Scottish Perinatal Network

NHS SCOTLAND

Scottish Perinatal Network Guidelines Development Standard Operating Procedure

Document Control

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Process Overview

In the context of this Standard Operating Procedure (SOP), the term "guideline" is predominantly understood as referring to clinical guidance agreed as best practice expert consensus within the maternity, neonatal and perinatal clinical community in Scotland.

While this guideline development process is expected to be informed by relevant and up to date empirical evidence, the process described in this SOP is not designed to be able to produce guidelines that are fully compliant with all aspects of clinical guideline development described in the AGREE II tool. Full compliance with AGREE II is not achievable within Scottish Perinatal Network (SPN) resources.

If a guideline development requires full AGREE II compliance, this must be raised with other relevant guideline producers for inclusion in their own development schedule. Most likely in an NHS Scotland context, this would be SIGN. Topics for new SIGN guidelines can be proposed here: www.sign.ac.uk/get-involved/propose-a-topic . There is more information about the development process at: www.sign.ac.uk/what-we-do/methodology/sign-50-a-guideline-developers-handbook.

The SPN guideline SOP includes five key components, summarised in the process overview below:

1: Topic Selection Process

1.1 Proposer:

Submits proposal for a new national maternity or neonatal guideline, in writing, to the SPN Programme Team at

nss.perinatalnetwork@nhs.scot

1.2 Proposer and SPN Team:

If relevant guidance on the proposed topic does not already exist, prepare detailed submission

(topic proposal form)

Information to include:

- a synopsis of the proposed topic
- the need for this guideline, e.g. response to incident
- the type of guideline to be developed :
  - Adaptation of existing national guideline (e.g. RCOG or BAPM)
  - Adaptation of existing local Health Board guidelines into a Scottish guideline
  - Update existing guideline
  - New guideline
- the intended target audience
- the subject matter expertise required to develop this guideline

1.3 NMN or NNN Guideline Governance/Oversight Group:

- Proactively horizon scan for topics for development, both within the group and those raised by external proposers
- Review completed topic proposal forms and make a decision
- If further information is needed to make a decision, refer back to proposer for resubmission

Criteria:

1) Is there a clinical need?
2) Will this national guideline add value in line with Realistic Medicine?
3) Is SPN the appropriate developer/owner for this guideline?
4) Is there SPN capacity to deliver in time?

If 'yes' to all criteria:

Agreement to add guideline to SPN work programme with appropriate deadline

See section 2

If 'no' to criteria 1 or 2:

Reject proposal

If 'yes' to criteria 1 & 2 but 'no' to criteria 3 & 4:

Refer topic to other, more appropriate developer (e.g. SIGN, NICE, RCOG, BAPM)

If 'yes' to criteria 1 - 3 but 'no' to criteria 4:

Refer to NMN / NNN Core Steering Group for decision

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Guidance developed as part of other agreed SPN work streams, or agreed at Core Steering Group level, is not subject to this selection process, recognising that governance is already in place. However, it is expected to follow the processes in sections 2-5

2: Guideline Development Process

2.1 SPN Team

Appoint guideline development group

- Clear terms of reference
- Suitable chair
- Membership to be geographically and professionally representative of the intended target audience and subject matter expertise specified in the agreed topic proposal, including service user and/or third sector input as appropriate

2.2 Guideline Development Group (GDG):

Collate and review relevant evidence base (using available librarian support)

- collate relevant guidelines from appropriate bodies incl. all relevant local Health Board guidelines
- a systematic review may not always be necessary but authors should have a detailed understanding of the published literature
- consider a systematic review when no relevant guidelines or high-quality reviews exist on the topic

2.3 Lead authors:

Produce draft guideline using SPN template (**see Appendix 2**)

Recommendations should:

- be explicit and clear
- be laid out in a logical, incremental manner
- be explained concisely
- present the strength of recommendation
- present the level of evidence with key references where applicable

2.4 GDG / Lead authors:

Review and amend draft guideline

2.5 SPN Team:

Circulate draft guideline to relevant wider stakeholder groups for consultation

The consultation should include:

- the target audience and subject matter experts relevant to the topic, incl. those outside of maternity or neonatal services
- relevant service user input
- all relevant Scottish Boards / services

(**See appendix 1**)

Replies (submitted via SPN standard feedback form) will be collated by the SPN team

