Family Practice, 2018, Vol. 35, No. 4, 475–480
doi:10.1093/fampra/cmx134
Advance Access publication 29 January 2018

OXFORD

Health Service Research

International definition of a point-of-care test in family practice: a modified e-Delphi procedure

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Abstract

Background: The use of point-of-care tests (POCTs) in family practice is increasing, and the term POCT is often used in medical literature and clinical practice. Yet, no widely supported definition by several professional fields exists.
Objective: To reach consensus on an international definition of a POCT in family practice.
Methods: We performed a modified international e-Delphi procedure of four rounds among expert panel members from different professional backgrounds—family practitioners, laboratory specialists, policymakers, researchers and manufacturers.
Results: Of 27 panel members from seven different countries, 26 participated in all rounds. Most panel members were active in POCT research or policymaking and 70% worked in family medicine. After choosing important components, structuring of answers and feedback, the following definition was chosen as the best or second best definition by 81% of panel members: a point-of-care test in family practice is a test to support clinical decision making, which is performed by a qualified member of the practice staff nearby the patient and on any part of the patient's body or its derivatives, during or very close to the time of consultation, to help the patient and physician to decide upon the best suited approach, and of which the results should be known at the time of the clinical decision making.
Conclusion: The definition emerging from this study can inform family practitioners, laboratory specialists, policymakers and manufacturers on the most widely supported and recognized definition and could act as a clear starting point for the organization and execution of professional point-of-care testing in family practice worldwide.

Key words: Definition, Delphi procedure, family practice, general practice, point-of-care testing.

Introduction

The term point-of-care test (POCT) is often used throughout the medical literature and in clinical practice. In family practice, in particular, POCTs are increasingly used and wanted by physicians to assist clinical decision making (1). There are various definitions and alternative names that have been used for a POCT (2). Yet no widely supported and recognized international definition of a POCT in family practice exists. Differences in definitions may lead

to misconceptions and confusion, especially since those working in family practice may define a POCT differently from those coming from a laboratory background.

A suitable approach for seeking consensus on a definition is the Delphi technique, in which a series of questionnaires is used to collect data from a panel of selected experts. This technique uses multiple iterations designed to develop a consensus of opinions concerning a specific topic. The controlled feedback process allows and encourages the selected panel members to reassess their initial judgements, while doing this without the direct influence of other panel members, as anonymity and confidentiality are facilitated by the research team (3,4). In this study, we performed a modified e-Delphi procedure to reach consensus on an international definition of a POCT in family practice, supported and recognized by those professions working with POCTs in family practice.

Method

Participants

We compiled an international expert panel using purposive sampling combined with the quota and snowball method (5); the research group compiled an international list of potential panel members (purposive sampling) and we asked all potential panel members who responded to our invitation to provide the name of another potential panel member (snowball method). We purposely aimed to include panel members from four different fields (quota method): (i) family practitioners directly involved in POCT research or policymaking (35%); (ii) family practitioners without special involvement in point-of-care testing (35%); (iii) laboratory specialists (15%) and (iv) manufacturers of POCTs (15%). In total, we invited 40 potential panel members via a personal e-mail, aiming to include about 25 to 30 panel members to be able to have at least three panel members representing their field.

Data collection and analyses per round

We performed four rounds of an online questionnaire—each questionnaire based on the analysis of the previous round—starting with a completely open questionnaire, supplemented with some questions on personal characteristics, followed by an increasingly more specific questionnaire. We allowed panel members the opportunity to write down free comments in each round. We piloted all questionnaires by asking at least two family physician trainees to fill out the questionnaires—checking if all instructions and questions were clear—and adjusted the questionnaires when needed. At the start of every round, panel members were given feedback on the previous round. We aimed for an agreement proportion of 80% by the last round (6,7). Data of each round were analysed by three researchers (AS, GD, JC). Quantitative and qualitative data analyses were discussed in a consensus meeting, in which decisions—based on the analysis—were made for the next round. When discussion points remained, the other co-authors were asked to comment on these points. We used Survey Monkey to distribute the questionnaires. After the last round, an English language expert evaluated the final definition to provide possible language-related suggestions for the definition as a whole.

Round 1 (divergence)

We wanted to explore ideas for different components of the definition. As a framework we used the W5H1 Kipling problem-solving model (8), asking respondents open questions on the 'who, what, where, when, why and how' of a POCT and providing one common example per question from the literature. Hence, we performed a modified e-Delphi procedure (9). We asked all panel members to give their best answer to the questions, provide any relevant alternatives and add any relevant questions we might have missed.

During the analysis of this round, we organized and discussed all suggested answers, after which we clustered and excluded answers if necessary. Excluded answers were misspellings or general remarks given by the respondent not related to that particular question.

