|

Development of the Principles of Evidence-based Reporting in Forensic Medicine (PERFORM) Guidelines

STUDY PROTOCOL

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# Background

Forensic medicine is a branch of medicine that uses medical knowledge and technology to assist the law and inform legal proceedings1,2. It plays an important role in processing and interpreting raw physical evidence gathered from medical and other forensic investigations resulting in an expert opinion suitable for presentation to a judicial fact finder. The results of a forensic medical investigation are usually presented in the form of an expert opinion, which serves to assist legal proceedings by helping fact finders understand the significance of physical evidence in cases involving the injury or death of a human being3. There are several methods and means commonly used to formulate forensic expert opinions, such as the use of evidence-based medicine principles, literature review, databases, experience, physiologic and pathologic principles, and common sense.

Despite the important role of forensic medical expert opinion in the justice system, the methods used in formulating such opinions are not always evidence-based, or based on standardised methods. A number of authors have reported that many experts in forensic medicine currently rely more on experience and individual customary practices in formulating their expert opinion than on evidence-based practices4. Furthermore, operational principles and procedures used by forensic experts in formulating expert opinions, have not been standardised and therefore may vary greatly in terms of content and quality between experts and centres5,6. Additionally, there is still some scepticism about the use of evidence-based medicine, including epidemiological data and methods, in formulating expert opinions in legal proceedings7. This situation poses a danger to the justice system because misleading8, or unreliable expert opinion, which cannot be readily recognised as such by fact finders can lead to the conviction of an innocent person or the acquittal of a guilty perpetrator. In many cases, expert opinions (whether given verbally or written) play an important role in forming the judge’s conviction. Therefore, it is of the utmost importance that expert opinions are formulated and expressed using evidence-based practice (EBP), based on best available physical and clinical evidence, and reported in a standardised fashion.

Current practice in expert opinions formulation is, however, not always evidence-based. In other words, it does not use the integration of best available clinical and scientific evidence with professional expertise and patient values, which are applied in everyday practice9,10. In addition, the methodology with which expert formulate their opinions is not always transparent. Experts usually use various approaches to justify their opinion, which are not always clear to the readers of the reports, thereby making judgement on their value in a particular case difficult. Moreover, experts in forensic medicine often rely on their personal experience alone, or what has been taught to them during their education, sometimes decades ago. This experience-based practice could affect the validity and reliability of their expert opinion in legal proceedings due to their lack of personal experience in handling cases with similar circumstances, lack of scientifically-sound clinical evidence on which they base their expert opinion, or random error.

To overcome that problem, efforts have been made to make scientific expert opinions in legal proceedings more admissible, e.g. the Daubert standard and the Frye test. Another endeavour is the emergence of a new discipline called Forensic Epidemiology (FE). Basically, FE utilises epidemiologic methods and data to formulate probabilistic conclusions about the type and quantity of specific causality between an antecedent and an outcome regarding individuals in a legal or forensic setting11. In other words, FE aims at determining the specific causation in a particular case using best available epidemiologic data. This can be achieved by using data from medical research in a population, and applying them to the individual case at hand to increase the scientific accountability of an expert opinion.

To date, no attempts have been made to develop an international guideline to standardise reporting in forensic medicine. Thus, this research project aims at developing evidence-based reporting guidelines in forensic medicine using FE principles. These guidelines will be dubbed “The Principles of Evidence-based Reporting in Forensic Medicine (PERFORM) Guidelines” and will be accompanied by an explanation and elaboration document (the E&E).

# Terms in this Protocol

##### Evidence-based practice (EBP)

Integrating best research evidence, clinical expertise, and patient values by formulating a clinical question, searching for and critically appraising evidence, applying evidence into practice, and evaluating the previous steps to achieve self-improvement9.

##### Forensic medicine

A branch of medicine that uses medical knowledge and technology to assist the law and inform legal proceedings1,2.

##### Forensic epidemiology

The utilisation of epidemiologic methods and data to formulate probabilistic conclusions about the type and quantity of specific causality between an antecedent and an outcome regarding individuals in a legal or forensic setting11.

##### Delphi consensus process

A group communication process to achieve convergence of expert opinion on a specific issue using iterative data collection12.

##### Research team

The research team consists of DIM, as the Principal Investigator (PI), who is conducting this study as part of a doctoral program at the Faculty of Health, Medicine and Life Sciences, Maastricht University. She is supported by her supervisors (MPZ, MDF, and H).

Steering committee

The Steering Committee consists of the Research Team and several internationally acclaimed experts in the field of Forensic Medicine, Epidemiology, or Law, who will also act as co-authors.

