A systematic literature review to support a framework for the development of standards for clinical practice guidance

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National Clinical Effectiveness Committee (NCEC)

The NCEC is the National Clinical Effectiveness Committee. It was set up as part of the Patient Safety First Initiative in September 2010. The NCEC’s mission is to provide a framework for national endorsement of clinical guidelines and audit to optimise patient and service user care. The NCEC has developed and provided a mechanism for the prioritisation and quality assurance of clinical guidelines so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines. Further information on the NCEC is available at www.health.gov.ie/patient-safety/ncce

The NCEC was requested by the Minister for Health to develop standards for clinical practice guidance as per recommendation 19 of the Portlaoise Report 2014.¹ This is to ensure consistency of approach and utilisation of appropriate methodology to develop clinical practice guidance nationally.

The NCEC sought invitations to tender for a systematic literature review to support a framework for the development of standards for clinical practice guidance.

Membership of the Research Advisory Steering Committee

Dr Kathleen Mac Lellan, National Clinical Effectiveness Committee, Department of Health, Ireland
Dr Mary O’Riordan, National Clinical Effectiveness Committee, Department of Health, Ireland
Dr Jenifer Martin, Health Service Executive
Ms Aveen Murray, Health Service Executive

¹ HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date). Report to the Minister for Health, Dr. James Reilly TD from Dr. Tony Holohan, Chief Medical Officer, 24th February 2014
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<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>AGREE</td>
<td>Appraisal of Guidelines for Research and Evaluation</td>
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<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
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<td>NCEC</td>
<td>National Clinical Effectiveness Committee</td>
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<td>NICE</td>
<td>National Institute for Health and Clinical Effectiveness</td>
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<tr>
<td>PICOS</td>
<td>Population, Intervention, Comparison, Outcomes of interest, and Setting</td>
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<tr>
<td>RCT</td>
<td>Randomised Control Trial</td>
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<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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<td>MRSA</td>
<td>Methicillin-Resistant Staphylococcus Aureus</td>
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<td>IOM</td>
<td>Institute of Medicine</td>
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<td>EBP</td>
<td>Evidence Based Practice</td>
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<td>EPA</td>
<td>European Pathways Association</td>
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<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>PBMA</td>
<td>Programme Budgeting and Marginal Analysis</td>
</tr>
<tr>
<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
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<tr>
<td>GIT</td>
<td>Gastrointestinal Tract</td>
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<tr>
<td>SORT</td>
<td>The Strength of Recommendation Taxonomy</td>
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<tr>
<td>QUADAS</td>
<td>Quality Assessment of Studies of Diagnostic Accuracy</td>
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<tr>
<td>GRADE</td>
<td>Grading of Recommendations Assessment, Development and Evaluation</td>
</tr>
<tr>
<td>IPDAS</td>
<td>International Patient Decision Aid Standards</td>
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<tr>
<td>VAP</td>
<td>Ventilator-Associated Pneumonia</td>
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Executive Summary

Patient safety and quality assurance is a priority across all components of the Irish healthcare system. Clinical guidance documents are systematically developed statements that synthesise the evidence into a usable framework to assist the practitioner and patient in making decisions about the most appropriate health care for the specific clinical context. To date, there has been an emphasis on methodological processes for the development of guidelines with less emphasis placed upon other guidance types (e.g. pathway, policy, protocol, bundle, standard, algorithm, checklist, decision aid, model of care).

The broad aim of this research was to complete a systematic literature review to support a framework for the development of standards for clinical practice guidance, of varying complexity and scope. Key databases and grey literature sources were searched for systematic reviews which evaluated guidance (guidance, pathway, policy, protocol, bundle, standard, algorithm, checklist, decision aid, model of care) development, implementation, evaluation processes. A total of 51 papers were included in this systematic review. There was considerable variation across the papers reviewed regarding the extent to which the 13 questions relevant to this review were addressed specific to guidance development, implementation and evaluation. Terms were used interchangeably; however definitions, key components and reasons for their development for each guidance type are outlined. The provision of formal guidance facilitates the distillation of empirical data and expert opinion into strategies which can be helpful in the standardisation of approaches to clinical care and decision-making.

At a national level evidence based guidance can be provided through: statements which assist clinical decision making (clinical guidelines); statements of intent (policy), and the articulation of national standards against which practice can be benchmarked. The implementation of guidance in clinical practice can be supported through the use of implementation tools: protocols; algorithms and checklists. Protocols, algorithms and checklists are ordinarily developed alongside guidelines, however in some instances they are developed independently. In terms of national approaches to the organisation and provision of evidence based care, these can include clinical care pathways and care bundles.

Multi-stakeholder involvement was identified as a key requirement for the effective development of guidance. Methodological processes for the development of guidance appeared to generally follow the formats described for guideline development. However no comparative guidance development manuals were sourced or referenced for the guidance types within this review. Quality appraisal tools used were diverse i.e. some were specific to quality assessment of specific research designs; whilst others focused on quality appraisal of systematic reviews.
and others focused on the quality appraisal of guidelines. No tool was sourced within this review that quality appraised guidance types specifically (other than guidelines).

Owing to the lack of level-one evidence, and heterogeneity of methodologies and outcomes, definitive conclusions cannot be made as to the ‘effectiveness’ of the various guidance types reviewed. However, from the analysis of papers within this systematic review it can be surmised that the implementation of guidance had a positive effect on patient outcomes and on the processes of care.

This review revealed barriers and facilitators at the patient, healthcare professional, team, organisation and health system level. Improvements in adherence to clinical guidance could be secured if barriers are tracked and a systems approach is taken to the development, implementation and evaluation of guidance.

Recommendations are made pertaining to the development, implementation and evaluation of guidance.
Chapter 1: Introduction and Review Methods

Structure of Review

The review is divided into 3 sections. In the Introduction and Review Methods herein, the first chapter provides a context for the systematic review and an overview of the methodology used. The findings relating to each guidance type are presented in chapter 2. The discussion and overview of recommendations are outlined in chapter 3. The detailed data extraction tables are provided within the Appendices.

Context

Patient safety and quality assurance is a priority across all components of the Irish healthcare system. The Report of the Commission on Patient Safety and Quality Assurance ‘Building a Culture of Patient Safety’ (Department of Health and Children, 2008) emphasised the need for implementation of nationally agreed clinical standards i.e. having mechanisms to ensure that evidence-based practice is applied in everyday clinical practice. A core element of this involves developing clinical guidance and associated standards and indicators that enable healthcare professionals to monitor their performance at an individual, team and organisation level against nationally, and internationally recognised comparative parameters.

Consistent with the movement towards the standardisation of care, in 2010, the Minister for Health established The National Clinical Effectiveness Committee (NCEC) with representation from a range of stakeholders. These stakeholders included patients, clinicians, patient safety experts, the Department of Health, regulatory bodies, public and private health service providers, and training and education bodies. The role of the NCEC is to prioritise and quality assure National Clinical Guidelines, National Clinical Audit. Further information available at www.health.gov.ie/patient-safety/ncec. Notably, the Health Information and Quality Authority published national quality assurance criteria for clinical guidelines in 2011 and the Health Service Executive (HSE) issued procedures to support the development of policies, procedures, protocols and guidelines in 2012.
Similar initiatives to support the standardisation of guidance provision and/or the development of clinical practice guidance have been established in other countries. These include *The National Institute for Health and Care Excellence (NICE)* in the UK (www.nice.org.uk); *the Scottish Intercollegiate Guidelines Network* in the NHS in Scotland (www.sign.ac.uk); *the Institute of Medicine*, USA (http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx) and the *Health Care Committee* of the National Health and Medical Research Council in Australia (https://www.nhmrc.gov.au/guidelines/).

When patients and their families come in contact with the Irish healthcare system, they expect treatment and care that is evidence based, effective, safe, and of high quality. Underpinning this expectation is the implementation of standards for clinical practice guidance by healthcare professionals across all disciplines (e.g. medicine, nursing, pharmacy, dentistry, occupational therapy, physiotherapy and speech and language therapy). Clinical practice guidance generally comprises of systematically developed statements designed to support practitioners and patients in making clinical decisions (Every et al., 2000; Health Service Executive, 2012; Schünemann et al., 2014). The growth in clinical practice guidance in recent years is characterised by diversity in terms of clinical guidelines, protocols, and care pathways to name but a few. These types of clinical practice guidance vary in scope and complexity. However, regardless of these differences, clinical practice guidance must be underpinned by the best available evidence for practice in the healthcare context. Hiller et al. (2011) note that empirical research into the safety and effectiveness of different courses of clinical action is necessary to guide best practice in healthcare.

In Ireland, the implementation of national standards for clinical practice guidance is in its infancy. To date, six Irish National Clinical Guidelines have been published, which include: *National Early Warning Score* (NCEC 2014a); *Prevention and Control of Methicillin-Resistant Staphylococcus Aureus (MRSA)* (NCEC 2014b); *Clostridium Difficile* (NCEC 2014c); *Irish Maternity Early Warning System (IMEWS)* (NCEC 2014d); *Communication (Clinical Handover) in Maternity Services* (NCEC 2014e), and Sepsis Management (NCEC 2013f). Guideline Development Groups are established through the NCEC for the development of each new national guideline. As more standards for clinical practice guidance are developed, it can be anticipated
that Guideline Development Groups will increase in number. The education of these groups in the methodology of developing standards for clinical practice guidance has already been commenced by the NCEC (2013).

Over the past 15 years, a substantial body of literature on various aspects of clinical practice guidance has emerged, and more recently a growing number of systematic reviews are being published on this topic. There is literature available on:

- Definitions (e.g. De Bleser et al., 2006);
- Updating clinical practice guidelines (e.g. NCEC, 2012; Vernooij et al., 2014; Becker et al., 2014);
- Methods for formulating and grading recommendations in evidence based practice guidance (Canfield and Dahm, 2011; Guyatt et al., 2011; Institution of Medicine of the National Academics, 2011; Bafeta et al., 2013; The Joanna Briggs Institute, 2014) and appraisal of guidelines (e.g. Brouwers et al., 2010; Siering et al., 2013);
- Implementation of evidence based practice (e.g. Kitson et al., 2008);
- Evaluation of the impact of guidance e.g. care pathways (Allen et al., 2009; Deneckere et al., 2012).

Since the early 1990s there has been a growing emphasis on supporting clinicians in the implementation of evidence based practice interventions. In parallel, systematic review methodologies are increasingly being used to source the evidence for clinical guidance. Clinicians, as part of the clinical decision making process, need to have clarity in relation to the source of evidence and the quality of that evidence. Evidence is a somewhat ambiguous concept. Hansen (2014) outlined that the broad perspective of evidence incorporates five areas (1) impact; (2) implementation; (3) attitudinal; (4) economic and (5) ethical evidence. To capture this broad perspective within clinical guidance development, a distinction has been made between “research-based evidence (satisfying the critical reviews of the specific area of research) and practice-based evidence” (as articulated and agreed by consensus by experts within that profession) (Hansen, 2014, p.12). Thus, to help to differentiate between various types of evidence, it is necessary to appraise the available evidence taking account of the quality of the empirical studies and the confidence or
certainty with which recommendations for practice can be made. Empirical evidence in the form of well-conducted systematic reviews of randomised controlled trials (RCTs) and/or meta-analyses are predominantly used to underpin guidance recommendations (Paul and Leibovici, 2014). Some are critical of such evidential hierarchies citing a realist perspective (Pawson, 2006) as being more fruitful. Realist approaches could take into account the reality of clinical practice and the variety of review questions that are not amenable to RCT designs.

Clinical guidance documents are systematically developed statements that synthesise the evidence into a usable framework to assist the practitioner and patient in making decisions about the most appropriate health care for the specific clinical context. The Institute of Medicine Guideline Development Process (IOM, 2011) noted the process of guideline development should be completed by a:

“knowledgeable, multidisciplinary panel of experts and representatives from key affected groups”; “include a systematic review of the existing evidence”; include considerations of “important patient subgroups and patient preferences”; all processes be “explicit and transparent” to minimalize “distortions, biases, and conflicts of interest”; explain logical “relationships between alternative care options and health outcomes” and provide “ratings of both the quality of evidence and the strength of recommendations” and update as “appropriate when important new evidence warrants modifications of recommendations” (p.2).

According to the IOM (2011) the potential benefits of clinical guidelines are only as good as the quality of the clinical guidance development, implementation, and evaluation methodological processes. To date, there has been an emphasis on methodological processes for the development of guidelines with less emphasis placed upon other guidance types (e.g. pathway, policy, protocol, bundle, standard, algorithm, checklist, decision aid, model of care). This desk-based research is therefore timely in preparing a thorough systematic review of evidence underpinning the development, implementation, and evaluation of these types of guidance.
Review Methods

Healthcare decision makers in their search for reliable information increasingly turn to systematic reviews for a summary of the evidence. Such rigorous reviews help to identify, select, assess, and synthesise the evidence, and can help clarify what is known and not known about the potential benefits and harms of health care interventions inclusive of various guidance types.

This desk-based secondary research was undertaken using systematic review methodology guided by the principles of conducting systematic reviews The Cochrane Handbook for Systematic Reviews, and the National Clinical Effectiveness Committee Developers Manual (NCEC, 2013).

Aim and Objectives

The broad aim of this research was to complete a systematic review of literature pertaining to the development, implementation and evaluation of clinical practice guidance (not inclusive of guidelines). The specific objectives of the research were to:

1. Source existing national and international frameworks, guidelines, practice standards, policies, procedures and/or other literature relevant to the development, implementation and evaluation of clinical practice guidance.

2. Appraise and synthesise the evidence to inform recommendations for good practices in the development, implementation and evaluation of standards for clinical practice guidance.

Specific review questions included:

1. What is the spectrum of definitions that exist for clinical practice guidance?

2. What are the core elements of the various types of clinical practice guidance?

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2 The aim of the research was specified by the Department of Health’s National Clinical Effectiveness Unit, within the original tender underpinning the conduction of the review. The broad aim of the systematic review was to provide evidence based information to support a framework for the development of standards for clinical practice guidance, of varying complexity and scope. Such a framework would promote consistency of approach and utilisation of appropriate evidence based approaches and quality assurance measures in the development of practice guidance nationally.

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3. What criteria determine the decision to create a specific type of clinical practice guidance for the spectrum of clinical practice guidance?

4. What expected methodological processes are required for the development of various types of clinical practice guidance, for example, evidence reviews and consultation etc.?

5. What quality measures/criteria are available to examine the robustness of the methodological process utilised to develop the various types of clinical practice guidance?

6. What is the impact of each type of clinical practice guidance on the intended setting? How is that impact validated/assessed? How is each type of clinical practice guidance reviewed and/or audited both in terms of its implementation and the outcomes of that implementation?

7. What are the resource (time/costs) that are associated with each type of clinical practice guidance?

8. What processes are in place for updating the various types of clinical practice guidance?

9. What expertise is required in the development of the various types of clinical practice guidance?

10. Are there particular layout/format considerations pertinent to the various types of clinical practice guidance?

11. What are the strengths and weaknesses of each type of clinical practice guidance?

12. What are the barriers to development of clinical practice guidance?

13. What are the key facilitation factors for the development of clinical practice guidance?

3. Identify examples of good practices nationally and internationally that have been demonstrated to support the development and evaluation of evidence based clinical practice guidance.

4. Present recommendations to support the development of a framework supporting the development, implementation, and evaluation of standards for clinical practice guidance.
Search processes

A full search strategy was developed by the research team in consultation with the librarian on the team to include key terms and their variations. The search strategy for each guidance type was checked by two team members for accuracy. Key terms included a combination of terms associated with “clinical practice guidance” (with the exception of guideline).

Key Terms:
- Guidance
- Pathway
- Policy
- Protocol
- Bundle
- Standard
- Algorithm
- Checklist
- Decision Aid
- Model of Care

For each search, consideration was given to search term combinations using PICOS by identifying: Patient Population or Problem, Intervention (treatment/test), Comparison (group or treatment), Outcomes, and Setting when searching for systematic reviews (and or meta-analysis, meta-synthesis) which have formally evaluated any of the review questions outlined above. It was decided not to use the PICOS concepts in the search strategy for each individual review question given the breadth of guidance being reviewed as well as the breadth of population groups and clinical contexts included within the initial scoping of the search (Table 1, Appendix 1). The PICOS framework is more applicable when addressing a clearly defined clinical question relevant to a defined population group and clinical context (Caldwell et al., 2012).

Full details of the search performed including complete search strings are available in Appendix 1.
Search of Databases and Grey Literature

The published literature was identified by searching the following sources:

**The electronic databases:**
- MEDLINE (hosted by EBSCO)
- CINAHL Plus with Full-Text (hosted by EBSCO) only
- Cochrane Library (www.cochrane.org)

**The search of the grey literature was limited to a systematic search of the selected websites of Major Clearing Houses**
- Australian Government NHMRC
- NHS Quality Improvement Scotland
- DOH Australian Government
- World Health Organisation (WHO)
- US: Institute of Medicine
- Institute for Healthcare Improvement
- United States National Guidelines Clearinghouse
- The Guidelines International Network
- New Zealand Guidelines Group, NLH
- National Library of Guidelines (UK) Includes NICE
- Scottish Intercollegiate Guidelines Network
- Health Technology Assessment (UK and Ireland)

Search approaches used in the search of the grey literature involved the utilisation of “Advanced Search” interfaces where available to include synonyms and the application of limits as stated elsewhere, where possible. A notable limitation of the grey literature is the potential absence of peer reviewed publications and therefore the grey literature is subject to some biases which a peer review process is designed to diminish.

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3 Evidence suggests that the benefit of searching both Embase and Medline varies depending on topics (Falck-Ytter et al., 2012; Bara et al., 1995) but can be minimal. Eisinga et al. (2004), and Paul and Lefebvre (1998) suggest that the inclusion of Cochrane Controlled Trials Register, as part of the main search captures unique Embase records added by Cochrane and therefore reduces duplication of effort.
Inclusion/Exclusion criteria

Papers with the following characteristics were included:

- Meta-analyses, meta-syntheses and systematic reviews which evaluated any one or more types of clinical practice guidance (development, implementation, and/or evaluation) processes/procedures which provided evidence to answer the review questions. Clinical guidance types included for review were: guidance, pathway, policy, protocol, bundle, standard, algorithm, checklist, decision aid, model of care.
- The systematic search was limited to publications in English, published on or after 2009 (i.e. within the last 5 years).

Papers excluded from this review included primary studies, case notes or discussions on the content of various clinical practice guidance, their development, implementation or evaluation processes, or the application of an appraisal tool. Papers pertaining to clinical “guideline” development, implementation, and evaluation were excluded.

Review process

Results of the search process were exported to Endnote (Version 7) where duplicates were identified and removed. Given the large volume of citations returned, one team member initially screened all titles and abstracts to identify papers that were very obviously irrelevant (e.g. left bundle branch block referring to a cardiac problem rather than bundle as a guidance type). At this stage, 5% of excluded records were crosschecked by a second team member to ensure that they had been appropriately excluded. Subsequently the search results for each guidance type were screened by two independent reviewers (i.e. 2 team members allocated to each guidance type) according to the predefined inclusion criteria. Agreement was reached on the full text articles which needed to be sourced. These full text articles were independently evaluated by the same two reviewers for each guidance type. Disagreements were resolved by consensus involving a third reviewer. A record was maintained of all decisions made during this process.

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4 Liberati et al. (2009) referred to such an approach stating “a single person may screen the identified records while a second person independently examines a small sample of them”. Inter-rater reliability between reviewers for this sample of 5% was recorded and was noted to be high.
A summary of the search is provided as a PRISMA flow chart in Figure 1. A total of 51 papers met the inclusion criteria. Details of the papers included are outlined in the “Characteristics of Included Papers” section of Chapter 2.

Quality Appraisal

For this review, we noted the quality of studies included in the systematic reviews as reported by authors as well as the quality of evidence reported and the criteria used to judge this quality where reported. The findings are reported in the next Chapter.

Data Abstraction

Data were presented in tabular format using guidance from The Cochrane Handbook for Systematic Reviews. Data extracted included authors, their country of origin, type of evidence, aim of paper, and data specific to each of the 13 review questions outlined previously. In addition, the reporting of quality of the included studies in each paper reviewed was abstracted and presented within the context of Q.5 in data abstraction tables. A final column was included for general comments and recommendations made by the authors of papers reviewed. For each guidance type, data were extracted by two members of the team independently (i.e. 2 team members allocated to each guidance type). Any disagreements were resolved following discussion between the two reviewers, and a third reviewer as necessary. The indicative data extracted for each guidance type are presented in tabular format (Appendix 3).

Search Output

The search output yielded over 14,465 hits. Following the review process, a total of 51 publications were deemed eligible for inclusion in this review comprising 49 peer reviewed published papers and 2 papers from the grey literature. A flow diagram of search outputs is presented in Figure 1.
Data Synthesis
Evidence retrieved from the search of electronic databases and grey literature pertaining to the 7 types of clinical practice guidance reported in 51 papers overall was synthesised to address the review questions. A narrative summary of findings is presented. Each type of guidance is presented separately in the Results chapter.

Summary
In summary, a systematic review was conducted which sought to appraise and synthesise the evidence to support a framework for the development of standards for clinical practice guidance of varying complexity and scope. The key findings from this review are presented in the next chapter.
Figure 1: The identification, screening, eligibility of publications for inclusion\textsuperscript{5} in the review.

\textsuperscript{5} 51 publications were included in the review (Guidance (0), Pathway (15), Policy (9) Protocol (8), Bundle (4) Standard (2), Algorithm (9), Checklist (4), Decision aid (0), Model of Care (0)).
Chapter 2: Results

Introduction

In this chapter, the results of the systematic review are presented. A narrative summary of the findings is presented in relation to each guidance type.

Characteristics of Included Papers

A total of 51 papers were included in this systematic review, 49 of which were identified in peer reviewed journals and 2 of which were identified in the grey literature. The papers from the grey literature related to algorithms and policies. The majority of papers related to care pathways (n=15) followed by algorithms (n=9) and policies (n =9), protocols (n=8), checklists (n=4) and bundles (n=4), with fewest identified for standards of care (n=2). The papers reviewed represent 7 category types as presented in Table 2. As shown in this table, the majority of papers were systematic reviews on primary studies (n=33). A total of 10 papers included meta-analyses either as the principal purpose of papers (n=4), conducted in conjunction with systematic review (n=5) or as part a systematic review that had meta-analyses as part of the inclusion criteria (n=1).

Table 2. Category of papers for each type of guidance

<table>
<thead>
<tr>
<th></th>
<th>Algorithms</th>
<th>Bundles</th>
<th>Checklists</th>
<th>Pathways</th>
<th>Policy</th>
<th>Protocols</th>
<th>Standards of care</th>
<th>TOTAL</th>
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<td>2. MA</td>
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<td>3. SRs &amp; MA</td>
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<td>4</td>
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<td></td>
<td>10</td>
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<td>4. SRs of SRs</td>
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<td></td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>5. SR of studies</td>
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<td>1</td>
<td>3</td>
<td>8</td>
<td>8</td>
<td>7</td>
<td>1</td>
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<td>6. SR &amp; Expert opinion</td>
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<td>1</td>
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<tr>
<td>7. Paper on developing guidance incl. SRs</td>
<td>1</td>
<td>1</td>
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<td><strong>8</strong></td>
<td><strong>2</strong></td>
<td><strong>51</strong></td>
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</table>

SR = systematic review; MA = meta-analysis.

*Note: 15 papers reviewed on pathways but three papers related to the same body of evidence (Rotter et al., R009; 2010; 2012)
All guidance types, apart from policies, focused on clinical problems, practices or services. The 9 papers on algorithms addressed 7 different contexts: 2 were on wound management and 1 paper on each of the following: basic life support; orthopaedic examination, congenital muscular torticollis; intra-operative haemodynamics indices; constipation in children with autism; and the management of pulmonary dysfunction in critically ill patients. Two of the papers on bundles related to infection control (hand hygiene, central line infections) with the remaining 2 papers on sepsis resuscitation and ventilator associated pneumonia. Of the 4 papers on checklists, 3 were on surgical safety; the fourth paper related to management of children in intensive care units. Regarding care pathways, the 15 papers comprised of 4 on orthopaedic care, 2 on GIT surgery, 2 on hospice/care of the dying, 2 on barriers and/or facilitators, and 1 each on heart failure, children with acute asthma, and 2 that focused on a range of clinical contexts. Each of the 8 protocol papers related to different clinical contexts, namely, perioperative care, ICU, asthma management, emergency care, management of select problems in elderly, cancer care, and broadly on a range of contexts concerning the contribution of nurses to protocol development and implementation. Of the standard of care papers, one was on peri-operative care and one was on emergency care. In contrast to papers on the aforementioned guidance types which focused on specific clinical contexts, most policy papers related to broader issues including national policies on immunisation (n=1); AIDS/HIV (n=2); health (n=1), and transferability of evidence from one country to another (n=1). Three papers were on the use of evidence from systematic reviews by policymakers. Only one paper on policy guidance related to a specific clinical context which was on the management of labour stage for childbirth.

There was considerable diversity across the papers on the extent to which the 13 questions relevant to this review were addressed regarding guidance development, implementation and evaluation. Taken as a whole, the percentage of papers addressing individual questions or part of ranged from 8% (n =4) for Q.8 on updating processes to 62% (n=31) for Q.13 on facilitators to implementing guidance types. An analysis of coverage in terms of the number of papers that addressed each question according to guidance type is presented in Table 3.
Table 3. Number of papers providing data on each question addressed in this Report.

<table>
<thead>
<tr>
<th>Question</th>
<th>Algorithms (n=9)</th>
<th>Bundles (n=4)</th>
<th>Checklists (n=4)</th>
<th>Pathways (n=15)***</th>
<th>Policy (n=9)</th>
<th>Protocols (n=7)</th>
<th>Standards of care (n=2)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1. Definitions</td>
<td>2</td>
<td>3*</td>
<td>2</td>
<td>10</td>
<td>2</td>
<td>5</td>
<td>0</td>
<td>24</td>
</tr>
<tr>
<td>Q2. Core elements</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>11</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>22</td>
</tr>
<tr>
<td>Q3. Decision criteria</td>
<td>7</td>
<td>0</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>23</td>
</tr>
<tr>
<td>Q4. Methodological processes*</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td>6</td>
<td>6</td>
<td>6**</td>
<td>1</td>
<td>29</td>
</tr>
<tr>
<td>Q5. Quality criteria**</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>&amp;/or assessment of quality of studies in review paper</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>10</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>Q.6. (i) Impact i.e. outcomes</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>12</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>29</td>
</tr>
<tr>
<td>(ii) Method of impact validation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>(iii) Implementation audit incl. outcome of implementation</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Q.7 Resource implications (time/cost)</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>Q.8 Updating processes</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Q.9 Expertise needed</td>
<td>5</td>
<td>0</td>
<td>3</td>
<td>8</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>26</td>
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<tr>
<td>Q.10 Layout/format</td>
<td>4</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>Q.11 (i) Strengths</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>11</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>(ii) Weaknesses</td>
<td>6</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>Q.12 Barriers</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>21</td>
</tr>
<tr>
<td>Q.13 Facilitators</td>
<td>5</td>
<td>0</td>
<td>3</td>
<td>7</td>
<td>7</td>
<td>6</td>
<td>3</td>
<td>31</td>
</tr>
</tbody>
</table>

*Most papers addressed development processes, some of which also reported on implementation & evaluation.

