

**GUIDANCE ON
DEVELOPING POLICIES, PROCEDURES, PROTOCOLS AND GUIDELINES
FOR HEALTHCARE FACILITIES
IN THE
KINGDOM OF BAHRAIN**

***THE PURPOSE OF THIS DOCUMENT IS TO PROVIDE GUIDANCE AND A STANDARD METHODOLOGY FOR
HEALTHCARE FACILITIES IN THE KINGDOM OF BAHRAIN TO DEVELOP POLICIES, PROCEDURES, PROTOCOLS
AND GUIDELINES.***

ADDITIONAL SUPPORT AND GUIDANCE IS ALSO AVAILABLE ON A NUMBER OF KEY AREAS.

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PLEASE ENSURE YOU READ THE MOST UP-TO-DATE GUIDE AVAILABLE ON OUR WEBSITE***

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1. Introduction

The National Health Regulatory Authority in Bahrain has developed this guidance on developing policies, procedures, protocols and guidelines (PPPGs). The intention is to provide a standardised methodology for the development of PPPGs and assist healthcare facilities in ensuring PPPGs are developed, maintained, evidence based and up to date.

Policies, procedures, protocols and guidelines are essential tools in improving the quality of health care provision. They articulate consistent approaches for best practice. They serve to:

- Promote best practice
- Standardise practice and service delivery
- Ensure that legislative and regulatory requirements are met
- Ensure employees and line managers are clear on their roles and responsibilities
- Facilitate effective staff induction
- Act as educational tools
- Act as a basis for audit and evaluation

2. Roles and Responsibilities

It is the role of health care facility management to ensure that all policies, procedures, protocols and guidelines are developed using evidenced based practice. It is the responsibility of management to:

- ensure employees are aware of the PPPGs that have been developed,
- facilitate training for employees where necessary,
- ensure that employees comply with the PPPGs in place,
- monitor performance through audit and review.

It is the responsibility of all staff:

- to be professionally accountable for their practice,
- to be answerable for decisions he/she makes and being prepared to make explicit the rationale for those decisions and justify them in the context of legislation, case law, professional standards and guidelines, evidence based practice, professional and ethical conduct.

It should be recognised that PPPGs represent a statement reflecting an expected standard of care within the healthcare facility. Health care professionals should be aware that a PPPG could be submitted as evidence of the standard of care expected should there be a complaint or court case brought by either a patient, colleague or other injured party. There may be occasions when it is acceptable to deviate from a PPPG, but clinical judgment in such a decision must be evidence based and clearly documented.

The public may request access to policies, procedures, guidelines and protocols and public bodies may be called on to publish such documents to ensure openness and transparency in treatment protocols.

3. Glossary of Terms and Definitions

Clinical Audit	Organized review of current clinical procedures compared with predetermined standards. Action is then taken to rectify any identified deficiencies in current practices. The review is repeated to see if the standards are being met. (WHO 2009)
Evaluation	Evaluation is defined as assessment/appraisal of the degree of success in meeting the goals and expected results (outcomes) of the organisation, service, program, population or patients/clients (Quality and Risk Taxonomy Governance Group report 2008).
Evidence Based Practice	Consensus approaches for handling recurring health management problems aimed at reducing practice variability and improving health outcomes (WHO 2009).
Guidelines	A guideline is defined as a principle or criterion that guides or directs action (Concise Oxford Dictionary 1995).
Guideline Development	Development using clear evidence from the existing literature, rather than expert opinion alone, as the basis for advisory materials (WHO 2009).
Healthcare Audit	Healthcare audit is audit of current practice against standards in any aspect of healthcare and includes both clinical and non-clinical audit (Clinical Audit Criteria and Guidance Working Group 2008).
Monitor	Any parameter that is regularly and consistently used to evaluate the quality of care (WHO 2009).
Policy	A policy is a written statement that clearly indicates the position and values of the organisation on a given subject (HIQA 2006).
Procedure	A procedure is a written set of instructions that describe the approved and recommended steps for a particular act or sequence of events (HIQA 2006).
Protocol	A protocol is defined as a written plan that specifies procedures to be followed in defined situations; a protocol represents a standard of care that describes an intervention or set of interventions. Protocols are more explicit and specific in their detail than guidelines, they specify who does what, when and how (An Bord Altranais 2000). Protocols are most typically used when developing instructions for drug prescription, dispensing and administration, i.e. drug protocols.
Scope	This includes both the target users and target population (only refer to a target population if the PPPG is referring to specific groups for example all service users aged 16 years and over) of the policy, procedure, protocol or guideline. It identifies to whom the policy, procedure, protocol or guideline applies.