##### Participants of Delphi consensus process

The participants of the Delphi consensus process consist of international forensic medical specialists, forensic epidemiologists, EBP experts, as well as consumers of forensic medical expert opinions, such as police investigators, lawyers, public prosecutors, and judges. These participants of the Delphi will be mentioned in the acknowledgement of the papers.

##### Forensic medical reports

Written reports produced by experts in forensic medicine, which consist of a description of objective findings and an expert opinion formulated based on the findings. They are used to facilitate legal decision making in a specific case, by answering specific questions concerning identification, sustained injuries/pathologies, and causation.

# Methods

This study will be conducted in three phases, which are modified from the recommended steps for developing reporting guidelines in the fields of clinical and public health13:

1. To develop a long-list of items to be considered in the reporting guidelines through systematic surveys,
2. To conduct a Delphi study with international experts to obtain a consensus on the minimum items to be included in the reporting guideline,
3. To conduct a face-to-face consensus workshop to finalize the design of the reporting guideline and its accompanying manual, and to disseminate the results.

## Phase 1: Development of long-list of candidate items

The purpose of phase 1 is to develop a long-list of candidate items that could potentially be incorporated in the reporting guideline. This long-list will serve as input for the Delphi process. The prospective items will be collected from a systematic survey of existing forensic medical reports and a survey among experts.

### Systematic review of existing forensic medical reports

The aim of this step is to determine how expert opinions in forensic medicine have been or are being reported. The study will be based on a random selection of 150 anonymised forensic medical reports. The reports will be identified by searching forensic reports that are publicly available on websites, such as <http://www.autopsyfiles.org> and <https://www.archives.gov>. Additional reports will be identified through manual selection of non-electronically recorded reports produced in Indonesian academic centres of forensic medicine from 2011 – 2015. Data to be extracted from these reports are shown in the table below.

**Proposed data extraction sheet**

|  |  |  |
| --- | --- | --- |
| Domain | Information | Example |
| Administrative | Identification of case and examiner | Case registration number, name of examiner |
| Identification | Identification of examinee | Name and date of birth of examinee |
| External/physical examination | Findings from external examination/physical examination | Physical features, injuries |
| Internal examination | Findings from internal examination (if performed) | Description of internal organs, haemorrhage |
| Ancillary testing | Findings from ancillary testing (if performed) | Result of toxicology test, histopathology |
| Additional information | Information from police report, medical record, literature review, data-bases etc | Findings at the crime scene, ECG records |
| Opinion | Opinion from examiner regarding the case | Opinion on cause and time of death |
| Justification of opinion | Method with which the expert formulated his/her opinion | Analysis of findings, result of literature review |

After data extraction has been completed, a descriptive analysis of the data will be performed. The analysis will include which items have been reported in each domain and how often the items have been reported. In addition, a narrative synthesis of the domains in the included studies will be described. As a summary, a list of reported items that were mentioned more than once from all included reports will be compiled and put into the long-list of candidate items to be considered in the Delphi process.

### Survey of Experts

This survey will be conducted using two methods. First, a paper-based questionnaire will be distributed during the National Congress of the Indonesian Forensic Medical Doctors Association (*Perhimpunan Dokter Forensik Indonesia*/PDFI), which will be held in May 2016 in Bandung, Indonesia. This annual congress is attended by 150 – 200 forensic medical specialists from all centres in Indonesia, and will also be attended by international experts in Forensic Medicine and Forensic Sciences. This congress is chosen because it is the largest gathering of forensic medical specialists that is accessible to the research team and is the timeliest. Second, it will also be conducted through a web-based questionnaire (using Qualtrics©) that will target international experts in forensic medicine. The invitation to participate in the questionnaire will be sent through email.

Participants will be asked to fill a questionnaire which gathers data as outlined in Annex 1. Before being used in this study, the questionnaire will be piloted by 5 specialists in forensic medicine with varying background. The testers will be asked to provide feedback regarding the scope and content of the questions, their ability to understand the wording of the questions, their level of interest towards the questionnaire, the usefulness of the questionnaire to answer the research questions, and the amount of time necessary to answer the questions properly. The suggestions from the testers will be used to revise the questionnaire, if necessary.

Data from the survey will be analysed using SPSS® Statistics version 17.0. Data analysis will consist of descriptive statistics of categorical, numeric, and free-text data. Categorical data will be presented as absolute numbers, frequencies, and proportions, whereas numerical data will be presented using mean and standard deviation. Free-text answers from the questionnaire will be described and summarised using narratives. The results of the analysis will consist of the following:

* + Outcome 1: Participant demographics and characteristics
  + Outcome 2: Case load and case types handled by experts in forensic medicine
  + Outcome 3: Current practice in the formulation and reporting of forensic medical expert opinions
  + Outcome 4: Participants’ perception regarding and attitude towards evidence-based practice and the perceived need for evidence-based reporting guidelines in forensic medicine
  + Outcome 5: A refined long-list of items that participants think should be described in expert opinions

At the end of phase 1, the prospective items collected from the survey of expert opinion and the survey of experts will be extended with recommendations from the steering committee and compiled in a long-list of items to be considered in the Delphi process. These will include a heading and description, similar those in existing reporting guidelines of clinical research.

