direction of investments, the orientation of technological development, and institutional change are all in harmony and enhance both current and future potential to meet human needs and aspiration".(45) This trans-disciplinary conceptualisation of sustainability construes it as a multi-dimensional dynamic interplay of economic, social and ecological factors.(42)

Regarding the sustainability of improvement programs in health care, a focus on innovation and organisational development has led to the conceptualisation of sustainability as the "ongoing delivery of health programmes, which may be measured by the longevity of independent projects, or how well programmes become institutionalised in organisation or health and social systems".(44)(p1580) This

approach has been criticised for promoting the continuation and institutionalisation of health programs with insufficient prioritisation of enduring health outcomes. Gruen et al. (2008) suggest that sustainability instead requires "ongoing cycles of reflection, planning, and action".(44)(p1587) Hudson and Vissing (2013) argue that health benefits may be better achieved through alternate programs or treatments, therefore requiring the constant evaluation and evolution of existing programs and interventions.(43) They contend that a blinkered adherence to program maintenance may fail to promote population health.

Envisaging sustainable interventions as static tools fails to take into account the complex adaptive nature of health care systems.(43, 44, 46) Within a complex adaptive system framework, sustainable interventions can be better seen as another variable(47) which act on, and respond to, the dynamic system. We can potentially refine and improve interventions over time, to sustainably meet contextual needs and maintain desirable patient outcomes.(33)

Earlier this decade, Wiltsey Stirman et al. (2012) noted that the current body of sustainability research is limited by a lack of working definitions and models of sustainability to guide researchers.(35) In their review of sustainable interventions, 65% of studies did not provide an operational definition of sustainability, whereas those that did, frequently cited Scheirer's (2005) definitions, which are based on earlier work of Shediac-Rizkallah and Bone (1998).(48, 49) Scheirer (2005) describes three separate operational definitions for interventions which promote sustainability: 1) the continued health benefits for individuals beyond the initial funding period; 2) the continuation of program activities within an organisation; and 3) the continued ability of a community to develop and deliver health promotion programs.(48) In a later paper, Scheirer and Dearing (2011) defined sustainability as "the continued use

of program components and activities for the continued achievement of desirable program and population outcomes".(47)(p2060) In our review we will consider an amalgam of Scheirer (2005) and Scheirer and Dearing's (2011) definitions.(47, 48) We have selected these characterisations of sustainability based on an understanding of health systems as complex adaptive systems and the prioritisation of health outcomes alongside the maintenance of programs, or program elements.

Prior reviews of sustainable health interventions and programs

Several reviews have investigated the sustainability of interventions and programs and their effects on outcomes, typically looking at different areas or levels of the health sector.(35-44) Some have focused on sustainability in specific regions, such as Canada and the United States,(36) or sub-Saharan Africa.(37) Others have looked at specific types of programs or interventions, such as chronic disease programs and interventions,(38, 39) medical professionals' adherence to clinical practice guidelines,(40) and the influence of interventions on sustaining culture change.(41) Approaches to achieving program sustainability have also been investigated, without examining outcomes.(42, 43)

Gruen et al. (2008) conducted a broader systematic review looking at both empirical studies and conceptual frameworks of health program sustainability.(44) They focused on health programs assessed over a defined period. The authors identified factors they believed to be associated with the programs' sustainability. These factors include program design elements (e.g., stakeholder involvement), organisational setting characteristics (e.g., favourable organisational culture), and environmental features (e.g., community engagement). The authors developed a conceptual

framework for sustainability planning grounded in sustainability science, which regards health programs as complex systems.

Likewise, Wiltsey Stirman et al.'s (2012) review took a more expansive approach to studying sustainable interventions, whilst maintaining a focus on empirical studies.(35) Without limiting their review by context, the authors examined a broad scope of studies to assess the sustainability of interventions, the outcomes they provided, and their influences in a variety of countries and health settings.(35) They revealed a "fragmented and underdeveloped" body of research, suffering from a lack of methodological rigor and definitional consensus.(35)(p13) The authors note that the absence of validated measures, of program monitoring post implementation and of real-time observations have also affected the evidence-base. Five years later, with growing pressure on health systems, and increased interest in sustainable health care, there is a need to establish the current state of the evidence.

Objectives

Following Wiltsey Stirman and colleagues,(35) the objective of our review is to provide an account of the sustainability of interventions, improvement efforts, and change strategies across health settings. We aim to analyse research conducted since Wiltsey Stirman et al.'s 2012 review in order to provide an updated synthesis of the literature in the past five years. As Figure 1 shows, considerable growth in publications focused on sustainability in health care has occurred between 2013-2016, supporting the need for an updated review of the evidence.

<Insert Figure 1 here>

Figure 1: Publication titles containing the words "health" and "sustainability", 1978-present. Adapted from Hudson and Vissing (2013), using data from Google Scholar.