** One paper on protocols reported only on implementation process.

*** This includes use of a grading system to assess the quality of evidence relevant to the development of guidance type.

**** Three of these papers relate to one body of evidence (Rotter 2009, 2010, 2011) presented as one paper in Table.

Summary of Quality Appraisal and Grading of Evidence

Papers for inclusion in this review were restricted to systematic reviews. There was considerable variation in the study designs across these reviews and also within the context of each guidance type. Only 2 papers conducted meta-analyses exclusively on RCTs both of which were on pathways (Adamino et al. 2011; Allen et al. 2011). As noted earlier, time constraints in undertaking this review prohibited a quality appraisal of systematic reviews included in this report or a grading of the evidence reviewed. However, we did extract data on these parameters as reported by the authors of included systematic reviews and so it is possible to offer some insights into the quality of studies and grading of evidence.

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6 A fourth definition is provided but is specific to WHO bundle on hand hygiene rather than a definition of bundles per se (Schweizer et al., 2014).
There was considerable variation across papers on how the methodological quality of included studies was assessed. The most common criteria for assessing the quality of studies were explicitly or implicitly based on those recommended by the Cochrane Collaboration in relation to risk of bias (e.g. randomisation generation, blinding, and allocation concealment), applicable to randomised or controlled trials. These criteria were used in 6 papers overall relating to pathways (Chen et al. 2014; Rotter et al. 2012), policies (Perrier et al. 2012), protocols (White et. al 2011) and algorithms (Clark et al. 2011). The next most common set of criteria used was based on the Jadad methodological approach for randomised or controlled trials as evident in 4 papers, 3 of which related to pathways (Barbieri et al. 2009; Kul et al. 2012; Leigheb et al. 2012), and 1 of which related to bundles (Scheizer et al. 2014).

Although the majority of papers across all guidance types stated the criteria used to assess methodological quality of included studies, findings on quality appraisal were not reported in many papers. It was noted however either in the presentation of quality data in some papers (e.g. Leigheb et al. 2012; Scheizer et al. 2014) or in discussion or concluding commentaries (e.g. Allen et al. 2009; Furuta et al. 2012) that the quality of studies was generally poor or low. The reporting of good or high quality studies was evident in a small number of papers only relating to pathways (Adamina et al. 2011; Barbieri et al. 2009), protocols (Stacey et al. 2013) and algorithms (Biederwolf et al. 2013).

The grading of evidence was reported in 9 papers overall including pathways (Leigheb et al. 2012), policies (Yassi et al. 2009), protocols (Yue et al. 2014), and algorithms (Beitz et al.2012; Christensen et al.2013; Feldheiser et al.2012; Furuta et al. 2012; Hanekom et al.2011; van Rijswijk et al.2013). There was little consistency in the approach used to grade the evidence which included the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (Furuta et al.2012; Hanekom et al. 2011; Yassi et al. 2009), the SORT approach i.e. strength of recommendation taxonomy (Beitz et al. 2012; van Rijswijk et al.2013), criteria of the Oxford Centre for evidence based medicine (Felheiser et al. 2012), and level of evidence according to type of study (Christensen et al. 2013; Leigheb et al. 2012; Yue et al. 2014). Although not all 9 papers explicitly presented conclusions on the grading of evidence, recommendations from evidence were graded as strong in 1
paper (Feldheiser et al. 2012), and of limited or low quality (Beitz et al. 2012; Yassi et al. 2009; van Rijswijk et al. 2013).

**Guidance**

The literature search for "guidance" resulted in 818 hits, which were reduced to 32 for full text analysis independently by two members of the team. It was agreed that all papers were outside the scope of this review. The papers used the word "guidance" in a broad context but actually focused on guideline development, implementation and/or evaluation. A number of publications (e.g. Assasi et al., 2014; Becker et al., 2014; Gagliardi et al., 2011) provided interesting perspectives specific to the processes of guideline development and implementation. A systematic review by Assasi et al., (2014) was notable in its review of the most useful and practical approach to address ethical aspects in the provision of clinical guidance. One publication detailed an implementation framework (inclusive of domains, elements and examples which can help with the implementation of a guideline (Gagliardi et al., 2011). Becker et al. (2014) provided an algorithm explicating the decision making associated with guideline updates either scheduled every 3-5 years or on an exceptional basis i.e. as needed. As the term "guidance" was used broadly and did not encompass a particular guidance type, the papers sourced were not included in this report.

**Pathway**

A total of 15 papers on pathway guidance were reviewed with three of these papers reporting on the same body of evidence (Rotter et al., 2009, 2010, 2012). The evidence across all papers is drawn from seven systematic reviews, two meta-analysis, two systemic reviews with meta-analysis, one systematic overview, and one integrative review with systematic appraisal. Overall, the reviews provided evidence on some aspects of care pathway development, implementation and/or

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10 The evidence from Rotter will be presented as one paper
evaluation. However, the majority aimed to provide evidence on the effectiveness of pathways in clinical contexts (Adamina et al., 2011; Allen et al., 2008; Chen et al., 2014; Kul et al., 2012; Leigheb et al., 2012; Leigheb et al., 2013; Lemmens et al., 2009; Phillips et al., 2011; Rotter et al., 2009, 2012; Van Herck et al., 2010).

Definitions of pathways were reported in ten papers with some variations. Most definitions presented in individual papers were drawn from cited references. A consistency noted in four papers is that a definition of clinical pathway was drawn from the European Pathways Association (EPA) either partially (Barbieri et al., 2009; Leigheb et al., 2012; Leigheb et al., 2013; Van Herck et al., 2010) or fully (Kul et al., 2012). As presented by Kul et al. (2012, p. 2 and 3), according to the EPA. Clinical pathways are defined as:

“A complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period”.

The core elements of pathway guidance were extracted from eleven papers. The papers varied on the number of core elements that constitute a care pathway, and on some indicative detail regarding the core elements. However, a general consensus across most papers is that care pathways should be evidence based (Adamina et al., 2011; Allen et al., 2008; Chen et al., 2014; Kul et al., 2012; McConnell et al., 2013; Phillips et al., 2011) and a multicomponent mapping of the patient’s journey of care that is standardised and pre-determined (Adamina et al., 2011; Allen et al., 2008; Chen et al., 2014; Leigheb et al., 2012; Lemmens et al., 2009; Phillips et al., 2011; Rotter et al., 2010, 2012) and involving multidisciplinary teams (Adamina et al., 2011; Allen et al., 2008; Kul et al., 2012). Notably, in four papers (Allen et al., 2009; Kul et al., 2012; Leigheb et al., 2012; Leigheb et al., 2013) the core elements of care pathways were drawn from the EPA’s defining characteristics which were explicitly presented by Kul et al. (2012) as follows:

(i) Explicit statement of the goals and key elements of care based on evidence, best practice, and patients’ expectations and their characteristics;

(ii) The facilitation of communication among team members, with patients and families;
(iii) The coordination of the care process by coordinating the roles and sequencing the activities of the multi-disciplinary care team, patients and their relatives;

(iv) The documentation, monitoring, evaluation of variances and outcomes;

(v) The identification of the appropriate resources. The aim of a care pathway is to enhance the quality of care, across the continuum, by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources.

Only two papers referred to criteria for decisions to create a pathway with reference to quality improvement initiatives relating to service co-ordination and efficiency, practice and role changes; adherence to best practice guidelines, and reducing practice variations (Allen et al., 2009). The need for care pathways to improve patient outcomes was also reported (Allen et al., 2009; Lemmens et al., 2009).

Methodological processes were reported in three papers (Allen et al., 2009; Leigheb et al., 2012; Van Herck et al., 2010) with reference to the development or implementation of care pathways. However, descriptions of methodological processes were limited with reference only to pathway development needing multidisciplinary team involvement and evidence from Cochrane Reviews, applying SIGN guidelines and/or national guidelines summarised into single documents (Allen et al., 2009). Van Herck et al. (2012), with reference to joint arthroplasty reported on the need for a clear, systematic development and implementation approach using the Belgian Dutch 30 step scenario as well as other existing frameworks. Other methodologies specific to implementation of pathways related to having a business management strategy (Allen et al., 2009), conducting staff tutorials and training; conducting a pilot phase (Allen et al., 2009) and having a dedicated co-ordinator role (Leigheb et al., 2012).

None of the papers reported on the use of quality criteria to examine the strength of the methodological methods utilised to develop pathway guidance. Similarly, no paper reported on the methods/processes for updating pathway guidance. However, it was acknowledged that there is a need for on-going evaluation of pathway
efficiency with regard to the development and implementation phase of care pathways (Allen et al., 2009; Philips et al., 2011; Van Herck et al., 2011).

No conclusive evidence can be drawn about resource implications associated with pathway guidance development or implementation which was referred to in terms of financial costs (Allen et al., 2009; Barbieri et al., 2009; Chen et al., 2014; McConnell et al., 2013) and time and effort of staff (Rotter et al., 2009, 2010, 2012). Specifically, McConnell et al. (2013) reported that care pathways will not be generated unless adequate funding is provided for facilitation, education, and training along with audit mechanisms. In addition, it remains unknown as to whether the costs of care pathway development and implementation are justified by any of their reported benefits (Allen et al., 2009; Barbieri et al., 2009).

The level of expertise required to develop and implement pathways was reported in eight papers with consistent evidence on the need for multidisciplinary team involvement (Adamina et al., 2011; Allen et al., 2009; Chen et al., 2014; Leigheb et al., 2012; Lemmens et al., 2009; McConnell et al., 2013; Philips et al., 2011; Rotter et al., 2010, 2012). The need for physician and nursing leadership was identified by Adamino et al. (2011) and a care co-ordinator with responsibility for staff training on implementation (Leigheb et. al., 2012). The need for managerial and researcher expertise was reported in one review only (Rotter et al., 2009, 2010, 2012).

At least one or more features regarding the layout and format of pathways were addressed in four papers. These include: simply formatted for implementation, using a step by step format of a comprehensive and select set of items of care (Adamina et al., 2011), compiled into a single document that incorporates relevant guidelines or protocols (Allen et al., 2009). While, Barbieri et al. (2009) identified the need for pathways to be structured in a standardised manner, the need for flexibility and specificity to accommodate diverse patient needs was noted by Allen et al. (2009). On a similar vein, McConnell et al. (2013) noted that clinical pathways need to be structured in ways that help to understand and explain a vast array of possible factors affecting both their implementation and sustainability.

Given that the majority of papers aimed to synthesise evidence on the effectiveness of care pathways, it is possible to draw some conclusions on the impact of care pathways on a range of outcomes. Clearly, a consistent finding is that clinical care
pathways contribute to better clinical outcomes compared to usual or standard care processes. The most frequently reported outcomes with significant positive effects were: reduced length of hospital stay, evident in eight papers (Adamina et al., 2011; Allen et al., 2008; Barbieri et al., 2009; Chen et al., 2014; Kul et al., 2012; Leigheb et al., 2012; Lemmens et al., 2009; Van Herck et al., 2010); and reduction in post-operative or medical complications or morbidity, evident in seven papers (Adamina et al., 2011; Barbieri et al., 2009; Leigheb et al., 2012; Leigheb et al., 2013; Lemmens et al., 2009; Rotter et al., 2009, 2010, 2012; Van Herck et al., 2010). Significantly positive reductions in mortality rates were observed in three papers (Allen et al., 2008; Kul et al., 2012; Leigheb et al., 2012). A reduction in prescribing errors or improved documentation was also found (Allen et al., 2008; Rotter et al., 2010, 2012). Cost effectiveness was evaluated in five papers, four of which reported positive outcomes (Adamina et al., 2011; Barbieri et al., 2009; Leigheb et al., 2012; Van Herck et al., 2010). Although the evidence points to some positive effects of care pathways, most papers lacked higher order quality evidence in the form of meta-analysis or inclusion of RCTs. Only two papers exclusively drew on RCTs (Adamina et al., 2011; Allen et al., 2009), one of which conducted a meta-analysis (Adamina et al., 2011). A number of authors noted the need for improved study designs to evaluate the effectiveness of care pathways including high quality RCTs (Chen et al., 2014, Lemmons et al., 2009; Rotter et al., 2009, 2010, 2012) that are multi-centred (Leigheb et al., 2012; Leigheb et al., 2013) and addressing a wide range of outcomes (Chen et al., 2014; Leigheb et al., 2012).

The strengths of care pathways were reported in nine papers. A consistent strength reported across the papers is that care pathways enhance quality and effectiveness of healthcare settings, including patient outcomes (Adamina et al., 2011; Allen et al., 2009; Barbieri et al., 2009; Kul et al., 2011, Leigheb et al., 2013; Lemmens et al., 2009; McConnell et al., 2013; Rotter et al., 2010; 2012, Van Herck et al. 2010). Care pathways positively aid organisational improvements through greater efficiency in service delivery, and possibly cost reductions (Adamina et al., 2011). They have the potential to bring about behavioural change (Allen et al. 2009), and allow for standardisation of care (Barbieri et al., 2009). In addition, care pathways increase accessibility outside of specialist services; clarify goals of care with the patient, family and care teams; promote effective multidisciplinary interaction (Van Herck et
provide structure to care processes; promote proactive management and decision making; acts as a benchmarking and audit tool; reduces documentation requirements; assist in identifying further areas for research; helps to address previously challenging care issues; aligns care delivered with policy; can be easily translated into other languages; and promotes the adoption of best evidence care (Phillips et al., 2011). With regard to weaknesses of care pathways, reported in only three papers, little consistency was evident. Care pathways can be complex interventions to develop and implement because of their multifaceted nature (Van Herck et al., 2010), and requirement for strong clinical leadership with the capacity to devote time, as well as having strong financial commitments (Phillips et al., 2011). They may limit flexible approaches to care; be less effective on service quality and efficiency in variable patient journeys (Allen et al., 2009). Likewise, care pathways are often dependent on timely recognition and diagnosis. It is questioned as to whether care pathways can be sustained over time (Phillips et al., 2011).

Barriers to the development and evaluation of pathway guidance were reported in six papers. The uptake of care pathways has been slower in general units than in specialist units due to the complexity of multicomponent elements within a care path, and also slower in care settings involving greater nursing and junior medical staff involvement (Adamina et al., 2011). In addition, low levels of care pathway training, training schedules that failed to respond to high staff turnover, staff shortages, and patients not fulfilling the care pathway criteria presented as further barriers to implementation (Stocker et al., 2013). The complexity of care pathways limits simple application in practice which is often concurrent with other organisational initiatives, therefore, improving or reducing their effects (Barbieri et al., 2009). Other barriers identified were a lack of organisational readiness for and capacity to change, as well as poorly performing teams with lack of interest in organisational improvements (Kul et al., 2012). Clinicians have viewed the introduction of the pathway to be an additional documentation burden and workload (Phillips et al., 2011). Developing a pathway without including improvements in the coordination mechanisms within a team might not lead to improved outcomes, and are often dependent on social context and the circumstances of implementation (Van Herck et al., 2010).

Facilitators to the development and implementation of clinical pathways were included in eight papers. These included: team co-ordination and communication...
(Allen et al., 2009; Van Herck et al., 2010), leadership including a named co-
ordinator or facilitator to support staff training and education (McConnell et al., 2013; Phillips et al., 2011; Stocker et al., 2013). A high level of organisational and senior management support was reported as a facilitator to successful implementation of care pathways (McConnell et al., 2013; Phillips et al., 2011) including reference to an organisational change management approach (Adamina et al., 2011).

In summary, the evidence on the effectiveness of care pathways is promising in terms of improved clinical outcomes especially reducing length of stay and complication rates. Further evaluation research is needed to inform the development, implementation and sustainability of care pathways, as well as outcomes including wider system effects, critical success factors, and the effectiveness of care pathways in particular situations/contexts, with reference to the relationship between context, mechanism and outcome (Allen et al., 2009). There is a need for studies to evaluate care pathways as complex interventions to further understand which mechanisms within the care pathways can actually improve the quality of care (Barbieri et al., 2009; Stocker et al., 2013). Moreover, it is recommended that well-designed multi-centre studies and well selected outcome measures are created to evaluate the effectiveness of care pathways (Leigheb et al., 2012, 2013). It was noted that methodological limitations make it difficult to fully evaluate the impact of the end-of-life care pathway on care of the dying (Phillips et al., 2011). Van Herck et al. (2010) identified the need for development and implementation methods to be as detailed and systematic as possible. Furthermore, assessing the success of implementation is essential to distinguish between implementation failure and intervention concept or theory failure when research results are negative (Van Herck et al., 2010). Stocker et al. (2013) reported on the need for a more robust reporting systems to discover which clinical contexts welcome the care pathways, leading to the development of more responsive and context specific care pathways. Finally, there is an urgent need to adopt a clear and strict definition for care pathways, as they are often confused with other guidance interventions e.g. guidelines, protocols (Kul et al., 2012; Leigheb et al., 2013; Lemmens et al., 2009).

Policy
A total of 9 systematic reviews were included on policy guidance, one of which included the development and piloting of a prototype for policy makers (Lavis et al.,
2010). The aims of the reviews varied in terms of relevance to guidance methodology and collectively provide evidence on some aspects of: policy development, policy implementation and policy evaluation. The context of aims across the reviews included an evaluation of the effectiveness of implementing policies to reduce elective induction of labour (Akinsipe et al., 2012), synthesising information on immunisation policies from around the globe (Bryson et al., 2010), to establish the transferability of evidence (in HTAs) for policy making from one country to another (Lavis et al., 2010), to identify factors that promote the development of evidence based health policy (Morgan, 2010), the use of evidence by decision or policy makers (Orton et al., 2011; Perrier et al., 2011; Wouters et al., 2010) including barriers and facilitators (Oliver et al., 2014).

A definition of ‘policy’ was presented in two papers only. Oliver et al. (2014) defined policy as:

“…decisions made by a state organisation, or a group of state organisations at national, regional or conurbation level” (p. 3 online).

Policy making as defined by Lavis et al. (2010) was presented within two contexts as follows:

“Policy making about the health system relates to governance, financial, and delivery arrangements within which clinical (and public health) programs and services are provided” (p.406).

“Policy making within health systems relates to programs, services, drugs and devices to fund, cover or deliver” (p.406).

The core elements of policy guidance were extracted from four papers. However, there was little consistency apart from two papers which noted that policies should be evidence based (Akinsipe et al., 2012; Morgan, 2010). Other core elements noted in individual papers indicate that policies need to be: statements of harm; benefits; costs; associated uncertainties; differential effects on subgroups (Lavis et al., 2010) linked to national recommendations (Akinsipe et al., 2012) with Government support (Morgan, 2010); and local sensitivity in terms of implementation (Lavis et al., 2010;
Morgan 2010). Policies need to be user friendly (Lavis et al., 2010), representative of multidisciplinary and stakeholder perspectives (Morgan et al., 2010) and human rights based with reference to the context of the AIDS/HIV epidemic in Africa (Wouters et al., 2010). A circular relationship between policy and research was identified by Morgan (2010) such that research informs policy development and is needed for impact evaluation and on-going revision of policy.

At least one or more aspects of policy development were addressed in eight reviews although generally scant in detail in most reviews. Criteria for decisions to create a policy mostly related to national level priorities and were noted to be linked to: health system and patient safety and risk factors (Akinsipe et al., 2012; Bryson et al., 2010); health problem epidemic (Wouters et al., 2010; Yassi et al., 2009) and burden of disease (Bryson et al., 2010; Morgan 2010). Policy recommendations from other countries influenced decisions to create national policies (Bryson et al., 2010) as did national policies influence decisions to create local policies (Akinsipe et al., 2012). Other criteria included: feasibility of recommendations for policy implementation, and evidence of effectiveness (Bryson et al., 2010); economic evaluation or financial sustainability of implementation (Bryson et al., 2010; Orton et al., 2011); public perceptions or opinions (Bryson et al., 2010) and stakeholder pressure (Orton et al., 2011); as well as strategic fit or local competition (Orton et al., 2011).

The methodological processes for developing policies was reported in five reviews (Bryson et al., 2010; Lavis et al., 2010; Orton et al., 2011; Wouters et al., 2010; Yassi et al., 2009) and in one paper for evaluating policy implementation (Akinsipe et al., 2012). Policy development has been informed by systematic reviews of the literature (Bryson et al., 2010; Orton et al., 2011; Yassi et al., 2009), summarised reports from health technology assessments (HTAs) including input from managers and policy makers on how to make systematic reviews user friendly for policy making (Lavis et al., 2010), and analysis of grey literature such as information accessed through Google, clearinghouse policy documents and experts in the area (Orton et al., 2011). In addition, recommendations to Government from national advisory groups which may include open public meetings (Bryson et al., 2010) and widespread and national consultations with multiple stakeholders (Wouters et al., 2010) was reported. Yassi et al. (2009) outlined extensive research conducted prior to undertaking a systematic review to provide guidance on how to accelerate implementation of policies. This
research included a preliminary review of the literature, the development of a concept paper outlining draft policy statements by a Guideline Group, undertaking a major commissioned study in 5 African countries, and a survey of national policies worldwide. In one review, Bryson et al., (2010) noted the use of mathematical modelling to inform policy development. None of the papers reported on the use of quality measures or criteria to examine the robustness of the methodological processes utilised to develop or update policy guidance. Likewise, none of the papers reported on processes used to review or audit policy implementation and the outcomes of that implementation.

With regard to the level of expertise required to develop policies which was reported in five reviews, the evidence was largely consistent on the need for multiple stakeholder involvement such as relevant disciplines, professionals and researchers (Bryson et al., 2010; Morgan et al., 2010; Orton et al., 2011; Perrier et al., 2011). The need for policy makers to be involved in research (Oliver et al., 2014) with researchers and policy makers working together was noted (Orton et al., 2011; Yassi et al., 2009). Reference to resource implications was noted in one review only (Morgan, 2010) stating that validation methodologies from health economics such as Programme Budgeting and Marginal Analysis (PBMA) are needed to promote the development of policies. In terms of the layout of policies, most data related to presentation of evidence by policy makers by researchers such as structured summaries with relevant and tailored take home messages or information (Lavis et al., 2010; Perrier et al., 2011). The availability of web publications of policies from various countries was noted as helpful to informing policy development in countries outside their country of origin (Lavis et al., 2010).

Evidence on the impact of policies was notably scant and reported in one review only (Akinsipe et al., 2012). This review found that the implementation of hospital policies concerning labour management for child birth had positive effects in reducing elective induction rates, caesarean sections and operative vaginal delivery, and neonatal complications. The potential for positive impacts on processes of care was reported as a strength of policies, and particularly policies based on national recommendations because these were found to have more significant outcomes (Akinsipe et al., 2012). None of the reviews reported on weaknesses of policies.
As is evident in four reviews (Morgan, 2010; Oliver et al., 2014; Orton et al., 2011; Wouters et al., 2010), a range of barriers to policy development or implementation were identified. The most common reported barrier related to cost implications followed by human factors such as negative attitudes, lack of time or resources, lack of experience or training in research interpretation and utilisation, conflicts between stakeholders and between policy makers and researchers. Other barriers included limited or lack of scientifically sound evidence to inform policy, time lags between production of research and policy making. At a macro level, barriers included failure to address the complexity of multi-component health systems, and lack of government leadership and commitment to support policy development and implementation. On the other hand, the most frequently reported key facilitators for the development and implementation of policies as evident in seven reviews (Akinsipe et al., 2012; Lavis et al., 2010; Morgan 2010; Oliver et al., 2014; Orton et al., 2011; Perrier et al., 2011; Wouters et al., 2010) related to human factors such as staff empowerment, multidisciplinary involvement and collaboration including researchers and policy makers, commitment and positive attitudes toward changes (see Table 4 for other facilitators reported for guidance overall).

In summary, the evidence to support a framework for the development, implementation and evaluation of policy guidance is piecemeal and scant. The need for further research to better understand best practices in the processes of policy development, policy implementation, and evaluation of impact was a clear message gleaned from most papers reviewed.

**Protocol**

Eight papers were reviewed on protocols. The term *Protocol* is acknowledged to be both ambiguous and generic (Illot et al., 2010). It is frequently used interchangeably with the term *guideline* (e.g. Dexheimer et al., 2014; Yue et al., 2014). Despite this ambiguity, definitions of protocols, as distinct from other guidance types were provided, highlighting how they differ in nature but remain closely related to guidelines and standards. For example Ebben et al. (2013) citing Grol et al. (2005) state:
“…a protocol can be developed, which yields a specification of a guideline and exactly formulates how to act and which steps to follow”.

Yue et al. (2014), in discussing the value of protocols note that they:

“…provide conceptual consistency between International standards”.

They note that a straightforward protocol can address the limitations of NICE guidelines and assist with its implementation at the bedside.

The specificity and precise nature of a protocol is a common theme in the literature, enabling both the standardisation of clinical practice and the reduction of ‘unacceptable variations in practice and outcomes’ (Ilott et al., 2010). They are considered particularly useful in guiding nursing practice (Stacey et al., 2013) and in supporting the expanded roles of nurses/midwives (Ilott et al., 2010). Local needs to standardise care or to restructure a workforce is often the driving force behind the ‘bottom up’ development of protocols, thereby improving the quality of care, patient experience and reducing adverse outcomes (Ilott et al., 2010). ‘Top down’ protocols can also be mandated by international/national professional bodies (Conrardy et al., 2010; Ebben et al., 2013).

Only one paper elaborated specifically on the core elements of a protocol (Stacey et al., 2013) and this was restricted to a nursing perspective. Referring to protocols as “knowledge translation tools”, the authors discussed the need for protocols to be developed based on the best available scientific evidence and formatted for use in clinical practice in specific situations. However Ilott et al. (2010) noted, in their interpretative systematic review of 33 studies that in practice, literature reviews informing the development of protocols were often weak, with no involvement of a librarian and in only one case was a patient involved in the process.