## Phase 2: Delphi consensus process

### Design and setting

A Delphi process will be conducted according to the description provided by Hsu et al12 and the checklist recommended by Sinha et al14 and Hasson et al15. The process will consist of three iterative rounds of questionnaire, participant response, and controlled feedback until a convergence of expert opinions is achieved. The long-list of prospective items collected in Phase 1 will inform the Delphi. Delphi participants are, however, invited up to the second round to add any items that are not on the list that they feel should be included in the guideline. The level of consensus that needs to be achieved for each item is determined will be set at 67%14.

### Participants

We will consult 100 experts that represent different key stakeholders in forensic medicine, including forensic epidemiologists, forensic medical experts, and consumers of forensic medical expert opinions (police officers, public prosecutors, lawyers, and judges) identified through nomination and snowballing. All participants should have relevant knowledge and experience; capacity, willingness and sufficient time to participate; a good command of the written English language; and should be located in various geographical regions.

Invitations to take part in a web-based Delphi survey will be sent by email. The invitation will include explanation about the background, purpose, and process of, the necessary commitment (time, energy) to, and how important it is to complete the Delphi process14,15. Reasons to decline will be elicited and documented.

Participants will be asked to provide their consent as a member of the Delphi panel, who will be acknowledged in every publication. Additionally, participants will be asked to provide relevant demographic data, such as their name, profession, place of employment, and self-perceived level of expertise16. This background information will be kept confidential and will only be known by the research team. Participants will also be randomly assigned an identification number for data collection and analysis process.

### Procedure

The whole Delphi consensus process will be performed using Qualtrics®. The link to the survey will be sent to the participants by email, accompanied by an explanation of the whole process, the ongoing round, and contact information of DIM, if they have any questions or comments regarding the process, or wish to withdraw at any stage of the Delphi. Each round will be conducted over 7 – 8 weeks (4 – 5 weeks to collect the responses, 2 week for analysis of responses, and 1 week to prepare the next round). A reminder will be sent to the participants at 14 and 7 days before the end of each response collection period.

#### Round 1

The participants will be asked to rate the importance of every item on a scale from 0 (not important at all/should be excluded) to 10 (most important item/must always be included)17. Participants will also be asked to provide a reason if they give a score of 3 or less. They will also be encouraged to add comments regarding individual items, the wording of items, the inclusion of an item in a particular domain, or any other comments. The number of participants who complete the survey will be recorded.

#### Round 2

Round 2 of the Delphi study will contain all round 1 items, which are re-grouped categorically by median scores rounded to the nearest whole number (median ≥ 8; 6 ≤ median ≥ 7; median ≤ 6). The definition of checklist items will be improved based on the comments from round 1 and advice of the steering committee. Newly nominated items from round 1 will be added. For each item, panelists will be provided with their previous rating, group summary ratings (medians, interquartile ranges (IQRs) and frequency distributions) and anonymized free text comments from round 1. Participants will be asked to re-rate the items (using the same scale as in round 1) and respond to existing comments, if desired.

#### Round 3

In Round 3, participants will be provided with the list generated in Round 2. Participants will be asked to re-rate each item on a scale from 0 to 10, as before. For each item, information about the median score and IQR from Round 2 will be provided to the participants as additional consideration. Again, participants will also be asked to provide the reason if they give a score of 3 or less. They will also be encouraged to add any comments regarding individual items, the wording of items, the inclusion of an item in a particular domain, or any other comments they feel necessary. Upon completion, the number of participants who complete Round 3 will be recorded. As in Round 2, the median and IQR for each item will be calculated. Then, all items will be allocated based on their median score into the following categories:

* 0 – 4: low importance, should be excluded
* 5 – 7: moderate importance, may be considered for inclusion
* 8 – 10: high importance, must be included

For items where ≥67% of all participants who have completed Round 3 have given a score in the same category as its median score, then consensus will be regarded as achieved for that particular item. Otherwise, that item will be set aside for further discussion in Phase 3, together with any comments from the rounds 2 and 3. The items that have met consensus with a median score of eight or more will be compiled into a list to be included in the guidelines.

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## Phase 3: Development and dissemination of the PERFORM guideline and E&E document

This third phase consists of the development of “The Principles of Evidence-based Reporting in Forensic Medicine (PERFORM) Guidelines” and its accompanying explanation and elaboration document, as its user manual. The PI will develop the first draft of the prototypes, which will be reviewed by the steering committee. The final draft will be developed in a face-to-face workshop with international experts in forensic medicine, forensic epidemiology, and law.

