NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

Tús Áite do Shábháilteacht Othar
Patient Safety First

National Clinical Effectiveness Committee

Standards for Clinical Practice Guidance

An Roinn Sláinte
DEPARTMENT OF HEALTH

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NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

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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). Once a National Clinical Guideline is endorsed it supersedes any other guidelines on that topic.
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).
Clinical Policy	A Clinical Policy is 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.
Clinical Procedure	A Procedure is a written set of instructions that describes the approved and recommended steps for a particular act or sequence of events.
Clinical Protocol	A Clinical Protocol is 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.
Clinical Decision Support	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.
Care Bundle	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.
Care Pathway	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, evidence-based plans that can incorporate local and national guidelines into everyday practice.
Flowchart	A Flowchart is a diagram of the sequence of movements or actions of people or things involved in a complex system or activity.

1 This definition will be aligned to the forthcoming Health Information and Patient Safety Bill.

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.
Checklist	A Checklist is a tool that condenses a large volume of information and allows for systematic verification of steps or practices.
Model of care	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.
Clinician	A Clinician is a health professional involved in clinical practice.
Standard	A Standard is a definable measure against which existing structures, processes or outcomes can be compared.

Acronyms

CEU	Clinical Effectiveness Unit.
CHO	Community Health Office.
CMO	Chief Medical Officer.
CPG	Clinical Practice Guidance.
DoH	Department of Health.
DoHC	Department of Health and Children.
HIQA	Health Information and Quality Authority.
HR	Human Resources.
HSE	Health Service Executive.
HTA	Health Technology Assessment.
IT	Information Technology.
MHC	Mental Health Commission.
NCEC	National Clinical Effectiveness Committee.
PPPG	Policies, Procedures, Protocols and Guidelines.

See Appendix D for a summary of definitions/nomenclature currently in use.

1 Purpose of this 'Standards for 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. Care pathways, clinical decision aids/tools, care bundles, flowcharts, checklists and algorithms can form components of policies, procedures, protocols or guidelines.

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:

- Improving and optimising patient outcomes
- Evidence-based practice
- Standardisation of approach to avoid duplication
- Facilitation of audit: provides parameters for audit
- 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.

Through consistency in approach and reduction in duplication, variation in practice can be reduced. Sharing of best practice will optimise use of health service resources and expertise.

NCEC approach to development of standards

The standards were developed by the NCEC, informed by a systematic literature review, advice from an Expert Advisory Group and feedback from a public consultation process.

Aim: to publish standards for clinical practice guidance for healthcare providers.
Objectives:

- Publish standards which will provide a standardised nomenclature and methodology for the development of evidence-based clinical practice guidance nationally.
- Ensure consistency of approach and minimise duplication in clinical practice guidance.

2 Scope

The Scope of the *Standards for Clinical Practice Guidance* includes Clinical Practice Guidance in healthcare, spanning the full multidisciplinary team. This includes all healthcare providers in the Republic of Ireland. The standards are applicable to healthcare in all settings e.g. acute care, social care, mental health, care of the elderly, primary care, disabilities.

	Scope of the Standards for Clinical Practice Guidance
All healthcare settings	• Clinical policies
	• Clinical procedures
	• Clinical protocols
	• Clinical guidelines
	The following can form components of policies / procedures / protocols / guidelines: • Care pathways, clinical decision aids/tools, care bundles, flowcharts (Organisation of care; to support systems of care) • Checklists, algorithms (Implementation)

The *Standards for Clinical Practice Guidance* include clinical policies, procedures, protocols and guidelines. Care bundles, care pathways and clinical decision aids can form part of the approach to organisation of care for clinical guidance. Checklists and algorithms can form part of the guidance implementation toolbox. These are included as components of policies, procedures, protocols and guidelines rather than stand-alone clinical practice guidance. Models of care, as described by the HSE Clinical Strategy and Programmes Division (Appendix D), will also be informed by the standards.

