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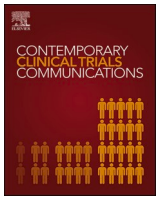

Ethical and legal considerations in non interventional health clinical trials in the French context

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ABSTRACT

While the development of regulations in the conduct of research in humans, has better allowed risks and associated contraints to be framed, it has also raised further questions. French regulations currently consider that research based on questionnaires or interviews has no impact on the care of patients or on the individual, a view that is too limited and is not shared by the ethics committees charged with the protection of those involved in studies. Any research relating to a person requires his or her active involvement. The intention of the researcher can be perceived by the participant and can therefore affect their responses. Hence, it is important to question the safety of procedures and consider the psychological risks of non-interventional research. Any evaluation process can create a potentially risky situation, not because of the intrinsic qualities of the tools used, but because of the conditions under which they are applied. As members of an ethics committee, our experience has enabled us to observe shortcomings and lack of acknowledgement by study sponsors of issues at stake in the research. This article revisits the foundational texts of the French Jardé law, with which sponsors and investigators in France are required to comply, considers the psychological implications for studies involving questionnaires and/or interviews and ethical questions or dilemmas. Finally, areas for consideration that could improve the framework for non-interventional research are proposed.

1. Introduction

In France, biomedical clinical trials involving psychological aspects, are regulated and framed by the Jardé law [1], which specifies compliance in both the way ethics submissions are structured and research protocols are written.

While studies relating to psychological assessment are usually referred to as Category 2 (minimal risk interventional research), studies requiring validated questionnaires and/or interviews most often qualify, according to sponsors, as non-interventional research in Category 3. This classification raises ethical questions that we explore through the lens of our experience as members of an ethics committee (known in France as Committees for the Protection of Persons (CPP)) in assessing and deciding on the acceptibility of submissions and providing recommendations as to whether or not the research can proceed.

In this paper, we firstly review the text of Jardé's law that constrain sponsors and investigators, and the implications for studies involving acquisition of subjective data. Secondly, we reflect on psychological issues associated with the use of assessment tools that have a psychological aspect. The ethical dilemmas arising from our experience with expert protocols are laid out and finally, we propose areas for consideration that could improve the framework for this type of subjective research.

2. Regulatory framework

Prior to institution of the Jardé law, studies involving psychometric assessment or interviews fell within the scope of non-interventional studies and were automatically classified as observational research on human subjects. It implied that interventional research is only interventional in the sense that it changes something in the person through corporeal intervention, and excluded intervention at the psychological

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level that acts on the subjectivity of the patient. This distinction illustrates the opposition between the dichotomous clinical approach to body and mind and the unitary approach of the person as a bio-psychosocial entity.

In order to harmonise with European regulations, the Jardé law was enacted to modify the categorization of research involving human subjects as follows:

- Category 1: Interventional research, involving intervention that is not risk-free for the participants and not justified by their usual care.
- Category 2: Interventional research with minimal risks and constraints. A fixed list established by order of the Minister of Health, following the opinion of the Director of the National Agency for the Safety of Medicines and Health Products (ANSM). This category was formerly called "research in routine care".
- Category 3: Non-interventional research, where all procedures are performed and products are used in the usual way, without additional or unusual diagnostic, treatment or monitoring procedures.

The description "non-interventional" is confusing, implying no procedures and no risk to the person. In fact, procedures can be performed, as long as they are risk-free. However, when a procedure is performed, risk is never absent. Moreover, the decree of April 12, 2018 setting out the research mentioned in 3° of article L1121-1 CSP (i.e. Category 3) [1], demonstrates this ambiguity: "The absence of risk is assessed in particular with regard to […] the *known foreseeable risks* of the acts or procedures […]".

While the Helsinki declaration [2] and most international regulations qualify human experimentation in terms of physical or psychological benefit/risk ratio, a different classification scheme is used, differentiating between interventional vs non-interventional researches. This classification scheme inherently focus on the level of intervention, and correlates it to the level of rik involved, thus relegating the notion of risk to the background. Moreover, risk is mainly considered in its physical acceptation, psychological risks being only implied if ever considered.