Prior to the workshop, the steering committee will hold meetings (face-to-face, by email, or online) to discuss the following issues:

* The structure and wording of the items in the list generated by the Delphi process,
* The items that have not met consensus in the Delphi and items that have moderate importance,
* The work arrangements for writing the first draft and revisions,
* The potential experts to be invited to participate in the workshop,
* The method of the workshop, including methods to resolve disagreements,
* The technical/logistic issues of the workshop.

The aim of the workshop is to review the draft of the PERFORM guideline and the E&E document that have been prepared by the steering committee. The experts will be asked to provide feedback and comments on the draft. They will also be asked to provide input about any items that are still controversial (whether a particular item should be included or not). As a consideration, the PI will present the findings of Phase 1 and any relevant supporting evidence from the literature for discussion. The comments, feedback, and input from the workshop will be recorded and used to finalise the PERFORM guideline.

We aim for a widespread adoption of the PERFORM guidelines. This will facilitate the drafting of expert opinions, the appraisal of the guidelines, and ultimately contribute to better legal decision making. We will register and publish our own research protocol (Paper 1. Developing a guideline for expert opinions in Forensic Medicine: Delphi consensus study) and write a document reporting on the rationale for the development of the guidance and its development process, including a brief description of the meeting and participants involved (Paper 2. PERFORM Statement: Defining Standard Reporting in Forensic Medicine). We will also publish an associated and elaborate manual that justifies and explains the recommendations. The manual will also include examples of good reporting, following the examples of STARD18, STROBE19, and PRISMA20 (Paper 3: PERFORM Explanation and Elaboration: guidance for the reporting of expert opinions in Forensic Medicine).

The recommendation will also be published on a dedicated website (www.perform-statement.org). This website will contain the reporting guideline checklist, reference to the publications, a list of the participants, funders, the names of organization that endorse the PERFORM recommendations, and an feedback and criticism section that can help to further improve the reporting guideline. Finally, we aim to link the guideline to the EQUATOR Network (Enhancing the QUAlity and Transparency Of health Research, http://www.equator-network.org).

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# Annex 1 Scope of Questionnaire

|  |  |
| --- | --- |
| Data | Data Type |
| Sample characteristics:   * Age group * Gender * Centre/work location * Length of work time since graduation * Educational background (what and where):   + Specialist in Forensic Medicine   + Relevant additional education | * Ordinal * Nominal * Nominal * Numeric * Nominal |
| Case-load:   * Per year (average) * Total | Numeric |
| Case-types:   * Traffic-related trauma * Homicide * Suicide * Accidental trauma * Natural (sudden) death * Drug-related * Medical negligence * Other | Nominal |
| Reports formulation methods:   * Evidence-based * Experience-based * Physiologic and pathologic principles-based * Common sense * A combination of methods * Others | Nominal |
| Description of steps commonly used in formulating reports (based on vignettes) | Text |
| Use of data sources:   * Always * Often * Sometimes * Rarely * Never | Nominal |
| Data sources:   * Published literature * Epidemiological databases * Institutional databases * Others | Text |
| Strengths of current practice:   * Based on scientific evidence/published literature * Based on physical evidence * Based on experience and commonly accepted practices among peers * Logical according to common sense * Accepted by legal fact finders (police investigators, public prosecutors, attorneys, etc) * Admissible in court * Others | Nominal |
| Weaknesses of current practice:   * No standardisation * Variation of methods among peers and/or centres * Prone to conflicting opinions among peers * Not accepted by legal fact finders (police investigators, public prosecutors, attorneys, etc) * Denied admissibility by court * Others | Nominal |
| Accuracy of reports formulated using current practice:   * Good accuracy * Questionable accuracy * Poor accuracy   Reason | Nominal  Text |
| Reliability of reports formulated using current practice:   * Good reliability * Questionable reliability * Poor reliability   Reason | Nominal  Text |
| Importance of evidence-based practice:   * Very important * Somewhat important * Neutral * Not very important * Not important at all   Reason | Nominal  Text |
| Likelihood of using standardised evidence-based reporting guidelines:   * Very likely * Somewhat likely * Neutral * Not very likely * Not likely at all   Reason | Nominal  Text |
| Checklist and suggestions of items that should be included in reporting guidelines | Text |

# 

# Annex 2 Time Table

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Activity | 2016 | | | | | | | | | | 2017 | | | | | |
| Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan | | Feb | Mar | Apr | May | Jun |
| Protocol writing |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Review of reports |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Survey |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Delphi R1 |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Delphi R2 |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Delphi R3 |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Pre-workshop preparation |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Workshop |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Prototype development |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |
| Start of dissemination |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |