Coming to a consensus: An Insider's Insight

Clinical consensus statements are agreed opinions formulated by a group of experts on specific clinical challenges. In contrast to clinical practice guidelines, which are based primarily on high-level evidence, clinical consensus statements are more applicable to situations where evidence is limited or lacking, but where there are opportunities to reduce uncertainty and improve quality of care for patients.

Here we describe the approach employed by Niche Science & Technology Ltd. to deliver comprehensive and well-informed clinical consensus statements in an efficient and timely fashion.

Before you start

Confirm that a consensus statement is appropriate and that the topic hasn't already been addressed

Identify topic experts and make initial contact to discuss requirements and the feasibility of developing a consensus

Define deliverables and build an ambitious but achievable delivery schedule (and plan to stick to it)

Prepare to succeed

Recruit candidates who are eager to make a contribution and who will be actively involved

Allocate key tasks at each stage to different team members to spread the commitment load and ensure that the project runs successfully and timely

Facilitate uptake of your practice consensus by planning your dissemination – plan beyond a publication in the scientific literature

Key Insights

The most important question to ask when you are considering making a clinical consensus statement is whether or not your problem falls within the scope of a statement or guideline. Clinical consensus statements provide a manifesto, based on expert opinion and the best available research evidence on a subject, arrived at using an explicit a priori methodology to identify areas of agreement and disagreement. The resulting position on which consensus is achieved should identify opportunities to improve patient care and clinical outcomes.

Characteristic	Clinical Consensus Statement	Clinical Practice Guideline
Primary output	Statements of expert consensus based on best evidence using an explicit and iterative process	Recommendations for action based on best evidence and explicit consideration of benefits, harms, values, and preferences
Level of evidence	Observational studies and expert consensus; higher levels of evidence when available	Systematic reviews and randomized controlled trials; lower-level evidence as need for research gaps
Group size	8 to 10; possibly more	15 to 20
Composition of development group	Mostly content experts may include other disciplines as needed	Multidisciplinary, including stakeholders in the target audience
Development group perspective	Member serves as experts based on knowledge and experience	Member advocates for the discipline or constituency they represent
Time frame	6 to 8 months	12 to 18 months
Meeting venues	Conference calls and electronic mail Limited review by stakeholders	In-person meetings, conference calls, and electronic mail
External review	Limited review by relevant stakeholders	Extensive review by all stakeholders and open public comment

A clinical consensus statement is most applicable to situations where the available evidence is not sufficient to develop a clinical practice guideline, where there are marked differences in clinical practice and where there are possible opportunities for improvements in quality and consistency of care. The target for improvement could involve a high-risk procedure or potential complications of a procedure that warrant additional guidance and/or consideration to reduce risks and complications, improving patient outcomes. In contrast to clinical practice guidelines, which provide explicit recommendations through action statements and evidence profiles, a clinical consensus statement simply expresses the considered opinions of a group of experts. See the table above to help you determine whether you should develop a consensus or guideline.

There are generally four key steps to follow when developing your clinical consensus statement. These are:

- Planning the process and identifying the focus
- Recognising the best team and giving participants appropriate information
- Establishing the group position and recording the statements
- Managing dissemination and implementation

Typically, clinical consensus statements are developed over a 6–8 month period and involve a series of consultations between experts in the field. These experts may be clinicians, policy makers and/or scientists with special skills or knowledge that they have derived from training and experience. A flowchart showing some of the key steps and possible pathways on the route to consensus statement development is presented in Figure 1.

Planning

Developing clinical consensus statements is often a complex, iterative and multifaceted process that requires an understanding of not only the academic needs, but also the operational management of the process itself. For this reason, it is important for the chair to have previous experience in similar exercises.

The individual steps in the development process often differ for each team and for each new consensus procedure. In all cases it remains essential to establish milestones and adhere strictly to agreed delivery timelines. To ensure this, the Chair needs to set-out an achievable delivery agenda at the outset. The key steps outlined in this document can be used to populate the schedule. Team members should be identified who can be responsible for coordinating delivery of the different components. All members of the team must commit to the agreed schedule of activities.

