The Best Practice Guidelines Pipeline: Process for Successful Completion of the BPG Cycle

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1. BACKGROUND

Best Practice Guidelines (BPGs) are evidence-based and created by consensus, with the purpose of making recommendations to ensure the highest possible standards of genetic testing are met. BPGs may be created for individual disorders, techniques or analytical processes and are aimed primarily for use by laboratory scientists and assessors of external quality assessment schemes.

The delivery of new or updated BPGs has traditionally involved a consensus-building workshop bringing together relevant experts in the area followed by an iterative guideline drafting process. The timeframe from concept to production of ratified BPGs is often significant and not always fit-for-purpose.

This document aims to provide a framework, the "BPG pipeline", for the timely delivery of high quality best practice guidelines, including both new and updates to existing guidelines, describing how to manage each stage of the BPG cycle from "Trigger" to "Publication".

2. STAGES OF THE BPG CYCLE

2.1 TRIGGER

A number of scenarios will trigger the BPG cycle, including the following:

a) No current guidelines exist
b) Current guidelines are out of date
c) Changes/standardisation in practice are required following the results of external quality assessment

The BPG cycle will be triggered in at least two ways, including the following:

a) Via the ongoing ACGS Quality subcommittee BPG review process
b) Via a request from laboratory or UKNEQAS

The request will be made using a proforma (to ensure efficient capture and standardised processing), accessed via the ACGS website, a single page detailing the need (new or update), the reason (see above), suggested co-ordinator(s) as well as other process requirements (such as workshop/questionnaire). The proforma should be forwarded for discussion and follow up actions to the ACGS Quality subcommittee.

2.2 PREPARATION

For new guidelines and those requiring a significant update it may be useful to call a Best Practice workshop as a mechanism of facilitating direct debate between individuals with the knowledge and expertise to ensure the production of appropriate high quality consensus guidelines.

Attendees are usually composed of representatives from laboratories currently undertaking testing of the condition, that have experience in the technology or analytical process in question as well as other relevant experts (clinicians, specialist research and/or diagnostic scientists).

It is important that appropriate preparation is undertaken prior to the workshop to ensure the day is effective. Preparation will vary according to the nature of the guidelines, however, in general the following preparation is considered essential:

a) Circulation and analysis of a questionnaire to gather relevant data/information specific to the guidelines in question.
b) Circulation of a draft text of the current guidelines (e.g., previous version with suggested areas for update or new text drafted by an expert group).
c) Circulation of an agenda incorporating all areas for discussion. The co-ordinator should request items for the agenda as appropriate (especially important for new guidelines) and map these against the outcomes of the questionnaire.
d) Confirmation of speakers as required.

2.3 WORKSHOP

The co-ordinator will chair the best practice workshop with support from a second nominated individual and/or a member from the ACGS Quality subcommittee (the “ACGS workshop representative”) to help as required, usually note taking and guiding discussion.

As time is limited it is important to adhere to the agreed agenda as much as possible, avoiding diversion of discussion in to general issues.

2.3.1 GENERAL CONFIGURATION OF THE WORKSHOP:

a) The ACGS workshop representative may wish to introduce the workshop to set the scene and give an overview of the day.
b) The co-ordinator or other nominated individual should then present data from the questionnaire or other sources as appropriate.
c) Invited expert(s) may wish to give presentations as appropriate to the guidelines, for example an overview of guidelines from another country, guidelines from the clinical perspective and applications of new/emerging technology.
d) Discussion session: centred on the draft text of the current guidelines as described in section 2.2. It may be useful to split the meeting into smaller groups to expedite the process, especially for lengthy complex guidelines, to ensure consensus can be agreed for all elements. The content of this session will be guideline-specific.
e) Summary of the day and agreed actions (by co-ordinator).
f) Identification of the expert group (including the co-ordinator as chair) responsible for putting together the first draft of the guidelines. It is important that any conflicts of interest are disclosed at this point. This group may wish to stay behind after the workshop to ensure timely delivery of the first draft.
g) Confirmation of timelines for the drafting process (this should be given by the ACGS workshop representative).

