



HSE National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs)



Feidhmeannacht na Seirbhíse Sláinte
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Foreword



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The Health Services Executive (HSE) Corporate Plan (2015-2017) is committed to improving the quality of care as set out in its vision: *'A healthier Ireland with a high quality health service valued by all'*. It sets out how we aim to improve our services through our core values of ***"Care, Compassion, Trust and Learning every day and in all we do"***. Embedding these values into everything we do will help make our vision a reality.

The delivery of healthcare is supported by a series of clinical and non-clinical Policies, Procedures, Protocols and Guidelines (PPPGs), inclusive of national clinical guidelines, nationally agreed protocols, care bundles and models of care. It is essential that a cohesive approach is taken when developing such documents, so as to ensure consistency in the way they will support the healthcare providers in their decision-making process.

This approach will enable the delivery of best outcomes to service users and staff, while maximising benefits and minimising unnecessary care treatment. The PPPG framework provides a comprehensive process and methodology to support the development of PPPGs in meeting this cohesive approach via the application of rigorous methodological standards.

It is essential that this national framework is implemented across all services. This framework will support service providers to develop and implement PPPGs to meet the required national standards (i.e.) (Department of Health [DoH], Health Information & Quality Authority [HIQA], and Mental Health Commission [MHC] etc.).

We would like to acknowledge the work of the Steering and Project Groups who were instrumental in the development of this framework and we wish to thank all those who participated in the public consultation process.

Purpose

It is well recognised and documented that high performing health systems should have robust (PPPGs) in place in order to deliver quality and safe care.

The benefits of having robust PPPGs serve to:

- Promote evidence-based practice
- Reduce variation in practice and service delivery
- Avoid unnecessary duplication
- Facilitate effective staff induction
- Act as educational tools
- Act as a basis for audit, evaluation and continuous improvement
- Meet the National Clinical Effectiveness Committee (NCEC) in the DoH *Standards for Clinical Practice Guidance* (2015) and other relevant national standards.
<http://health.gov.ie/wp-content/uploads/2015/11/NCEC-Standards-for-Clinical-Practice-Guidance.-Nov-2015.pdf>
- Promote clear governance in the development and implementation of PPPGs.

In Ireland a number of regulatory bodies i.e. MHC, HIQA, and Health & Safety Authority (H&SA) etc. have set out the requirements to have robust PPPGs in place at all levels across the health service. In addition several regulatory reports, inspections and recommendations from serious incidents have identified significant gaps in services in relation to PPPGs. The need for clear governance to ensure all PPPGs are appropriately developed and implemented has also been identified, along with effective assurance mechanism to monitor their effectiveness. The (HSE) quality and safety audits have also identified similar deficits.

Significant work has been done to address these deficits within the HSE; however there is still a need for improvement. In November 2015, (NCEC) developed *Standards for Clinical Practice Guidance*. The purpose of this document was to provide standards for healthcare staff developing evidence-based clinical practice guidance for healthcare services. The HSE was required by the DoH to put clear processes in place to implement and monitor these standards.

The HSE established a National Steering Group for PPPGs in 2015. Its purpose was to develop a HSE National Framework for developing PPPGs with guidance for service providers to implement the NCEC *Standards for Clinical Practice Guidance* and to outline the processes required for the establishment of a National Central Repository Office (NCRO) for all HSE national approved PPPGs.

Following extensive literature review a framework for developing PPPGs was developed. It aligned the NCEC *Standards for Clinical Practice Guidance* with the stages in the PPPG development cycle which are applicable to clinical and non-clinical PPPGs. As part of this process the HSE National Framework for developing PPPGs sets out the following:

- Section 1:** Definition of a Policy, Procedure, Protocol and Guideline and when to use them.
- Section 2:** Stages in the PPPG Development Cycle (stages 1-7).
- Section 3:** Revised HSE National Template for developing PPPGs (2016) (Part A and Part B).
- Section 4:** PPPG Checklist for developing Clinical and Non-Clinical PPPGs.
- Section 5:** Proposed HSE National Central Repository for HSE national approved PPPGs.
- Section 6:** Implementation of the Framework.

There should be a consistent clear approach to the development, implementation and evaluation of PPPGs. The two key innovative areas of this new HSE National Framework for developing PPPGs are that:

- PPPGs are evidence-based
- Approved PPPGs meet the standards outlined in the HSE National Framework for developing PPPGs

In 2016, the HSE developed a *Framework for Improving Quality* and it has a clear aim to foster a culture of quality that continuously seeks to provide safe, effective, person centred care across all services. It outlines the following six drivers for improving quality:

1. Leadership for Quality.
2. Person and Family Engagement.
3. Staff Engagement.
4. Use of Improvement Methods.
5. Measurement for Quality.
6. Governance for Quality.



Figure 1: Framework for Improving Quality (HSE, 2016)

Each driver outlined in the *Framework for Improving Quality* is linked to the Framework for developing PPPGs and will be integral to the implementation process.

Also aligned to the HSE National Framework for developing PPPGs, is the *Health Services People Strategy 2015-2018* <http://www.hse.ie/eng/staff/Resources/hrstrategiesreports/peoplestrategy.pdf>

It identifies the following people management priorities that will be targeted for action recognising the need for leadership and support at every level to implement improvements:



Figure 2: People Management Priorities (HSE, 2015)

In addressing these important areas as detailed in the *People Strategy* and associated *Work Plan*, performance will be improved, workforce will be optimised and future learning will be developed within the HSE.

Scope

The HSE National Framework for Developing PPPGs applies to all HSE staff and HSE funded services and covers clinical and non-clinical PPPGs. This includes:

Models of Care
Care Bundles
Care Pathways
Clinical Decision Aids.

Checklists and algorithms, as part of the implementation toolbox can be included in the PPPG in so far as they are components rather than stand-alone practice guidance. Diagrams or flowcharts can be utilised to assist in the visual process in the understanding of PPPGs.

Section 1.

Definitions of a Policy, Procedure, Protocol and Guideline and when to use them

What is a Policy?

A policy is a written statement that clearly indicates the position and values of the organisation on a given subject (HIQA, 2008). It is a written operational statement of intent and explains the organisations stand on a subject and why there is a rule about it.

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 and within which clinical (and public health) programmes and services are provided (Lavis et al.,2010).

When to use a Policy

A policy is used to provide a guiding principle and regulates organisational action. It is used to provide guidance, express rules, expectations and requirements. It explains the 'what' and 'why' however, it does not inform exactly how something will be done. A procedure deals with the 'how'.

Examples

- HSE National Consent Policy 2014.
http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/
- HSE Open Disclosure National Policy 2013.
http://hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure
- HSE National Safety Incident Management Policy 2014.
<http://www.hse.ie/eng/about/Who/qualityandpatientsafety/incidentrisk/Riskmanagement/SafetyIncidentMgtPolicy2014.pdf>
- HSE National Managing Attendance Policy (January 2009) revised 2014.
<http://www.hse.ie/eng/staff/Resources/hrppg/Managing%20Attendance%20Policy%20revised%20May%202014.pdf>
- HSE Policy on the Prevention of Sharps Injuries 2016.
[HSE Policy on the Prevention of Sharps Injuries \(2016\)](#)

What is a Procedure?

A procedure is a written set of instructions that describe the approved and recommended steps of a particular act or sequence of events (HIQA, 2008).

Procedures supplement polices with specifics and completes the information users need.

When to use a Procedure

A procedure is used to outline the specific method of how things are done. It is action orientated and outlines the 'why'. It describes specific step by step instructions and the sequence in which to perform those steps. It specifies what will be done, when, and by whom and what records are to be kept.

Examples

- HSE National Safety Incident Management Policy 2014.
https://www.hse.ie/eng/about/Who/qualityandpatientsafety/MeasuringandLearning/SCDQIQIProgramme/Safety_Incident_Management_Policy.pdf

- HSE Grievance and Disciplinary Procedures for the Health Service 2004.
http://www.hse.ie/eng/staff/Resources/hrppg/Grievance_and_Disciplinary_Procedure_for_the_Health_Service_2004.html

What is a Protocol?

A protocol is 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; in that they specify who does 'what', 'when' and 'how' (HSE, 2012).

When to use a Protocol

Protocols can be used when developing specific instructions, for example, the safe transfer of patients. Protocols are typically used for drug prescription, dispensing and administration, (i.e.) medication protocols (for Nursing and Midwifery Medication Protocols refer to Section 4 Medication Protocols *Guidance to Nurses and Midwives on Medication Management* (An Bord Altranais, 2007).

Examples

- National Cancer Control Programme Chemotherapy Protocols.
<http://hse.ie/NCCPchemoprotocols/>

What is a Guideline?

A guideline is defined as a principle or criterion that guides or directs action. Guideline development emphasises using clear evidence from the existing literature, rather than expert opinion alone (HSE, 2011).

What is an Evidence-Based Clinical Guideline?

Evidence-based clinical guidelines are recommendations to assist practitioners and patients to make decisions about appropriate healthcare for specific clinical circumstances. Guidelines should integrate best research evidence in conjunction with clinical expertise, patient values and cost (Sackett et al., 2000).

When to use a Guideline

Guidelines are used when recommendations on evidence-based clinical practice are required (source: *Healthcare Improvement Scotland Methodology Toolkit* NHS Scotland).

<http://www.sign.ac.uk/methodology/index.html>

Examples

- HSE Open Disclosure: National Guidelines 2013 Communicating with service users and their families following adverse events in healthcare.
http://www.hse.ie/eng/about/Who/qualityandpatientsafety/nau/Open_Disclosure/opendiscFiles/opdiscnationalguidelines2013.pdf
- National Clinical Guideline 2015: Diagnosis, staging and treatment of patients with breast cancer.
<http://www.hse.ie/eng/services/list/5/cancer/profinfo/guidelines/breast/breastguideline.pdf>
- National Clinical Guideline 2015: Management of Constipation in Adult Patients Receiving Palliative Care.
<http://health.gov.ie/wp-content/uploads/2015/11/Mgmt-of-Constipation-Guideline.pdf>
- HSE Guideline Document for Site Specific Safety Statements 2016.
<http://www.hse.ie/eng/staff/safetywellbeing/HealthSafetyand%20Wellbeing/SafetyStatementsandRiskAssessments.html>
- HSE Long Term Absence Benefits Scheme Guidelines 2012.
http://www.hse.ie/eng/staff/Resources/hrppg/Long_Term_Absence_Benefit_Schemes_Guidelines_December_2012.html

What is a Model of Care?

A 'Model of Care' is a multifaceted concept, which broadly defines the way health services are delivered (Queensland Health, 2000). It 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).

The broad objective is to make sure that 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).

When to use a Model of Care:

- As a support to clinical staff members in their delivery of care
- As a guide to communication between related services during the delivery of care
- As information on the type and level of care that can be expected by a patient/carer when entering a modelled care service
- When planning service delivery (e.g.) workforce planning
- To re-orientate staff on expected and acceptable level of care
- In the design and delivery of new services
- In the design and delivery of education programmes for staff and patients
- As consideration when defining the governance structure for services.