None of the papers specifically reported on the methodological processes of protocol implementation. However, Dexheimer et al. (2014), with reference to the terms ‘guideline’, ‘guidance’ and ‘protocols’ interchangeably, reported that a variety of methods are used to integrate guidance into the clinical workflow. These included:
paper-based implementation; computer-generated implementation with paper based reminders; and computerised reminders such as prompts that were completely electronic. The authors noted that paper-based implementation was most prevalent, and whilst computerised implementation is growing, the benefits of computerisation remain small. Interestingly, a framework developed by Kawamoto et al. (2005) was used by Dexheimer et al. (2014) to examine each method of implementation against evidence-based factors associated with success. Computer-based protocols had significantly more success factors than paper based methods and these factors provide a useful framework for consideration of all guidance types (Appendix 3). Other papers referred to the CAN-IMPLEMENT model (Stacey et al., 2013), IOM standards (Yue et al., 2014), and NICE guidance (Ebben et al., 2013) which are specific to the development of guidelines, as opposed to protocols per se. It was noted that such frameworks are often linear in nature and that a toolbox design may be more useful than a sequential process for outlining the development process so teams can select steps as appropriate (Ilott et al., 2010).

Whilst it is generally agreed that clinical indicators (performance indicators) should be embedded to determine the effectiveness of implementation (Ebben et al., 2013), it is noted that baseline measurement is often either not conducted or poorly reported (Ilott et al., 2010). Graham and Harrison (2005) estimates that only 5% of guidance implemented has been evaluated to determine impact on health outcomes. Methods of evaluating the implementation of protocols include chart audit and observation (Ebben et al., 2013) where primary outcomes such as protocol compliance and clinical indicators relevant to the care process are measured (e.g. patient outcomes/quality of life, length of stay, admissions, medication use, re-hospitalisation and educational outcomes (Dexheimer et al., 2014; White et al., 2011)). However in some cases, for example, where a universal protocol exists (e.g. Conrardy et al., 2010) there remains a need for universal measurement tools to be developed. Conrardy et al. (2010) suggest that mandatory reporting and anonymous reporting of deviations may also be useful. Furthermore, Sinuff et al. (2013) reported that interventions that included protocols (with or without education) were demonstrated to improve continuous process measures.
Adherence to protocols and guidelines varies widely. For example, Ebben et al. (2013) reviewed adherence to international guidelines and protocols in emergency settings noting that mean adherence to guidelines ranged from 7.8-95% in pre-hospital settings, and 0-98% in the emergency department setting. Where recommendations on monitoring were made, this resulted in higher median adherence in pre-hospital settings compared to treatment recommendations. Interestingly, for both settings, cardiology treatment recommendations came with relatively low median adherence percentages. Conrardy et al. (2010) recommended considering the use of more directive language e.g. ‘will do’ as opposed to ‘recommend’ or ‘should’, however they note the effect on compliance, of this change in language has not been measured. Ebben et al. (2013) cautioned against the use of guidance that makes too many recommendations, and recommends the use of algorithms where protocols are complex. They suggested that where strong evidence is available, protocols should make a clear link between recommendations and improved patient outcomes.

Only two papers referred to the resource implications of protocol development, noting that there may be an increased cost associated with time taken for staff to implement new protocols (Yue et al., 2014) and that this increased cost is not generally acknowledged in the literature (Ilott et al. 2010). Ilott et al. (2010) point out that whilst NICE recommends a timeframe of 3-6 months from start to implementation of protocols, this is an underestimation since studies show it takes between 6 months – 3 years, with an average of 15 months. They refer to a four level hierarchy to capture the spectrum of change that must be considered in protocol development, implementation and evaluation. Yue et al. (2014) also note that regular review and update of protocols is required every three years.

Bundle
The idea of care bundles developed from the recognition that healthcare delivery is overly dependent on the individual clinical practitioner’s knowledge, skills and attitudes which, results in approximately 50% of patients not receiving recommended
evidence based care. The concept of bundles was developed by the Institute for Healthcare Improvement (IHI) in order to provide assistance to healthcare workers so that they might more reliably deliver the appropriate care to patients. A bundle is a planned way of improving the practices of care and patient outcomes. Each is a small, straightforward set of evidence-based practices, usually three to five, that when implemented collectively, reliably and consistently, have been proven to improve patient outcomes.

None of the papers specifically refer to criteria used to inform the development of a bundle. However three papers highlighted the use of bundles as a quality improvement intervention targeting a reduction in specific adverse outcomes such as ventilator-associated pneumonia (VAP) (Zilberberg et al., 2009); death in patients with sepsis (Chamberlain et al., 2011) and central line associated bloodstream infections (Blot et al., 2014). A fourth paper examined the impact of bundles specific to improving hand hygiene compliance (Schweizer at al., 2014).

Rather than providing specific definitions of a bundle per se, authors generally referenced IHI or WHO bundles relevant to their area of study e.g. WHO bundle for hand hygiene (Schweizer et al., 2014). Chamberlain et al. (2011) specifically operationalised the term, drawing on a definition developed by Berwick (2006) stating:

“A bundle is a selected set of interventions or processes of care distilled from evidence based practice components that, when implemented as a group, presents a more robust picture of the quality care provided, benchmarks performance and improves patient outcomes”.

There is a general lack of agreement noted regarding the precise minimum and/or maximum number of components that constitute a bundle. Zilberberg et al. (2009) and Blot et al. (2014), refer specifically to the IHI definition, suggesting that they are generally made up of 3-5 practices proven to improve patient outcomes when performed collectively and reliability. Whereas Schweizer et al. (2014) reported from a meta-analysis of hand hygiene bundled interventions that the number of components ranged between 2 and 7, with a mean of three per bundled intervention.

None of the papers elaborated on the methodological processes or quality criteria used to develop and/or implement the bundle. They did not make any recommendations regarding the level of expertise required to develop, implement or evaluate a bundle. Nor did they give any consideration to the resource implications associated with their development, implementation and/or evaluation. The preferred procedure for updating a bundle was not discussed.

There is a low level of evidence that suggests that care bundles may be effective in reducing the risk of adverse outcomes associated with the use of central lines in ICU (Blot et al., 2014), improve survival in patients presenting with sepsis (Chamberlain et al., 2011), increase compliance with hand hygiene (Schweizer et al., 2014) and reduce VAP incidence (Zilberberg et al., 2009). However, in all cases, the paper authors have each urged caution in the interpretation of the findings due to a lack of randomised and controlled studies upon which to make firm recommendations. We concur with this cautiousness. In addition the papers reviewed have either not demonstrated an optimal bundle of components to reduce risk and standardise compliance or in cases where suggestions have been made, the design of the studies included in the review are methodologically weak. There is some evidence that the effect of a bundle may be greater when combined with a checklist (Blot et al., 2014) and in hand hygiene specific bundles, improved compliance was noted where bundles included education, reminders and feedback (Schweizer et al., 2014).

Whilst it has been suggested that the design, implementation and evaluation of care bundles should be rooted within a quality improvement framework as opposed to aligning outcomes to research, the lack of methodological rigour suggests a need for
investment in additional high-quality research studies of intervention and outcomes associated with bundle design and implementation.

**Standard**

Two papers were reviewed on standards of care guidance; i.e. a systematic review specific to peri-operative systems standards of care (Lee et al., 2011) and a report on a 3 year project inclusive of a systematic review and Delphi type surveys specific developing quality indicators for minimal standards of care for older adults in emergency departments (Carpenter et al., 2011). Definitions of standards of care were not provided in either paper. Core elements specific to peri-operative systems were outlined by Lee et al. (2011) which collectively point to characteristics of: whole systems approach; standardisation of care; prioritisation of care; pre-determined care planning. Criteria for creating standards of care included the need for evidence based standards of care; supporting a quality improvement agenda (Carpenter et al., 2011) and evidence of improvements in care processes (Lee et al., 2011).

Only one paper reported on methodological processes towards developing standards of care (Carpenter et al., 2011) with reference to using a multi-staged approach involving the establishment of a Task Force, identification of target areas for improvement, undertaking systematic reviews by content experts yielding critical evidence summaries, and finally Delphi-style surveys at scientific meetings. As described by Carpenter et al. (2011), this process seemed to be the preliminary steps for developing standards of care. The actual processes for completion of standards of care were not described. As evident in the development processes described by Carpenter et al. (2011) the level of expertise required includes multi-disciplinary teams and content experts, the latter needed to source and synthesise evidence from the literature. Evidence on layout and format considerations was not detailed in either of the two papers. Likewise, evidence on costs and resource implications of developing or implementing standards of care were not reported in either paper, although Lee et al. (2011) provided data on cost effectiveness as an outcome.

Evidence on impact was reported by Lee et al. (2011) regarding peri-operative standard model of care with reference to positive outcomes in relation to reduced
lengths of hospital stay, decrease in surgery cancellation rates, fewer tests ordered, reduced number of medical specialist consultations, and reduced costs. Some conflicting or inconclusive findings were also reported in relation to patient satisfaction, quality of life, and complications or morbidity. Notably, this systematic review had very little higher order quality evidence with only two RCTs included.

Data specific to strengths and weaknesses were not presented in either paper although the positive impact of peri-operative systems as a standard model of care as reported by Lee et al. (2011) points to strengths in terms of effectiveness. Barriers to the development of standards of care included lack of high quality research (Carpenter et al., 2011) whereas barriers to implementation phase were noted to be inadequate financial support and staff shortages (Lee et al., 2011). Multidisciplinary consultation and support was identified as a facilitator of successful development and implementation (Carpenter et al., 2011), in addition to the need for change agents as leaders (Lee et al., 2011). Lee et al. (2011) also recommended a systematic and phased approach as being necessary for implementation success.

In summary, the evidence (within this review) to support a framework for the development, implementation and evaluation of standards of care is very scant.

Algorithm

Nine reviews were sourced relating to algorithms. The term algorithm was used in a variety of contexts inclusive of mathematics, computer science, diagnostics to describe step by step calculations/procedures; computer data processing; risk stratification/diagnostics all of which were excluded from this review. Despite this wide use of the term algorithm it is clear that they are valued tools for the implementation of clinical guidance facilitating the standardisation of decision making and associated actions in the healthcare context (Christensen et al., 2013). They have been described as “cognitive forcing strategies” which facilitate “rules based” behaviours (Croskerry et al., 2003 cited in van Rijswijk et al., 2013). Algorithms provide evidence based step-by-step visual interpretation of the decision making and/or associated actions relating to a particular guidance area. Notably the steps within an algorithm are more narrowly defined than in a guideline (Beitz et al., 2012).
Whilst examples of algorithms where provided in some papers, very few reported on the core elements of an algorithm. It is clear however that an algorithm incorporates a series of decision steps or actions. A common feature across most papers is that each step is portrayed with an associated grading of the evidence underpinning that step (e.g. Beitz et al., 2012).

The criteria for the decision to create an evidence based validated algorithm varied and included: provision of a validated evidence based tool for implementation of guidelines (Beitz et al., 2012); clarification of the variance in available guidance (Briassoulis et al., 2011); specificity to assist clinical decision making (Christensen et al., 2013); bridging the gap between evidence and clinical practice (Hanekom et al., 2011); providing guidance as to when a treatment should be discontinued (Beitz et al., 2012); facilitating the systematic comparison of protocolised management approaches to care thus further clarifying the most effective approaches to the provision of care (Feldheiser et al., 2012; Furuta et al., 2012); and expediting the provision of safer health care (van Rijswijk et al., 2013).

The methodological processes required for the development of algorithms was described in one paper as inclusive of creation; validation and assessment of impact (Christensen et al., 2013). There was a general consensus across the papers that the “creation stage” involved a phased approach to searching for the evidence underpinning each step in the algorithm, appraisal of that evidence, creation of a draft algorithm, expert consensus using various modifications of an iterative Delphi approach (with emphasis variably placed on different areas i.e. level of evidence; ethical aspects; clinical relevance; risk; benefit ratios; degree of applicability; and feasibility of applying the algorithm in clinical practice (Feldheiser et al., 2012)). One paper described a six month feasibility testing process which helped identify points of concern within the algorithm which was separate from the validation of the algorithm (Furuta et al., 2012). In Greece, Briassoulis et al. (2011) specifically explored the factors that inhibited the available algorithms as part of the development phase, whilst another publication referenced the use of clinical utility statistics (Biederwolf et al., 2013). The “validation stage” generally included face validation and content validation. Whilst “evaluation” of the algorithm was described as part of the overall
development process details relating to evaluation methodologies were absent. In one paper the algorithm development process was guided by the IOM (2001) recommendations (van Rijswijk et al., 2013). No evidence was sourced which reviewed the utility of the methodological approaches described.

Development of algorithms is a lengthy process and requires the input of experts. In the papers reviewed these included: expert clinicians (e.g. anesthetists, wound care experts) and authors of peer reviewed publications pertinent to the topic area (Beitz et al., 2012; Feldheiser et al., 2012; Hanekom et al., 2011; van Rijswijk et al., 2013). A wider panel in terms of implementation science and patient experience may address some of the issues relating to application of algorithms in practice contexts.

Layout and format are important considerations in terms of the use of the algorithm in clinical practice. As algorithms are visual aids, Furuta et al. (2012) noted that a smooth-edged box indicated a starting or ending point, a sharp-edged box indicated a predefined process or specific action, and a diamond shape indicated a point of decision. The items in the accompanying text were points of elaboration whose number corresponded to the algorithm item number. Color schemes can be used to draw reader’s attention to critical steps (van Rijswijk et al., 2013).

The impact of algorithms in clinical practice is an important question. However variance in content of algorithms and the presence of variant algorithms for variant situations, clinical presentations can impact on the ability of the practitioner to remember the steps in an algorithm (Briassoulis et al., 2011). Compared with standard conventional haemodynamic management, use of the algorithm considerably reduced length of hospital stay, requirement for ventilation and incidence of prolonged hospital stay, thereby, resulting in reduced hospital costs (Feldheiser et al., 2012). Implementation of an algorithm was associated with alteration of medications, organisation of long term follow-up and an increase in the effective treatment of constipation (Furuta et al., 2012).

In terms of resource implications of algorithm development, implementation or evaluation, only one paper addressed this issue. Implementation of a haemodynamic management algorithm was associated with a reduction in cost and length of hospital
stay (Feldheiser et al., 2012). The importance of including a robust cost-benefit analysis within clinical trials and within the process of algorithm development, implementation needs to be reiterated. Notably none of the reviews made reference to updating processes. Biederwolf et al. (2013) noted that the algorithm should be modifiable as new studies with better data emerge.

The strengths of algorithms are that they can be designed for non-expert use and can improve healthcare outcomes. A great strength of the algorithm is that it captures research evidence and places it in one succinct visual aid (van Rijswijk et al., 2013 p. 38). Weaknesses include: absence of evidence; complex algorithms limit the individual’s ability to recall; algorithms may not include all possible patient clinical presentations (Briassoulis et al., 2011; Feldheiser et al., 2012; Furuta et al., 2012; Hanekom et al., 2011).

Barriers to implementation included: confusion over terminology; absence of evidence; large expert panels leading to difficulty in reaching consensus; application may be limited to particular patient care contexts (Beitz et al., 2012; Hanekom et al., 2011; van Rijswijk et al., 2013). Facilitators included: ease of implementation compared to clinical guidelines; education facilitates implementation; consideration of the impact of the algorithm on clinical work flow; not being litigious; be specific rather than general and in terms of appearance have clarity in flow and appearance (Beitz et al., 2012; Briassoulis et al., 2011; Furuta et al., 2012; van Rijswijk et al., 2013).

In summary, algorithms are evidence based tools that can be used to underpin clinical decision making at the bedside. However, our review indicates that the evidence to support or refute particular steps of an algorithm is limited in some instances and where it is present, the outcomes measured are not clinically relevant. Thus future researchers need to report on clinically pertinent robust outcomes.

Checklist

Checklists are becoming increasing popular tools in healthcare to direct and affirm clinical practice. Their origins stem from the aviation industry, where these short,
simple ‘cognitive tools’ allow for tasks to be completed efficiently and effectively (Winters et al., 2009). When applied in the clinical setting they have been shown to reduce mortality, particularly in the surgical setting (Thomassen et al., 2011). Checklists have been defined as tools that condense a large volume of pertinent information allowing the healthcare professional to identify and reduce errors (Hewson et al., 2006; Hales et al., 2008); they provide a systematic way of verifying that certain procedures are adhered to (WHO, 2008).

None of the four papers reviewed offer a specific definition of checklists. However, one paper references a definition by the WHO (Borchard et al., 2012), while another cites the work of Hewson et al. (2006) and Hales et al. (2008), to introduce the development of a KIDS SAFE checklist (Ullman et al., 2013).

The most widely accepted and applied checklist appears to be the WHO Safe Surgical Checklist with three of the four papers referring directly to either its implementation (Fudickar et al., 2012; Treadwell et al., 2014) or evaluation (Borchard et al., 2012).

Decisions to create a checklist or criteria for development were unambiguously centred on building a safety culture which is akin to its aviation background. Furthermore, three of the papers identified the use of checklists as reducing errors (Fudickar et al., 2012; Ullman et al., 2013; Treadwell et al., 2014), while improving communication and team-working were also reported (Fudickar et al., 2012). One paper also highlighted improving evidence base for practice as a criteria (Ullman et al., 2013).

There was no reference made in any of the four papers on the core elements or minimum/maximum number of components that are required to make up a checklist. There was consensus however, that checklists should only include very essential elements, which need to be elicited from practice and experts within that practice setting (Fudickar et al., 2012; Ullman et al., 2013). Fudickar et al. (2012) also suggests that a checklist should be designed to be completed within 2 minutes.

No paper reported on the methodological process for implementing or evaluating checklists. Equally none of the papers reported on the quality criteria for assessing certain methods, if applied. Furthermore there was a lack of recommendations to
address this knowledge gap. However, one paper outlined a methodology applied to developing a checklist. They described a phased approach which included an initial systematic review, extracting data from hospital incidence report forms and finally convening a Nominal Group Technique, which incorporated the use of an expert panel (Ullman et al., 2013); this method was not evaluated using predetermined criteria.

Resource implications were described in two of the four papers. These related to cost of development and implementation, particularly in terms of environmental adaptations and staff training (Treadwell et al., 2014), and time (Borchard et al., 2012). In contrast, one paper concluded that the implementation of checklists were cost neutral, when the reduction in adverse events and their associated costs were taken into consideration (Fudickar et al., 2012).

Recommendations in relation to level of expertise required to develop and implement checklists were offered in three papers. These studies did not offer a minimum criterion but stated that for development senior physicians, nurses, researchers and patients should be co-opted to the development group (Borchard et al., 2012; Ullman et al., 2013). With regard to implementation, leading physicians and key staff members are required to ensure successful embedding in practice (Fudickar et al., 2012).

There is consensus among the papers included that the format should be structured, standardised, simple and easy to follow. Ullman et al. (2013) suggest that short mnemonics provide an easy method for remembering the various facets of the checklist. No paper offered comprehensive guidance on the design or layout of checklists. Furthermore, the WHO (2008) state that a checklist must be straightforward, concise, evidence-based and applicable to the setting for which it is destined to be applied.

The tangible strengths of checklists in clinical practice were reported in three of the four papers. These included the improvement in inter and intra professional communication and the provision of pertinent information (Fudickar et al., 2012), improvement in patient safety and overall reduction in relative risk of mortality (Borchard et al., 2012; Treadwell et al., 2014). The latter paper offers these conclusions based on the systematic review (n= 22 articles, designs/methods
included survey and observational studies), a higher level of evidence is required before recommendations are made based on these conclusions.

According to the papers included checklists have a number of obvious weaknesses. Of importance is the fear that checklists may replace clinical judgment, especially if there is an over reliance and emphasis on a procedure based culture (Borchard et al., 2012). This has implications not only for successful implementation but also sustainability of checklists in practice, particularly if healthcare professional perceive a corresponding reduction in autonomy. In fact, the impact on autonomy has been categorised as a barrier to implementation (Fudickar et al., 2012). Other barriers encompass general resistance to change, staff attitudes, uncertainty regarding appropriate use (Treadwell et al., 2014) and lack of time (Borchard et al., 2012). Notwithstanding the barriers reported, three of the four papers report on facilitators to checklist development and implementation. Strategies such as designating a specific person to champion the implementation process (Fudickar et al., 2012; Treadwell et al 2014) and simulation based training/education for staff (Fudickar et al., 2012; Borchard et al., 2012; Treadwell et al., 2014) have been described as important implementation tools. Facilitators to evaluation were not reported.

Some specific development stages gleaned from one paper included; literature review, expert panel, local experience, piloting and validation (Ullman et al., 2013). Data gathered from the papers suggest that checklist development and implementation should apply the following principles:

- Ensure the checklist is well designed, short, standardised, related directly to safety risks within the host environment and evidence based (Thomassen et al., 2011; Fudickar et al., 2012; Borchard et al., 2012; Ullman et al., 2013; Treadwell et al., 2014)
- Explicitly state the what, when, how and by whom it should be conducted/completed by (Borchard et al., 2012)
- Conduct a pilot phase (Fudickar et al., 2012; Treadwell et al., 2014)
- Appoint a local champion (Fudickar et al., 2012; Treadwell et al., 2014)
- Organise staff training but specifically simulation based training (Thomassen et al., 2011; Fudickar et al., 2012; Borchard et al., 2012; Treadwell et al., 2014)
• Use stepwise implementation process (real time feedback on error reduction) 
  (Borchard et al., 2012; Fudickar et al., 2012)

The evidence upon which the above summary is based lacks methodological rigour in parts. High quality studies are recommended as is the development of a quality criteria/framework for developing, implementing and evaluating checklists.

**Decision Aid**

As highlighted on Figure 1, the search for Decision Aid generated 1949 hits. On review, 58 were considered potentially relevant for full text analysis, all items were subsequently excluded by both reviewers since the records, whilst important in their own right, could be broadly categorised into three types of evidence relevant to (1) Patient Decision Making Aids; (2) Electronic Decision Support Systems and (3) Healthcare Decision Making (distinct from decision aids per se) e.g. the effectiveness of journal clubs to aid healthcare decision making (Harris et al., 2011). It was unanimously agreed that these themes were areas outside the scope of this study.\(^\text{15}\)

**Model of Care**

The literature search for models of care resulted in 210 papers being considered for review after duplicates were removed. These were reduced to 18 for full text analysis by two researchers and it was agreed that all papers were outside the scope of this review. The papers identified focused on implementation of a specific model of care e.g. Chronic Care Model; the impact of redesign of specific services or staff allocation or on the primary/secondary care interface.

