Development of Clinical Practice Guidelines: Evaluation of 2 Methods

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Abstract

The aim of this study was to compare 2 methods for developing a clinical practice guideline (CPG) on the management of asymptomatic, impacted mandibular third molars. Outcome measures were the mean time invested by the participants for each method, the quality of the CPGs measured using the Appraisal of Guidelines for Research and Evaluation (AGREE) indicator and observations of the group discussions. We used a national consensus procedure following the Rand modified Delphi procedure (2 panels) and a local consensus procedure (2 existing dental peer groups). The mean time spent was about equal for the 2 methods. The quality of the CPGs developed by the expert panels was higher than that of the CPGs developed by the dental peer groups. Observation indicated that all group processes were influenced by the chairperson. We concluded that the expert panel method is suitable for developing reliable CPGs on a national or regional level.

MeSH Key Words: *dental care/standards; evaluation studies; evidence-based medicine; practice guidelines/standards*

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During the last 2 decades, there has been an increasing interest in the development of clinical practice guidelines (CPGs) in all areas of health care.[1] CPGs can be defined as systematically developed statements to assist the practitioner and the patient in making decisions about appropriate health care in specific clinical situations.[2] They are intended to improve the quality of care provided, particularly in areas of clinical uncertainty. In the medical profession, the first guidelines in primary care were developed without active participation of general practitioners. This resulted in guidelines that were, at best, only partly supported by the profession. Currently, in The Netherlands, professional organizations and primary care clinicians are involved in all stages of guideline development, which has increased both understanding and acceptance of CPGs by practising health care workers.[3]

In dentistry, only a few attempts have been made to develop and implement CPGs systematically.[4] Although CPGs are meant to be tools that support daily practice, dentists may view them with suspicion and feel that they may restrict their professional autonomy.[5] To enable the development of sound and useful dental CPGs and to minimize potential barriers to their use in practice, CPGs should be based on reliable evidence, developed rigorously, supported and promoted by a trusted, professional organization and disseminated systematically in formats that are user-friendly to busy practitioners.[5–8]

Several methods for creating CPGs are available. A profession-centred approach has been advocated.[7,8] In The Netherlands, the Dutch Dental Association developed and implemented a consensus procedure, as it was assumed that this would lead to better acceptance and use of the CPGs by the dental profession. This procedure should combine evidence from the scientific literature and the clinical experience of the profession for whom the CPG is developed. A local consensus procedure (a "bottom-up approach") has been advocated to establish ownership of the CPG[9] and might achieve this more readily than a national consensus procedure ("top-down approach"). However, a

Box 1 The structure and content of the AGREE instrument (adapted from Burgers[1])

The Appraisal of Guidelines for Research and Evaluation (AGREE) list comprises 23 items organized into 6 domains. Each domain is intended to capture a separate dimension of guideline quality.

Domains

1. Scope and purpose of the CPG (3 items) is concerned with the overall aim of the guideline, the specific clinical questions and the target patient population.
2. Stakeholder involvement (4 items) focuses on the extent to which the guideline represents the views of the intended users.
3. Rigour of development (7 items) relates to the process used to gather and synthesize the evidence and the methods used to formulate and update the recommendations.
4. Clarity and presentation (4 items) deals with the language and format of the guideline.
5. Applicability (3 items) pertains to the likely organizational, behavioural and cost implications of applying the guideline.
6. Editorial independence (2 items) is concerned with the independence of the recommendations and acknowledgement of possible conflicts of interest by the guideline development group.

Response scales

Each item is rated on a 4-point scale, ranging from 4 (strongly agree) to 1 (strongly disagree), which measures the extent to which an item has been fulfilled. A box for comments next to each item allows the rater to explain the reasons for the responses.

The AGREE list used in this study, which was a draft version of the now available AGREE instrument, contained 2 additional ratings: "no information to answer," and "not applicable." In the latest version of the AGREE instrument, these items are now covered by "strongly disagree."

Domain scores

Domain scores are calculated by adding the scores of the individual items in each domain and standardizing the total as a percentage of the maximum possible score for that domain (see calculation below). The domain scores are independent of each other and should not be combined into a single quality score. Note: Domain scores may be very useful for comparing CPGs and influencing the decision to use or recommend the CPG, but they are not meant to be used to rate the CPG as "good" or "bad." The standardized domain score can be calculated as[1]:

$$\frac{\text{Domain score} - \text{minimum possible domain score}}{\text{Maximum possible domain score} - \text{minimum possible domain score}} \times 100\%$$

comparison of the quality of the CPGs produced by these 2 methods has yet to be carried out.