2.6 GDG / Lead authors:

Review collated consultation responses and amend guideline

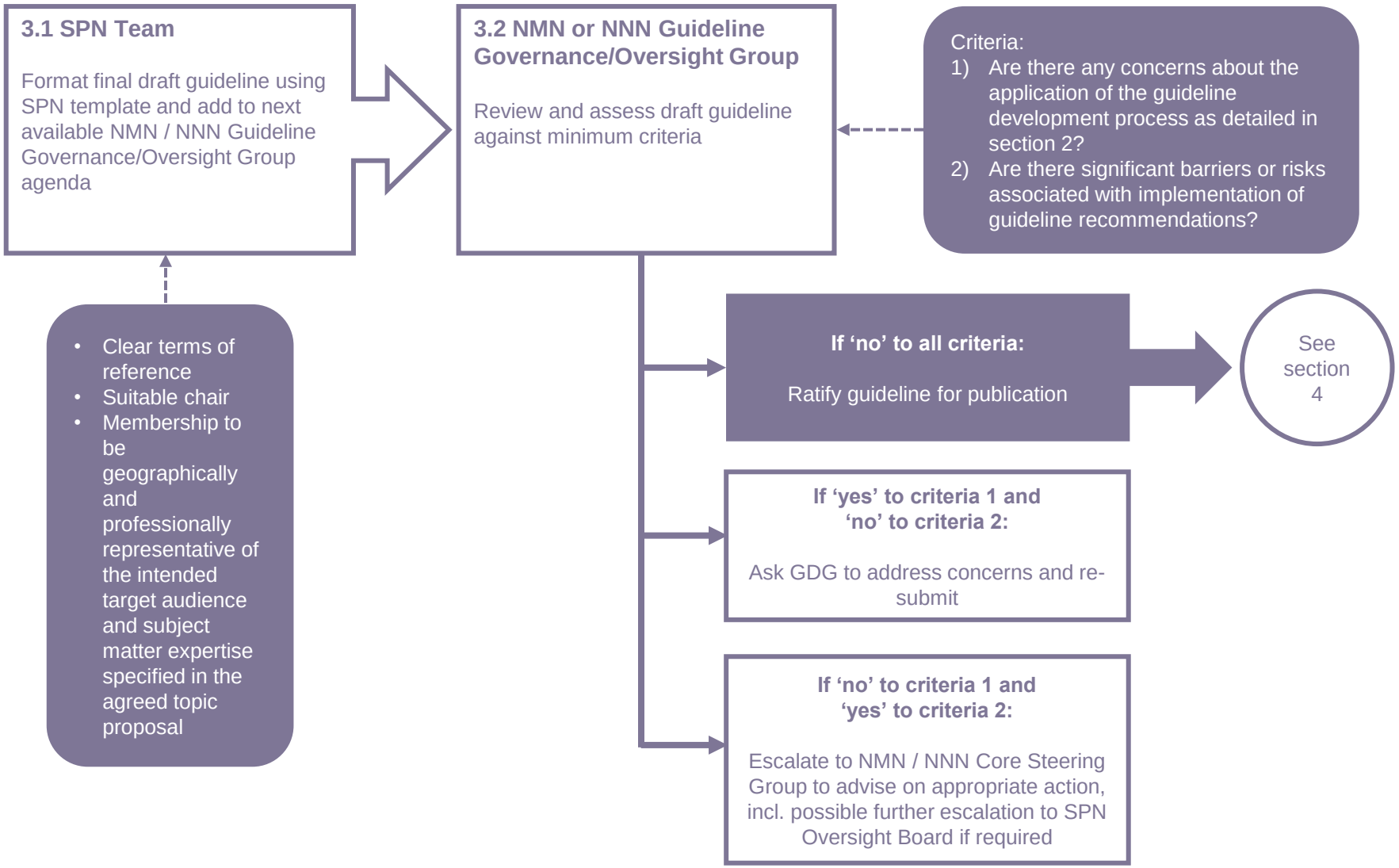
(if required to address complex issues, repeat steps 2.5 and 2.6)