\(^{15}\) For reference, the authors note that in relation to the development of Patient Decision Aids, a special supplement has been published in celebration of the 10\(^{th}\) Anniversary of the International Patient Decision Aid Standards (IPDAS) Collaboration in which 102 authors from 10 countries have made important contributions in this field (Bara et al., 1995).
**Barriers and Facilitators**

Understanding the barriers that impede the translation of evidence into clinical practice will ultimately expedite the implementation of clinical guidance. In responding to the two review questions (Q12, Q13) relating to the barriers and facilitators to development, implementation and/or evaluation of clinical practice guidance, pertinent data was extracted from the papers and reported in tabular format in relation to each guidance type (Appendix 3). In this section a narrative synthesis has been completed. Analyses of barriers to effecting change in clinical practice, reveal that difficulties can arise at different stages in the health-care system: from the level of the patient; the individual health care professional; the health-care team; the health-care organisation; or the wider environment (health services, government or policy context) (Table 4).
Table 4. Barriers and facilitators of CPG development and implementation

<table>
<thead>
<tr>
<th>Level</th>
<th>Factors</th>
<th>Details of Barriers</th>
<th>Facilitators (solution focus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Expectations and experiences</td>
<td>Differing patient/parent/family expectations</td>
<td>Optimise communication. Inclusion of patients as part of the guidance development process.</td>
</tr>
<tr>
<td>Healthcare Professional</td>
<td>Difficulties in accessing, understanding and using research.</td>
<td>Lack of knowledge in research methods and challenges interpreting research. Difficulties in access to research and in managing high volumes of evidence. Scientific uncertainty, sometimes contradictory evidence. Research addressing the question unavailable, irrelevant. Undue focus on RCTs. Time constraints.</td>
<td>Education and training on research methods. Access to clear relevant, reliable research findings. Access to online systematic reviews.</td>
</tr>
<tr>
<td>Guidance development team</td>
<td>Awareness and knowledge of new guidance</td>
<td>Lack of knowledge and awareness of guidance</td>
<td>Guidance development and implementation teams should have access to experts in information science, clinical epidemiology (evidence synthesis), implementation science and systems engineering. Guidance development teams have a valuable role in highlighting research gaps. Limit number of recommendations in new guidance and consider use of algorithm where larger numbers of steps are required. Individual mnemonic(s) can help health care providers remember guidance steps (e.g. checklist). Intuitive user interface with new guidance. Communicate using multimedia e.g. availability of summary statements, accessibility e.g. through emails. Targeted education, training, simulation.</td>
</tr>
<tr>
<td></td>
<td>Attitudes</td>
<td>Perception that guidance places a limit</td>
<td>Staff need to understand the rationale for the</td>
</tr>
<tr>
<td>Level</td>
<td>Factors</td>
<td>Details of Barriers</td>
<td>Facilitators (solution focus)</td>
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<td>on professional autonomy, may limit flexible approaches to care (which are perceived to accommodate diverse patient needs). Resistance to change, concerns regarding legal liabilities, additional workload.</td>
<td>guidance and identified outcome benefits e.g. through evaluation-- track the effect of guidance implementation on prevention of adverse events/error reduction. Details of the outcomes which are to be tracked (where evidence is available) should be included within the guidance.</td>
<td></td>
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<tr>
<td>Human factors</td>
<td>Working in high stress environments, clinical emergency situations, under time pressure reduces compliance with guidance.</td>
<td>Need to understand the human factors linked to error and seek to reduce same (e.g. haste, in-experience, workload, fatigue). Guidance should explicitly address communication and organisation processes.</td>
<td></td>
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<tr>
<td>Healthcare team</td>
<td>Leadership</td>
<td>Absence of Leadership</td>
<td>Leadership and team focus on patient safety and quality care. Active involvement of local opinion leader/ a local champion. A co-ordinator per department, targeted training, assess physicians/others ability to adapt to the new processes and educate/demonstrate use to other staff. Support of management is critical. Facilitate a perception of collective ownership, user involvement in development process creating a culture of evidence based practice.</td>
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<td></td>
<td></td>
<td>Lack of robust economic data</td>
<td>Pilot test on a small scale and then initiate a stepwise implementation process to include real time feedback and consideration of financial and resource utilisation at all stages of the guidance development, implementation and evaluation.</td>
</tr>
<tr>
<td>Healthcare organisation</td>
<td>Local culture and practice</td>
<td>System level: difficulty in applying the evidence to the local context. Conflict between stakeholders, culture of poor communication. Conflicting aspirations of different parts</td>
<td>Identification of system level and cultural barriers. Consider the distinct contextual characteristics associated with the intended care settings. Engage early with governance structures, executive management teams when changing practice.</td>
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<tr>
<td>Level</td>
<td>Factors</td>
<td>Details of Barriers</td>
<td>Facilitators (solution focus)</td>
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<td>of the organisation/system.</td>
<td>Need to balance the interests and values of all stakeholders involved in the continuum of care. Multidisciplinary staff engagement/involvement and stakeholder input in the development process leads to more successful implementation. Consider workflow implications of the guidance, access to resources, avoid duplication of information already routinely collected, integrated ICT. Observe health care providers in their attempt to implement guidance and seek to understand and address their concerns. Use a systems approach to implementation of guidance. Such an approach could be achieved by using technology and the electronic medical record to ensure patients receive the recommended interventions.</td>
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<tr>
<td>Wider environment</td>
<td>Lack of government leadership and commitment</td>
<td>Lack of clarity as to which agencies/departments should bear the costs. Perception of interruption of workflow to facilitate added guidance (e.g. checklist).</td>
<td>Increase collaboration between policy makers and researchers. Decisions regarding guidance prioritisation should include consideration of: variation in treatment among practitioners for the same condition (and if this would be resolved via evidence based guidance); the level of evidence; clinical relevance (the burden of disease, risk: benefit ratio); economic evaluation; ethical considerations and feasibility of applying the guidance. Guideline based upon national recommendations and with government support have more significant outcomes. Guidance integrated into a comprehensive safety plan or systems approach to safety.</td>
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<td>Failure to address multi component</td>
<td>Time lag between research and policy making. Policy makers unskilled in research methods.</td>
<td>Need to determine a governance model that serves the interest of the community while preserving the...</td>
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<tr>
<td>Level</td>
<td>Factors</td>
<td>Details of Barriers</td>
<td>Facilitators (solution focus)</td>
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<td>systems</td>
<td>guidance documents. Multiple guidance, checklists can lead to “checklist fatigue” and ultimately reduce compliance.</td>
<td>autonomy of individual organisations. Guidance developers should collaborate to integrate guidance across conditions that commonly co-exist. Develop a transparent, easily accessible system for centralising the storage and access to guidance across the health system. Guidance documentation to include details of guidance version, update date.</td>
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<td></td>
<td>An absence of systems for monitoring local implementation of guidance and the availability of different codes for the same procedure which make monitoring some practices unreliable.</td>
<td>Consider the process of guidance implementation across the macro, meso and micro level. Consider the length of guidance documentation and accessibility.</td>
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<td>Time and resource constraints</td>
<td>The more complex the guidance the slower the rate of uptake. Some guidance can be considered as a complex intervention thus it is difficult to determine which active components are the determinants of the observed effects. Evaluation of clinical guidance is made more difficult by the lack of transparency on costing of clinical events.</td>
<td>Document and share lessons learnt. Invest in communication. Have an agreed financial model to support the implementation of guidance – particular those that involve multidepartment, multisite, multiagency and those that traverse acute, secondary and tertiary care. Accurate costs for clinical events are fundamental to the creation of health economic models that allow for comparison of treatment options or new intervention pathways. The development of guidance should include plans for evaluation and updates.</td>
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<td></td>
<td>Difficulties in evaluating clinical guidance</td>
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Chapter 3: Discussion

There was considerable variation across the papers reviewed regarding the extent to which the 13 questions relevant to this report were addressed specific to guidance development, implementation and evaluation. Most papers described, discussed and/or evaluated the impact of guidance types, with little available evidence on the methodological processes of development, implementation and/or their evaluation. A comprehensive understanding of the barriers and facilitators associated with guidance has emerged from the literature. These barriers and enablers were largely consistent across all guidance types and settings.

It is clear from this review that the criteria for creating a guidance type include: the implementation of evidence-based health care; modernizing service delivery to take account of established or emerging evidence on a topic area; implementation of policy; concerns about variation in practice; the possibility of litigation, and the promotion of the quality and safety agenda.

There is some evidence to suggest that the development, implementation, evaluation of guidance can be resource intensive in terms of human resources with less evidence available on the associated financial costs. Therefore health care systems should: prioritise areas for guidance development using transparent processes and in doing so should endeavour to centralise resources (e.g. methodological guidance, output of guidance development). In addition economic evaluations and budget impact analyses are needed.
The inclusion of systematic reviews as the primary source of evidence for this report was intended to represent the highest level of evidence for each guidance type. However, the systematic reviews sourced varied in the types of included studies and few were found to have included high-quality randomised controlled trials and meta-analysis. Thus the quality of evidence is limited. A total of 51 papers were included across 7 guidance categories. For three categories no pertinent systematic reviews or meta-analyses were sourced, suggesting a gap in the evidence base regarding the appraisal of development, implementation and evaluation processes of “models of care” and “decision aids” for healthcare staff. The third term “guidance” is a broad term and is most often used to refer to practice guidance in the broadest sense and is a term used interchangeably with guidelines in many instances.

**Definitions for clinical practice guidance**

A lack of agreed definitions for the various guidance types was apparent. Whilst definitions were offered for algorithms, bundles, checklists, pathways, policy, protocols, there was considerable variation between the citations and instances of interchangeable use of terms e.g. protocol and guideline. Key definitions (where available) are presented in Table 5, together with key components to be considered in the development of each guidance type, and the rationale for their development. Alternate definitions where available from the Irish health care context are also presented within the Table 5 for comparison purposes.

A review of the definitions reveals that formal guidance supports evidence-based clinical decision-making. The provision of formal guidance facilitates the distillation of empirical data and expert opinion into strategies which can be helpful in the standardisation of approaches to clinical care and decision-making. Ultimately the provision of formal clinical guidance forms an integral component of a quality assurance programme as their implementation seeks to decrease the amount of variation in clinical practice processes which in turn have been demonstrated (or are strongly believed to) to lead to better healthcare outcomes.

The Commission on Patient Safety and Quality Assurance in 2008 recommended that a leadership role should be developed in relation to the capture and analysis of
international evidence and research, and to the production of evidence-based information and guidance for use in policy-making, system reform and individual patient and professional interactions” p 11. Thus knowledge translation tools are required at national, health service provider and health care practitioner level to support the implementation of evidence based quality patient care.

At a national level guidance can be provided through: evidence based statements which assist clinical decision making (clinical guidelines); statements of intent (policy), and the articulation of national standards against which practice can be benchmarked. The implementation of clinical guidance in clinical practice can be supported through the use of implementation tools such as protocols; algorithms, and checklists. Protocols, algorithms and checklists are developed alongside guidelines, however in some instances they are developed independently.

In terms of national approaches to organisation of care, these can include clinical care pathways and care bundles (Figure 2).

Such implementation tools focus on making explicit the clinical steps in a format that is much briefer and potentially useable by the health care professional. A potential critique of algorithms and protocols is the high degree of certainty (i.e. evidence) each discrete step requires (Beitz et al. 2012).

The development of protocols, algorithms and checklists should be underpinned by a rigorous appraisal of the evidence underpinning the sequence of steps outlined therein. At the health service provider level there needs to be clarity around the benchmarking criteria which are to be used to both assess the impact of implementation of guidance and to ensure that practice is meeting the appropriate national standards.
One method of differentiating between closely related terms is to conduct a concept analysis. Using a concept analysis approach Ilott et al. (2006) distinguished between clinical guideline, care pathway and protocol as follows: clinical guideline relates to “a graded set of recommendations to assist clinical decision making or service planning”; care pathway relates to the mapping of a journey of a typical patient with a specific diagnosis (crosses team and possibly organisational boundaries), and a protocol was defined as a detailed set of instructions (who, why, when and where) regarding a specific intervention/ task. A differentiation is also made in terms of the length of the publications associated with different guidance types with some guidelines running to hundreds of pages resulting in documents which are increasing in complexity and which are difficult to navigate. As a consequence some of the guidance tools (e.g. algorithms, checklists) are more focused on making the evidence accessible to practitioners in the clinical practice context.
<table>
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<tr>
<th>Guidance Type</th>
<th>Definition</th>
<th>Key Components</th>
<th>Reasons for guidance development</th>
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<tr>
<td>Policy</td>
<td>National Health Systems level policy can be considered conceptually as an overarching, higher level set of statements which can relate to governance, financial and delivery arrangements within which clinical (and public health) programmes and services are provided (Lavis et al., 2010). In contrast a clinical policy can be defined as “a written operational statement of intent which helps staff to make appropriate decisions and take actions, consistent with the aims of the service provider and in the best interests of service users (HIQA, 2011, p.11).”¹⁶</td>
<td>• Evidence based.</td>
<td>National Policies</td>
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<td>• National level priorities.</td>
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<td>• Development in other jurisdictions.</td>
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<td>• Response to health system patient safety agenda.</td>
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<td>• Response to stakeholders, public opinion.</td>
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<td>• Identified risks.</td>
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<td>• Disease burden.</td>
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<td>Protocol</td>
<td>Specific and precise step by step approach often used to support the implementation of clinical guidelines which are aimed at reducing variations in clinical practice and outcomes (Ilott et al., 2010; Ebben et al., 2013). “An agreed statement about a specific clinical issue, with a precise sequence of activities to be adhered to, with little scope for variation. Clinical protocols are usually based on guidelines and/or organisational consensus” HIQA, 2011 p.11).¹⁶</td>
<td>• Specific and precise. • Template should meet criteria for guidelines (AGREE II in terms of rigour). • Evidence based. • Formatted for use in clinical situations. • Be integrated into electronic health record.</td>
<td>Local need to standardise care (in particular across care settings).</td>
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<td>• Workforce restructuring.</td>
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<td>• Improve quality of care.</td>
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<td>• Improve patient experience.</td>
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<td>• Reduce adverse outcomes.</td>
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<td>• Mandated by professional bodies.</td>
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<tr>
<td>Bundle</td>
<td>Berwick (2006) definition: “a selected set of interventions or processes of care distilled from evidence based practice components that, when implemented as a group, presents a more robust picture of the quality care provided, benchmarks performance and improves patient outcomes”.</td>
<td>• Usually 3-5 interventions/practice proven to improve patient outcomes. • Mechanisms of increasing health</td>
<td>Reduce adverse outcomes / events.</td>
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<td>• Increase compliance with a process.</td>
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¹⁶ Health Information and Quality Authority (HIQA) (2011). National quality assurance criteria for clinical guidelines. HIQA: Dublin
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<tr>
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<td>Checklist</td>
<td>Tools that condense a large volume of information and allow for systematic verification of steps or practices (Hewson et al., 2006; Hales et al., 2008; WHO 2008).</td>
<td>• Include only essential elements elicited from practice experts. • Brief (approx. 2 min completion time).</td>
<td>• Building a safety culture. • Reducing errors. • Improve communication and teamwork.</td>
</tr>
<tr>
<td>Standard</td>
<td>No definition offered in the literature reviewed for systematic review. A “standard” helps to create a common understanding of the standard of care service users can expect to receive. A national standard provides a strategic approach and a clear benchmark with the aim of improving safety, quality and reliability within the health services (HIQA, 2012).</td>
<td>NR.</td>
<td>• Need for evidence based standard of care. • Supporting a quality improvement agenda. • Evidence of improvements in care processes.</td>
</tr>
<tr>
<td>Algorithm</td>
<td>Algorithms provide evidence based step-by-step visual interpretation of the decision making and/or associated actions relating to a particular guidance area. Notably the steps within an algorithm are more narrowly defined than in a guideline (Beitz et al., 2012).</td>
<td>• Process or specific actions clearly defined. • Navigation through algorithm facilitated through use of symbols. • Colour used to facilitate interpretation and to draw attention to specific points.</td>
<td>• Need for an evidenced based tool for implementation of guidelines. • To clarify the variance in available guidance. • Assist clinical decision making. • Bridge gap between evidence and practice. • Expedite safer healthcare • Enable comparison of approaches and evaluation of care.</td>
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| Pathway       | EPA definition: “A complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period” (Barbieri et al., 2009, p. 2). | - The items in the accompanying text facilitate points of elaboration whose number corresponded to the algorithm item number. | - Quality improvement.  
- Service co-ordination and efficiency.  
- Role and practice changes.  
- Adherence to best practice guidelines.  
- Reducing practice variations.  
- Improve patient outcomes. |
|               | A clinical pathway includes:  
- A structured multidisciplinary plan of care- (mandatory)  
- Is used to translate guidelines or evidence into local structures  
- Details the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other 'inventory of actions'  
- Has timeframes or criteria-based progression  
- Is aimed to standardise care for a specific clinical problem, procedure or episode of healthcare in a specific population.  
An intervention is called a clinical pathway if it meets the first criteria plus three out of the other four criteria (Kinsman et al., 2012). | Based on EPA defining characteristics:  
- Explicit statement of goals, key elements of care.  
- Statement based on evidence, best practice, patients expectations and characteristics.  
- Facilitates team communication.  
- Standardised, pre-determined multicomponent mapping of the patients journey enabling sequencing care process and activities of the MDT and service users.  
- Documents, monitors |
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<tr>
<td>Integrated care pathway (clinical care pathway): “a multidisciplinary care plan that outlines the main clinical interventions that are carried out by different healthcare practitioners for patients with a specific condition or set of symptoms. They are usually locally agreed, evidenced-based plans that can incorporate local and national guidelines into everyday practice” (HIQA, 2011, p.11).</td>
<td>and evaluate variance and outcomes.</td>
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Table 5: Details of guidance type, associated definitions, key components and reasons for guidance development
Methodological processes underpinning the development of various types of clinical practice guidance

The review has demonstrated that the development of clinical guidance is a multistage process. In general guidance development incorporates the following stages:

- Engagement of a multi-stakeholder guidance development team - (consider conflicts of interest)
- Agreement on processes underpinning the development of the guidance
- Formulation of questions and sourcing of evidence
Quality appraisal of the evidence to assist in creating guidance recommendations which are clearly linked to the supporting evidence.

Engaging in an iterative process of guidance development to achieve consensus.

Validation, feasibility testing, piloting of guidance

Implementation phase which is inclusive of education and reminders systems

Evaluation of impact

Plan for update

Some authors note that the development process is not strictly linear, as it appears to be framed in theory and a toolbox to support the process may be more useful (Hanekom et al. 2011; Ilott et al. 2010). In many instances the development, implementation, evaluation processes were reported as separate distinct phases with an absence of a holistic approach from the outset. Consequently the majority of the energy of the guidance development groups seems to be targeted at the development phase. Whilst many of the papers reviewed seemed to be targeted at evaluation of the impact. There is benefit in viewing the three phases as running concurrently so that each is part of the original design of the guidance.

Multi-stakeholder involvement was identified as a key requirement for the effective development of guidance. Guidance development requires access to: content experts (multidisciplinary team leads, pertinent health care professionals, researchers, and service users); methodological expertise (e.g. information specialists, individuals with expertise in systematic review methodology, health economics, and knowledge translation); systems knowledge (quality, safety and risk personnel, individuals with knowledge of informatics and health system processes). The team needs to consider all phases of guidance development from the outset.

Methodological underpinnings of processes used to develop guidance were not well described in the papers reviewed. Reference was made to: Institute of Medicine (2011) Standards for Developing Trustworthy Clinical Practice Guidelines and the CAN – IMPLEMENT guide and resources which were designed to facilitate guideline
adaptation and knowledge activation (Harrison, 2005; den Hoek et al., 2012)\(^\text{18}\). In contrast a comparative review of clinical practice guideline development handbooks (n=19)\(^\text{19}\) revealed that four guideline development handbooks scored over 80% of the maximum possible score; these were developed by the National Institute for Health and Clinical Excellence\(^\text{20}\), Swiss Centre for International Health, Scottish Intercollegiate Guidelines Network (recently updated \(^\text{21}\)) and World Health Organisation\(^\text{22}\). The key tasks identified as critical in guideline development were, “selecting the guideline topic”, ‘determining the guideline scope’, ‘identifying relevant existing guidelines’, ‘involving the consumers’, ‘forming a guideline development group’, ‘developing clinical questions’, ‘systematic search for evidence’, ‘selecting relevant evidence from the searches’, ‘appraising identified research evidence’, ‘making group decision and reaching consensus’, ‘grading available evidence’, ‘creating recommendations’, ‘final stakeholder consultation’, ‘guidelines implementation strategies’, ‘updating recommendations and correcting potential errors’ are the necessary tasks for guideline development”. No comparative guidance development manuals were sourced or referenced for the other guidance types within this review. However, a focused review to search for such manuals (pertaining to the various guidance types) may identify such manuals/handbooks.

A key stage of guidance development was identified as sourcing of evidence (e.g. primary studies, systematic reviews, existing published guidance, grey literature and expert consultation). It is notable that the development of evidence-based guidance is stymied in some instances by the lack of high quality directed research on the subject to support a clear recommendation.

\(^\text{18}\) ADAPTE Collaboration Guideline Resource Centre accessible at: http://www.cancerview.ca/cv/portal/Home/TreatmentAndSupport/TSPProfessionals/ClinicalGuidelines/GRCMain/GRCGDGuidelineAdaptation?_afrLoop=9309277185349000&jsessionid=D5jnrb_RxD-6-EEBUpP DHwT-EP74jdr1402r5HOtV9Oz_EEkvvVc%2197426976&lang=en&_adf.ctrlstate=f2ub2c8tw_85&_afrWindowMod e=0&_adf.ctrl-state=1denevm59j_4


Quality appraisal tools used were diverse i.e. some were specific to a research design; whilst others focused on quality appraisal of systematic reviews and others focused on the quality appraisal of guidelines (e.g. AGREE II). Within this review it was clear that there was a lack of a widely accepted generic tool that can be applied equally well across the quality assessment of various study types. Whilst the AGREE II tool was developed specifically for appraisal of guidelines; no other comparable evaluation tool specific to other guidance types in their totality was sourced within this review. Siering et al. (2014) in a systematic review of guideline appraisal tools identified 40 published guideline appraisal tools. Their review revealed the percentage of criteria covered in each appraisal tool as follows: “evaluation of evidence” (88%), “presentation of guideline content” (85%), “transferability” (83%), “independence” (80%), “scope” (75%), and “information retrieval” (73%), “consideration of different perspectives” (50%) and “dissemination, implementation and evaluation of the guideline” (45%). Only one English language tool included all quality criteria, which was the AGREE II tool.  

A Delphi process may be useful for achieving consensus in the interpretation of the evidence and/or in pooling clinical expertise (i.e. good practice in most situations) in the absence of such evidence. Guidance panels as part of the consensus development process consider the level of evidence, clinical relevance (utility), ethical aspects, risk-benefit analysis, degree of applicability, and feasibility of applying guidance in the practice context. A number of methods can be used to reach consensus. A modified Delphi methodology was the predominant methodology used within this review. Other methods could include: Nominal Group Technique, RAND/UCLA Appropriateness Method (RAM), and National Institutes of Health (NIH) consensus development conference methodology. Each consensus methodology has its unique attributes, and the choice of methodologies depends on: (1) clinical question; (2) audience; and (3) available resources (Nair et al., 2011).

Whilst updating of guidance was only addressed by 8% of the studies reviewed, it was generally accepted that updates are either scheduled every 3-5 years or on an

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exceptional basis i.e. as needed subject to emerging new evidence. Increasingly the move is towards updates occurring as new evidence emerges.

**Impact of clinical practice guidance**

The impact of each guidance type on the intended setting varied amongst each category. Methods of assessing and validating impact, as well as reviewing and auditing of implementation and outcomes were not reported within the reviewed papers. Guidance types relating to organisation of care including pathway implementation showed significant effects on improving outcomes. Such positive effects included a shorter length of hospital stay, decrease in readmissions, reduced morbidity, fewer complications, improved prescribing, improved documentation, earlier mobilisation, and lower hospital costs. In general, bundles had a significant effect within healthcare settings e.g. improved hand hygiene, reduced length of hospital stay, and reduced incidences of ventilator-associated pneumonia.

Only one study evaluating standards of care reported on its impact within a clinical setting. Comparing the implementation of a perioperative system against standard care; showed a significant reduction in the length of stay, decrease in surgery cancellations, reduction in perioperative test, and reduction in hospital costs (Lee et al., 2011). However, it was noted that that the implementation of a new perioperative systems involves substantial changes in hospital organisation, culture, clinical practice and staff behaviours. Likewise, algorithm guidance reported having a substantial impact throughout clinical settings. Compared with standard conventional haemodynamic management, use of the algorithm considerably reduced length of hospital stay, requirement for ventilation, reduction in systolic blood pressure, and incidence of prolonged hospital stay (Clark et al., 2011; Feldheiser et al., 2012). Thus, resulting in reducing hospital costs (Feldheiser et al., 2012). It is noted that algorithm implementation did not interrupt clinic flow and was readily applicable to the clinical context (Furata et al., 2012). Finally, only two studies reported on the impact of checklists on surgical settings only (Fudicker et al., 2012; Treadwell et al. 2014). Impact on these settings included decrease in patient mortality, inpatient complications, avoidance of incidences, increased use in prophylactic antibiotics, and improved safety attitudes. Other impacts identified included reduction in wrong surgery site marking, correct implementation of guidelines, and significant
improvement in knowledge of team names and roles as well as the patient’s identity and past/current medical history (Fudicker et al., 2012).

**Barriers and facilitators**

In an effort to reduce variance in practice there is a propensity to try and specify every conceivable aspect of care. This leads to multiple guidance on the same area and in many cases very complex guidance (Carthey et al., 2011). Adherence to clinical guidance remains suboptimal which in turn contributes to preventable harm and suboptimal patient outcomes. Improvements could be secured if barriers are tracked and a systems approach is taken to the development, implementation and evaluation of guidance. This review revealed barriers and facilitators at the patient, healthcare professional, team, organisation and health system level. Interestingly another review of evidence based practice (EPB) barriers and facilitators (n=31 studies, 10,798 respondents from 17 countries) by Ubbink et al. (2013) revealed that barriers to EBP are amazingly similar. These barriers require an integrative approach with interventions at a “micro level, middle level and macro level” targeted at international, national and local organisations inclusive of policy makers, health care professionals, managers, educators and researchers. Carthey et al. (2011) as part of an NHS project aimed at understanding barriers to implementation of guidance recommended that: “lean thinking” is applied to simplify the local Trust’s policy development and implementation processes; a reduction in the number of trust-wide policies; greater dialogue with healthcare professionals during guidance development/implementation, and improve accessibility of health care professionals to guidance.

**Strengths and limitations**

A strength of this systematic review is that it was conducted by a multidisciplinary team from the disciplines of nursing, medicine and pharmacy and in addition included a clinical informationist on the team. The review has been conducted systematically and rigorously guided by recommended practice for undertaking systematic reviews. In addition to peer reviewed publications, grey literature was sourced and included. Given the breadth of questions addressed, the review offers a comprehensive report addressing the development, implementation and evaluation
of seven guidance categories. Therefore, the nature of this systematic review, to our knowledge is unique in both scope and focus. Other reviews have focused specifically on one guidance type as opposed to considering a cross-section of guidance types. This lack of clarity was one of the driving forces behind the commissioning of this review and it is evident that there is no one clear framework within which the 7 guidance types described here logically fit. Healthcare Improvement Scotland have developed a particularly user friendly Methodology Toolkit for staff to determine which evidence based methodologies they should select, depending on what they seek to achieve (e.g. Policy making, clinical and cost effectiveness or measuring quality). However, only one area relevant to this review is included (standards). Therefore it is hoped that the results of this review will support the NCEC in Ireland and possibly other policy makers in the development of standards for the clinical practice guidance.

This systematic review also has limitations. The review was conducted over a period of 9 weeks which presented time constraints. Because of time constraints, it was not feasible to conduct a quality assessment of papers reviewed nor did we grade the evidence to determine strength of recommendations in papers. However, we did report on quality assessment methods used by authors as well as the grading of evidence where applicable. From this, we can conclude that the methodological quality of studies included in papers is generally poor. The grading of evidence, reported in very few papers, suggests that both the quality and strength of evidence was low. For many papers, it was noted that the authors did not present findings from their quality assessment of included studies or from the grading of evidence. Contact with authors may have helped to source additional data in this regard. However, due to time constraints, we did not attempt to contact authors.

Summary

In summary, an over-view of the guidance types has been provided accompanied by a narrative synthesis in relation to the thirteen review questions. It is clear from the review that clinical guidance regardless of format must be evidence based.

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Guidelines by their nature are usually quite large and complex documents. However the guidance types reviewed provide implementation solutions which may bring the evidence closer to the patient at either an organisation level (pathways, bundles) or in healthcare professional-service user interactions (algorithms, checklists and potentially protocols).

**Recommendations from the Research Team to inform the development of standards for clinical guidance practice.** These recommendations reflect key considerations emerging from the systematic literature review.

| R1. | The development, implementation and evaluation of clinical guidance need to be considered from the outset as key phases which are interlinked. |
| R2. | Streamline processes underpinning the development of clinical guidance. The following should be considered: |
| ➢ | Minimum reporting criteria and templates that will assist clinical guidance development teams when reporting on guidance development, implementation and evaluation. The templates will vary according to guidance types. |
| ➢ | Collaboration between relevant national bodies and health service providers with the aim of reducing the volume of clinical guidance and avoidance of conflicting guidance. |
| ➢ | A central repository of clinical guidance (inclusive of title, guidance type, date of development, version number, date of evaluation, contact name, contact details, pdf of guidance attached). This could build on an existing inventory\(^{25}\) of HSE clinical guidance. |
| ➢ | The use of information technology to support the development and implementation of guidance. |

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R3. Utilise an implementation science approach including ‘human factors’ in the development, implementation and evaluation of guidance.

