Title	Standards for Clinical Document Management Clinical Policies, Procedures, Protocols, Guidelines and Standard Operating Procedures
Document Type	Policy
Version Number	V7
CGQ & RDS ID Number	CG003/07
Approval/Issue date	September 2022
Review date	September 2025
Owner/Responsible Person	Laura Jones, Director of Quality and Improvement
Developed by	Group listed on page 9 (2008)
Reviewed by	Clinical Governance Steering Group (2010) Associate Directors of Nursing and Clinical Governance & Quality Facilitator – Clinical Effectiveness (2013) Review/Consultation Group 2015 Review/Consultation Group 2018 Review/Consultation Group 2021 Review/Consultation Group 2022
Approved by	Clinical Executive Operational Group (awaiting approval)
Health Inequality Impact Assessment (HIIA) **(statutory for policies)**	September 2022

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Contents

Intent

The aim of this policy is to ensure all NHS Borders clinical policies, protocols, procedures and guidelines (referred to hereafter as clinical documents) are:

- developed using a systematic and co-ordinated approach
- revised and updated by the identified review date
- reviewed and updated by the appropriate person(s)
- approved by the appropriate group
- logged on a central register held by Clinical Governance & Quality
- published on the Right Decision Service (RDS) app/website
- fully implemented with all relevant staff being made aware of the clinical documents and where to access them as required
- compliant with the requirements of the Public Records (Scotland) Act 2011

This policy is designed to provide a framework for the development and review of all clinical documents within NHS Borders. The policy applies to all staff employed by NHS Borders or contracted to work with NHS Borders on a fixed term or temporary basis.

Introduction

The development and implementation of clinical documents is a process of continuous improvement. NHS Borders recognises the importance of locally developed clinical documents. These provide a framework within which staff will work to ensure high standards of clinical practice and the delivery of safe, effective and person centred care to all NHS Borders' patients.

In taking control of clinical documents NHS Borders is demonstrating a proactive approach to risk management principles as outlined in the Risk Management Policy, ensuring systems are in place to monitor and assure the effectiveness of implementation of locally developed clinical documents.

Definitions

Clinical Document	Any publication that provides direction, evidence and/or patient documentation relating to the assessment, treatment and care of patients. A clinical document can be a policy, procedure, protocol or guideline, for example: o Public Protection Policy o Remote/telephone Prescribing Procedure o Medical Infusion Device Protocol o Vitamin D deficiency Guideline	
Policy	• written statement that conveys the general intentions, approach and objectives of an organisation • enables management and staff to make appropriate decisions and administer and comply with relevant legislation, organisational rules and good working practices • not open to interpretation or professional judgement and is non-negotiable • policies often reflect statutory legislation and or NHS mandatory objectives	Mandatory
Procedure	• detailed steps/instructions that describe the official or accepted way something is to be done, with deviations from the procedure being required to be recorded • may be attached to a policy or stand alone	Mandatory
Protocol	• defines the rules, expected behaviour and method for managing a particular situation or may form an arrangement between partners • when implemented, ensures uniformity of standards • used to translate national guidelines into local practice	Mandatory
Guideline	• provides advice on how something should be done, i.e. is a recommended approach, parameter, for undertaking a task or activity, using a product or equipment , etc • designed to help practitioners assimilate, evaluate and implement the ever increasing volume of evidence and opinion on current best practice	Good Practice

Standards

1 Clinical Document Register

1.1 A central register of all locally developed clinical documents will be maintained by Clinical Governance & Quality.

1.2 The owner/lead for the development/review of a clinical document is responsible for registering it with Clinical Governance & Quality.

1.3 Review reminders will be issued to the identified owner of the clinical document, by Clinical Governance & Quality, three months in advance of the review date, when the document is due and then when document is out of date.

1.4 Clinical Governance & Quality will provide clinical document status reports to the Clinical Board Governance groups to enable operational management; the reports will identify all clinical documents on the register that are due for review within three months and those which have exceeded their review date.

2 Format of Clinical Documents

2.1 All approved clinical documents will have a uniform front cover page (*Appendix 1).*

2.2 Clinical documents will contain all necessary information in a concise format.

2.3 A statement about the purpose of the clinical document will be included.

2.4 UK English spellings, plain English and the active rather than passive voice, will be used, as far as possible, ensuring wording is clear and easily understood.

2.5 Do not use jargon and abbreviations; any abbreviations used should be written in full in the first instance with the abbreviation in brackets.