2.7 GDG / Lead authors:

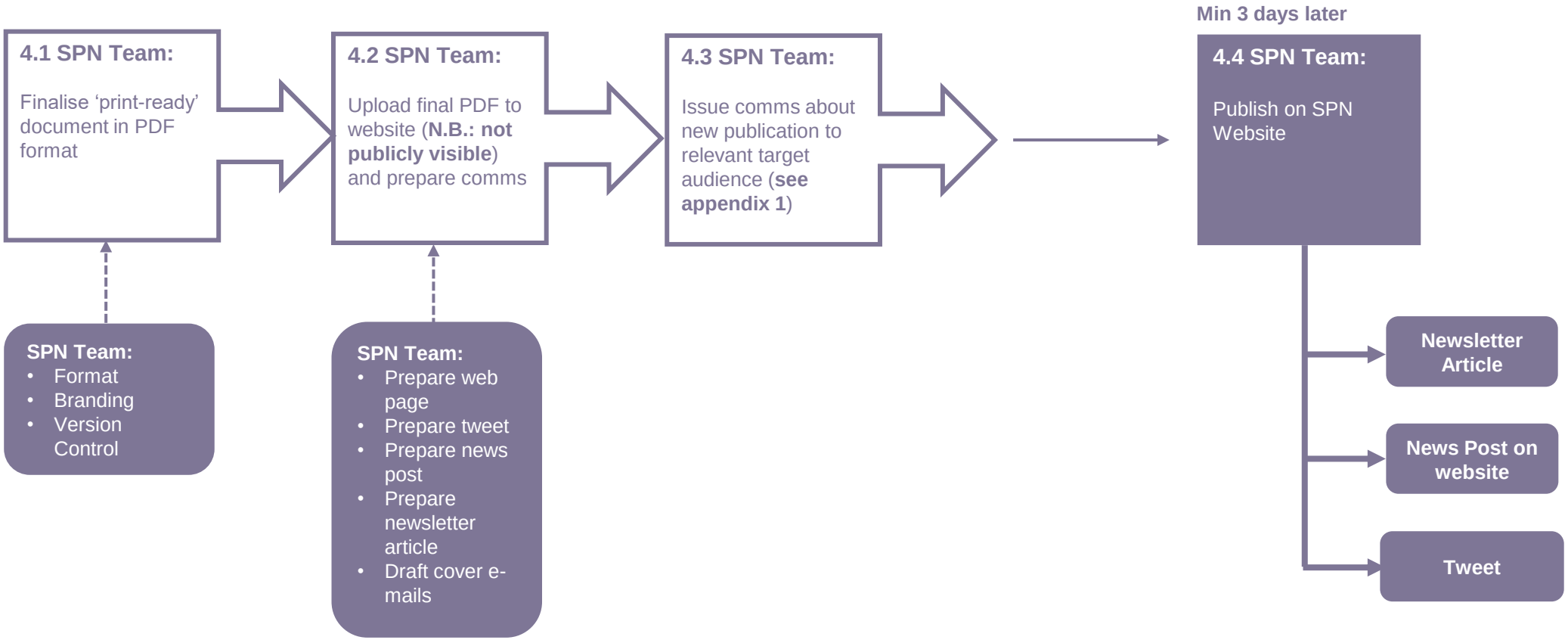
Finalise content of draft guideline for ratification

See section 3

3: Ratification and Governance of SPN Guidelines



4: Publication and Dissemination Process



5: Guideline Review Process

5.1 SPN Team

Monitor review dates (usually 3 years after original publication) of SPN guidelines and flag up documents due for review 6 months prior to their review date

5.2 Lead Author(s)

Initial review to advise if guideline needs to be updated

If the original lead author(s) are not available, refer to the Guideline Governance / Oversight Group to advise

Full revision required:

Proceed as new guideline development → See section 2

Minor updates required:

Lead author(s) amend and submit for consultation → See step 2.7

No updates required:

SPN Team to extend review date and re-publish → See section 4

Guideline no longer required:

Remove guideline from SPN website and issue communication that it has been retired

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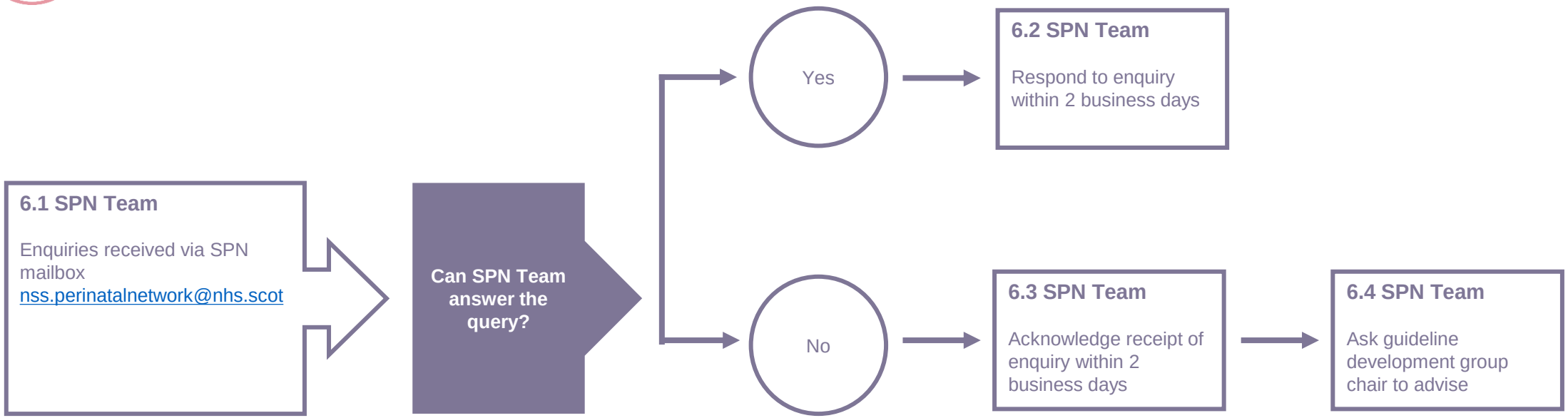
Old versions and retired guidelines must be archived by the SPN programme team for possible future reference

