OG001.v1 Guideline Development

1. Key Recommendations for operational use		
1	Topic Proposal	• submit a synopsis of a new guideline or the existing time expired guideline to the clinical standards group (CSG) chair • define: type, need, authors required and compatibility • author, CSG chair and SAS representatives complete checklist 1
2	Authorship	• appoint writing group and a chairperson • consider GP, external expert and SAS representative as members of the writing group
3	Distribution	• identify target users at the proposal stage • includes: ScotSTAR teams, trauma teams, rural GPs, BASICS
4	Literature review	• a formal systematic review is not required but authors should have a detailed understanding of the published literature • relevant guidelines from appropriate bodies should be utilised • consider librarian support for a systematic review when no relevant guidelines or high quality reviews exist on the topic
5	Recommendations	• should be explicit and clear in a logical, incremental manner • present concise explanatory statements • present the strength of recommendation • present the level of evidence with key references
6	Layout	• section 1: key recommendations alone • section 2: authors, reviewers, distribution, objectives, disclaimers • section 3: explanatory statements and references
7	Review Process	• submit completed document to the CSG chair • CSG chair and SAS representatives complete checklist 2
8	Approval process	• ScotSTAR AMD completes checklist 2 • ScotSTAR AMD approves guideline and releases for use
9	Update and feedback	• user feedback can be submitted to the CSG chair if indicated • authors should be aware of relevant interim developments • routine review is every 3 years unless interim review is needed • a process for complete withdrawal of the guideline is defined
10	External reference	• CSG chair reports ongoing work streams to the CSG and ScotSTAR clinical governance group • ScotSTAR AMD reports overall activity to SAS national clinical governance group

2. Document History			
Reference Number	OG001		
Version	1		
Writing group (Chair in bold)	Keith Colver	Clinical Governance Manager	SAS
	Kenny Freeburn	Head of Service, Tayside	SAS
	Andrew Inglis	Associate Medical Director	ScotSTAR
	Richard Price	Consultant	EMRS
Associate Medical Director	Andrew Inglis		
Date issued	14th September 2017	Format revisions: 23rd April 2019	
Date for review	September 2020		
Distribution	ScotSTAR	EMRS West	✓
		EMRS North	✓
		Paediatric	✓
		Neonatal	✓
	Referring centres via service websites		✓
	BASICS Scotland		✓
	Medic 1		✓
	Tayside Trauma Team		✓
	Rural GPs Association of Scotland		✓
	SAS Air Ambulance Division		✓

3. Scope and purpose

- Overall objectives:

This guideline describes the process of guideline development, formatting, approval and SAS impact assessment. The aim is to provide pragmatic, high quality guidelines that can be used in a remote, rural, transport and prehospital environment. The process is based upon SIGN50 (summary in in appendix 1) for clinical guidelines but the principles and process applies equally to other guidelines.

- Feedback:

Comments on this guideline can be sent to: scotamb.CPG@nhs.net

- Equality Impact Assessment:

Applied to the ScotSTAR Clinical Standards group processes.

- Guideline process endorsed by the Scottish Trauma Network Prehospital, Transfer and Retrieval group.

4. Explanatory Statements
4.1 Topic Proposal
• *submit a synopsis of a new guideline or the existing time expired guideline to the clinical standards group (CSG) chair* The role of the CSG chair is to act as a single point of contact for all participating groups and the role is one of co-ordination.
• *author, CSG chair and SAS representatives complete checklist 1* • *should define: type, need, authors required and compatibility* The purpose of this is to optimise the writing group at an early stage; integrate with existing SAS materials and limit duplication of effort. The SAS representatives will advise as to existence of any current SAS guidelines and the potential for the guideline to impact upon SAS. They will advise an appropriate point of liaison within SAS as required.