We investigated this issue by using 2 methods to develop guidelines for patients with asymptomatic, impacted mandibular third molars. This is an important and relevant topic for dentists,[4,10] as large interpractitioner variation has been documented.[11,12] Moreover, many publications have appeared concerning third molars.[12]

We compared 2 practitioner-oriented methods of CPG development — a local guideline development procedure and a national, structured, evidence-based panel method — to determine which yields the best recommendations and may, therefore, be used for developing other dental CPGs in The Netherlands. Outcome measures were the mean time invested by the participants, observation during group discussions and the scores on the Appraisal of Guidelines for Research and Evaluation (AGREE) list (**Box 1**), which is a validated indicator of the quality of the CPGs.

Materials and Methods

The main steps in the study are summarized in **Table 1**.

Participants

Method A — Panels using the Rand modified Delphi method of CPG development (expert panel method or top-down approach)

Two panels, each consisting of 8 general dental practitioners and 2 oral surgeons, used a structured Rand modified Delphi procedure[13–19] to develop a statement on the management of asymptomatic, impacted mandibular third molars. This method is especially useful when the literature does not supply sufficient indications for rating the appropriateness of medical procedures.[20] The panels were asked to convert their consensus statements into a CPG. A chairperson and a secretary were appointed to lead the consensus meeting and to write the CPG.

Stratification criteria for selection of the participating dentists were years of professional experience and university of graduation (Dental College of Amsterdam, Groningen, Nijmegen, or Utrecht). Stratification criterion for the oral surgeons was practice location: university medical centre or

Table 1 **Summary of study methods and information provided to the dental peer groups[a] and the expert panel groups[b], and characteristics[13] of both methods**

Step 1: Provision of materials

A literature search was conducted by the research group.[11] The results of this search, i.e., 18 publications (see **Appendix 1**) was provided to all participants, accompanied by instructions on how to read and study the articles. In addition, a description of 36 patient cases, which covered all possible clinical situations related to asymptomatic, impacted mandibular third molars, was provided.

	Method A Expert panel	Method B Dental peer group
Step 2: Development of a CPG		
Mailed questionnaires	+	
Private decisions elicited	+	
Formal feedback on group decisions	+	
Multi-professional	+	
Face-to-face contact	+	+
Interaction structured	+	
Aggregation method	Explicit	Implicit
Consensus meeting(s)	1	6
External chairperson	+	
External secretary	+	
Observation of process	+	+

Step 3: Appraisal of the 4 CPGs by an external panel, using the AGREE instrument

The time spent on each CPG method was calculated. The observations of the 2 independent observers were discussed.

[a]*Local consensus method via structured discussion*
[b]*Structured evidence-based panel method*

regional hospital. The panels were asked to develop a CPG within 6 months.

Method B — Dental peer group method of CPG development (local development method or bottom-up approach)

Two existing local dental peer groups participated in the study. A dental peer group consists of general dental practitioners (maximum 10), who attend monthly sessions during which practice-related topics are discussed as part of a national quality assurance program. The Dutch Dental Association supports dental peer groups extensively, e.g., by offering personal and financial support, feedback, courses and evaluation of results and topics.

Procedure

Cases of Asymptomatic, Impacted Mandibular Third Molars

An extensive MEDLINE search for relevant studies published between 1966 and 1999 was conducted. MeSH headings and the search terms "third," "molar," "wisdom," "tooth," "removal," "extraction," "decision," "indication" were used to locate studies related to the topic. In addition, the latest publications on the topic and relevant references found in the articles identified in the electronic search were also used. This resulted in 18 relevant articles that were independently selected by 4 researchers using explicit inclusion criteria (see **Appendix 1**).

Figure 1 depicts an information sheet for 1 of the 36 cases of asymptomatic, impacted lower third molars identified in the literature. After studying the selected articles, participants used individual assessment of these cases as a starting point for discussion. The cases have been described and evaluated elsewhere[11] and represent the entire range of impaction types.

Method A

The selected articles were sent to the expert panels in 2 batches along with instructions for reading and studying them. Six weeks after the second batch of articles was sent, the Delphi procedure was started using the 36 cases as the basis for group discussions. The results of this round were made anonymous and returned to each participant. The median of all scores[19] (from 1 to 9) of the probability that pathology would occur if the third molar were retained was calculated. For each participant, their own responses were printed in bold to facilitate comparison with those of their colleagues in the same group. All participants were asked to assess the cases again with the group results in mind. The results of this second round were again made anonymous, returned to the participants and used as the starting point for the final panel consensus meetings. The meetings resulted in 2 draft CPGs, which were sent to the members of the involved panel. The comments on this version were incorporated into a second draft version, which was again sent to the panel members. This procedure was repeated until all panel members agreed. The final draft CPG was sent to the researchers. All participants were asked to record the time they spent studying the literature, assessing the cases and preparing and participating in the consensus meeting.