Examples

- Model of Care for Trauma and Orthopaedics Surgery, by the National Clinical Programme for Trauma and Orthopaedics 2015.
<http://www.hse.ie/orthopaedicsprogramme>
<http://hse.ie/eng/about/Who/clinical/natclinprog/orthopaedicsprogramme/modelofcare/>
<https://www.hse.ie/eng/about/Who/clinical/natclinprog/orthopaedicsprogramme/moctrauma.pdf>
- Model of Care for Pre-Admission Units, by National Clinical Programme for Anaesthesia 2014.
<https://www.hse.ie/eng/about/Who/clinical/natclinprog/anaesthesia/modelofcare.pdf>

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Section 2. Stages in the PPPG Development Cycle

Section 2.

Stages in the PPPG Development Cycle

National frameworks, such as the *National Standards for Safer Better Healthcare* (HIQA, 2012) www.hiqa.ie and the *Quality Framework for Mental Health Services* (MHC, 2007) <http://www.mhcirl.ie/File/qframemhc.pdf> have outlined essential requirements in relation to the development, implementation, monitoring and auditing of PPPGs.

A number of key national documents were also developed to support the development and implementation of PPPGs and are available at:

NCEC (2013) Guideline Developers Manual www.health.gov.ie/patient-safety/ncec

HIQA (2011) National Quality Assurance Criteria for Clinical Guidelines www.hiqa.ie

HSE (2012) Principles for Clinical Governance <http://www.hse.ie/go/clinicalgovernance>

In 2015, NCEC developed *National Standards for Clinical Practice Guidance* <http://health.gov.ie/wp-content/uploads/2015/11/NCEC-Standards-for-Clinical-Practice-Guidance.-Nov-2015.pdf> and in 2016; the HSE National Framework for developing PPPGs aligned these standards with the stages in the PPPG development cycle. These standards apply to both clinical and non-clinical PPPGs.

Each stage outlined in the PPPG development cycle must be completed sequentially before moving to the next stage. These stages are outlined in the diagram below:

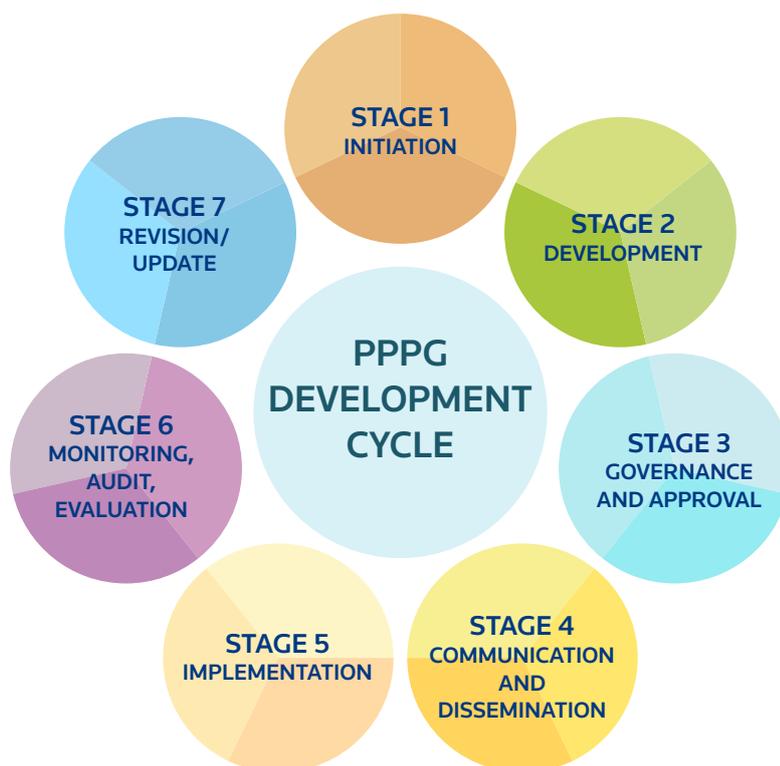


Figure 3: PPPG Development Cycle



Stage 1. Initiation

Initiation refers to the beginning or first step in developing a PPPG.

Standards required for Initiation

- The decision making approach relating to type of PPPG guidance required, coverage of the PPPG (national, regional, local) and applicable settings are described.
- Synergies are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS) to avoid duplication and to optimise value for money and use of staff time and expertise.
- The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.
- The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.
- The views and preferences of the target population have been sought and taken into consideration (as required).
- The overall objective(s) of the PPPGs 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).
- Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.
- Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.
- The PPPG is informed by the identified needs and priorities of service users and stakeholders.
- There is service user/lay representation on the PPPG Development Group (as required).
- Information and support is available for staff on the development of evidence-based clinical practice guidance.

Steps to meet these standards for stage 1

(for additional information on initiation Stage 1 refer to Appendix Ia: pages 22 - 24)

- Identify the need for the development of a new PPPG or update of an existing one. Agree the mandate to proceed with the development of the PPPG. Sponsor/Commissioner is identified (as appropriate).
- Identify the legislation or regulation that determines the PPPG (as appropriate), and clearly outline the supporting evidence from the literature.
- Register the intention to develop a National PPPG with the HSE NCRO when in place.
- Utilise the HSE National Template for developing PPPGs (2016).
- Establish the PPPG Development Group ensuring representation of all relevant stakeholders including service users (as appropriate), and identify chairperson and outline the role of each member. Determine agreed terms of reference (refer to Appendix II in the HSE National Template for developing PPPGs (2016) for Membership of PPPG Development Group Template).
- Describe the overall purpose of the PPPG.
- Outline the scope: What will and will not be covered by the PPPG.
- Identify the target users to whom the PPPG is meant to apply and how they may use the PPPG.
- Describe the population/patient groups to which the PPPG is meant to apply and whether their views and preferences have been sought (as appropriate). Identify who will and will not be covered by the PPPG, age range, sex, (clinical) description, co-morbidity, if applicable.
- Outline the objective(s) of the PPPG. This deals with the potential impact of the PPPG on society, population of patients or individuals. The specific objective(s) of the PPPG should be described in detail.
- Outline the outcome(s) of the PPPG, this deals with the end result or the consequence of the PPPG. The expected benefits from the PPPG should be specific to a problem or topic.
- Describe/specify the governance structure for the PPPG being developed.
- Conflict of interest must be declared by all members and recorded (refer to Appendix III in the HSE National Template for developing PPPGs (2016) , where the Conflict of Interest Declaration Form Template is located).
- Information and support should be available for staff on the development of PPPGs. Staff should complete PPPG development training and evidence-based practice training as required.



Stage 2. Development

Development describes the methodology by which the PPPG is developed. It involves the integration of the best research evidence with clinical/professional expertise, patient/client values and cost.

Standards required for Development

- The clinical question(s) covered by the PPPG are specifically described.
- Systematic methods used to search for evidence are documented (for PPPGs 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 PPPG.
- There is an explicit link between the PPPG guidance and the supporting evidence.
- The PPPG guidance/recommendations are specific and unambiguous.
- The potential resource implications of developing and implementing the guidance are identified (e.g.) equipment, education/training, staff time and research.
- There is collaboration and education and training across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.
- Budget impact is documented, (resource required, if applicable).
- Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).

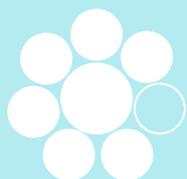
Three additional standards are required for a small number of more complex PPPGs

- Cost effectiveness analysis is documented.
- A systematic literature review has been undertaken.
- Health Technology Assessment (HTA) has been undertaken.

Steps to meet these standards for Stage 2

(for additional information on development Stage 2 refer to Appendix Ib: pages 25 - 28)

- **Develop the specific questions that are the subject of the PPPG:**
Identify areas of new and emerging evidence or areas where there is variation in practice, which will form the basis of the PPPG and the type of evidence being gathered. In order to identify the evidence required to address the PPPG topic it is essential to define one or more key questions. Where applicable, clinical questions should be broken down into PICO(T) format (Population, Intervention, Comparison, Outcome, Time). The clinical questions should be clear, unambiguous, focused and concise (NCEC, 2013).
- **Search for the evidence using a clearly defined and documented search strategy:**
Based on the key question(s) defined above, a search strategy should be developed. The search strategy should be documented explicitly in order for it to be replicated. The following should be included: Databases searched, search terms, search limits, inclusion and exclusion criteria. If undertaking searches, utilise a librarian or other information specialist who has experience and expertise in this area (NCEC, 2013).
- **Describe the method of appraising the evidence:**
Appraise all evidence for validity and applicability to the setting using a systematic method and record results. Critically appraise the quality, validity and relevance of all evidence gathered as part of your search. As a first step, studies can be categorised according to the 'hierarchy of evidence' (e.g.) meta-analyses and systematic reviews (Cochrane) are a higher level of evidence than randomised controlled trials, which are a higher level of evidence than Cohort or Case-Control Studies (NCEC, 2013). There are critical appraisal tools available at:
SIGN: <http://www.sign.ac.uk/methodology/checklists.html>
AGREE II appraisal tool:
http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-Users-Manual-and-23-item-Instrument_2009_UPDATE_2013.pdf
These tools can be used to appraise the strengths and weaknesses of the research. There are three main points to consider when appraising all research evidence:
 1. Are the results valid?
 2. What are the results?
 3. Are the results applicable/generalisable to the population of the PPPG?
- **Describe the process the PPPG Development Group used to formulate recommendations:**
Ensure the PPPG guidance is linked to supporting evidence. Recommendations may be formulated through a formal structured process whereby the following may be considered and documented:
 - What evidence is available to answer the clinical question(s)?
 - What is the quality of the evidence?
 - Is the evidence applicable to the Irish population and healthcare setting?
 - What is the potential benefit versus harm to the population/patient?
- **Provide a summary of the evidence from the literature in the PPPG:**
The summary of the evidence should include the type of evidence used to answer the PPPG/topic being considered (i.e. Randomised Controlled Trials (RCTs), Meta-analyses etc.) and what the evidence says about the topic being considered.
- **Detail resources necessary to implement the PPPG recommendations:**
Document resources required to implement the PPPG recommendations including training, audit, equipment, skills etc.
- **Describe the PPPG step by step using a clearly defined process:**
Outline the step by step process: (An algorithm, a process flowchart or Standard Operating Procedure (SOP) can be used and included to describe the process as appropriate).
- **Some complex PPPGs require additional steps (e.g.):**
Cost effectiveness analysis is documented
A systematic literature review is undertaken
Health Technology Assessment (HTA) is undertaken.



Stage 3. Governance and Approval

Approval refers to the process of acceptance, agreement and assessing quality standard of PPPGs

Standards required for Governance and Approval

- Formal governance arrangements for PPPGs at local, regional and national level are established and documented.
- The PPPG has been reviewed by independent experts prior to publication (as required).
- Copyright and permissions are sought and documented.