2.4 GUIDELINE DRAFTING

This is most often the cause of significant delay in the production of new/updated guidelines. To reduce delay the following timeline is recommended and should be monitored accordingly:

a) A draft text should be available and circulated before the workshop as a starting point for the process. As described above this may take the form of a previous set of guidelines or new text drafted by an expert group.
b) The first draft should be put together by the expert group (selected at the workshop) within **TWO** weeks of the workshop. It is essential that the key recommendations decided at the workshop are quickly put to paper to ensure everything is captured as efficiently as possible.
c) The first draft should then be circulated by the co-ordinator to all attendees of the workshop (including the ACGS workshop representative), giving a **TWO** week window for comments.
d) A second draft should then be created by the co-ordinator to incorporate comments as appropriate within a **TWO** week window and sent to the ACGS workshop representative. It may be necessary to re-circulate to the working group if a significant update of the first draft is required.
e) The final workshop group draft will then be posted on the ACGS website for a **TWO** week consultation period. A global email will be circulated to notify the ACGS membership. Comments should be fed back directly to the co-ordinator and the ACGS workshop representative.
f) A final draft should be created by the co-ordinator to incorporate comments as appropriate within **TWO** weeks.
g) The final draft should be returned to the ACGS Quality subcommittee (via the ACGS workshop representative) for ratification at the next subcommittee meeting or if more than one month away then by email. Ratification requires support by at least 5 additional members of the subcommittee to confirm that the appropriate process has been followed.

2.5 PUBLICATION

The BPG cycle is completed upon the final publication of guidelines on the ACGS website. Publication in a peer-reviewed journal should also be encouraged and supported by the ACGS Quality subcommittee. Journal editors are required to allow the guidelines to be published on the ACGS website.

3. RESPONSIBILITIES

3.1 CO-ORDINATOR

The co-ordinator will have responsibility for the following:

a) Triggering the BPG cycle (see section 1 above).
b) Overseeing the preparation process (see section 2 above).
c) Selection of an expert group to compose the draft text of the current guidelines ready for the workshop.
d) Selection of an appropriate venue and speakers as needed.
e) Chairing the workshop and arranging appropriate note taking.
f) Working together with the ACGS workshop representative to oversee the drafting process to ensure timely delivery of all drafts.
g) Review of guidelines after agreed timeframe and selection of alternative co-ordinator if required to oversee the next BPG cycle.

3.2 WORKSHOP ATTENDEES

A successful BPG cycle requires active engagement by the workshop attendees, with the following responsibilities:

a) Timely return of the workshop questionnaire.
b) Timely review of the first draft and feedback of appropriate comments. Comments should be focussed on the outcomes of the workshop itself and where possible additional considerations (unless essential) should be avoided to reduce delay in the drafting process.

3.3 ACGS QUALITY SUBCOMMITTEE

The ACGS Quality subcommittee has overall responsibility for BPG management. Specific responsibilities linked to the BPG cycle are as follows:

a) Triggering the BPG cycle (see section 1 above).
b) Preparation support as required (e.g., nomination of ACGS workshop representative, composition and format of questionnaire, workshop organisation, first draft format).
c) Recording of key points of the workshop (mini-minutes) to help steer the drafting process
d) Mediation to support the consensus process as appropriate.
e) Monitoring of the drafting process to ensure timely delivery (partnership between ACGS workshop representative and co-ordinator).
f) Circulation of drafts as appropriate and final editing to ensure consistent formatting and design of guidelines.
g) Ratification (via ACGS Quality subcommittee meetings or by email).
h) Publication of final guidelines onto website and support for peer-reviewed publication.
i) Financial support if possible (workshop and peer-review publication).
j) BPG review process (3 years unless otherwise stated within specific guidelines).
k) Linking to other Best Practice organisations, such as EMQN.