Round 2 (convergence)

We aimed to determine which components from the first round should be included in the final definition and which descriptions per component were preferred. The questionnaire consisted of one main question per component; each question consisting of a long list of possible descriptions. Possible descriptions were arranged according to the frequency of the answers given in the previous round and/or by logical order. We asked panel members to carefully read all descriptions, choose the best description and indicate the importance of a specific component being part of the final definition, on a scale of 1 to 5 (1 being not important – 5 being very important).

At the end of this round, we included all components that were considered by at least 80% of the panel members to be at least moderately important (≥3). If this percentage was not met, we performed a qualitative analysis of the chosen answers and free comments to confirm that the component should not be included in the definition. With regard to the different descriptions per component, any option that was chosen by more than 25% of respondents was included in the third questionnaire. Other descriptions were only included after qualitative analyses of the answers and comments.

Round 3 (convergence)

We wanted to reach consensus on which description per component best fitted the definition. We again asked panel members to choose the best option out of two or three possible descriptions most often chosen by the panel in the second round. All the most frequently chosen answers were added to the possible definitions of round 4. When the quantitative data were not convincing, the qualitative data were used to make a final decision or both descriptions were added in the candidate definitions.

Round 4 (convergence)

We presented four candidate definitions. We asked the panel members to grade these possible definitions on a scale of 1 to 10 (<6 being insufficient, 6–7 sufficient, 8–9 good and 10 excellent) and to prioritize the four definitions based on their preference. We combined the analysis of the individual grades and ranking of definitions as well as the free comments, to assess if one of the definitions would be preferred by at least 80% of the panel.

Results

Participants

In total, 27 panel members from seven different countries—the Netherlands, USA, Belgium, Germany, UK, Australia and Finland—were included in this Delphi study. Seven (26%) participants were included via snowballing. About two-thirds of the panel members were active in POCT research or policymaking. Nineteen (70%) participants were active in family medicine, of which about 60% were active in POCT research or policymaking. Eight (30%) participants were active in other fields like laboratory medicine and POCT development. The panel consisted of seven females, the average age was 50 years, and on average they had 20 years of working experience. In the second round one person dropped out, because he moved to another position within his company. We performed the four Delphi rounds between October 2015 and August 2016.

Round 1

On average, 53 answers (range 35–67) per question were given. All answers were carefully discussed by our research team and most answers were included in the second questionnaire unchanged. To reduce the list of possible options per question, we clustered a few very similar answers and excluded a small number of answers; for example, we clustered the answers 'before visit' with 'before consultation' and 'bodily fluid' with 'body fluids'. After discussion with all co-authors, we decided to not add any extra questions in the second round.

Round 2

Table 1 shows the most important results of the second round. The components 'Where should the test NOT be performed and analysed?' and 'How should the test results be fed back to the user of the test?' were not included in the next round, as only 77% (<80%) of panel members considered these components at least moderately important to be included. Qualitative data supported the exclusion of these elements (Table 1). With regard to the question 'When should the results be known?', panel members convincingly preferred the answer 'at the time of clinical decision making'. This element was included in the candidate definitions of the last round.

Round 3

Table 2 shows the quantitative results of round 3. The following answers to the 'what, whom and why questions' were most frequently chosen and included in the definition of the last round: 'any part of the body or its derivatives', 'by any qualified member of the medical staff', 'to support clinical decision making'. Some comments were made about the element 'medical staff'. After consideration of these comments and advice from a linguist, 'medical staff' was replaced by 'practice staff', as this better reflected the most chosen answers in all rounds. The preferred answers to the 'where and when questions' were less convincing, and, therefore, candidate definitions were made for both answer options.

Round 4

Table 3 shows the candidate definitions of round 4 and a summary of the responses. Three of four definitions were considered sufficient by at least 88% of panel members and one definition insufficient by more than 20% of the panel. The final definition, see Box 1, was chosen

Table 1. Summary of the qualitative and quantitative results of Delphi round 2 on the definition of a point-of-care test performed in 2016 (January–March)