There are existing regulatory frameworks which encompass requirements in relation to the development, implementation and monitoring stages of clinical practice guidance, such as the *National Standards for Safer Better Healthcare* (HIQA, 2012) and the *Quality Framework for Mental Health Services* (MHC, 2007). The *Standards for Clinical Practice Guidance* are intended to support and complement these existing processes.

It is expected that the HSE and all organisations will develop all new and updated guidance in line with these standards. Where clinical practice guidance is already in place, a plan to review this guidance should be made, with key patient safety areas prioritised. Review of existing guidance is recommended every 3 years, or sooner if required by law or new evidence, audit or information indicates required change.

Outside scope

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

In exceptional circumstances, where interim clinical guidance is required on an emergency basis (e.g. public health emergencies, hazards and emerging infectious threats such as Ebola virus), this guidance should be developed by experts, based on the best available evidence. If sustained as guidance following the initial emergency, this interim guidance can be further developed using the standards.

3 Monitoring and Implementation

Organisations should put processes in place to implement and monitor these standards.

Formal governance arrangements for clinical practice guidance at local, regional and national level should be established and documented by healthcare providers. This governance process should clearly outline quality assurance mechanisms, specific roles and responsibilities, accountability and authority. Clear processes for developing, approving, disseminating, implementing, monitoring, auditing and updating clinical practice guidance within the organisation needs to be clearly outlined and available for staff.

The Health Service Executive has established a National PPPG Steering Group for policies, procedures, protocols and guidelines (PPPG) to develop a framework that will clearly define the process for the use and implementation of the NCEC *Standards for Clinical Practice Guidance*. A governance process, standard template, staff training and national repository for HSE CPGs is also planned by the HSE.

The *Standards for Clinical Practice Guidance* provide a framework for assessment and audit. It is expected that the health system regulators will assess the corporate assurance arrangements in place to ensure effective implementation of these standards.

4 Expert advisory group

An expert advisory group was established to provide advice and information to the NCEC in the development of the standards. The members of this group are listed below.

Organisation / Division (nominated by)	Nominee
Clinical Effectiveness Unit, Department of Health	Dr Niamh O'Rourke (Chair)
HSE Quality Improvement Division (Dr Philip Crowley)	Ms Brid Boyce
HSE Mental Health Division (Ms Anne O'Connor)	Ms Margaret Brennan
HSE Quality Assurance Verification (QAV) Division (Mr Patrick Lynch)	Dr Edwina Dunne
Independent Hospital Association of Ireland (Ms Catherine Whelan)	Dr Stephen Frohlich
HSE Social Care Division (Mr Pat Healy)	Dr Siobhan Kennelly
HSE Clinical Strategy and Programmes Division (Dr Áine Carroll)	Ms Aveen Murray
HSE Acute Hospitals Division (Mr Liam Woods)	Ms Deirdre O'Keeffe
HSE Primary Care Division (Mr John Hennessy)	Ms Virginia Pye

5 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 Health Information and Quality Authority, Mental Health Commission, Health and Social Care Regulatory Forum, Health Products Regulatory Authority, State Claims Agency, Forum of Postgraduate Training Bodies, Nursing and Midwifery Education Bodies, Forum of Hospital Group CEOs, HSE Clinical Programmes, HSE Quality Improvement Division, HSE Office of Nursing and Midwifery Services, National Office for Clinical Audit, Independent Hospital Association of Ireland, Department of Health, Health Insurance Council, Health Research Board and two patient representatives.

The NCEC Terms of Reference are to:

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish Standards for Clinical Practice Guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and quality-assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
9. Establish sub-committees for NCEC work-streams.
10. Publish an Annual Report.

