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Original Research Article

Midwifery Practice: Perception of Respect for Ethical Standards on Free and Informed Consent by Finalists of the Instituts Supérieurs Des Techniques Médicales Du Congo

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Abstract

***Background*:** Free and informed consent (FIC) is, first and foremost, a privileged process of exchange between the researcher and the participant, from the beginning to the end of the research and even beyond. The participant will confirm his or her willingness to participate, after having been informed of all aspects of the study. The ELC takes the form of a written, signed and dated form. It must contain 21 items and be placed in the appendices of the brief. Our study has two objectives: to analyze the perception of the ELC among students; and to propose solutions to facilitate the conduct and respect of the participant's dignity. This qualitative study took place from May 19, 2021 to March 10, 2022. Data collection was conducted through focus groups (FGs) and individual interviews in neutral locations based on an evolving interview guide. Transcription was manual and data analysis was performed by grounded theory, after the realization of context of enunciation. Triangulation of data and researchers was respected. Eight GD and two individual interviews (46 subjects) were carried out to reach data saturation. Low interest in respecting the elements of the ELC, different definitions and negative views of the ELC were noted in the statements of the respondents. The majority of the ELC process (70%) does not respect GCP. The understanding and production of the form raises several ethical issues. It is appropriate to train supervisors and students in research ethics, evaluation and monitoring of research protocols.

Keywords: Free and informed consent, participant, research, Good Clinical and Ethical Practice.

INTRODUCTION

Over the past twenty years, academic research involving human subjects has evolved considerably and can take many forms (individual, team, funded, unfunded, sponsored, pure or basic, or basic, applied, free or directed) and can be carried out in all disciplinary areas without exception (from philosophy to mechanical engineering, computer science to biochemistry). Moreover, since university research is generally carried out in a context of training researchers, ethical responsibility takes on even greater significance since it is the very future of the research that is at stake [1-5].

In the DRC, in the Instituts Supérieurs des Techniques Médicales (ISTM), the activities inherent in research involving human subjects are relatively similar in all sections or faculties, insofar as they are mostly carried out on human subjects.

The Congolese Ministry of Health defines research involving human subjects as any biomedical, behavioural, epidemiological or social science study involving the systematic collection or analysis of data and the generalisation of results. All research involving human subjects must be conducted in accordance with the following ethical principles: respect for persons, beneficence and non-maleficence and justice [1-3].

The principle of respect for persons refers to respect for the dignity and autonomy of the human being. The principle of the dignity of the human being "prohibits subjecting the subject to degrading or humiliating ordeals" [2]. The autonomy of the person confers on the participant the right to decide on the

interventions to be made on his or her body when legally capable of doing so. Therefore, respect for this autonomy presupposes the existence of free and informed consent. Therefore, "the purpose of informed consent is first and foremost to protect patients from unacceptable interference with their bodies and their lives" [3]. It also aims "to help the patient retain control over his or her own life" [4]. The second principle at stake is that of beneficence and non-maleficence. It is not enough to require free and informed consent from the research subject. It is also necessary to protect the research subject from the dangers that might result from participation in the research [5]. The third principle is that of justice. The researcher must be fair and equitable in sharing the expected risks and benefits among various social groups [6]. Care must be taken to ensure that risks are not unfairly placed on the infirm and/or on those who are disadvantaged for racial, economic or other reasons [3-5].

FIC is a process by which a subject voluntarily confirms his or her willingness to participate in a study involving the human subject, after being informed of all aspects of the study that may affect his or her decision. Free and informed consent is recorded on a written, signed and dated form [4, 5].

In the DRC, for all biomedical research involving human beings, the researcher must obtain free and informed consent from the prospective subject. If the subject is unable to give consent, the authorisation of a representative duly mandated for this purpose in accordance with the law is required. The waiver of informed consent should be considered unusual and exceptional and should, in any case, be approved by an ethics committee [6-9].

Before seeking consent to participate in research, the researcher should, using language or other forms of intelligible communication, inform the individual of the following.