Component	Percentage whom considered this component to be at least moderately important to be included and most important qualitative comments	Most frequently chosen answer(s)
1. On what entity/elements should the test be performed?	85%; - Replace it's by its - Also include (exhaled) breath	- Blood, urine, saliva, sputum, faeces - Any element/part of the body or it's derivatives/secretions
2. By whom should the test be performed?	81%; - Add qualified or authorized	- Authorized medical professional - By any member of the medical staff (physician, nurse, auxiliaries)
3. Where should the test be performed and analysed?	92%	- Nearby the patient/near patient side/next to the patient - In any room/premises where there is sufficient hygiene and safety precautions for the patient and the POC tester
4. Where should the test NOT be performed and analysed?	77% (<80%); Also qualitative analysis supported the exclusion of this component, e.g. the most frequently chosen option was 'in situations negatively affecting the reliability of the outcome', which overlapped with the most frequently chosen option of component 3. Also free comments confirmed that this component could better be excluded, e.g. 'There is an overlap with element 3. There are too many options to exclude…'.	Not included in definition
5. When should the test be performed?	92%; - Combine both components in one option and add 'and physician' in the second part of this component (comment). - For the component 'at the time of the clinical decision making' also see component 6.	- During or very close to the time of the consultation - When it helps the patient to get the answer required to take the best suited action
6. When should the result be known?	96%; - For the component 'during consultation' also see component 5.	- At the time of clinical decision making
7. Why should the test be performed (expectations of test)?	92%; - 'To support' might be better than 'to inform' (comment).	- To inform clinical decision making - Exclude or confirm diagnosis, assess disease severity, monitor disease or therapy
8. How should the test results be fed back to the user of the test?	77% (<80%); Also qualitative analysis supported the exclusion of this component, e.g. most frequently chosen option 'depends on the test…' added nothing of interest to the definition, and comments like 'doesn't matter…', 'this really depends on what you are testing', 'many options are quite fine…' made by respondents supported this decision.	Not included in definition

Table 2. Summary of the quantitative results of Delphi round 3 on the definition of a point-of-care test performed in 2016 (March–June)

On what entity/elements should the test be performed?	
any part of the body or its derivatives	**76.92%**
blood, urine, saliva, sputum, faeces, (exhaled) breath	23.08%
By whom should the test be performed?	
by any member of the medical staff	19.23%
by any *qualified* member of the medical staff	**80.77%**
Where should the test be performed and analysed?	
in any room where there is sufficient hygiene and safety precautions	23.08%
nearby the patient	**30.77%**
nearby the patient in a room where there is sufficient hygiene and safety precautions (combination of the two answers above)	**46.15%**
When should the test be performed?	
during or very close to the time of the consultation	**50.00%**
during or very close to the time of the consultation, when it helps the patient and physician to the answer required to take the best suited action	**50.00%**
Why should the test be performed (expectations of test)?	
exclude or confirm diagnosis, assess disease severity, monitor disease or therapy	38.46%
to inform clinical decision making	61.54%
to *inform* clinical decision making	30.77%
to *support* clinical decision making	69.23%

Bold values: these descriptions were included in the candidate definitions.

Table 3. Quantitative results of the preference of four candidate definitions; Delphi round 4 on the definition of a point-of-care test performed in 2016 (June–August)

Definition	Panel members considering this definition as the best or second best definition	Median grade (range)
A test to support clinical decision making in family practice, that is performed by any qualified member of the practice staff, during or very close to the time of the consultation, nearby the patient and on any part of the patient's body or its derivatives, and of which the results should be known at the time of the clinical decision making.	54%	8 (4–10)
A test to support clinical decision making in family practice, that is performed by a qualified member of the practice staff, during or very close to the time of consultation, and nearby the patient *in a room where there is sufficient hygiene and safety precautions*, on any part of the patient's body or its derivatives, and of which the results should be known at the time of the clinical decision making.	15%	7 (4–10)
A test to support clinical decision making in family practice, that is performed by a qualified member of the practice staff, nearby the patient and on any part of the patient's body or its derivatives, during or very close to the time of consultation, *when it helps the patient and physician to an answer required to take the best suited action*, and of which the results should be known at the time of the clinical decision making.	81%	8 (5–10)
A test to support clinical decision making in family practice, that is performed by a qualified member of the practice staff, nearby the patient *in a room where there is sufficient hygiene and safety precautions*, on any part of the patient's body or its derivatives, during or very close to the time of consultation, *when it helps the patient and physician to an answer required to take the best suited action*, and of which the results should be known at the time of the clinical decision making.	50%	8 (4–10)

as the best or second best definition by 81% of the panel and was considered sufficient by 88% with a median grade of 8 (range 5–10).

Discussion

Summary

With a multidisciplinary international panel of POCT experts consisting of family practitioners, laboratory specialists, policymakers, researchers and manufacturers, we reached consensus on a widely supported and recognized international definition of a POCT in family practice, with 88% of panel members considering this definition sufficient with a median grade of 8: a POCT in family practice is a test to support clinical decision making, which is performed by a qualified member of the practice staff nearby the patient and on any part of the patient's body or its derivatives, during or very close to the time of consultation, to help the patient and physician to decide upon the best suited approach, and of which the results should be known at the time of the clinical decision making.

BOX 1: Final definition of a point-of-care test in family practice.

A point-of-care test in family practice is a test to support clinical decision making, which is performed by a qualified member of the practice staff nearby the patient and on any part of the patient's body or its derivatives, during or very close to the time of consultation, to help the patient and physician to decide upon the best suited approach, and of which the results should be known at the time of the clinical decision making.