The NCEC framework is outlined in Figure 1 below. Further information on the NCEC framework and NCEC documentation including endorsement and quality assurance criteria for National Clinical Guidelines and National Clinical Audit is available at: www.health.gov.ie/patient-safety/ncec

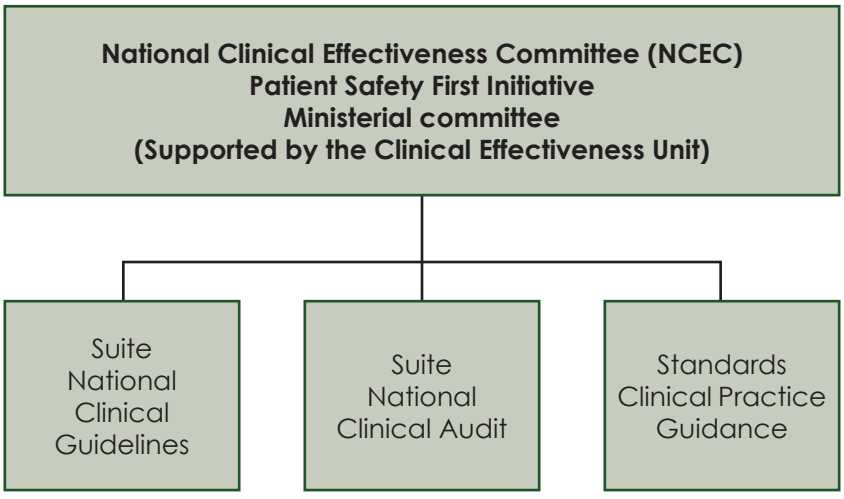

Figure 1: NCEC framework

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.

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. The development of *Standards for Clinical Practice Guidance* builds on existing frameworks such as *Safer Better Healthcare* (HIQA 2012), *Building a Culture of Patient Safety* (DoHC 2008) and the *Quality Framework for Mental Health Services* (MHC 2007).

Clinical Effectiveness			
	Recommendation	Responsible body	
R.19	The National Clinical Effectiveness Committee should develop standards for clinical practice guidance.	NCEC	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.

National context

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 of the Commission on Patient Safety and Quality Assurance, *Building a Culture of Patient Safety* (DoHC 2008) and the *Quality Framework for Mental Health Services* (MHC 2007) also recommend 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 and duplication 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:

National Standards for Safer Better Healthcare (HIQA, 2012)

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.

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.

Standard 7.2. Service providers have arrangements in place to achieve best possible quality and safety outcomes for service users for the money and resources used.

Building a Culture of Patient Safety (DoHC, 2008) (See appendix C for full text of recommendation)

- 5.5: Organisational performance indicators and targets in the area of safety and quality.
- 5.16: Mandatory standards and key performance indicators.
- 5.19: Strong emphasis on safety and quality in the training and education of healthcare professionals.
- 6.6: Licencing should be linked to compliance with stated standards.
- 6.9: HIQA should progress urgently the development of standards on safety and quality.
- 6.11: The regulations that determine the criteria for obtaining a licence should include implementation of evidence-based practice.
- 7.1: Production of evidence-based information and guidance for use in policy making, system reform and individual patient and professional interactions.
- 7.2: Evidence based service frameworks covering the major health conditions.
- 7.4: Evidence based national standards should be developed, with multidisciplinary input, in both primary and secondary care settings, and for the transition between care settings.

Quality Framework for Mental Health Services (MHC, 2007)

Standard 8.1 The mental health service is delivered in accordance with evidence-based codes of practice, policies and protocols.

- 8.1.3 The mental health service has uniform policies across service areas.

Standard 8.3 Corporate governance underpins the management and delivery of the mental health service.

- 8.3.2 The mental health service facilitates service user involvement at all stages of policy and service development, delivery and evaluation.
- 8.3.7 The mental health service implements a clinical governance system for improving clinical practice.

6 Standards for Clinical Practice Guidance – rationale

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. Further information is available at 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 policies, protocols, protocols and guidelines. 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.

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.[2] In summary, the published evidence on effectiveness of clinical practice guidance is 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 clinical 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/

7 Development of Clinical Practice Guidance

These standards aim to promote consistency of clinical practice guidance across the country and avoid duplication. Synergies should be maximised across departments/organisations to optimise value for money and use of staff time and expertise. It is not in the interests of patient safety for individual organisations/units to develop or implement different guidance for similar clinical circumstances. Where feasible and appropriate organisations should promote and utilise national clinical practice guidance developed in line with these standards, to avoid any unnecessary duplication, encompassing any local implementation requirements as required.