R4. Consider the importance of raising awareness of guidance among health care professionals and actively engage all stakeholders in the guidance development and implementation processes:

- Optimise consultation with healthcare professionals and service users during the development, implementation, and evaluation of clinical guidance.
- Consider the healthcare professionals interaction with the guidance e.g. consider implementing strategies which can demonstrate that health care professionals have read and understood key guidance messages.
- When developing guidance consider: 1) the typical service user e.g. patients with multiple comorbidities and 2) the multitude of health care contexts and situations in which the guidance will be operationalised.
- Raise awareness amongst health care professionals of the evidence underpinning guidance recommendations and the benefits of implementing guidance in practice. This will increase the likelihood of the guidance being adopted in clinical practice.
- Evidence based practice (inclusive of clinical guidance types) needs to be embedded within undergraduate and postgraduate curricula for health care professionals.
References


Allen, D. & Rixson, L. (2008) How has the impact of ‘care pathway technologies’ on service integration in stroke care been measured and what is the strength of the evidence to support their effectiveness in this respect? International Journal of Evidence Based Healthcare 6(1), 78-110.


http://www.plosmedicine.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.1000097&representation=PDF


NCEC (2012b). *Clinical Guideline Screening and Prioritisation Criteria, V3*. Available at: [http://www.lenus.ie/hse/handle/10147/317570](http://www.lenus.ie/hse/handle/10147/317570)


Appendix 1: Final Search Strings

1. **Guidance – TOTAL WITH DUPLICATES REMOVED: 818**

(a) **MEDLINE**

S1: TI guidance
S2: AB guidance
S3: S1 OR S2
S4: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S5: DT 2009-2014 AND LA English
S6: S4 AND S5
S7: S6 AND S3 **Number of Records: 694**

(b) **CINAHL**

S1: TI guidance
S2: AB guidance
S3: S1 OR S2
S4: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S5: DT 2009-2014 AND LA English
S6: S4 AND S5
S7: S6 AND S3 **Number of Records: 350**
2. Pathway – TOTAL WITH DUPLICATES REMOVED: 1233

(a) MEDLINE

S1: TI Path OR TI Paths OR TI Pathway OR Pathways

S2: AB Path OR AB Paths OR AB Pathway OR AB Pathways

S3: S1 OR S2

S4: MH Critical Pathways

S5: S4 OR S3

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S8 AND S5 Number of Records: 1,043

(b) CINAHL

S1: TI Path OR TI Paths OR TI Pathway OR Pathways

S2: AB Path OR AB Paths OR AB Pathway OR AB Pathways

S3: S1 OR S2

S4: MH Critical Path

S5: S4 OR S3

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S8 AND S5 Number of Records: 372

(a) MEDLINE

S1: TI policy OR policies
S2: AB policy OR policies
S3: S1 OR S2
S4: MH: Health policy OR MH organisational policy OR MH policy making
S5: S3 OR S4
S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S7: DT 2009-2014 AND LA English
S8: S6 AND S7
S9: S8 AND S5  **Number of Records: 1,648**

(b) CINAHL

S1: TI policy OR policies
S2: AB policy OR policies
S3: S1 OR S2
S4: MH: Hospital Policies
S5: S3 OR S4
S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S7: DT 2009-2014 AND LA English
S8: S6 AND S7
S9: S8 AND S5  **Number of Records: 920**

4 Protocol – **TOTAL WITH DUPLICATES REMOVED: 2408**

(a) **MEDLINE**

S1: TI Protocols OR AB Protocols
S2: AB Protocol OR TI Protocol
S3: S1 OR S2
S4: MH Clinical protocols
S5: S3 OR S4
S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S7: DT 2009-2014 AND LA English
S8: S6 AND S7
S9: S5 AND S8  **Number of Records: 2151**

(b) **CINAHL**

S1: TI Protocols OR AB Protocols
S2: AB Protocol OR TI Protocol
S3: S1 OR S2
S4: MH Protocols
S5: MH Nursing Protocols
S6: S4 OR S5
S7: S3 OR S6
S8: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S9: DT 2009-2014 AND LA English

S10: S8 AND S9

S11: S10 AND S7  Number of Records: 688

5. Bundle - TOTAL WITH DUPLICATES REMOVED = 94

(a) MEDLINE

S1: TI Bundl*

S2: AB Bundl*

S3: S1 OR S2

S4: MH Patient Care Bundles

S5: S3 OR S4

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S5 AND S8 Number of Records: 81

(b) CINAHL

S1: TI Bundl*

S1: AB Bundl*

S3: S1 OR S2

S4: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S5: DT 2009-2014 AND LA English

S6: S4 AND S5
S7: S3 AND S6 Number of Records: 29

6. Standard – TOTAL WITH DUPLICATES REMOVED: 1125

(a) MEDLINE

S1: TI Standard N3 (care OR clinical OR treatment)
S2: TI “Standard Operating Procedure” OR TI “SOP”
S3: S1 OR S2
S4: AB Standard N3 (care OR clinical OR treatment)
S5: AB “Standard Operating Procedure” OR AB “SOP”
S6: S4 OR S5
S7: S3 OR S6
S8: MH Standard of Care
S9: S7 OR S8
S10: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S11: DT 2009-2014 AND LA English
S12: S10 AND S11
S13: S12 AND S9 Number of Records: 1,065

(b) CINAHL

S1: TI Standard N3 (care OR clinical OR treatment)
S2: TI “Standard Operating Procedure” OR TI “SOP”
S3: S1 OR S2
S4: AB Standard N3 (care OR clinical OR treatment)
S5: AB “Standard Operating Procedure” OR AB “SOP”
S6: S4 OR S5
S7: S3 OR S6
S8: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S9: DT 2009-2014 AND LA English
S10: S8 AND S9
S13: S7 AND S10  **Number of Records: 535**

7. **Algorithm – TOTAL WITH DUPLICATES REMOVED: 844**

(a) **MEDLINE**

S1: TI algorithm OR TI algorithms
S2: AB algorithm OR AB algorithms
S3: S1 OR S2
S4: MH Algorithms
S5: S3 OR S4
S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S7: DT 2009-2014 AND LA English
S8: S6 AND S7
S9: S8 AND S5  **Number of Records: 687**

(b) **CINAHL**

S1: TI algorithm OR TI algorithms
S2: AB algorithm OR AB algorithms
S3: S1 OR S2
S4: MH Algorithms OR MH Decision Trees

S5: S3 OR S4

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S8 AND S5  **Number of Records: 263**

8. **Checklist – TOTAL WITH DUPLICATES REMOVED: 1080**

(a) **MEDLINE**

S1: TI checklist OR TI checklists

S2: AB checklist OR AB checklists

S3: S1 OR S2

S4: MH Checklist

S5: S3 OR S4

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S8 AND S5  **Number of Records: 762**

(b) **CINAHL**

S1: TI checklist OR TI checklists

S2: AB checklist OR AB checklists

S3: S1 OR S2

S4: MH Checklist

S5: S3 OR S4

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S8 AND S5  **Number of Records: 762**
S4: MH Checklists
S5: S3 OR S4
S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S7: DT 2009-2014 AND LA English
S8: S6 AND S7
S9: S8 AND S5  Number of Records: 538

9. Decision Aid – TOTAL WITH DUPLICATES REMOVED = 1949

(a)  MEDLINE

S1: AB Decision N3 (aid OR aids OR support OR tool OR tools OR system OR systems OR making)
S2: TI Decision N3 (aid OR aids OR support OR tool OR tools OR system OR systems OR making)
S3: S1 OR S2
S4: MH “Decision Support Techniques”
S5: S3 OR S4
S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)
S7: DT 2009-2014 AND LA English
S8: S6 AND S7
S9: S5 AND S8  Number of Records: 1373

(b)  CINAHL

S1: AB Decision N3 (aid OR aids OR support OR tool OR tools OR system OR systems OR making)
S2: TI Decision N3 (aid OR aids OR support OR tool OR tools OR system OR systems OR making)

S3: S1 OR S2

S4: (MH "Decision Support Systems, Clinical") OR (MH "Decision Support Techniques") OR (MH "Decision Support Systems, Management") OR (MH "Decision Making, Organizational") OR (MH "Decision Trees") OR (MH "Decision Making, Clinical") OR (MH "Decision Making")

S5: S3 OR S4

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S5 AND S8 Number of Records: 1008

10. Care Models: TOTAL WITH DUPLICATES REMOVED = 210

(a) MEDLINE

S1: AB Care N3 Model

S2: TI Care N3 Model

S3: S1 OR S2

S4: MH Models, Nursing

S5: S3 OR S4

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S5 AND S8 Number of Records: 135
(b)  CINAHL

S1: AB Care N3 Model

S2: TI Care N3 Model

S3: S1 OR S2

S4: MH Nursing Models, Theoretical

S5: S3 OR S4

S6: PT Meta-Analysis OR (Meta-Synthesis OR Meta Synthesis OR Systematic Review)

S7: DT 2009-2014 AND LA English

S8: S6 AND S7

S9: S5 AND S8  **Number of Records: 123**
Table 1: Application of PICOS framework within the search strategy

<table>
<thead>
<tr>
<th>PICOS</th>
<th>Search terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient/Problem: any patient, population group</td>
<td>Human studies only, in the context of health/illness/health care provision, no other restrictions applied. Note- the absence of any restrictions here was problematic given the large search volumes returned.</td>
</tr>
</tbody>
</table>
| Intervention: clinical practice guidance of any type | 1. Guidance  
Keyword | MeSH Heading  
Title search: (Guidance) | [No specific MeSH for guidance] |
|                                            | 2. Pathway  
Keyword | MeSH Heading  
Title search: (path OR paths OR pathway OR pathways) | (MH "Critical Pathways") |
|                                            | 3. Policy  
Keyword | MeSH Heading  
Title search: (policy OR policies) | (MH "Health Policy") OR (MH "Organizational Policy") OR (MH "Policy Making") |
|                                            | 4. Protocol  
Keyword | MeSH Heading  
Title search: (protocol OR protocols) | (MH "Clinical Protocols") |
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<tr>
<td></td>
<td><strong>5. Bundle</strong></td>
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<td><strong>Keyword</strong></td>
<td><strong>MeSH Heading</strong></td>
<td></td>
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<tr>
<td>Title search: Bundl*</td>
<td>(MH &quot;Patient Care Bundles&quot;)</td>
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<td></td>
<td><strong>6. Standard</strong></td>
<td></td>
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<tr>
<td><strong>Keyword</strong></td>
<td><strong>MeSH Heading</strong></td>
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<tr>
<td>Title search: standard OR standard operating procedure OR SOP</td>
<td>No suitable MeSH identified.</td>
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<td><strong>7. Algorithm</strong></td>
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<tr>
<td><strong>Keyword</strong></td>
<td><strong>MeSH Heading</strong></td>
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<tr>
<td>Title search: (algorithm OR algorithms)</td>
<td>(MH &quot;Algorithms&quot;)</td>
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<td></td>
<td><strong>8. Checklist</strong></td>
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<td><strong>Keyword</strong></td>
<td><strong>MeSH Heading</strong></td>
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<tr>
<td>Title search: (checklist OR checklists)</td>
<td>(MH &quot;Checklist&quot;)</td>
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<td><strong>9. Decision aid</strong></td>
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<tr>
<td><strong>Keyword</strong></td>
<td><strong>MeSH Heading</strong></td>
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<tr>
<td>Title search: (decision aid</td>
<td>(MH &quot;Decision Support&quot;</td>
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<td>OR decision aids)</td>
<td>Techniques&quot;)</td>
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<tr>
<td>Comparison: comparator/ usual care/ alternate clinical practice guidance</td>
<td>No search terms specifically applied here</td>
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<tr>
<td>Outcome: as per review questions</td>
<td>No search terms specifically applied here</td>
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<tr>
<td>Setting: any health care setting</td>
<td>No restrictions applied to setting</td>
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</tr>
<tr>
<td>Type of studies and systematic reviews (PT- publication type)</td>
<td>PT Meta-Analysis OR Meta-Synthesis OR Meta Synthesis OR Systematic Review</td>
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</tr>
</tbody>
</table>
Appendix 2 Grading the Evidence

Studies can be graded according to level of evidence (Grade A-D) and associated grade or utility of the evidence in practice (grade 1-2) as follows:

- **Grade A** Evidence from a meta-analysis of RCTs, or from at least one RCT.
- **Grade B** Evidence based on one controlled trial without randomisation, a quasi-experimental study, or extrapolated from RCTs.
- **Grade C** Evidence from comparative studies, correlation studies, case control studies or extrapolated from category A or B.
- **Grade D** Evidence from expert committees, reports or opinions, the clinical experience of respected authorities and the conclusions of the guideline development group.

*In addition:*

- **Grade 1** Most common recommended practice according to the retrieved literature for clinical practice guidance development.
- **Grade 2** Less common recommended practice according to the retrieved literature clinical practice guidance development.
- **NE** No evidence found.
### Appendix 3: Data extraction tables for each guidance type incorporates evidence on methodology of development, implementation and/or evaluation (for each review question i.e. Q 1-13)

#### Pathway

<table>
<thead>
<tr>
<th>Source and Type of Evidence</th>
<th>Aim</th>
<th>Q 1. Definition</th>
<th>Q 2. Core elements</th>
<th>Q 3. Criteria for decision to create pathway</th>
<th>Q 4. Methodological processes</th>
<th>Q 5. Quality criteria for assessing No. 4 above</th>
<th>Q 6. Impact on intended setting incl. method of assessing/validating impact and reviewing/auditing of implementation and outcomes</th>
<th>Q 7. Resource (e.g. time/cost) implications</th>
<th>Q 8. Method/ processes for updating</th>
<th>Q 9. Level of expertise</th>
<th>Q 10. Layout/format considerations</th>
<th>Q 11. (i) Strengths and (ii) weaknesses of pathway guidance</th>
<th>Q 12. Barriers to development and implementation</th>
<th>Q 13. Facilitators to development and implementation</th>
<th>Additional Comments e.g. key recommendations/messages; reported limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adamina et al. (2011) U.S.A., Canada and Switzerland. Meta-analysis (n= 6 RCTs; 452 patients).</td>
<td>“To provide the best evidence to support the implementati on of ERP (enhanced recovery pathway) in clinical practice” in the context of colorectal surgery” (p. 831).</td>
<td>1. ERP “encompass a systematic and evidence-based appraisal of all interventions performed in an episode of care” (p. 831). 2. Standardised and pre-set criteria of care; Evidence based; Itemised steps of care; Simple to use; Team driven. (Reported as context and not results).</td>
<td>4. NR.</td>
<td>5. Quality Assessment of RCTs achieved with reference to meeting the reporting criteria outlined in the 2010 CONSORT statement and Jadad et al. (1996)(^{26}). No comments provided in relation to use of these to quality assessment methods. No quality data provided other than to note overall quality of studies were good.</td>
<td>6. Compared to standard care, ERB groups showed: (i) Reduced length of stay by 2.5 days (95% credible interval [CrI] -3.92 to 7.94)</td>
<td>7. NR.</td>
<td>8. NR.</td>
<td>9. Nursing and physician leadership needed for implementation of ERPs.</td>
<td>10. Step by step format; Simplicity for implementation i.e. avoids too many items of care in pathways statements.</td>
<td>11. (i) Enhances quality and effectiveness of healthcare (see impact); Organisational improvements through greater efficiency in service delivery; Reduces costs to organisation (ii) NR.</td>
<td>12. Uptake of ERPs has been slow in general more than specialist units; Less adherence to ERPs in care settings involving greater nursing and junior medical staff (e.g. immediate post-operative); Complexity of multicomponent ERPs.</td>
<td>Overall quality of studies reported to be good. Recommended that colorectal surgery should routinely be performed within an ERP for improved outcomes. Wider application of the principles of ERP to other surgical specialties may result in significant health care benefits.</td>
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<tbody>
<tr>
<td>3.</td>
<td>NR.</td>
</tr>
<tr>
<td>4.</td>
<td>ICP Development: Local by MDT incorporating evidence from Cochrane reviews, SIGN guidelines and/or national guidelines into single documents that may include checklists/protocols of care. Business management strategy developed.</td>
</tr>
<tr>
<td>5.</td>
<td>Papers appraised against the Joanna Briggs Institute Critical Appraisal Checklist for Experimental Studies. No comments provided in relation to use of quality assessment.</td>
</tr>
<tr>
<td>7.</td>
<td>Remains unknown whether the costs of ICP development and implementation are justified by any of their reported benefits.</td>
</tr>
<tr>
<td>10.</td>
<td>Single document incorporating checklists/protocols of care; Flexibility and specificity needed to accommodate diverse patient needs.</td>
</tr>
<tr>
<td>11.</td>
<td>(i) For relatively predictable patient journeys, ICPs can lead to service improvement and greater efficiencies; and to improved patient outcomes.</td>
</tr>
</tbody>
</table>

**ICPs** (Integrated Care Pathways) are effective, for whom and in what contexts” (p. 61). **Sequence mapping of the patient’s expected journey and treatment/care activities**: Proactive goal. **ICP Development**: Local by MDT incorporating evidence from Cochrane reviews, SIGN guidelines and/or national guidelines into single documents that may include checklists/protocols of care. Business management strategy developed. **ICP Implementation**: Staff tutorials/training; Pilot phase; Dedicated co-ordinator role. **Papers appraised against the Joanna Briggs Institute Critical Appraisal Checklist for Experimental Studies. No comments provided in relation to use of quality assessment.**

Further evaluation research needed to inform development, implementation and sustainability of ICPs as well as outcomes including wider system effects, critical success factors, and the effectiveness of ICPs in particular situations/contexts, with reference to the relationship between context, mechanism and outcome.

Further characteristics of CPs included from the EPA, see Kul et al. (2012), Q.2.
setting and action plan statements; Specificity to patient population in question; Evidence based; Inclusive of best practice guidelines; Specifies roles of each professional.

3. Explicit identified need to: improve service co-ordination, efficiency and quality; improve patient outcomes; support practice and role changes; ensure adherence to best practice guidelines and reduce practice variations.

methods. No quality data provided other than to note that evidence of contamination existed for 2 trials.

6. Compared to SC, ICP groups showed:
   (i) Reduction in length of stay in 5 RCTs e.g. patients with fractured neck of femur (6.6 days vs 8 days, P 0.03), children discharged from ED (37.6 h 95% CI, 33.5–42.4 vs 40.7 h, 95% CI, 35.9–46); (ii) Improved prescribing documentation and associated errors in 1 RCT on children in ED (30% reduction (mean 10.4 vs. 14.8, P = 0.002); (iii) Earlier mobilisation in patients following hip and knee arthroplasty in 1 RCT (P 0.001). (iv) Reduced mortality rates in 1 RCT with patients in heart failure (4.41% vs. 23.08%; P < 0.01).

NOTE: No significant effects found on readmission rates or costs.

Barbieri et al. (2009)
Italy.
Meta-Analysis (n = 22; RCT; Interrupted Time Series).

To evaluate the use of clinical pathways (CPs) for hip and knee joint replacement when

1. CPs also known as care pathways/critical pathways, “are a methodology for the mutual decision making and organisation of

4. Noted that only some studies described the implementation of CPs at each site; details NR in review.

5. Quality of the included studies was based on the Jadad methodological

7. Noted that the studies reporting cost reductions did not analyse the single costs of the specific elements of CPs, therefore not possible to conclude that the implementation of CPs is cost effective.

10. CPs need to be structured in a standardised way.

11. (i) CPs can effectively improve patient outcomes and quality of care

12. Complexity of CPs limits simple application in practice which is often concurrent with other organisational initiatives, therefore,

Meta-analysis limited by the inclusion of only 1 RCT.

Noted that the complexity of CPs make it difficult to determine which active components contribute to the observed effects.
and Cohort Studies; 6,316 patients). Noted that most (n=20) were cohort studies.

Noted that most (n=20) were cohort studies.

Compared to standard medical care (p. 1 online).

Compared with standard medical care (p. 1 online).

Care for a well-defined group of patients during a well-defined period (p. 2 online).

Care for a well-defined group of patients during a well-defined period.

Approach and on the New Castle Ottawa Scale.27 No comments made in relation to their utility.

6. Compared to standard care, CP groups showed:
   i) Shorter length of stay (n = 13) with a combined result of: (WMD = -2.61, 95%CI = (-3.29, -1.94) days; P < 0.0001; I² = 90, 9%, P < 0.00001);
   ii) Fewer patients had postop. complications (n=11) e.g. DVT, PE with a combined result of: (RR = 0.68, 95%CI = 0.51-0.92, P = 0.01; I² = 47.2 P = 0.04);
   iii) Lower costs during hospital stay (n = 8) with combined result of: (WMD = (-) 1.54, 95%CI = (-1.99, -1.05) 1.09, P < 0.0001; I² = 97, 4%, P < 0.00001). However, see Q 7).

NOTE: No significant differences in ratio of discharges to home.

Chen et al. (2014)

Taiwan and Australia. Systematic review (n = 7, RCTs; CCT and Controlled

Comparing the effectiveness of clinical pathways (CPs) for paediatric asthma (children < 18) on length

"To evaluate the effectiveness of clinical pathways (CPs) for paediatric asthma (children < 18) on length

1. CPs are defined “as interventions that include multidisciplinary care plans have timeframes or criteria-based progression, and are used by

2. NR.

3. NR.

4. Noted that “no eligible studies found on manpower and workload required for implementation of CPs” (p. 487).

5. Details not reported; reference made to assessment of risk of bias.

6. This systematic review only looked at cost within a hospital setting. However, it is possible for CP interventions to result in capacity and/or cost shifting to other sectors of healthcare, i.e. to patients and their families.

7. This systematic review only looked at cost within a hospital setting. However, it is possible for CP interventions to result in capacity and/or cost shifting to other sectors of healthcare, i.e. to patients and their families.

8. NR.

9. NR.

10. NR.

11. NR.

12. NR.

13. NR.

14. NR.

15. NR.

16. NR.

17. NR.

18. NR.

19. NR.

20. NR.

21. NR.

22. NR.

23. NR.

24. NR.

25. NR.

26. NR.

before and after studies, 2600 participants).

of hospital stay, additional hospital visits due to asthma exacerbation s hospital cost, manpower and workload required for implementin g CPs'(p.480).

health services to detail essential steps in the care of patients with a specific clinical problem" (p.480- from Kinsman et al 2010).

2. Not explicit other than to note that CPs link evidence to practice, as well as optimise clinical outcome and efficiency.

3. NR.

6. Compared to usual/ traditional care, CP groups showed:
(i) Reduced length of stay (n =2) between 0.5 days (95% CI 0.43 [-0.78, -0.08] p< 0.01; and 1.4 days (95% CI -1.43 [-1.74, -1.12], p < 0.001.
(ii) A decrease in hospital costs (n=1; $1,685 (95% CI 1437–1933) vs. $2829 (95% CI 2496–3162; p< 0.001).

NOTE: No significant benefits from studies (n=4) in terms of fewer additional visits due to asthma exacerbations.

8. NR.

9. CPs implemented in the included studies were all developed by the target institutes.

Kul et al. (2012)
Turkey.
Systematic review including meta-analysis (n=7, RCTs, ITT; and controlled studies; 3,690 patients).

"To determine how care pathways (CPs) in the hospital treatment of heart failure affect inhospital mortality, length of inhospital stay, readmission rate and hospitalisation cost when compared with standard care" (p. 1

1. From European Pathway Association (EPA): "a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period".

2. From European Pathway

4. NR.

5. Methodological quality of the studies included assessed using the Jadad methodological approach, the New Castle Ottawa Scale and Guidance from Cochrane. It was noted that a quality assessment is difficult in some circumstances given that certain key quality criteria are not always apparent in publications.

6. Compared to SC, CP groups pooled analysis showed:
(i) Reduction in mortality rate (RR 0.45, 95%CI =

7. NR.

8. NR.

9. NR.

10. NR.

11. (i) Lead to improvements in quality care (see impact); Standardise care;

12. Lack of organisational readiness for and capacity to change; Poorly performing team with lack of interest in organisational improvements.

13. CPs may change behaviours in poorly performing teams.

Cautioned about using pathways as documents without being within the context of well-known quality improvement methodologies.

Noted that pathways are a learning tool at individual and team level.

Lack of consensus around definition of pathways raised and their characteristics. Kul et al. only included studies that met EPA definition and characteristics of CPs.


105
Association (EPA):
"(i) explicit statement of the goals and key elements of care based on evidence, best practice, and patients' expectations and their characteristics; (ii) The facilitation of communication among team members and with patients and families; (iii) The coordination of the care process by coordinating the roles and sequencing the activities of the multi-disciplinary care team, patients and their relatives; (iv) The documentation, monitoring, and evaluation of variances and outcomes; and (v) The identification of the appropriate resources. The aim of a care
pathway is to enhance the quality of care, across the continuum, by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources” (p.2, from Vanhaecht et al. 2007).

Leigheb et al. (2012) European (Italy, Belgium, Norway, Portugal).
Systematic review (n=15, RCTS and cohort studies; 5,791 patients).

To examine “the impact of CP implementation for HF (Care pathways for hip fracture) related to the acute and post discharge processes of care” (p.2).

1. CPs are “complex interventions designed to optimise clinical outcome and resource use and used worldwide for a variety of patient groups” (p. 2 online drawing on a number of references).
2. Mapping of care processes e.g. assessment/monitoring,
3. NR.
4. Reported that methods of development and implementation were not described in studies other than implementation coordinator in 3 studies.
5. Methodological quality of included studies judged against The Jadad scale (JS) for assessing the quality of RCTs and CCTs, the Newcastle-Ottawa Quality Assessment Scale (NOS) for assessing the quality of nonrandomised studies for the cohort studies and guidance from Cochrane.
6. NR.
7. NR.
8. NR.
9. Care coordinator responsible for staff training implementation of the CP (reserved conclusion about effectiveness).
10. NR.
11. (i) Leads to improved outcomes (see impact) (ii) NR.
12. NR.
13. NR.

Noted that there is a need for well-designed multi-centre studies and well selected outcome measures to evaluate the effectiveness of CPs.

Limitation of included studies noted e.g. representativeness of samples, little adjustment for confounding variables; mostly observational non-randomised designs.

Further characteristics of CPs from the EPA, as seen previously in Kul et al. (2012), Q.2.

1. Care pathways (CPs) are "complex interventions and can be one of the approaches to foster better outcomes and optimal resource use" (p. 738 online drawing).

2. To "perform a systematic overview of secondary literature studies on care pathways (CPs) for hip fracture (HF)" (p. 737).

3. NR.

4. NR (However, states the need for high quality methodological designs).

5. Not reported explicitly, referred to quality of studies being judged as to their match with defined characteristics of a clinical pathway (as specified by the European Pathway Association).