4. Procedure and Processes

To facilitate co-ordination and consistency, facilities should have oversight through a lead person, committee or group that commissions, develops, approves and/or authorises all policies, procedures, protocols and guidelines formulated and implemented within the facility.

This lead person, group or committee will ensure that all staff who develop PPPGs have adhered to the facility template prior to authorisation(see appendix one for template proposal). This template can be used in its entirety or adapted for facility-specific use.

4.1 Process

When the need for a PPPG has been identified and the health care facility management has authorized the development of same; the person or team responsible for the drafting of the PPPG should initially identify the following:

- The background for the development should be outlined,
- The overall purpose and objectives of the policy, procedure, protocol or guideline must be described,
- The people and services to which the PPPG applies,
- The extent of involvement of all stakeholders needs,
- The resources required to develop the policy,
- The consultation process that will be followed,
- The communications process to support the early stages of PPPG development needs to be outlined,
- The process of stakeholder engagement and staff ownership.

4.2 Review the available evidence/analysis

After the initial stage, a review and/or analysis should be undertaken. This review and or analysis may include any or all of the following:

- Review similar policies, procedures, protocols or guidelines devised by other groups or facilities/organizations. Other groups may have looked at this issue and reviewed evidenced based material relevant to the PPPG under development. It is acceptable to draw on existing PPPGs prepared by other groups provided that due permission and acknowledgement is sought and given and the content is deemed appropriate and reliable by experts in the area,
- Conduct a review of the literature if required,
- Consult with experts in the area if appropriate.

4.3 Devise the PPPG

The PPPG should be written using a PPPG Template (see appendix 1) and the accompanying template user guidance notes (appendix 2).

4.4 Format of PPPG

It is important that the document is accessible to users in terms of layout and language. Recommendations include:

- Standardise the type of font – e.g. Calibri or Verdana,
- Type size – e.g. Headings 12 and Text 10,
- Align the text throughout the document to the left in English, to the right in Arabic,
- Use single line spacing,
- Use double spacing between paragraphs,

- Section Headings – boldface typed,
- Every entry in a guideline, policy or protocol should be numbered,
- Paragraphs should be structured so that each main subheading represents a separate heading,
- Each subheading is represented by equal indentation.
- Abbreviations should be kept to a minimum, and explained early in the document if being used,
- 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, to facilitate corporate branding and identification.

4.5 Devise an Implementation Plan

An implementation plan that outlines how the PPPG will be put into practice and resources needed will be required. The following should be considered:

- Assignment of responsibility for implementation (named person/job title). This should be documented on the first page of template (Cover),
- Identify training needs,
- Identify realistic resources required to implement,
- Identify the most effective method to communicate the PPPG to all relevant staff.

PPPGs 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 users become aware of them and are able to easily access and make use of them. For example:

- those responsible for rolling out (implementation) the PPPG,
- For staff- what education and training will be required in order to implement the PPPG,
- For the service user (if applicable) – what education and training will be required for the patient or client in order to implement the PPPG.

Before a facility can implement a PPPG, an assessment of the resource and cost implications that this may have on their services should be undertaken.

4.6 Monitoring, Audit and Revision

Monitoring of the PPPG by means of regular audit and review is necessary to ensure it is meeting its intended purpose and objectives. A named person and title must be identified as the lead for this process and documented on first page (cover) of the template.

A schedule for regular monitoring, e.g. monitoring procedures such as safety checks on the emergency trolley, should be developed at the time the procedure is written and the schedule should be designed so as to ensure that assurance is given to management that the safety checks are being monitored as per the policy – this could mean that all safety check sign off check sheets are monitored for completeness once a month.

A schedule for regular audit on high risk or high volume PPPGs should be developed at the time the PPPG is being developed – this may mean six monthly or yearly audits by, for example, direct observation or chart review.

4.7 Sign-off Procedures

A process is required to ensure that appropriate governance arrangements are in place to sign off a PPPG in advance of final approval/sign off.

1. Peer Review
2. Key stakeholder review
3. Sign-off on PPPG

The purpose of this is to review and agree the content and recommend approval of the PPPG.

