



The role of organisational and cultural factors in the implementation of system-wide interventions in acute hospitals to improve patient outcomes: protocol for a systematic literature review

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Complete List of Authors:	Nosrati, Hadis; The Simpson Centre for Health Services Research, University of New South Wales Clay-Williams, Robyn; Centre for Clinical Governance Research, University of New South Wales Cunningham, Frances; University of NSW, Centre for Clinical Governance Research Hillman, Ken; The Simpson Centre for Health Services Research, University of New South Wales Braithwaite, Jeffrey; Centre for Clinical Governance Research, University of New South Wales
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Manuscripts

The role of organisational and cultural factors in the implementation of system-wide interventions in acute hospitals to improve patient outcomes: a systematic literature review

Authors:

Hadis Nosrati, PhD Research Fellow ¹
Robyn Clay-Williams, PhD Research Fellow ²
Frances Cunningham, ScD Senior Research Fellow ²
Ken Hillman, Professor and Director ¹
Jeffrey Braithwaite, PhD Professor and Director ²

Affiliations:

1 The Simpson Centre for Health Services Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia
2 Centre for Clinical Governance Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia

Contact details of corresponding author:

Dr Hadis Nosrati
Business: + 612 9385 8987
Fax: + 612 9663 8692
Mobile: + 61405 996330
Email: hadis@unsw.edu.au
Address: Australian Institute of Health Innovation Faculty of Medicine University of New South Wales Sydney NSW 2052, Australia

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Data sharing: Data available on request from the corresponding author.

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3 **The role of organisational and cultural factors in the implementation of system-wide**
4 **interventions in acute hospitals to improve patient outcomes: a systematic literature review**
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8 **ABSTRACT**
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11 **Introduction:** To reduce preventable adverse events, there is keen interest in more sustained
12 progress in improving patient safety. However, little is known about the role of organisational
13 culture in the success and sustainability of the hospital-wide interventions, and how local culture
14 affects patient outcomes in acute hospitals.
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21 **Methods and analysis:** A systematic literature review will be conducted to identify
22 organisational factors influencing hospital-wide interventions and patient outcomes. A search of
23 English language articles will be performed in MEDLINE, CINAHL, EMBASE, Web of
24 Science, PsychInfo and Global Health databases using Medical Subject Headings and keywords.
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JAMA, BMJ, BMJ Quality and Safety, New England Journal of Medicine and Implementation Science will be hand searched for the last five years. The ‘grey literature’ will be excluded. Randomised controlled trials, quasi-randomised trials, controlled before and after design studies and interrupted time-series analysis studies will be included. Two reviewers independently will undertake a title and abstract review using inclusion and exclusion criteria. Studies will be excluded only after discussion between at least two reviewers, who will assess and agree on the inclusion, risk of bias and quality rating of the studies. One author will extract summary descriptive data from these studies; the second author will review this documentation for accuracy and completeness. It is likely that the studies will be heterogeneous in nature and so a narrative synthesis of the findings will be conducted. We will discuss characteristics of the studies and stratify the results according to the type of hospital-wide interventions, organisational factors associated with them and outcomes measured.

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Ethics and dissemination: The findings of this systematic literature review will be reported via peer-reviewed publications, conference and seminar presentations. The PRISMA checklist will be applied. No ethics approval is considered indicated, as this is a literature review only.

For peer review only

ARTICLE SUMMARY

Article focus

- This review aims to identify the organisational factors that affect the implementation of hospital-wide interventions in acute hospitals, and how these organisational factors and hospital-wide interventions influence patient outcomes.

Key messages

- Silos, or vertical structures within hospitals such as wards, units, and departments, are well developed in acute care hospitals, but the system may fail at the intersection between silos for patients with complications of the original illness, which are outside the expertise of the admitting clinician.
- To bridge these intersections and thereby reduce the potential preventable adverse events for an increasingly aged and ill hospital population with comorbidities, organisation-wide patient safety interventions are becoming a major focus of health care delivery.
- Little is known about the cultural and organisational determinants of hospital-wide interventions and their effects on patient outcomes.

Strengths and limitations of this project

- This study aims to increase our knowledge of organisational culture, which we believe is an important element in the success or failure of the implementation of hospital-wide interventions.
- We will investigate how the adoption of a system-wide intervention can affect patient outcomes.

- We will be including observational studies as well as controlled before and after studies in the systematic review, as it is likely they will provide valuable information.
- We include only English language studies.
- Risk of bias may occur by inclusion of non-randomised studies, but we will mitigate this risk by only accepting papers with high quality evidence and validated data.

For peer review only

INTRODUCTION

Despite the remarkable advances in healthcare delivery and considerable changes in hospital patient populations and expectations associated with modern medicine, the fundamental organisation of hospitals has changed little into the twenty first century. The system is constructed around the admitting doctor and patient relationship.¹ In acute hospitals, wards are able to manage the day-to-day aspects of a patient's condition, but the system can fail when the patient's condition deteriorates and the admitting doctor no longer has the skills or knowledge to neither recognise nor manage the deteriorating patient.¹⁻³ One of the first organisation wide and patient centred systems, known as the Medical Emergency Team (MET) or Rapid Response System (RRS) has been implemented in many hospitals around the world to address this situation.^{4 5} When the criteria that define an at-risk or deteriorating patient are met, a team of clinicians with appropriate skills urgently responds to the patient. However, because of the nature of hospitals, and depending on the existence of necessary infrastructure to provide the continuity of care,² the effectiveness of the few-implemented hospital-wide interventions, such as an RRS, varies significantly from one health organisation to another.⁶ While there is keen interest in how to optimise and implement the system, little is known about the role of organisational culture⁷⁻¹⁰ in the success and sustainability of the hospital-wide interventions, and how the culture could affect patient outcomes in acute hospitals. Patient safety interventions working at an organisational level that include participative principles, such as the involvement of workers in design and implementation, may provide the greatest hope of improving patient safety.¹¹⁻¹³ This protocol details the processes of a systematic literature review that aims to identify the organisational and cultural factors^{10 14} affecting the adoption and success of hospital-wide interventions in acute hospitals, and to assess the effects of those factors on patient

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3 outcomes.

4 5 **METHODS AND ANALYSIS**

6 7 8 **Search Strategy**

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11 We will search MEDLINE, CINAHL, EMBASE, Web of Science, PsychInfo, Global Health,
12 using Medical Subject Headings and keywords, from 1946, 1991, 1947, 1934, 1967, 1910,
13 respectively to September 2012. The general search strategy is shown in Box 1 and the subject
14 heading will be adjusted for each database. We will use multiple terms to identify culture and
15 intervention. We will restrict the search to English language articles and we will hand search the
16 journals, JAMA, BMJ, BMJ Quality and Safety, New England Journal of Medicine and
17 Implementation Science, separately for the last five years (from 2007-2012). We will also hand
18 search the reference lists of the relevant Cochrane systematic reviews.

19 20 21 **Box 1. General search strategy**

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60 | <ol style="list-style-type: none">1. Organisational culture OR organisational climate OR organisational context OR organisational characteristics OR workplace culture OR organisational goal OR organisational value2. AND [(adopting organisation) OR (adherence to protocol) OR (organisational innovation) OR (diffusion of innovation) OR (intervention) OR (diffusion) OR (organisational change) OR (protocol change) OR (practice change) OR (structure change) OR (adoption) OR (leadership)]3. AND (patient outcome)4. AND [healthcare organisation OR hospital OR healthcare facility] |
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59 60 **Study Selection and exclusion criteria**

Under the review's inclusion and exclusion criteria, research must focus on a hospital-wide intervention, i.e., mere implementation in the operation theatre, a few general units or ICU is not sufficient. Other inclusion criteria include investigating the organisational factors that may affect

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3 the implementation. Studies should also provide patient outcome data before and after the
4 hospital-wide intervention. The review will only include interventions in an acute care setting,
5 i.e., rehabilitation centres, primary health cares, ambulatory services, and psychiatric facilities
6 will be excluded. Other inclusion criteria include that the study report on empirical research, in
7 peer reviewed, English language, scholarly journals, and that abstract and full text are available.
8 Therefore, we will not include 'grey literature'.
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18 We will not limit our search to randomised controlled trial studies, since we believe
19 observational studies and controlled before and after studies -- with validated data about patient
20 outcomes -- can provide useful information to identify the organisational and cultural
21 determinants of hospital-wide interventions.
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28 References identified in the search will be reviewed for inclusion by two researchers. Studies
29 will be excluded only after discussion between at least two reviewers, who will assess and agree
30 on the inclusion and quality rating of the studies. All papers excluded by consensus will be
31 depicted in a document explaining reason for exclusion. This process will be conducted
32 according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses
33 (PRISMA) guidelines^{15 16} and literature selection will be presented in a PRISMA flow chart.¹⁵
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43 **Participants**

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46 Participating hospitals may include any acute care facility, including metropolitan or rural, and
47 private or public hospitals.
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51 **Type of interventions**

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3 As noted, we will only include interventions that are hospital-wide and are associated with
4 patient outcomes through validated data collected before and after implementation of the
5 intervention. Also, the organisational elements of the intervention should have been explained in
6 the study to make it qualified for our review.
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12 13 **Comparisons**

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15 Comparisons may include acute hospitals with similar nursing-patient ratio, size and region with
16 no intervention.
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21 22 **Types of outcome measures**

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24 Patient outcomes may include mortality rate, the rate of adverse events, patient satisfaction, and
25 infection rate.
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30 31 **Assessment of risk of bias**

