Research protocol

Content

Lisanne Welink

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Together for Evident Evidence

1. Introduction and rationale

Evidence-based medicine (EBM) is "the conscientious, explicit and judicious use of current best evidence, in combination with the physician's clinical expertise and patients' preferences in making decisions about the care of individual patients" (1). Currently, in many curricula, teaching EBM predominantly involves the first three steps of EBM: ask, acquire and appraise (2,3). The final steps of EBM are to consider best evidence, clinical expertise and patient preferences in clinical decision making in practice, and evaluate upon this. These steps are more difficult to teach (4). Recently, Trish Greenhalgh, a well-known advocate of EBM, stated that: "*clinical training must go beyond searching and critical appraisal to hone expert judgment and shared decision making skills*" (5). Less clear is how the ability to combine this expert judgment, these shared decision making skills and evidence is learned. It seems therefore urgent to investigate in more detail learning of the final two steps of EBM.

GP trainees could learn this in the workplace through reflection, discussion or observation of their GP supervisor role models (6). They might for example learn through observing how their supervisor talks to patients about evidence, how they explain risks or how they are being open about uncertainties (7,8). Or trainees could discuss with their supervisor about their struggles on how to consider evidence, patients' preferences and clinical expertise in daily clinical practice. However, not much is known about the way GP trainees in the workplace learn this.

GP supervisors in turn could learn from their trainees during the tutorial dialogues. Tutorial dialogues are meetings which, to be considered an optimal learning experience, have to be an interactive process of questions and clarifications from both sides. Supervisors have more clinical expertise, but are presumably not equally skilled in the first three steps of EBM (ask, acquire, appraise) and might learn in this respect from their trainees. Unexplored is whether, and how, GP supervisors use these learning opportunities.

In theory, informal collaborate learning of GP supervisors and trainees in the workplace can be mutually beneficial but we expect that these learning processes do not occur optimally. Thus far, in studies that looked into the language used during consultations (9,10) very often the use of evidence was not clearly visible. It seems plausible that trainees will have difficulties to learn through observation. Supervisors, as experts, will not always explicitly mention how they reason and take decisions while using, adapting or disregarding evidence (11), which suggests that their own challenges with these EBM aspects are not always part of the tutorial dialogues.

In present day medical care, and in postgraduate GP training, it is important to perform and learn the full spectrum of EBM and therefore it is essential to determine what helps to support and enhance informal EBM learning in the workplace. How to support and enhance informal learning is not self-evident (12–14). Which measures would stimulate participation of people in activities that help informal learning, for example through critical reflective dialogues (15)? We intend to explore the (design of such) measures and how GP supervisors and trainees could become competent in embedding these measures in the GP workplace.

This project will contribute to the body of knowledge on informal workplace learning in the GP practice, with a focus on the final two steps of EBM. It is urgent to obtain this knowledge because it has turned out that learning the three first steps of EBM alone does not sufficiently contribute naturally to use of best evidence in clinical practice. This problem is not limited

to GPs but is true for other medical professionals as well. Another contribution of our study will be enriched understanding of how to support and enhance informal learning, first of all in the GP workplace but relevant for similar workplaces.

2. Research goals

Main question:
How do GP supervisors and trainees informally and collaboratively learn to apply and evaluate EBM in daily clinical practice (considering the evidence, patients' preferences and clinical expertise), and how can we support and enhance these learning processes in the GP workplace?

Sub questions:
Phase 1: Video recordings and interviews:

1. How do GP supervisors and trainees informally and collaboratively learn to integrate evidence, patients' preferences and clinical expertise in daily clinical practice?

    a. Observation(s) of videos of the consultations:
        i. In what ways do GP supervisors and trainees integrate evidence, patients' preferences and clinical expertise during consultations, explicitly and implicitly?