2.6 Sources of evidence and good practice must be listed in the references/supporting evidence section these should be in Vancouver style, including web addresses and/or the Digital Object Identifier (DOI) of articles. Evidence can be provided by the Clinical Librarian (*Appendix 2)*

2.7 Where appropriate, clinical documents will be cross-referenced to other clinical/non-clinical documents.

2.8 Only use images owned by NHS Borders or by other copyright owners with written permission. (Images to be provided to Clinical Governance & Quality as separate high quality files for upload to RDS).

2.9 Break up text into chunks so that RDS users will be able to navigate quickly to relevant content.

2.10 Number pages at the bottom right on each page; the number does not need to be visible on the title page. (Headings & sub heading should be numbered) still need some clarification re numbering

3 Clinical Document Development and Review

3.1 Clinical documents must be developed and reviewed by a group of staff, both clinical and non-clinical, with the appropriate level of knowledge and experience, and be representative of the range of groups/individuals involved in the delivery of patient care.

3.2 Evidence to support clinical documents, if required should be obtained from the Clinical Librarian. (*Appendix 2*)

3.3 Representation should be sought, as appropriate, from partner organisations e.g. social work and voluntary sector as required for clinical document development and review.

3.4 Health Inequality Impact Assessment (HIIA) for all new and substantial revisions to existing public sector policies as a legal requirement for all public bodies must be undertaken. This assessment is necessary to ensure that all clinical policies meet statutory requirements in relation to equality and diversity. Please refer to the Equality and Diversity microsite on NHS Borders intranet.

3.5 The owner/lead for the development/ review will be able to make changes to their content on RDS. Consultation should be sought as appropriate (see paragraph 4 Consultation)

- content with no changes will be re-published on RDS with new review dates without further consultation / approval
- content with minor changes not affecting working practice, such as:
    - spelling corrections
    - update of job titles
    - update to links/references
    - additional text to provide clarity which does not affect overall intention/process of document

  Will be re-published on RDS without further consultation / approval
- content with minor changes which may affect working practice will trigger a consultation, before re-publication on RDS
- substantial changes to an existing document will trigger a consultation, before re-publication on RDS
- documents that exceed their review date must be reviewed but may remain on RDS for up to one year, an automatic warning will appear against overdue documents showing how many days past the review date it is.

4 Consultation

4.1 All new clinical documents must be consulted on prior to approval.

4.2 Reviewed clinical documents should be consulted on if there has been a full re-write or substantial changes made.

4.3 A timescale for consultation must be identified and made known to all individuals and groups being invited to provide comment/feedback on the draft document;

- **four** weeks minimum period of consultation for all new clinical documents
- **two** weeks consultation where there are substantial changes to existing document
- **one** week to allow agreement from stakeholders/topic specialists where any minor amendments made

4.4 The owner/lead for the development/review is responsible for ensuring all areas, departments and staff groups, to whom the clinical document is relevant, are given the opportunity to contribute to the consultation.

4.5 The development/review group will agree and make changes to the clinical document that reflect comments received during the consultation, prior to the clinical document going to the appropriate group or individual for approval.

5 Approval

5.1 The owner/lead for the development/review group is responsible for ensuring that appropriate approval is sought prior to a new or reviewed clinical document being implemented.

5.2 All clinical documents requiring approval will be sent to the appropriate group as follows:

- **NHS Borders Operational Planning Group (OPG)** – where implementation will be organisation wide or where at clinical board or service level there is considered a budgetary or reputational risk to the organisation. All clinical policies should be signed off through OPG or a designated sub-group of OPG
- **Clinical Board Clinical Governance Group** – where implementation is within a single clinical board area
- **Departmental Group/Clinical Director/Head of Department** - where implementation is within a single specialty or department

6 Dissemination/Implementation of Clinical Documents

6.1 Following approval and/or upload of the clinical document, the owner/lead for the development/review is responsible for ensuring the appropriate persons are notified that the document is to be implemented; this information is for dissemination to all relevant staff. The process for notification is as follows:

- applicable across the organisation - communication sent to the General Managers, Associate Medical Directors, Associate Nurse Directors and Associate Director of AHPs for the Clinical Boards and relevant Heads of Corporate Services
- specific to a Clinical Board - communication sent to the General Manager(s), Associate Medical Directors, Associate Nurse Directors, Associate Director of AHP's and the Director of Pharmacy
- departmental/clinical speciality/clinical area – communication sent to the Clinical Directors, Operational Managers, Clinical Service Managers, Heads of Departments, Clinical Nurse Managers, Senior Charge Nurses, and relevant AHP Professional Leads