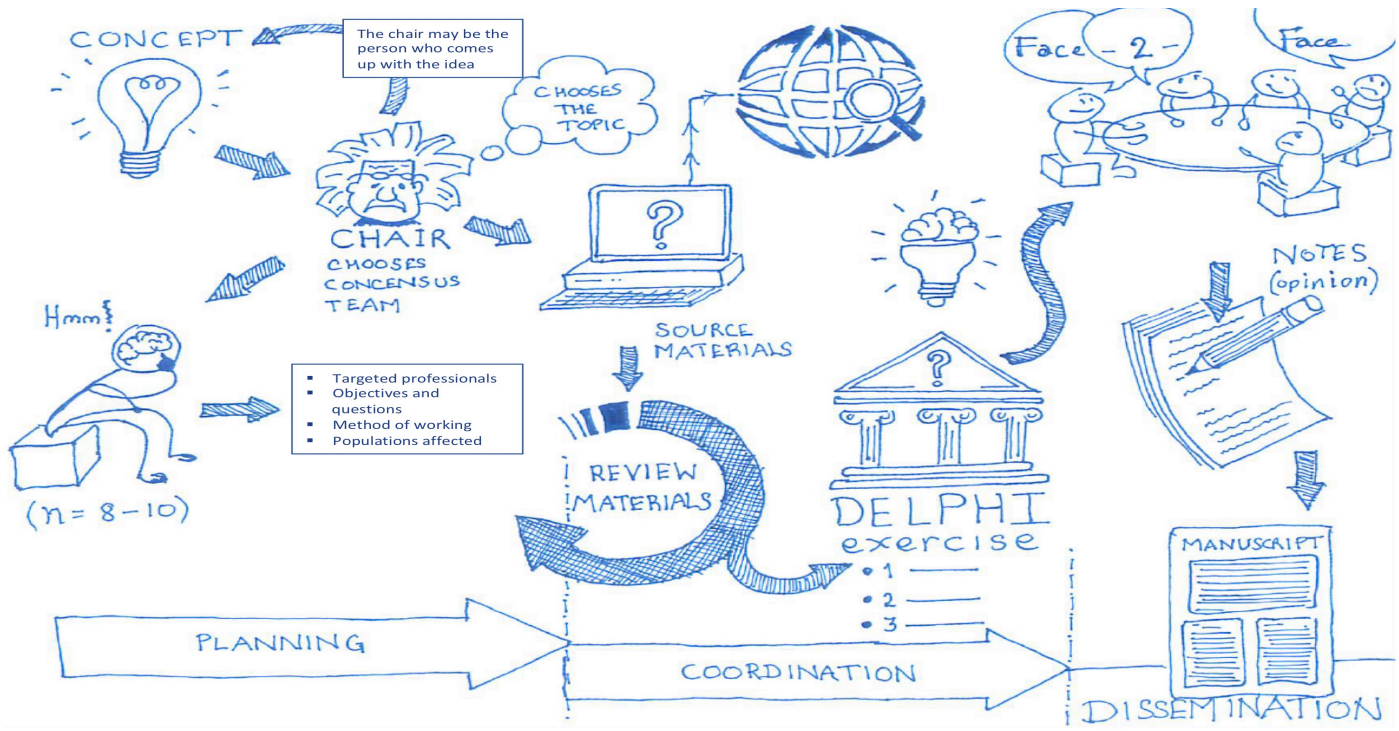

Figure 1: Flowchart detailing steps in consensus development

It is essential to establish the mechanism by which the consensus will be derived. Various options are available. In this day of electronic communications and information exchange, it is possible for all the aspects of consensus development to be completed without the group actually meeting in person. For example, the American Academy of Otolaryngology — Head and Neck Surgery Foundation provides an excellent and comprehensive guide on the development of consensus statements fully remotely [1].

However, in most cases it is advisable to involve at least one face-to-face meeting, supported by teleconferences. Development can also involve any number of online surveys of opinion and draft iterations on the road to delivering the final product.

Topic definitions and timelines

Topic selection should be based on the two fundamental questions: what and why. For example, a clinical condition/procedure that has high prevalence or incidence, uncertainty in management, variability in care and exhibits high risk and/or potential complications is an ideal target for the development of a clinical consensus statement. The aim is to provide expert and consistent guidance for safe, ethical and significantly improved patient outcomes. A preliminary search is always recommended to ensure that there isn't already a serviceable consensus statement available for the therapy area or for similar conditions/procedures.

Choosing the right people

To achieve a consensus position it is necessary to compile and integrate the opinions of your team of qualified clinical professionals. The process requires a leader. Experienced clinicians who 'call' for the development of consensus statements often head up development. However, it is important that the chair also has the correct skill set. They should have knowledge of the topic, prior experience of serving on a clinical consensus statement panel, sufficient time to spend on the process and no relevant conflicts of interest.