In this context, studies involving questionnaires or interviews would be classified as Category 2 only if they lead to a change in the participant's usual medical care. This implies that some research would have no impact on clinical management and thus calls into question the interest or value of such research, if it does not lead to any alteration in management either as an outcome of the study or in future research based on the results.

Research qualifying as Category 3 can include interview, test and questionnaire procedures that are without risks and constraints, or that do not change the usual care, if these have as their sole endpoint the "development of biological or medical knowledge". The public health code includes documents constituting the *restricted file* for research mentioned in the Category 3 [1], for which the intervention in the person "only gives rise" to questionnaires or interviews. These terms imply an absence of effect and harmlessness of these procedures on the participants, thus not requiring the same rigor nor the same completeness in constituting the file for their evaluation by the ethics committee. However, non-interventional research (Category 3) may involve acts or procedures defined by an intervention order, which are considered to be without risk and do not modify the person's care.

3. Issues related to the acquisition of subjective data

3.1. Research involvement and intentionality

It is important to consider the notion of "research involving the person", where involvement recognises the engaged participation of the person taking part in the research. Etymologically, "involve" is derived from the latin *implicare* meaning fold, interweave or entwine. In this sense, any action carried out on a person brings about a change in him or her, whether psychological or physical, through the way in which it is represented and the way in which the person appropriates it, adapts to it and responds.

Intentionality, in the research context, refers to the deliberate nature of a procedure as clarified in a protocol. It is characterized by the fact that it effectively responds to the desire to produce scientific knowledge. Its relationship to cognitive aims (knowledge) is not accidental, spontaneous nor incidental, but the result of deliberation. Thus, the intentionality of the researcher is taken into consideration by the participant who, by including it in his or her thinking when deciding whether or not to participate in the research (and hence their own intention towards it) will also have their responses affected. Indeed, the intentionality of the research as perceived by the participant (production of knowledge *vs* collection of data with a view to encouraging prescribing, i.e. scientific endorsement for commercial purposes), will affect the response behaviour of the participant.

3.2. The designation "non-interventional research"

The aim of an interventional clinical trial is to test an action that is directed towards and modifies the clinical care of that person, unless the intervention is part of usual care. Non-interventional research is limited to collecting data from individuals' files without intervening directly with the person or changing their usual care. However, active subjective data collection, requiring interaction between a researcher and a participant, can become interventional. Indeed, although the scientific approach is not strictly speaking an intervention on his or her body, it does involve intrusion of privacy or intimacy that is neither neutral nor without effect.

Questionnaires and interviews can be considered interventional insofar as they require engagement of psychological processes in eliciting a response [3]. The response is not immediately available to nor "collected" or "sampled" from the participant, who constructs their response according to the perception he or she has of him- or herself and the questionnaire, his or her introspective potential, the supposed expectations of the investigator, and the degree of social desirability. A questionnaire or an interview changes the way a subject looks at themself (awareness), has an impact on psychological dynamics and can lead to a change in care, by identifying disorders or even updating a diagnosis.

Any test tool taken has a social dimension and therefore has consequences for the person concerned, in the sense that it brings about a change. Thus, the participant's anticipation of a questionnaire or an interview can have an impact on their answers. Similarly, the test results will have corrective, adaptive and psychological repositioning effects, e.g. according to whether the results were expected or unexpected. Moreover, section L1122-1 of the French public health code (dealing with research categories) allows only limited information to be provided to the participant, in order to preserve the spontaneity of responses [1].

Undertaking questionnaires or interviews are subjective experiences that mobilize latent processes which, as defined by Smith et al., 2007 [4], are characterized by psychological and physiological, emotional, affective and cognitive dimensions in a person confronted with a situation, particular objectives, a tool and an interlocutor. Indeed, response behaviours differ according to the mode of presentation of the test and, as explained by Kiesler and Sproull in 1986 [5], computerisation of a test is likely to reduce the social desirability bias, through it being perceived as more anonymous and impersonal than that induced by a test in paper form.

As soon as one applies a tool aiming to collect data through active involvement of a participant, the approach becomes interventional. The impact of the intervention on the life of the participant, could thus be comparable to the accidental discovery of a pathology during an examination. Also, unlike biological or imaging investigations, the outcomes of which are recognised as frequent sources of worry for the participant, when it comes to administering interviews or questionnaires

this risk appears to be consistently underestimated by both the sponsor and investigators, as well as the participant. Moreover, it is then impossible to undo and erase data relating to that which he or she reveals about themself.