Following Wiltsey Stirman et al. (2012), the review will be guided by the following research questions: 1) For the change strategy or intervention studied, has sustainability been defined and deployed in accordance with the evidence? 2) At what levels and units of analysis has it been studied? 3) What research methods have been used? 4) Over what time periods? 5) What outcomes have been reported in the empirical literature? 6) What were the findings? 7) What has research told us to date about influences on sustainability? and, 8) Were health outcomes sustained with continuation of the change strategy or intervention?

This systematic review will provide an essential contribution by synthesising the most relevant and up-to-date literature in this area. It seeks to provide important information for decision-makers, researchers, health professionals, clinicians and patients interested in collaborating on sustainable interventions, programs and improvement efforts.

METHODS

Eligibility criteria

Guided by previous reviews,(35, 37, 46, 48, 50) studies will be included if they report on either the status of an ongoing intervention, program or improvement, or the continued health benefits after the initial program period, or program funding, ends. Similar to Wiltsey Stirman and colleagues, there is no specified time frame between

program or funding completion, and assessment of outcomes. Rather, each study with be evaluated on a case-by-case basis. Studies that provide evidence on factors that influence sustainability will be included regardless of whether this was the primary aim of the study.

Outcome measures

Outcome measures will include objective measures of sustainability, such as improved health and safety,(35, 44) or cost reduction with sustained quality over time.(38) Indicators of sustainability are expected to be highly heterogeneous, and consequently multiple methods of measuring sustainability will be considered.

Report characteristics

Following earlier reviews,(35, 37, 46, 48, 50) publications will be assessed against the following inclusion criteria: English language, peer-reviewed, primary, empirical research articles published after 2011, in scholarly journals, for which the full text is available. No restrictions on location will be applied. In order to provide a comprehensive review of the peer-reviewed evidence, grey literature will be excluded.

Information sources and search strategy

Our search terms, as detailed in the search strategy (Table 1), are intended to cover a wide range of terminology used to define, measure and study sustainability. Search terms will be applied to the databases CINAHL, EMBASE, and Ovid MEDLINE. These databases were selected due to their specific focus on biomedical, health system, allied health, and nursing research. Health care-related subject headings (e.g., Health care delivery) will be employed to limit the search to health care settings.

Table 1: Search strategy

Topic	Search terms
Sustainability	Sustainab* OR "sustainable development" OR continuation OR continual OR institutionali* OR resilien* OR durab* OR viab* OR stability OR stable OR persist* OR maintenance OR routin*
AND	
Improvement/ intervention	Improvement OR improve OR innovation OR reform* OR intervention OR program* OR strateg* OR project OR plan OR "change management"

Additional search methods will be conducted to reduce the likelihood that relevant articles are overlooked. Applying a snowballing approach, a hand search of bibliographic references of key systematic reviews will be conducted, and experts in the field will be contacted for advice on potential studies for inclusion. Additionally, a title search will be conducted using the Scopus and Web of Science databases, which include articles from medicine and health sciences, in addition to the arts, humanities and social sciences.

Study records

Data management

Using the strategy specified in Table 1, and informed by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement, the initial search will be carried out by three researchers (JHe, KL and EM). These researchers will also examine the reference lists of pertinent reviews and contact

appropriate experts in the field for advice on potentially relevant articles. Data will be imported into an EndNote library by LT and duplicates will be deleted.

Selection and data collection processes

To ensure consensus on the retained articles, abstracts from 5% of the EndNote library will be randomly assigned for assessment by pairs of reviewers (EM, JHe; KL, LT; GL, JH) against the inclusion criteria. Inter-rater agreement rates will be calculated for each pair using Cohen's Kappa. Any discrepancies between authors concerning the inclusion or exclusion of articles will be discussed by all reviewers as a group, with JB as arbitrator, until a consensus is reached. Each researcher will then independently review the remaining abstracts against the inclusion criteria.

Following this process, included abstracts will be randomly assigned to the reviewers for a full text review against the inclusion criteria. A data extraction sheet will be used to record relevant information from included studies and reasons for exclusion for omitted studies (Supplementary file 1). It is expected that this process will begin soon after publication of the protocol, and we are scheduling to complete by mid-2018.

Data items

The data extraction sheet will record article details, definition of sustainability (if provided), context and setting, number of sites, type of study, details of improvement or intervention, assessment period, measures of sustainability, and key findings for individual studies.

Outcomes and prioritization

Following Wiltsey Stirman et al.,(35) and in line with Scheirer's, and Scheirer and Dearing's definitions of sustainability,(47, 48) outcomes refer to the ongoing impact or health benefits of interventions, programs, change strategies, and improvement efforts that continue after initial implementation efforts or cessation of funding. Priority will be given to studies that address sustainability over a longer time frame. For example, studies assessing the sustainability of an improvement intervention over years, as opposed to months, will provide more valuable information about sustainability and its long-term effects. Other studies to be prioritised include those that provide a working definition of sustainability, and those that report on multiple sustainability outcomes.