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33 Two reviewers will independently assess risk of bias in eligible studies as outlined in the
34 Cochrane Handbook for Systematic Reviews:¹⁷ selective outcome reporting, and blinding of the
35 research personnel to data collection and analysis. For any non-randomised trials included in the
36 review, the authors will assess any selection bias that may lead to confounding of the outcome.
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38 Disagreement regarding assessment of risk of bias will be resolved through discussion between
39 two reviewers. If consensus is not reached, a third reviewer will be consulted.
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49 50 **Data Collection and Analysis**

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52 Using a standard form, one author will abstract summary descriptive data from these studies. The
53 same author will compile a tabular presentation the study participants and setting, objective,
54 design and method, type of hospital-wide intervention, organisational/cultural factors,
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3 patient/process outcomes, and findings. The second author will independently review this
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5 documentation for accuracy and completeness.
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8 9 **Strategy for data synthesis**

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11 It is likely that included studies will be heterogeneous in nature and so we will conduct a
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13 narrative synthesis of the findings. We will discuss characteristics of the studies and stratify the
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15 results according to the type of hospital-wide interventions, organisational factors associated with
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17 them, and outcomes measured. We anticipate that we will not be able to use a quality assessment
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19 tool to formally assess the quality of the studies due to their heterogeneous nature.
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23 24 25 **ETHICS AND DISSEMINATION**

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28 Ethics is not required given the protocol is a systematic literature review. The findings of this
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30 review will be disseminated through mechanisms including peer-reviewed publications and
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32 conference presentations. The PRISMA checklist¹⁵ will be used for writing the final review.
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36 **ACKNOWLEDGEMENTS:** We acknowledge Dr. Isla Hains from the Centre for Health
37
38 Systems and Safety Research in the Australian Institute of Health Innovation who provided
39
40 guidance regarding the search strategy.
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44 **COMPETING INTERESTS:** The authors have no conflict of interest to declare.
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48 **AUTHORS' CONTRIBUTIONS:** All authors contributed to the design, drafting and revision
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50 of the paper, and approved the final version to be published.
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Affiliations:

1 The Simpson Centre for Health Services Research Australian Institute of Health Innovation University of New South Wales Sydney, Australia
2 Centre for Clinical Governance Research Australian Institute of Health Innovation University of New South Wales Sydney, Australia

Contact details of corresponding author:

Dr Robyn Clay-Williams
Business: + 614 2158 2638
Fax: + 612 9663 8692
Mobile: + 614 2158 2638
Email: r.clay-williams@unsw.edu.au
Address: Australian Institute of Health Innovation Faculty of Medicine University of New South Wales Sydney NSW 2052, Australia

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Conflict of interest: The authors have no conflict of interest to declare.
Contributorship: All authors contributed to the design, drafting and revision of the paper, and approved the final version to be published.
Data sharing: Data available on request from the corresponding author.

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4 **interventions in acute hospitals to improve patient outcomes: a systematic literature review**
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8 **ABSTRACT**
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10
11 **Introduction:** Little is known about the role of organisational culture in the success and
12 sustainability of the hospital-wide interventions, and how local culture affects patient outcomes
13 in acute hospitals.
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18 **Methods and analysis:** A systematic literature review will be conducted to identify
19 organisational factors influencing hospital-wide interventions and patient outcomes. A search of
20 English language articles will be performed in MEDLINE, CINAHL, EMBASE, Web of
21 Science, PsychInfo and Global Health databases using Medical Subject Headings and keywords.
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3 **Ethics and dissemination:** Findings will be reported via peer-reviewed publications, conference
4 and seminar presentations. The PRISMA checklist will be applied. No ethics approval was
5
6 required, as this is a literature review only. The protocol has been registered in the international
7
8 prospective register of systematic reviews, PROSPERO (Registration No: CRD42013003050).
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For peer review only

ARTICLE SUMMARY

Article focus

- This review aims to identify the organisational factors that affect the implementation of hospital-wide interventions in acute hospitals, and how these organisational factors and hospital-wide interventions influence patient outcomes.

Key messages

- Silos, or vertical structures within hospitals such as wards, units, and departments, are well developed in acute care hospitals, but the system may fail at the intersection between silos for patients with complications of the original illness, which are outside the expertise of the admitting clinician.
- To bridge these intersections and thereby reduce the potential preventable adverse events for an increasingly aged and ill hospital population with comorbidities, organisation-wide patient safety interventions are becoming a major focus of health care delivery.
- Little is known about the cultural and organisational determinants of hospital-wide interventions and their effects on patient outcomes.

Strengths and limitations of this project

- This study aims to increase our knowledge of organisational culture, which we believe is an important element in the success or failure of the implementation of hospital-wide interventions.
- We will investigate how the adoption of a system-wide intervention can affect patient outcomes.

- We will be including observational studies as well as controlled before and after studies in the systematic review, as it is likely they will provide valuable information.
- We include only English language studies.
- Risk of bias may occur by inclusion of non-randomised studies, but we will mitigate this risk by only accepting papers with high quality evidence and validated data.

For peer review only

INTRODUCTION

Despite the remarkable advances in healthcare delivery and considerable changes in hospital patient populations and expectations associated with modern medicine, the fundamental organisation of hospitals has changed little into the twenty first century. The system is constructed around the admitting doctor and patient relationship.¹ In acute hospitals, wards are able to manage the day-to-day aspects of a patient's condition, but the system can fail when the patient's condition deteriorates and the admitting doctor no longer has the skills or knowledge to neither recognise nor manage the deteriorating patient.¹⁻³ One of the first organisation wide and patient centred systems, known as the Medical Emergency Team (MET) or Rapid Response System (RRS) has been implemented in many hospitals around the world to address this situation.^{4 5} When the criteria that define an at-risk or deteriorating patient are met, a team of clinicians with appropriate skills urgently responds to the patient. However, because of the nature of hospitals, and depending on the existence of necessary infrastructure to provide the continuity of care,² the effectiveness of the few-implemented hospital-wide interventions, such as an RRS, varies significantly from one health organisation to another.⁶ Ultimately, we are interested in determining why interventions such as MET are successful in some settings but not in others. By examining hospital-wide interventions in acute care systems (including non-MET interventions) via this systematic literature review, we hope to shed some light on the problem.

While there is keen interest in how to optimise and implement the system, little is known about the role of organisational culture⁷⁻¹⁰ in the success and sustainability of the hospital-wide interventions, and how the culture could affect patient outcomes in acute hospitals. Patient safety interventions working at an organisational level that include participative principles, such as the involvement of workers in design and implementation, may provide the greatest hope of

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3 improving patient safety.¹¹⁻¹³ We note the identification of limitations in the literature such as
4 those identified by Kaplan et al. 2010,¹⁴ including the lack of a practical conceptual model, the
5 lack of clear definitions of contextual factors and the lack of well-specified measures. This
6 protocol details the processes of a systematic literature review that aims to identify the
7 organisational and cultural factors^{10 15} affecting the adoption and success of hospital-wide
8 interventions in acute hospitals, and to assess the effects of those factors on patient outcomes.
9

17 **METHODS AND ANALYSIS**

20 **Search Strategy**

21 We will search MEDLINE, CINAHL, EMBASE, Web of Science, PsychInfo, Global Health,
22 using Medical Subject Headings and keywords, from 1946, 1991, 1947, 1934, 1967, 1910,
23 respectively to September 2012. The general search strategy is shown in Box 1 and the subject
24 heading will be adjusted for each database. We will use multiple terms to identify culture and
25 intervention. The search will be restricted to English language articles (the authors do not have
26 resources for translation) and we will hand search the journals, JAMA, BMJ, BMJ Quality and
27 Safety, New England Journal of Medicine and Implementation Science, separately for the last
28 five years (from 2007-2012). The peer reviewed journals were chosen as the most likely to
29 publish studies that meet inclusion criteria. We will also hand search the reference lists of the
30 relevant Cochrane systematic reviews.
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48 **Box 1. General search strategy**

1. Organisational culture OR organisational climate OR organisational context OR organisational characteristics OR workplace culture OR organisational goal OR organisational value
2. AND [(adopting organisation) OR (adherence to protocol) OR (organisational innovation) OR (diffusion of innovation) OR (intervention) OR (diffusion) OR (organisational change) OR (protocol change) OR (practice change) OR (structure change) OR (adoption) OR (leadership)]
3. AND (patient outcome)
4. AND [healthcare organisation OR hospital OR healthcare facility]

Study Selection and exclusion criteria

Under the review's inclusion and exclusion criteria, research must focus on a hospital-wide intervention, i.e., mere implementation in the operation theatre, a few general units or ICU is not sufficient. Other inclusion criteria include investigating the organisational factors that may affect the implementation. Studies should also provide patient outcome data before and after the hospital-wide intervention. The review will only include interventions in an acute care setting, i.e., rehabilitation centres, primary health cares, ambulatory services, and psychiatric facilities will be excluded. Other inclusion criteria include that the study report on empirical research, in peer reviewed, English language, scholarly journals, and that abstract and full text are available. The 'grey literature' will be excluded as it is unlikely to yield study designs that meet inclusion criteria.

We will not limit our search to randomised controlled trial studies, since we believe observational studies and controlled before and after studies -- with validated data about patient outcomes -- can provide useful information to identify the organisational and cultural determinants of hospital-wide interventions.

