GEPURE Study

Participant Information Sheet for General Practitioners

Study title: Management of uncertainty through a reasoned use of EBM tools (GEPURE)

Scientific coordinator:
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Sponsoring administrative structure:
French Society of General Practice (Société Française de Médecine Générale, SFMG)

Why you are being invited to take part in this study

This research focuses on the management of uncertainty in general practice and on the use of an evidence-based decision support tool, EBMFrance, in ambulatory clinical practice.

The primary objective of the study is to assess the impact of using EBMFrance over a 12-month period on perceived uncertainty among general practitioners, both in individual consultations and in practice analysis groups (GAP), using the PRU score (Physicians' Reactions to Uncertainty Scale). The project forms part of primary care research conducted by academic and scientific structures in general practice.

What your participation involves

Your participation is voluntary. If you agree to take part, you will be asked to complete an initial questionnaire, then follow-up questionnaires relating to the use of EBMFrance in consultations and/or GAP, and finally a satisfaction questionnaire at the end of the study.

The protocol includes in particular:

- Collection of sociodemographic and professional data at inclusion
- Initial and final collection of the PRU score
- For each use of EBMFrance, collection of information regarding perceived complexity, decision confidence before and after using the tool, any changes in patient management, and the modalities of use of the tool
- Possible participation in a focus group at the end of the study, in order to explore perceived usefulness, strengths, limitations, and practicality of the tool

Your participation does not involve any additional healthcare procedures, any technical acts, any mandatory modification of your clinical practice, nor any direct collection of nominative data relating to your patients.

Benefits and burdens

This study does not provide any guaranteed direct individual benefit. It aims to better understand how an EBM tool can support medical decision-making in situations of uncertainty and to contribute to knowledge development in primary care research.

The foreseeable constraints are mainly the time required to complete the questionnaires, to participate in any collective sessions, and to describe certain clinical situations in a sufficiently de-identified manner to preserve confidentiality.

Expected risks are minimal. They mainly concern possible discomfort related to self-assessment of your practice or to discussing situations of uncertainty. You remain free not to answer certain questions and to withdraw from the study at any time.

Data collected and confidentiality

The data collected concern your professional profile, your use of decision-support tools, your responses to the questionnaires, and, where applicable, your contributions during focus groups. The data must be limited to what is strictly necessary for the research purpose, in accordance with MR-004.

Data will be pseudonymised. A correspondence table, separate from the analysis dataset, will be kept apart with restricted access limited to persons expressly authorised by the research team. Data recipients are the investigators and individuals authorised to conduct the scientific analysis, in compliance with the security and confidentiality rules applicable to health research.

No nominative patient data must be entered in the questionnaires or mentioned during focus groups. Clinical cases discussed must be presented in a non-identifiable way.

The duration of data retention, the specific data-hosting arrangements, and the contact details of the Data Protection Officer (DPO) of the data controller will be specified in the final version of the protocol, in accordance with the information requirements for data subjects.

Regulatory framework and your rights

This study falls within the scope of health research not involving human subjects as defined by French regulations. The CNIL reference methodology MR-004 covers this type of research, study, or evaluation, and provides for information of data subjects, data security and confidentiality, as well as the exercise of the rights laid down by the GDPR.

Your participation is free and may be discontinued at any time, without justification and without any consequence on your professional activity, your relationship with your practice setting, or your access to the tools under study. Standard information notices used in general practice also recall your rights of access, rectification, erasure, restriction of processing, and the right to lodge a complaint with the CNIL.

You may exercise your rights through the scientific coordinator of the study and the Data Protection Officer of the structure acting as data controller.

Voluntary nature of participation

Your participation is entirely voluntary. You may refuse to take part without having to provide any justification.

If you agree to participate, you may withdraw your consent at any time, without prejudice. Data already collected prior to your withdrawal may nonetheless be retained and used in pseudonymised form, unless you object and provided that erasure is legally and methodologically feasible.

Contact persons

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