Steps to meet these standards for Stage 3

- Consider national or international expert review of the draft PPPG (as appropriate). This will identify any problems in presentation, process of development, robustness of the search, content, acceptance of the PPPG and its implementation (NCEC, 2013).
- Ensure all feedback and subsequent changes are accompanied by supporting evidence.
- Review and sign the PPPG Checklist to ensure compliance with the standards outlined in the PPPG Development Cycle.
- The signed PPPG Checklist must accompany the final PPPG document on submission to the appropriate senior management/relevant governance process in order for the PPPG to be approved. This is to confirm that all stages in the PPPG Checklist have been completed and meet the NCEC *National Standards for Clinical Practice Guidance*.
The following information must be completed in the PPPG Checklist:
 - ◆ Name of the PPPG
 - ◆ Name, title and signature of the person signing off on the PPPG Checklist
 - ◆ Date
- The final PPPG document must be signed off by senior management/relevant governance process etc., confirming the PPPG meets the standard required for a robust PPPG.
- Once approved by the appropriate governance structure, the final version should be converted to a PDF document to ensure the integrity of the PPPG.
- A signed and dated master copy should be retained in an agreed central location with signatures which are either written or electronic where it will be document controlled before dissemination.



Stage 4. Communication and Dissemination

Dissemination refers to the active spread of new practices to the target audience using planned strategies (Nilsen, 2015)

Standards required for Communication and Dissemination

- A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.
- Plan and procedure for dissemination of the PPPG is described.
- The PPPG is easily accessible by all users (e.g. PPPG repository).

Steps to meet these standards for Stage 4

- Determine the dissemination methods which are effective and best suited to address identified needs and barriers.
- Develop a system to manage approved PPPGs in line with good governance and document control practice.
- Develop a communication plan to support the stages of PPPG development, dissemination and implementation. Include the most effective methods of distribution to all relevant staff, service users and other stakeholders. Outline implementation and audit processes including awareness training/support to staff.
- Once the PPPG is approved by the appropriate senior management/relevant governance processes etc., it must be appropriately disseminated to all stakeholders for implementation within the organisation/division/service.
- Establish good governance structures to ensure that the learning from the PPPG development and implementation process is shared appropriately within the organisation/division/service.



Stage 5. Implementation

Implementation refers to the process of putting to use or integrating new practices within a setting (Nilsen, 2015). Implementation science is the study of implementation and refers to the process of implementing programmes and practices that have some evidence from the research field to suggest they are worth replicating. It is the study of how a practice that is evidence-based or evidence-informed gets translated to different, more diverse contexts in the real world (Metz *et al.*, 2015).

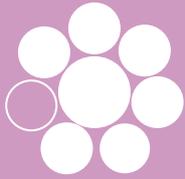
Standards required for Implementation

- 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.
- Education and training is provided for staff on the development and implementation of evidence-based PPPGs (as required).
- There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.

Steps to meet these standards for Stage 5

(for additional information on implementation Stage 5 refer to Appendix Ic: page 29)

- Develop an implementation plan, including identification of responsible person(s), specifying the actions to implement the PPPG and timeframes for implementation.
- Identify and record barriers and facilitators for implementation and use of the PPPG.
- Align the implementation plan with the service plan and budgetary process.
- Outline the supports required for education and training for staff on the implementation of the PPPG.
- Establish good governance structures including strong leadership for the effective implementation of the PPPG being developed.



Stage 6. Monitoring, Audit and Evaluation

Monitoring can be defined as a systematic process of gathering information and tracking over time. Monitoring provides a verification of progress towards achievement of objectives and goals (HIQA, 2012).

Audit is a formal review that usually includes planning, identifying risk areas, assessing internal controls, sampling of data, testing of processes, validating information and formally communicating recommendations and corrective action measures to both management and the board/or appropriate governance structures <http://www.ahia.org/>.

Clinical Audit is defined as a quality improvement process that seeks to improve outcomes through systematic review against explicit criteria and the implementation of change (HIQA, 2012).

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved (HIQA, 2012).

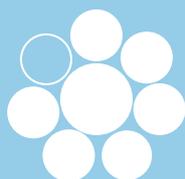
Standards required for Monitoring, Audit and Evaluation

- Process for monitoring and continuous improvement is documented.
- Audit criteria and audit process/plan are specified.
- Process for evaluation of implementation and effectiveness is specified.

Steps to meet these standards for Stage 6

(for additional information on monitoring, audit and evaluation Stage 6 refer to Appendix Id: page 30)

- Establish good governance structures, including strong leadership for the monitoring, audit and evaluation of PPPGs.
- Develop a monitoring, audit and evaluation plan for continuous improvement. The plan must include details of timelines and lead person(s) responsible for these processes. (Link with the appropriate person(s) with the expertise within your area to assist you with these processes, as appropriate).
- Outline specific outcomes which the PPPG aims to achieve (in terms of benefit/healthcare outcomes/service improvement/risk reduction etc.) and outline how these outcomes can be measured (there may be short-term and long-term outcomes).
- Develop mechanisms to evaluate the effectiveness of the PPPG in meeting its defined purpose, objective(s) and outcome(s).
- Communicate the findings to the relevant stakeholders (as appropriate). Good governance structures must be in place to ensure there is continuous improvement in the development, implementation, monitoring, auditing and evaluation of PPPGs (i.e. PPPG Development Group, project sponsors or appropriate governance group, quality and safety groups/committees etc.).



Stage 7. Revision/Update

Revision/Update refers to the process to ensure that the learning from the PPPG development and implementation process is used to amend and update or revise the original PPPG as new evidence emerges.

Standards required for Revision/Update

- Documented process for revisions/updating and review, including timeframe is provided.
- Documented process for version control is provided.

Steps to meet these standards for Stage 7

- Update of the PPPG must take place on a consistent, planned ongoing basis, as referenced on the revision date on the front page or cover of the PPPG. The revision date must be agreed by the PPPG Development Group.
- Update of the PPPG will be carried out every three years unless the need to revise the PPPG is identified by: Audit, evaluation, serious incident, organisational structural change, scope of practice change, advances in technology, significant changes in international evidence or legislation etc.
- If there are no amendments required to the PPPG following the revision date, the detail on the version tracking box must still be updated which will be a new version number and date.

Appendices

Appendix Ia: Additional Information on Initiation (Stage 1)

Identify the need for a PPPG:

- Is an evidence-based PPPG already available for this topic/clinical question (local, national or international)?
- Is the existing PPPG up to date, peer reviewed with rigorous methodology, generalisable to target population and applicable to Ireland?
- Is this PPPG being developed as creating a new PPPG (*de novo*) or adapting or adopting an existing PPPG?, or is this PPPG a combination of adopting or adapting some aspects of a PPPG and creating *de novo* recommendations where existing PPPGs are lacking (NCEC, 2013).
- Is this PPPG being developed as a national document, or for service delivery systems (e.g. Hospital Group/ CHOs/NAS etc.) or for local guidance?
- Will the proposed PPPG be relevant for use in a wider geographical area or wider clinical area? If so, wider collaboration needs to be considered. In general, PPPGs should not vary by location, although the mechanism for local implementation may differ.
- Other factors that can be drivers in the development of PPPGs are: Legislation, Regulation, European Union Directives, Court/Inquest decisions, recommendations from regulatory reports, incidents/near misses identified through quality, safety and risk management systems, variability in practice etc.
- If a PPPG is not on the HSE National PPPG Registry/Central Repository but needs to be developed nationally, a notice of intent to develop a PPPG is requested by the relevant national director/service. The proposed author/development group must then notify the HSE (NCRO) of intent to create a new PPPG. In time this will prevent duplication of PPPGs in different areas of the HSE and will reduce variation in practice and service delivery.

Synergies/(co-operations) should be maximised across the organisation, Hospitals/Hospital Groups & CHOs/ NAS etc:

- It is important that PPPGs are aligned with other national standards, initiatives and levers for implementation. Standardised PPPGs aim to promote consistency of guidance across the country, avoid duplication and optimise value for money and use of staff time and expertise.
- It is not in the interests of patients, staff or safety for individual Hospitals/Hospital Groups/CHOs/NAS etc., to develop or implement different guidance for similar circumstances. Where appropriate, Hospitals/ Hospital Groups /CHOs/NAS etc., must adopt national guidance, encompassing any local implementation requirements as necessary.

Scope of the PPPG is clearly described:

- The scope of the PPPG should be clearly described. Determining the scope sets the boundaries, and establishes exactly what the PPPG Development Group is trying to achieve, including the issues that the PPPG will cover and will not cover.

Target users are specifically described:

- The target users should be clearly defined in the PPPG, so the reader can immediately determine if the PPPG is relevant to them (e.g. the target users for a PPPG on breast cancer may include nurses, radiologists, pathologists, surgeons, medical oncologists, and radiation oncologists etc.).

Population to whom it applies:

- A clear description of the population (i.e. patients, public, etc.) covered by a PPPG document should be provided. The age range, sex, clinical description, and co-morbidity may be provided (e.g. a guideline on the diagnosis, staging and treatment of patients with prostate cancer would include men 18 years or older with newly diagnosed prostate cancer and those with metastases arising from prostate cancer).

Objective(s) are specifically described:

- The overall objective(s) are specifically described in detail. The objective(s) need to be SMART (Specific, Measurable, Achievable, Relevant/Realistic, and Time-bound). Clear, tangible objective(s) will facilitate implementation and audit.
- Objective(s) deals with the potential health impact of the PPPG on society and populations of patients or individuals.

Outcome(s):

- The outcome(s) deals with the end result or the consequence of the PPPG. The expected (health) benefits from the PPPG should be specific to the (clinical) problem or (health) topic (source: AGREE II).
<http://www.agreetrust.org/agree-ii/>

The potential for improved health is described:

- Outcome(s) need to be specified in terms of potential for improved health
- How will this PPPG improve (health) outcomes?
- How will this PPPG lead to improved healthcare and/or health?
(source: NCEC *Guideline Development Manual, 2013*).

Conduct key stakeholder analysis:

- One of the requirements for organisation-level PPPG development is that it is sponsored at management team/director/senior line manager level. This discussion should take place at the stage when the need for the PPPG development is identified.
In setting up a PPPG Development Group, consider the following:
 - ◆ Who has the lead responsibility and who will be accountable for ensuring that this PPPG is in place?
 - ◆ What service(s)/function areas have key responsibilities in respect of this PPPG?
- Are there any service(s)/function areas that may require specific modification to the implementation plan?
- Are there any specific areas that have a legislative responsibility in relation to this PPPG?
- What service areas will be expected to drive the implementation of this PPPG?
- What group(s) of service users will this PPPG impact on?
- Is external expertise required? Is clinical/technical/organisational expertise required? Where is this expertise available within the organisation?
- What service(s)/organisational spread is needed?

