National Clinical Effectiveness Committee

Standards for Clinical Practice Guidance

DRAFT for public consultation, June 22nd 2015
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### Glossary of Terms

| **Clinical Practice Guidance** | Clinical practice guidance is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate health care for specific clinical circumstances, with the type of clinical practice guidance determined by evidence-based criteria and clinical requirements. Such clinical guidance includes clinical policies, procedures, protocols and guidelines. |
| **Clinical Guideline** | Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances, across the entire clinical spectrum. |
| **NCEC National Clinical Guideline** | NCEC National Clinical Guidelines are a suite of guidelines that meet specific prioritisation and quality assurance criteria and that have been recommended by the National Clinical Effectiveness Committee (NCEC) and endorsed by the Minister for Health for implementation. |
| **Clinical Audit** | Clinical audit is a cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards.¹ |
| **NCEC National Clinical Audit** | NCEC National Clinical Audits are national audits which have been prioritised and quality assured by the National Clinical Effectiveness Committee (NCEC). |
| **Clinician** | A clinician is a health professional involved in clinical practice. |
| **NCEC** | National Clinical Effectiveness Committee. |
| **CEU** | Clinical Effectiveness Unit. |
| **HSE** | Health Service Executive. |
| **HTA** | Health Technology Assessment. |
| **PPPG** | Policies, procedures, protocols and guidelines. |

¹ This definition will be aligned to any in the forthcoming Health Information Bill
### Glossary of Terms – continued

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical policy</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Clinical procedure</strong></td>
<td>A procedure is a written set of instructions that describes the approved and recommended steps for a particular act or sequence of events.</td>
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<tr>
<td><strong>Clinical protocol</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Checklist</strong></td>
<td>A tool that condenses a large volume of information and allows for systematic verification of steps or practices.</td>
</tr>
<tr>
<td><strong>Care pathway</strong></td>
<td>A care pathway is a multidisciplinary care plan that outlines the main clinical interventions that are carried out by different healthcare practitioners for service users 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.</td>
</tr>
<tr>
<td><strong>Care bundle</strong></td>
<td>A care bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes.</td>
</tr>
<tr>
<td><strong>Algorithm</strong></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.</td>
</tr>
<tr>
<td><strong>Clinical decision support</strong></td>
<td>Clinical decision support refers to the provision of clinical knowledge and patient specific information to help clinicians and patients make decisions that enhance patient care.</td>
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<tr>
<td><strong>Flowchart</strong></td>
<td>A diagram of the sequence of movements or actions of people or things involved in a complex system or activity.</td>
</tr>
<tr>
<td><strong>Model of care</strong></td>
<td>A model of care is a multifaceted concept, which broadly defines the way health services are delivered. A model of care outlines best practice patient care delivery through the application of a set of service principles across identified clinical streams and patient flow continuums. The broad objective of developing a model of care is ensuring people get the right care, at the right time, by the right team and in the right place.</td>
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</table>

See Appendix D for a summary of definitions / nomenclature currently in use.
Purpose of this Standards of Clinical Practice Guidance document

The purpose of this document is to provide standards for healthcare staff developing evidence-based clinical practice guidance for health care.

What is Clinical Practice Guidance?
Clinical practice guidance is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate health care for specific clinical circumstances, with the type of clinical practice guidance determined by evidence-based criteria and clinical requirements. Such clinical guidance includes clinical policies, procedures, protocols and guidelines. Bundles of care, care pathways and clinical decision aids may form part of the approach to organisation of care for clinical guidance. Checklists and algorithms may form part of the clinical guidance implementation toolbox.

Does Clinical Practice Guidance improve patient care?
Clinical effectiveness is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes such as clinical practice guidance, promotes healthcare that is up to date, effective and consistent.