7 Document Control

7.1 All clinical documents must be version controlled:

- clinical document must be clearly marked as 'draft' preferably using a watermark throughout the document until it is approved. All approved clinical documents will have a version number clearly marked on the front cover, for example the first version of the document may be numbered 01, first review 02, second review 03 and so on
- the version number will be amended each time the clinical document is reviewed and /or updated
- Clinical Governance & Quality will provide a unique identifier that will include the version number at point of registration

7.2 The owner/lead for the development/review will ensure that the final approved version of the clinical document for implementation is sent to Clinical Governance & Quality to be uploaded to the NHS Borders Right Decision Service (RDS) app and website.

7.3 Clinical Governance & Quality will send a link to the clinical document on the RDS to the owner/lead for the development/review. Required/desired access to the clinical document from other microsites should be made via this link to the master version on RDS.

7.4 Clinical Governance and Quality will ensure that any previous version is removed from RDS and archived, confirmation of this will be sent to the owner/lead for the development/ review with a copy of document for departmental archive.

7.5 The owner/lead for the development/review will be responsible for ensuring that the previous version of the approved clinical document is retained in a file on a network shared drive.

7.6 Clinical documents will be retained by person/department responsible in line with retention periods as per the Scottish Government Records Management: Health & Social Care Code of Practice (Scotland) 2020 & NHS Borders Records Management Policy

References/ Supporting Evidence

1. Public Records (Scotland) Act 2011 https://www.legislation.gov.uk/asp/2011/12/contents/enacted

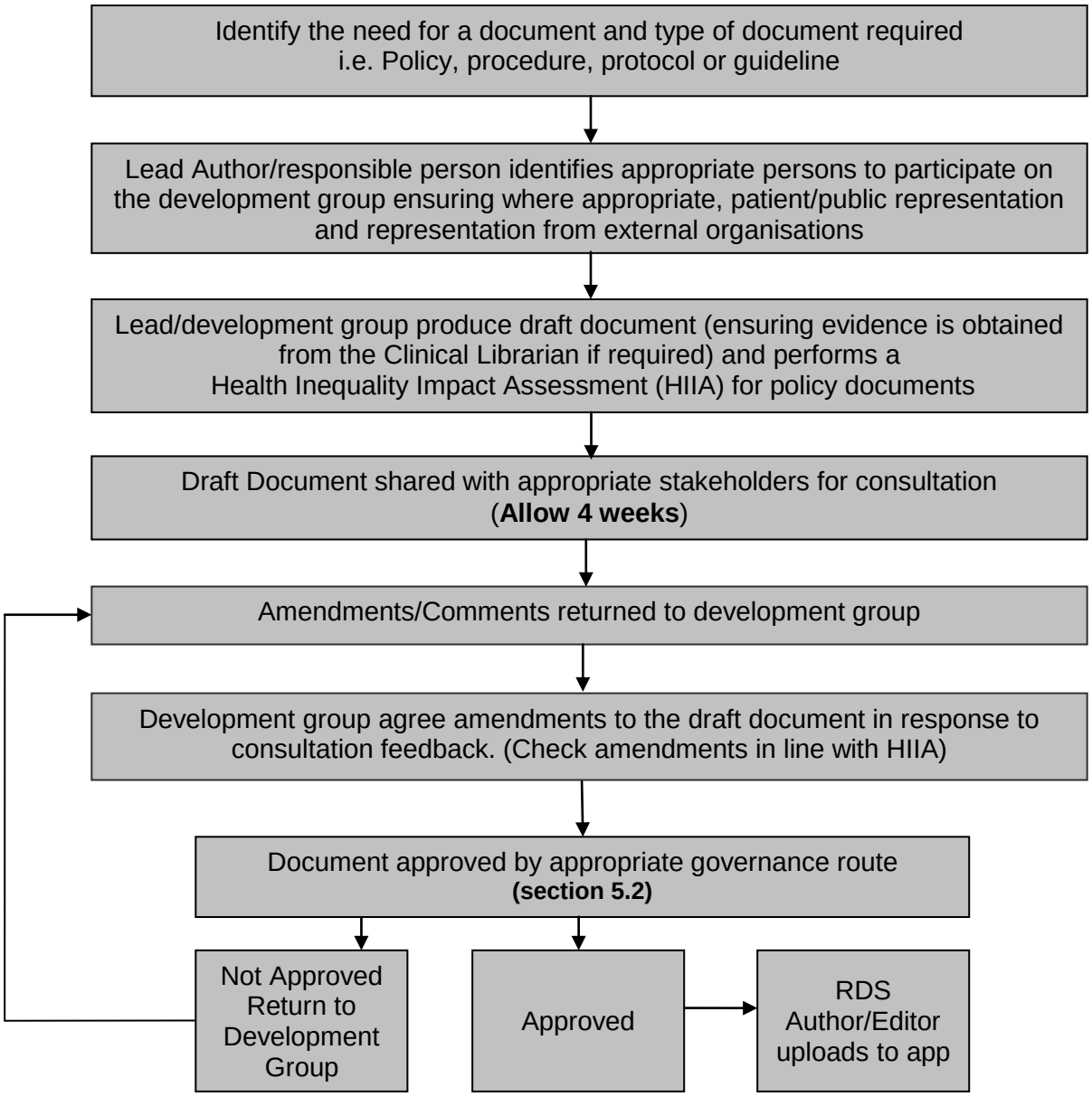
2. NHS Borders Risk Management Policy http://intranet/resource.asp?uid=30000