3.3. Risks and constraints

What often underpins ethical reflection, when considering categorisation of studies involving questionnaires or interviews, is the safety of these tests and thus the risk to the physical and psychological health of participants. Any evaluative process is considered to be a situation of risk, recognised by the principle that *"no one is obliged to reveal anything about him- or herself"* [6].

If voices such as ethics committees have been raised to challenge evaluation bodies, it is to warn of the potential risks of certain tools on the mental health of individuals. The few studies available do not confirm this hypothesis of risk [7,8] finding in contrast, that mental health questionnaires are generally perceived as positive and a source of enhancement. However, the recent changes to the legislation, to take into account ethical considerations of research in humans, have revived reflection on the issues related to the use of questionnaires. The discarding of the risk hypothesis is based on the studies being carried out by people who are highly qualified in the methodology, under optimal conditions or on healthy subjects. Thus, the few studies on this theme dedicated to evaluating the psychometric qualities of the tools, reinforce the idea that there may be a potential risk of inducing pejorative consequences on the mental health of participants, particularly as the majority of those studies are aimed at vulnerable people.

In a social context where evaluation is omnipresent, precedence is given to understanding the analysis and implications of the evaluation, and potential subjective impacts are overlooked. Psychological assessment with questionnaires or interview can cause anxiety in the respondent, either about the content of the questionnaire itself or its mode of delivery. Indeed, Cambre and Cook, 1985 [9] identified and studied computer anxiety and its impact on response behaviour. This form of anxiety is defined as apprehension, referring to negative emotions and cognition evoked by a real or imagined interaction with the computer-based tool [10].

4. Considerations based on expert reviews of research evaluated by an ethics committee

The moral imperative of medicine is the principle of beneficence (*"to do no harm"*) to which is added the principle of respect for patient autonomy, taking into account the patient's values and preferences, which is also at the core of information and consent procedures. While questionnaires are not inherently a source of risk to mental health, the conditions under which the tools are administered do need to be considered. Indeed, the validity and reliability of the results obtained may be affected if, for example, standard conditions for carrying out assessments are not adhered to, or if training of the professionals carrying out assessments does not ensure acquisition of the required methodological, psychometric, statistical and theoretical knowledge.

Gathering a participant's point of view concerning psychological aspects requires scientific and ethical consideration of the entire research process. Indeed, concern about anticipation and predictability of the potential effects of the encounter between the participant, the researcher and the measurement tool, permanently underpins the ethical nature of a research project and its credibility.

The interventional nature of research involving questionnaires appears well before they are administered: in the presentation of the research proposed (context, objectives, expected benefits, etc.); the relational dynamic between the investigator and the participant due to their mutual involvement; and in the degree of spontaneity and constraint of the measurement tools that are selected according to three criteria (themes investigated, formulation of the questions and modality of response). Only results derived from research that has been properly formulated with hypotheses, aims and methodology appropriate to testing them, can be considered of sufficient general interest to justify the use of personal data. Clinical trials using tools such as questionnaires and scales can only be ethically acceptable according to their scientific validity, the population studied, the representativeness of the groups studied, the objectives and purpose of the research, and the qualifications of the researchers employing the tools.

4.1. Choosing between "no objection" or "informed consent"

If we accept that to give consent is also to assume and adhere to the achievement of a certain goal, in order to advance health, consent is still necessary. In this regard, Marliac-Négrier [11] asks: *"Is it not in the general interest to ensure that all persons are provided with fair information so that they can measure the importance of the interests at stake and give their prior and considered consent?"* However, the classification of studies involving questionnaires as Category 3 requires the sponsor to collect only the participant's non-objection. The use of non-objection is understandable for certain epidemiological studies (Category 3), where refusal to participate by one or more individuals may have scientific consequences and may, for example, compromise the quality of information in a data registry. On the other hand, the ethical argument relates to collective imperative and to risk assessment: the data studied are available, intended for anonymous and impersonal use, and the risks are negligible.