In order to ensure that the diversity of stakeholder perspectives is taken into account these questions should help identify the range of service(s)/function areas that need to either be represented directly or linked to the development of the PPPG. It is essential in some circumstances to identify the specific expertise required to set the agenda and develop the PPPG. This process will assist to identify the core PPPG Development Group to scope and/or develop the PPPG.

Conflict of Interest:

- In some instances members of the PPPG Development Group may have a conflict of interest in relation to the specific PPPG being developed, and this can impede or interfere with best practice in developing the PPPG.
- The member(s) should declare if they have a conflict of interest or whether there are moral or ethical considerations that would impede/prevent them from making an objective contribution.
- It is incumbent on any member of the group to declare any 'Conflict of Interest' which might compromise impartiality or to be reasonably be perceived as doing so, in the development of this PPPG. Any such 'Conflict of Interest' should be notified immediately to the chairperson of the PPPG Development Group.
- All members of the PPPG Development Group need to sign a Conflict of Interest Declaration Form.
- Where conflicts/interests are declared, the process for dealing with this conflict must be documented (refer to Appendix III in the HSE National Template for developing PPPGs (2016) where the Conflict of Interest Declaration Form Template is located).

Service user/lay representation involvement:

The following principles should be adhered to in order to support and inform service user and community involvement in PPPG development processes:

- A rights-based approach to public and patient partnership
- A commitment to creating an atmosphere where building trust is supported and encouraged
- A flexible and accessible communication process that is honest, open and transparent about the implications of health care decisions
- Motivation and commitment to partnership on the part of both service users and service providers
- Flexibility and willingness to adapt to changing circumstances.

PPPG is informed by the needs and priorities of service users and stakeholders:

- A full range of interests and views created through the involvement of stakeholders is taken into account in the development of PPPGs; this involves taking a holistic approach to PPPG development in order to ensure that all these stakeholders are appropriately and effectively involved.
- It will require analysis of the policy environment and of the activities, processes and interactions that relate to it. This will give a complete picture of the context within which changes might be considered and where unintended consequences might take place.
- It is necessary to look at the impact on and/or meet the needs of all people directly or indirectly affected by the PPPG. It is essential that all key stakeholders are involved in the PPPG process. This will involve consulting with those responsible for service delivery/implementation/auditing and those who are at the receiving end or otherwise affected by the PPPG (staff and service users).
- In addressing involvement and participation of staff, service users or representatives of other agencies in PPPG development, it is important to consider the following:
 1. Who should be involved?
 2. When to involve them and (i.e. at what stage)?
 3. How to involve them?
 4. What may hinder involvement and how can these issues be overcome?
 5. How does their involvement relate to the development process of the PPPG itself?
 6. How do you encourage the best contribution from those involved?
 7. What supports are needed to enable people to contribute fully to the process?

The views and preferences of the target population:

- In developing PPPGs it may be necessary to obtain the views and preferences of target population within or outside the organisation to assist in the development/consultation process. Part of the process will involve assessing the impact of the PPPG on existing practices and the changes that will be required.

Education and training is provided for staff on the development and implementation of PPPGs:

- Education and training is provided for staff on the development and implementation of PPPGs.
- Identify the current skills of the team and determine the deficits.
- Establish a training plan to ensure all staff who are involved have the necessary experience, skills and abilities to develop and implement PPPGs.
- Organise workshops and ongoing training as appropriate to facilitate up-skilling staff that are responsible for developing and implementing PPPGs.

Appendix Ib: Additional information on development (Stage 2)

Clinical question(s) are specifically described:

- The first step in PPPG development is to agree the (clinical) questions to be answered. These questions form the basis for the types of evidence gathered, the literature search strategy, and the inclusion and exclusion criteria.
- Using the PICO(T) format for clinical questions, the elements of each clinical question are defined in order to direct the literature search to relevant and precise evidence.

Systematic methods used to search for evidence are documented:

- It is important that the development of PPPGs is underpinned by an evidence-based approach.
- The clinical questions formulated are used to conduct literature searches of the primary literature.
- The following bibliographic databases can be searched using keywords implicit in the PICO(T) question(s) and any identified subject headings:
 - ◆ Cochrane Library
 - ◆ Point-of-Care Reference Tools
 - ◆ Medline
 - ◆ Embase (where available)
 - ◆ Other bibliographic databases (e.g. CINAHL/PsycINFO)
 - ◆ Trial Registers (including Clinical Trials.gov, Cochrane Central Register of Controlled Trials (Central), EU Clinical Trials Register, International Prospective Register of Systematic Reviews (Prospero), WHO International Clinical Trials Registry). This is not an exhaustive list and may be tailored for specific PPPGs. Searches may also be supplemented by material identified from individual members of the group.
- The literature should be searched based on the hierarchy of evidence. All literature searches should be updated prior to publication.
- Details of the literature review protocol and full literature search strategy should be included in the PPPG Appendix (or be available on request).
- Establish links with the HSE library/clinical librarian and with academic partner/third-level institution.
- Ensure replicability of the literature search strategy so that it can be used for the PPPG update. Further information is available from (HSE/NCCP Systematic Literature Review Protocol, NCCP *Guideline Methodology Manual*).

Critical appraisal/analysis of evidence using validated tools is documented:

There are three main points to consider when appraising all the research evidence:

1. Are the results valid (internal validity)?
 2. What are the results (statistical and clinical significance)?
 3. Are the results applicable/generalisable to the patient/population of the guideline (external validity)?
- Existing guidelines should be appraised using the Appraisal of Guidelines for Research and Evaluation II instrument (AGREE II, Brouwers, et al., 2010) to assess the methodological rigour of how that guideline was developed.
 - Guidelines are appraised on six domains:
 - ◆ Scope and purpose
 - ◆ Stakeholder involvement
 - ◆ Rigour of development
 - ◆ Clarity of presentation
 - ◆ Applicability
 - ◆ Editorial independence.

- Primary literature should also be appraised, to ensure validity using critical appraisal checklists (e.g. SIGN appraisal checklists). When assessing the relevance of selected studies, consideration should be given to each element of the clinical question and how close it is to the PICO(T) of the appraised study, as well as how well that study was conducted, and how applicable the results are to the patients and clinical setting under investigation.
- Studies that have not undergone this process should not be used as evidence to support a recommendation in the PPPG (source: *NCCP Guideline Methodology Manual*).
- Additional information is available at:
CEBM: (Centre for Evidence Based Medicine): <http://www.cebm.net/>
SIGN: <http://sign.ac.uk/>
GRADE: <http://www.gradeworkinggroup.org/>
AGREE: <http://www.agreetrust.org/agree-ii/>

Health benefits, side effects and risks have been considered and documented:

- The PPPG should consider health benefits, side effects, and risks when formulating recommendations (e.g. guideline on breast cancer may include a discussion on overall outcomes, including survival, quality of life, adverse effects, and symptom management or a discussion comparing one treatment option to another). There should be evidence that these issues have been addressed (source: *AGREE II Manual*).

Explicit link between the clinical guidance, and the supporting evidence:

- PPPGs should be formulated through a structured formal process that is documented. The following items may be considered:
 - ◆ What evidence is available to answer the clinical question(s)?
 - ◆ What is the quality of the evidence?
 - ◆ Is the evidence applicable to the Irish population and healthcare setting?
 - ◆ What is the potential benefit versus harm to the population/patient?
 - ◆ Are there any resources required to implement the recommendations?

Guidance/recommendations are specific and unambiguous:

- The evidence gathered to address a topic should be synthesised into an evidence statement and the final PPPG should be formulated based on that evidence, in conjunction with clinical expertise.
- Recommendations/guidance should be graded (e.g. Oxford CEBM, 2009; SIGN grading system, GRADE).
CEBM: <http://www.cebm.net/>
SIGN: <http://sign.ac.uk/>
GRADE: <http://www.gradeworkinggroup.org/>
- The level of consensus among each group, in relation to the PPPG recommendations should also be recorded (unanimous, consensus, or majority/minority).
- A recommendation should provide a concrete and precise description of which option is appropriate in which situation and in what population group, as informed by the body of evidence.
- It is important to note that in some instances, evidence is not always clear cut and there may be uncertainty about the best care option(s). In this case, the uncertainty should be stated in the guidance (sources: *NCCP Guideline Methodology Manual*).

Potential resources are identified:

- Many PPPGs may represent current practice and may therefore be cost neutral and in other instances implementation of national PPPGs will lead to cost savings.
- However, where a PPPG has identified areas that require change to ensure full implementation, the potential resource implications of applying these recommendations must be considered (source: *NCCP Guideline Methodology Manual*)
- In areas where additional resources are required they may be sought through the appropriate service planning process.

There is collaboration across all stakeholders:

- Consulting with all relevant stakeholders is vital for successful planning and implementation phases to optimise patient flow and integrated patient care. It allows those implementing the PPPG to assess current needs, and levels of capacity and readiness.
- Consultation is also critical in terms of identifying, acknowledging and addressing any resistance which exists to the implementation of the PPPG being implemented. Involving all stakeholders is essential to create awareness about the PPPG and should generate buy-in for it.
- Leaders can create readiness by consulting all stakeholders in the decision-making process, by giving clear direction on the change and by acknowledging and validating concerns stakeholders may have.

Budget Impact Analysis (BIA):

Budget Impact Analysis (BIA) has been defined as a tool to predict the potential financial impact of the adoption and diffusion of a new technology into a healthcare system with finite resources (Mauskopf et al., 2007). BIA refers to an analysis of the added financial impact of implementing a new PPPG for a finite period; it estimates the cost of implementing the PPPG less any savings that might accrue and therefore addresses the affordability of the recommendations (HIQA, 2015). Further detailed guidance on conducting a BIA can be found at: <https://www.hiqa.ie/publications/guidelines-budget-impact-analysis-health-technologies-ireland>

Literature review of cost effectiveness is documented:

The aim of economic evaluations of health technologies is to compare the costs and consequences of new or existing health technologies (such as drugs, diagnostics, devices, etc.) with one or more relevant alternatives (often referred to as the comparator[s]). An economic evaluation also provides evidence of the cost-effectiveness of implementing the PPPG (i.e. the benefit to be derived is worth the additional investment).

The first step is to assess the existing evidence of cost-effectiveness by conducting a systematic review of the cost-effectiveness literature.

The search strategy for economic literature should be based on the search used in the clinical literature review, with the addition of an economic filter (e.g. SIGN Economic Studies Filter for Medline) and should be performed in the following specialised databases:

- Database of Abstracts of Reviews of Effects.
- NHS Economic Evaluation Database (EED).
- Health Technology Assessment Database.
- Cochrane Library.
- Cochrane Economic Evaluations.
- EBSCO Discovery.
- Google Scholar.

This is not an exhaustive list and may be tailored for specific PPPGs. Searches may also be supplemented by material identified from individual members of the group.

Further information at:

SIGN <http://sign.ac.uk/pdf/sign50.pdf>

NCEC *Guideline Methodology Manual* 2013.