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, generalisable 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/community health office) 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 local implementation may differ.
Multidisciplinary	Does the CPG group membership include all relevant stakeholders and professional groupings, to ensure integrated care for the service user?
Governance	Has a governance model been established for the development, approval, dissemination, implementation, monitoring, audit, updating and repository of Clinical Practice Guidance in your organisation?
Model	What type of guidance is required for this topic/clinical question? (E.g. policy, procedure, protocol, guideline), based on the clinical requirements.
Evidence base	Have you established access to a library or clinical librarian? Have you established links with an academic partner/third level institution?

The description of core components in this document provides a useful checklist for monitoring and audit.

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, planning and 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 these standards, while some will be developed to a higher standard as required (denoted complex CPGs below).

Core components – Standards for evidence-based Clinical Practice Guidance

Governance	Governance model
	Audit, monitoring, review & evaluation process
	Service user and stakeholder involvement
	Knowledge management
Methodology	Clarity of scope and purpose
	Evidence-based
Planning & Implementation	Resource implications
	Planning & Implementation
Communications	Communications

These standards will be reviewed and updated by the NCEC as required.

The current version is available on www.health.gov.ie/patient-safety/ncec

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.

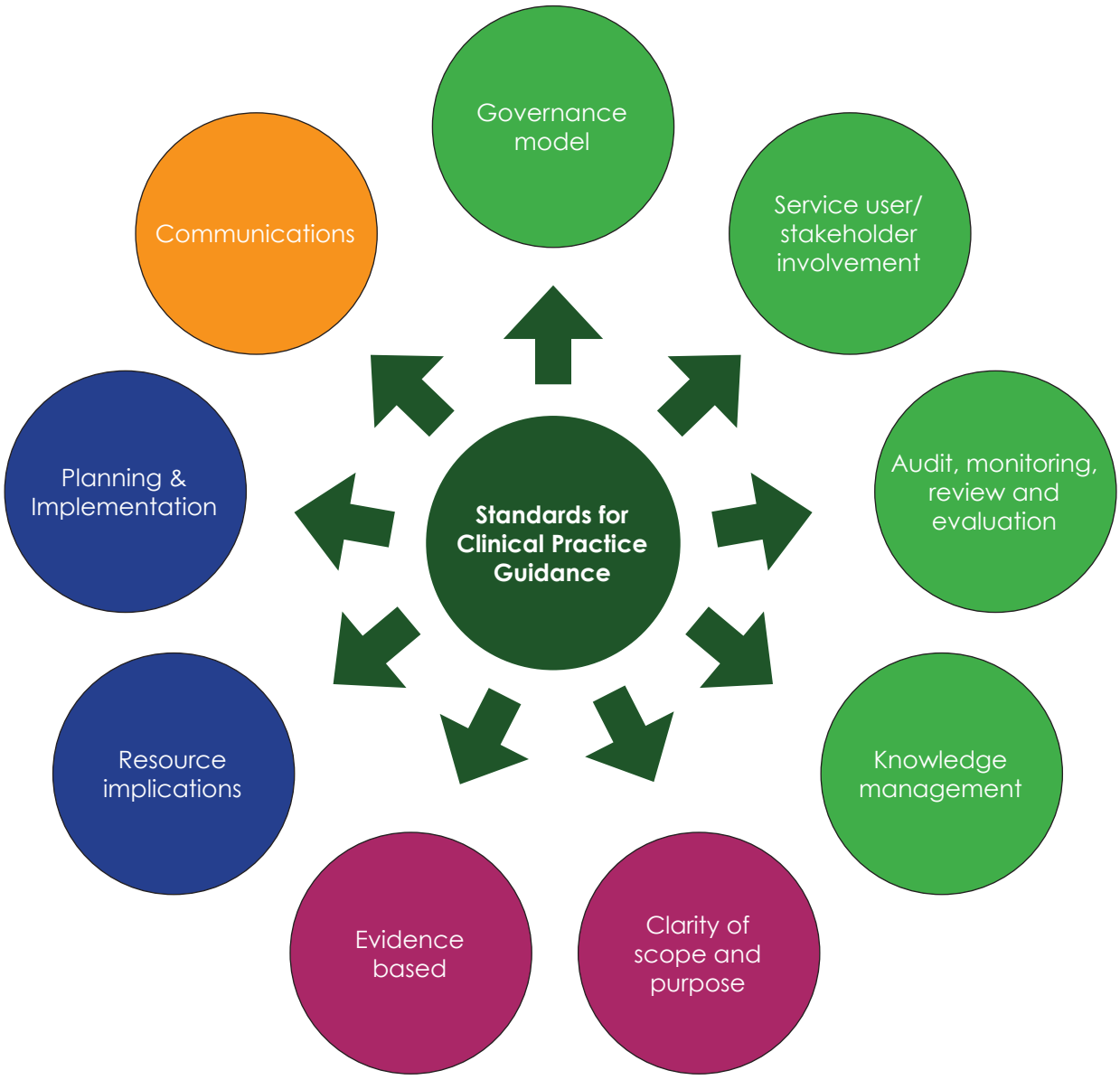

Figure 2: Core Components – Standards for Clinical Practice Guidance

Standards for Clinical Practice Guidance

1. Clarity of scope and purpose

The decision making approach relating to type of guidance required (policy, procedure, protocol, guideline), coverage of the guidance (national, regional, local) and applicable settings are 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).	❒
The scope of the CPG is clearly described, specifying what is included and what lies outside the scope of the CPG.	❒