However, in the case of Category 3 studies that rely on use of questionnaires or interviews, these arguments no longer apply. Obtaining consent *"I voluntarily and freely agree to participate in this research"*, is not equivalent to obtaining non-objection *"I do not object"*. Non-objection downplays what is at stake in the research and the active involvement of participants. By lending themselves to research involving psychometric tools, they will produce responses based on emotional, attitudinal and perceptual reactions. Such responses will reflect their perception of themselves in a given context, influenced by the perceived intentionality of the researcher, the perceived purpose of the research and their own expectations of the outcome.

Therefore, the procedure by which the participant is informed and gives consent should not be left until the researcher and potential subject meet. It must promote the autonomy of participants and protect them from non-consensual intrusion into their private life. It is also important to emphasise the value of involving participants, by informing them of the scientific aspects of the protocol when seeking their consent, as this can improve the study's scientific quality. A participatory approach allows the subjects to be informed of the value of the data they agree to provide when completing a questionnaire or an interview. It promotes greater involvement in the collection of data, thereby increasing the reliability of the data.

These considerations thus promote a substantive and qualitative view of information and consent, not just a procedural one.

4.2. The value of expertise in certain types of submissions within ethics committees

In our experience as members of an ethics committee, we have seen significant failings in research involving questionnaires and/or interviews. This suggests a lack of recognition, on the part of sponsors, of the issues at stake in this type of study, leaving room for numerous approximations that are not ethically acceptable.

A number of Category 3 applications were not approved, or had objections raised and requests for modifications where the following were found:

- A mismatch between the purpose of the study and its designation as Category 3

- Poor methods of participant recruitment: the use of posters or social networks instead of a one-on-one investigator/participant meeting
- Inadequate qualifications of the investigators
- Mismatch between aims and methods
- Use of inappropriate tools
- Lack of caution regarding the contextual psychological vulnerability of participants
- No planning for care of the participant should elements of concern be identified during questionnaires or interviews
- Impersonal or remote methods of administration of the instruments, such as self-administered questionnaires or interview by telephone
- Lack of precision and precaution in documents provided to participants for information
- No guaranteed minimum time allowed for reflection on whether to participate
- Hardship of taking part in the protocol

4.3. Epidemiological studies

Prevalence and determinants studies, requiring the use of questionnaires and provision of information about one's private life, raise questions about the balance between the choice of elements of interest and respect for privacy. Even when information is collected only for creation of personal databases and the research intervention does not objectively modify the participant's care or their life circumstances, the issue of attaining knowledge of one person by another person cannot be exempt from ethical review.

Attitudes to data collection based on questionnaires are downplayed if not neglected, ranging from general mistrust to casualness about the risk of disseminating personal data (e.g. "we have nothing to hide these days"). Such considerations necessarily minimise researchers' attitudes towards questionnaires. Therefore, the ethical prism needs to be oriented towards contemporary challenges of protecting the confidentiality of private life.

It is possible to consider collection of personal data as the paradigm of ethical reflection of research on the human. Any person who has consented to take part in a research project, and who therefore agrees to provide personal data, by answering questionnaires or by data concerning him or her being retrieved, is in a way making a gift of themself. As Anne Fagot-Largeault [12] writes, "they lend themself entirely, commit their very person, and not just a detachable and objectionable part of themself".

4.4. Psychopathological studies

Another aspect of our reflections within our ethics committee focused on the use of psychometric scales, in particular a questionnaire evaluating post-traumatic stress in a study on the impact of current health practice on perinatal psychopathology. The stumbling point here was the use of the questionnaire in the context of a pandemic and of social, physical and psychological vulnerability, for no other purpose than to obtain data on the existence of this ailment in the participants.

The questionnaire implied that childbirth is a traumatic event, which would have consequences for the way the questionnaire would be received by the participants and for the psychological impact of filling it out. In this respect it was strictly a tool which, in its conception and prerogative for use, could only be administered by a professional qualified in the particular field, only during or after a medical and/or psychological consultation, where post-traumatic stress was suspected. It was a clinical tool, not designed for research purposes. The vulnerability of the participants was not taken into account at all, as the questionnaire was proposed to be administered just after the birth, in the form of a self-assessment.