The vision of the Standards for Clinical Practice Guidance is quality improvement for patient safety. The added value of standards for clinical practice guidance for policy, health system, public and patients can include:

- Evidence based practice
- Standardisation of approach to avoid duplication
- Facilitation of audit: provides guidance to audit against
- Reduction of variation in clinical practice
- Consistency of nomenclature
- Improvement of methodological rigour

Why do we need Standards for Clinical Practice Guidance?
In clinical practice, there are different types of guidance that vary in complexity and scope. For example, guidance can be a comprehensive overarching National Clinical Guideline or a more specific clinical protocol. Regardless of the variation in scope and focus, it is important that the development of all clinical guidance is underpinned by core standards using an evidence-based approach, to assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances.

NCEC approach to development of standards
Draft standards have been developed, informed by the systematic literature review and advice from the Expert Advisory Group. The draft standards are the subject of this public consultation. Final draft standards will presented to the NCEC for review.

Aim: National Clinical Effectiveness Committee (NCEC) to publish standards for clinical practice guidance in Q3 2015.

Objective: Develop standards which will provide standardised methodology and nomenclature for clinical practice guidance to ensure consistency of approach and utilisation of appropriate methodology to develop evidence-based clinical practice guidance nationally.

Timeframe

<table>
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<tr>
<th>Event</th>
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<tr>
<td>Public consultation of draft standards</td>
<td>June 22nd – July 31st 2015</td>
</tr>
<tr>
<td>Present draft final standards to NCEC</td>
<td>September 2015</td>
</tr>
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</table>
Scope

Scope of the Standards for Clinical Practice Guidance includes healthcare spanning the full multidisciplinary team.

Inclusions

- Clinical policies
- Clinical procedures
- Clinical protocols
- Clinical guidelines

The following are included as components of policies / procedures / protocols / guidelines:

- Care pathways, clinical decision aid/tools, bundles, flowcharts (Organisation of care; to support systems of care)
- Checklists, algorithms (Implementation)

The standards for clinical practice guidance will include clinical policies, procedures, protocols and guidelines.

Bundles of care, care pathways and clinical decision aids may form part of the approach to organisation of care for clinical guidance. Checklists and algorithms may form part of the guidance implementation toolbox. These are included as components of policies, procedures, protocols and guidelines rather than stand-alone guidance.

Models of care, as described by the HSE Clinical Strategy and Programmes Division (Appendix D), may be informed by the standards.


Where national standards have already been developed, such as quality indicators (HIQA), adverse events (HSE/HIQA), and audit (NCEC / Health Information Bill), these are not included in the scope of this project.

The Standards for Clinical Practice Guidance are applicable to processes which assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances and are not intended to include operational or non-clinical processes e.g. specimen transport, HR policies etc.

The Health Service Executive (HSE) has established a National Policy Governance (PPPG) Steering Group to develop a Framework outlining the process for the implementation of the NCEC Standards for Clinical Practice Guidance.

This framework, when implemented will provide a clear governance process for defining, developing, approving, disseminating, implementing, auditing and updating HSE PPPGs, which will assist in compliance with the National Standards for Safer Better Healthcare (HIQA, 2012).

The NCEC will work with the HSE group on policies, procedures, protocols and guidelines (PPPG) to ensure consistency with the HSE governance structure for developing, implementing and auditing CPGs across the HSE.
**Expert advisory group**
An expert advisory group has been established to provide advice and information to the NCEC in the development of the draft standards. The nominees to this group are listed below.