<http://health.gov.ie/patient-safety/ncec/resources-and-learning/ncec-processes-and-templates/>

HIQA, *Guidelines for the Retrieval and Interpretation of Economic Evaluations of Health Technologies in Ireland*

<http://www.hiqa.ie/publications/guidance-guidelines-retrieval-and-interpretation-of-economic-evaluations>

Health Technology Assessment (HTA):

It may be required to conduct a HTA inclusive of a *de novo* economic model of cost-effectiveness in relation to the implementation of the PPPG in the Irish setting. The evidence of cost-effectiveness in the literature must be evaluated for relevance and applicability to the Irish setting as outlined in the HIQA *Guidelines for the Retrieval and Interpretation of Economic Evaluation of Health Technologies in Ireland* (2014). If the available literature is not applicable to the Irish setting (e.g. healthcare delivery system is not comparable to the Irish system) or if the outcome of the systematic review is inconclusive with regard to cost-effectiveness, it may be necessary to conduct a *de novo* economic model of cost-effectiveness in the Irish setting. Further detailed guidance on the conduct of economic evaluation can be found at: <https://www.hiqa.ie/system/files/Economic-Evaluation-Guidelines-2014.pdf> An analysis across other HTA domains may also be relevant (e.g.) social, organisational, ethical or medico legal aspects of implementing the PPPG.

Appendix Ic: Additional information on implementation (Stage 5)

What to consider when developing an implementation plan: Implementation should be considered at the initiation stage and throughout the PPPG development process.

- **Change in practice:** Identify the target behaviour change in current practice. Determine the implementation strategies that are effective and best suited to address identified needs and barriers. Consider equity, acceptability, feasibility and balance of consequences.
- **Appropriateness:** Consider the appropriateness of the intervention: Affordability, practicability, effectiveness, acceptability, side effects/safety and equity (Michie, Atkins & West, 2014).
- **Feasibility:** Ensure PPPG recommendations are implementable.
- **Resources:** Specify any resources required to implement the PPPG and incorporate into the service planning process.
- **Timeframe:** Specify milestones and timeframes for implementation. Specify when the PPPG is due to be fully implemented and embedded into practice.
- **Roles & Responsibilities:** Specify who or what group/discipline is responsible for implementing the PPPG.
- **Communication:** Effective ongoing communication is essential for implementation. All relevant employees and stakeholders must be informed of the PPPG. Effective, on-going communication is critical in motivating staff, overcoming resistance to change and giving and receiving feedback.
- **Implementation supports:** Implementation tools may be useful to assist implementation of the PPPG (e.g.) toolkits, pathways, algorithms, presentations, podcasts, patient leaflets, local champions, teaching aids and training modules for health professionals linked to CPD points. Publish implementation tools at the same time as the PPPG.
- **Education & training:** Building staff capacity is a core component of implementation. Careful staff selection, quality training and on-going assistance are all crucial in building capacity for effective implementation. Identify the current skills of the team and determine education and training needs.
- **Provision of education and training for staff on the development and implementation of evidence-based practice:** The HSE PPPG resources will include toolkits, training video, workshops, train the trainer and all other relevant information on the HSE website.
- **Identify any risks:** In relation to non-implementation of the PPPG and the associated control measures.
- **Implementation outcome variables:** Indicators of success of implementation include acceptability, adoption, appropriateness, feasibility, implementation cost, fidelity, coverage and sustainability (Proctor, 2011).
- **Implementation levers:** Levers for implementation may include endorsement from government or senior management, implementation mandate, indemnity, regulators, insurers, activity based funding, organisational culture, service plan and accountability frameworks (NCEC, 2016).

Appendix Id: Additional information on monitoring, audit and evaluation (Stage 6)

Resources to assist with monitoring, audit and evaluation.

The Practical Guide to Clinical Audit was developed by the HSE Quality and Patient Safety Division in 2013, to equip healthcare professionals with the necessary knowledge to plan, design and conduct a clinical audit. It contains sample templates, checklists and summaries and can be accessed through the following link:

<http://www.hse.ie/eng/about/Who/qualityandpatientsafety/>.

HSE Quality Assurance & Verification Division

<http://www.hse.ie/go/developmentsites/QAVD/>

Department of Health

www.health.gov.ie/patient-safety/ncec

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%20>
- NICE Evidence Services: <https://www.evidence.nhs.uk/>

AGREE II –International tool to assess the quality and reporting of practice guidelines

<http://www.agreetrust.org/agree-ii/>

Section 3.

Revised HSE National Template for
developing PPPGs (2016)

Section 3.

Revised HSE National Template for developing PPPGs (2016)

The new template (2016) in the HSE National Framework for developing PPPGs replaces the following document: *Procedure for developing Policies, Procedures, Protocols and Guidelines Document (reference no. OQR029 Revision no. 3 Revised March 2012).*

What makes this template different from the previous HSE National Template (2012) is: NCEC *Standards for Clinical Practice Guidance* (2015) were developed to provide standards for healthcare staff when developing evidence based clinical guidance for healthcare services. The HSE has taken these standards and aligned them to each stage in the PPPG development cycle so that all future PPPGs being developed must meet these standards and are applicable to both clinical and non-clinical PPPGs. The steps/processes to develop and or advise the PPPG must be adhered to by all staff to ensure compliance with the HSE's National Framework for developing PPPGs.

The template is developed in two parts: Part A and Part B.

Part A: Outline PPPG Steps.

Outline the step by step process to follow, algorithm, process flow chart, or Standard Operating Procedure (SOP) which has been developed using the framework for developing PPPGs. *(Part B should be completed first to develop the PPPG and then the core PPPG steps that have been developed are inserted in Part A).*

Part B: Outlines the Stages in the PPPG Development Cycle.

Part B: is completed first, as each stage in the PPPG development cycle is addressed.

Insert Logo as appropriate



HSE National Template for developing PPPGs (2016)
INSERT TITLE OF DOCUMENT:

Is this document a:

Policy Procedure Protocol Guideline

Insert Service Name(s), Directorate and applicable Location(s):

Title of PPPG Development Group:	
Approved by:	
Reference Number:	
Version Number:	
Publication Date:	
Date for revision:	
Electronic Location:	

Version	Date Approved	List section numbers changed	Author

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http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/PPPG_Document_Development_and_Inventory/

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PART A: Outline of PPPG Steps

Outline the step by step process to follow, algorithm, process flow chart, or (SOP) which has been developed using the HSE National Framework for developing PPPGs. *(Part B should be completed first to develop the PPPG and then the core PPPG steps that have been developed are inserted in Part A).*

Title:

Outline of PPPG Steps:

PART B: PPPG Development Cycle

1.0 INITIATION

1.1 Purpose

This describes the overall purpose of the PPPG.

1.2 Scope

The scope of this PPPG identifies what will (and will not) be covered by the PPPG

1.2.1 Target users; identify who the intended audience is and how they may use the PPPG.

1.2.2 Population to whom it applies; identify who will (and will not) be covered by the PPPG, age range, sex, (clinical) description, comorbidity (if applicable).

1.3 Objective(s)

The objective(s) of the PPPG deals with the potential impact of the PPPG on society and populations of patients or individuals. The specific objective(s) of the PPPG should be described in detail.

1.4 Outcome(s)

The outcome(s) of the PPPG deals with the end result or the consequence of the PPPG. The expected benefits from the PPPG should be specific to a problem or topic.

1.5 PPPG Development Group

See Appendix II for Membership of the PPPG Development Group Template.

See Appendix III for PPPG Conflict of Interest Declaration Form Template.

1.6 PPPG Governance Group

1.6.1 See Appendix IV for Membership of the Approval Governance Group.

1.7 Supporting Evidence

1.7.1 List relevant legislation/PPPGs.

1.7.2 List PPPGs that are being replaced by this PPPG.

1.7.3 List related PPPGs.

1.8 Glossary of Terms (attach Appendix as appropriate).

2.0 DEVELOPMENT OF PPPG

2.1 List the questions (clinical/non-clinical)

Identify areas of new and emerging evidence or areas where there is variation in practice, which will form the basis of the PPPG and the type of evidence being gathered. In order to identify the evidence required to address the PPPG topic it is essential to define one or more key questions. Where applicable, clinical questions should be broken down into PICO(T) format (Population, Intervention, Comparison, Outcome, Time). The clinical questions should be clear, unambiguous, focused and concise (NCEC, 2013).

2.2 Describe the literature search strategy (attach Appendix as appropriate)

Based on the key question(s) defined, a literature search strategy should be developed. The literature search strategy should be documented explicitly in order that it can be replicated. The following should be included: Databases searched, search terms, search limits, inclusion and exclusion criteria. If undertaking searches, utilise a librarian or other information specialist who has expertise and experience in this area (NCEC, 2013).

2.3 Describe the method of appraising evidence (attach Appendix as appropriate)

Critically appraise the quality, validity and relevance of all evidence gathered as part of your search. As a first step, studies can be categorised according to the 'hierarchy of evidence' (e.g. meta-analyses and systematic reviews are a higher level of evidence than randomised controlled trials, which are a higher level of evidence than cohort or case-control studies (NCEC, 2013).

There are various critical appraisal tools available (e.g.):

SIGN: <http://www.sign.ac.uk/methodology/checklists.html>

AGREE II appraisal tool: http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-Users-Manual-and-23-item-Instrument_2009_UPDATE_2013.pdf

These tools can be used to appraise the strengths and weaknesses of the research. There are three main points to consider when appraising all research evidence:

- Are the results valid?
- What are the results?
- Are the results applicable/generalisable to the population of the PPPG?

2.4 Describe the process the PPPG Development Group used to formulate recommendations

Recommendations may be formulated through a formal structured process whereby the following may be considered and documented:

- What evidence is available to answer the clinical questions?
- What is the quality of the evidence?
- Is the evidence applicable to the Irish population and healthcare setting?
- What is the potential benefit verses harm to the population/patient?

2.5 Provide a summary of the evidence from the literature

Outline a summary of the supporting evidence from the literature for the PPPG.

2.6 Detail resources necessary to implement the PPPG recommendations

Are there resource implications? Outline same.

2.7 Outline of PPPG Steps/Recommendations

Insert the PPPG process/steps in Part A (as appropriate).

3.0 GOVERNANCE AND APPROVAL**3.1 Outline Formal Governance Arrangements**

3.1.1 Refer to Appendix IV for Membership of the Approval Governance Group.

3.2 List method for assessing the PPPG in meeting the Standards outlined in the HSE National Framework for developing PPPGs.**3.3 Attach any copyright/permission sought** (attach Appendix as appropriate).**3.4 Insert approved PPPG Checklist** (refer to section 4 of the HSE National Framework for developing PPPGs).**4.0 COMMUNICATION AND DISSEMINATION****4.1 Describe communication and dissemination plans** (attach Appendix as appropriate).