Primary responsibilities of the chair include:

- To confirm that team members are comfortable with the scope and content
- Lead and facilitate discussions
- Encourage constructive debate, resolve disagreements and facilitate consensus
- Review literature search results and help fine-tune search strategies to identify the best resources to inform the team of the current status of the field of study
- Employ all available methodologies creatively to gain consensus quickly and efficiently
- Troubleshoot issues relating to participation or adherence to the agreed methodology and facilitate/negotiate delivery
- Express opinion and contribute to the development of the clinical consensus statement
- Assist with writing, allocate writing tasks and provide editorial support
- Prepare the Introduction and Conclusion of any subsequent clinical consensus statement manuscript used to report on the findings
- Provide insight into how best to disseminate and promote adoption of any proposed change in treatment pathways to emerge from the consensus process

"Coming together is a beginning. Keeping together is progress. Working together is success."

Henry Ford
(July 30, 1863 – April 7, 1947)

The consensus team

The challenge of managing inputs from different team members increases exponentially with team size. So, it is best to recruit only a modest number (around 8–10) to your team. Since the specific focus and content of the clinical consensus statement is normally finalised once the group is formed, there will undoubtedly be some fields of interest for which specific members have more familiarity and better capacity to make a useful contribution.

Team members should understand evidence-based medicine, but they do not need to have prior experience of serving on a consensus team. They should be comfortable expressing their opinions on the background materials provided and relevant data while avoiding non-qualified responses that could otherwise skew outcomes.

Members of the clinical consensus development team must be committed to:

- Actively participate in all meetings
- Maintain confidentiality
- Disclose any conflicts of interest
- Complete all Delphi surveys and writing assignments in a timely manner (see Delphi Techniques (page 7).
- Review all materials and/or data
- Respond to all communications promptly and efficiently

It is important for the consensus organisers to be able to demonstrate the unbiased nature of the candidate selection process when it comes to writing the final reports and any publications. Therefore, when recruiting members to the group, the rationale behind your selection criteria should be recorded. Information should be captured on:

- Academic publishing record
- Membership of editorial boards and/or learned societies
- Geographic location and language
- Availability to commit to the project
- Potential conflicts of interest

Project coordination and administration

The consensus team are often busy people and have little time to undertake the administration necessary to deliver the consensus position in a timely and efficient manner. Ideally, management is performed by a non-voting operational individual or team, serving in an administrative and advisory role both supporting and guiding the chair.

A learned society or academic institution requesting or supporting development of a consensus might undertake the management role. Alternatively, the chair may use resources at their disposal (junior department members etc.) to support the process. Sometimes, the development of consensus statements is supported indirectly by a grant, from the pharmaceutical industry for example. In these cases, commercial medical education organisations such as Niche Science & Technology Ltd. may be engaged to manage the process. In such cases, resource is often available to address all aspects of the process.

Those assisting the chair should have some understanding of the content area, experience with evidence-based medicine and knowledge of how clinical consensus statements are developed. In addition to general administrative tasks they may also get involved with:

- Recruiting content experts from medical specialty societies, committees, and pertinent organizations
- Collating and assisting with background literature searches and organizing results
- Organizing conference calls and face-to-face meetings, including scheduling, creating agendas, and sending email reminders to those involved
- Planning and facilitating dissemination activities

Management team

In addition to supporting and guiding the chair a management team serving in an administrative and advisory role should focus on facilitating delivery, issue resolution and day-to-day management.

Primary responsibilities of the management team include:

- Ensuring that the team adheres to pre-defined methods and/or process and timelines
- Keeping the team focused on the scope and purpose
- Assisting the chair on all conference calls to ensure active participation of all group members and to prevent 'group-think' and other biases
- Collecting data on team members relating to their selection as well as conflict of interest statements
- Reviewing and editing survey questions and summarising findings
- Limiting results that emerge to statements of consensus and discouraging language that might imply recommendations for action
- Assisting with writing and editing the associated outcomes: meeting minutes, final reports, manuscripts etc.
- Coordinating approval of the final version of the outcome documents

Likert scales

Consensus exercises often employ psychometric Likert scales with questionnaires. Widely used for scaling responses in survey research, the scale is named after its inventor, Rensis Likert, who distinguished between a scale proper, emerging from collective responses to a set of items (usually eight or more), and the format in which responses are scored along a range. Technically speaking, a Likert scale refers only to the latter [2].

The difference between these two concepts relates to the distinction Likert made between the underlying phenomenon being investigated and the means of capturing variation that points to the underlying phenomenon [3]. Respondents specify their level of agreement or disagreement on a symmetric agree-disagree scale for a series of statements. Thus, the range captures the intensity of their feelings for a given item [4], making them perfect for use in consensus projects.