Method B

The cases, articles and the same instructions for reading and studying them were presented to the members of both dental peer groups at a regular meeting. They were asked to develop a CPG within 6 months, using their usual procedure. The groups independently developed draft CPGs, which were sent to the researchers. The participants were asked to record the total time spent.

Observation

All meetings were tape-recorded (with the consent of all participants) and observed independently by 2 observers (WvdS, DM), using a structured form (**Table 2**). A microphone was placed at the centre of the meeting table and operated by the observers who were positioned outside the group. At the beginning of each meeting, a seating plan was

Female, 31 years of age

The asymptomatic, impacted mandibular third molar is partly covered by soft tissue.

A. Should this asymptomatic, impacted lower third molar be removed 0 Yes 0 No

B. Please indicate *your* assessment of the indication for removal of this third molar.

1	2	3	4	5	6	7	8	9

1 = Very low **9 = Very strong**

C. Please indicate *your* assessment of the risk of development of pathology associated with third molar.

1	2	3	4	5	6	7	8	9

1 = Very small **9 = Very strong**

D. What is *your* assessment of the risk of development of pathology with respect to the specific conditions as listed below:

Caries in the second molar	1	2	3	4	5	6	7	8	9
Root resorption of the second molar	1	2	3	4	5	6	7	8	9
Pericoronitis	1	2	3	4	5	6	7	8	9
Periodontitis	1	2	3	4	5	6	7	8	9
Cyst formation of third molar	1	2	3	4	5	6	7	8	9
Development of neoplasms	1	2	3	4	5	6	7	8	9

1 = Very low **9 = Very strong**

Figure 1: *An example of the 36 cases of asymptomatic lower third molars.*

prepared to enable identification of speakers and to examine changes in social behaviour over time. The points of observation were: behaviour (e.g., leadership, domination by forceful members, chairing strategies), organization (e.g., agenda, taking minutes, etc.), evidence (e.g., literature, tasks such as preparing a discussion about an article and summarizing its main findings) and guideline (e.g., consensus, references). Within a week after the meeting, the researchers listened to the tapes in conjunction with their transcripts and field notes, discussed and combined their observations into 1 final report of the meeting. After all groups had finished their discussion rounds, observations were combined into an overall report.

Appraisal of the Draft CPGs

The 4 guidelines were assessed independently by 4 senior researchers, using AGREE, an internationally validated instrument for the appraisal of guidelines.[1] The CPGs were presented in a different order to each of the 4 appraisers to prevent confounding of the appraisal process by sequence. The resulting domain scores were selected as an indicator of the quality of the CPGs.[1]

Data Analysis

For each method, the mean time invested per participant was calculated. Quality scores were calculated for each AGREE domain for all 4 CPGs and were represented as a percentage of the maximum possible score for that domain.[1] The qualitative findings of the 2 observers were tabulated.

Results

Both panels submitted their draft CPG before the deadline. One dental peer group required 1 reminder, and the other dental peer group received 2 reminders. Finally, 3 months after the deadline, all draft CPGs were available for appraisal. All groups changed the number of age categories from 3 to 2 and used the 36 cases to structure the discussion. **Figure 2** presents an outline of the recommendations of the 4 groups. The CPGs of the 2 panels contained similar recommendations and advised the prophylactic removal of asymptomatic, impacted mandibular third molars in 3 specific situations. The CPGs of the dental peer groups contained recommendations that were somewhat different from each other and recommended the removal of an asymptomatic, impacted mandibular third molar in 8 and 9 specific situations. The quality scores for each domain of the CPGs are presented in **Table 3**. **Table 4** shows the mean time spent per participant and the time needed to write the CPG. **Table 2** summarizes the observations.