A psychometric tool does not *a priori* possess any intrinsic ethical value. Ethical dimensions lie with the user (qualification), the appropriateness of its use (adequacy of the objectives/methods), the manner of its use (mode of use, noting that self-administered questionnaires must be prohibited), the aims of the research, the population studied (noting vulnerability) and the outcomes (expected results).

5. Avenues for consideration in better framing subjective research

5.1. Methodologies

Ethical problems arise most often from lack of rigor and methodological approximations that come with the perception that questionnaires are neutral and innocuous. In fact, validation procedures for questionnaires have extremely heavy and rigorous psychometric qualities, thus testifying to the extreme precautionary measures that must be taken when using any scale. The corollary of this methodological requirement is the extreme caution and rigor with which these tools must be used, and they must not be used in an *ad hoc* way.

From this standpoint, the collection of subjective, or psychological data in clinical trials, whatever category it falls under, should be restricted to the use of validated questionnaires. Similarly, the use of questionnaires initially validated in a foreign language and then used in a French version, should be subjected to a cross-cultural validation procedure, not simply a translation [13]. Thus, the use of these scales should be restricted to qualified professionals, trained in the issues of these tools, the dimensions they are supposed to measure and their use in a research context. Emphasis may be placed on the use of tests in certain vulnerable situations, where decisions or changes in care may have serious consequences for the participant.

The slide that has occurred in their correct usage coincided with the emergence of mass distribution and above all, free access to questionnaires and modes of self-administration, especially psychometric tests. The proper use of these tools does not only depend on the way they are administered, but also on the investigator's ability to understand the implications for the patient and to plan modalities of care.

Another aspect of ethical reflection relates to the requirements of the aims and objectives of research, as well as their appropriateness, the tools being only the means to achieve them. Furthermore even if minimal, the potential risk of deleterious impact on the participant should be taken into consideration, as well as the possibility of uncovering previously unknown psychopathological disorders. This potential should be guarded against by the use of individual interim analyses, in order to identify possible difficulties at an individual level and to adapt medical care as necessary. In view of this, the modalities of inclusion of participants could be restricted to:

- individual in-person meetings between the investigator and the patient, not by remote means;
- the investigator going to the patient, not the patient coming to the investigator.

5.2. Reclassification

At a broader level, as ethical considerations focus on the classification of studies involving subjective data, studies that do not appear to meet the Category 3 criteria could be required to be reclassified. For legislative consideration, and in order to legitimise the interventional nature of research involving questionnaires and/or interviews, as long as the study objectives promote improvements in care, the classification of these studies deserve reconsideration and perhaps creation of a specific classification within Category 2. This idea seems to be supported by some sponsors who systematically classify their studies that involve the use of questionnaires as Category 2, even though according to the regulations they could be classified as Category 3.

In 2009, at a meeting organised by the Institute of Law and Health (Institut Droit et Santé at the University of Paris) it was envisaged that research using questionnaires would be considered as biomedical and

strictly interventional in nature [14]. Similarly, consistent with previous considerations, exclusive recourse to informed consent can be beneficial in order to guarantee the involvement of the patient and take into consideration his or her presumed vulnerability. Indeed, the systematic use of informed consent would make it possible to reduce the discrepancy between the investigator's anticipation of the results of an element deemed relevant to be measured, and the participant's lack of preparedness for the evaluation of this element, which may come as a surprise. In this regard, some sponsors whose projects remain in Category 3 are nonetheless making use of informed consent.

6. Conclusion

In view of the increased pervasiveness of measuring subjective dimensions in research in humans, we have been able to explore to what extent and with regard to what arguments this phenomenon needs rethinking from an ethical perspective. It was important to emphasise that the use of questionnaires or interviews is not only never neutral, because it is coloured by subjectivity and respective intentions, but also contributes to the validation of values, or even the production of new values [15]. Thus, the aspects examined were able to reveal more clearly the interventional nature of such research, involving the respective involvement of the investigator and the participant. Moreover, a review is currently underway at the legislative level, with the CPP proposing that Category 3 non-interventional research be reclassified as "interventional research involving only minimal risks and constraints".

In conclusion, it is important that ethics committees scrutinize non-interventional questionnaire/interview-based studies to ensure that the use of psychometric tests takes into account the interests and dignity of the individuals participating in the research, the society that financially supports the work, and the scientific principles that underlie and legitimize the activity of knowledge production.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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