Ground work

Any number of factors can 'kick off' the first 'idea' that a particular treatment paradigm would benefit from a new consensus statement guiding the clinical pathway. Whenever and however it starts, it is necessary to define a target problem at the outset, put together a team of contributors that can be employed to create the 'call-to-arms' and collect background materials to inform the development process. At this point it is often advised for interested parties to hold an initial planning call.

Coordination

About a week before the first planning call, the Chair and/or management team should distribute an agenda and background information and proposed suggestions regarding group member roles and responsibilities as well as proposed delivery milestones and timelines.

The initial call typically discusses proposed topics and confirms that no key stakeholders have been missed from the initial line-up. It also allows for team introductions. Attendees gain an overview of background, purpose, and scope/focus, population, target audience (proposed stakeholders) and care settings from the the viewpoint of the Chair. Roles and responsibilities can be allocated and members asked to complete any missing financial disclosure and conflicts of interest statements. An outline of the development process, preliminary delivery milestones and timelines should be confirmed – these will form the basis of the reported methodology appearing in any final reports. If the resources are available you may decide to prepare a formal protocol.

The minutes of the meeting should be written up and approved (within a week). The agreed outcomes should be converted into timetables, delivery schedules and an action plan. Dates of future meetings should be bookmarked in calendars. The Chair should use the discussions to assemble a list of draft consensus questions to be distributed to the team for their consideration. The team should be reminded that the draft consensus statements are written as expert views, not recommendations for action.

Scope

It is important to keep the scope at the front of the clinical consensus statement development process. It should **NOT** be overly broad. Points to consider when defining the scope include:

- Prevention and prognosis
- Target condition, procedure, diagnosis or clinical presentation
- Patient inclusion and exclusion criteria
- Intended audience, practice settings and future applications
- Treatments/interventions for consideration and/or exclusion
- Outcomes

Refining the scope

As a prompt to refining the scope, each development group member can be asked to submit at least five questions to the staff liaison based on what they perceive to be key opportunities that address controversial clinical issues, reduce variability in care, clarify evidence gaps, and improve quality of care through structured expert consensus. The project coordinator should collate and organize the submitted questions (i.e., diagnosis, medical therapy) and provide them to the chair for review and revision.

As a guide, the list of topic questions in the first instance should consist of at least 20 questions which can be distributed to the team, who can rank them in order of considered importance [5].

The chair should review the list of topic questions to identify specific areas on which to focus and to prioritise the clinical statements that the group will assess. The Chair can decide on whether or not they want to run a Delphi survey to better define the purpose of the exercise and when this technique is best applied. There is no reason not to employ multiple ways of driving progress and obtaining opinions – for example, no reason not to run multiple Delphi exercises, beyond the time it takes (remembering that any marked change should be recorded as a protocol amendment .

The face-to-face meeting

Although you may hold TCs to discuss various iterations of the consensus materials to be developed and specific issues, the face-to-face meeting remains the most important aspect of any consensus process.

Pre-meeting activities

The management team should provide group members with source materials (detailing the parameters of any background searches), a draft list of statements derived during preliminary discussions and topic questions provided by the group members along with a meeting agenda. The management team should follow up on missing disclosures of potential conflicts of interest. The team should also try to condense all information into a simple package for easy distribution and liaise with all participants to determine date, location and logistics/requirements for the meeting.

On the day

The chair reviews the prioritized list of topic questions with participants to see if any changes are required. Next, the questions are discussed along with the associated draft consensus statements previously submitted. The goal is to agree any draft consensus statements related to the topic question, which may later be confirmed using a Delphi process. The draft statements should facilitate discussion relating to the credibility/ value of the evidence and the span of opinions. The goal at this time is not linguistic perfection but rather to have a final list of statements that the group may refine and rank after the call through an interactive process of review.

Delphi Techniques

The Delphi method is a systematic, iterative approach to identifying consensus that can be performed without face-to-face interaction [5,6]. Variations of the Delphi method are often used when developing consensus statements. They are a useful way of getting 'the team' to agree where to best focus their efforts. The process of focusing can be facilitated through the use of free online tools such as Survey Monkey (www.surveymonkey.com) [7], which you can use to capture the general consensus of a group.

A nine-point scale is a good way to measure agreement when conducting surveys. When employing web-based software use the following anchors: strongly disagree (1), disagree (3), neutral (5), agree (7), and strongly agree (9). Statements should be clear and concise and avoid leading language that could bias responses or prescribe specific actions. You may also ask for feedback on the rationale behind each response from the team, which can inform post-survey discussions.

Rank tables can be collated to determine the mean rank score for each topic. This process facilitates discussion, identifies the focus and streamlines review.