1. That she is invited to participate in the research as a subject;
2. The reasons why it meets the requirements and the voluntary nature of its participation;
3. That they are free to refuse to participate and may terminate their participation at any time without being penalised or losing any benefit to which they would normally be entitled;
4. What is the purpose of the research and what procedures are to be used by the investigator and the subject, and how does the research differ from usual medical care?
5. For controlled trials, what are the research procedures (e.g. randomisation, double-blind) and that the subject will only be informed of the assigned treatment after the study has been completed and the double-blind procedure has ended;
6. The expected duration of participation (including the number and duration of visits to the research centre and its total duration) and the possibility of early termination or participation in the trial;
7. Whether money or other material rewards will be given for the subject's participation and, if so, their nature and amount;
8. That, after completion of the study, subjects will be informed of the research findings in general terms and that they will be informed individually of any findings that relate to their personal health status;
9. That subjects will be able to access, upon request, data about themselves even if these data have no immediate clinical use;
10. 10) Any foreseeable risks, pain or discomfort or inconvenience to the subject (or others) arising from participation in the research, including risks to the health or welfare of the subject's spouse or partner;
11. The expected benefits of the research to the community or society, or the contributions of the research to scientific knowledge;
12. When and how any products or interventions that have been shown by research to be safe and effective are most likely to be made available to subjects after they have ceased participation in the research. Any alternative interventions or treatments currently available;
13. The arrangements that will be made to ensure the privacy of subjects and the confidentiality of records where subjects are identified;
14. Legal and other limitations on the ability of investigators to maintain confidentiality, and the possible consequences of breaches of confidentiality;
15. The rules applicable to the use of genetic test results and family genetic information, and the precautions taken to prevent disclosure of a subject's genetic test results to close family or third parties (e.g. insurance companies or employers) without the subject's consent;
16. The sponsors of the research, the institution to which the investigators belong and the nature and sources of funding for the research;
17. The potential direct or secondary uses of the subject's medical records and biological samples collected in clinical care. Whether it is anticipated that the biological samples collected in the research will be destroyed at the end of the research, and if not, a detailed description of how they will be preserved (where, how, for how long, and how they will be disposed of) and the future uses contemplated; and whether subjects have the right to decide on these future uses, to refuse their retention, and to require their destruction Whether commercial products may be derived from biological samples, and whether the

participant is to receive monetary or other benefits from the development of such products; whether the investigator's sole function is as an investigator or whether the investigator is both an investigator and the subject's treating physician;

18. The extent of the investigator's responsibility for providing medical services to the participant;
19. That treatment will be provided free of charge for specified types of personal injury or research-related complications, the nature and duration of such treatment, the name of the organisation or individual who will provide the treatment, and whether there are any uncertainties about the funding of such treatment;
20. How and by which body the subject, the subject's family or dependants will be compensated for any disability or death resulting from such personal injury (or, if applicable, that no provision is made for this);
21. Whether, in the country where the prospective subject is invited to participate in the research, the right to compensation is guaranteed by law, and in any case what measures are taken in this study, whether an ethics committee has approved or authorised the research protocol (Name and date) [10, 11].

In accordance with Good Clinical Practice as described in international guidelines and the guidelines of the Congolese Ministry of Health, these 21 essential elements of the ELC should be applied in midwifery practice during the management of labour. Labour is defined as the set of physiological phenomena that lead to the expulsion of the fetus from the genital tract. It corresponds to the periods of effacement, dilation of the cervix and fetal and placental expulsion. This labour is the result of myometrial contractions, which are in turn enabled by maternal oxytocin secretion [12, 13].

In the context of a health care relationship, free and informed consent implies fair and sufficiently complete information including explanation of the health condition, prognosis and possible therapies, expected and likely adverse effects and their possible alternatives [10-13].

The article of the Congolese Civil Code provides that "[...] no one may be subjected without his or her consent to care, whatever its nature, whether it be examinations, samples, treatments or any other intervention" [14]. Care is any act performed on a person with the aim of ensuring or restoring his or her health or well-being. According to this definition, care includes the medical act performed by the doctor and extends, in the hospital field, to acts performed not only by the doctor but also by the nursing staff in the context of examinations and taking samples [13, 14].

In law, the existence of free and informed consent is verified by three elements: the presence of a context of freedom that characterises the request for consent and its obtaining, the relevant information given to the cared-for person, and the ability of the parturient to consent. It is essential to emphasise that our proposal to identify parturients as a vulnerable population does not imply that every parturient is vulnerable. It is also important to note that the qualification of vulnerable should not be understood as a situation of incapacity or the like [15].

In the context of our problem, we will only examine the situation of standard therapeutic care in eutoctal or normal childbirth [12-16].