6. Compared to SC, CP groups showed:
   (i) Reduced mortality rates for inpatients in 2 studies (P < 0.001) and at 1 year post CP implementation (6.8% vs. 14.1%, P < 0.01);
   (ii) Improvement in functional recovery and mobility in 4 studies e.g. walking alone at discharge (73% vs 36 % p = 0.033); restored high level of ADLs at discharge (21 % vs. 5 %, p = 0.003);
   (iii) Reduction in medical complications including individual e.g. pressure ulcers (n=3) and multiple complications (n = 5). Reduction in overall multiple complications (8.9 % vs. 25 %, p = 0.003); (iv) Reduction in length of stay in acute settings (n=10) ranging from 1 day (p < 0.034) up to 14 days (p < .0001); (v) Reduction in cost by 40% in terms of cost-effectiveness (n =1).

7. NR.

8. NR.

9. NR.

10. NR.

11. (i) Lead to improvements in quality care (see impact).
    (ii) NR.

12. NR.

13. NR.

Difficulty in comparing different studies in the review noted because of the lack of a common definition for CP. Much confusion remains in relation to what a CP is and there is an urgent need to adopt a clear and strict definition for CP. Noted that CPs often confused with other guidance interventions e.g. guidelines, protocols.
referred to European Pathway association definition – a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period."

2. Quality improvement tool and practice method; Care Continuum; Tool for improving risk-adjusted patient outcomes; Promoting patient safety; Increasing patient satisfaction; Optimizing the use of resources.

3. NR.

6. Compared to SC, CP groups showed:
   (i) Shorter hospital length of stay (LOS) (n = 2) with a mean reduction of 5.3 days in 1 SR-MA with reference to 3 primary studies; Other SR/SOs (n = 2) found conflicting results across primary studies (increased/reduced LOS);
   (iii) Improved functional recovery when included multidisciplinary care and involving intensive OT and/or PT exercises and early mobilization (n = 1 SR with reference to 4 primary studies);
   NOTE: for (i), (ii), (iii) above, levels of significance not presented.
   (iv) Lower odds of common complications after HF in the SR-MA:
       DVT in 4 primary studies (OR 0.33, 95 % CI 0.14–0.75); pressure ulcers in 5 primary studies (OR 0.48, 95 % CI 0.30–0.75); surgical site infection in 3 primary studies (OR 0.48, 95 % CI 0.25–0.89) urinary tract infection in 5 primary studies (OR 0.71, 95 % CI 0.52–0.98).

Unclear whether the results were attributable to the CPs or to some specific intervention included in the CPs. Although some positive impacts of CPs found, the authors cautioned against making formal recommendations given the limitations of available evidence.

There is a need for adequately powered multicentre and high quality studies to investigate the effectiveness of CPs.

Further characteristics of CPs from the EPA, as seen previously in Kul et al. (2012), Q.2.

<table>
<thead>
<tr>
<th>Lemmens et al. 2009</th>
<th>To “analyse the content, i.e. the</th>
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<tbody>
<tr>
<td>1. NR.</td>
<td>2. Mapping of</td>
</tr>
<tr>
<td>4. NR.</td>
<td>5. Not reported explicitly;</td>
</tr>
<tr>
<td>7. NR.</td>
<td>8. NR.</td>
</tr>
<tr>
<td>10. NR.</td>
<td>11. (i) Lead to</td>
</tr>
<tr>
<td>12. NR.</td>
<td>13. NR.</td>
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</table>

Noted that the level of description of the clinical pathways differs between articles. e.g. some articles present
<table>
<thead>
<tr>
<th>The Netherlands</th>
<th>Systematic review (n=13, 1 RCT, 3 CCT, 2 CCS, 1 CS and 6 s pre-pathway period (control group) and post-pathway (intervention group).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions of clinical pathways (CPs) for digestive surgery and their effects on postoperative outcome measures</td>
<td>Care plan; statements of key medical content with multi-components e.g. nutrition, pain management, patient education; Statements of organisational content e.g. discharge plan; time intervals of care stated.</td>
</tr>
<tr>
<td>3. CPs will improve a patients’ physical condition before and after surgery by implementing specific interventions.</td>
<td>Referred to study designs having to have used a comparative design that is compared to usual care (i.e. control).</td>
</tr>
<tr>
<td>9. Surgeons and anaesthetists in this area.</td>
<td>Improvements in quality care (see impact).</td>
</tr>
<tr>
<td>12.</td>
<td>Complete day-to-day time task matrices, while other articles only give a brief description of the clinical pathway.</td>
</tr>
<tr>
<td>McConnell et al. (2013) Ireland and Northern Ireland</td>
<td>To “identify and investigate factors that help or hinder successful implementation and”</td>
</tr>
<tr>
<td>1. ICPs “are plans for patient care “that embed guidelines, protocols and locally agreed, evidence-based, patient-centred,”</td>
<td>4. NR.</td>
</tr>
<tr>
<td>5. Included studies assessed based upon Pawson’s (2006) quality appraisal criteria for realist review: relevance and rigour. Methodological decisions aided the</td>
<td>7. Successful implementation of CPs will not be generated without adequate funding for programme inputs such as facilitation, education and training along with audit mechanisms.</td>
</tr>
<tr>
<td>10. Provide a structured way to both understand and explain the vast array of possible factors affecting both implementation and sustainability</td>
<td>12. NR.</td>
</tr>
<tr>
<td>13. The key components of the intervention (a Dedicated facilitator; education and training, audit</td>
<td></td>
</tr>
<tr>
<td>Poor quality as only one RCT was presented. Therefore, more rigorous study designs are needed to rule out adverse effects.</td>
<td></td>
</tr>
</tbody>
</table>

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Systematic Realist Review (n=58, study designs not specifically stated; included e.g. SR, quasi-experimental, pilot studies, and audits).

- **sustainability of the LCP** (p.218).
- 2. ICPs increase the efficiency of care and improve outcomes for patients in some conditions; to change behaviours.
- 3. NR.
- **STROBE checklist** (Vandenbroucke et al. 2007)\(^\text{31}\) and the Critical Appraisal Skills Programme (CASP) checklist for qualitative studies (CASP 2006)\(^\text{32}\).
- 6. NR.
- 8. NR.
- 9. Specialist Palliative Care Team.
- 11. (i) Lead to improvements in quality care (see impact). (ii) NR.
- and feedback) must be configured to influence the beliefs of staff in relation to end of life care, and increase their motivation and self-efficacy in relation to using the LCP. The support of senior managers is vital to the release of necessary resources, and a dominant culture of cure, which sees every death as a failure, works against effective communication and collaboration in relation to the LCP.
- Implementing CPs.

Key factors identified in the implementation of the LCP included: a dedicated facilitator, education and training, audit and feedback, organisational culture, and adequate resources.

Based on findings from the review the following recommendation were made:
- Top management support; Facilitators should aim to demonstrate benefits of the CP, allowing for timely feedback of audit results; education and training building on the confidence of staff; local audits; facilitate a major culture shift in the ways of working, education, training, and incorporating communication skills.

**Phillips et al. (2011)**

Australia

An Integrative Review (with systematic appraisal) (n=26, mixed-

- To "identify published studies evaluating the impact of an end-of-life care pathway in the acute and hospice 1. NR.
- 2. Map of essential elements of care for clinical problem; Evidence based; Include a framework for 4. NR.
- 5. Two evidence evaluation tools developed by the Australian Palliative Residential Aged Care (APRAC) Project Guidelines were used. \(^\text{33}\)
- 6 End-of-life CP impacted 7. NR.
- 8. Limited acknowledgment of the need for ongoing evaluation of pathway efficiency.
- 9. Experienced nurses. 10. NR.
- 11. (i) CPs increased the accessibility of palliative care outside of specialist services; clarifies the goals of care 12. Clinicians view that the introduction of the pathway would be an additional documentation burden and workload.
- There was limited acknowledgment in these studies of the need for ongoing evaluation of the pathway’s effectiveness.
- These methodological limitations make it difficult to fully evaluate the impact of the end-of-life care pathway on care of the dying.


| method, retrospective, prospective, qualitative, CR, and NCR studies, audit) | care setting from January 1996 to April 2010\(^\text{p.940}\) | auditing and benchmarking Care. 3.NR. | positively in some studies on care of the dying through better coordination of care, enhanced communication, and greater adherence to evidence-based clinical guidelines. NOTE: mostly descriptive statistics with no indication of effect sizes where applicable and only a small number of studies (n = 6) providing r levels of significance. | with the patient, family and care teams; promotes more effective multidisciplinary, structures care and promotes proactive management; engages decision making; promotes patient-centred care; acts as a benchmarking and audit tool; reduces documentation requirements; assists in identifying further areas for research; helps address previously challenging care issues; aligns care delivered with policy; can be easily translated into other languages; promotes the adoption of best evidence based end-of-life care regardless of care setting or competencies. (ii) Dependent on timely recognition and diagnosing; questioned as to whether appropriate CPs 13. Clinical education sessions, high-level organisational support, strong clinical leadership and the presence of a pathway facilitator were all identified as critical success factors, as well as health professionals having the necessary competencies to initiate and use the pathway. |
Rotter et al. (2009, 2010, and 2012) The Netherlands, Australia, Germany. Cochrane systematic review and meta-analysis (n=27, RCTS, CBAs, ITAs and CCTs; 11,398 participants).

To “summarize the evidence and assess the effect of clinical pathways on professional practice, patient outcomes, length of hospital stay, and hospital costs” (p.5 2012).

1. Clinical pathways (CPs) are defined as “structured multidisciplinary care plans which detail essential steps in the care of patients with a specific clinical problem” (p.4).

2. Translates guidelines or evidence into local structures; details the steps in the course of treatment or care in a plan, pathway, algorithm, guideline, and protocol of other inventory of actions; includes time frames or criteria-based progression; and aims to standardise care for particular clinical problems.

4. NR.

5. Referred to using Effective Practice and Organisation of Care (EPOC) methodological design and quality criteria (risk of bias tool).

Evidence was also classified against the presence/use of 7 CPW quality indicators: “evidence based content, adaption of evidence for local circumstances, clinician involvement in CPW development”, “use of an implementation team, identification of evidence practice gaps, use of audit and feedback and incorporation of education sessions” p. 36.

6. The main results were a (i) reduction in hospital complications (odds ratio 0.58: 95% CI [0.36, 0.94]) (ii) Improved documentation (odds ratio 11.95: 95% CI [4.72, 30.30]).

7. Clinicians and health care managers are using time and effort when trying to establish and appraise the evidence regarding CPs.

8. NR.


10. NR.

11. (i) Lead to improvements in quality care (see impact).

(ii) NR.

12. NR.

13. NR.

14. NR.

15. NR.

16. NR.

17. NR.

18. NR.

19. NR.

20. NR.

21. NR.

22. NR.

23. NR.

24. NR.

25. NR.

26. NR.

27. NR.

28. NR.

29. NR.

30. NR.

31. NR.

32. NR.

33. NR.

34. NR.

35. NR.

36. NR.

37. NR.

38. NR.

39. NR.

40. NR.

41. NR.

42. NR.

43. NR.

44. NR.

45. NR.

46. NR.

47. NR.

48. NR.

49. NR.

50. NR.

51. NR.

52. NR.

53. NR.

54. NR.

55. NR.

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57. NR.

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66. NR.

67. NR.

68. NR.

69. NR.

70. NR.

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83. NR.

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100. NR.

101. NR.

102. NR.

103. NR.

104. NR.

105. NR.

106. NR.

107. NR.

108. NR.

109. NR.

110. NR.

111. NR.

112. NR.

113. NR.

Substantial variation in study design and settings prevented statistical pooling of results for length of stay (LOS) and hospital costs.

Studies assessing the impact of CPWs should incorporate EPOC standards into design to maximise the quality of evidence underpinning this model that is being used in numerous health care settings.

Poor design/layout in most studies. It is noted by the authors that “well-designed evaluation like time-series analysis that meets the EPOC gold standard methodological criteria can produce meaningful, rigorous results with the use of relatively few resources” (p.23).
| Van Herck et al. (2010) Belgium and Italy | To “assess pathway components and effectiveness on a wide range of measures in joint arthroplasty patients” (p40). | 1. “Clinical pathways or critical pathways are one of the possible methods to manage and structure care processes. The development and implementation of a pathway is a complex intervention” (p.39). |
|  | 2. Time task matrix; goal setting; variance tracking; the interdisciplinary nature of phased order and protocol standardisation; performance feedback; evidence-based | 4. Some CPS “are based on a clear, systematic development and implementation approach, such as the Belgian Dutch 30 step scenario, and the framework used by Panella et al. or by Bertholf” (p.41) Further methodological descriptions are limited. |
|  | 5. The Quality Assessment Tool for Quantitative Studies, developed by the Effective Public Health Practice Project in Canada was used to apprise the quality of included studies. Qualitative studies were | 7. NR. |
|  | 8. It is important to do a process evaluation with regard to the development and implementation phase of CPs. | 9. NR. |
|  | 10. NR. | 12. Developing a pathway without including improvements on the coordination mechanisms within the team might not lead to improved outcomes; often dependent on social context and the circumstances of implementation than single interventions. |
|  | 11.(i) Lead to improvements in quality care (see impact); help multidisciplinary teams in improving their coordination and follow-up of a care process (ii) Can be complex interventions because of their multifaceted nature. | 13. Communication; coordination; interdisciplinary fine-tuning are likely to elicit the effects of CPs research through a better team functioning. |
|  | 11.(ii) Lead to improvements in quality care (see impact); help multidisciplinary teams in improving their coordination and follow-up of a care process (ii) Can be complex interventions because of their multifaceted nature. | The Medical Research Council advises the use of appropriate designs to study complex interventions. A lack of long-term longitudinal outcome research. Identifying development and implementation methods as detailed and systematic as possible and assessing the success of implementation is essential to distinguish between implementation failure and intervention concept or theory failure when research results are negative. |

34 Effective Public Health Practice Project (EPHPP) (2007) Quality assessment tool for quantitative studies dictionary. McMaster University, Faculty of Health Sciences, School of Nursing. Available at: http://www.myhamilton.ca/myhamilton/CityandGovernment/HealthandSocialServices/Research/EPHPP/ (last accessed 1 July 2008).
standards or guidelines.

3. NR.

6. CPs had significant effects on (main examples)

1) Clinical outcomes:
   (i) Discharge improvement (78% effect size, \( P < 0.001 \)); decrease in no. of postoperative days before attaining specific functional mobility goals (36% average effect size, \( P < 0.05 \)); positive effects on proportion of patients with a decreased range of motion (9.85% effect size, \( P < 0.01 \)); no. of days to sitting out of bed (43.9% effect size, \( P < 0.001 \)); no. of days to ambulation (39% effect size, \( P < 0.05 \)); decrease of DVT and PE rate (3.1% effect size, \( P < 0.05 \)).

2) Process outcomes:
   (i) preoperative length of stay (LOS) (72.44% average effect size, \( P < 0.05 \)) and on postoperative LOS (10% effect size, \( P < 0.001 \), 23% effect size, \( P < 0.001 \)).
   (ii) an increase in patients discharged within 8 postoperative days (19.6% effect size, \( P < 0.01 \); 39% effect size, \( P < 0.001 \)); LOS is reduced significantly by utilising CPs (n=11, \( P < 0.001 \) effect size ranging

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36 Popay, J., Rogers, A. & Williams, G. (1998) Rationale and standards for the systematic review of qualitative literature in health services research. Qualitative Health Research 8(3), 341–351.
from 17.8% to 58.6%, with an average of 33.32%.

3) Financial outcomes:
   (i) Overall cost savings range from $800 to $3000 per patient, with an average of $1877.5.
   (ii) Resource utilisation rates show a significant decrease in three studies e.g. (71.4% effect size, \( P < 0.05 \); 56% effect size, \( P < 0.05 \)).

| Stocker et al. (2013) | U.K. | A comprehensive systematic review (n= 17, baseline audits, including 2 pre-post-test designs; 18,052 patients). | 1. NR. | 2. To support care coordination; open communication between patients and careers. | 3. NR. | 4. NR. | 5. NR. | 6. NR. | 7. | 8. | 9. | 10. NR. | 11. NR. | 12. Potential reasons for non-uptake of LCP include unexpected death, low levels of LCP training, training schedules that failed to respond to high staff turnover, staff shortages, and patients not fulfilling the LCP criteria; Clinicians need to have open discussions with patients about death and LCP; often seen as “a one way street” and this may cause clinical reluctance if patients are unsure of the terminal diagnosis; Media reports associating it with There is an urgent need for perspective studies to evaluate the impact of LCP on the quality of care for patients. Further research is needed to evaluate the process of decision making when considering a patient for the LCP, versus the quality of care experienced by those not on the LCP. Need for more robust reporting systems to discover which clinical contexts welcome the LCP - which might lead to the development of more responsive and context specific care pathways. |
13. Noted in discussion: pathway facilitators, availability of speciality palliative care teams, high levels of structures education, taking into account patient’s wishes and needs.
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<tr>
<td>Akinsipe et al (2011) U.S.A. Systemic review (n=9; retrospective and prospective observation evaluation studies; . 47,840 labouring women).</td>
<td>&quot;To evaluate the effect of implementing hospital policies aimed at reducing elective labour induction and increasing spontaneous labour rates&quot; (p.5).</td>
<td>1. NR.</td>
<td>2. Evidence based; Linked to national recommendations.</td>
<td>3. Known risks to mother/ child; Health system patient safety agenda; National recommendations.</td>
<td>4. Systematic review - mostly retrospective designs with baseline and post intervention outcome data collected to evaluate a process improvement.</td>
<td>5.NR.</td>
<td>6. Compared to pre-intervention, policy intervention showed: (i) Reduced induction rates (n=5) including early term and elective. Overall reduction rates reported in 2 studies (24.9% vs.16.6%, p &lt; .001 and 13% vs. 8% (p &lt; .0027); (ii) Reduced caesarean (n=3, e.g. 4.5% vs. 13.8%, p = .01) and operative</td>
<td>7. NR.</td>
<td>8. NR.</td>
<td>9. NR.</td>
<td>10. Varied across studies e.g. standardised checklist/policy/ Guidelines.</td>
<td>11. (i) Implementation of process improvement policies is superior to lack of standardisation; Policies based on national recommendations have more significant outcomes. (ii) NR.</td>
<td>12. NR.</td>
<td>13. Staff empowerment to implement a 'hard stop' policy (i.e. refuse scheduling elective deliveries &lt;39 week gestation) led to greatest positive impact on outcomes.</td>
<td>Noted that retrospective designs are limited in evaluating effects of policy implementation because of limited ability to clarify record inconsistencies as well as cause-and-effect interpretation. Explanation for no impact/worsening impact on outcomes noted as likely to be that policies were not sensitive to outcomes. Policies need to be evidence based and outcome sensitive. Further research in hospital policy implementation is needed in the areas of patient and provider satisfaction.</td>
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</table>
vaginal delivery (n = 1, 19.8% vs. 16.9% (p < .0001).
(iii) Reduced length of stay in labour and delivery (n=1, 8.3 +/- 5.6 hours vs. 7.8 +/- 5.2 hours (p < .01);
(iv) Reduced neonatal complications (n = 3) including improved apgar scores e.g. < 5 at 1 min (OR = 0.80, 95% CI [0.73, 0.87].

<table>
<thead>
<tr>
<th>1. Bryson et al. (2010) Canada.</th>
<th>Systematic review (n=29, publications and reports and (n=5, Govn websites.</th>
<th>“To collect and synthesize information available on immunization policy making processes across the globe” (p.6).</th>
<th>1. NR.</th>
<th>2. NR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Burden of disease; Economic evaluation; Feasibility of recommendation; Recommendation of other countries; public perception; vaccination safety; vaccination effectiveness.</td>
<td>4. Varied across countries e.g. recommendations to Government by national advisory groups some of which included open public meetings; medical technology assessment/literature review; mathematical modelling; quality appraisal of evidence in some countries.</td>
<td>5. NR.</td>
<td>6. NR other than stated that no data available on outcome of policy making.</td>
<td>7. NR.</td>
</tr>
<tr>
<td>8. Not explicit – although referred to annual updates in some countries.</td>
<td>9. Clinical medicine, epidemiology, immunology, health economics, health planning, infectious disease, internal medicine, microbiology, nursing, paediatrics, public health, and vaccine research.</td>
<td>10. Web publication of policy in some countries.</td>
<td>11. (i) and (ii) NR.</td>
<td>12. NR.</td>
</tr>
<tr>
<td>Disease burden and economic evaluation most common criteria influencing decision to develop a policy. Publication of policies and decision making processes (e.g. web based) would be helpful to other countries. More attention to policy making processes needed to document best practices. In addition, data on outcome evaluation of immunisation policy are needed.</td>
<td>13. NR.</td>
<td></td>
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</tbody>
</table>
**Lavis et al. (2010).**
Canada.
Review of HTAs (n=223); and description of developing and qualitatively piloting a prototype (3 page executive summary). designed for policy makers.

"(i) To assess whether HTAs from Canada and other countries have potential to inform policy making about health systems in jurisdictions outside their origins of production; (ii) to develop and pilot prototypes to test the relevance of HTAs for health system managers and policy makers” (p. 406-407).

<table>
<thead>
<tr>
<th>1. Policy making about health systems relates to governance, financial, and delivery arrangements within which clinical (and public health) programs and services are provided. Policy making within health systems relates to programs, services, drugs and devices to fund, cover or deliver.</th>
<th>4. Summarised HTAs with input managers and policy makers on how to make SRs user friendly. Prototype pilot tested by interview with healthcare managers and policy makers.</th>
<th>8. NR.</th>
<th>10. Structured summaries of HTAs to assist scanning for decision relevant information and take home messages (i.e. conclusions and recommendations).</th>
<th>12. NR.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. User –friendly; Statement of harms benefits, costs, associated uncertainties; and differential effects on subgroups; Local applicability.</td>
<td>5. NR.</td>
<td>9. NR.</td>
<td>11. NR.</td>
<td>13. Structured decision relevant information could assist dissemination of HTAs.</td>
</tr>
<tr>
<td>3. NR.</td>
<td>6. NR.</td>
<td>7. Noted that validation methodologies from health economics needed such as Programme Budgeting and Marginal Analysis (PBMA).</td>
<td>10. NR.</td>
<td>12. NR.</td>
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<tr>
<td>4. NR.</td>
<td>11. NR.</td>
<td>8. NR.</td>
<td>11. NR.</td>
<td>The six identified factors (see No. 2) provide a potential framework on which evidence-based health policy may be developed. Research is needed on the impact of policy following which amendments can be made if required.</td>
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**Morgan (2010)**
U.K.
Systematic review (n=8, published reviews).

"To identify some of the underpinning factors that promote the development of evidence-based health policy” (p.43).

<table>
<thead>
<tr>
<th>1. NR.</th>
<th>4. NR.</th>
<th>7. Noted that validation methodologies from health economics needed such as Programme Budgeting and Marginal Analysis (PBMA).</th>
<th>10. NR.</th>
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<tbody>
<tr>
<td>2. Multi-disciplinary input; Stakeholder input; Evidence based; Research and policy circularity; Local sensitivity; Government support.</td>
<td>5. NR.</td>
<td>8. NR.</td>
<td>11. NR.</td>
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<tr>
<td>Reference</td>
<td>Title</td>
<td>Methods</td>
<td>Identification of Barriers and Facilitators</td>
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<tr>
<td>Oliver et al. (2014)</td>
<td>“To identify new barriers of and facilitators to the use of evidence by policymakers” (p. 1 online).</td>
<td>Systematic review (n=145, observational, documentary analysis, qualitative, surveys, longitudinal, cross-sectional, systematic reviews, case studies).</td>
<td>1. Policy defined as “decisions made by a state organisation, or a group of state organisations at national, regional or conurbation level” (p. 3 online).</td>
</tr>
<tr>
<td>Orton et al. (2011)</td>
<td>“To synthesise research evidence on its use by public health decision makers in settings with universal health care systems” (p. e21704).</td>
<td>Systematic review (n=18; qualitative and surveys).</td>
<td>1. Noted that public health policy at macro level is difficult to define since most ultimately affect health.</td>
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| Perrier et al. (2011) Canada. | Systematic review (n=4, cross-sectional survey and RCT). Note – 3 of the papers | To review the impact of interventions to support use of SRs by policy makers (and managers). | 1. NR. 2. NR. 3. NR. 4. NR. 5. Data Collection Checklist from the Cochrane EPOC (available at: http://www.epoc.cochrane.org) was used for randomised trials, and a modified Downs and Black tool \(^{38, 39}\) was used for observational studies. 7. NR. 8. NR. 9. Multiple stakeholder expertise and input e.g., health, business, academics. 10. Tailored messages recommended for research use from SRs in health policies. 11. NR. 12. NR. 13. Tailored, targeted messages and access to online SRs significantly improved SR research use in public health policies. | divisiveness; lack of training skills on research utilisation. 13. Research uptake for policy making facilitated by: researchers and practitioners working together; Support and commitment of personnel who could influence change; availability of summary statements; accessibility e.g. through emails, bulletins; evidence that is unbiased; alignment with current and future policy environments; relevance to health targets; recommendations for implementation. | policy making processes (public health). |

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<tr>
<th>Study</th>
<th>Objective</th>
<th>Methods</th>
<th>Findings</th>
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<tbody>
<tr>
<td>Wouters et al. (2010) South Africa.</td>
<td>To examine failure and success factors relating to AIDS policy making and policy implementation.</td>
<td>1. NR. 2. Core elements for policy analysis include: context (when and where?), process (how?), actors (who?) and content (what?); Human rights based. 3. Health problem (HIV/AIDS) epidemic.</td>
<td>4. Inclusive approach to policy making involving widespread and national consultation with multiple stakeholders. 5. NR. 6. NR.</td>
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<tr>
<td>Sourced through Grey literature. Yassi et al. (2009)* WHO – Geneva.</td>
<td>To conduct a systematic review to support development of policy guidelines for improving health worker access to prevention, treatment, and care services for HIV and TB i.e. to provide</td>
<td>1. NR. 2. NR. 3. Known poor uptake of clinical guidelines on access to prevention, treatment, and care services for HIV and TB.</td>
<td>4. Systematic review for Guideline group (GG). In addition, an outline of work previously completed included: Preliminary review of the literature; development of concept paper outlining draft policy statements by GG; major study in 5 African countries commissioned by GG with finding prepared as a synthesis report; a survey of national</td>
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<td></td>
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<td></td>
<td>7. NR. 8. NR. 9. Not explicit but the involvement of guidance groups with researchers noted. 10. NR. 11. NR. 12. NR.</td>
</tr>
<tr>
<td>Study reviewed noted to be methodologically weak. Only one RCT included in the evidence. Longitudinal study with cluster RCT recommended to fine tune policy guideline implementation and to determine impact of implementation. However, noted that implementation of guidelines should not be delayed until further research undertaken.</td>
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<tr>
<td>designs, descriptive, cluster RCT)</td>
<td>guidance on how to accelerate implementation of policies.</td>
<td>policies worldwide. Note the systematic review reported in this paper was designed to address specific questions from the GG that needed further exploration. WHO Handbook for Development of Guidelines was used.</td>
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<td>6. GRADE criteria used for assessing evidence gleaned for policy guidelines. 6. NR (not applicable) re impact of policy. Outcomes reported from studies on interventions/programmes relating to access to prevention, treatment, and care services.</td>
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*Although evidence of Guideline development is not part of this Report, this paper was included because the focus is on developing guidelines for policy implementation*
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<tr>
<td>Conrardy et al. (2010)</td>
<td>America</td>
<td>Systematic search and review of literature (n=34 documents).</td>
<td>To determine the current state of knowledge concerning the implementation of the Joint Commission's Universal Protocol.</td>
<td>1. NR.</td>
<td>2. NR.</td>
<td>3. NR.</td>
<td>4. Endorsement by professional bodies.</td>
<td>5. Ongoing monitoring of error rates was used a mechanism to assess the effectiveness of a Universal Protocol. In terms of quality assessment of included articles reference made to quality assessment broadly.</td>
<td>6. Establish baseline before implementing new process. Measurement tools should be established. 5 studies audited protocol – review of charts and/or observation of practice. No universal method for auditing exists – standard tool required. Mandatory</td>
<td>7. NR.</td>
<td>8. NR.</td>
<td>9. NR.</td>
<td>10. Use more directive language e.g. ‘will do’ rather than ‘recommend or should” – effect of language change not measured.</td>
<td>11. NR.</td>
<td>12. Despite implementation and endorsement by professional bodies’ noncompliance is problematic. Communication, procedural compliance and leadership top 3 root causes for non-compliance.</td>
<td>Challenge of emergencies, workload, time pressure, and high stress environments, human factors (haste, experience, workload, and</td>
<td>Reported that further research is required to identify successful strategies e.g. MDT collaboration, patient involvement, universal checklist, best practice for implementation.</td>
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reporting and anonymous reporting of deviations may be useful.