2. Governance model

Formal governance arrangements for clinical practice guidance at local, regional and national level are established and documented.	❒
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 reviewed by independent experts prior to publication. (as required, complex CPGs).	

3. Communications

A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	❒
Plan and procedure for dissemination of the CPG is described.	❒

4. Service user and stakeholder involvement

Stakeholder identification and involvement: The guidance development group includes individuals from all relevant stakeholders, staff and professional groups.	❒
Guidance is informed by the identified needs and priorities of service users and stakeholders.	❒
The views and preferences of the target population have been sought and taken into consideration (as required).	
There is service user/lay representation on guidance development team (as required).	

5. 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 clinical guidance and the supporting evidence.	❒
The guidance/recommendations are specific and unambiguous.	❒
A systematic literature review and Health Technology Assessment (HTA) has been undertaken (as required, complex CPGs).	

6. Knowledge management (Accessibility/sharing of best practice)

The clinical guidance is easily accessible by all users e.g. CPG repository.	❒
Documented process for version control is provided.	❒
Copyright and permissions are sought and documented.	❒

7. Resource implications

The potential resource implications of developing and implementing the guidance are identified e.g. equipment, education & training, staff time and research.	❒
Synergies are maximised across departments/organisations to avoid duplication and to optimise value for money and use of staff time and expertise.	❒
Budget impact analysis is documented (as required, complex CPGs).	
Literature review of cost effectiveness is documented (as required, complex CPGs).	

8. Planning and 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, and aligned with implementation levers.	❒
Information and support is available for staff on the development of evidence-based clinical practice guidance.	❒
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated patient care.	❒
Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as required, complex CPGs).	