    b. Interviews of the consultations:
        i. What are the perceptions of GP supervisors and trainees in how they explicitly and implicitly consider evidence, patients' preferences and clinical expertise during consultations?
        ii. What are the perceptions of GP supervisors and trainees in how their supervisor or trainee explicitly and implicitly considers evidence, patients' preference and clinical expertise during consultations?
        iii. How do GP supervisors and trainees discuss considerations of evidence, patients' preferences and clinical expertise when observing consultations?
        iv. How do GP supervisors and trainees think they can learn from each other to consider evidence, patient's preferences and clinical expertise when discussing observed consultations?

    c. Observation(s) of videos of the tutorial dialogues:
        i. In what ways do GP supervisors and trainees discuss the integration of evidence, patients' preferences and clinical expertise during tutorial dialogues?

    d. Interviews about the tutorial dialogues:
        i. What are the perceptions of GP supervisors and trainees in how they discuss the integration of evidence, patients' preferences and clinical expertise in daily clinical practice during tutorial dialogues?

ii. What are the perceptions of GP supervisors and trainees in how their supervisor or trainee discusses evidence, patients' preference and clinical expertise during tutorial dialogues?
iii. Do GP supervisors and trainees think they have learned during tutorial dialogues to consider the integration of evidence, patients' preference and clinical expertise during consultations? If so →
iv. How do GP supervisors and trainees perceive they have learned during tutorial dialogues to consider the integration of evidence, patients' preference and clinical expertise during consultations?
v. How do GP supervisors and trainees think they can improve learning from each other to consider evidence, patient's preferences and clinical expertise during tutorial dialogues?

Broad question about phase 1b and 1d:

a. Which improvements do GP supervisors and trainees suggest to enhance their learning about the integration of evidence, patients' preferences and clinical expertise in daily clinical practice?

Phase 2: Formulating ways to support and enhance these learning processes:

b. How can we support and enhance these learning processes in the GP workplace?
    a. Which design principles that help to define measures that can support and enhance informal learning can be developed?
        1. *Based on earlier research (part 1) and scoping literature review*
    b. How do educational experts rate the importance and relevance of these design principles?
    c. How do GP supervisors, GP trainees and staff of postgraduate GP training institutes think about the feasibility and acceptability of the measures that can support and enhance informal learning?
        i. Are these measures acceptable?
        ii. Are these measures feasible?
        iii. Which formal training would GP supervisors and trainees need to embed these measures in the workplace?

Because of the complexity of the whole project, it has been divided in different phases. Below the different phases are stated; these will be used during the rest of the protocol.

Explanation of further use of terms:

Phase	**Brief explanation**
Phase 1a	Recording and analyzing consultations
Phase 1b	Interviews based on recordings of consultations
Phase 1c	Recording and analyzing tutorial dialogues
Phase 1d	Interviews based on recordings of consultations
Phase 2a	Use earlier findings and literature to formulate design principles that can

	help define measures to support learning processes
Phase 2b	Let experts rate importance and relevance of the design principles using a Delphi study
Phase 2c	Explore acceptability and feasibility of the measures by asking stakeholders using focus groups

3. Participants

The population for every phase of the study will be described separately. The following aspects will be described:

Phase 1 of the study:

- Sampling of participants (GP supervisors and GP trainees)
- Sampling of cases that will be recorded (consultations and tutorial dialogues)

Phase 2 of the study:

- Sampling of participants

Sampling of phase 1 of the study:

Sampling of participants (GP supervisors and GP trainees):

Number of participants:

In our qualitative studies at least 24 GP supervisors and at least 24 GP trainees affiliated to the GP specialty training in Utrecht (The Netherlands) or Gent (Belgium) will be involved for phase 1a-1d of this study. The number will increase or decrease when saturation is reached later or earlier. The couples of supervisors and trainees will be asked to participate in both phase 1a-b (observation of and interviews about consultations) and phase 1c-d (observation of and interviews about tutorial dialogues).

Sampling:

GP supervisors and trainees will be sampled on characteristics that are expected to influence the use of and learning about EBM in medical practice. Since the purpose of our study will be to investigate how different supervisors and trainees learn to apply and evaluate EBM, sampling will be aimed at obtaining maximum variation of these characteristics.

Characteristics that were perceived most important to influence learning and practicing EBM were determined. It was decided that the selected couples need to at least vary maximal on the following criteria:

- Distribution participants Belgium/Netherlands;
- Experience of trainees (how far are they within their GP specialty training);
- Previous supervising experience of the supervisor.

Furthermore, since we will look at tutorial dialogues as well, it is important to select couples that already execute tutorial dialogues with an educational aim in their daily clinical practice. Mainly in Belgium this is not common practice yet amongst all supervisors. We will select couples that already practice tutorial dialogues as part of their normal daily routines.

Because of the qualitative nature of this research, a cyclic way of data collection and analysis will be used. As a start, there will be aimed for a maximum variation of the basic list of criteria stated above, but it might be that relevant criteria will only be identified when analyzing the first data. Consequently, criteria can be added or adjusted (16). To keep track on criteria that also might influence learning and practicing EBM, we will ask the participants to fill in a short

questionnaire on additional demographic characteristics after they agreed to participate. Characteristics that we want to keep overview over and that will be registered using a short questionnaire will be:

- Age
- Gender
- Year of graduation (medical school/GP specialty training);
- PhD-degree;
- Involvement in guideline development;
- Solo-/group practice;
- Composition of patient population;
    - Big city/small city/rural
    - Average level of education
    - Mean age

This questionnaire will be filled out by both the supervisor and the trainee.

Since we will look at pairs of trainees and supervisors in the same GP practice, GP trainees that are asked to be included are the trainees that are having their traineeships with the selected supervisors. However, it will be explicitly stated that if the trainee is not willing to participate, the supervisor will also not be selected and another supervisor/trainee couple will be approached.

However, since we expect that it will not be easy to recruit participants for this study, we will use two sampling techniques to on one hand enhance maximum variation sampling and on the other hand try to meet the planned number of participants. Amongst other reasons, this is why we will not sample all participants at once. First, we will sample a group of participants using *opportunistic sampling*: when participants agree to participate, they will be selected. To keep a good overview of the characteristics of the participants we selected, we will ask them to fill in the short questionnaire mentioned above. During the study we will see how much variation there is within the first sampled group. Since we will not sample all participants of phase 1 at once, we will have the opportunity to adjust the variation within the sample by influencing the composition of the second batch of participants. This means that based on the variation within the first group, we will approach selected supervisors and trainees to enhance maximum variation.

Method of sampling of cases (consultations and tutorial dialogues):

We will gather a large sample of recordings of consultations of GP supervisors and GP trainees. This large sample is needed because we will select a variety of medical cases, with diversity in 'the expected need to consider evidence, patients' preferences and clinical expertise'. We aim for 480 consultations to reach diversity. This means that each GP supervisor and each trainee needs to record 10 consultations. This will be done by asking every participant to record all consultations of one representable part of a regular working day, except the consultations of patients who didn't consent. More ethical considerations of this procedure will be described in the chapter about 'ethical aspects'.

We will record a large sample of tutorial dialogues as well. Participants will be asked to record a random tutorial dialogue at month 0, 2 and 4 of participation of the study to take development of abilities and development of the relationship between trainee and supervisor into account. We will look at regular, random tutorial dialogues that are already part of daily clinical practice, not at special dialogues where GP supervisors have been instructed (as part of this study for example) to behave in a certain way.
With 24 pairs of supervisors-trainees, we will aim for a minimum of 72 recordings (3 recordings for each pair).

Sampling of phase 2 of the study:

For this part of the study, we will use a Delphi method, for which we will invite a diverse and large enough group of experts in the field of workplace learning and informal learning. Experts who will take part will have to have demonstrated their area of expertise by international publications. As we will use an online technique, national as well as international experts will be included.
A next step will be focus groups for which we will invite postgraduate GP training staff members, practicing GPs, GP supervisors and trainees who all have experience with the theory or practice of teaching EBM. At least three groups within both the Netherlands and Belgium (and based on saturation of the data more groups) will be composed with same type of experts. Specific attention will be paid to obtain an optimal spread of variation of participants of the groups.