<table>
<thead>
<tr>
<th>Organisation / Department</th>
<th>Nominee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Effectiveness Unit, Department of Health</td>
<td>Ms Niamh O’Rourke (Chair)</td>
</tr>
<tr>
<td>HSE Quality Improvement Division</td>
<td>Ms Brid Boyce</td>
</tr>
<tr>
<td>HSE Clinical Strategy and Programmes Division (Dr Áine Carroll)</td>
<td>Ms Aveen Murray</td>
</tr>
<tr>
<td>HSE Acute Hospitals Directorate (Mr Liam Woods)</td>
<td>Ms Deirdre O’Keeffe</td>
</tr>
<tr>
<td>HSE Quality Assurance Verification (QAV) Division (Mr Patrick Lynch)</td>
<td>Dr Edwina Dunne</td>
</tr>
<tr>
<td>HSE Social Care Directorate (Mr Pat Healy)</td>
<td>Dr Siobhan Kennelly</td>
</tr>
<tr>
<td>HSE Mental Health Directorate (Ms Anne O’Connor)</td>
<td>Ms Margaret Brennan</td>
</tr>
<tr>
<td>HSE Primary Care Directorate (Mr John Hennessy)</td>
<td>Ms Virginia Pye</td>
</tr>
<tr>
<td>Independent Hospitals (Ms Catherine Whelan)</td>
<td>Dr Stephen Frohlich</td>
</tr>
</tbody>
</table>

**National Clinical Effectiveness Committee**
The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee established by the Department of Health as part of the Patient Safety First Initiative to provide oversight for the national clinical effectiveness agenda which includes National Clinical Guidelines, National Clinical Audit and Clinical Practice Guidance.

Membership of the Committee is multidisciplinary and includes representatives from the Clinical Indemnity Scheme, Department of Health, Health Information and Quality Authority, Health Service Executive, Mental Health Commission, independent hospital sector, postgraduate training bodies, professional regulatory bodies, private medical insurers and patient advocates.

The NCEC Terms of Reference are:
1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
9. Establish sub-committees for NCEC work-streams.
Clinical Effectiveness Processes

Clinical effectiveness is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes, promotes healthcare that is up to date, effective and consistent. Clinical effectiveness processes include guidelines, audit and clinical practice guidance.

Background

This work emanates from a request by the Minister for Health that NCEC would develop standards for clinical practice guidance following the Report of the CMO into Portlaoise Perinatal Deaths (2014) as outlined in the box below.

<table>
<thead>
<tr>
<th>Clinical Effectiveness</th>
<th>Responsible body</th>
</tr>
</thead>
<tbody>
<tr>
<td>R.19 The National Clinical Effectiveness Committee should develop standards for clinical practice guidance.</td>
<td>NCEC</td>
</tr>
<tr>
<td>Standard definitions and criteria should be developed in relation to the various forms of clinical practice guidance such as guidelines, checklists, procedures, clinical guidance, clinical protocols etc. This will ensure consistency of approach and utilisation of appropriate methodology to develop clinical practice guidance nationally.</td>
<td></td>
</tr>
</tbody>
</table>

National context

The development of Clinical Practice Guidance builds on existing frameworks such as Safer Better Healthcare (HIQA 2012) and Building a Culture of Patient Safety (DoHC 2008).

The Health Information and Quality Authority developed National Standards for Safer Better Healthcare in 2012 to describe what a high quality, safe service looks like. These standards are an important driver for the implementation of clinical guidance as they set out the need for clinical decisions to be based on best available evidence and information; “to drive improvements in the quality and safety of healthcare it is important that decisions, including clinical decisions, are based on the best available evidence and information”.

The report on the Commission on Patient Safety and Quality Assurance, Building a Culture of Patient Safety (DoHC 2008) also recommends the development of evidence based standards.

It is important that the NCEC Standards for Clinical Practice Guidance are aligned with other national standards, initiatives and levers for implementation. The HSE work on PPPGs will complement and support the implementation of the NCEC Standards for Clinical Practice Guidance through a shared vision for evidence based practice that reduces variation in clinical practice.

The existing regulatory and policy frameworks encompass the development, implementation and monitoring stages of clinical practice guidance and are summarised in the box below:
Safer Better Healthcare, (HIQA 2012)

Safer Better Healthcare: Standard 2: Effective Care and Support

Standard 2.1. Healthcare reflects national and international evidence of what is known to achieve best outcomes for service users.