Strengths and limitations

This is the first study that developed a widely supported and recognized international definition among expert panel members from different professional backgrounds, all involved in point-of-care testing in family practice. Even though the diversity in the panel made it more difficult to reach agreement on the best definition, it was important to evaluate the ideas of all professionals involved because of the multidisciplinary nature of point-of-care testing. The dropout rate was low, with only 1 in 27 panel members dropping out before the last round. Although the Delphi technique is prone to influences of the researcher, we tried to reduce this by analysing the results in a team of at least three researchers, and if in doubt by all co-authors, to ensure that the data were interpreted as objectively as possible.

A limitation of this study might be the framework for the questionnaire in the first round, which was based on a general problem-solving model. We initially piloted a first Delphi round based on different components of definitions found in the existing literature. However, during pilot testing it proved difficult to have an open first round to explore additional options for the definition. Therefore, we chose to have a completely open first round. This made it more complicated to strictly follow the rules of the Delphi technique when aiming for consensus in four rounds. Furthermore, differences in languages across healthcare systems sometimes proved challenging and not all panel members were native English speakers. Therefore, some minor alterations by the research team and an English language expert were necessary.

Comparison with existing literature

In daily clinical practice and medical literature, many alternative names for a POCT exist. However, these alternative names might lead to confusion as to what in essence sets a POCT apart from any other test, as it is not the speed (rapid test), or the location (at the bedside, near the patient), or the aspect of the device (handheld or not) that differentiates a POCT from other tests. It is in fact the immediate influence of the test result on the clinical decision making during the consultation that sets it apart. The same kind of confusion is seen in the definition of a POCT in the literature. Definitions range from mainly defining the location where the test is being performed, 'any pathology testing performed outside a hospital laboratory where the result is available without the sample being sent to a laboratory for analysis' (10), to defining its role in the clinical decision making of the doctor, 'any test taken by or on behalf of the treating doctor on-site at the time of consultation that allows the test result to be used to make immediate decisions about patient treatment' (11). During this Delphi procedure, we reached agreement on all relevant aspects of the definition.

Implications for research and practice

With the increasing use of POCTs in the past few decades, many point-of-care testing guidelines have been published (2). Recently, a Dutch multidisciplinary working group on point-of-care testing in family practice suggested in its guideline that it is important to consider point-of-care testing as a process, in which all elements of the chain—including indication, execution, interpretation, documentation and follow-up—need to be taken into account (12,13). So, although the definition of a POCT in this study is clear as to what test should be considered a POCT, the process of point-of-care testing entails a broader multidisciplinary concept.

Several considerations are important with regard to this process. First of all, before implementation, the clinical need for a POCT should be assessed, different devices should be evaluated for quality and a clinical diagnostic pathway should be developed to prevent misuse and overuse. When using a biochemical or biophysical POCT, a quality management system should be implemented. Responsibility and accountability need to be discussed with all professionals involved. As also described in the final definition of this study, adequate training and certification—including basic health and safety issues and standard operating procedures—are important to make sure that the user of a POCT is qualified to adequately and safely use a POCT. It is vital that results of a POCT are clearly documented and connectivity with GP patient record systems should aid correct documentation. Family practices using a POCT should participate in appropriate internal quality control and external quality assurance to make sure that the test outcomes are precise and accurate (2,14–19). Cooperation with medical laboratories and manufacturers is important to support family practitioners in the implementation of point-of-care testing, training and certification of staff and to ensure quality control and device maintenance.

Conclusion

With the increase of POCTs in family practice, it is important to have a clear definition of a POCT that is supported and recognized by all professional fields involved in the use and development of POCTs. Such a definition informs stakeholders as to how a POCT can be part of a clinical diagnostic work-up of a patient. In so doing, it can help researchers and manufacturers in the design of a POCT, and family practitioners and patients in regard to expected clinical, process and economic outcomes. It is important to realize that the benefit of a POCT is only achieved if the test result is known and acted upon at the time of the clinical decision making. The definition emerging from this Delphi study can inform family practitioners, laboratory specialists, policymakers, researchers and manufacturers on the most widely supported international definition and could act as a clear starting point for the organization and execution of professional point-of-care testing worldwide.

Acknowledgements

The authors thank all experts who participated in the Delphi study and all family physician trainees who assisted in piloting the questionnaires.

Declaration

Funding: This work was supported by a Veni-grant, assigned to JWLC (91614078), of the Netherlands Organisation for Health Research and

Development (ZonMw). In the case of CPP, this article presents independent research funded by the National Institute for Health Research (NIHR) Diagnostic Evidence Co-operative Oxford. The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health. The study sponsors had no role in the design, analyses or reporting of the study. The researchers retained complete independence in the conduct of this study.
Ethical approval: Ethical approval for this study was obtained from the Medical Ethics Committee of Maastricht University in the Netherlands (METC 14-4-199).
Conflict of interests: None.

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