Vulnerable Systems Syndrome – blame, denial and pursuit of wrong kind of excellence.

13. MDT approach, active staff, patient participation, supportive hospital admin / leadership and active communication that promotes a healthy work environment. Timely and constructive feedback. Staff education and local marketing.

| Dexheimer et al. (2014) America. | To determine the most prevalent method of guideline implementation to establish which methods improve clinical care and identify factors most commonly associated with successful and sustainable implementation. | 1. Despite using protocol in the title, the introduction focuses on guidelines and therefore an interchangeable use of terms is assumed. | 4. A variety of reminder methods are used to integrate guidance into the clinical workflow. These include: a) Paper-based implementation (e.g. use of paper within the patient’s charts i.e. stickers, tags, or sheets of paper; patients identified manually by administrative staff), b) Computer-generated implementation (e.g. application of computerised algorithms to identify appropriate patients), | 7. NR. | 10. Paper based implementation most prevalent method. Moderate increase with ICT in implementation - expected to increase with Electronic Health Records but benefit remains small. | 12. NR. | 13. Each included article was evaluated against a listing of 22 possible success factors (outlined previously by Kawamoto et al 2005 - see comments section); computerised studies had an average of 7.1 success factors. | Reported that asthma guidelines improve patient care and practitioner performance regardless of the implementation method. However evidence base is weak partly because RCTs difficult to implement due to issues with blinding and randomisation. Those improving patient care had an intuitive user interface with prominent display of advice, active involvement of local opinion leaders, local user involvement in development process. Reminder systems effective in changing behaviour and improving care and are more successful when designed for a specific environment. |
however the reminder or protocol printed out and placed in the patient chart or given to the clinician during the visit).

c) Computerised reminders included prompts that were completely electronic (i.e., computerised algorithms identify eligible patients, and prompts provided upon access to the electronic clinical information system.

Findings: Reminders entailed paper-based (n=82), computer generated (n=8), fully computerised (n=12), and other modalities (n=10). The guidance interventions were protocol-based (n=61), treatment-based (n=53), focused on the continuity of care (n=17), scoring based (n=19), and encompassed an educational component (n=48).

5. Study quality was assessed following the methodology of Wang et al 2005- (no comment made on its utility).

6. Primary outcomes measured included protocol compliance (n=32), clinical indicators e.g. patient outcomes/quality of life (n=20), length of stay (range: 2 - 15); computer-generated studies 5.7 success factors (range: 3 - 11); and paper-based studies applied an average of 3.7 success factors (range: 0 - 12).

Within the review of the studies that reported improving patient care an average of 4.5 success factors were reported. The most common success factors reported were “Clear and intuitive user interface with prominent display of advice” (50%), “Active involvement of local opinion leaders” (41%), and “Local user involvement in development process” (41%).

Consider workflow of the environment when implementing reminders.

Kawamoto et al (2005) success factors ranged from:

Guidance developed through an iterative refinement process with local user involvement (including local opinion leaders).

Guidance accompanied by: conventional education; clear and intuitive user interface with prominent display of advice.

Guidance includes: accurate assessments and recommendations

Implementation of guidance saves the time of clinicians, is fast; requires minimal time to implement; requires no additional clinician data entry; provides decision support to patients and clinicians; provides recommendations; allows for periodic performance feedback; integrates with workflow; aligns with organizational priorities and with the beliefs and financial interests of individual clinicians; promotes evidence based action; provides evidence based rationale for decisions; automatically (e.g. with a computer) provides decision support to the clinician at the time and location of decision making; records agreement with recommendations or requests reason for not following recommendations.
<table>
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<tr>
<th>Ebben et al. (2013)</th>
<th>To provide an overview of adherence to international guidelines and protocols in emergency settings and explore factors influencing adherence.</th>
<th>(n=19), admissions (n=8), medication use (n=8), re-hospitalisation (n=4) educational outcomes (n=2). It is notable that no study reported either a decrease in patient outcomes or health care provider performance. A majority of 63% (n=86 studies) demonstrated improved health care provider performance and 31% (n=32) studies noted no change in performance. Improved patient outcomes were noted in 33% (n=34) studies and 36% (n=37) resulted in no change in patient outcomes.</th>
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<tr>
<td>The Netherlands. Systematic Review (with qualitative synthesis) of 35 studies. Retrospective (n=24), prospective (n=9), and cross sectional (n=2) design.</td>
<td>1. A guideline recommendation is defined as &quot;any statement that promotes or advocates a particular course of action in clinical care&quot; [cited by Lugtenberg et al., 2009]. The authors differentiate between guideline and protocol when they noted that &quot;a protocol can be developed, which yields a specification of a guideline and 4. Often developed by (inter)national professional organisations. 5. Used a checklist system based on the STROBE (for the reporting of cohort and cross-sectional studies (Von Elm et al 2008)) and the TREND statement (for the reporting of interventional studies (Des Jarlais et al., 2004). 6. Median adherence to guidelines ranged from 7.8-95% in pre-hospital settings, and 0-98% in the ED setting. Recommendations on monitoring came with higher median adherence in pre-hospital settings 7. NR. 8. NR. 9. NR. 10. Caution urged regarding listing too many recommendations to be adhered to. Consider use of algorithms where protocols are complex with too many decisions to make. Make clear link to guideline recommendations and improved patient outcomes where possible but evidence base often weak. Need studies 12. NR. 13. Eight studies identified factors which influenced adherence. These were classified as: patient (age, race, sex, weight, time of presentation, insurance status, current disease/condition and comorbidity) and to the organizational factors (presence of an emergency physician, ownership (non-federal or governmental) hospital/Reported that adherence to (inter)national pre-hospital and emergency department guidelines shows a wide variation. The researchers noted possible explanations for the sizable variation in adherence rates e.g. the existence of barriers to the implementation of individual recommendations; the strength of evidence and the impact on patient outcomes may have varied across individual recommendations; guidelines generally contain too many recommendations therefore providers choose which recommendations to implement (possible due to time and resource constraints). Therefore to assist with implementation complex guidelines need to be translated into more efficient, practical, applied and feasible protocols, algorithms, and decision aides.</td>
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Ilott et al. (2010) in United Kingdom. Interpretative systematic review of a purposive sample of 33 papers published in the UK –

| To explore how nurses and midwives and health visitors contribute to development, implementation and audit of protocol based care. | 1. “Protocol-based care is a generic term for standardised approaches to clinical care that aim to reduce unacceptable variations in practice and outcomes” p. 770. Protocols | 4. Poor reporting of literature reviews – no reports of clinical librarians used. Poor reports of mapping baseline care. Development process includes pilot studies. Only one study indicated patient involvement in development. | 7. Authors note gap in literature re: resource cost of protocol based care. Costs not noted in NICE (2002) or in literature. Authors highlight that NICE indicate 3-6 months’ timeframe from start to implementation of protocols. Authors suggest this is an underestimate as studies specific to settings. | 10. Cites UK guidance (NICE) – 12 step process but literature shows development process varies. See Fig 1 in paper. Acknowledges that process is rarely linear or follows all 12 steps. | 12. NR. | Understanding factors influencing adherence is limited – more studies required in this area. |
most of which were descriptive in nature. Used QARI version 2 and inductively and deductively recorded the review process.

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<td>show 6 months – 3 years average of 15 months. Time and effort required can be categorised using a four level hierarchy which seeks to capture the spectrum of change: 1) Macro level, policy driven change (top-down change, through national to local guidance). 2) Problem-orientated, bottom-up change (bottom-up and locally owned development process). 3) Micro level, minimal change (involves the least change in practice because the protocol-based care involves formalising current practice). 4) Adopting and adapting documents developed elsewhere (an existing document is adopted and adapted to the local setting) p. 777.</td>
<td>show 6 months – 3 years average of 15 months. Time and effort required can be categorised using a four level hierarchy which seeks to capture the spectrum of change: 1) Macro level, policy driven change (top-down change, through national to local guidance). 2) Problem-orientated, bottom-up change (bottom-up and locally owned development process). 3) Micro level, minimal change (involves the least change in practice because the protocol-based care involves formalising current practice). 4) Adopting and adapting documents developed elsewhere (an existing document is adopted and adapted to the local setting) p. 777.</td>
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<tr>
<td>A tool box design may be more useful than a sequential process for outlining the development process so teams can select steps. 11. Concerns that protocol can impact on the way that health care practitioners work and on their autonomy and professional identity.</td>
<td>A tool box design may be more useful than a sequential process for outlining the development process so teams can select steps. 11. Concerns that protocol can impact on the way that health care practitioners work and on their autonomy and professional identity.</td>
</tr>
<tr>
<td>Strategies should be utilised to assist with adoption. A four level model of change described on p777.</td>
<td>Strategies should be utilised to assist with adoption. A four level model of change described on p777.</td>
</tr>
<tr>
<td>Sequential frameworks underplay what is known about complex innovation and change in health. Protocol development is rarely a linear process, with many studies describing a toolbox approach rather than a stepped approach to protocol development. Assumption often made that standardisation is a good thing – little consideration to adverse effects, resource costs, professional implications of bureaucratic decision making – may be due to bias in reporting. The role of nurses and midwives in the development, implementation and evaluation of protocol based care needs to be made more explicit.</td>
<td>Sequential frameworks underplay what is known about complex innovation and change in health. Protocol development is rarely a linear process, with many studies describing a toolbox approach rather than a stepped approach to protocol development. Assumption often made that standardisation is a good thing – little consideration to adverse effects, resource costs, professional implications of bureaucratic decision making – may be due to bias in reporting. The role of nurses and midwives in the development, implementation and evaluation of protocol based care needs to be made more explicit.</td>
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| Stacey et al. (2013) Canada. | **Develop and evaluate a template for evidence informed symptom protocols for use by nurses over the phone for management of patients with cancer receiving treatment.**

"An agreed upon standardized approach to guide nursing practice" which is based upon "the best available scientific evidence and formatted for ease of use to fit with usual clinical routines or practices for a specific patient situation". Also referred to protocols as "knowledge translation tools" (p. 2).

Principles for clinical nursing protocol template features identified as:
- Evidence based
- Template should meet **included role expansion, workforce redesign, increased service demand, setting standards, changing care settings.**

4. Refers to the use of CAN – IMPLEMENT method (Harrison & van den Hoek, 2010) a resource designed to facilitate guidelines adaptation and knowledge activation. 3-part resource which provides guidance to those a) using already developed guidance, b) adapting guidance recommendations for the local context and c) guidance implementation. During protocol development process authors specifically refer to:
- Searching for the evidence, screening the evidence, quality appraising the evidence.
- Data extraction.
- Engaging in an iterative protocol development process.
- Evaluation of symptom protocol (initial acceptability and

7. NR.

8. NR.

9. Included 24 stakeholders including:
- expertise in oncology nursing and methodological expertise (knowledge translation, CAN IMPLEMENT methodology, library searching, health services research and the electronic and experts in the systems used in the health system).

10. NR.

11. NR.

12. NR.

13. Fit with clinical work flow, user-friendly format, training local opinion leader.

Authors developed new template for nurses to use when assessing, triaging, documenting, and guiding patients to manage their cancer treatment-related symptoms. Evidence gap noted - need to evaluate impact of protocols on outcomes.
the criteria for guideline (AGREE II-rigour).
- Useable in clinical practice.
- Should be integrated into electronic health record and clinical practice.
- Be in plain language.
- Consider National guidance on common criteria and terminology for adverse events.
- Ensure consistency across guidance.

3. NR.

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<th>5. AGREE Instrument, 4 raters reviewed each included guideline independently. The quality of systematic reviews was appraised using AMSTAR.</th>
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<td>6. Preliminary evaluation of protocol in terms of usability and acceptability (n= 12 clinical oncology nurses) demonstrated. &quot;high readability (n = 12), just the right amount of information (n = 10), appropriate terms (n = 10), fit with clinical work flow (n = 8), and being self-evident for how to complete (n = 5)&quot; p. 1.</td>
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<td>White et al. (2011)</td>
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<td>3. NR.</td>
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<td>Yue at al. (2014)</td>
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<td>2. NR.</td>
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<td>America.</td>
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A systematic review (with meta regression analysis) (n=119; 50 non-RCTs (details not provided) and 7 RCTs related to protocols specifically).

To review “ICU-based knowledge translation studies to assess the impact of knowledge translation interventions on processes and outcomes of care” p. 2630.

1. NR.
2. NR.
3. NR.
4. NR.
5. Quality review methodological details not disclosed in paper (see additional comments).
6. Interventions that included protocols with and without education showed to improve continuous process measures (7 observational studies and 1 randomised controlled trial; standardised mean difference [95% CI]: 0.26 [0.1, 0.42]; p = 0.001 and four observational studies and one randomised controlled trial: 0.83 [0.37, 1.29]; p = 0.0004, respectively.
7. Not dealt with specifically in the review. However in the discussion referred to a recommendation that interventions need to be affordable and sustainable (i.e. by identifying “the minimal components of an intervention that render them effective” p. 2635.
8. NR.
9. NR.
10. NR.
11. NR.
12. NR.
13. NR.

The meta regression analysis revealed a trend indicating that studies of lower quality tended to inflate the effect size (i.e. A 1% decrease in study quality was linked to a 6% increase in effect size (p=0.08).

Protocols with or without education were associated with the greatest improvement in processes of care.

Future recommendations: Research could be enhanced by having a common taxonomy (classification) of knowledge translation interventions; conducting multisite pilot tests of interventions; focus on processes of care that are linked to patient outcomes; and studies including organisational and clinical context details to allow for appropriate comparisons.
## Bundle

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<td>Blot et al. (2014) Australia. Systematic review (n=65 articles) and Meta-analysis (n=43 – before and after studies, interrupted time series, RCTs, non-RCTs). Of these, 11 trials related to bundles with/without checklists. Additional 18 trials were on checklists and not included in this table).</td>
<td>To examine the impact of quality improvement interventions on central line-associated bloodstream infections (CLABSI) in adult intensive care unit (n=564).</td>
<td>1. A short list of at least 2 Institute for Healthcare Improvement (IHI) prevention measures to be used during CVC insertion and/or maintenance.</td>
<td>5. NR.</td>
<td>6. In trials with care bundles (and checklists), CLABSI risk reduction was stronger (OR, 0.34 (95% CI, .27-.41)) than in trials without these (stronger (OR, 0.45 (95% CI, .36-.55) P .026).</td>
<td>7. NR.</td>
<td>8. NR.</td>
<td>9. NR.</td>
<td>10. Combine with a checklist.</td>
<td>11. NR (other than impact).</td>
<td>12. NR in results but noted in discussion as: lack of problem awareness, poor familiarity or non-agreement with guidelines, low self-efficacy, inability to change practice, or lack of resources.</td>
<td>13. NR.</td>
<td>Implementation of care bundles and checklists appears to yield stronger risk reductions in CLABSI. Lack of randomised or controlled study designs, inconsistent reporting of prevention measure compliance, and heterogeneity evident. Suggested framework for future research with improved methodological rigour and longitudinal follow up.</td>
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<td>Chamberlain</td>
<td>To assess the 1. &quot;a selected set of...&quot;</td>
<td>4. NR.</td>
<td>7. NR.</td>
<td>10. Compliance</td>
<td>12. Beneficial</td>
<td>Studies reported as lacking in...</td>
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Note: 2 types of bundles evaluated: (i) Sepsis Resuscitation 6hr. Bundle – to be completed within 6hrs of admission; (ii) Sepsis Management 24hr. Bundle- to be completed within 24hrs of admission.

| Interventions or processes of care distilled from evidence-based practice components that when implemented as a group presents a more robust picture of the quality of care provided, benchmarks performance and improves patient outcomes” (from Berwick, 2006). | 5. NR. |
| 6. The Resuscitation 6 hour bundle pooled analysis (1819 Patients) twice more likely to be associated with survival than standard care and had greatest survival effects (odds ratio (OR) 2.124, 95% CI 1.701—2.651, p < 0.000). The Management 24 hour Bundle pooled analysis (16,521 patients) was 1.6 times more likely to be associated with survival than standard care and had the lowest survival (OR 1.646, 95% CI 1.036—2.614, p < 0.035). When both bundles were combined (Complete Bundle) the combined survival effect was (OR 1.744, 95% CI 1.421—2.141, p < 0.000) and 1.7 times more likely to be associated with survival than standard care. With Bundles was achieved in only 50% of patients. Reasons not reported. | 8. NR. |
| Effect of the sepsis bundles on patients’ outcomes is not yet of sufficient understanding and quality in Australia to promote the guidelines as a global standard of care. | 11. NR. |

Schweizer. et al. (2014) America. Meta-analysis To review all studies of interventions to improve hand hygiene compliance to

| 1. Refers to a WHO Bundle specific to hand hygiene. 2. Refers to components of Bundles specific to 3. NR. 4. NR. 5. NR. 6. In trials where education, reminders, | 4. NR. |
| 7. NR. 8. NR. 9. NR. | 7. NR. |
| Appears to be an increased adoption of hand hygiene bundles. Reported that studies were of moderate to low methodological quality and higher quality studies. | 13. NR (other than impact). |
n=46 studies. Randomised controlled trials observational study designs. Evaluate existing bundles and identify areas of promise to target high-quality studies. Hand hygiene noting most common component interventions were education, reminders, feedback, and access to ABHR. Components specific to bundles as processes of care not reported. Note: in this analysis 78% of studies assessed a bundle of >1 intervention. Mean number of interventions assessed in a bundle was 3 (range, 2–7).

Zilberberg et al. (2009). America. Systematic review of 4 studies using 3 or more of the IHI ventilator bundle. Before and after (n=3) and time series (n=1) designs. Review of the literature to determine the effectiveness of the bundle to prevent VAP.

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<td>1.</td>
<td>A small straightforward set of practices – generally 3-5 – that when performed collectively and reliably have been proven to improve patient outcomes (IHI definition).</td>
<td>4.</td>
<td>IHI provides methodology to implement and assess compliance. Goal 95% adherence to 4 elements of bundle.</td>
</tr>
<tr>
<td>2.</td>
<td>NR.</td>
<td>5.</td>
<td>NR.</td>
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<tr>
<td>3.</td>
<td>NR.</td>
<td>6.</td>
<td>Adherence reported in 2 studies and 2 used LOS as outcome measure. VAP incidence (per 1000 MV days) reduced in all four studies.</td>
</tr>
<tr>
<td>7.</td>
<td>NR.</td>
<td>10.</td>
<td>NR.</td>
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<td>8.</td>
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<td>9.</td>
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<td>13.</td>
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No conclusive statements regarding the effectiveness and/or cost effectiveness of bundles to prevent VAP reported due to lack of methodological rigor of the reported studies.

Reported that robust studies required evaluating strategies to prevent VAP to determine best practice and establish baseline for new technologies to compare outcomes.
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<tr>
<td>Carpenter et al. (2011) U.S.A. Report on a 3 year project inclusive of Systematic Review and Delphi type studies. Note: The number and type of studies included in systematic review were not reported. Given the detail presented on methodological...</td>
<td>“…to identify the main research opportunities that can be used to develop QIs (Quality Indicators) for a minimum standard of emergency care for older adults” (p.644). Note: Originally, the project aimed to develop emergency care specific QIs for elderly patients on</td>
<td>1. NR.</td>
<td>2. Evidence based.</td>
<td>3. Evidence of substandard care; Quality improvement agenda; Public demands.</td>
<td>4 Multi-stage approach – (i) Establishment of Task Force who identified target areas for improvement; (ii) Identification of content experts to conduct systematic reviews; (iii) Critical evidence summaries and potential QIs prepared from systematic reviews; (iv) Delphi- style vetting and prioritisation of proposed QIs with professional stakeholders mainly at scientific meetings) followed by revisions.</td>
<td>5. NR.</td>
<td>7. NR.</td>
<td>8. NR.</td>
<td>9. Multi-disciplinary and content experts.</td>
<td>10.</td>
<td>11.</td>
<td>12. Lack of high-quality research evidence to support development phase of QIs.</td>
<td>13. Multi-disciplinary consultation and support for development phase.</td>
<td>QIs for standards of care must be must be based on the highest quality evidence and requires broad-based multidisciplinary support.</td>
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<td>Lee et al. (2011) Australia. Systematic review (n=22, RCTs, Interrupted time series, Cohort, Case–control, and Before–after studies; 400,000 patients, mostly adults).</td>
<td>“to outline the rationale for new Perioperative Systems, synthesize the evidence supporting these new systems and consider the current state of Perioperative Systems and its future development” (p.214).</td>
<td>1.NR. 2.Common features specific to Perioperative Systems: “(1) Early preadmission assessment and preparation of patients booked for surgery or procedures. (2) Development of centralized systems to gather health and other information about patients before hospital admission, such as by patient questionnaires. (3) Development of Preadmission clinics for early assessment of patients. (4) A triage system to identify which patients need to 4.NR. 5.NR. 6. Compared to standard care, perioperative systems showed that: (i) Reduction in length of stay (n=1, mean difference −0.35 days, 95% CI, −0.27 to −0.43); and in outpatients more than inpatients (n=1, 5.5 days vs. 6 days; mean difference=−0.5 days, 95% CI −2.0 to 1.1). (ii) Decrease in surgery cancellation rate (n=6) of between 1% and 8%; children three times less likely to be cancelled (n=1, odds ratio 3.18, 95% CI 1.32–7.63). (iii) Reduction in perioperative tests ordered (n=5) ranging 7. NR other than on impact (see No. 6 (v). 9.NR. 10.NR. 11. Not explicit apart from data on positive impact (See. No. 6) indicating strengths of perioperative systems). 12. Inadequate financial support; anaesthetic staff shortages. 13. Co-operation cooperation of anaesthetists; Change agents as leaders; Highly motivated and co-operative teams; Systematic and gradual staged implementation. Noted that implementation of new Perioperative Systems involves substantial changes in hospital organisation, culture, clinical practice and staff behaviours. However, there is limited evidence published on the contributing factors to driving, modifying, or resisting the implementation of changes associated with new perioperative systems. Only 2 RCTs were included in the studies reviewed in this paper.</td>
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attend a Preadmission clinic. (5) Use of a multidisciplinary team based within the hospital to coordinate complex preparation of patients before surgery. (6) Admission to hospital of most patients having surgery only shortly before the procedure. (7) Admission and preparation of patients through a centralized preoperative area, rather than in the same ward where the patient would be managed postoperatively” (p. 215).

3. Evidence of improvements (e.g. patient flow) from pre- and post-perioperative implementation studies.

from 40% to 59%; (iv) Reduction on medical specialist consultations (n=2, ranging from 66% to 70%; (v) Reduced costs (n=3, e.g. ranging from 8% to 18% relative reduction in mean cost per patient.