9. Audit, monitoring, review & evaluation process

Process for monitoring and continuous improvement is documented.	❒
Process for evaluation of implementation and clinical effectiveness is specified.	❒
Audit criteria and audit process/plan are specified.	❒
Documented process for revisions/updating and review, including timeframe is provided.	❒

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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 49 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

		Algorithms	Bundles	Checklists	Pathways	Policy	Protocols	Standards of Care	TOTAL
1	SR of SRs, MAs & primary studies	1							**1**
2	Meta –analysis (MAs)		2		2				**4**
3	SRs & MA	1	1		2				**4**
4	SRs of SRs				1				**1**
5	SR of primary studies	6	1	3	8	8	7	1	**34**
6	SR & expert opinion	1							**1**
7	Papers on developing guidance inc. SRs			1		1	1	1	**4**
Total		**9**	**4**	**4**	**13***	**9**	**8**	**2**	**49**

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., 2009; 2010; 2012)

Source: Hegarty, J., Savage E., Cornally, N., Byrne S., Henn P, Flynn M, McLoughlin K, Fitzgerald S, (2015). A systematic literature review to support a framework for the development of standards for clinical practice guidance. Department of Health; Dublin. Available at: http://health.gov.ie/patient-safety/ncec/clinical-practice-guidance/

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 literature review

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

*Pathways: Three of these papers relate to one body of evidence (Rotter 2009, 2010, 2011), presented as one paper in table.
**Methodological processes: Most papers addressed development processes, some of which also reported on implementation & evaluation.
***Protocols: One paper on protocols reported only on implementation process.
****Quality criteria: This includes use of a grading system to assess the quality of evidence relevant to the development of guidance type.

Source: Hegarty, J., Savage E., Cornally, N., Byrne S., Henn P, Flynn M, McLoughlin K, Fitzgerald S, (2015). A systematic literature review to support a framework for the development of standards for clinical practice guidance. Department of Health; Dublin. Available at: http://health.gov.ie/patient-safety/ncec/clinical-practice-guidance/

Appendix B: Examples of International resources

Health Improvement Scotland: Methodology toolkit
http://www.healthcareimprovementscotland.org/about_us/what_we_do/knowledge_management/knowledge_management_resources/methodology_toolkit.aspx

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
http://www.safetyandquality.gov.au/our-work/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 guidelines: the manual (2014) https://www.nice.org.uk/article/pmg20/chapter/1%20Introduction%20and%20overview
- 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: Building a Culture of Patient Safety

The report of 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

	NCEC/ HIQA 2015	UCC systematic review 2015 (pp 58-61)	HSE PPPG 2012
Clinical Policy	**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.	**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).	**Policy:** A policy is a written statement that clearly indicates the position and values of the organisation on a given subject (HIQA, 2008).
Clinical Procedure			**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, 2008).
Clinical Protocol	**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.	**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).	**Protocol:** A protocol is defined as a written plan that specifies procedures to be followed in defined situations; a protocol represents a standard of care that describes an intervention or set of interventions. Protocols are more explicit and specific in their detail than guidelines, they specify who does what, when and how (An Bord Altranais 2000). Protocols are most typically used when developing instructions for drug prescription, dispensing and administration, i.e. drug protocols.

	NCEC/ HIQA 2015	UCC systematic review 2015 (pp 58-61)	HSE PPPG 2012
Clinical Guideline	**Clinical guideline**: 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.		**Guideline:** 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).
National Clinical Guideline	**NCEC National Clinical Guidelines:** A suite of guidelines that meet specific quality assurance and prioritisation criteria and that have been recommended by the National Clinical Effectiveness Committee.		
Checklist		**Checklist:** 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).	

	NCEC/ HIQA 2015	UCC systematic review 2015 (pp 58-61)	HSE PPPG 2012
Pathway	**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.	**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). 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).	
Care bundle	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)	**Bundle:** 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. (Berwick, 2006)	

	NCEC/ HIQA 2015	UCC systematic review 2015 (pp 58-61)	HSE PPPG 2012
Algorithm		**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).	
Standard	**Standard**: A definable measure against which existing structures, processes or outcomes can be compared.	**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).	

Flowchart	A diagram of the sequence of movements or actions of people or things involved in a complex system or activity. (Oxford dictionary)	A flowchart or flow diagram is a graphic representation of a series of activities that define a process. (The improvement guide, Langley 1987)
Clinical decision aid/tool	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)	
Model of care	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] Model of care overview and guidelines (2007) Department of Health, W Australia	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

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