- The PPPG should be sent to the managers of all those who have a stake in the PPPG, in advance of approval of the PPPG, in order to confirm to the development group that they have seen and agree to the PPPG. This consultation can be evidenced by either email or signature sheet (see appendix four).
- The final document then needs to be signed off by the group or committee to assure that the standardized facility template has been adhered to and approve the PPPG for use in the facility.

A signed Master Copy of the PPPG with all the relevant signatures should be retained in an agreed central location where it will be document controlled. A dissemination list should be retained to facilitate retrieval of PPPGs when necessary for example, when reviewing and updating PPPGs. It is not necessary to have the written signatures on the PPPG that will be disseminated as long as the Master Copy with signatures (either written or electronic) is retained as above.

4.8 Action Implementation Plan

- Relevant employees must be informed of PPPG
- Disseminate the PPPG to relevant employees
- All staff members must sign a signature sheet to confirm they have read, understand and agree to adhere to the PPPG. (see Appendix 3 for sample Signature sheet template)

4.9 Action Monitoring, Audit and Revision Plan

The monitoring, audit and revision must take place on a consistent, planned ongoing basis, as referenced on the review date on the cover of the PPPG. This review and audit date must be agreed to. The feedback from the audit must be communicated to the relevant people in order to ensure continuous improvement. This will facilitate the sharing of best practice and learning from experiences and knowledge of what works best in the facility.

The feedback must also be used to address any barriers to implementation and influence future development of the PPPG.

A review should be carried out on a two-yearly basis unless for example, an audit, serious incident, organisational structural change, scope of practice change, advances in technology, significant changes in international best practice or legislation identifies the need to update the PPPG.

5. References

- An Bord Altranais (2000) <http://www.nursingboard.ie/en/policiesguidelines>.
- Conceptual Framework for the International Classification for Patient Safety Technical Report (January 2009). World Health Organisation
- Concise Oxford Dictionary. (1995). Oxford. Oxford University Press.
- Health Information and Quality Authority (2006). Hygiene Services Assessment Scheme
- Health Service Executive, Office of Quality and Risk (2008). Quality and Risk Taxonomy Governance Group Report on Glossary of Quality and Risk Terms and Definitions (2008)
- Taxonomy report.

- NHS Scotland (2005) Clinical Governance and Risk Management: Achieving Safe Effective patient Focused Care and Services. Edinburgh: NHS Quality Improvement Scotland.
- Plan for Clinical Governance Development 2011-21013, (2012) HSE Quality and Patient Safety Directorate
- UPDATE REFERENCE TO NEW DOCUMENT Health Care Audit Criteria and Guidance (2008).
- http://hse.net/hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OQR014_2_Healthcare_Audit_Criteria_and_Guidance.pdf (accessed 18/05/09)

APPENDICES

LOCAL LOGO

PPPG Template TITLE

Document reference number		Document developed by	
Revision number		Document approved by	
Approval date		Responsibility for implementation	
Revision date		Responsibility for review and audit	

Table of Contents:

1.0 Policy

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2.0 Purpose

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3.0 Scope

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4.0 Legislation/other related policies

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5.0 Glossary of Terms and Definitions

--

6.0 Roles and Responsibilities

--

7.0 Procedure/Protocol/Guideline

--

8.0 Revision and Audit

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9.0 References

--

10.0 Appendices

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11.0 Revision History (electronic or hardcopy)

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Template User Guidance

Page One (Cover):

Title: title of the Policy, Procedure, Protocol or Guideline

Document Development and Control:

- **Document reference number:** Assigned for each PPPGs,
- **Revision number:** Assign a number each time the document is revised.
- **Approval date:** date when the PPPG has been approved
- **Revision date:** date the PPPG is due for revision
- **Document developed by:** This should be the name of person responsible for the development, the members of the working group should be listed as an appendix.
- **Document approved by:** This is the name of the person or group who has final sign off.
- **Responsibility for Implementation:** identify and name the individual who is responsible for rolling out the implementation of the PPPG. This individual's job title should also be documented.
- **Responsibility for revision and audit:** Identify and name the person(s) with responsibility for revision and audit. This individual's job title should also be documented.
- **How to insert a Header/Footer:** On toolbar select, View– Header and Footer – Select Header/Footer – Insert the following information as it pertains to document: Title, document reference number, revision number, approval date.

Page Two (Table of contents):

This is usually completed when the PPPG is fully developed. It is preferable to formulate a table of contents, which can be hyperlinked.