After discussing the highest priority topics on the list, the chair should continue down the list until an adequate number of consensus statements are drafted. The exact number of statements will vary according to the topic background information and group coherence. Statements that achieve consensus are reviewed for meaning and importance and to ensure that language is clear and unambiguous. Statements that are near consensus should be discussed until the group can agree on whether to retain the statement with potential rewording or clarification, or reject the statement from further consideration. It should be agreed whether or not statements that do not reach consensus should be dismissed without further discussion or included if heavily reworked. Once all aspects have been discussed and the rough composition of the statements agreed the mechanism by which the final product may be achieved laid out to the team and agreed upon. The chair should also assign development group members to assist with writing the manuscript (see also below in Dissemination).

Follow-up

It is essential that the minutes of the meeting are written up and approved promptly detailing next actions and details of the writing assignments. Consensus development concludes when all statements have been adequately discussed and decisions finalised about what will appear in the finished statement – this often follows shortly after the the face-to-face meeting.

Dissemination

Publishing the consensus statements in the form of a scientific manuscript is generally considered the final step in the development process. The manuscript should follow a traditional structure: abstract, background, methods, results, discussion, a summary of research needs, and conclusion. A timeline for manuscript development should be finalized, and the development group should feel comfortable with all final results of the development process. The management team should provide instructions on writing and review and send reminders of all deadlines to ensure that authors stick to the writing schedule.

It is generally accepted that the Chair writes the Introduction – and this can be done as soon as the team starts working on the consensus. Specified team members should work on the Methods and Results. The method should summarise how the statements were developed (using the protocol if available). Meeting minutes should be checked to ensure that there were no marked deviations from the proposed methodology (which should be recorded). Results should focus primarily on areas of strong agreement (or disagreement). The Chair often writes the first draft of the Discussion. Once a draft is available all authors should review to ensure that the text is clear and concise. Once all authors are satisfied it should be formatted for publication in its peer-reviewed journal.

We are living in the Information Age where the internet, computers and smartphones are an essential part of our everyday lives, allowing us to access immediately and share information. Digital technologies have changed every aspect of our lives – from the way we work and learn to the way we play and socialise. The internet has transformed how scientific findings are communicated and data shared. Technological capabilities are advancing faster than our ability to comprehend their full potential. For the opinions captured in your consensus statement to have greatest impact on patient outcomes it is imperative that your dissemination **NOT** stop at publication – that is only the start. Plan to exploit your publication through various communication channels to have the maximum impact on patient outcomes. Some hints on winning the dissemination game are provided here [8].

It is important to note that developing a consensus statement is not a one-off affair. How it is going to be updated/ modified should be consider at its time of development . This allows you to take clinical, scientific and technological developments into account. Thus arrangements should be in place for regular review and feedback on the clinical consensus statement and its future

An interview with our Managing Director

Q What is the key characteristic of a good team member?

A A good team member is eager to contribute and yet willing to compromise. They should respond to requests to contribute to and/or review materials promptly to keep the project on schedule.

Q What is the most challenging aspect of the face-to-face meeting?

A Members of a contributing team are often well informed and opinionated and discussions can often get caught up in minutiae. When starting the meeting you should identify one member of the team to point out when discussions have gone on too long.

Q What oversight do planners make most frequently?

A Most chairs try to build a team with the broadest range of experience – often recruiting from different countries However, they often don't consider how language differences can slow progress and confound development.

Q What is it the biggest oversight you can make?

A Avoiding mediocrity is your greatest challenge. It is relatively simple to undertake multiple iterative refinements of your consensus statements, incorporating comments from all the participants. Take care not to engineer the teeth out of your position in an attempt avoid contention.

And finally…

It is important to remember to set clear bounds for the intended use of your document as clinical consensus statements are often provided to cover the gaps in our understanding, where our knowledge is limited. The consensus process serves to overcome the uncertainties by reaching consensual opinion which is markedly different from practice guidelines.

It is advised that your text should include a clear statement underlining this position. For example *"Clinical consensus statements are based on the opinion of carefully selected content experts and are provided for information and educational purposes. The aim of the development group was to synthesise information and experience, along with possible conflicting interpretations of the data, into clear and accurate answers to questions of interest".*

When considering developing your consensus position you should remember that if you have identified a need to establish a treatment pathway then others are also likely to have noticed the same thing. It isn't a race but consensus development can generate tangible results much faster than actual research. Keep process moving forward by using our guide on good meeting practice [9]. When you combine our two guides to your approach you get successful results [10].

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Next Steps

We created this Insider's Insight into conducting the consensus process to share a few helpful pointers and key learnings that we have gained over the years.

I hope you found our guide useful, if you would like to discuss support with any of consensus development challenges please contact me at the email address below.

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