Discussion

The main finding of this study is that good quality CPGs can be obtained through a systematic and structured procedure, such as the Rand modified Delphi method. This

Table 2 **Recorded observations of the 2 independent observers**

	Method A		Method B	
	Expert panel 1	**Expert panel 2**	**Peer group 1**	**Peer group 2**
Chairperson				
Chairing skills	Good	Good	Poor	Poor
Chairperson	Competent	Competent	Changing chairs	Informal
Participation in discussion	No	No	Yes	Yes
Dominance of chairperson	No	No	Moderate	No
Chairperson summarizes	Yes	Yes	Depends on chair	Sometimes
Organization				
External advisors used	No	No	No	No
Taking minutes	Secretary	Secretary	Group member	Group member
Agenda	Structured	Structured	Sometimes	Sometimes
Structured discussion	Yes	Yes	Most of time	Most of time
Task orientation	Good	Good	Poor/social talk	Poor/social talk
Group processes				
Unproductive discussion	None	None	Very often	Very often
Dominance by (forceful) individuals	No	No	Moderate	Moderate
Open discussion	Partly	Partly	Partly	Partly
"Follower" (does not participate in discussion)	Yes	Yes	Yes	Yes
Full participation in discussion	Yes	Yes	No	No
Intention to reach consensus	Yes	Disputable: 1 oral surgeon	Yes	Yes
Consensus reached	Yes	Yes	Yes	Yes
Voting by disagreement	Yes	Yes	No	No
Evidence				
Literature read	Yes	Yes	Dubious	Dubious
Literature referred to	Partly	Partly	Partly	Partly
Formulation of points of discussion	Yes, by chairperson	Yes, by chairperson	Yes, by referent	Yes, by referent
Practice situation considered in formulation of CPG	Yes, but evidence from literature more important	Yes, but evidence from literature more important	Yes, main part of CPG	Yes, main part of CPG
CPG				
Description of group results	Partly	Partly	Partly	Partly
Use of references	Partly	Partly	None	None
Agreement of all participants	No (oral surgeons partly disagreed)	No (oral surgeons partly disagreed)	Unknown, but assumed	Unknown, but assumed

is consistent with studies in the area of medicine, which showed that CPGs produced by specialist societies were lower in quality than CPGs developed by major agencies following a structured development program.[21]

The time investment for the 2 methods did not differ much (**Table 4**), but the quality of the CPGs did (**Table 3**). The domain scores, as indicators of the quality of the CPGs, are not meant to differentiate between "good" and "bad" CPGs,[1] but to provide information about the procedure followed and, consequently, the quality of the product. The dental peer groups spent a substantial part of the total development time in group meetings; the members of the panels required more time to study the literature. This may partly explain the differences in the quality of the CPGs. With comparable time investment, the expert panels produced better CPGs than the dental peer groups.

Our results suggest that the expert panel method was more robust than the dental peer group method (**Table 2**). This is associated with differences in the performance of the chairperson, the organization of the meeting and the reading and use of literature by the expert panel members. Moreover, the expert group only met once, whereas the peer groups convened several times. From the observations, we found that the members of the peer groups tended to rely more on their colleagues in the group than did the expert panel members. This may influence group processes and behaviour of participants and, therefore, affect the outcome.

The use of multidisciplinary panels, with representatives of all relevant health care groups and patients, has been recommended for developing CPGs.[1] In this study, none of the groups contained representatives of patient associations. Patients may have distinctly different opinions about the prophylactic removal of asymptomatic, impacted third molars than general dental practitioners and may not support the removal of these molars. Their absence might have affected the recommendations in the 4 CPGs.

Age	Younger than 25–30 years			Older than 25–30 years		
Position \ Type of impaction	Partly covered by soft tissue	Completely covered by soft tissue	Completely covered by soft tissue and by bone	Partly covered by soft tissue	Completely covered by soft tissue	Completely covered by soft tissue and by bone
Vertical 	2			2		
Horizontal 	1, 2, 3, 4	1		1, 2	1	
Mesio-angular 	2, 3, 4			1, 2	1	
Disto-angular 	1, 2, 3, 4	1		1, 2		

Figure 2: *Recommendations made in the CPGs by the local dental peer groups (1,2) and the expert panels (3,4) to remove asymptomatic, impacted mandibular third molars.*

Table 3 Domain scores for the 4 CPGs as standardized percentages (the domain "editorial independence" is not included, as all panels were completely independent from funding)

CPG group	Scope and purpose (%)	Stakeholder involvement (%)	Rigor of development (%)	Clarity and presentation (%)	Applicability (%)
Method A					
Expert panel 1	83	42	62	54	25
Expert panel 2	86	46	55	58	6
Method B					
Peer group 1	31	13	5	23	0
Peer group 2	58	31	35	40	3

Table 4 Mean time spent in preparing the 4 CPGs, including travel time per participant and group and the time needed to write the CPG

CPG group	Mean time per participant; h (SD)	Secretary; h	Chairperson; h	Writing CPG; h
Method A				
Expert panel 1	22.7 (2.1)	8	24	15.5
Expert panel 2	22.6 (3.0)	8	19.5	14
Method B				
Peer group 1	20.9 (3.4)	None	None	10
Peer group 2	20.3 (0.3)	None	None	16

SD = standard deviation.