- 2.1.1 Healthcare that is delivered according to policies, guidelines, protocols and care pathways that are based on best available evidence.
- 2.1.2 Use of National Clinical Guidelines and nationally agreed protocols, care bundles and care pathways where available.
- 2.1.6 An evidence-based process for the development of policies, guidelines, protocols and care pathways.
- 2.1.7 Support for, and facilitation of, the workforce in making decisions based on the best available evidence.
- 2.1.8 Support for healthcare professionals in making clinical decisions based on evidence which will maximise benefits to service users and minimise unnecessary treatment and care.

Safer Better Healthcare: Standard 2.6. Care is provided through a model of service designed to deliver high quality, safe and reliable healthcare.

2.6.2 Delivery of care using high quality, safe and reliable models of service delivery that have the required clinical services, meet legislative requirements and take into account best available evidence, national policies, National Clinical Guidelines if available, local population health needs and available resources.

Building a Culture of Patient Safety (DoHC 2008)

R5.5: Organisational performance indicators and targets in the area of safety and quality.
R5.16: Mandatory standards and key performance indicators.
R5.19: Strong emphasis on safety and quality in the training and education of healthcare professionals.
R6.6: Licensing should be linked to compliance with stated standards.
R6.9: HIQA should progress urgently the development of standards on safety and quality.
R6.11: The regulations that determine the criteria for obtaining a licence should include implementation of evidence based practice.
R7.1: Production of evidence-based information and guidance for use in policy making, system reform and individual patient and professional interactions.
R7.2: Evidence based service frameworks covering the major health conditions
R7.4: Evidence based national standards should be developed, with multidisciplinary input, in both primary and secondary care settings, and for the transition between care settings.

(See appendix C for full text of recommendations)
Standards for Clinical Practice Guidance

Different types of clinical guidance will vary in complexity and scope, with the choice of clinical practice guidance model determined by evidence-based criteria and clinical requirements. Not all guidance requires the same pathway of development as an NCEC National Clinical Guideline http://health.gov.ie/patient-safety/ncec/national-clinical-guidelines-2/. However, regardless of the variation in scope and focus, it is important that the development of all clinical guidance is underpinned by an evidence-based approach and quality assurance measures to assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances.

In terms of clinical practice guidance, the health system as a whole is engaged with the development of processes to support clinical decision making at local, regional and national level as part of the quality improvement process. These processes involve the development of local guidelines, policies, protocols, checklists etc. The methodology to develop these processes is variable and the provision of NCEC Standards for Clinical Practice Guidance will promote consistency of approach and utilisation of appropriate methodology to develop evidence-based clinical practice guidance nationally.

Systematic literature review

The NCEC sought to establish the extent and quality of the evidence internationally on clinical practice guidance in terms of effectiveness, rigour of development and quality assurance processes. A systematic literature review to support a framework for the development of standards for clinical practice guidance was completed in March 2015. In summary, the published evidence on effectiveness of clinical practice guidance was limited. The evidence review however provides a useful backdrop for the development by NCEC of Standards for Clinical Practice Guidance.

The key messages from the literature included:

- There is a lack of standardisation of terminology, methodology and quality assurance of clinical practice guidance development, implementation and evaluation internationally.
- There is a lack of evidence relating to cost effectiveness and clinical effectiveness of clinical practice guidance internationally.
- Clinical practice guidance must be evidence-based.
- Multi-stakeholder involvement is a key requirement for the effective development of guidance.
- The literature revealed barriers and facilitators at the patient, healthcare professional, team, organisational and health system level.
- Improvements to clinical guidance can be secured if barriers are tracked and a systems approach is taken to the development, implementation and evaluation of guidance.