Risk of bias in individual studies

Where appropriate, study bias will be assessed using a Risk of Bias Template, specifically the Cochrane Collaboration's tool for assessing risk of bias, adapted from the Cochrane Handbook for Systematic Reviews.(51) Articles will be independently assessed and classified as 'high' or 'low' risk of bias. Consideration of bias will be given when interpreting the results of the review.

Data synthesis

Based on previous systematic reviews of this type,(35, 44, 52) a quantitative meta-analysis of data may not be feasible. In the event that it is possible, a random-effects model will be used.(53) Depending on the findings from the literature review, a scoping meta-review may also be undertaken.(54)

Where meta-analysis is not appropriate, data will be summarised using a narrative

synthesis approach.(55) The synthesis will focus on the overall evidence for sustained effectiveness of interventions, programs and change strategies, including barriers and facilitators to their sustainability and the outcomes they produce. Articles will be grouped and discussed according to similarities and differences in their setting, participants, the research methods (e.g., quantitative, qualitative or mixed-method; cross-sectional versus longitudinal), and results obtained. Possible areas of comparison include differences between; micro and macro interventions, short-term and long-term programs, and between low-, middle- and high- countries. Results will be used to determine factors associated with sustainability.(35, 44)

Meta-biases

In publishing this protocol we aim to avoid publication bias or selective outcome reporting by detailing our search and inclusion criteria, and by employing a data extraction form.(56) Publication bias will also be limited by searching the reference lists of key systematic reviews and with the use of snowballing techniques to locate articles that may not have been detected in the database searches.(53)

Confidence in cumulative evidence

We will assess the quality of evidence using an appropriate assessment tool, such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.(57) Each study will be categorised by level of quality, in accordance with the chosen assessment tool.

CONCLUSION

The challenge of creating and maintaining a sustainable health system is an enduring problem faced by all health system stakeholders, including politicians, funders, providers, insurers, policymakers, taxpayers and patients. Ageing populations and increasing demands for services present substantial challenges to the affordability of health care systems, making the need for an urgent solution all the more necessary. We do not know enough about how interventions, programs and improvement efforts, especially recent ones, are contributing to sustainability, nor the effect which they may have on system durability. The proposed review will provide a contemporary synthesis of the factors that influence the sustainability of interventions, improvement efforts, and change strategies in health settings. It is anticipated that this review will be of value to researchers, policymakers and others interested in contributing to sustainable improvements in health settings and ultimately in health system performance.

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Amendments

Any deviations from this protocol will be reported in the final systematic review, accompanied by a justification of why these alterations are necessary.

Author's Contributions

JB conceptualized the study and leads the team's work. LT and GL drafted the initial manuscript and search strategy, assisted by KL and JHe. Important contributions to refine and improve the manuscript were provided by JB, KL, JHe, EM, JHo and MC.

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Competing Interests

There are no competing interests.

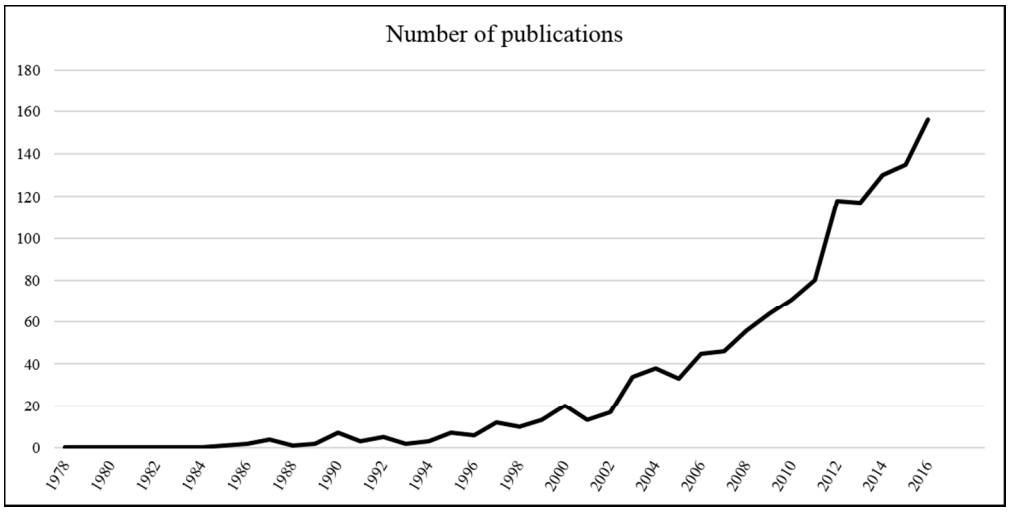

Figure 1: Publication titles containing the words "health" and "sustainability", 1978-present. Adapted from Hudson and Vissing (2013), using data from Google Scholar.

99x49mm (300 x 300 DPI)

Supplementary file 1. Data extraction sheet

Article details (authors, title, endnote reference)			
Definition of sustainability			
Context; setting			
Number of sites			
Type of study: qualitative, quantitative, mixed method; cross-sectional, longitudinal			
Details of improvement/intervention			
Assessment period (or period of program/intervention)			
Measures of sustainability			
Key findings			