4. Design and procedure:

All steps within this project will be qualitative research, conducted within two locations: the Julius Center for Health Sciences and Primary Care, UMC Utrecht, the Netherlands and the department of Family Medicine and Primary Health care, Ghent University, Belgium.

The study will be performed by an AIOTHO who alternates between her training in the GP practice and this research. Therefore the study will take three years of actual research, but the whole process will last six years.

The complete research can be summarized in the following steps:

	Step	**Aim**	**Design**
1a	Video record and analyze consultations of GP supervisors and GP trainees.	To get insight in how evidence, patients' preferences and clinical expertise are considered during consultations by GP supervisors and trainees	Video recordings of 10 consultations per GP supervisor or GP trainee; the recordings will be analyzed and suitable fragments will be selected by the investigators.
1b	Interviews with pairs	To get insight in the perceptions of GP supervisors and trainees on how they consider evidence, patients' preferences and clinical expertise during consultations and how and what they learn from observation and consultation on this field.	Joined video-stimulated recall (VSR) interviews with GP supervisors and trainees, showing fragments of the recordings.
1c	Video record and analyze recordings of tutorial dialogues	Get insight in how pairs of GP supervisors and trainees talk and learn about the three EBM aspects during tutorial dialogues	Video recordings of at least three tutorial dialogues per supervisor/trainee couple; the recordings will be analyzed and suitable fragments will be selected by the investigators.
1d	Individual interviews	To get insight in the perceptions of supervisors and trainees on how they consider evidence, patients' preferences and clinical expertise during tutorial dialogues and how and what they learn from these tutorial dialogues.	Separate video-stimulated recall (VSR) interviews with GP supervisors and trainees, showing fragments of the recordings
2a	Develop measures which potentially	Distil what seems to be missing in opportunities for informal collaborative learning and how these	Analyzing results from previous steps by the investigators and conducting a scoping literature

	support and enhance EBM informal collaborative learning in the workplace	gaps may be filled	review, summarizing the results of these two steps and developing measures using design principles
2b	Delphi study	Explore how educational experts rate the importance and relevance of the design principles formed at step 2a; prioritize the design principles	Delphi study amongst educational experts.
2c	Focus groups	Explore how GP supervisors, GP trainees and staff of postgraduate GP training institutes think about the feasibility and acceptability of the measures that can support and enhance informal learning 1. Are the measures acceptable and feasible; 2. Which formal training supervisors and trainees would need to embed these measures in the workplace.	Focus group sessions with stakeholders (postgraduate GP training staff members, practicing GPs, GP supervisors and trainees)

Because of the extent of this study, the detailed procedure for every phase will be described separately. The following aspects will be described:

- Phase 1 of the study: Procedure of data collection per participant;
- Connection between phase 1 en phase 2 of the study;
- Phase 2 of the study: Basic procedure of data collection;

Phase 1 of the study:

Participants of phase 1a-1d of the research are asked to participate in the following steps:

Steps	Actions by researcher	Actions by participants (supervisors and trainees)
First meeting	Visit GP practice: - Introduction; - Informed consent of both supervisor and trainee; - Make a feasible planning for phase 1a-1d; - Tell supervisor and trainee about informed consent of patients in phase 1a;	- One introductory meeting of approximately one hour;
Phase 1a	- Accessible in case of questions or emergencies; - Transport data from secured electronic environment to secured storage system within UMCU; - Analyse the recordings and select cases that will be shown during interviews;	- Record ten random consultations; no special actions are needed whilst recording. - Ask informed consent and record permission of the patients that are recorded; - Upload the recordings via a secured connection to a secured electronic environment.
Phase 1b	- Approximately one-hour VSR interview at place that is preferred by the supervisor/trainee.	- Approximately one-hour combined VSR interview at place that is preferred by the supervisor/trainee.
Phase 1c	- Reachable in case of questions or emergencies; - Transport data from secured electronic environment to secured storage system within UMCU; - Analyse the recordings and select cases that will be shown during interviews;	- Record three random tutorial dialogues. There should be two months between the dialogues. - Upload the recordings via a secured connection to a secured electronic environment.
Phase 1d	- Two approximately one-hour VSR interviews (supervisor and trainee separate) at place that is preferred by the supervisor/trainee.	- Approximately one-hour VSR interview at place that is preferred by the supervisor/trainee.