3. Equality Act 2010 http://www.legislation.gov.uk/ukpga/2010/15/contents

4. Scottish Government Records Management: Health & Social Care Code of Practice (Scotland) 2020 https://www.informationgovernance.scot.nhs.uk/wp-content/uploads/2020/06/SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf

5. Scottish Intercollegiate Guidelines Network (2015), SIGN 50 A guideline developers' handbook https://www.sign.ac.uk/assets/sign50_2015.pdf

Process for New Clinical Document Development



Clinical Librarian will:
Support Lead for development group to ensure evidence is relevant and up to date as appropriate

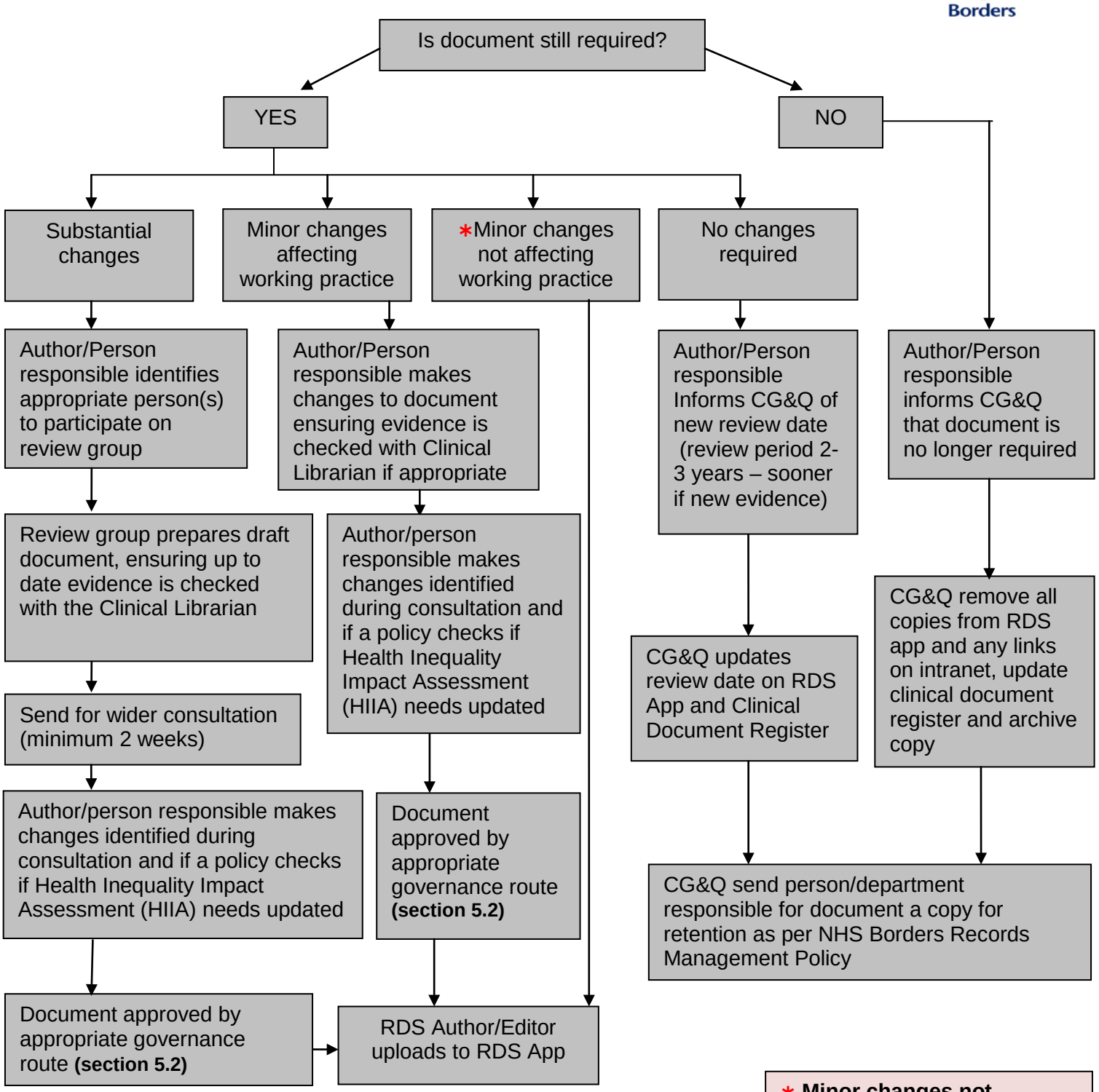
CG&Q will:

- check document formatting and readability
- perform quality checks on RDS app vs RDS style guide
- add RDS ID number to document cover sheet
- add to clinical document register
- publish to RDS app
- provide link if required to be added to NHS Borders microsites
- retain copy of document on RDS shared drive

Owner/lead for the development will:

- ensure appropriate persons are notified that the document is available on the RDS app
- ensure document is implemented and disseminated to all relevant staff

Process for Clinical Document Review



Clinical Librarian will:
Check evidence in document is up to date and amend as appropriate

Clinical Governance & Quality (CG&Q) will:

- check document formatting and readability
- perform quality checks on RDS app vs RDS style guide
- add RDS ID number to document cover sheet
- add to clinical document register
- publish to RDS app
- provide link if required to be added to NHS Borders microsites
- retain copy of document on RDS shared drive

*** Minor changes not affecting working practice:**

- spelling corrections
- update of job titles
- update to links/references
- additional text to provide clarity which does not affect overall intention/ process of document

Development Group (2008)

Ross Cameron	Medical Director
Elaine Cockburn	Head of Midwifery
Tom Cripps	Associate Medical Director Clinical Governance
Sandra Little	Ward Manager, Kelso Hospital
Bruce Low	Consultant Psychiatrist
Heather Maughan	Director of Nursing & Midwifery
Beverly Meins	Senior Nurse Community Hospitals
Irene Morris	Director of Organisational Change
Erica Nisbet	Head of Clinical Governance & Quality
Marion Paterson	Manager of Assessment & Treatment, Learning Disability Service
Alasdair Pattison	Lead Clinician Podiatry/Lead AHP
Andrew Riley	Director of Public Health
Leonie Smith	Associate Director of Nursing
Isabel Swan	Lead Nurse, Mental Health
Jim Torrance	Chair of Primary and Community Services Partnership

Review/Consultation Group (2015)

Katie Buckle	General Manager Planned Care and Commissioning
Simon Burt	General Manager Mental Health and Learning Disability Services
Jonathan Kirk	Associate Medical Director Primary and Community Services
David Love	Associate Medical Director Clinical Governance
Philip Lunts	General Manger Unscheduled Care
Sheena MacDonald	Medical Director
Karen McNicoll	Associate Director AHP
Hamish McRitchie	Associate Medical Director Acute Services
Alasdair Pattinson	General Manager Primary and Community Services
Evelyn Rodger	Director of Nursing and Midwifery
Cliff Sharp	Associate Medical Director Mental Health and Learning Disability Services
Charlie Sinclair	Associate Director of Nursing Acute, Primary, Acute and Community Services
David Thomson	Associate Director of Nursing Mental Health and Learning Disability Services

Review/Consultation Group (2018)