6: Enquiries



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Enquiries about SPN adopted documents originally developed elsewhere will be routed to the chair of the original development group for advice on the response.

Appendix 1: Key Contacts

As described in step 2.5, each draft guideline will need to be consulted upon widely including:

- the target audience and subject matter experts relevant to the topic, including those outside of maternity or neonatal services
- relevant service users and/or their representatives
- all relevant Scottish Boards / services

There will naturally be a degree of variation to reflect the specific nature of each guideline. As a minimum the consultation should address the undernoted groups:

Maternity Services:

1. Guideline Development Group
2. NMN Guideline Governance Group
3. NMN Core Steering Group
4. Obstetric Clinical Directors (ask to cascade on to local obstetric colleagues)
5. Heads of Midwifery (ask to cascade on to local midwifery colleagues)
6. Royal College of Midwives Scotland
7. Scottish Group of the Royal College of Obstetricians and Gynaecologists

Neonatal Services:

1. Guideline Development Group
2. NNN Guideline Oversight Group
3. NNN Core Steering Group
4. Neonatal Consultant Forum
5. Scottish Neonatal Nurses Group
6. Neonatal AHP Forum
7. Scottish Neonatal and Paediatric Pharmacists Group

Others:

1. Relevant patient groups / third sector partners, e.g. MVPs or Bliss
2. Other relevant clinical specialties or sub-specialties
3. Relevant MCNs, e.g. PMHNS, SCANS, SOCN, SPRUN, SPEG etc

As described in step 4.2, each final guideline needs to be communicated widely prior to publication.

It is anticipated that the key contacts for this communication will in most cases be the same as the key contacts for the consultation listed in this appendix.

Appendix 2: Guideline Template

Each guideline development group will need to consider how best to ensure the guideline they are developing is well structured and appropriately reflects the unique requirements of its subject matter so that it is fit for purpose as clinical guidance, enabling the reader to get the necessary information quickly, especially in acute or time sensitive situations.

Guideline development groups may wish to consider :

a. Including flow charts
b. Including short / quick-read versions
c. Avoiding lengthy paragraphs
d. Moving explanatory / educational background information into appendices where possible.

It is anticipated that all SPN guidance will include the following sections as a minimum standard.

1. **Title**
2. **Document Control**
3. **Table of Content**
   (hyperlinked to allow readers to move directly to relevant chapters)
4. **Background and Scope**
   (incl. definitions, risk factors, complications)
5. **Recommendations and Supporting Evidence**
   (giving succinct, clear and action-focused recommendations; indicating the weight of the recommendation and the grade of evidence it is based on)
6. **Measurement / Implementation**
   (consider how the guideline would be implemented in practice and how benefit of the guideline can be demonstrated)
7. **Useful Links and Support**
   (e.g. patient information leaflets, signposting to relevant national guidance, websites)
8. **Guideline Developers and Conflicts of Interest**
9. **References**

Appendix 3: Medico-Legal Considerations

All guidelines should carry a disclaimer informing readers of the medico-legal status of the guideline:

> This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

(Adapted from *SIGN 50: A guideline developer's handbook*, section 1.4 (page 7): sign50_2019.pdf)

The Chief Medical Officer has previously issued advice on the medico-legal considerations around the application of clinical guidelines:

> "It is distinct from standards which generally reflect a minimum expectation. One of the core principles of Realistic Medicine is that Evidence Based Medicine is comprised of three separate components – not solely the scientific evidence, but taken together with clinical judgement and elicitation of patient preferences. Were legal proceedings arising, it would seem reasonable for a person raising a case about the actions of a Health Board to ask whether the Board had had reasonable regard to this guidance in the way they had acted. But there would be nothing novel in that: it would be a normal course of action to assess whether a public authority had had regard to extant guidance."