The data collection of these phases is planned to take place between July/Augustus 2016 and

September 2017. Ethical aspects of these steps are elaborated in chapter 7 of the protocol: 'Ethical aspects'.

Connection between phase 1 and phase 2 of the study:

From the first part of our study we will derive insight about the way supervisors and trainees explicitly and implicitly use EBM and how they informally and collaboratively learn from this. Also we will collect information on what supervisors and trainees find helpful with regard to informal and collaborative learning of the final steps of EBM. The next step in our study will be to find out whether informal learning could be supported or (when suboptimal) enhanced through measures in the workplace. We are interested in (the design of) measures which (outside the life cycle of this research project) will support and enhance informal collaborative learning in the workplace. With a small group of researchers in workplace learning we will develop a preliminary set of such design principles, based on (our knowledge of) literature and the previous findings. In this way, the results from the first part of the research will be emphatically used as input during this second part of the research.

Phase 2 of the study:

Basic procedure of data collection;

We will use an online Delphi design, used as a kind of "rating device", to get multi-disciplinary perspectives on which principles are considered important and which ones less so (17). The Delphi technique allows for anonymity of the respondents towards one another and participants do not have insight into the answers of the other respondents. We will conduct the Delphi study, using an online questionnaire, in a number of rounds.

Focus groups will take place at each of the participating institutes and a 2-hour time slot will be reserved for the sessions. A researcher and a moderator, with knowledge of workplace learning in GP practice and well instructed in the background of the design principles developed, will perform the focus groups. A short checklist with demographic data as well as written informed consent is retrieved from all attendants. Sessions will start by telling them briefly about the earlier studies and about how GP supervisors and GP trainees learn collaboratively and informally. Afterwards, a list of maximum of 10 design principles (the top-ten from the Delphi study) will be discussed on acceptability and feasibility with the participants. Last, it will be discussed whether formal training for supervisors and trainees would be needed to embed these measures in the workplace.

5. Method:

Phase 1:

Selection of relevant fragments to be used in the VSR-interviews:

Fragments that can be used for the VSR-interviews will be selected from the collected recordings. Not all recordings will be shown during the interviews: we will look for critical moments that we expect to have the greatest or smallest influence on informal learning behavior regarding the three main aspects of EBM. To select those relevant fragments, key dimensions were defined.

The key dimensions that make a critical case are defined as followed:

- Recordings in which a consideration of evidence, patient's preferences or the doctor's own clinical expertise is explicitly present;
- Recordings in which consideration of evidence, patient's preferences or the doctor's own clinical expertise is present, but seems to happen implicitly;
- Recordings in which the consideration of evidence, patient's preferences or the doctor's own clinical expertise is not present.

Because of the great amount of recordings, the selection of relevant fragments will be done by several researchers. In the beginning, a small number of recordings will be looked at in depth by two or more researchers. Based on these first recordings, an observation scheme / checklist will be constructed based on the above mentioned key dimensions. For this, the recordings will be looked at in detail to observe not only the explicit expressions but to also identify implicit use of EBM. This observation scheme enables researchers to select relevant fragments. Several individual researchers will select relevant fragments from the remaining recordings based on these criteria. Subsequent, these selected fragments will be looked at by two researchers to select the final fragments that will be shown during the interviews; disagreements between the two researchers will be solved by discussion.

Procedure of VSR-interviews:

First, a joint semi-structured interview about recordings of the consultations will be conducted by the primary researcher (LW). Since data collection of the tutorial dialogues takes at least four months, the individual semi-structured VSR-interviews about the recordings of the tutorial dialogues will be held later. An interview form for both interviews will be made based on the research questions; a draft of these forms is attached.