The research team made recommendations pertaining to the development, management, implementation and evaluation of guidance, including IT systems. A summary of the literature search strategy and results are outlined in Appendix A.

\[2\] Completed by a research team based in UCC. Literature review is available at: http://health.gov.ie/patient-safety/ncec.
Prior to commencing the development of clinical practice guidance, the following should be established:

| Existing CPGs | Is evidence-based clinical practice guidance already available for this topic/clinical question? (local, national or international)  
Is the existing CPG up to date, peer reviewed with rigorous methodology, generalizable to target population and applicable to Ireland? |
| Adapt/adopt | Is this CPG being developed *de novo* or being adapted/adopted from existing guidance nationally/internationally? |
| Coverage/geography | Is this CPG being developed as national, regional (e.g. hospital group / CHO) or local guidance?  
Will the proposed CPG be relevant for use in a wider geographical area or wider clinical area? If so, wider collaboration needs to be considered.  
In general, clinical practice guidance should not vary by location, although the mechanism for implementation may differ. |
| Multidisciplinary | Does this CPG include all relevant professional groupings, to ensure integrated care for the service user? |
| Model | What type of guidance is required for this topic/clinical question? (e.g. policy, procedure, protocol, guideline), based on the clinical requirements. |

**Core components**

A number of core components form the basis for high quality evidence-based clinical practice guidance, which can be grouped into the four categories of governance, methodology, implementation and communications.

Each of these components is described below, with a checklist of criteria to assist in the development of clinical practice guidance. All clinical practice guidance should meet minimum standard, while some will be developed to a higher standard as required.
Core components – Standards for evidence-based Clinical Practice Guidance

<table>
<thead>
<tr>
<th>Governance</th>
<th>Governance model</th>
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<tbody>
<tr>
<td></td>
<td>Audit /monitoring &amp; evaluation process</td>
</tr>
<tr>
<td></td>
<td>Service user / stakeholder involvement</td>
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<td></td>
<td>Accessibility / sharing of best practice</td>
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<tr>
<td>Methodology</td>
<td>Clarity of scope and purpose</td>
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<tr>
<td></td>
<td>Evidence based</td>
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<tr>
<td></td>
<td>Resource implications</td>
</tr>
<tr>
<td>Implementation</td>
<td>Implementation</td>
</tr>
<tr>
<td>Communications</td>
<td>Communications</td>
</tr>
</tbody>
</table>

Figure 1. Core Components – Standards for Clinical Practice Guidance
Level of complexity

Clinical practice guidance may require different levels of complexity, proportionate to the type of guidance. For example, a National Clinical Guideline will require a full budget impact analysis and possibly a Health Technology Assessment (HTA), whereas a protocol may only require consideration of the resources required to develop and implement the protocol. It is expected that all clinical practice guidance will meet all minimum standards, whereas more complex guidance may require additional rigour. The standards below differentiate between minimum standards and more rigorous requirements for complex guidance.

1. **Clarity of scope and purpose**
   - The decision making approach relating to type of guidance required (policy, procedure, protocol, guideline), the coverage of the guidance (national, regional, local) and applicable settings is described.
   - The overall objective(s) of the clinical guidance are specifically described.
   - The clinical question(s) covered by the guidance are specifically described.
   - The target users and the population/patient group to whom the guidance is meant to apply are specifically described.
   - The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).

2. **Governance model**
   - Formal governance arrangements for clinical practice guidance are established and documented at local, regional and national level (clearly outline quality assurance mechanisms, specific roles and responsibilities, accountability, approval/ratification processes and authority).
   - Conflict of interest statements from all members of the guidance development group are documented, with a description of mitigating actions if relevant.
   - The guidance has been externally reviewed prior to publication (as required, complex CPGs).

3. **Audit / monitoring & evaluation process**
   - Process for monitoring, evaluation and continuous improvement is documented.
   - Audit criteria are specified.
   - Audit process/plan is specified.

4. **Service user and stakeholder involvement**
   - The guidance development group includes individuals from all relevant professional groups.
   - Guidance is informed by the needs of service users.
   - The views and preferences of the target population have been sought and taken into consideration (as required, complex CPGs).
   - Service user representation on guidance development team (as required, complex CPGs).
5. **Accessibility / Sharing of best practice**
   - Clinical guidance is easily accessible by all users.
   - Documented process for revisions/updating, including timeframe is provided.
   - Documented process for version control is provided.
   - National repository for clinical practice guidance established (HSE PPPG)
   - National template for format of clinical practice guidance established (HSE PPPG)

6. **Evidence based**
   - Systematic methods used to search for evidence are documented (for CPGs which are adapted/adopted from international guidance, their methodology is appraised and documented).
   - Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).
   - The health benefits, side effects and risks have been considered and documented in formulating the guidance.
   - There is an explicit link between the guidance and the supporting evidence.
   - The guidance/recommendations are specific and unambiguous.
   - Systematic review and Health Technology Assessment (HTA) (as required, complex CPGs).