Furthermore, it should be noted that midwives promote a philosophy of "empowerment" of the woman in labour by carrying out an important transfer of knowledge before and during childbirth. In this context, it is up to the woman to decide what is right for her. To ensure that information is provided and that a free and informed consent form is produced, the Congolese legislator requires proof of the provision of this information. Similarly, Hippocrates wrote: "I will spend my life, I will practise my art in innocence and purity, whatever I may see, whatever I may perceive, outside the existence of my art, in the ordinary commerce of my life, which it is not appropriate to reveal, I will wrap myself in silence and I will consider everything as a secret.

We realised that the researchers (finalists in the bachelor's and master's degree) had difficulties in producing them. Several authors mention that situations of non-compliance with the essential elements of the CLE are conducive to the emergence of ethical issues.

Considering that these issues may have negative consequences for human subjects participating in research or care, as well as for researchers (finalists), it is important to address them in the context of obtaining and respecting the ELC of human subjects during research [17].

With respect to the ELC, research in physiotherapy has documented the importance of understanding the concept of the ELC in order to obtain and maintain it. Also, nursing studies have documented several barriers to obtaining and adhering to the ELC as well as several strategies used by these professionals to facilitate this process. However, very little has been written about student finalists' perceptions of the ELC, their strategies for obtaining and adhering to it, the barriers and facilitators to obtaining and adhering to it, and the ethical issues that may arise from it. For this reason, it is important to take a first step by exploring the perception of compliance with ethical standards for free and informed consent (FIC) in research practice

involving human subjects by future Congolese midwives [15-18].

Generally speaking, the main objective of our research is to identify the perception of respect for Good Clinical Practice and ethical standards in relation to CLE in research involving human subjects by finalist students of higher institutes of medical techniques in the DR Congo. While the secondary objective is to find solutions to overcome these difficulties and thus facilitate responsible conduct and respect for the human dignity of subjects involved in research conducted by finalists of the DRC's ISTM.

MATERIALS AND METHODS

The present study was conducted in the Instituts Supérieurs des Techniques Médicales ("ISTM") of Kananga (in Central Kasai), KIKWIT (in Kwilu province) and in the capital (Kinshasa). These ISTMs organise the following sections (faculties): nursing (SI), community health (SACO), laboratory (LABO), nutrition-dietetics (ND), management of health institutions (GIS) and the midwifery section (SF).

This is a qualitative study as we felt it was the most appropriate way to capture the perceptions of the finalist students regarding the CLÉS.

The qualitative research method we chose was grounded theory. This was a specific method developed by Glaser and Strauss in 1967 [19] whose aim was to build theory from the data collected and not from predetermined hypotheses.

The data was collected by the three participants. The technique used was mainly that of focus groups, involving three protagonists for each group interview: a facilitator and two observers. During our study, three different facilitators led the focus groups. They were chosen because of their knowledge of group facilitation. They were volunteers, of different genders, ages and professions.

We supplemented the data collection with two individual interviews due to a lack of participants to conduct a focus group.

The focus groups were held in locations that were suitable for groups of four to nine people, that were neutral, that were as close as possible to the finalists and that were easily accessible for them (often a room at their placement site: hospital, section, etc.). These places were allocated and managed by the sections as they corresponded to the places where the compulsory academic activities took place. This allowed the finalists to avoid travelling. The Focus Groups were conducted from 19 May 2021 to 10 March 2022.

To collect the data, the focus groups were structured by an interview guide written by the research team. The questions were based on our reflections and the literature.

Number and Average Duration of Interviews Conducted

We conducted 10 interviews, including 8 group interviews or focus groups and 2 individual interviews (IE), each with a verbatim, a context of enunciation, and coding with proofreading.

The duration of the interviews was different. The first one was long because of our inexperience.

Data Saturation

It was from the 7th Focus Group (FG 7 ISTMKGA) onwards that we reached theoretical data saturation. Indeed, we had not had any new ideas. An 8th Focus Group (FG 8 ISTMKGA) was then conducted to confirm this data saturation. The number of participants was not a criterion for defining and achieving it.

Data Analysis

We used VLC Player® software to listen to the interviews slowly in order to facilitate transcription. They were transcribed manually using Microsoft Office Word®. Each transcript was proofread with a replay of the interview by each researcher, which allowed the correction of spelling mistakes or the completion of passages not heard or misunderstood during the first listening.

Grounded theory analysis of the data: the verbatim was analysed using grounded theory to identify the key concepts that corresponded to the finalists' representations of KEY.

The assumption was that it was necessary to use the data "from the field" and to be as close as possible to the student finalists.

The criteria for judging the information were
Full information

a) Explanation of the reason for the implementation of the Labour Directorate;
b) Explanation of the expected effects of the scheme;
c) Explanation of possible adverse effects;
d) Explanation of possible alternatives or not.