All interviews will be transcribed. Template analysis will be performed on these transcripts (18). An a priori code will be formed, identifying themes that are expected to be relevant to our research questions. When examining all transcripts, these codes will be modified if needed. Reading, coding and identifying themes will be done by at least two researchers to enhance quality.

The procedure will be iterative: emerging themes that are identified when analyzing the first interviews will be used in subsequent interviews. Furthermore, we will keep an open eye on

saturation of the data. When no new themes can be identified when analyzing data from new supervisor/trainee-couples, saturation is reached.

Phase 2:

Delphi-study: The Delphi study will be conducted in a number of rounds. Participants will be asked to rate the relevance of design principles on a four-point scale (4 very relevant, 3 relevant, 2 hardly relevant, 1 not relevant). In the following round, the opinions on the design principles from all participants in the first round are summarized. Participants are asked whether they want to change their opinion about the principle. We will aim for consensus regarding the design principles which should be used for the development of learning support measures. The Delphi study gives an indication of the importance of the design principles. If necessary, further rounds will be planned to reach consensus.

Focus groups: The sessions will be recorded and recordings will be transcribed. In order to ensure reliability, random selected sections of transcripts will be checked for accuracy by an independent researcher. Two reviewers will independently analyze the transcripts of the focus groups using conventional content analysis. Open coding by the two reviewers will result in a list of relevant themes, which will be compared in a consensus meeting. Using an iterative process of re-reading the transcripts and refining the coding system, all statements of the participants will be assigned to a specific category. During the coding process, focus will be on acceptability and feasibility and on what competencies would be necessary to implement these measures. New sessions will be planned when saturation is not yet reached. Also new sessions will be planned to explore views resulting from the first series of focus group sessions if needed.

6. Analysis

Phase 1:

It might be that the fragments of consultations and tutorial dialogues that are selected to show during the VSR-interviews, will be analyzed more in depth using an ethnographic approach with for instance conversation analysis (19). In this way we aim to get a more thorough understanding of the explicit and implicit use of EBM during consultations and tutorial dialogues. Besides, we will look at the structure of a tutorial dialogue. During this, we will take previous literature about what makes a 'good tutorial dialogue' into account.

For the interviews, an inductive approach will be chosen. The interviews will be analyzed on the themes of evidence-based medicine, informal learning and collaborative learning, using NVivo software, but we will be open for additional themes and codes during the analysis. When reading the transcripts, memos will be written, based on which codes and themes will be identified. These results will be discussed by a group of researchers to enhance quality of coding. When the themes are identified, we will try to interpret these themes to answer the main research questions of phase 1.

To do this, we also will adopt a within and across case approach (20). The across case comparisons will be international (between cases derived from GP pairs in the Netherlands as well as Belgium) and between cases derived from pairs with a first year trainee and pairs with a third year trainee. Furthermore, in across case analysis, VSR interviews will be analyzed as

a whole, while during within case analysis we will analyze the VSR interview in combination with the associated consultations.

Phase 2:

Recordings of the Delphi study and of the focus groups will be transcribed and analyzed in a qualitative manner. Details will be provided in an amendment to this request for ethical approval to the ERB in a later stage because it depends on phase 1.

7. Ethical aspects

Phase 1:

Ethical considerations regarding the selection of participants (supervisors and trainees):

To inform and consent participants the following steps will be taken:

1. Informing presentations will be held by the main researcher (LW) at several educational moments at the GP specialty training in Utrecht and Gent. These presentations will be adjusted to regular educational meetings of the supervisors and trainees to reach as many possible participants as possible. During these presentations general information about the study will be presented, the information letter (see appendix) will be handed out and possible questions will be answered. It will be made clear that even though the presentation is held at the GP specialty training institute, participation is completely voluntarily and that participation or refusal to participate has no influence on the educational program or way of practice. The non-normative, non-judgmental aspect of this study will be explicitly pointed out: negative findings will not influence the relation that supervisors and trainees have with the specialty training. Afterwards, supervisors and trainees will have the opportunity to register immediately if interested, but if needed, they will be given time to think about it first.
2. The supervisors and trainees that were present at these informing presentations will receive a summary of the presentation via e-mail after some days. In this e-mail supervisors and trainees will be asked to contact the main researcher (LW) when interested to participate;
3. If the desired amount of participants is not reached using step 1 and 2 or when the variation within the sampled group is not diverse enough yet, participants will be approached individually by the researchers. Since some researchers have teaching or managing roles at the GP specialty training which might make participants hesitant to refuse, approaching of the participants will be done by LW. The information and consent will be the same as described in step 1 and 2.