7. **Resource implications**
   - The potential resource implications of applying the guidance are identified e.g. equipment, training.
   - Budget impact analysis is documented (as required, complex CPGs).
   - Literature review of cost effectiveness is documented (as required, complex CPGs).

8. **Implementation**
   - Written implementation plan is provided, with timelines, identification of responsible persons/units and integration into service planning process.
   - Barriers and facilitators for implementation are identified.
   - Care pathways, clinical decision aids, bundles of care and flowcharts may form part of the approach to organisation of care. Checklists and algorithms may form part of the clinical guidance implementation toolbox.
   - Education and information is available for staff on clinical practice guidance.
   - Collaboration across all stakeholders is considered in the implementation plan to optimise integrated patient care.
   - Implementation plan is linked to audit process.

9. **Communications**
   - Communications plan is developed to ensure effective communication and collaboration with all stakeholders.
   - Plan and format for dissemination is described.
Sources for core components:


Australian Commission on Safety and Quality in Health Care (2015) *Guide to the National Safety and Quality Health Service standards for health service organisational boards.* NSQHS.


References


Health Information and Quality Authority (2012). *National Standards for Safer Better Healthcare.* Dublin, HIQA

Health Information and Quality Authority (2013). *Guiding Principles for National Health and Social Care Data Collections.* Dublin, HIQA.


Department of Health (2014). *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date).* Report to the Minister for Health, Dr James Reilly TD from Dr Tony Holohan, the Chief Medical Officer.
Sources of definitions / nomenclature


Health Information and Quality Authority. (2014) Report of the review of the governance arrangements as reflected in the safety, quality and standards of services at UL Hospitals. Dublin; HIQA


Appendix A. Systematic literature review

Key databases and grey literature sources were searched for evidence which evaluated guidance (guidance, pathway, policy, protocol, bundle, standard, algorithm, checklist, decision aid, model of care), development, implementation and evaluation processes. A total of 51 papers were included in this systematic review (Table 1). Owing to the lack of level one evidence (i.e. RCTs, meta-analysis, systematic reviews of RCTs) and heterogeneity of methodologies and outcomes, definitive conclusions could not be made as to the effectiveness of the various guidance types reviewed. However, the analysis of papers within the systematic review surmised that the implementation of guidance had a positive effect on patient outcomes and on the processes of care.

Table 1: Systematic review - Category of papers for each type of guidance

<table>
<thead>
<tr>
<th>Category of papers</th>
<th>Algorithm</th>
<th>Bundles</th>
<th>Checklists</th>
<th>Pathways</th>
<th>Policy</th>
<th>Protocols</th>
<th>Standards of care</th>
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<tr>
<td>1. SR of SRs, MAs &amp; primary studies</td>
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<td></td>
<td></td>
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<td>2. MAs</td>
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<td>3. SRs &amp; MA</td>
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<td>5. SR of studies</td>
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<td>6. SR &amp; Expert opinion</td>
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<td>1</td>
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<td>7. Paper on developing guidance incl. SRs</td>
<td></td>
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<td>1</td>
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<td>1</td>
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<td>8</td>
<td>2</td>
<td>51</td>
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</table>

SR = systematic review; MA = meta-analysis.

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. In terms of national approaches to the organisation and provision of evidence based care, these can include clinical care pathways and care bundles.