Janet Bennison	Associate Medical Director BGH
Nicky Berry	Associate Director of Nursing BGH and Head of Midwifery
Simon Burt	General Manager Mental Health and Learning Disabilities
Amanda Cotton	Associate Medical Director Mental Health
Ros Gray	Head of Quality & Clinical Governance
Annabel Howell	Associate Medical Director Clinical Governance
Laura Jones	General Manager Planned Care and Commissioning
Peter Lerpiniere	Associate Director of Nursing Mental Health, Learning Disabilities and Older People

Nicola Lowdon	Associate Medical Director Primary and Community Services
Phillip Lunts	General Manager Unscheduled Care
Kenny Mitchell	General Manager Primary and Community Services
Claire Pearce	Director of Nursing, Midwifery and Acute Services
Sandra Pratt	Associate Director Strategic Change
Erica Reid	Lead Nurse Primary and Community Services
Cliff Sharp	Medical Director

Review Group (2021) – minor amendments – addition of flow charts

Laura Jones	Head of Clinical Governance & Quality
Justin Wilson	Quality Improvement Facilitator, Effective
Diane Laing	Clinical Effectiveness Administrator

Review Group (2022) – following introduction of RDS app

Laura Jones	Director of Quality and Improvement
Justin Wilson	Quality Improvement Facilitator, Effective
Diane Laing	Clinical Effectiveness Administrator
Olive Herlihy	Associate Medical Director Clinical Governance
Moira Mitchell	Clinical Librarian
Suzy Cuthbert	Assistant Librarian
Kath Liddington	Knowledge Management Co-ordinator
Brian Magowan	Consultant Gynaecologist

Roles and Responsibilities

Role	Responsibilities
Medical Director, Director of Nursing, Midwifery and AHPs	Will secure agreement on the process for development, approval and review of clinical documents.
General Managers and Heads of Corporate Services supported by Associate Directors of Nursing/ Associate Medical Directors/ Associate Director of AHPs	Will ensure dissemination of policy within the Clinical Boards/Directorates and seek assurance adherence to the process for the development, approval and review of clinical documents.
Service and Operational Managers/Clinical Directors	Will support implementation and compliance with this policy and where applicable audit implementation and compliance. Will ensure clinical documents for their areas of responsibility remain up to date within review timescales.
Clinical Governance and Quality	Will support the document management process in relation to policy: • log documents on central register with a unique ID and version number • publish documents on the Right Decision Service (RDS) app and send a link to the owner/lead • send review reminders to the owner/lead • remove previous versions from RDS; retain copy of document on RDS shared folder; confirm with owner/lead and provide a copy for the departmental archive • provide clinical document status reports to the four Clinical Board Governance groups • Obtain high quality image files from the owner/lead
Owner/lead for the development/review	Will • oversee the development / review group • ensure effective consultation • ensure appropriate approval prior to implementation • make / propose changes to the content on RDS • send the final approved version of the clinical document to Clinical Governance & Quality for upload to the RDS app/website and inclusion on Clinical Document register. • notify appropriate persons of implementation • retain a Departmental archive of previous versions
Clinical Librarian	Will provide up to date evidence to support document development/review
RDS Author/Editor	Will upload clinical documents to RDS, adhering to RDS style guide
Ward/Departmental Managers	Will ensure that all staff who are involved in clinical document development/review are familiar with policy and support compliance.
Individual Clinical Staff	All clinical staff involved in the development and review of clinical documents will comply with policy.

Appendix 1 Clinical Document Template

Title	
Document Type	*e.g. Policy/guideline/procedure/protocol*
Version Number	*Current version of document*
CGQ & RDS ID Number	*Clinical Governance & Quality Use only*
Approval/Issue date	*Date of approval/issue of current version – mm/yyyy*
Review date	*Date next review due to be completed – mm/yyyy*
Owner/Responsible Person	*Person responsible for the document (this should be a named individual/post not a group) – using format Smith JC (no full stops) accompanied by e-mail address*
Developed by	*May be a group – membership should be included in document – this applies to the original version of the document and should include the original approval/issue date – mm/yyyy*
Reviewed by	*May be a group – membership should be included in document – all reviews should be listed either here or in separate table within the document – mm/yyyy*
Significant resource implications (financial/workload)	
Approved by	*Group/Committee*
Health Inequality Impact Assessment (HIIA) (only statutory for policies)	*Date impact assessment completed – mm/yyyy*

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Contents

Purpose

Introduction

Definitions *(where applicable)*

Standards *(this may be changed to reflect your policy)*

Remember to link as appropriate throughout text.