References identified in the search will be reviewed for inclusion by two researchers. Studies will be excluded only after discussion between at least two reviewers, who will assess and agree

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3 on the inclusion and quality rating of the studies. All papers excluded by consensus will be
4 depicted in a document explaining reason for exclusion. This process will be conducted
5 according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses
6 (PRISMA) guidelines^{16 17} and literature selection will be presented in a PRISMA flow chart.¹⁶
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8 The selection criteria may limit the generalisability of study findings, however the scope of the
9 search is appropriate to identify the majority of articles published in the peer review literature
10 and meeting the study criteria.
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20 **Participants**

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23 Participating hospitals may include any acute care facility, including metropolitan or rural, and
24 private or public hospitals.
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28 **Type of interventions**

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31 As noted, we will only include interventions that are hospital-wide and are associated with
32 patient outcomes through validated data collected before and after implementation of the
33 intervention. Also, the organisational elements of the intervention should have been explained in
34 the study to make it qualified for our review.
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42 **Comparisons**

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45 Comparisons may include acute hospitals with similar nursing-patient ratio, size and region with
46 no intervention.
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50 **Types of outcome measures**

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53 Patient outcomes may include mortality rate, the rate of adverse events, patient satisfaction, and
54 infection rate.
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Assessment of risk of bias

Two reviewers will independently assess risk of bias in eligible studies as outlined in the Cochrane Handbook for Systematic Reviews:¹⁸ selective outcome reporting, and blinding of the research personnel to data collection and analysis. For any non-randomised trials included in the review, the authors will assess any selection bias that may lead to confounding of the outcome. Disagreement regarding assessment of risk of bias will be resolved through discussion between two reviewers. If consensus is not reached, a third reviewer will be consulted.

Data Collection and Analysis

Using a standard form created for the review, one author will extract summary descriptive data from these studies. The same author will compile a tabular presentation the study participants and setting, objective, design and method, type of hospital-wide intervention, organisational/cultural factors, patient/process outcomes, and findings. The second author will independently review this documentation for accuracy and completeness.

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If suitable data are available, a meta-analysis will be completed; however it is likely that included studies will be heterogeneous in nature. Where trial data cannot be combined, two of the authors will conduct a narrative synthesis of the findings in accordance with the review objectives. We will discuss characteristics of the studies and stratify the results according to the type of hospital-wide interventions, organisational factors associated with them, and outcomes measured. We anticipate that we will not be able to use a quality assessment tool to formally assess the quality of the studies due to their heterogeneous nature.

ETHICS AND DISSEMINATION

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13 Systems and Safety Research in the Australian Institute of Health Innovation who provided
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15 guidance regarding the search strategy.
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23 **AUTHORS' CONTRIBUTIONS:** All authors contributed to the design, drafting and revision
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25 of the paper, and approved the final version to be published.
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The role of organisational and cultural factors in the implementation of system-wide interventions in acute hospitals to improve patient outcomes: a systematic literature review

Authors:

Hadis Nosrati, PhD Research Fellow ¹
Robyn Clay-Williams, PhD Research Fellow ²
Frances Cunningham, ScD Senior Research Fellow ²
Ken Hillman, Professor and Director ¹
Jeffrey Braithwaite, PhD Professor and Director ²

Affiliations:

1 The Simpson Centre for Health Services Research Australian Institute of Health Innovation University of New South Wales Sydney, Australia
2 Centre for Clinical Governance Research Australian Institute of Health Innovation University of New South Wales Sydney, Australia

Contact details of corresponding author:

Dr Robyn Clay-Williams
Business: + 614 2158 2638
Fax: + 612 9663 8692
Mobile: + 614 2158 2638
Email: r.clay-williams@unsw.edu.au
Address: Australian Institute of Health Innovation Faculty of Medicine University of New South Wales Sydney NSW 2052, Australia

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3 **The role of organisational and cultural factors in the implementation of system-wide**
4 **interventions in acute hospitals to improve patient outcomes: a systematic literature review**
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8
9 **ABSTRACT**
10

11 **Introduction:** ~~To reduce preventable adverse events, there is keen interest in more sustained~~
12 ~~progress in improving patient safety. However, little~~Little is known about the role of
13 organisational culture in the success and sustainability of the hospital-wide interventions, and
14 how local culture affects patient outcomes in acute hospitals.
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20
21 **Methods and analysis:** A systematic literature review will be conducted to identify
22 organisational factors influencing hospital-wide interventions and patient outcomes. A search of
23 English language articles will be performed in MEDLINE, CINAHL, EMBASE, Web of
24 Science, PsychInfo and Global Health databases using Medical Subject Headings and keywords.
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31 ~~JAMA, BMJ, BMJ Quality and Safety, New England Journal of Medicine and Implementation~~
32 ~~Science will be hand searched for the last five years. Randomised controlled trials, quasi-~~
33 ~~randomised trials, controlled before and after design studies and interrupted time-series analysis~~
34 ~~studies will be included. The 'grey literature' will be excluded, however, peer reviewed~~
35 ~~journal that are likely to publish relevant studies (JAMA, BMJ, BMJ Quality and Safety, New~~
36 ~~England Journal of Medicine and Implementation Science) will be hand searched for the last five~~
37 ~~years. Randomised controlled trials, quasi-randomised trials, controlled before and after design~~
38 ~~studies and interrupted time-series analysis studies will be included.~~ Two reviewers
39 independently will undertake a title and abstract review using inclusion and exclusion criteria.
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3 for accuracy and completeness. It is likely that the studies will be heterogeneous in nature, ~~and~~
4 ~~so~~ therefore a narrative synthesis of the findings will be conducted. We will discuss
5
6 characteristics of the studies and stratify the results according to the type of hospital-wide
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8 interventions, organisational factors associated with them and outcomes measured.
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11
12 **Ethics and dissemination:** ~~The findings of this systematic literature review~~ Findings will be
13 reported via peer-reviewed publications, conference and seminar presentations. The PRISMA
14 checklist will be applied. No ethics approval ~~is considered indicated~~ was required, as this is a
15 literature review only. The protocol has been registered in the international prospective register
16 of systematic reviews, PROSPERO (Registration No: CRD42013003050).
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ARTICLE SUMMARY**Article focus**

- This review aims to identify the organisational factors that affect the implementation of hospital-wide interventions in acute hospitals, and how these organisational factors and hospital-wide interventions influence patient outcomes.

Key messages

- Silos, or vertical structures within hospitals such as wards, units, and departments, are well developed in acute care hospitals, but the system may fail at the intersection between silos for patients with complications of the original illness, which are outside the expertise of the admitting clinician.
- To bridge these intersections and thereby reduce the potential preventable adverse events for an increasingly aged and ill hospital population with comorbidities, organisation-wide patient safety interventions are becoming a major focus of health care delivery.
- Little is known about the cultural and organisational determinants of hospital-wide interventions and their effects on patient outcomes.

Strengths and limitations of this project

- This study aims to increase our knowledge of organisational culture, which we believe is an important element in the success or failure of the implementation of hospital-wide interventions.
- We will investigate how the adoption of a system-wide intervention can affect patient outcomes.

- We will be including observational studies as well as controlled before and after studies in the systematic review, as it is likely they will provide valuable information.
- We include only English language studies.
- Risk of bias may occur by inclusion of non-randomised studies, but we will mitigate this risk by only accepting papers with high quality evidence and validated data.

For peer review only

INTRODUCTION

Despite the remarkable advances in healthcare delivery and considerable changes in hospital patient populations and expectations associated with modern medicine, the fundamental organisation of hospitals has changed little into the twenty first century. The system is constructed around the admitting doctor and patient relationship.¹ In acute hospitals, wards are able to manage the day-to-day aspects of a patient's condition, but the system can fail when the patient's condition deteriorates and the admitting doctor no longer has the skills or knowledge to neither recognise nor manage the deteriorating patient.¹⁻³ One of the first organisation wide and patient centred systems, known as the Medical Emergency Team (MET) or Rapid Response System (RRS) has been implemented in many hospitals around the world to address this situation.^{4 5} When the criteria that define an at-risk or deteriorating patient are met, a team of clinicians with appropriate skills urgently responds to the patient. However, because of the nature of hospitals, and depending on the existence of necessary infrastructure to provide the continuity of care,² the effectiveness of the few-implemented hospital-wide interventions, such as an RRS, varies significantly from one health organisation to another.⁶ Ultimately, we are interested in determining why interventions such as MET are successful in some settings but not in others. By examining hospital-wide interventions in acute care systems (including non-MET interventions) via this systematic literature review, we hope to shed some light on the problem.

While there is keen interest in how to optimise and implement the system, little is known about the role of organisational culture⁷⁻¹⁰ in the success and sustainability of the hospital-wide interventions, and how the culture could affect patient outcomes in acute hospitals. Patient safety interventions working at an organisational level that include participative principles, such as the involvement of workers in design and implementation, may provide the greatest hope of

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3 improving patient safety.¹¹⁻¹³ We note the identification of limitations in the literature such as
4 those identified by Kaplan et al. 2010,¹⁴ including the lack of a practical conceptual model, the
5 lack of clear definitions of contextual factors and the lack of well-specified measures. This
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10 protocol details the processes of a systematic literature review that aims to identify the
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12 organisational and cultural factors^{10 15} affecting the adoption and success of hospital-wide
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14 interventions in acute hospitals, and to assess the effects of those factors on patient outcomes.
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17 **METHODS AND ANALYSIS**

18 **Search Strategy**

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21 We will search MEDLINE, CINAHL, EMBASE, Web of Science, PsychInfo, Global Health,
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23 using Medical Subject Headings and keywords, from 1946, 1991, 1947, 1934, 1967, 1910,
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25 respectively to September 2012. The general search strategy is shown in Box 1 and the subject
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27 heading will be adjusted for each database. We will use multiple terms to identify culture and
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29 intervention. ~~We will restrict the~~The search will be restricted to English language articles (the
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31 authors do not have resources for translation) and we will hand search the journals, JAMA, BMJ,
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33 BMJ Quality and Safety, New England Journal of Medicine and Implementation Science,
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35 separately for the last five years (from 2007-2012). The peer reviewed journals were chosen as
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37 the most likely to publish studies that meet inclusion criteria. We will also hand search the
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39 reference lists of the relevant Cochrane systematic reviews.
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48 **Box 1. General search strategy**

1. Organisational culture OR organisational climate OR organisational context OR organisational characteristics OR workplace culture OR organisational goal OR organisational value
2. AND [(adopting organisation) OR (adherence to protocol) OR (organisational innovation) OR (diffusion of innovation) OR (intervention) OR (diffusion) OR (organisational change) OR (protocol change) OR (practice change) OR (structure change) OR (adoption) OR (leadership)]
3. AND (patient outcome)
4. AND [healthcare organisation OR hospital OR healthcare facility]

Study Selection and exclusion criteria

Under the review's inclusion and exclusion criteria, research must focus on a hospital-wide intervention, i.e., mere implementation in the operation theatre, a few general units or ICU is not sufficient. Other inclusion criteria include investigating the organisational factors that may affect the implementation. Studies should also provide patient outcome data before and after the hospital-wide intervention. The review will only include interventions in an acute care setting, i.e., rehabilitation centres, primary health cares, ambulatory services, and psychiatric facilities will be excluded. Other inclusion criteria include that the study report on empirical research, in peer reviewed, English language, scholarly journals, and that abstract and full text are available.

The 'grey literature' will be excluded as it is unlikely to yield study designs that meet inclusion criteria. Therefore, we will not include 'grey literature'.

We will not limit our search to randomised controlled trial studies, since we believe observational studies and controlled before and after studies -- with validated data about patient outcomes -- can provide useful information to identify the organisational and cultural determinants of hospital-wide interventions.

References identified in the search will be reviewed for inclusion by two researchers. Studies will be excluded only after discussion between at least two reviewers, who will assess and agree

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25 of the paper, and approved the final version to be published.
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Manuscript ID:	bmjopen-2012-002268.R2
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Complete List of Authors:	Nosrati, Hadis; The Simpson Centre for Health Services Research, University of New South Wales Clay-Williams, Robyn; Centre for Clinical Governance Research, University of New South Wales Cunningham, Frances; University of NSW, Centre for Clinical Governance Research Hillman, Ken; The Simpson Centre for Health Services Research, University of New South Wales Braithwaite, Jeffrey; Centre for Clinical Governance Research, University of New South Wales
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Evidence based practice
Keywords:	health service research, Performance measures, Healthcare quality improvement

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Authors:

Hadis Nosrati, PhD Research Fellow ¹
Robyn Clay-Williams, PhD Research Fellow ²
Frances Cunningham, ScD Senior Research Fellow ²
Ken Hillman, Professor and Director ¹
Jeffrey Braithwaite, PhD Professor and Director ²

Affiliations:

1 The Simpson Centre for Health Services Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia
2 Centre for Clinical Governance Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia

Contact details of corresponding author:

Dr Robyn Clay-Williams
Business: + 614 2158 2638
Fax: + 612 9663 8692
Mobile: + 614 2158 2638
Email: r.clay-williams@unsw.edu.au
Address: Australian Institute of Health Innovation Faculty of Medicine University of New South Wales Sydney NSW 2052, Australia

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13 in acute hospitals.
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18 **Methods and analysis:** A systematic literature review will be conducted to identify
19 organisational factors influencing hospital-wide interventions and patient outcomes. A search of
20 English language articles will be performed in MEDLINE, CINAHL, EMBASE, Web of
21 Science, PsychInfo and Global Health databases using Medical Subject Headings and keywords.
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Randomised controlled trials, quasi-randomised trials, controlled before and after design studies and interrupted time-series analysis studies will be included. ‘Grey literature’ will be excluded, however peer reviewed journals that are likely to publish relevant studies (JAMA, BMJ, BMJ Quality and Safety, Lancet, New England Journal of Medicine and Implementation Science) will be hand searched for the last five years. Two reviewers independently will undertake a title and abstract review using inclusion and exclusion criteria. Studies will be excluded only after discussion between at least two reviewers, who will assess and agree on the inclusion, risk of bias and quality rating of the studies. One author will extract summary descriptive data from these studies; the second author will review this documentation for accuracy and completeness. It is likely that the studies will be heterogeneous in nature, therefore a narrative synthesis of the findings will be conducted. We will discuss characteristics of the studies and stratify the results according to the type of hospital-wide interventions, organisational factors associated with them and outcomes measured.

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3 **Ethics and dissemination:** Findings will be reported via peer-reviewed publications, conference
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6 required, as this is a literature review only. The protocol has been registered in the international
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8 prospective register of systematic reviews, PROSPERO (Registration No: CRD42013003050).
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For peer review only

ARTICLE SUMMARY

Article focus

- This review aims to identify the organisational factors that affect the implementation of hospital-wide interventions in acute hospitals, and how these organisational factors and hospital-wide interventions influence patient outcomes.

Key messages

- Silos, or vertical structures within hospitals such as wards, units, and departments, are well developed in acute care hospitals, but the system may fail at the intersection between silos for patients with complications of the original illness, which are outside the expertise of the admitting clinician.
- To bridge these intersections and thereby reduce the potential preventable adverse events for an increasingly aged and ill hospital population with comorbidities, organisation-wide patient safety interventions are becoming a major focus of health care delivery.
- Little is known about the cultural and organisational determinants of hospital-wide interventions and their effects on patient outcomes.

Strengths and limitations of this project

- This study aims to increase our knowledge of organisational culture, which we believe is an important element in the success or failure of the implementation of hospital-wide interventions.
- We will investigate how the adoption of a system-wide intervention can affect patient outcomes.

- We will be including observational studies as well as controlled before and after studies in the systematic review, as it is likely they will provide valuable information.
- We include only English language studies.
- Risk of bias will be assessed using standard Cochrane criteria.

For peer review only

INTRODUCTION

Despite the remarkable advances in healthcare delivery and considerable changes in hospital patient populations and expectations associated with modern medicine, the fundamental organisation of hospitals has changed little into the twenty first century. The system is constructed around the admitting doctor and patient relationship.¹ In acute hospitals, wards are able to manage the day-to-day aspects of a patient's condition, but the system can fail when the patient's condition deteriorates and the admitting doctor no longer has the skills or knowledge to neither recognise nor manage the deteriorating patient.¹⁻³ One of the first organisation wide and patient centred systems, known as the Medical Emergency Team (MET) or Rapid Response System (RRS) has been implemented in many hospitals around the world to address this situation.^{4 5} When the criteria that define an at-risk or deteriorating patient are met, a team of clinicians with appropriate skills urgently responds to the patient. However, because of the nature of hospitals, and depending on the existence of necessary infrastructure to provide the continuity of care,² the effectiveness of the few-implemented hospital-wide interventions, such as an RRS, varies significantly from one health organisation to another.⁶ Ultimately, we are interested in determining why interventions such as MET are successful in some settings but not in others. By examining hospital-wide interventions in acute care systems (including non-MET interventions) via this systematic literature review, we hope to shed some light on the problem.

While there is keen interest in how to optimise and implement the system, little is known about the role of organisational culture⁷⁻¹⁰ in the success and sustainability of the hospital-wide interventions, and how the culture could affect patient outcomes in acute hospitals. Patient safety interventions working at an organisational level that include participative principles, such as the involvement of workers in design and implementation, may provide the greatest hope of

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3 improving patient safety.¹¹⁻¹³ We note the identification of limitations in the literature such as
4 those identified by Kaplan et al. 2010,¹⁴ including the lack of a practical conceptual model, the
5 lack of clear definitions of contextual factors and the lack of well-specified measures. This
6 protocol details the processes of a systematic literature review that aims to identify the
7 organisational and cultural factors^{10 15} affecting the adoption and success of hospital-wide
8 interventions in acute hospitals, and to assess the effects of those factors on patient outcomes.
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17 **METHODS AND ANALYSIS**

20 **Search Strategy**

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22 We will search MEDLINE, CINAHL, EMBASE, Web of Science, PsychInfo, Global Health,
23 using Medical Subject Headings and keywords, from 1946, 1991, 1947, 1934, 1967, 1910,
24 respectively to September 2012. The general search strategy is shown in Box 1 and the subject
25 heading will be adjusted for each database. We will use multiple terms to identify culture and
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27 resources for translation) and we will hand search the journals, JAMA, BMJ, BMJ Quality and
28 Safety, Lancet, New England Journal of Medicine and Implementation Science, separately for
29 the last five years (from 2007-2012). The peer reviewed journals were chosen as the most likely
30 to publish studies that meet inclusion criteria, in particular validated patient outcomes. Although
31 PLOS Medicine and BMJ Open are also likely to publish studies that meet our criteria, both are
32 open access online journals with all articles linked to PubMed at time of publication, therefore
33 we expect that the online search engines will capture relevant papers from these journals. We
34 will also hand search the reference lists of the relevant Cochrane systematic reviews.
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55 **Box 1. General search strategy**

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1. Organisational culture OR organisational climate OR organisational context OR organisational characteristics OR workplace culture OR organisational goal OR organisational value
2. AND [(adopting organisation) OR (adherence to protocol) OR (organisational innovation) OR (diffusion of innovation) OR (intervention) OR (diffusion) OR (organisational change) OR (protocol change) OR (practice change) OR (structure change) OR (adoption) OR (leadership)]
3. AND (patient outcome)
4. AND [healthcare organisation OR hospital OR healthcare facility]

Study Selection and exclusion criteria

Under the review's inclusion and exclusion criteria, research must focus on a hospital-wide intervention, i.e., mere implementation in the operation theatre, a few general units or ICU is not sufficient. Other inclusion criteria include investigating the organisational factors that may affect the implementation. Studies should also provide patient outcome data before and after the hospital-wide intervention. The review will only include interventions in an acute care setting, i.e., rehabilitation centres, primary health cares, ambulatory services, and psychiatric facilities will be excluded. Other inclusion criteria include that the study report on empirical research, in peer reviewed, English language, scholarly journals, and that abstract and full text are available. The 'grey literature' will be excluded as it is unlikely to yield study designs that meet inclusion criteria.

We will not limit our search to randomised controlled trial studies, since we believe observational studies and controlled before and after studies -- with validated data about patient outcomes -- can provide useful information to identify the organisational and cultural determinants of hospital-wide interventions.

References identified in the search will be reviewed for inclusion by two researchers. Studies will be excluded only after discussion between at least two reviewers, who will assess and agree

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3 on the inclusion and quality rating of the studies. All papers excluded by consensus will be
4 depicted in a document explaining reason for exclusion. This process will be conducted
5 according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses
6 (PRISMA) guidelines^{16 17} and literature selection will be presented in a PRISMA flow chart.¹⁶
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8 The selection criteria may limit the generalisability of study findings, however the scope of the
9 search is appropriate to identify the majority of articles published in the peer review literature
10 and meeting the study criteria.
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20 **Participants**

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22 Participating hospitals may include any acute care facility, including metropolitan or rural, and
23 private or public hospitals.
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29 **Type of interventions**

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31 As noted, we will only include interventions that are hospital-wide and are associated with
32 patient outcomes through validated data collected before and after implementation of the
33 intervention. Also, the organisational elements of the intervention should have been explained in
34 the study to make it qualified for our review.
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42 **Comparisons**

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44 Comparisons may include acute hospitals with similar nursing-patient ratio, size and region with
45 no intervention.
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50 **Types of outcome measures**

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52 Patient outcomes may include mortality rate, the rate of adverse events, patient satisfaction, and
53 infection rate.
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Assessment of risk of bias

Two reviewers will independently assess risk of bias in eligible studies as outlined in the Cochrane Handbook for Systematic Reviews:¹⁸ selective outcome reporting, and blinding of the research personnel to data collection and analysis. For any non-randomised trials included in the review, the authors will assess any selection bias that may lead to confounding of the outcome. Disagreement regarding assessment of risk of bias will be resolved through discussion between two reviewers. If consensus is not reached, a third reviewer will be consulted.

Data Collection and Analysis

Using a standard form created for the review, one author will extract summary descriptive data from these studies. The same author will compile a tabular presentation the study participants and setting, objective, design and method, type of hospital-wide intervention, organisational/cultural factors, patient/process outcomes, and findings. The second author will independently review this documentation for accuracy and completeness.

Strategy for data synthesis

If suitable data are available, a meta-analysis will be completed; however it is likely that included studies will be heterogeneous in nature. Where trial data cannot be combined, two of the authors will conduct a narrative synthesis of the findings in accordance with the review objectives. We will discuss characteristics of the studies and stratify the results according to the type of hospital-wide interventions, organisational factors associated with them, and outcomes measured. We anticipate that we will not be able to use a quality assessment tool to formally assess the quality of the studies due to their heterogeneous nature.

Limitations

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3 The review findings will be limited by the number and quality of studies identified by the search
4 strategy. In particular, limiting the hand search to restricted access general medicine publications
5 that are likely to publish studies with validated patient outcomes places reliance on the search
6 engines to deliver relevant papers from open access online publications such as BMJ Open and
7 PLOS Medicine.
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14 15 16 **ETHICS AND DISSEMINATION** 17

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19 Ethics is not required given the protocol is a systematic literature review. The findings of this
20 review will be disseminated through mechanisms including peer-reviewed publications and
21 conference presentations. The PRISMA checklist¹⁶ will be used for writing the final review.
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28 **ACKNOWLEDGEMENTS:** We acknowledge Dr. Isla Hains from the Centre for Health
29 Systems and Safety Research in the Australian Institute of Health Innovation who provided
30 guidance regarding the search strategy.
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36 **COMPETING INTERESTS:** The authors have no conflict of interest to declare.
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39 **AUTHORS' CONTRIBUTIONS:** All authors contributed to the design, drafting and revision
40 of the paper, and approved the final version to be published.
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The role of organisational and cultural factors in the implementation of system-wide interventions in acute hospitals to improve patient outcomes: a systematic literature review

Authors:

Hadis Nosrati, PhD Research Fellow ¹
Robyn Clay-Williams, PhD Research Fellow ²
Frances Cunningham, ScD Senior Research Fellow ²
Ken Hillman, Professor and Director ¹
Jeffrey Braithwaite, PhD Professor and Director ²

Affiliations:

1 The Simpson Centre for Health Services Research Australian Institute of Health Innovation University of New South Wales Sydney, Australia
2 Centre for Clinical Governance Research Australian Institute of Health Innovation University of New South Wales Sydney, Australia

Contact details of corresponding author:

Dr Robyn Clay-Williams
Business: + 614 2158 2638
Fax: + 612 9663 8692
Mobile: + 614 2158 2638
Email: r.clay-williams@unsw.edu.au
Address: Australian Institute of Health Innovation Faculty of Medicine University of New South Wales Sydney NSW 2052, Australia

Keywords:

Organisational culture, hospital-wide intervention, patient outcomes, acute care hospitals
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Figures: 1
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Conflict of interest: The authors have no conflict of interest to declare.
Contributorship: All authors contributed to the design, drafting and revision of the paper, and approved the final version to be published.
Data sharing: Data available on request from the corresponding author.

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3 **The role of organisational and cultural factors in the implementation of system-wide**
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5 **interventions in acute hospitals to improve patient outcomes: a systematic literature review**
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8
9 **ABSTRACT**
10

11 **Introduction:** Little is known about the role of organisational culture in the success and
12 sustainability of the hospital-wide interventions, and how local culture affects patient outcomes
13 in acute hospitals.
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18 **Methods and analysis:** A systematic literature review will be conducted to identify
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ARTICLE SUMMARY**Article focus**

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Key messages

- Silos, or vertical structures within hospitals such as wards, units, and departments, are well developed in acute care hospitals, but the system may fail at the intersection between silos for patients with complications of the original illness, which are outside the expertise of the admitting clinician.
- To bridge these intersections and thereby reduce the potential preventable adverse events for an increasingly aged and ill hospital population with comorbidities, organisation-wide patient safety interventions are becoming a major focus of health care delivery.
- Little is known about the cultural and organisational determinants of hospital-wide interventions and their effects on patient outcomes.

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- Risk of bias ~~may occur by inclusion of non-randomised studies, but we will mitigate this risk by only accepting papers with high quality evidence and validated data~~ will be assessed using standard Cochrane criteria.

INTRODUCTION

Despite the remarkable advances in healthcare delivery and considerable changes in hospital patient populations and expectations associated with modern medicine, the fundamental organisation of hospitals has changed little into the twenty first century. The system is constructed around the admitting doctor and patient relationship.¹ In acute hospitals, wards are able to manage the day-to-day aspects of a patient's condition, but the system can fail when the patient's condition deteriorates and the admitting doctor no longer has the skills or knowledge to neither recognise nor manage the deteriorating patient.¹⁻³ One of the first organisation wide and patient centred systems, known as the Medical Emergency Team (MET) or Rapid Response System (RRS) has been implemented in many hospitals around the world to address this situation.^{4 5} When the criteria that define an at-risk or deteriorating patient are met, a team of clinicians with appropriate skills urgently responds to the patient. However, because of the nature of hospitals, and depending on the existence of necessary infrastructure to provide the continuity of care,² the effectiveness of the few-implemented hospital-wide interventions, such as an RRS, varies significantly from one health organisation to another.⁶ Ultimately, we are interested in determining why interventions such as MET are successful in some settings but not in others. By examining hospital-wide interventions in acute care systems (including non-MET interventions) via this systematic literature review, we hope to shed some light on the problem.

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3. AND (patient outcome)
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Assessment of risk of bias

Two reviewers will independently assess risk of bias in eligible studies as outlined in the Cochrane Handbook for Systematic Reviews:¹⁸ selective outcome reporting, and blinding of the research personnel to data collection and analysis. For any non-randomised trials included in the review, the authors will assess any selection bias that may lead to confounding of the outcome. Disagreement regarding assessment of risk of bias will be resolved through discussion between two reviewers. If consensus is not reached, a third reviewer will be consulted.

Data Collection and Analysis

Using a standard form created for the review, one author will extract summary descriptive data from these studies. The same author will compile a tabular presentation the study participants and setting, objective, design and method, type of hospital-wide intervention, organisational/cultural factors, patient/process outcomes, and findings. The second author will independently review this documentation for accuracy and completeness.

Strategy for data synthesis

If suitable data are available, a meta-analysis will be completed; however it is likely that included studies will be heterogeneous in nature. Where trial data cannot be combined, two of the authors will conduct a narrative synthesis of the findings in accordance with the review objectives. We will discuss characteristics of the studies and stratify the results according to the type of hospital-wide interventions, organisational factors associated with them, and outcomes measured. We anticipate that we will not be able to use a quality assessment tool to formally assess the quality of the studies due to their heterogeneous nature.

Limitations

The review findings will be limited by the number and quality of studies identified by the search strategy. In particular, limiting the hand search to restricted access general medicine publications that are likely to publish studies with validated patient outcomes places reliance on the search engines to deliver relevant papers from open access online publications such as BMJ Open and PLOS Medicine.

ETHICS AND DISSEMINATION

Ethics is not required given the protocol is a systematic literature review. The findings of this review will be disseminated through mechanisms including peer-reviewed publications and conference presentations. The PRISMA checklist¹⁶ will be used for writing the final review.

ACKNOWLEDGEMENTS: We acknowledge Dr. Isla Hains from the Centre for Health Systems and Safety Research in the Australian Institute of Health Innovation who provided guidance regarding the search strategy.

COMPETING INTERESTS: The authors have no conflict of interest to declare.

AUTHORS' CONTRIBUTIONS: All authors contributed to the design, drafting and revision of the paper, and approved the final version to be published.

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The role of organisational and cultural factors in the implementation of system-wide interventions in acute hospitals to improve patient outcomes: protocol for a systematic literature review

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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Evidence based practice
Keywords:	health service research, Performance measures, Healthcare quality improvement

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Manuscripts

The role of organisational and cultural factors in the implementation of system-wide interventions in acute hospitals to improve patient outcomes: a systematic literature review

Authors:

Hadis Nosrati, PhD Research Fellow ¹
Robyn Clay-Williams, PhD Research Fellow ²
Frances Cunningham, ScD Senior Research Fellow ²
Ken Hillman, Professor and Director ¹
Jeffrey Braithwaite, PhD Professor and Director ²

Affiliations:

1 The Simpson Centre for Health Services Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia
2 Centre for Clinical Governance Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia

Contact details of corresponding author:

Dr Robyn Clay-Williams
Business: + 614 2158 2638
Fax: + 612 9663 8692
Mobile: + 614 2158 2638
Email: r.clay-williams@unsw.edu.au
Address: Australian Institute of Health Innovation Faculty of Medicine University of New South Wales Sydney NSW 2052, Australia

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Contributorship: All authors contributed to the design, drafting and revision of the paper, and approved the final version to be published.

Data sharing: Data available on request from the corresponding author.

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3 **The role of organisational and cultural factors in the implementation of system-wide**
4 **interventions in acute hospitals to improve patient outcomes: a systematic literature review**
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8 **ABSTRACT**
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11 **Introduction:** Little is known about the role of organisational culture in the success and
12 sustainability of the hospital-wide interventions, and how local culture affects patient outcomes
13 in acute hospitals.
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18 **Methods and analysis:** A systematic literature review will be conducted to identify
19 organisational factors influencing hospital-wide interventions and patient outcomes. A search of
20 English language articles will be performed in MEDLINE, CINAHL, EMBASE, Web of
21 Science, PsychInfo and Global Health databases using Medical Subject Headings and keywords.
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Randomised controlled trials, quasi-randomised trials, controlled before and after design studies and interrupted time-series analysis studies will be included. ‘Grey literature’ will be excluded, however peer reviewed journals that are likely to publish relevant studies (JAMA, BMJ, BMJ Quality and Safety, Lancet, New England Journal of Medicine and Implementation Science) will be hand searched for the last five years. Two reviewers independently will undertake a title and abstract review using inclusion and exclusion criteria. Studies will be excluded only after discussion between at least two reviewers, who will assess and agree on the inclusion, risk of bias and quality rating of the studies. One author will extract summary descriptive data from these studies; the second author will review this documentation for accuracy and completeness. It is likely that the studies will be heterogeneous in nature, therefore a narrative synthesis of the findings will be conducted. We will discuss characteristics of the studies and stratify the results according to the type of hospital-wide interventions, organisational factors associated with them and outcomes measured.

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3 **Ethics and dissemination:** Findings will be reported via peer-reviewed publications, conference
4 and seminar presentations. The PRISMA checklist will be applied. No ethics approval was
5
6 required, as this is a literature review only. The protocol has been registered in the international
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8 prospective register of systematic reviews, PROSPERO (Registration No: CRD42013003050).
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For peer review only

ARTICLE SUMMARY

Article focus

- This review aims to identify the organisational factors that affect the implementation of hospital-wide interventions in acute hospitals, and how these organisational factors and hospital-wide interventions influence patient outcomes.

Key messages

- Silos, or vertical structures within hospitals such as wards, units, and departments, are well developed in acute care hospitals, but the system may fail at the intersection between silos for patients with complications of the original illness, which are outside the expertise of the admitting clinician.
- To bridge these intersections and thereby reduce the potential preventable adverse events for an increasingly aged and ill hospital population with comorbidities, organisation-wide patient safety interventions are becoming a major focus of health care delivery.
- Little is known about the cultural and organisational determinants of hospital-wide interventions and their effects on patient outcomes.

Strengths and limitations of this project

- This study aims to increase our knowledge of organisational culture, which we believe is an important element in the success or failure of the implementation of hospital-wide interventions.
- We will investigate how the adoption of a system-wide intervention can affect patient outcomes.

- We will be including observational studies as well as controlled before and after studies in the systematic review, as it is likely they will provide valuable information.
- We include only English language studies.
- Risk of bias will be assessed using standard Cochrane criteria.

For peer review only

INTRODUCTION

Despite the remarkable advances in healthcare delivery and considerable changes in hospital patient populations and expectations associated with modern medicine, the fundamental organisation of hospitals has changed little into the twenty first century. The system is constructed around the admitting doctor and patient relationship.¹ In acute hospitals, wards are able to manage the day-to-day aspects of a patient's condition, but the system can fail when the patient's condition deteriorates and the admitting doctor no longer has the skills or knowledge to neither recognise nor manage the deteriorating patient.¹⁻³ One of the first organisation wide and patient centred systems, known as the Medical Emergency Team (MET) or Rapid Response System (RRS) has been implemented in many hospitals around the world to address this situation.² When the criteria that define an at-risk or deteriorating patient are met, a team of clinicians with appropriate skills urgently responds to the patient. However, because of the nature of hospitals, and depending on the existence of necessary infrastructure to provide the continuity of care,^{4 5} the effectiveness of the few-implemented hospital-wide interventions, such as an RRS, varies significantly from one health organisation to another.⁶ Ultimately, we are interested in determining why interventions such as MET are successful in some settings but not in others. By examining hospital-wide interventions in acute care systems (including non-MET interventions) via this systematic literature review, we hope to shed some light on the problem.

While there is keen interest in how to optimise and implement the system, little is known about the role of organisational culture⁷⁻¹⁰ in the success and sustainability of the hospital-wide interventions, and how the culture could affect patient outcomes in acute hospitals. Patient safety interventions working at an organisational level that include participative principles, such as the involvement of workers in design and implementation, may provide the greatest hope of

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3 improving patient safety.¹¹⁻¹³ We note the identification of limitations in the literature such as
4 those identified by Kaplan et al. 2010,¹⁴ including the lack of a practical conceptual model, the
5 lack of clear definitions of contextual factors and the lack of well-specified measures. This
6 protocol details the processes of a systematic literature review that aims to identify the
7 organisational and cultural factors^{9 15} affecting the adoption and success of hospital-wide
8 interventions in acute hospitals, and to assess the effects of those factors on patient outcomes.
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17 **METHODS AND ANALYSIS**

20 **Search Strategy**

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22 We will search MEDLINE, CINAHL, EMBASE, Web of Science, PsychInfo, Global Health,
23 using Medical Subject Headings and keywords, from 1946, 1991, 1947, 1934, 1967, 1910,
24 respectively to September 2012. The general search strategy is shown in Box 1 and the subject
25 heading will be adjusted for each database. We will use multiple terms to identify culture and
26 intervention. The search will be restricted to English language articles (access to translation
27 services is not available for the review), however we note that a recent systematic review of
28 empirical studies on the effect of English-language restriction on systematic reviews found "no
29 evidence overall of a systematic bias from the use of language restrictions in systematic review-
30 based meta-analyses in conventional medicine."¹⁶ In addition to searching the specified
31 databases, to check that the database searches have not missed any studies that may be relevant
32 to our review we will hand search the journals, JAMA, BMJ, BMJ Quality and Safety, Lancet,
33 New England Journal of Medicine and Implementation Science, separately for the last five years
34 (from 2007-2012). The topic of hospital-wide interventions is broad and complex, and it is
35 possible that relevant articles may be classified differently to the review search terms. The hand
36 search will serve to check that our search criteria are broad enough, and that an extension of the
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3 search criteria is not required. These peer-reviewed journals were chosen as the most likely to
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5 publish studies that meet the inclusion criteria, in particular, validated patient outcomes. We will
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7 also hand search the reference lists of the relevant Cochrane systematic reviews. Two researchers
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9 will conduct the hand search; if disagreement about inclusion of a study occurs a third researcher
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11 will arbitrate.
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14 15 16 **Box 1. General search strategy**

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60 | <ol style="list-style-type: none">1. Organisational culture OR organisational climate OR organisational context OR organisational characteristics OR workplace culture OR organisational goal OR organisational value2. AND [(adopting organisation) OR (adherence to protocol) OR (organisational innovation) OR (diffusion of innovation) OR (intervention) OR (diffusion) OR (organisational change) OR (protocol change) OR (practice change) OR (structure change) OR (adoption) OR (leadership)]3. AND (patient outcome)4. AND [healthcare organisation OR hospital OR healthcare facility] |
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32 **Study Selection and exclusion criteria**

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34 Under the review's inclusion and exclusion criteria, research must focus on a hospital-wide
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36 intervention, i.e., mere implementation in the operation theatre, a few general units or ICU is not
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38 sufficient. Other inclusion criteria include investigating the organisational factors that may affect
39
40 the implementation. Studies should also provide patient outcome data before and after the
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42 hospital-wide intervention. The review will only include interventions in an acute care setting,
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44 i.e., rehabilitation centres, primary health cares, ambulatory services, and psychiatric facilities
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46 will be excluded. Other inclusion criteria include that the study report on empirical research, in
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48 peer reviewed, English language, scholarly journals, and that abstract and full text are available.
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50 The 'grey literature' will be excluded as it is unlikely to yield study designs that meet inclusion
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60 criteria.