Specific review questions were included in the research objectives for the systematic review including; definitions of clinical practice guidance, core elements, decision criteria, quality criteria, impact, resources, updating processes, expertise required, format, strengths and weaknesses, barriers and facilitators. Table 2 summarises the papers reviewed for each of these areas.
Table 2: Number of papers providing data on each question addressed in the systematic review

<table>
<thead>
<tr>
<th>Question</th>
<th>Algorithm (n=9)</th>
<th>Bundle (n=4)</th>
<th>Checklist (n=4)</th>
<th>Pathways (n=15)****</th>
<th>Policy (n=9)</th>
<th>Protocol (n=7)</th>
<th>Standard of care (n=2)</th>
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<td>Q.4. Methodological processes*</td>
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<td>&amp;/or assessment of quality of studies in review paper</td>
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<td>Q.6. (i) Impact i.e. outcomes</td>
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<td>(ii) Method of impact validation</td>
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<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>(iii) Implementation audit incl. outcome of</td>
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<td>Q.13. Facilitators</td>
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</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.
Appendix B.

International resources

Health Improvement Scotland: Methodology toolkit

Health Improvement Scotland: Evidence for healthcare improvement: evidence, advice, guidance and standards
http://www.healthcareimprovementscotland.org/evidence.aspx

Australian Commission on Safety and Quality in Health Care: Clinical care standards

National Institute for Health and Care Excellence (NICE), UK;
- NICE pathways: http://pathways.nice.org.uk/
- NICE guidance https://www.nice.org.uk/guidance
- NICE standards and indicators https://www.nice.org.uk/standards-and-indicators
- NICE Evidence Services https://www.evidence.nhs.uk/

AGREE - international tool to assess the quality and reporting of practice guidelines
http://www.agreetrust.org/agree-ii/
Appendix C.
The report on the Commission on Patient Safety and Quality Assurance, *Building a Culture of Patient Safety* (DoHC 2008) recommends the development of evidence based standards:

### Leadership and accountability

**R5.1** Key leadership roles must be assigned to designated professionals and agencies at national level for the purpose of providing strong clinical leadership to the system in the area of patient safety and quality. Such leadership roles must include advocacy for safety and quality, the development and dissemination of patient safety knowledge and learning and the promotion of good practice.

**R5.5** Organisational codes of governance must be implemented which clearly identify safety and quality as a core objective and which specify the processes by which these objectives will be achieved. Organisational performance in these areas should be monitored, through, for example, the setting of specific organisational performance indicators and targets in the area of safety and quality and the requirement for regular reports via internal and external accountability mechanisms on delivery against those targets. Patients should be provided with an accessible opportunity to contribute to such accountability mechanisms.

**R5.16** The Board must review, on a regular basis, the systems of governance, including risk management and audit, relating to healthcare safety, quality and performance. This should include: mandatory standards and key performance indicators.

**R5.19** There should be a strong emphasis on safety and quality in the training and education of healthcare professionals. All bodies responsible for the training and continuing development of healthcare professionals should review their curricula to ensure that patient safety and quality, including technical and human factors, is incorporated into the modules.

### Organisational and Professional Regulatory Framework

**R6.6** Licencing should be linked to compliance with stated standards, enforceable through inspection and imposition of sanctions if necessary. The sanctions should range from warnings, with time limits for compliance, up to withdrawal of licence either for a specific service within the hospital or the hospital itself if required.

**R6.9** In advance of the introduction of legislation providing for licensing, HIQA should progress urgently the development of standards on safety and quality to be applied to hospitals and all future licensed healthcare facilities. HIQA should also be asked to commence work immediately on standards in respect of any area where a high and intermediate risk to the health and/or welfare of patients or the public is identified. Subject to current legal provisions, arrangements should be put in place by which private healthcare providers would voluntarily adhere to such standards, agree to be monitored and the resulting reports published. Private health insurers should require all private healthcare facilities to adhere to the standards set by HIQA where such standards exist.

**R6.11** The regulations that determine the criteria for obtaining a licence should include; implementation of evidence based practice.