5.0 IMPLEMENTATION

- 5.1 Describe implementation plan listing actions, barriers and facilitators and timelines** (include implementation tools such as algorithms, teaching resources, checklists etc.).
- 5.2 Describe education/training plans required to implement the PPPG** (attach Appendix as appropriate).
- 5.3 Identify lead person(s) responsible for the implementation of the PPPG.**
- 5.4 Outline specific roles and responsibilities.**

6.0 MONITORING, AUDIT AND EVALUATION

- 6.1 Describe the plan and identify lead person(s) responsible for the following processes:**
 - 6.1.1 Monitoring.
 - 6.1.2 Audit.
 - 6.1.3 Evaluation.

7.0 REVISION/UPDATE

- 7.1 Describe procedure for the update of the PPPG** (including date for revision).
- 7.2 Identify method for amending PPPG if new evidence emerges.**
- 7.3 Complete version control update on PPPG Template cover sheet.**

8.0 REFERENCES

9.0 APPENDICES

- Appendix I Signature Sheet
- Appendix II Membership of the PPPG Development Group Template
- Appendix III Conflict of Interest Declaration Form Template
- Appendix IV Membership of Approval Governance Group Template
- Appendix V Explanatory Guidance Manual for the PPPG Template

Appendix II: Membership of the PPPG Development Group (Template)

Please list all members of the development group (and title) involved in the development of the document.

Type Name here Type Title here	Signature: _____ Date: _____
Type Name here Type Title here	Signature: _____ Date: _____
Type Name here Type Title here	Signature: _____ Date: _____
Type Name here Type Title here	Signature: _____ Date: _____
Chairperson: Type Name here Type Title here	Signature: _____ Date: _____

Appendix III: Conflict of Interest Declaration Form (Template)



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CONFLICT OF INTEREST DECLARATION

This must be completed by each member of the PPPG Development Group as applicable

Title of PPPG being considered:

Please circle the statement that relates to you

1. I declare that I DO NOT have any conflicts of interest.

2. I declare that I DO have a conflict of interest.

Details of conflict (Please refer to specific PPPG)

(Append additional pages to this statement if required)

Signature

Printed name

Registration number (if applicable)

Date

The information provided will be processed in accordance with data protection principles as set out in the Data Protection Act. Data will be processed only to ensure that committee members act in the best interests of the committee. The information provided will not be used for any other purpose.

A person who is covered by this PPPG is required to furnish a statement, in writing, of:

(i) The interests of the person, and

(ii) The interests, of which the person has actual knowledge, of his or her spouse or civil partner or a child of the person or of his or her spouse which could materially influence the person in, or in relation to, the performance of the person's official functions by reason of the fact that such performance could so affect those interests as to confer on, or withhold from, the person, or the spouse or civil partner or child, a substantial benefit.

Appendix IV: Membership of the Approval Governance Group (Template)

Please list all members of the relevant approval governance group (and title) who have final approval of the PPPG document.

Type Name here Type Title here	Signature: _____ Date: _____
Type Name here Type Title here	Signature: _____ Date: _____
Type Name here Type Title here	Signature: _____ Date: _____
Type Name here Type Title here	Signature: _____ Date: _____
Chairperson: Type Name here Type Title here	Signature: _____ Date: _____

Appendix V: Guidance Manual for the PPPG (Template)

(to be removed when complete)

- Please use pages Section 3 of the HSE National Framework for developing PPPGs (2016) as the Template
- This Guidance Manual section should be removed when PPPG is approved

Format of PPPG; it is important that the document is accessible to users in terms of layout and language. Recommendations from the National Adult Literacy Agency (NALA) should be followed:

- Type of Font – NALA approve Verdana, Calibri, and Arial (choose one)
- Type size – Headings **12 Bold** Text 12
- Align the text throughout the document to the left
- Use single line spacing
- Use double spacing between paragraphs
- Section Headings – boldface typed
- Every entry in a Policy, Procedure, Protocol or Guideline must be numbered
- Paragraphs are structured so that each main subheading represents a separate heading
- Each subheading is represented by equal indentation
- Abbreviations should be kept to a minimum
- When working with draft documents ensure a draft number and date is identified clearly on the cover page
- Include definitions for all terms used in the text
- A local logo can be inserted on the front cover on the right hand side where appropriate.
- Due regard should be given to the Official Languages Act 2003.

Accessibility

PPPGs should be adapted to ensure accessibility for service users and family members to meet the requirements of the Disability Act 2005.

Table of contents

This is usually completed when the PPPG is fully developed. The electronic template which is available to download from HSEnet has been formatted to formulate a table of contents.

http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/PPPG_Document_Development_and_Inventory/

PPPG Making Process Stage	Section
Cover Page	
Stage 2 Development	Title: Title of the Policy, Procedure, Protocol or Guideline.
Stage 2 Development	Document reference number: Assigned locally for local PPPGs, assigned by National Central Repository Office (NCRO) for HSE National PPPGs.
Stage 2 Development	Document developed by: This is the name of the PPPG Development Group. The members of the Development Group should be listed as in Appendix II.
	Version number: Version 0 is the original approved document, and then each time the document is revised it changes to version 1, 2 etc.
Stage 3 Governance & approval	Publication date: Date when the PPPG has been approved (Month, Year) Electronic location: State location.
Stage 6 Monitoring, Audit, Evaluation	Responsibility for monitoring, audit and evaluation: This must be specified.
	Version tracking: Version control is updated on template cover sheet this will facilitate staff to easily see the changes contained in each revision
	Double click on Footer: Insert the following information as it pertains to document: PPPG Title, PPPG Reference Number, Version Number, Approval Date, Revision Date.
Stage 7 Revision/Update	Date for Revision: Date the PPPG is due for revision (minimum every three years).
Part A	
Part B should be completed first to develop the PPPG and then the core PPPG steps that have been developed are inserted in Part A.	
Part B	
PPPG Sections	
PPPG Making Process Stage	
Stage 1: Initiation	Purpose: This describes the overall purpose of the PPPG.
	1.2 Scope: This identifies the users of the PPPG. It identifies to whom the PPPG applies.
	1.3 Objective(s): The objective(s) of the PPPG deals with the potential impact of the PPPG on society and populations of patients or individuals. The specific objective(s) of the PPPG should be described in detail.
	1.4 Outcomes: The outcome(s) of the PPPG deals with the end result or the consequence of the PPPG. The expected benefits from the PPPG should be specific to a problem or topic.
	1.7 Supporting Evidence: <ul style="list-style-type: none"> ▪ List relevant legislation /PPPGs. ▪ List PPPGs that are being replaced with this PPPG. ▪ List related PPPGs.

PPPG Making Process Stage	Section
Stage 1: Initiation	<p>1.8 Glossary of Terms, Definitions and Abbreviations: Explanation of key technical terms or terminology that are referred to in the PPPG.</p> <ul style="list-style-type: none"> ▪ List terms and their definitions in alphabetical order. If this is an extensive list then they may be included in an Appendix. ▪ Definitions used should be in accordance with HSE National Framework for developing PPPGs and any other relevant legislation.
Stage 2: Development	<p>Policy or Procedure or Protocol or Guideline: Describe the development process of the PPPG using the guidance in the Template and the HSE National Framework document.</p>
Stage 3 Governance and Approval	<p>Document approved by: Document the name of the Chairperson of the Governance Group who has final sign off.</p> <p>A formal process is necessary to ensure that appropriate governance structures are in place to ratify the PPPG within your organisation/division/service.</p> <p>PPPGs that require approval must be put on the agenda of the relevant governance structure for discussion. The appropriate governance structure will agree to approve the PPPG within the division/service organisation.</p> <p>The draft PPPG document should be reviewed by the Development Group to ensure that there is an explicit link between the PPPG and the supporting evidence and analysis.</p> <p>List the method for assessing the PPPG in meeting the standards.</p> <ul style="list-style-type: none"> ▪ Review and sign the PPPG Checklist to ensure compliance with the standards outlined in the PPPG Development Cycle. ▪ The signed PPPG Checklist must accompany the final PPPG document on submission to the appropriate senior management/relevant governance process in order for the PPPG to be approved. <p>The following information must be completed in the PPPG Checklist:</p> <ul style="list-style-type: none"> ▪ Name of the PPPG. ▪ Name, title and signature of the person signing off on the PPPG Checklist. ▪ Date. <p>The final PPPG document needs to be reviewed and signed off by the relevant Governance Group and other key stakeholders, including the PPPG sponsor/commissioner/relevant division(s) (as appropriate). Include the relevant approved PPPG Checklist for clinical or non-clinical PPPGs.</p>
Stage 4 Communication and Dissemination	<p>4.1 Communication and Dissemination: Refer to the steps outlined in the HSE National Framework for developing PPPGs.</p>

PPPG Making Process Stage	Section
Stage 5 Implementation	<p>5.0 Implementation Plans: Refer to the steps outlined in the HSE National Framework for developing PPPGs.</p> <p>5.4 Roles and Responsibilities: Clearly define the appropriate personnel to fulfill the following roles and responsibilities in relation to the steps outlined in this PPPG:</p> <ul style="list-style-type: none"> ▪ Those responsible for complying with the PPPG. ▪ Those responsible for ensuring compliance to the PPPG.
Stage 6 Monitoring, Audit, Evaluation	<p>6.1 Outline the plan for monitoring, audit and evaluation. Identify and name the person(s) with responsibility for monitoring, audit and evaluation. This individual(s) job title should also be documented.</p>
Stage 7 Revision/Update	<p>7.0 Revision/Update A formal <u>review</u> will be carried out on a three-yearly basis unless there is a change informed by legislation, best practice, the Regulator or the EU Directives etc., which would identify the need to update the PPPG sooner.</p> <p>Processes must be put in place to ensure that the learning from the PPPG development and implementation process is used to amend, update and change the original PPPG version. If there are no amendments to the PPPG following the review process, the date and detail on the version tracking box must still be updated.</p>
References	<p>8.0 References: List all references used in the Policy, Procedure, Protocol or Guideline.</p>
Appendices	<p>9.0 Appendices:</p> <ul style="list-style-type: none"> ▪ Additional information is included in this section that will support, and provide a rationale for the PPPG. ▪ Each appendix should be incrementally numbered using Times New Roman font (i.e. Appendix I, II, III, IV etc.)

Section 4.
PPPG Checklist for developing
Clinical and Non-Clinical PPPGs

Section 4.

PPPG Checklist for developing Clinical PPPGs

The PPPG Checklists were developed to assist staff to meet standards when developing Clinical PPPGs.

Standards for developing Clinical PPPG	Checklist
Stage 1 Initiation	
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	<input type="checkbox"/>
Synergies/co-operations are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	<input type="checkbox"/>
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	<input type="checkbox"/>
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	<input type="checkbox"/>
The views and preferences of the target population have been sought and taken into consideration (as required).	<input type="checkbox"/>
The overall objective(s) of the PPPGs are specifically described.	<input type="checkbox"/>
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	<input type="checkbox"/>
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	<input type="checkbox"/>
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	<input type="checkbox"/>
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	<input type="checkbox"/>
There is service user/lay representation on PPPG Development Group (as required).	<input type="checkbox"/>
Information and support is available for staff on the development of evidence-based clinical practice guidance.	<input type="checkbox"/>

Stage 2 Development	Checklist
The clinical question(s) covered by the PPPG are specifically described.	<input type="checkbox"/>
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/ adopted from international guidance, their methodology is appraised and documented).	<input type="checkbox"/>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	<input type="checkbox"/>
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	<input type="checkbox"/>
There is an explicit link between the PPPG and the supporting evidence.	<input type="checkbox"/>
PPPG guidance/recommendations are specific and unambiguous.	<input type="checkbox"/>
The potential resource implications of developing and implementing the PPPG are Identified e.g. equipment, education/training, staff time and research.	<input type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input type="checkbox"/>
Budget impact is documented (resources required).	<input type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).	<input type="checkbox"/>
Three additional standards are applicable for a small number of more complex PPPGs: Cost effectiveness analysis is documented. A systematic literature review has been undertaken. Health Technology Assessment (HTA) has been undertaken.	<input type="checkbox"/>

Stage 3 Governance and Approval	Checklist
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	<input type="checkbox"/>
The PPPG has been reviewed by independent experts prior to publication (as required).	<input type="checkbox"/>
Copyright and permissions are sought and documented.	<input type="checkbox"/>

Stage 4 Communication and Dissemination	Checklist
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	<input type="checkbox"/>
Plan and procedure for dissemination of the PPPG is described.	<input type="checkbox"/>
The PPPG is easily accessible by all users e.g. PPPG repository.	<input type="checkbox"/>

Stage 5 Implementation	Checklist
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	<input type="checkbox"/>
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	<input type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	<input type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input type="checkbox"/>

Stage 6 Monitoring, Audit, Evaluation	Checklist
Process for monitoring and continuous improvement is documented.	<input type="checkbox"/>
Audit criteria and audit process/plan are specified.	<input type="checkbox"/>
Process for evaluation of implementation and (clinical) effectiveness is specified.	<input type="checkbox"/>

Stage 7 Revision/Update	Checklist
Documented process for revisions/updating and review, including timeframe is provided.	<input type="checkbox"/>
Documented process for version control is provided.	<input type="checkbox"/>

I confirm that the above Standards have been met in developing the following PPPG:

Name of PPPG: _____

Name of person signing off on the PPPG Checklist: _____

Title of person signing off on the PPPG Checklist: _____

Signature of person signing off on the PPPG Checklist: _____

Date: _____

This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved.

PPPG Checklist for developing Non-Clinical PPPGs

The PPPG Checklists were developed to assist staff to meet standards when developing Non-Clinical PPPGs.

Standards for developing Non-Clinical PPPGs	Checklist
Stage 1 Initiation	
The decision making approach relating to type of PPPG guidance required (Policy, Procedure, Protocol, Guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	<input type="checkbox"/>
Synergies/co-operations are maximised across departments/organisations Hospital/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)) to avoid duplication and to optimise value for money and use of staff time and expertise.	<input type="checkbox"/>
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	<input type="checkbox"/>
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	<input type="checkbox"/>
The views and preferences of the target population have been sought and taken into consideration (as required).	<input type="checkbox"/>
The overall objective(s) of the PPPGs are specifically described.	<input type="checkbox"/>
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	<input type="checkbox"/>
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	<input type="checkbox"/>
The PPPG is informed by the identified needs and priorities of staff, service users and others (as appropriate).	<input type="checkbox"/>

Stage 2 Development	Checklist
Systematic methods used to search for and appraise evidence are documented (for PPPGs which are adapted/adopted from international guidance, their methodology is appraised and documented as required).	<input type="checkbox"/>
There is an explicit link between the PPPG and the supporting evidence.	<input type="checkbox"/>
PPPG guidance/recommendations are specific and unambiguous.	<input type="checkbox"/>
The potential resource implications of developing and implementing the PPPG are Identified e.g. education/training/information, staff time and research.	<input type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	<input type="checkbox"/>

Stage 3 Governance and Approval	Checklist
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	<input type="checkbox"/>
The PPPG has been reviewed by independent experts prior to publication (as required).	<input type="checkbox"/>
Copyright and permissions are sought and documented (as required).	<input type="checkbox"/>

Stage 4 Communication and Dissemination	Checklist
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	<input type="checkbox"/>
Plan and procedure for dissemination of the PPPG is described.	<input type="checkbox"/>
The PPPG is easily accessible by all users e.g. PPPG repository.	<input type="checkbox"/>

Stage 5 Implementation	Checklist
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	<input type="checkbox"/>
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	<input type="checkbox"/>
Education and training is provided for staff in the development and implementation of PPPGs.	<input type="checkbox"/>

Stage 6 Monitoring, Audit, Evaluation	Checklist
Process for monitoring and continuous improvement is documented.	<input type="checkbox"/>
Audit criteria and audit process/plan are specified.	<input type="checkbox"/>
Process for evaluation of implementation and effectiveness is specified.	<input type="checkbox"/>

Stage 7 Revision/Update	Checklist
Documented process for revisions/updating and review, including timeframe is provided.	<input type="checkbox"/>
Documented process for version control is provided.	<input type="checkbox"/>

I confirm that the above Standards have been met in developing the following PPPG:

Name of PPPG: _____

Name of person signing off on the PPPG Checklist: _____

Title of person signing off on the PPPG Checklist: _____

Signature of person signing off on the PPPG Checklist: _____

Date: _____

This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved.

Section 5.
Proposed HSE National Central Repository
for HSE national approved PPPGs

Section 5.

Proposed HSE National Central Repository for HSE national approved PPPGs

A survey was carried out by the HSE National HSE PPPG Project Group during Autumn 2015 to determine current practice in the HSE in relation to the management processes of PPPGs. In November 2015 a literature review was also conducted to review practice in relation to the development and management process of PPPGs in a large health organisation.

Specifically the aims of the literature review were to:

1. Describe what process is currently in place in the HSE for the development of PPPGs.
2. Identify processes for PPPGs in other large health systems.
3. Find evidence of good practice around PPPG processes according to the literature.
4. Outline the barriers and facilitators from the literature in the use of research evidence/PPPGs in healthcare practice.

The survey highlighted the following:

- Lack of awareness of whether there is a process in place or not in place
- Misunderstanding around PPPG terminology, what is a Policy, Procedure, Protocol and Guideline and when to use them
- The need for a national central database for PPPGs
- Variance in the communication and dissemination of PPPGs across the system
- Approach to implementation and evaluation not standardised
- Significant duplication of PPPGs across the system.

The findings of the literature review suggest that a robust process for the management, implementation and dissemination of PPPGs requires the following:

- Clear governance around leadership and accountability for PPPGs
- An online PPPG system that is easily accessible, secure with up to date PPPGs
- Standardised templates including a coding system or taxonomy for easy identification of PPPGs
- Education and training in the development and implementation of PPPGs
- A knowledge translation strategy (using evidence in practice)
- Resources are identified and available to support process (e.g. funding, staff, time, access to quality routine data)
- Clear and open communication channels between policy makers, intermediaries and users
- Three requirements for the use of knowledge (PPPGs) in practice are identified:
 1. **Relevance:** (In order for PPPGs to be used in practice they need to be relevant)
 2. **Legitimacy:** (Clear governance regarding leadership and accountability for the development and implementation of PPPGs)
 3. **Accessibility:** (PPPGs must be easily accessible).

The survey and literature review report is available at: <http://www.lenus.ie/hse/handle/10147/608343>

The findings of the survey and literature review informed the development of the HSE National Framework for developing PPPGs and also highlighted the requirement for the development of a HSE National Central Repository for all approved HSE National PPPGs, and the need for education and training to support the development and implementation of evidence-based PPPGs.

Purpose of the HSE National Central Repository Office (NCRO):

It is recommended that there will be a small number of staff within the PPPG NCRO who will manage and oversee the national repository for PPPGs.

The function of NCRO will:

- Provide a reference number for all new HSE National PPPGs being developed
- Upload the newly approved HSE National PPPG onto the HSE National Document Management Control System and also publish it on the HSE website so that it can be viewed and downloaded by staff and the public
- Act as a contact focal point for general information on PPPGs.

Transition Period:

- There will be a transition period regarding the current PPPG process and the new proposed process
- From January 2017 all existing HSE National approved PPPGs that are in place will remain in place until they are due for review
- From January 2017 any new HSE National PPPGs that need to be developed, or any existing HSE National approved PPPGs that are due for review must use the new Template, new PPPG Checklist and must meet the PPPG standards outlined in the framework
- Each national division will be required to review their existing current HSE National PPPGs in relation to expiry dates, and will update their PPPGs when they are due to be reviewed. A three year transition period will be required to update all existing approved HSE National PPPGs. The updated HSE National PPPGs will be migrated onto the new proposed system once they have met the required standards.

Process for creating a PPPG on the HSE National Central Repository:

The HSE National Central Repository **will be** for all HSE National approved PPPGs. PPPGs developed within local services i.e. CHO areas and Hospital Groups etc. will be stored and accessible (as appropriate) within their own agreed governance structure processes.

The process for managing the HSE National Central Repository for HSE National approved PPPGs will be outlined in a separate document once resources are made available.

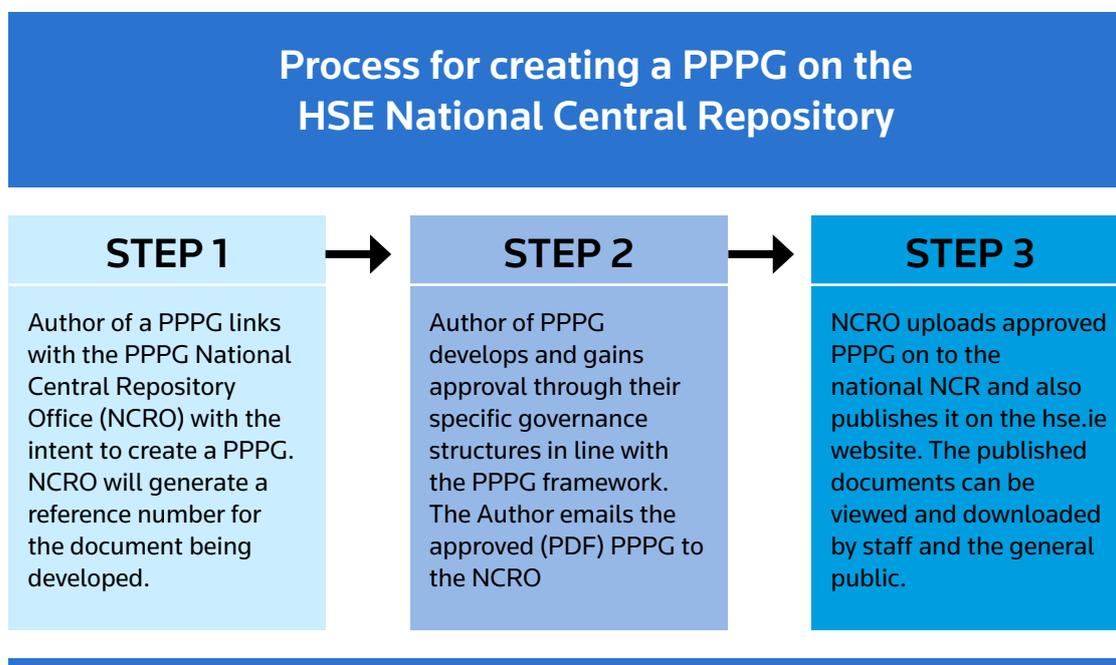


Figure 4: Process for creating a PPPG on the HSE National Central Repository

6

Section 6. Implementation of the Framework

Section 6: Implementation of the Framework

This is a whole health system framework and is applicable across the different governance levels that currently exist. It is the role and responsibility of all managers to ensure this framework is implemented at all levels within their areas of responsibility. All staff are required to implement this framework when developing PPPGs.

Recommendations to support the implementation of the framework:

1. Nominate a National Director to lead the implementation on behalf of the HSE Leadership Team.
2. Implement a communication plan to raise awareness of the PPPG standards in the framework.
3. Set out actions required to ensure that all PPPGs developed throughout the system meet the standards outlined in the framework.
4. Establish a National PPPG Group to advise on the required structures and processes to support division/services to comply with the PPPG standards.
5. All divisions to put in place structures and processes to ensure their PPPGs are consistent with the framework standards.
6. Services to identify lead person(s) at appropriate levels (National, CHO, Hospital Groups, NAS) etc. to support their services to develop PPPGs to meet the required standards.
7. Develop a National PPPG Network with nominated leads to advise on implementation and development of PPPGs that meet the required standards.
8. Develop and implement an education and training programme e.g. train the trainer programme, e-learning tools, webinars, etc. to support divisions/services to meet the standards in the development of PPPGs.
9. Secure resources to enable the development and on-going management of a NCRO for HSE national approved PPPGs.
10. Identify processes to monitor implementation of required standards for PPPGs through the *Performance Accountability Framework for the Health Services 2016*.
11. Work with Senior Managers, CHO, Hospital Groups, NAS etc. to develop synergies/co-operations across the HSE to avoid duplication and to optimise value for money and use of staff time and expertise. PPPGs should be developed within these groups and across services as appropriate and become national PPPGs to avoid unnecessary duplication.

References

- Australian Commission on Safety and Quality in Healthcare (2015) *Guide to the National Safety and Quality Health Service standards for health service organisational boards*. Sydney. NSQHS
- Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ* 2016;352:i1152
- Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Med Assoc J*. 2010 Health Improvement Scotland: Methodology toolkit <http://healthcareimprovementscotland.org/>
- Department of Health and Children (2008) *Building a Culture of Patient Safety*. Report of the Commission on Patient Safety and Quality Assurance. Dublin, Stationary Office <http://health.gov.ie/blog/publications/building-a-culture-of-patient-safety-report-of-the-commission-on-patient-safety-and-quality-assurance/>
- Healthcare Improvement Scotland Methodology Toolkit NHS Scotland
<http://www.sign.ac.uk/methodology/index.htm>
- Healthcare Improvement Scotland Methodology Toolkit NHS Scotland
<http://www.sign.ac.uk/pdf/sign50.pdf>
- Healthcare Improvement Scotland Methodology Toolkit NHS Scotland
<http://www.sign.ac.uk/pdf/50steps.pdf>
- Health Information and Quality Authority (2012) *National Standards for Safer Better Healthcare* Dublin, HIQA www.hiqa.ie
- Health Information and Quality Authority (2011) *National Quality Assurance Criteria for Clinical Guidelines*. Dublin, HIQA www.hiqa.ie
- Health Service Executive (2012) *HSE Procedure for the developing Policies, Procedures, Protocols and Guidelines: Document reference no.OQRO29 Revision no 3 Revised March 2012*
- Mental Health Commission (2007) *Quality Framework*. Mental Health Services in Ireland. Dublin, MHC <http://www.mhcirl.ie/File/qframemhc.pdf>
- Michie, S., Atkins, L., West, R. (2014) *The Behaviour Change Wheel: A Guide to Designing Interventions*. (1st ed.). Great Britain: Silverback Publishing
- National Clinical Effectiveness Committee (2013) *Guideline Developers Manual* Dublin DoH www.health.gov.ie/patient-safety/ncec
- National Clinical Effectiveness Committee (2015) *Standards for Clinical Practice Guidance*. Dublin DoH
- National Clinical Effectiveness Committee & Health Information and Quality Authority (2015) *National Quality Assurance Criteria for Clinical Guidelines. Version 2. To provide quality assurance of National Clinical Guidelines in Ireland* Dublin NCEC/HIQA
- North Eastern Health Board (2004) *Guidelines for Policy making promoting good governance in policy development*
- Nilsen P. (2015) Making sense of implementation theories, models and frameworks. *Implementation Science* 10(1): 53
- Page, Stephen B. (1998) *Establishing a system of Policies and Procedures*, BookMaster, Inc, Mansfield Ohio
- Page, Stephen B. (2000) *Achieving 100% Compliance of Policies and Procedures*, BookMaster, Inc, Mansfield Ohio
- Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Arons, G., Bunker, A., et al. (2011). Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. *Adm Policy Ment Health*; 38(2):65-76
- Sackett DL, Strauss SE, Richardson WS, et al. (2000) *Evidence-based medicine: how to practice and teach EBM*. London: Churchill-Livingstone

The AGREE Next Steps Consortium (2009) *Appraisal of Guidelines for Research & Evaluation 11. AGREE11 Instrument*. The Agree Research Trust <http://www.agreetrust.org/agree-ii/>

University College Cork (2015) *A systematic literature review to support a framework for the development of standards for Clinical Practice Guidance* <http://health.gov.ie/patient-safety/ncec/clinical-practice-guidance/>

WA Health Networks (2007) *Model of Care: overview and guidance. Ensuring people get the right care, at the right time, by the right team and in the right place*. Western Australia, Department of Health <http://cedd.org.au/wordpress/wp-content/uploads/2014/04/Model-of-Care-Overview-and-Guidelines-WA-Health-Networks.pdf>

Glossary of Terms

Term	Definition	Source
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.	UCC systematic review report 2015(Beitz et al., 2012)
Audit	Audit is a formal review that usually includes planning, identifying risk areas, assessing internal controls, sampling of data, testing of processes, validating information and formally communicating recommendations and corrective action measures to both management and the board/or appropriate governance structures.	http://www.ahia.org/
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's outcome.	HIQA, 2014
Checklist	A Checklist is a tool that condenses a large volume of information and allow for systematic verification of steps or practices.	Hewson et al., 2006; Hales et al., 2008; WHO, 2008
Clinical Audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Clinical Audit is a cyclical process that aims to improve patient care and outcomes by a systematic, structured review and evaluation of clinical care against explicit clinical standards.	HIQA, 2012
Clinical Guideline	Clinical Guidelines are 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.	NCEC/HIQA, 2015
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 interest of service users	NCEC/HIQA 2015
Clinical Practice Guidance	Clinical Practice Guidance is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate healthcare 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.	NCEC, 2015
Clinical Procedure	A Clinical Procedure is a written set of instructions that describes the approved and recommended steps for a particular act or sequence of events.	HIQA, 2008
Clinical Protocol	An agreed statement about a specific clinical issue, with a precise sequence of activities to be adhered to with little scope of variation. Clinical Protocols are usually based on guidelines and/or organisational consensus.	NCEC/HIQA, 2015

Evaluation	Evaluation is a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.	HIQA, 2012
Evidence-Based Clinical Guideline	Evidence-Based Clinical Guidelines are recommendations to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. They should integrate the best research evidence in conjunction with clinical expertise, patient values and cost.	Sackett, et al. 2000
Evidence-Based Practice	Evidence-Based Practice is the practice of using current best available clinical evidence and individual clinical expertise or judgement to make decisions about the care of individual service users.	HIQA, 2012
Flowchart	A Flowchart is a diagram of the sequence of movements or actions of people or things involved in a complex system or activity. A Flowchart or flow diagram is a graphic representation of a series of activities that define a process.	Oxford Dictionary Langley, 1987
Guideline	A Guideline is defined as a principal or criterion that guides or directs action. Guideline development emphasises using clear evidence from the existing literature, rather than expert opinion alone.	HSE, 2011
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 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.	NCEC/HIQA, 2015
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.	Queensland Health, 2000 Waikato Health Board, 2004 (HSE Clinical Strategy and Programmes Division) Model of care overview and guidelines 2007 Department of Health, W Australia.
Monitoring	Systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals.	HIQA, 2012
NCEC National Clinical Guideline	NCEC National Clinical Guidelines are a suite of guidelines that meet specific quality assurance and prioritisation criteria and that have been recommended by NCEC.	NCEC/HIQA, 2015
Policy	A Policy is a written statement that clearly indicates the position and values of the organisation on a given subject.	HIQA, 2008
Procedure	A Procedure is a written set of instructions that describe the approved and recommended steps of a particular act or sequence of events.	HIQA, 2008

Protocol	<p>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'. Protocols are mostly typically used when developing instructions for drug prescription, dispensing and administration, i.e. medication protocol.</p>	HSE, 2012
Standard	<p>A Standard is a definable measure against which existing structures, processes or outcomes can be compared.</p> <p>A Standard is a statement which describes the high level outcome required to contribute to quality and safety.</p> <p>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.</p>	<p>NCEC/HIQA, 2015</p> <p>NCEC/HIQA, 2012</p> <p>HIQA, 2012</p>

Acronyms

BIA	Budget Impact Analysis
CHO	Community Healthcare Organisation
DMCS	Document Management Control System
DoH	Department of Health
EED	Economic Evaluation Database
EU	Europe Union
H&SA	Health & Safety Authority
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
MHC	Mental Health Commission
HTA	Health Technology Assessment
NAS	National Ambulance Service
NCCP	National Cancer Control Programme
NCEC	National Clinical Effectiveness Committee
NCRO	National Central Repository Office
NCSP	National Clinical Strategy and Programmes
NHS	National Health Service (UK)
PDF	Portable Document Format
PICO(T)	<p>Population – the population concerned and characteristics of disease or condition</p> <p>Intervention – the intervention(s) or diagnostic test of interest</p> <p>Comparison – to which the intervention is compared</p> <p>Outcome – the expected outcomes, including service user outcomes, system outcomes and or/public health outcomes</p> <p>(T)ime - What is the time frame? (Not always applicable)</p>
PPPG	Policy, Procedure, Protocol, Guideline
QID	Quality Improvement Division
WHO	World Health Organisation

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Patient Safety **1** First