4.1 (a) Checklist 1.
Is this a clinical, equipment, safety or operational guideline?
Is the subject matter appropriate for a guideline?
Who are proposed users of the guideline?
Is there an existing guideline or SOP within ScotSTAR or SAS?
Who are proposed authors and reviewers?
Is there a need for a GP, external expert or SAS representative as an author or reviewer?
Is a fast track process warranted?

4.2 Authorship
• *appoint primary author(s) and reviewer(s)* • *consider GP, external expert and SAS representative as authors or reviewers* The author, CSG chair and SAS representatives should agree the author(s) and reviewer(s) as well as the need for a GP; a subject matter expert or SAS representative. The writing group should ideally reflect the target users of the guideline.

4.3 Distribution

- *identify target users at the proposal stage*
- *includes: ScotSTAR teams, trauma teams, rural GPs, BASICS*

The guidelines may be utilised by a single team or a number of teams and groups who respond on behalf the of SAS. Certain guidelines should be shared with referring centres to enable seamless and co-ordinated care of a patient who will come under the care of SAS. Such guidelines are then publicly accessible and the content should reflect that.

4.4 Literature review

- *a formal systematic review is not required but authors should have a detailed understanding of the published literature*
- *relevant guidelines from appropriate bodies should be utilised*
- *consider librarian support for a systematic review when no relevant guidelines or high quality reviews exist on the topic*

The recommendations of clinical guidelines in particular need to be supported by the published literature. It is likely however that many guidelines may draw upon existing high quality guidelines and apply them to the retrieval environment. Such guidelines, providing they are methodologically sound, should be utilised. Authors should be conversant with the remaining literature on the topic. If high quality evidence summaries do not exist then a formal review should be considered.

4.5 Recommendations

- *should be explicit and clear in a logical, incremental manner*

Each recommendation should be clear and succinct. There should be a logical order, for example based upon incremental interventions required for a given problem. For a given action, it should be clear if the user “should” do or can “consider” the action.

- *present concise explanatory statements*
- *present the strength of recommendation*

The strength of recommendation is either “strong” or “conditional” denoting the certainty with which the recommendation is made. This takes into account the quality (level) of the evidence. A particular level of quality does not automatically lead to a particular strength of recommendation; other factors include external validity; consistency and the balance of benefits and harms. For “strong” recommendations, interventions “should” be used as (the author considers) the intervention will do more good than harm. For “conditional” recommendations, interventions should be “considered”, as the intervention will do more good than harm for most patients. A “good practice point” can be made based on the clinical experience of the authors.

- *present the level of evidence with key references*

The level of evidence is shown in the table. If a guideline is cited then this is written as “guideline” and referenced accordingly. Key references should be cited in Vancouver style with the lead author and second author or et al only.

4.5 (a) Levels of evidence

1^{++}	High-quality meta-analyses, systematic reviews, or RCTs with a very low risk of bias
1^{+}	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1^{-}	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2^{++}	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2^{+}	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2^{-}	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, *eg* case reports, case series
4	Expert opinion

4.6 Layout

- *section 1: key recommendations alone*

Section 1 should ideally be confined to one page that lists the key recommendations. The aim is that these are readily apparent and are easily read at an operational level.

- *section 2: authors, reviewers, distribution, objectives, disclaimers*

The first table should contain names authors and reviewers and version history. The distribution (target users) should be listed with relevant logos. Next is a one paragraph brief objective of the guideline, a generic disclaimer around the use of guidelines and a statement on the equality and diversity process.

- *section 3: explanatory statements and references*

Each point can have an explanatory statement which should be brief and to the point. It may not always be necessary to expand upon a key recommendation. The strength of recommendation, level of evidence and reference should accompany each point.

4.7 Review process

- *submit completed document to the CSG chair*
- *CSG chair and SAS representatives complete checklist 2*

Once the authors and reviewers consider the guideline complete, it should be submitted to the CSG chair, again as a central point of contact. The purpose of the review is to ensure appropriate process, correct formatting and potential impact on SAS, not to contest the key recommendations of the writing group. The CSG chair can refer the guideline back to the writing group for revisions. The SAS representatives will advise on a case by case basis the process if SAS impact has been identified. The intention is that any impact on SAS is identified at the proposal stage.