### Quality Improvement and Learning Systems

**R7.1** A leadership role in relation to the 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 should be developed.

**R7.2** A rolling programme should be developed by the Department of Health, HIQA and the HSE to deliver evidence-based service frameworks covering the major health conditions within the public healthcare system, similar to the National Service Frameworks model in the UK. Such frameworks should be reviewed periodically to encompass new evidence on effectiveness and performance.

**R7.4** Evidence based national standards should be developed, with multidisciplinary input, in both primary and secondary care settings, and for the transition between care settings.
Appendix D
Definitions / nomenclature - examples currently in use

<table>
<thead>
<tr>
<th>NCEC/ HIQA 2015</th>
<th>UCC systematic review 2015 (pp 58-61)</th>
<th>HSE PPPG 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Policy</td>
<td>Clinical policy: 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.</td>
<td>Policy: 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).</td>
</tr>
<tr>
<td>Clinical Procedure</td>
<td></td>
<td>Procedure: A procedure is a written set of instructions that describe the approved and recommended steps for a particular act or sequence of events (HIQA 2006).</td>
</tr>
<tr>
<td>Clinical Protocol</td>
<td>Clinical protocol: 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.</td>
<td>Protocol: 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).</td>
</tr>
<tr>
<td>Clinical Guideline</td>
<td><strong>Clinical guideline</strong>: Systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.</td>
<td><strong>Guideline</strong>: A guideline is defined as a principle or criterion that guides or directs action (Concise Oxford Dictionary 1995). Guideline development emphasizes using clear evidence from the existing literature, rather than expert opinion alone, as the basis for advisor materials (WHO 2009).</td>
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<tr>
<td>National Clinical Guideline</td>
<td><strong>NCEC National Clinical Guidelines</strong>: A suite of guidelines that meet specific quality assurance and prioritisation criteria and that have been recommended by the National Clinical Effectiveness Committee and endorsed by the Minister.</td>
<td></td>
</tr>
<tr>
<td>Checklist</td>
<td><strong>Checklist</strong>: 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></td>
</tr>
<tr>
<td>Pathway</td>
<td>NCEC/ HIQA 2015</td>
<td>UCC systematic review 2015</td>
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</table>
| Pathway | **Integrated 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. | **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). 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). |         |
<table>
<thead>
<tr>
<th>NCEC/ HIQA 2015</th>
<th>UCC systematic review 2015 (pp 58-61)</th>
<th>HSE PPPG 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Care bundle</strong></td>
<td>A care bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes. (HIQA 2014)</td>
<td>Bundle: 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>
</tr>
<tr>
<td><strong>Algorithm</strong></td>
<td>Algorithm: 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></td>
</tr>
<tr>
<td><strong>Standard</strong></td>
<td>Standard: A definable measure against which existing structures, processes or outcomes can be compared.</td>
<td>Standard: 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>
</tr>
<tr>
<td><strong>Flowchart</strong></td>
<td>A diagram of the sequence of movements or actions of people or things involved in a complex system or activity.</td>
<td>A flowchart, or flow diagram is a graphic representation of a series of activities that define a process. The improvement guide, Langley 1987</td>
</tr>
<tr>
<td><strong>Clinical decision aid/tool</strong></td>
<td>Clinical decision support refers to the provision of clinical knowledge and patient specific information to help clinicians and patients make decisions that enhance patient care. Osheroff JA, Pifer EA, Teich JM 2005 (AHRQ, 2010)</td>
<td></td>
</tr>
<tr>
<td><strong>Model of care</strong></td>
<td>A ‘model of care’ is a multifaceted concept, which broadly defines the way health services are delivered (Queensland Health 2000). A model of care outlines best practice patient care delivery through the application of a set of service principles across identified clinical streams and patient flow continuums. (Waikato Health Board 2004). [HSE Clinical Strategy and Programmes Division]</td>
<td>The broad objective of developing a model of care is ensuring people get the right care, at the right time, by the right team and in the right place. Model of care overview and guidelines (2007) Department of Health, W Australia</td>
</tr>
</tbody>
</table>

Model of care overview and guidelines (2007) Department of Health, W Australia |