Note: Conflicting or inconclusive findings reported for patient satisfaction; complications, and morbidity, and quality of life.
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<tr>
<td>Beitz et al. (2012) Philadelphia</td>
<td>To “1) develop evidence-based algorithms for the safe use of Negative Pressure Wound Therapy (NPWT) in adults with acute and chronic wounds by non-wound expert clinicians, and 2) obtain face validity for the algorithms” (p.50).</td>
<td>1. Algorithms provide a step-by-step visual interpretation of guidelines. Algorithm steps more narrowly defined than guideline recommendations. 2. Examples of layout provided in article. 3. Algorithms providing a step-by-step visual interpretation of some NPWT guidelines which had been developed for specific types of wounds. However, most are based on expert consensus, have 4. A flow diagram of NPWT algorithm development process (Figure 1) was provided. A phased approach to searching for evidence, followed by development of algorithm, refinement of algorithm structure, expert validation (face and content) and final algorithm refinement was used. 5. The Strength of Recommendation (SORT) Taxonomy was used to extract and record the level of evidence (study quality) and strength of recommendation in the spreadsheet for all publications reviewed. Comments relating to utility of SORT included: Strengths (its patient outcome orientation, clarity regarding the criteria to differentiate between types 6. NR. 7. NR. 8. Larger content validation. 9. Development: Non-wound expert clinicians. Following the development, wound experts were utilised in relation to face validation. 10. NR. 11. (i) Designed for non-expert use. (ii)Only one NPWT-related recommendation had sufficient and consistent evidence for an A strength of recommendation. 12. Some evidence ratings would be stronger if a clinical guideline instead of an algorithm format is used, because, by definition, algorithm steps are more narrowly defined than guideline recommendations. Algorithms must be tested. Need to scrutinize care issues for paediatric use. Some confusion over wound terminology among experts. 13. With appropriate education</td>
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<td>Clinical and clinically relevant publications</td>
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| Briassoulis et al. (2011) Greece | To “perform a systematic review of the pooled effect of articles presenting current BLS algorithms (2005) distributed to health care providers (HCPs) and lay persons (LPs) for the treatment of cardiac arrest; and to record and classify potential inherent factors that might unpredictably influence | 1. NR.  
2. NR.  
3. Various BLS differentiations have been found created on “variants of victims’ age, rescuers’ qualifications and instructors’ specialty rather than on simple unique pathophysiologic mechanisms” (p. 463).  
4. Phase 1: Literature search exploring inhibiting factors of currently available BLS algorithms. Phase 2: Reconstruction – 1) real time situation implicating victims and rescuers in one model 2) a hypothetical challenging all in on BLS algorithm model.  
5. NR.  
6. Dissimilar CPR options were reported: five contrasting algorithms (21.8%); three two-option models (13%); six vague technical or scientific suggestions (26%); and nine multiple choices of action (39.1%). Identified references contributed in a different way to the “development of educationally polymorphic | 7. NR.  
8. NR.  
9. NR.  
10. Hypothetical ‘all-in-one’ BLS algorithm could be a starting point in searching for a simple universal model able to optimise CPR teaching, learning, retention and performance.  
11. (i) NR  
(ii) Inhibitory factors cited as: contrasting algorithms, “two-option models, and vague technical or scientific suggestions of algorithmic polymorphisms” overly complicate algorithms which | 12. NR.  
13. Future trials coupled with further research in simplifying other aspects of CPR might be worthwhile in the development process. |
simplicity in teaching, learning and retention of CPR (p.463).

BLS options in each of the four categories ($P < 0.0001$) and were all brought about by variants of victims and rescuers” (p.462). Participants of CPR seminars responded that in an emergency they could remember the hypothetical BLS model (90%, $P = 0.007$) rather than a current BLS algorithm for adults (42.2%) or children (36%).

compromise the individual’s ability to remember the algorithm and mitigate against ease of use of the BLS algorithm (p. 456).

Biederwolf (2013)  
U.S.A.  
Systematic review (publications relating to n=26 diagnostic test).

<p>| To “identify orthopedic shoulder physical examination special tests with the best clinical utility statistics to ease the diagnostic process through usage of an examination algorithm, and to expedite the diagnostic process by guiding the practitioner to select only the special tests that are necessary based on pattern recognition | 1. NR. | 2. NR. | 3. NR. | 4. Using Pre-test and post-test probabilities, specificity, sensitivity to calculate clinical utility statistics. Evidence-based statistical utility profile was chosen as threshold criteria for inclusion of test in the proposed examination algorithm. Test Item Cluster (TIC). 5. The Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool (Whiting et al 2004) was used to test the internal and external validity – no comments provided in relation to utility of same. 6. NR. | 7. NR. | 8. NR. | 9. NR. | 10. NR. | 11. NR. | 12. NR. | 13. NR. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| This special testing algorithm should be modifiable for the future, as studies with better statistical data emerge for specific special tests and/or categories of shoulder diagnosis. | | | | | | | | | | | | | |</p>
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<tr>
<th>Study</th>
<th>Country</th>
<th>Methodology</th>
<th>Key Points</th>
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<tr>
<td>Christensen et al. (2013)</td>
<td>U.S.A.</td>
<td>Systematic search and Review (n=17, RCTs prospective cohort studies, CCS, SR)</td>
<td>To &quot;present an algorithm with accompanying treatment parameters for the management of congenital muscular torticollis (CMT) based on the best available literature&quot; (p.453). 1. Medical algorithms &quot;provide clinicians with current evidence-based information that helps them in decision-making&quot; (Verkerk et al., 2006, p.456). 2. Systematic analysis of current evidence, strength of recommendation, various grading systems. 3. A number of CMT algorithms have been published to rule out discrepancies in diagnoses or to guide treatment; however, they lack the specificity to assist in clinical decision-making. 4. Development of an algorithm is a three-stage process includes creation (literature search), validation, and assessment of impact (McGinn et al., 2000). 5. Quality assessment using Sacketts level of evidence (Sackett et al., 2000), no comments made regarding its utility. 6. NR.</td>
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<td>Feldheiser et al. (2012)</td>
<td>Europe</td>
<td>Meta-Analysis and Systematic Literature</td>
<td>To &quot;create a treatment algorithm by identifying clinically relevant intraoperative haemodynamic management may 1. NR 2. NR 3. Using an algorithm for goal-directed haemodynamic management may 4. Methodology of development: Appraisal of the evidence, creation of draft algorithm, expert consensus through modified Delphi method (with emphasis placed on the &quot;level of evidence, ethical aspects, clinical 7. Against standard management reimbursed costs were reduced 86.3 ± 258.8 versus 17.3 ± 95.5, P =0.024, as was time in days (3.18 ± 12.9 versus 0.58 ± 4.3, P = 0.018). 10. NR 11. (i) Reduced length of hospital stay, requirement for ventilation and incidence of prolonged hospital stay, and reduced 12. NR 13. Evaluation of the validity and effectiveness of the proposed CMT algorithm is needed.</td>
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| Review (n=41, types of studies not specifically stated—mainly RCTs). | indices* (p.1227). | allow for a comparison of different monitoring studies and infusion regimens; minimising the confounding effect of non-protocolised haemodynamic management in peri-operative care. | relevance, risk: benefit ratios, degree of applicability, and feasibility of applying the algorithm* p. 1228, followed by a feasibility study. 
5. All included publications were evaluated against criteria described by the Oxford Centre for Evidence-based Medicine (2009). No comments made on its utility. 
Within the algorithm each recommendation grading was derived according to the requirements of the Council of Europe (2001) which placed weight on both the level of evidence and utility in clinical practice e.g. “Recommendations not supported by adequate external evidence but considered indispensable to clinical practice, according to expert experience, could receive the highest grade of recommendation following consensus agreement” p. 1230. 
6. Compared with standard conventional haemodynamic management, use of the algorithm considerably reduced length of hospital stay (mean ± SD 25.9 | 8. NR. 
Furuta et al. (2012)
U.S.A.
Expert opinion and systematic literature review (n=2, clinical studies).

| 1. NR. | 2. NR. | 3. There is a lack of published data on the management of GI disorders in this subset of children. | 4. Two stages: Modified the original guidelines by consensus, expert opinion through a series of teleconferences, and face-to-face meetings. Draft documents were reviewed and revised by ATN developmental paediatricians. Feasibility testing of the algorithm over a 6-month period (4 pilot sites) to help identify points of concern; the intent was not to validate the algorithm. Pilot sites participated in monthly conference calls to provide updates, understand variance, and recommend changes to the algorithm. | 5. Adaptation of the GRADE system used to grade evidence (Guyatt et al 2008). No commentary made in relation to its utility. | 6. In the context of algorithm testing: Patients who responded to impaction treatment but were not symptom free at | 7. Pilot tested 4 sites—| 8. NR. | 9. GI specialists. | 10. Within the algorithm, a smooth-edged box indicates a starting or ending point, a sharp-edged box indicates a predefined process or specific action, and a diamond shape indicates a point of decision. The items in the accompanying text are points of elaboration whose number corresponds to the algorithm item number. | 11. (i) NR (ii) Scant evidence available to underpin algorithm (only 2 applicable ASD specific studies identified in review of literature). | 12. NR. | 13. This algorithm is readily usable and did not interrupt the flow of clinics. To assist practical implementation of the algorithm throughout the patient–health care provider interaction, the Constipation Checklist summarised key steps. |
the time of follow-up, treatment medications were altered 69% (18/26). Long-term follow-up was organised for 82% (28/34) of patients for whom treatment was deemed to be effective. Pilot sites noted that the algorithm did not interrupt the clinic flow and was readily applicable to the clinical context.

| Hanekom et al. (2011) South Africa and Australia. | To “report on the content validation of an evidence-based clinical management algorithm (EBCMA) aimed at the prevention, identification and management of PDF in critically ill patients” (p.801). | 1. NR. | 2. NR. | 3. A paucity of a practice oriented synthesis of related studies and the need to bridge the gap between evidence and clinical practice, thus the need to report on the content validation of an EBCMA. | 4. A three round iterative Delphi process was used to validate the evidence based clinical management algorithm (EBCMA). A six-step process was used to convert the best practice recommendations into a linear algorithm (Lobach et al., 2000). | 5. Three unidentified critical appraisal tools were used to appraise the methodology of the eligible papers (no comments made regarding utility of same). | Recommendations graded according to GRADE (Guyatt et al., 2008; Schumeman et al., 2006). Possible explanations for where the panel did not reach agreement where: 1) when the quality of evidence is judged as poor and experts then rely on clinical experience 2) the algorithm contained statements which were rated “essential, important, to be considered, thereby offering a hierarchical framework of options” p. 807. Researchers need to report on critically relevant outcomes. | 7. Developing an EBCMA is further supported by the cost effectiveness of using practice guidelines to reduce variation in practice (Supported by a number of references). | 8. NR. | 9. Authors of peer-reviewed publications relating to the management of PDF in critically ill patients. | 10. NR. | 11. (i) NR (ii) The sample was limited to researchers with a proven track record in the specific subject areas. New researchers in specific areas of interest were therefore not included. This could limit the external validity of the clinical algorithm. It was noted by the authors that algorithms have the potential to diminish variability in clinical practice and thus maximise safety and treatment outcomes for patients. | 12. When experts judge to quality of evidence to be poor, outcomes not clinically relevant, paucity of research reports, and confronted with the same evidence. Variations in initial rating of statements due to a large expert panel. |
outcomes reported in research are not clinically relevant 3) when scientific evidence does not match clinical evidence, 4) empirical evidence can be interpreted differently by different people.

Authors noted that “physiological, clinical and empirical evidence” considered by panellists in judging statements (p. 808).

6. NR.

van Rijsikw et al. (2013)
Philadelphia.

Systematic Literature Review
(n=117 publications used in the creation of the algorithm and the n= 55 publications used to populate the evidence table; types of studies were not stated).

To “perform an evidence-based algorithm for inclusion in an existing industry-sponsored, evidence-based wound care program that will: 1) help clinicians assess and document overall patient PU risk; 2) help clinicians assess and address modifiable PU risk factors; and 1. NR.
2. NR.

3. “Cognitive forcing strategies such as checklists and algorithms can aid optimal clinical decision making and actions, thus expediting safe patient care” (p. 28, Croskerry et al., 2003, Sherbino et al., 2011).


5. Quality of each study rated using SORT (Ebell et al., 2004), authors noted that the decision to use same was guided by the fact that SORT meets IOMs criteria for the 7. NR.
8. NR.

6. NR.


10. Colour Schemes to bring attention to critical steps. Users enter the algorithm at the point of patient assessment for evident risk or history of recent PU. Specific steps should be unambiguous.

11. (i) Good strength of recommendation (Level B), only minor modifications post CVI. Will also assist with promoting patient safety in a fast-paced clinical environment. (ii) Some 12. Cannot be guaranteed appropriate or effective for neonatal and/or paediatric populations.

Regarding the CVI: “several steps (interventions) with the lowest quality studies and level of evidence (C strength of recommendation) had the highest CVI”. For example some related to skin care and preventing skin exposure to moisture, which had a CVI >0.9. Practitioners consider these interventions important, however they lack good quality evidence.

Quantitative analysis provided an overall mean score of all algorithm decision statements/steps was 3.6 (SD 0.8), CVI 0.89. Qualitative analysis generated themes regarding individual decision statements/steps:
3) guide clinicians toward an evidence-based protocol of care for patients with impaired skin integrity” (p.28).

conduction of systematic reviews and guideline development and it is patient-centred. SORT was noted to be "useful" as it included clear criteria for rating identified studies.

6. NR.

concerns re legal implications of timeframes mentioned in algorithm.

issues with timing, specifying the content of pertinent education, defining limited mobility, appearance of the algorithm (strengths and weaknesses), wording, and specification of products.

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<th>Source through Grey Literature Search</th>
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<td>Clark et al 2011 U.K.</td>
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Systematic review (n=11 studies i.e. N=4 cluster trials and n=7 two armed randomised studies). N=8 studies related to a stepped treatment algorithm and n=5 included nurse prescribing, with some overlap.

To present a systematic review of nurse-led interventions to control blood pressure in people with diabetes mellitus.

1. NR.
2. NR.
3. NR.
4. NR.
5. NR.
6. There was overlap between nurse led interventions and algorithm. For all studies pooled analysis demonstrated a greater reduction in systolic blood pressure compared with usual care however data across the 8 studies could not be pooled.

7. Future clinical trials should include a robust cost-effectiveness analysis.
8. NR.
9. NR.
10. NR.
11. NR.
12. NR.
13. NR.

Authors noted that the small sample sizes may have meant that studies were underpowered to establish differences in dichotomous outcomes. Reporting findings relating to "absolute blood pressure reductions" may well be the more robust outcome measure for comparative purposes in future reviews (p. 259).
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<td>Fudicker et al. (2012)</td>
<td>Germany. Review (n=20, evaluation studies - prospective longitudinal, retrospective, prospective randomised, survey, structured interviews, observational, and chart review designs; 310 participants /charts).</td>
<td>To present data on the implementation of the “WHO Surgical Safety checklist and its effects on operative morbidity, mortality, and safety culture.” (p.697).</td>
<td>1. NR.</td>
<td>2. NR.</td>
<td>3. Identified need to improve communication, teamwork, and safety culture as a strategy to reduce errors.</td>
<td>4. NR from evidence but recommended that pilot phase needed prior to full implementation.</td>
<td>5. NR.</td>
<td>6. (i) Significant relative reduction (36%) in complication rate (n=1); (ii) Significant relative reduction (62%) in mortality (n=1); (iii) 14.9% prevention of all wrong-side errors (n=1 e.g. marking the wrong side); (iv) Checklist contributed to correct implementation of guidelines for thrombosis prevention (n=2); (v) Significant improvement in</td>
<td>7. NR other than to state that implementation is cost-neutral when found to reduce 5 serious complications per year (n=1).</td>
<td>8. NR.</td>
<td>9. Not explicit but noted that leading physicians and staff members must be involved for successful implementation.</td>
<td>10. Include only the most essential items designed to be used in under 2 minutes; Checklist completion needs at least 2 professionals using read aloud technique; Written instructions on use should be available; They should become part of a comprehensive safety plan or system.</td>
<td>11. (i)Strengths – Dismantle the hierarchical barriers to communication and improves</td>
<td>12. Lack of compliance in partial/complete implementation in 8 studies – possible reasons being culture of poor communication; interruption of workflow by having to do checks; adverse impact on professional autonomy of surgeons.</td>
<td>Two studies in the review showed a relative risk reduction of mortality by 47% and 62%.</td>
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knowledge of team names and roles as well as the patient's identity and past/current medical history (n=1).

Note: Only descriptive data presented on the effect on safety culture, morbidity and mortality and practical implementation. Levels of significance statistical values were not reported.

**Ullman et al 2013**

*Australia.*

Paper reporting on checklist development— including a systematic review (n=8, observational, RCT, cross-sectional studies).

"To develop a PICU (paediatric intensive care unit) specific checklist to improve evidence based management and thereby prevent errors of omission" (p. 61).

1. Checklists are "tools that condense large quantities of information, reduce the frequency of errors of omissions, create reliable and reproducible evaluations, improve quality standards and use of best practice" (p. 62 from (Hewson et al 2006 and Hales et al 2008).

2. NR.

3. Desire to improve EBP and prevent error omissions

4. Two phased approach to development: Phase 1: systematic review of the literature on characteristics of adverse events, summarising and categorising or local hospital reports of adverse events Phase 2: Nominal Group Technique (NGT) – used to determine the structure and content of the checklist drawing on experiences and literature from Phase 1. MDT participated in the group. The output was the development of KID Safe Checklist representing 8 areas of care.

5. NR.

6. NR.

7. NR.

8. NR.

9. NGT team consisted of senior paediatric intensive care representatives from medical, nursing, research and patient safety domains.

10. Structured/Standardised that is short and simple; Select inclusion of items of care to avoid checklist fatigue; Mnemonic structure aids recall (KID SAFE – Kids developmental needs, Infection, DVT prophylaxis, Sedation, Analgesia, Family, Enteral needs).

11. (i) Checklist has potential to: contribute to holistic care; prevent adverse events; be adaptable to local needs.

12. NR.

13. NR.

Noted that a limitation of the study is that team member volunteers from a single site were part of the NGT. However, strength of the study was that a systematic review and review of actual adverse events was undertaken by staff to identify most important elements to include in checklist.

Noted that further research using prospective designs are needed to determine the effectiveness of the KID Sage checklist in reducing preventable adverse events.
<table>
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<tr>
<th>Treadwell et al. (2014)</th>
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<tr>
<td><strong>U.S.A.</strong> Systematic review (n=33, before-after, case series, qualitative descriptive; involving 18 hospital sites).</td>
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<td><strong>To summarise experience with surgical checklist use and efficacy for improving patient safety</strong> (p.299).</td>
<td><strong>6. NR.</strong></td>
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Checklists (CLs) reviewed were: the WHO checklist (n=23); the Surgical Patient Safety System (SURPASS) checklist; and a wrong-site surgery checklist.

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<td><strong>1. NR.</strong></td>
<td><strong>4. NR other than to state a stepwise implementation process facilitates success. Noted the need for research to inform implementation.</strong></td>
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<td><strong>2. NR.</strong></td>
<td><strong>5. NR.</strong></td>
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<tr>
<td><strong>3. Prevention of errors and complications during surgery or peri-operatively; Ensure patient safety.</strong></td>
<td><strong>6. Compared to baseline/control data post implementation of CLs showed positive results e.g.:</strong></td>
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(i) Decreases in mortality for WHO CL (n=2) e.g. from 1.5% to 0.8%; and from 3.13% to 2.85%.
(ii) Reduction in inpatient complications for WHO (n=3) e.g. 11% to 7%; from 22.9% to 10%; and also site infections (AOR 0.28, 95% CI 0.15 to 0.54).
(iii) Avoidance of 9 potential incidents within one month of piloting WHO CL; (iv) Increased use of prophylactic antibiotics.

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<td><strong>7. Costs relate to checklist development, modifications, staff notification/training and additional Operating Room time.</strong></td>
<td><strong>8. NR.</strong></td>
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<tr>
<td><strong>9. NR.</strong></td>
<td><strong>10. Tailoring needed for different contexts (WHO CL); Poster presentation of CL (may increase compliance); Design to avoid duplication of information already routinely collected; Short format recommended.</strong></td>
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<tr>
<td><strong>11. (i) Inexpensive strategy to improve patient safety/care.</strong></td>
<td><strong>12. Confusion on how to use; Pragmatic challenges to efficient work-flow; Access to resources; Staff attitudes; Resistance from surgeons; Resistance to change; Legal implications if complications occurred.</strong></td>
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<tr>
<td><strong>(ii) NR.</strong></td>
<td><strong>13. Good training; Senior leaders as local champion; Supportive upper management; Feeling of ownership; Stepwise implementation process (with real-time feedback).</strong></td>
</tr>
</tbody>
</table>

Noted that influences on positive results for WHO CL are likely to have been multifactorial e.g. checklist itself, the hawthorn effect, increase in other safety technologies and otherwise improved safety culture in the site due to a variety of environmental conditions.

Need for further research noted to clarify the unique nature of the contribution of checklists and to inform effective implementation.
Borchard et al. 2012 Switzerland. A systematic review of

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Checklists or protocols are instruments that are completed or marked preoperatively or during the procedure with WHO CL from 57% to 77%;</td>
</tr>
<tr>
<td>2.</td>
<td>Improved compliance to ≥4 (out of 6) safety processes with WHO CL (n=1).</td>
</tr>
<tr>
<td>3.</td>
<td>NOTE: Most studies reviewed on WHO CL did not include health outcomes. The SURPASS CL reported as decreasing % of patients with complications, in-hospital mortality, and need for reoperations; however no data were presented.</td>
</tr>
<tr>
<td>4.</td>
<td>Studies reviewed on wrong site checklists did not include health outcomes. Not explicit – reported on the outcomes, facilitators and barriers to checklist implementation from 33 studies; impact on setting included decrease in patient mortality, inpatient complications, improved safety attitudes.</td>
</tr>
<tr>
<td>5.</td>
<td>Not explicit – reported on the outcomes, facilitators and barriers to checklist implementation from 33 studies; impact on setting included decrease in patient mortality, inpatient complications, improved safety attitudes.</td>
</tr>
<tr>
<td>6.</td>
<td>7. Cost implications not measured but time was cited as a factor.</td>
</tr>
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<td>7.</td>
<td>8. NR.</td>
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<tr>
<td>8.</td>
<td>9. Surgeons, surgical</td>
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<tr>
<td>9.</td>
<td>10. Simple easy to follow format</td>
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<td>10.</td>
<td>11. (i) Strengths-relative risk for mortality is reduced with</td>
</tr>
<tr>
<td>11.</td>
<td>12. Barriers include lack of time</td>
</tr>
<tr>
<td>12.</td>
<td>13. Implementation needs to be led by a multidisciplinary team – which meets</td>
</tr>
<tr>
<td>13.</td>
<td>For effective implementation it is important to communicate to staff why and how the checklist should be used. Staff engagement in the development process leads to more successful implementation.</td>
</tr>
<tr>
<td>studies (n=22), mostly prospective observational studies, surveys or pre/post design.</td>
<td>initiation and implementation of checklists or protocols in surgical theatres.</td>
</tr>
</tbody>
</table>
**Appendix 4: A Synopsis of the barriers and facilitators to the development, implementation and evaluation of guidance**

<table>
<thead>
<tr>
<th>Level</th>
<th>Factors</th>
<th>Facilitators (solution focus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Expectations and experiences</td>
<td>Optimise communication. Inclusion of patients as part of the guidance development process.</td>
</tr>
<tr>
<td>Healthcare Professional</td>
<td>Difficulties in accessing, understanding and using research</td>
<td>Education and training on research methods. Access to clear relevant, reliable research findings. Access to online systematic reviews.</td>
</tr>
<tr>
<td>Guidance development team</td>
<td>Awareness and knowledge of new guidance</td>
<td>Guidance development and implementation teams should have access to experts in information science, clinical epidemiology (evidence synthesis), implementation science and systems engineering. Guidance development teams have a valuable role in highlighting research gaps. Limit number of recommendations in new guidance and consider use of algorithm where larger numbers of steps are required. Individual mnemonic(s) can help health care providers remember guidance steps (e.g. checklist). Intuitive user interface with new guidance. Communicate using multimedia e.g. availability of summary statements, accessibility e.g. through emails. Targeted education, training, simulation.</td>
</tr>
<tr>
<td>Attitudes</td>
<td></td>
<td>Staff need to understand the rationale for the guidance and identified outcome benefits e.g. through evaluation-- track the effect of guidance implementation on prevention of adverse events/error reduction. Details of the outcomes which are to be tracked (where evidence is available) should be included within the guidance.</td>
</tr>
<tr>
<td>Human factors</td>
<td></td>
<td>Need to understand the human factors linked to error and seek to reduce same (e.g. haste, in-experience, workload, fatigue). Guidance should explicitly address communication and organisation processes.</td>
</tr>
<tr>
<td>Healthcare team</td>
<td>Leadership</td>
<td>Leadership and team focus on patient safety and quality care. Active involvement of local opinion leader/ a local champion. A co-ordinator per department, targeted training, assess physicians/others ability to adapt to the new processes and educate/demonstrate use to other staff. Support of management is critical. Facilitate a perception of collective ownership, user involvement in development process creating a culture of evidence based practice.</td>
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<tr>
<td>Financial and</td>
<td>Pilot test on a small scale and then initiate a stepwise implementation process to include real time feedback and</td>
<td></td>
</tr>
<tr>
<td>Level</td>
<td>Factors</td>
<td>Facilitators (solution focus)</td>
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<tr>
<td></td>
<td>resource constraints</td>
<td>consideration of financial and resource utilisation at all stages of the guidance development, implementation and evaluation.</td>
</tr>
<tr>
<td>Healthcare organisation</td>
<td>Local culture and practice</td>
<td>Identification of system level and cultural barriers. Consider the distinct contextual characteristics associated with the intended care settings. Engage early with governance structures, executive management teams when changing practice. Need to balance the interests and values of all stakeholders involved in the continuum of care. Multidisciplinary staff engagement/involvement and stakeholder input in the development process leads to more successful implementation. Consider workflow implications of the guidance, access to resources, avoid duplication of information already routinely collected, integrated ICT. Observe health care providers in their attempt to implement guidance and seek to understand and address their concerns. Use a systems approach to implementation of guidance. Such an approach could be achieved by using technology and the electronic medical record to ensure patients receive the recommended interventions.</td>
</tr>
<tr>
<td>Wider environment</td>
<td>Lack of government leadership and commitment</td>
<td>Increase collaboration between policy makers and researchers. Decisions regarding guidance prioritisation should include consideration of: variation in treatment among practitioners for the same condition (and if this would be resolved via evidence based guidance); the level of evidence; clinical relevance (the burden of disease, risk: benefit ratio); economic evaluation; ethical considerations and feasibility of applying the guidance. Guidance based upon national recommendations and with government support have more significant outcomes. Guidance integrated into a comprehensive safety plan or systems approach to safety. Need to determine a governance model that serves the interest of the community while preserving the autonomy of individual organisations. Guidance developers should collaborate to integrate guidance across conditions that commonly co-exist. Develop a transparent, easily accessible system for centralising the storage and access to guidance across the health system. Guidance documentation to include details of guidance version, update date. Consider the process of guidance implementation across the macro, meso and micro level. Consider the length of guidance documentation and accessibility. Document and share lessons learnt. Invest in communication. Have an agreed financial model to support the implementation of guidance – particular those that involve multidepartment, multisite, multiagency and those that traverse acute, secondary and tertiary care. Accurate costs for clinical events are fundamental to the creation of health economic models that allow for comparison.</td>
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<td></td>
<td>Failure to address multi component systems</td>
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<td></td>
<td>Difficulties in</td>
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<tr>
<td>Level</td>
<td>Factors</td>
<td>Facilitators (solution focus)</td>
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<td></td>
<td>evaluating clinical guidance</td>
<td>of treatment options or new intervention pathways.</td>
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<td></td>
<td></td>
<td>The development of guidance should include plans for evaluation and updates.</td>
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