When a supervisor or trainee agrees to participate, the respective trainee or supervisor that is matched to this participant will be approached. The procedure of informing will be the same: the possible participants will be individually informed by an information letter and an oral elucidation, if needed. In the case that a supervisor already agreed to participate, the trainee will be individually approached by the researchers and not by the supervisor to make sure the trainee doesn't feel obliged to participate because of pressure from his/her supervisor. When the trainee shows interest to participate after the information from the researcher, there will

be given time to discuss participation with his/her supervisor, since it is important that the supervisor and the trainee are both willing to participate and they will probably not consent without discussing this with each other.

Informed consent:
As soon as both the GP supervisor and trainee informally consented to participate in the study, the primary researcher (LW) will visit the couples to meet. At that point the informed consent form will be signed by both the supervisor and trainee. This informed consent form will be valid for part 1a until part 1d of the study, including the starting questionnaire.

Advantages and disadvantages of participating:
We expect that participating in this research doesn't take a lot of extra effort of the trainees and supervisors. Recording consultations for educational purposes is already common procedure in most training practices, especially in the Netherlands. In this way, most trainees are already used to record consultations for their specialty training; the supervisors are not used to this but know the procedure from their trainees. Also we expect the patients in these training practices to be used to getting asked to record their consultation. An argument to participate could be that supervisor and trainee in this way will get more insight in their own management of consultations and tutorial dialogues. Both supervisors and trainees can use their recordings for educational purposes as well. Moreover, this study can add to improving the quality of the GP specialty training.

Disadvantage of taking part in this study is that it takes time. Besides, permission to record the consultations has to be asked from the patients.

Ethical considerations regarding the patients that will be recorded during phase 1a:
Since patients and their medical issues will be audible at the recordings of consultations, the GP supervisors and GP trainees will inform the patients before recording. The procedure of this informing and consenting is identical to the procedure as followed when recording consultations for the Dutch GP specialty training.
The patient will get a short information letter about the goal of the recordings before the consultation in the waiting room (see appendix). In this information letter it is stated what the goal is of the recordings, who will be allowed to watch the recordings and how long the material will be stored. It will be made clear that participation doesn't influence treatment and that participation is totally voluntary. Furthermore, it will be made clear that the aim of the study is to observe the doctor's behavior and not the patient's. Also it will be stated that the patient will not be visible; the camera will be on the doctor all the time. In addition to the written information, the supervisor or trainee will give extra explanation to the patient if needed. Before the recording starts, the supervisor or trainee asks permission of the patient to record the consultation. The supervisor or trainee explicitly states that the patient is not obliged to participate and that it is possible to withdraw the consent during the recording. The patient will have enough possibility to decline the recordings. Only after the patient gave permission, the recording will start. The consent will be repeated on tape. The supervisor/trainee will ask: "I just explained to you why I will make a recording of this consultation. You consented on this recording. Is that correct?". The patient should answer this question clearly audible.

The patient has the right to withdraw the consent at any moment during the consult. In such a case, the recording will be immediately stopped and erased.

Transportation and storage of the data:

Short demographic questionnaires:

The demographic questionnaires that will be filled in by the participants to establish maximum variation sampling, will be coded and stored together with the recordings of the consultations and tutorial dialogues. The original data will only be accessible by the main researcher (LW).

