Guideline/ Policy/ Protocol

TEMPLATE AND USER MANUAL

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Health Service Executive

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Contents *Page*

Foreword *1*

Introduction *2*

Developing the Guideline/Policy/Protocol – Key Assumptions *3*

Definitions *4*

Guideline/Policy/Protocol Template *6-11*

Template User Manual *12-22*

References *23*

Bibliography *24*

Working Group *25*

Foreword

Clinical guidelines, policies and protocols are intended to help practitioners assimilate, evaluate and utilise the best evidence in their current practice. Equally, for the service user, rigorous development and regular review of guidelines, policies and protocols underpins the quality of the service delivered.

While acknowledging the absolute and fundamental importance of a rigorous guideline/policy/protocol development process this document presents a template with key headings in which data and evidence-based material can be assimilated in a standardised format. The publication of this document supports the implementation of recommendations in A Nursing and Midwifery Strategy for Ireland (Government of Ireland, 2003) and Making Knowledge Work for Health : A Strategy for Health Research (Government of Ireland, 2001). Parallel initiatives that have been established which support the development of guidelines/policies/protocols include increased access to IT resources, educational support in relation to research awareness and a two year part-time regional project to facilitate the process of guideline/policy/protocol development, dissemination, implementation and evaluation.

Finally, I wish to congratulate and thank the Guideline/Policy/Protocol Template Development Working Group for their commitment to the development of this document. Furthermore, I would like to acknowledge and commend the continuing work of this group in relation to the development of a reference document which will provide further reading and back-up for practitioners when developing guidelines/policies/protocols in their practice areas.

Joan Phelan
Director, Nursing and Midwifery Planning and Development Unit, HSE-SE

Introduction

In January, 2004, a working group was convened to develop a standardised Guideline/Policy/Protocol framework document which would assist staff in the development of clinical guidelines, policies and protocols. The group focused their work on three aspects of guideline/policy/protocol development and divided these into short, medium and long-term objectives.

The first objective, the short-term goal, was the development of a standard template on which all guidelines, policies and protocols could be based. This template and user manual was completed in November, 2004.

The second objective, the medium-term goal, is the development of a reference document to support the use of the guideline/policy/protocol template. Work is underway on this initiative, which will include an audit tool for use in the review and revision of guidelines/policies/protocols.

The third and final objective, the long-term goal is to establish a regional database of clinical guidelines, policies and protocols, which will be accessible to all staff via local intranet services.

A draft of the guideline template was circulated to all disciplines in what was then the South Eastern Health Board for review and feedback in August, 2004.

There are two sections to this document. The first, the template itself, is simply a blank guideline/policy/protocol template which is based broadly on the work of Stephen Page. The second section, the template user manual, clarifies in detail what each section of the template entails and how to complete each section. It outlines key headings under which information may be inserted in relation to the development, implementation and dissemination stages of the guideline/policy/protocol.

Developing the Guideline/Policy/Protocol – Key Assumptions

The process and rigour of guideline/policy/protocol development is fundamental to the ultimate effectiveness and implementation of the guideline/policy/protocol. As indicated in the literature (National Institute for Clinical Excellence, 2004; New Zealand Guidelines Group, 2001; Scottish Intercollegiate Guidelines Network, 2004) the following important components of the development process must be adhered to:

- A rigorous approach to searching, reviewing and grading the evidence

- Multidisciplinary input is almost always required and is recommended. Where relevant and at a minimum, the draft guideline/policy/protocol should be circulated to all key stakeholders for comment

- The consumer perspective is an important component and must be considered. Ideally, a consumer may be a member of the development group. Alternatively, local recent surveys of the user perspective can be considered.

Definitions

Guidelines

Clinical guidelines are care management tools (Tingle, 2000). They are systematically developed statements, which assist clinicians and patients in making decisions about appropriate treatment of specific conditions (Wilson, 1996). Knowledge, skills and competencies must be used in order to apply guidelines appropriately; practitioners are still accountable for the practices they deliver. Guidelines are often less prescriptive than protocols and policies generally allow a certain level of professional judgement and decision-making and offer a degree of flexibility.

Policy

A policy is a statement of organisational intent for a given issue and gives a clear position statement for the organisation's customers and employees on its values and beliefs (Parsley and Corrigan, 1999).

A policy is a guiding principle which mandates or contains actions and is made at strategic level for the organisation as a whole. Policies change infrequently and require approval at at least senior management team level. Policies help to ensure compliance to overarching principals, legislation or professional guidance.

Protocol

A protocol can be defined as 'a written plan that specifies procedures to be followed in defined situations. It represents a standard of care that describes an intervention or set of interventions' (Ohio Nurses Association, 1992).

Protocols are more specific and explicit in their detail than guidelines, in that they specify who does what, when and how. Protocols have more legal connotations as they are meant to be followed exactly through the stages. There is little room for clinical freedom or professional judgement.

Procedure

A procedure is a series of inter-related steps that are taken to help implement a policy [or a guideline or a protocol]. (Parsley and Corrigan, 1999)

Evidence-based Practice

Evidence-based practice (EBP) has its origins in evidence-based medicine (EBM) (Ingersoll, 2001). The term EBM was developed in Canada in the 1980's to describe the clinical learning strategy used at the McMaster Medical School (Rosenburg and Donald, 1995). The tenets of EBM represents a profound paradigm shift for both medical education and medical practice because the EBM paradigm is founded on rules of evidence that lower the value of authority opinion and raise the value of research studies. In subsequent years the EBM concept has broadened to become evidence-based practice (EBP), which is more inclusive of all aspects of healthcare.
Sackett et al (2001) define EBM as 'the integration of best evidence with clinical experience and patient values'. EBP guidelines, policies and protocols encourage more focused and individualised patient/client care.

The process of EBP is as follows:

- Step 1: reflecting on practice and identifying areas of uncertainty/problem/issue.
- Step 2: translating these areas of uncertainty into focused, searchable questions.
- Step 3: searching the literature for studies that use appropriate designs to help answer the question.
- Step 4: critically appraising the literature.
- Step 5: decisions made based on evidence
- Step 6: implementation of evidence in practice
- Step 7: evaluation of patient/client outcomes.

What counts as evidence?

Determining what counts as best evidence is paramount in EBP. Within EBP research studies are ranked in an evidence hierarchy. The randomised control trial resides at the top because it represent the strongest form of evidence in support of the effectiveness of interventions. There are various systems for determining best evidence. Evans (2000) advocates that in order for the reader to evaluate the strength of the research base, each reference is graded as follows:

I. Randomised controlled trials, including meta-analysis
II. Non-randomised controlled trials and retrospective studies
III. Clinical experience and anecdote.

Guideline/Policy/Protocol Template

TITLE OF ORGANISATION

TITLE OF GUIDELINE, POLICY OR PROTOCOL

TITLE OF GUIDELINE/POLICY OR PROTOCOL	Index No:	
	Date of Approval:	
	Revision Date:	
	Revision No:	
	Page No:	1 of 5

	Signature	***Date***

Developed by:

Consultation with:

Approved by:

Disclaimer:

Each situation must be judged on its own merits and it is unreasonable for readers to follow instructions in the guideline, policy or protocol without proper assessment of individual circumstances. The information contained within this guideline, policy or protocols is accurate and up to date, at date of approval.

Contents page

CONTENTS PAGE 3

1.0 PURPOSE 4

2.0 APPLIES TO 4

3.0 DEFINITIONS 4

4.0 RESPONSIBILITIES 4

5.0 PROCEDURES 4

6.0 DISSEMINATION AND IMPLEMENTATION PLAN 4

7.0 RESOURCE IMPLICATIONS 4

8.0 EVALUATION / AUDIT 4

9.0 REVISION HISTORY 4

10.0 REFERENCES 4

11.0 APPENDICES 4

TITLE OF GUIDELINE/POLICY OR PROTOCOL	Index No:	
	Date of Approval:	
	Revision Date:	
	Revision No:	
	Page No:	4 of 5

1.0 Purpose

2.0 Applies to

3.0 Definitions

4.0 Responsibilities

5.0 Procedures

6.0 Dissemination and Implementation plan

7.0 Resource Implications

8.0 Evaluation / Audit

9.0 Revision History

10.0 References

11.0 Appendices

Sourced from:

Page S (2001) 7 Steps to Better Written Policies and Procedures. Ohio: Process Improvement Publishing.

TITLE OF GUIDELINE/POLICY OR PROTOCOL	Index No:	
	Date of Approval:	
	Revision Date:	
	Revision No:	
	Page No:	5 of 5

The information contained in the attached document must be read and fully understood by all staff.

Please print and sign your name below when you have done so.

DATE	PRINT NAME	SIGNATURE

Template User Manual

The following information will assist you in writing and developing a guideline, policy or protocol using the generic template. The information is sequenced from page one through to page five of the template. Also included is information relating to the formatting and presentation of any guideline, policy or protocol.

Page One of the Template

Title of organisation (Block capitals)

Title of Guideline, Policy or Protocol (Block capitals)

Insert Footer on Page One and a Header on subsequent pages

Information to be contained in the Header and Footer:

- Index No: as per a local index system if one exists
- Date of Approval: date when the guideline, policy or protocol has been approved
- Revision date – date the guideline, policy or protocol is due for revision
- Revision number – number of times revision has occurred (If a guideline, policy or protocol has been developed for the first time, insert 'Not Applicable'. For subsequent documents, insert the revision number incrementally, starting at number one)
- Page number – insert the page number and the total number of pages

Set up a Footer on Page One

- On toolbar select: File – Page Set up – Layout – Headers and Footers – Click different first page
- Then select: View – Header and Footer – Select Footer – Insert the following information:

TITLE OF GUIDELINE/POLICY OR PROTOCOL	Index No:	
	Date of Approval:	
	Revision Date:	
	Revision No:	
	Page No:	1 of **

- To set up Page No: insert page number (Number 1) – click on number of pages (the total number of pages will update automatically)

Page Two of the Template

Set up a Header on Page Two

- Select: View – Header and Footer – Select Header – Insert the same information as in the Footer on Page One:

TITLE OF GUIDELINE/POLICY OR PROTOCOL	Index No:	
	Date of Approval:	
	Revision Date:	
	Revision No:	
	Page No:	2 of **

- Set up Page No: insert page number (Number 2) – click on number of pages (the total number of pages will update automatically)
- This Header will automatically appear on subsequent pages

Developed by: identification of those persons involved in devising the guideline, policy or protocol.

Consultation with: consultation with key stakeholders / relevant personnel is an integral part of the guideline, policy or protocol development process. Comments received from stakeholders are a vital part of the quality-assurance and peer-review processes.

Approved by: Once the consultation process is complete and comments have been addressed, the guideline, policy or protocol is signed off (approved and authorised) by the relevant manager, supervisor or the organisation's core committee.

- Ensure that all persons involved in the developing and consulting stages sign and date the guideline, policy or protocol before the document is forwarded for approval.
- Following the approval stage, ensure that all persons involved sign and date the guideline, policy or protocol for the final hard copy prior to circulation.

Disclaimer – to be included in all guidelines, policies or protocols.

Page Three of the Template

Table of contents – this is usually completed when the guideline, policy or protocol is finished.

To set up an automatic table of contents:

For each heading that is to be included in the table of contents, ensure the 'Style' is: Header 1.

On toolbar select: Insert – Index and Tables – Table of Contents – Format: formal – Show levels: 1.

Page Four of the Template

All of the following sections must be included in a guideline, policy or protocol. If a section is not applicable, the words 'Not Applicable' should be entered.

SECTION HEADINGS:

1. Purpose

Describes the objective(s) for writing the guideline, policy or protocol
Provides the rationale for why the guideline, policy or protocol is required.

⊙ This should be comprehensive and concise in its meaning.

2. Applies to

Identifies the users of the guideline, policy or protocol.
Identifies to whom the guideline, policy or protocol applies.

3. Definitions

Explanation of key technical terms or terminology that are referred to in the guideline, policy or protocol.

- Define any term that could possibly be misinterpreted.
- List definitions in alphabetical order.

4. Responsibilities

Summary of the roles and responsibilities of the individuals that perform the actions of a guideline, policy or protocol.

5. Procedures

Outlines the steps to be taken to achieve the objectives of the guideline, policy or protocol.

6. Dissemination and Implementation plan

Guideline/policies and protocols should be disseminated and implemented in ways that take into account the particular audiences they are for. They need to be disseminated in such a way that practitioners and consumers become aware of them and are able to easily access and make use of them.

For staff – what education and training will be required for staff in order to implement the guideline, policy or protocol?

For the patient or client (if applicable) – what education and training will be required for the patient or client in order to implement the guideline, policy or protocol?

7. Resource Implications

Before an organisation can implement a guideline, policy or protocol, an assessment of the resource and cost implications that this may have on their services must be undertaken.

8. Evaluation / Audit

The guideline, policy or protocol should be evaluated at an appropriate time after the guideline has been disseminated and implemented.

9. Revision History

Displays list of changes to the document and shows an audit trail.

Date	Review Number	Section Number	Change/s

If a guideline, policy or protocol is new, this section is included but 'Not Applicable'.

10. References

Lists of all references used in the guideline, policy or protocol adhering to the Harvard method for referencing.

References must be listed in alphabetical order.

In order that the reader may evaluate the strength of the research base, each reference is to be graded as follows:

I. Randomised controlled trials, including meta-analysis
II. Non-randomised controlled trials and retrospective studies
III. Clinical experience and anecdote (Evans 2000)

Evans D T (2000) Homophobic in evidence based practice. Nurse Researcher. 8 (1), 47-51.

Examples:
NICE (2003) Infection Control: prevention of healthcare-associated infection in primary and community care (clinical guidelines 2). London: NICE (1).

Nugent K and Chernecky C (2002) Using focus groups to evaluate patients' involvement in decision-making. Journal of Vascular Access Devices. Summer, 33-37. (II)

Hewitt-Taylor J (2004) Clinical guidelines and care protocols. Intensive and Critical Care Nursing. 20 (1), 45-52. (III)

11. Appendices

Additional information is included in this section that will support and provide a rationale for the procedure stated in Section Five. This could include a Glossary of Terms or relevant diagrams, forms, flow charts or models.

Each appendix must be incrementally numbered (e.g. Appendix One).

Page Five of the Template

All persons must date and sign this page, after they have read and understood the guideline, policy or protocol.

General information relating to the use of the template

- When working with draft copies of any guideline, policy or protocol, ensure the draft number and date is identified clearly on the cover page of the document and each draft updated chronologically. Once the guideline, policy or protocol has been approved, the draft number is removed from the cover page.

- Abbreviations should **not** be used in any guideline, policy or protocol.

- When a guideline, policy or protocol has been approved, it is useful to maintain a list of all persons that it was circulated to, when it was circulated and whether it was circulated manually and / or electronically.

Format and Presentation Settings

- Type of Font: Times New Roman
- Type size: 12
- Justify alignment throughout document
- Use single line spacing, with double spacing between paragraphs
- Section headings are bold-faced typed

- Every entry in a guideline, policy or protocol must be numbered
- Paragraphs are structured such that each main idea or subheading, represents a separate heading
- Each subheading of a heading or another subheading, is represented by equal indentation

An example of an outline format for the **Procedures** section follows:

7.0 Procedures (Section headings)

7.1 Subheading

7.1.1 Subheading
7.1.2 Subheading

7.1.2.1 Subheading
7.1.2.2 Subheading

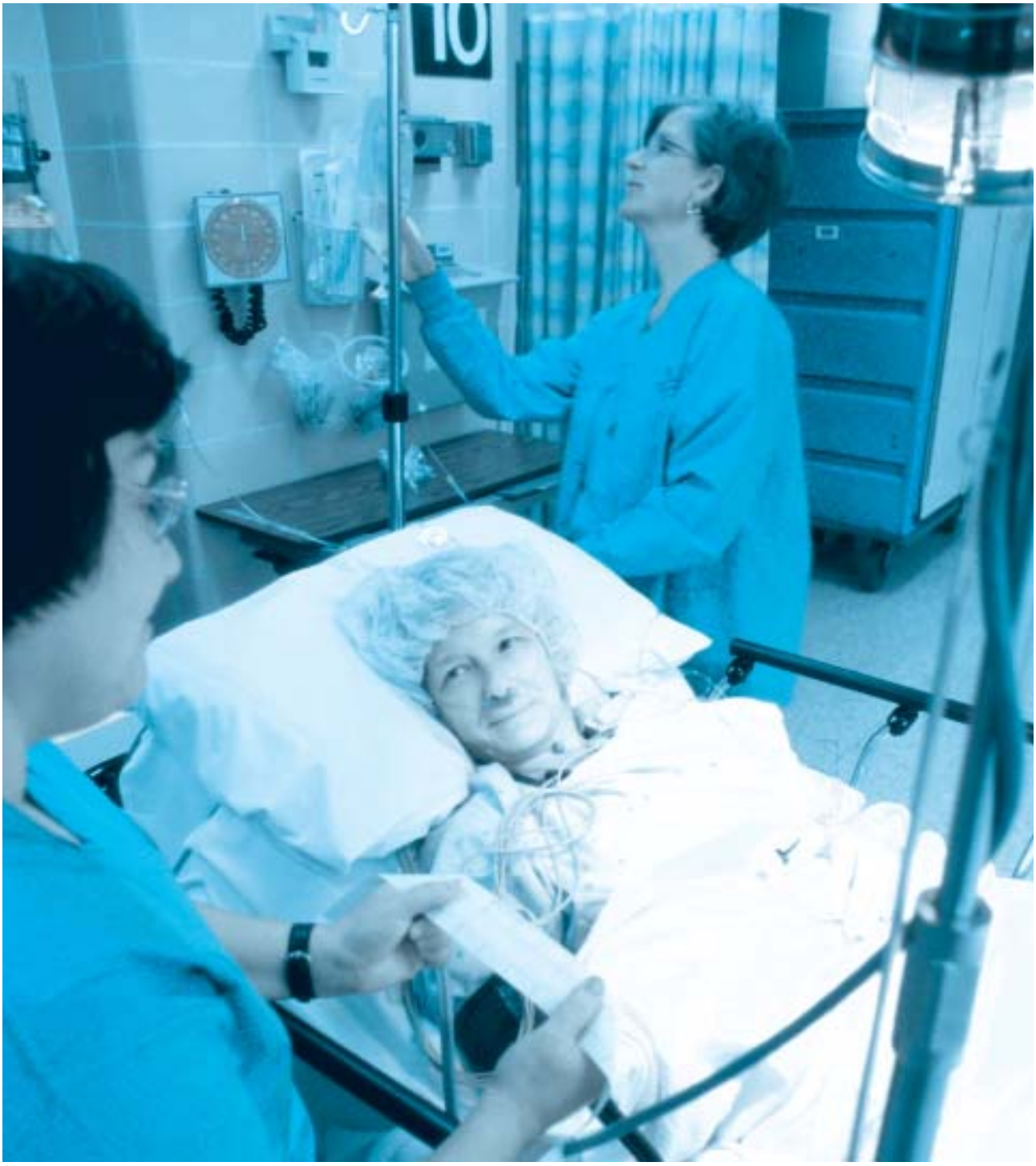
- Insert page breaks at the end of sections rather than pressing return until you get a new page. This will ensure that as you add to sections the next section will always start on the next page. This is one of the most common omissions from documents resulting in a huge amount of time being required to format a document even when the simplest of changes are made.

- Bold-faced type and underlining should only be used when really necessary to highlight text.

Finally

This template is available in electronic format on the South Eastern Health Board intranet website, on-line publications section, on the Nursing and Midwifery Planning and Development Unit webpage.

The members of the Regional Guideline Working Group as listed on page three of this document are also available as a resource, if further information on the template is required.



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Rosenberg W. and Donald A. (1995) Evidence based medicine: an approach to clinical problem solving British Medical Journal 310, pp 1122 - 1126

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New Zealand Guidelines Group (2001) Handbook for the Preparation of Explicit Evidence-Based Clinical Practice Guidelines Wellington New Zealand Group

Scottish Intercollegiate Guidelines Network (2004) SIGN: Guideline Development Manual. Edinburgh SIGN

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