The 4 groups were unanimous in their recommendation to remove a lower third molar in 2 out of 24 cases, and to retain the third molar in 12 cases (**Fig. 2**). The dental peer groups recommended prophylactic removal of third molars in more cases than the expert panels. These recommendations disagree with the evidence from literature. Moreover, the recommendations of 1 dental peer group (number 1) were ambiguous. It recommended the removal of mesio-angular impacted third molars that are completely covered by soft tissue, but only in the group older than 25–20 years of age. However, the literature does not recommend this course of action. Also these findings indicate that dental CPGs may be better developed within a structured and coordinated program, such as the expert panel method.

It was interesting to observe divergent opinions among the oral surgeons regarding the indication to remove asymptomatic, impacted mandibular third molars; they were more likely to advise a prophylactic removal then the general dental practitioners. This may be partly explained by the differences in patient populations seen by general

dental practitioners and oral surgeons, as the latter merely see referred patients with symptomatic third molars. Their clinical expertise will be influenced by the high frequency of third-molar related pathology. This aspect is important and needs attention in the development of future CPGs, as experts may also have other conflicts of interest in their area of specialty. The use of multispecialty panels could prevent bias in the formulation of the recommendations of a CPG.[21]

Quality of dental care has numerous aspects, and reduction of large interpractitioner variation is an important issue.[5,11] The CPGs developed by the local dental peer groups might be user-friendly and could establish ownership more effectively, but they are unlikely to reduce interpractitioner variation. These CPGs were not unambiguous in their recommendations. Moreover, the "applicability" (**Table 3**), which refers to the effectiveness of guidelines in daily practice, was not any higher for the CPGs developed by the dental peer groups than that for the CPGs developed by the expert panels. This suggests that CPGs developed by local peer groups may not improve the quality of dental care.

At the time this study was conducted, other international organizations had also started to develop evidence-based CPGs for the management of third molars[22,23]; these resulted in different recommendations. As has been shown, the same scientific evidence may sometimes lead to conflicting or different recommendations,[1] possibly as a result of national, local or cultural factors. However, the recommendations from the expert panels only differ minimally from these 2 CPGs from outside this study, and from each other, strengthening the recommendation to use the expert panel method for developing CPGs on a national level.

Consensus development is a process for making policy decisions, not a scientific method for creating new knowledge.[13] It might make the best use of the available information, i.e., literature or the collective knowledge of the participants. In this study, a chaired, prepared, structured discussion among the members of expert panels resulted in more evidence-based recommendations compared with those of the dental peer group. Although they were provided with appropriate literature, the dental peer groups merely described their common practice in their CPGs. Furthermore, the peer groups were unable to indicate the level of evidence of their recommendations or cite referenced literature.

Developing high-quality CPGs requires a sufficiently skilled team and an adequate budget.[1] In general, dental peer groups, which work on a voluntary basis, will not have large financial resources and this might also explain why their CPGs scored lower in terms of quality. Nevertheless, if these groups were encouraged to apply a structured procedure, they could have great potential for modifying nationally developed CPGs and implementing CPGs within a region.

In several other countries, robust methods for the development of national dental CPGs have been established. In Canada, for example, the Canadian Collaboration on Clinical Practice Guidelines in Dentistry uses a hybrid procedure.[8] The CPGs are based on systematic reviews and also include values and preferences of patients and practitioners. However, this is a costly, time-consuming method,[24] whereas the methods described in this study are moderate to low in cost. Good-quality systematic reviews are still scarce in dentistry. The Oral Health Group of the Cochrane Collaboration has become increasingly active over the past few years in providing the dental profession with high-quality systematic reviews in many areas of oral health care.[25] Unfortunately, a Cochrane or other systematic review of the management of patients with asymptomatic, impacted mandibular third molars was not available at the time of this study.[26] However, in areas in which uncertainty exists, such as the topic in this study, formal consensus is a well-accepted method for developing guidelines,[13,20] as this approach combines research findings from published literature and information obtained from clinical experience.[27]

Within the limitations of this study, it can be concluded that the expert panel method is suitable for developing reliable CPGs on a national or regional level. ➧

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