4.7 (a) Checklist 2
Is the writing group as agreed at the proposal stage?
Have any key relevant guidelines been considered?
Is there likely to be a wider impact on SAS?
Are the recommendations clear and definitive?
Are the recommendations linked to evidence?

4.8 Approval process

- *ScotSTAR AMD completes checklist 2*
- *ScotSTAR AMD approves guideline and releases for use*

Once the review has been completed by the CSG chair and SAS representatives, the CSG chair passes the guideline to the ScotSTAR AMD. If no further issues are identified, the guideline is authorised for use and the guideline is dated at this point. The AMD can ask for clarification of any recommendation if required; this should again be referenced to the published literature. Comments; the writing group's response and final outcome should form part of the checklist 2 file (page2).

4.9 Update and feedback

- *user feedback can be submitted to the CSG chair if indicated*
- *author should be aware of relevant interim developments*
- *routine review is every 3 years unless interim review is needed*

The guidelines require periodic review. If there is a requirement to review in the interim with operational experience, event report or substantial new evidence then a request for early review can be made to the CSG chair.

- *a process for complete withdrawal of the guideline is defined*

If withdrawal of a guideline is required then the Guideline Withdrawal Checklist should be used. The reasons for withdrawal from use should be summarised. The CSG chair, SAS representatives and AMD review this. If agreement is reached, the relevant users are notified of the intention to withdraw. If no objection is received after a one month notice period, the guideline is withdrawn.

4.10 External reference

- *CSG chair reports ongoing work streams to the CSG and ScotSTAR clinical governance group*
- *ScotSTAR AMD reports overall activity to SAS national clinical governance group*

The role of these groups is to provide strategic overview rather than review of individual guidelines.

Appendix 1. Summary of SIGN50

		SIGN 50 Section
SCOPE AND PURPOSE		
1.	The overall objective(s) of the guideline should be specifically described.	**8.2**
2.	The health question(s) covered by the guideline should be specifically described.	**4.3**
3.	The population (patients, public, etc.) to whom the guideline is meant to apply should be specifically described.	**8.2**
STAKEHOLDER INVOLVEMENT		
4.	The guideline development group should include individuals from all relevant professional groups.	**2**
5.	The views and preferences of the target population (patients, public, etc.) should be sought.	**10.2**
6.	The target users of the guideline should be clearly defined.	**8.2**
RIGOUR OF DEVELOPMENT		
7.	Systematic methods should be used to search for evidence.	**4**
8.	The criteria for selecting the evidence should be clearly described.	**4.3, 4.4**
9.	The strengths and limitations of the body of evidence should be clearly described.	**5**
10.	The methods for formulating the recommendations should be clearly described.	**6**
11.	The health benefits, side effects and risks should be considered in formulating the recommendations.	**6.2**
12.	There should be an explicit link between the recommendations and the supporting evidence.	**6.3**
13.	The guideline should be externally reviewed by experts prior to publication.	**7.2**
14.	A procedure for updating the guideline should be provided.	**3.3**
CLARITY OF PRESENTATION		
15.	The recommendations should be specific and unambiguous.	**6.3, 8.2**
16.	The different options for management of the condition or health issue should be clearly presented.	**6.3, 8.2**
17.	Key recommendations should be easily identifiable.	**6.5, 8.2**
APPLICABILITY		
18.	The guideline should describe facilitators and barriers to its application.	**9**
19.	The guideline should provide advice and/or tools on how the recommendations can be put into practice.	**9**
20.	The potential cost implications of applying the recommendations should be considered.	**6.2**
21.	The guideline should present monitoring and/or auditing criteria.	**8.2, 9.4**
EDITORIAL INDEPENDENCE		
22.	The views of the funding body should not influence the content of the guideline.	**1.2**
23.	Competing interests of guideline development group members should be recorded and addressed.	**1.7**