Supporting Evidence& References *(this may be changed to reflect your policy)*

Remember to link as appropriate throughout text.

Development Group

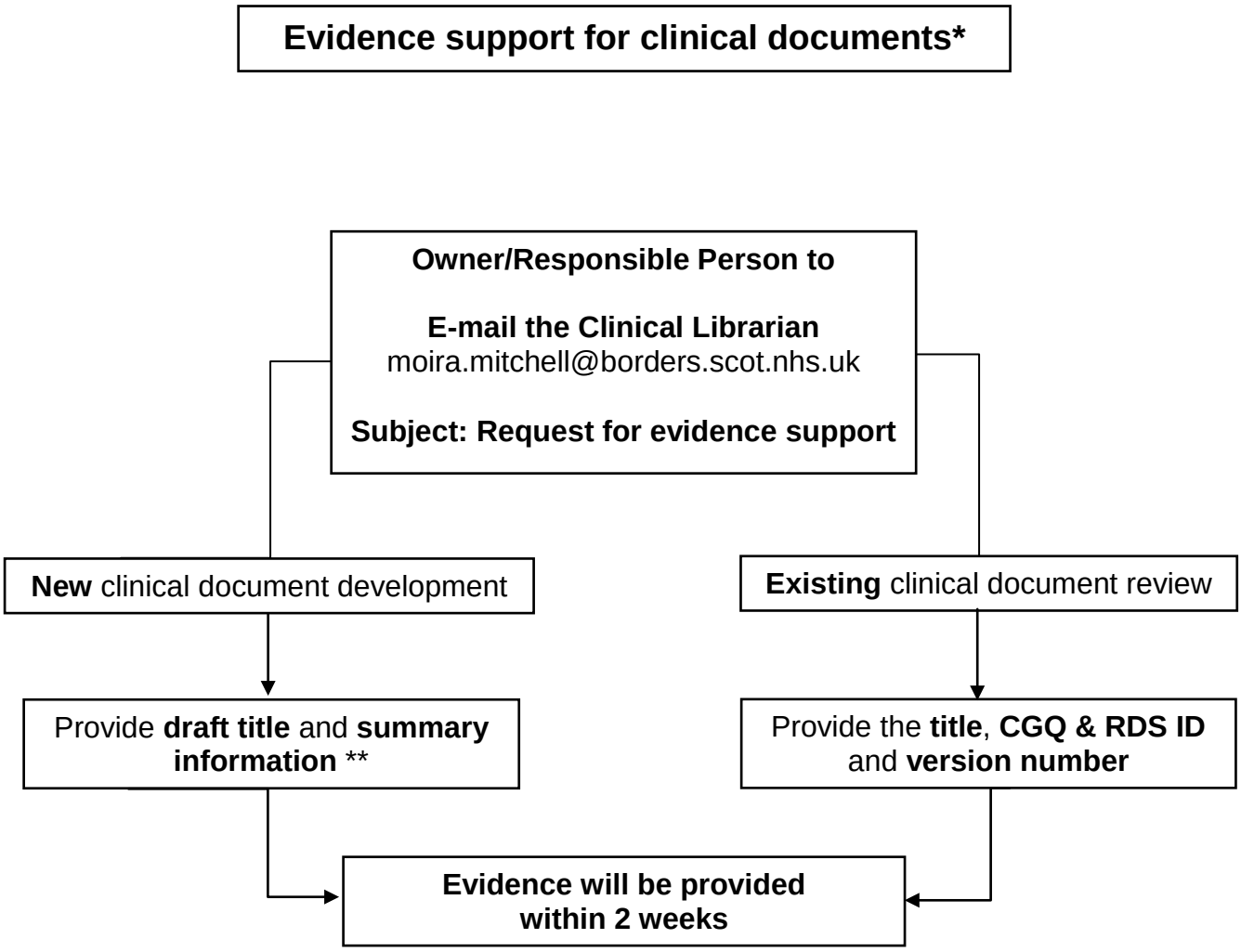
Review Group

Roles and Responsibilities

Role	Responsibilities

Appendices

Appendix 2 – Evidence Support from Clinical Librarian



* step 3 of Process for New Clinical Document Development algorithm
step 4 of the Process for Clinical Document Review algorithm

** relevant medical subject headings may be helpful
https://meshb-prev.nlm.nih.gov/treeView