Recordings of consultations and tutorial dialogues:

After recording the consultations and tutorial dialogues, the recordings will be uploaded by the trainees and supervisors to a secured server of the educational learning environment (Elektronische LeerOmgeving, ELO) of the GP specialty training in Utrecht using a secured connection. This secured server is already being used to upload consultations for educational purposes and meets the relevant standards of the GP specialty training in the Netherlands. The supervisors and trainees will get a private uploading environment, which is only accessible by the participants themselves and the primary researcher of the study (LW). Due to limited storage capacity, this server will only be used to safely transport the data from the GP practices to the Julius Center, Utrecht. The recordings will be transferred to a secured storage server within the Julius Center, UMC Utrecht.

Since the recordings of consultations and tutorial dialogues give insight in daily clinical practice in our current time and could be very valuable for future research, the recordings will be preserved to enable historic research in future. Recording these consultations takes time and effort from participants; storing these recordings prevents new burden of recording for participants in future research. When the recordings might be used for research other than this project, consent of the participants will be asked again. The recordings will only accessible for the researchers of this project and for the supervisors/trainees who recorded the specific recordings. The supervisors and trainees are only allowed to access their own recordings and not those of other participants. Coded transcripts will be made of fragments of the consultations that the researchers perceive as being very useful or illustrating for the research questions. These transcripts will be stored coded and will be destroyed after ten years, due to the fact that this whole project will take six years.

All other transportation of data (e.g., transportation of selected fragments to the site of the interviews) will be done using secured data carriers such as secured USB-sticks and hard disks.

Recordings of interviews:

Interviews will be recorded using video recording as well. Transcripts will be made of the consultations and the interviews; these transcripts will be stored coded. The original recordings will only be stored during the data collection and –analysis; afterwards they will be destroyed. The coded transcripts will be stored during ten years before being destroyed, due to the length of the whole project.

Ethical considerations during data collection and analysis

During the interviews, the video-stimulated recall (VSR) method will be used. VSR interviewing is a methodology that could be perceived as being intrusive. Therefore, we will take strict ethical procedures into account, not only with regard to the formal operations, but also in our behavior as researchers. At all times, we will reflect on what the potential ethical consequences of looking at video recordings of specific events could be for patients, GP trainees or supervisors and discuss about those with interviewers who work at the center where they are closely connected to. In literature, no ethical concerns are mentioned when using this VSR-method (20), but we plan to be sensitive to these during the study throughout.

The VSR-interviews will be conducted by a researcher (LW) who has no assessing role in the GP specialty training. Before starting the interview, the explicit statement from the information letter will be repeated that this study will be strictly non-normative and non-judgmental. Statements or conclusions made during the interviews will not influence the relation that supervisors and trainees have with the specialty training. To ensure this, those researchers who have authorization to assess trainees or supervisors will only have access to the anonymized data of trainees and supervisors affiliated to their institution.

When wrongful behavior on any topic is noted on the recordings of the consultations or the tutorial dialogues, this will have no consequences for the supervisor or trainee. These recordings will be used as any other fragment: when the concerning fragment is valuable for the research goals in the study, it will be used and shown during the VSR-interviews.

During the analysis NVivo software will be used to analyze the data. The process of analyzing will be made transparent by keeping memo's. These memo's will be used to keep track of ethical dilemmas and other considerations during the process.

Ethical considerations during the reporting phase

When reporting on these studies, we will make sure that privacy, confidentiality and anonymity of the participants are assured. Reporting on fragments will always be done in such a way that it is not possible to track this back to a particular participant. We will not use stills from the video recordings in presentations or other forms of dissemination. Since the aim of our study is not normative, we will be alert to also report on our findings in a non-judgmental way.

General comments on ethical aspects:

During the whole study, no rewards for participation will be used.

Phase 2:

All participants of the Delphi-study and the focus groups will receive an information letter and informed consent form explicitly stating that participation is voluntary and full confidentiality will be assured. Since the exact execution of this part of the study will be dependent on part 1, the information letter and informed consent will be written and ethically approved later as an amendment to this protocol.
No rewards will be given to the participants.

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