To set up an automatic table of contents:

Place the cursor where you want to insert the table of contents. On toolbar select: Insert - Index and Tables- Table of Contents- Format: formal- Show levels:1

Page Three (section headings):

1.0 Policy Statement: This is a written statement that clearly indicates the position of the facility regarding the Procedure, Protocol or Guidance that follows.

For example; “It is policy of the NHRA to use this procedure in the development of all PPPGs. It clearly indicates the position and values of the organisation on a given subject”.

2.0 Purpose: This describes the objective for writing the PPPG. It provides the rationale for why the PPPG is required. It should be comprehensive and concise in its meaning.

3.0 Scope: This identifies the users of the policy, procedure or guideline. It identifies to whom the PPPG applies. (only refer to a target population if the PPPG is referring to specific groups for example all service users aged 16 years and over).

4.0 Legislation/other related policies: List any relevant legislation and policies within your service or within the Kingdom of Bahrain.

5.0 Glossary of Terms and Definitions: Explanation of key technical terms or terminology that are referred to in the PPPG.

- List definitions in alphabetical order. If this is an exhaustive list then they may be included in an appendix.

6.0 Roles and Responsibilities: Clearly define the appropriate personnel to fulfill the roles and responsibilities in relation to the steps outlined in this PPPG:

- those responsible for complying with the PPPG
- those responsible for ensuring compliance to the PPPG

7.0 Procedure/Protocol/Guideline: Outline the steps to be taken to achieve the objectives of the PPPG. This will be titled either a Procedure OR a Protocol OR a Guideline as is applicable.

8.0 Revision and Audit: The PPPG should be reviewed and audited at an appropriate time after the PPPG has been disseminated and implemented – this revision and audit date should be agreed by the committee developing the PPPG at the time of final sign off.

- those responsible for revision the PPPG
- those responsible for auditing the PPPG and providing feedback to relevant employees
-

9.0 References/bibliography: List all references used in the policy, procedure or guideline and include in the bibliography. The following are some examples of references:

- Reference to a Journal article Evans DT (2000) evidence based practice. Nurse Researcher. 8 (1), 47-51
- Reference to a book Mercer, P.A. and Smith G, (1993). Social dimensions of software development. 2nd ed. London.
- Reference to a website: www.abcdefg.bh (accessed 19/10/08)
- Reference to a corporate body e.g. Government department Ministry of Health (2001) Quality and Patient Safety in a health system. Manama: Government Publications.
- For further details on the Harvard referencing system please see <http://www.ucd.ie/library/guides/pdf/blackrock/BICGuide27HarvardReferencing.pdf>

10.0 Appendices: Additional information is included in this section that will support and provide a rationale for the procedure. This could include:

- Relevant diagrams
- Flow charts
- Models
- Each appendix should be incrementally

11.0 Revision History: This captures any changes that are made to a PPPG when it has been revised. This may be placed at the back or close to the front of the document according to local preference.

12.0(Signature Page):

All persons must sign and date this page after they have read and understood the PPPG.

Appendix 3

Key Stakeholders Review of Policy, Procedure, Protocol or Guidance Reviewer Statement

Reviewer: The purpose of this statement is to ensure that a Policy, Procedure, Protocol or Guideline (PPPG) proposed for implementation in the _____ (insert facility name) is circulated to Managers and Employees who have a stake in the PPPG, in advance of approval of the PPPG. You are asked to sign this form to confirm to those developing this Policy or Procedure or Protocol or Guideline that you have seen and agree to the following Policy, Procedure, Protocol or Guideline:

Title of Policy, Procedure, Protocol or Guideline:

I acknowledge the following:

- I have been provided with a copy of the Policy, Procedure, Protocol or Guideline described above.
- I have read the Policy, Procedure, Protocol or Guideline document.
- I agree with the Policy, Procedure, Protocol or Guideline and recommend its approval

Name

Signature

Date

Please return this completed form to:

Signature Sheet Template:

I have read, understand and agree to adhere to the attached Policy, Procedure, Protocol or Guideline:

Print Name	Signature	Area of Work	Date

Revision History Sheet Template:

Facility Name: _____

PPPG: _____

Person Responsible: _____

Document Control No. - _____ (Revision No. _____)	
Section	Changes Made
3.0 Removed	Example - Removed aims of policy and integrated into section2 policy statement also added patient safety to 2.3
3.0 Added	
4.1 Added	
5.1.1 Deleted	

Flow chart summarizing the steps involved in the PPPG development