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3 We will not limit our search to randomised controlled trial studies, since we believe
4 observational studies and controlled before and after studies -- with validated data about patient
5 outcomes -- can provide useful information to identify the organisational and cultural
6 determinants of hospital-wide interventions.
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13 References identified in the search will be reviewed for inclusion by two researchers. Studies
14 will be excluded only after discussion between at least two reviewers, who will assess and agree
15 on the inclusion and quality rating of the studies. The methodological quality of the reported
16 research will be assessed in accordance with Cochrane Collaboration guidelines.¹⁷ The quality of
17 the reporting of the identified studies will be assessed using appropriate critical appraisal tools,
18 such as CONSolidated Standards of Reporting Trials (CONSORT),¹⁸ Strengthening the Reporting
19 of Observational Studies in Epidemiology (STROBE)¹⁹ or Preferred Reporting Items for
20 Systematic Reviews and Meta-Analyses (PRISMA).²⁰ All papers excluded by consensus will be
21 depicted in a document explaining reason for exclusion. Our review will be conducted according
22 to PRISMA guidelines^{20 21} and literature selection will be presented in a PRISMA flow chart.²⁰
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Participants

Participating hospitals may include any acute care facility, including metropolitan or rural, and private or public hospitals.

Type of interventions

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3 As noted, we will only include interventions that are hospital-wide and are associated with
4 patient outcomes through validated data collected before and after implementation of the
5 intervention. Also, the organisational elements of the intervention should have been explained in
6 the study to make it qualified for our review.
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12 13 **Comparisons**

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15 Comparisons may include acute hospitals with similar nursing-patient ratio, size and region with
16 no intervention.
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21 22 **Types of outcome measures**

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24 Patient outcomes may include mortality rate, the rate of adverse events, patient satisfaction, and
25 infection rate.
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30 31 **Assessment of risk of bias**

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33 Two reviewers will independently assess risk of bias in eligible studies as outlined in the
34 Cochrane Handbook for Systematic Reviews:¹⁷ selective outcome reporting, and blinding of the
35 research personnel to data collection and analysis. For any non-randomised trials included in the
36 review, the authors will assess any selection bias that may lead to confounding of the outcome.
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38 Disagreement regarding assessment of risk of bias will be resolved through discussion between
39 two reviewers. If consensus is not reached, a third reviewer will be consulted.
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49 50 **Data Collection and Analysis**

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52 Using a standard form created for the review, one author will extract summary descriptive data
53 from these studies. The same author will compile a tabular presentation the study participants
54 and setting, objective, design and method, type of hospital-wide intervention,
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3 organisational/cultural factors, patient/process outcomes, and findings. The second author will
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5 independently review this documentation for accuracy and completeness.
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9 10 **Strategy for data synthesis**

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12 If suitable data are available, a meta-analysis will be completed; however it is likely that
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14 included studies will be heterogeneous in nature. Where trial data cannot be combined, two of
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16 the authors will conduct a narrative synthesis of the findings in accordance with the review
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18 objectives. We will discuss characteristics of the studies and stratify the results according to the
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20 type of hospital-wide interventions, organisational factors associated with them, and outcomes
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22 measured.
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25 26 **Limitations**

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28 The review findings will be limited by the number and quality of studies identified by the search
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30 strategy. A potential limitation is in selection of the search terms. The concept of a ‘hospital-
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32 wide intervention’ is subject to classification, and it is possible that studies could be published
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34 that would meet our inclusion criteria, but are not identified by the search engines due to use of
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36 alternate terms or categorisation. We have attempted to ameliorate this with a hand search over
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38 the last five years of six prominent general medical journals that we believe are likely to publish
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40 studies relevant to our review. The hand searching provides an additional check on the reliability
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42 of the search strategy of the electronic databases and will serve to check that an extension of the
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44 search criteria is not required. By restricting the search to English language articles we are also
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46 potentially eliminating relevant studies from inclusion in our review.
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52 53 **ETHICS AND DISSEMINATION**

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56 Ethics is not required given the protocol is a systematic literature review. The findings of this
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3 review will be disseminated through mechanisms including peer-reviewed publications and
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5 conference presentations. The PRISMA checklist²⁰ will be used for writing the final review.
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9 **ACKNOWLEDGEMENTS:** We acknowledge Dr. Isla Hains from the Centre for Health
10
11 Systems and Safety Research in the Australian Institute of Health Innovation who provided
12
13 guidance regarding the search strategy.
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17 **COMPETING INTERESTS:** The authors have no conflict of interest to declare.
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20 **AUTHORS' CONTRIBUTIONS:** All authors contributed to the design, drafting and revision
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22 of the paper, and approved the final version to be published.
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The role of organisational and cultural factors in the implementation of system-wide interventions in acute hospitals to improve patient outcomes: a systematic literature review

Authors:

Hadis Nosrati, PhD Research Fellow ¹
Robyn Clay-Williams, PhD Research Fellow ²
Frances Cunningham, ScD Senior Research Fellow ²
Ken Hillman, Professor and Director ¹
Jeffrey Braithwaite, PhD Professor and Director ²

Affiliations:

1 The Simpson Centre for Health Services Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia
2 Centre for Clinical Governance Research
Australian Institute of Health Innovation
University of New South Wales
Sydney, Australia

Contact details of corresponding author:

Dr Robyn Clay-Williams
Business: + 614 2158 2638
Fax: + 612 9663 8692
Mobile: + 614 2158 2638
Email: r.clay-williams@unsw.edu.au
Address: Australian Institute of Health Innovation Faculty of Medicine University of New South Wales Sydney NSW 2052, Australia

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3 **The role of organisational and cultural factors in the implementation of system-wide**
4 **interventions in acute hospitals to improve patient outcomes: a systematic literature review**
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8 **ABSTRACT**
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11 **Introduction:** Little is known about the role of organisational culture in the success and
12 sustainability of the hospital-wide interventions, and how local culture affects patient outcomes
13 in acute hospitals.
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18 **Methods and analysis:** A systematic literature review will be conducted to identify
19 organisational factors influencing hospital-wide interventions and patient outcomes. A search of
20 English language articles will be performed in MEDLINE, CINAHL, EMBASE, Web of
21 Science, PsychInfo and Global Health databases using Medical Subject Headings and keywords.
22 Randomised controlled trials, quasi-randomised trials, controlled before and after design studies
23 and interrupted time-series analysis studies will be included. ‘Grey literature’ will be excluded,
24 however peer reviewed journals that are likely to publish relevant studies (JAMA, BMJ, BMJ
25 Quality and Safety, Lancet, New England Journal of Medicine and Implementation Science) will
26 be hand searched for the last five years. Two reviewers independently will undertake a title and
27 abstract review using inclusion and exclusion criteria. Studies will be excluded only after
28 discussion between at least two reviewers, who will assess and agree on the inclusion, risk of
29 bias and quality rating of the studies. One author will extract summary descriptive data from
30 these studies; the second author will review this documentation for accuracy and completeness. It
31 is likely that the studies will be heterogeneous in nature, therefore a narrative synthesis of the
32 findings will be conducted. We will discuss characteristics of the studies and stratify the results
33 according to the type of hospital-wide interventions, organisational factors associated with them
34 and outcomes measured.
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3 **Ethics and dissemination:** Findings will be reported via peer-reviewed publications, conference
4 and seminar presentations. The PRISMA checklist will be applied. No ethics approval was
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6 required, as this is a literature review only. The protocol has been registered in the international
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8 prospective register of systematic reviews, PROSPERO (Registration No: CRD42013003050).
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For peer review only

ARTICLE SUMMARY

Article focus

- This review aims to identify the organisational factors that affect the implementation of hospital-wide interventions in acute hospitals, and how these organisational factors and hospital-wide interventions influence patient outcomes.

Key messages

- Silos, or vertical structures within hospitals such as wards, units, and departments, are well developed in acute care hospitals, but the system may fail at the intersection between silos for patients with complications of the original illness, which are outside the expertise of the admitting clinician.
- To bridge these intersections and thereby reduce the potential preventable adverse events for an increasingly aged and ill hospital population with comorbidities, organisation-wide patient safety interventions are becoming a major focus of health care delivery.
- Little is known about the cultural and organisational determinants of hospital-wide interventions and their effects on patient outcomes.

Strengths and limitations of this project

- This study aims to increase our knowledge of organisational culture, which we believe is an important element in the success or failure of the implementation of hospital-wide interventions.
- We will investigate how the adoption of a system-wide intervention can affect patient outcomes.

- We will be including observational studies as well as controlled before and after studies in the systematic review, as it is likely they will provide valuable information.
- We include only English language studies.
- Risk of bias will be assessed using standard Cochrane criteria.

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INTRODUCTION

Despite the remarkable advances in healthcare delivery and considerable changes in hospital patient populations and expectations associated with modern medicine, the fundamental organisation of hospitals has changed little into the twenty first century. The system is constructed around the admitting doctor and patient relationship.¹ In acute hospitals, wards are able to manage the day-to-day aspects of a patient's condition, but the system can fail when the patient's condition deteriorates and the admitting doctor no longer has the skills or knowledge to neither recognise nor manage the deteriorating patient.¹⁻³ One of the first organisation wide and patient centred systems, known as the Medical Emergency Team (MET) or Rapid Response System (RRS) has been implemented in many hospitals around the world to address this situation.² When the criteria that define an at-risk or deteriorating patient are met, a team of clinicians with appropriate skills urgently responds to the patient. However, because of the nature of hospitals, and depending on the existence of necessary infrastructure to provide the continuity of care,^{4 5} the effectiveness of the few-implemented hospital-wide interventions, such as an RRS, varies significantly from one health organisation to another.⁶ Ultimately, we are interested in determining why interventions such as MET are successful in some settings but not in others. By examining hospital-wide interventions in acute care systems (including non-MET interventions) via this systematic literature review, we hope to shed some light on the problem.

While there is keen interest in how to optimise and implement the system, little is known about the role of organisational culture⁷⁻¹⁰ in the success and sustainability of the hospital-wide interventions, and how the culture could affect patient outcomes in acute hospitals. Patient safety interventions working at an organisational level that include participative principles, such as the involvement of workers in design and implementation, may provide the greatest hope of

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3 improving patient safety.¹¹⁻¹³ We note the identification of limitations in the literature such as
4 those identified by Kaplan et al. 2010,¹⁴ including the lack of a practical conceptual model, the
5 lack of clear definitions of contextual factors and the lack of well-specified measures. This
6 protocol details the processes of a systematic literature review that aims to identify the
7 organisational and cultural factors^{9 15} affecting the adoption and success of hospital-wide
8 interventions in acute hospitals, and to assess the effects of those factors on patient outcomes.
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17 METHODS AND ANALYSIS

20 Search Strategy

21 We will search MEDLINE, CINAHL, EMBASE, Web of Science, PsychInfo, Global Health,
22 using Medical Subject Headings and keywords, from 1946, 1991, 1947, 1934, 1967, 1910,
23 respectively to September 2012. The general search strategy is shown in Box 1 and the subject
24 heading will be adjusted for each database. We will use multiple terms to identify culture and
25 intervention. The search will be restricted to English language articles (access to translation
26 services is not available for the review), however we note that a recent systematic review of
27 empirical studies on the effect of English-language restriction on systematic reviews found "no
28 evidence overall of a systematic bias from the use of language restrictions in systematic review-
29 based meta-analyses in conventional medicine."¹⁶ In addition to searching the specified
30 databases, to check that the database searches have not missed any studies that may be relevant
31 to our review we will hand search the journals, JAMA, BMJ, BMJ Quality and Safety, Lancet,
32 New England Journal of Medicine and Implementation Science, separately for the last five years
33 (from 2007-2012). The topic of hospital-wide interventions is broad and complex, and it is
34 possible that relevant articles may be classified differently to the review search terms. The hand
35 search will serve to check that our search criteria are broad enough, and that an extension of the
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3 search criteria is not required. These peer-reviewed journals were chosen as the most likely to
4 publish studies that meet the inclusion criteria, in particular, validated patient outcomes. The
5 ~~search will be restricted to English language articles (the authors do not have resources for~~
6 ~~translation) and we will hand search the journals, JAMA, BMJ, BMJ Quality and Safety, Lancet,~~
7 ~~New England Journal of Medicine and Implementation Science, separately for the last five years~~
8 ~~(from 2007-2012). The peer reviewed journals were chosen as the most likely to publish studies~~
9 ~~that meet inclusion criteria, in particular validated patient outcomes. Although PLOS Medicine~~
10 ~~and BMJ Open are also likely to publish studies that meet our criteria, both are open access~~
11 ~~online journals with all articles linked to PubMed at time of publication, therefore we expect that~~
12 ~~the online search engines will capture relevant papers from these journals.~~ We will also hand
13 search the reference lists of the relevant Cochrane systematic reviews. Two researchers will
14 conduct the hand search; if disagreement about inclusion of a study occurs a third researcher will
15 arbitrate.

Box 1. General search strategy

1. Organisational culture OR organisational climate OR organisational context OR organisational characteristics OR workplace culture OR organisational goal OR organisational value
2. AND [(adopting organisation) OR (adherence to protocol) OR (organisational innovation) OR (diffusion of innovation) OR (intervention) OR (diffusion) OR (organisational change) OR (protocol change) OR (practice change) OR (structure change) OR (adoption) OR (leadership)]
3. AND (patient outcome)
4. AND [healthcare organisation OR hospital OR healthcare facility]

Study Selection and exclusion criteria

Under the review's inclusion and exclusion criteria, research must focus on a hospital-wide intervention, i.e., mere implementation in the operation theatre, a few general units or ICU is not

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3 sufficient. Other inclusion criteria include investigating the organisational factors that may affect
4 the implementation. Studies should also provide patient outcome data before and after the
5 hospital-wide intervention. The review will only include interventions in an acute care setting,
6 i.e., rehabilitation centres, primary health cares, ambulatory services, and psychiatric facilities
7 will be excluded. Other inclusion criteria include that the study report on empirical research, in
8 peer reviewed, English language, scholarly journals, and that abstract and full text are available.
9 The 'grey literature' will be excluded as it is unlikely to yield study designs that meet inclusion
10 criteria.
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23 We will not limit our search to randomised controlled trial studies, since we believe
24 observational studies and controlled before and after studies -- with validated data about patient
25 outcomes -- can provide useful information to identify the organisational and cultural
26 determinants of hospital-wide interventions.
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34 References identified in the search will be reviewed for inclusion by two researchers. Studies
35 will be excluded only after discussion between at least two reviewers, who will assess and agree
36 on the inclusion and quality rating of the studies. The methodological quality of the reported
37 research will be assessed in accordance with Cochrane Collaboration guidelines.¹⁷ The quality of
38 the reporting of the identified studies will be assessed using appropriate critical appraisal tools,
39 such as CONSolidated Standards of Reporting Trials (CONSORT),¹⁸ Strengthening the Reporting
40 of Observational Studies in Epidemiology (STROBE)¹⁹ or Preferred Reporting Items for
41 Systematic Reviews and Meta-Analyses (PRISMA).²⁰ All papers excluded by consensus will be
42 depicted in a document explaining reason for exclusion. Our review~~his process~~ will be conducted
43 according to PRISMA guidelines^{20 21} and literature selection will be presented in a PRISMA
44 flow chart.²⁰ The selection criteria may limit the generalisability of study findings, however the
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3 scope of the search is appropriate to identify the majority of articles published in the peer review
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5 literature and meeting the study criteria.
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8 9 **Participants**

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11 Participating hospitals may include any acute care facility, including metropolitan or rural, and
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13 private or public hospitals.
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16 17 **Type of interventions**

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19 As noted, we will only include interventions that are hospital-wide and are associated with
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21 patient outcomes through validated data collected before and after implementation of the
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23 intervention. Also, the organisational elements of the intervention should have been explained in
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25 the study to make it qualified for our review.
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29 30 **Comparisons**

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32 Comparisons may include acute hospitals with similar nursing-patient ratio, size and region with
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34 no intervention.
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38 39 **Types of outcome measures**

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41 Patient outcomes may include mortality rate, the rate of adverse events, patient satisfaction, and
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43 infection rate.
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47 48 **Assessment of risk of bias**

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3 Two reviewers will independently assess risk of bias in eligible studies as outlined in the
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5 Cochrane Handbook for Systematic Reviews:¹⁷ selective outcome reporting, and blinding of the
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8 research personnel to data collection and analysis. For any non-randomised trials included in the
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10 review, the authors will assess any selection bias that may lead to confounding of the outcome.
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12 Disagreement regarding assessment of risk of bias will be resolved through discussion between
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14 two reviewers. If consensus is not reached, a third reviewer will be consulted.
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18 **Data Collection and Analysis**

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20 Using a standard form created for the review, one author will extract summary descriptive data
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22 from these studies. The same author will compile a tabular presentation the study participants
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24 and setting, objective, design and method, type of hospital-wide intervention,
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26 organisational/cultural factors, patient/process outcomes, and findings. The second author will
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28 independently review this documentation for accuracy and completeness.
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34 **Strategy for data synthesis**

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36 If suitable data are available, a meta-analysis will be completed; however it is likely that
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38 included studies will be heterogeneous in nature. Where trial data cannot be combined, two of
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40 the authors will conduct a narrative synthesis of the findings in accordance with the review
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42 objectives. We will discuss characteristics of the studies and stratify the results according to the
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44 type of hospital-wide interventions, organisational factors associated with them, and outcomes
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46 measured. ~~We anticipate that we will not be able to use a quality assessment tool to formally~~
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48 ~~assess the quality of the studies due to their heterogeneous nature.~~²⁰²¹¹⁷
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53 **Limitations**

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3 The review findings will be limited by the number and quality of studies identified by the search
4 strategy. A potential limitation is in selection of the search terms. The concept of a ‘hospital-
5 wide intervention’ is subject to classification, and it is possible that studies could be published
6 that would meet our inclusion criteria, but are not identified by the search engines due to use of
7 alternate terms or categorisation. We have attempted to ameliorate this with a hand search over
8 the last five years of six prominent general medical journals that we believe are likely to publish
9 studies relevant to our review. The hand searching provides an additional check on the reliability
10 of the search strategy of the electronic databases and will serve to check that an extension of the
11 search criteria is not required. By restricting the search to English language articles we are also
12 potentially eliminating relevant studies from inclusion in our review. In particular, limiting the
13 hand search to restricted access general medicine publications that are likely to publish studies
14 with validated patient outcomes places reliance on the search engines to deliver relevant papers
15 from open access online publications such as BMJ Open and PLOS Medicine.
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36 ETHICS AND DISSEMINATION

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39 Ethics is not required given the protocol is a systematic literature review. The findings of this
40 review will be disseminated through mechanisms including peer-reviewed publications and
41 conference presentations. The PRISMA checklist²⁰ will be used for writing the final review.
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47 **ACKNOWLEDGEMENTS:** We acknowledge Dr. Isla Hains from the Centre for Health
48 Systems and Safety Research in the Australian Institute of Health Innovation who provided
49 guidance regarding the search strategy.
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55 **COMPETING INTERESTS:** The authors have no conflict of interest to declare.
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