Partial Information: 1-2 of the above criteria are missing.
Almost No Information: Only one of the criteria is present.
Nil Information: No information is given.

In qualitative research, the definition of the concept of triangulation was attributed to the work of

Denzin [20]. This concept was defined more recently by Miles and Huberman [21] "triangulation is supposed to confirm a result by showing that independent measurements of it point in the same direction, or at least do not contradict it". Our aim was to use this approach to increase the validity and quality of the results obtained. It was therefore a strategic choice to control for possible biases.

In the first instance, our study was based on researcher triangulation, i.e. it involved the participation of several researchers who were observing the same phenomenon. During the interviews, there were two observers who had the point of view of a researcher outside the research: the independent researcher (our assistant). In fact, we had sent him our analyses as we went along so that he could come out and give his opinion on our possible disagreements.

In a second step, we used triangulation of the data as it was collected from different finalists, in different places and in a different time frame.

Ethical Consideration

The participant consent form was distributed, signed and collected before the focus group session or individual interview began. It guaranteed the anonymity of the participants, asked for their agreement to be recorded by Dictaphone and assured them that the data would be definitively destroyed at the end of our study. The anonymity of the participants mentioned was ensured during the transcription of each interview. As researchers, we declared the absence of any conflict of interest in the course of our research work.

We have obtained a favourable opinion from the Ethics Committee of the department of Notre Dame University and from the Research Commission on 17 May 2021.

SEARCH RESULTS

Table 1: Socio-demographic profile of our respondents

Interviews	**FG1 ISTM/KIN**	**FG2 ISTM/KIN**	**EI 1 ISTM Kin**	**EI 2 ISTM Kin**	**FG3 ISTM Kin**	**FG4 ISTM Kikuit**	**FG5 ISTM Kikuit**	**FG6 ISTM Kga**	**FG7 ISTM Kga**	**FG8 ISTM Kga**	**Total =10 services of which 8 FG and 2 EI**
Date	19/05/2021	22/02021	22/06/2021	22/06/2021	08/09/2021	06/01/2021	07/02/2022	11/02/2022	08/03/2022	10/03/2022	From 19 May 2021 to 10 March 2022
Number of participants	6	9	1	1	5	6	5	5	4	4	46
Duration of interviews	75 MIN	40 min	30 min	20 min	30 min	30 min	50 min	40 min	45 min	35	39.5 min
Graduation	6	8	1	0	4	4	4	1	3	1	32
Licence	0	1	0	1	1	2	1	4	1	3	14
Male	1	4	0	1	2	3	1	2	2	1	17
Women	5	5	1	0	3	3	4	3	2	3	29
Ages	25 to 28 years old	25 to 27 years old	26 years old	27 years old	24 to 28 years old	25 to 28 years old	24 to 28 years old	23 to 28 years old	26 to 28 years old	25 to 27 years old	22 to 26 years old on average
ISTMKGA	1	3	0	1	3	1	1	2	2	1	15
ISTMKKT	2	2	1	1	2	1	1	1	3	1	15
ISTMKGA	1	3	1	1	3	1	1	1	3	1	16

Source: Based on the field research results of our qualitative study from 19 May 2021 to 10 March 2022.

Caption

a) FGD: Focus Group Discussion;
b) IE: Individual Interview;
c) E: Entretien or Interview;
d) ISTM: Institut Supérieur des Techniques Médicales ;
e) Kin: Kinshasa;
f) Kga: Kananga.
g) KEY: Free consent.

This table 1 reveals that the population was diverse and covered all the characteristics of the finalists. The study had 46 participants with as many finalists having studied in the city (ISTM Kinshasa) (16 participants) and in the provinces ISTM Kananga [15] and Kikwit [15] (30 participants). The population covered both cycles (bachelor and master 1 or licence) and sections (SF). Ages ranged from 24 to 28 years with an average of 22 to 26 years. There were more women than men, which was consistent with the new demographics of students in the health field.

Table 2: Finalists' experience of the ELC, definition, purpose and interest, process, barriers to compliance and proposals for improvement of the ELC

Sub-theme	Category	Verbatim	Meaning
KEY Perception	Definition Understanding the KEY Enactment of the KEY	"It is a response that is voluntary p1, F 2". "It is that the person gives consent without feeling constrained, whether by other workers, whether by me, whether by their family. "[It is] the possibility [offered to the research participant] to say yes or no without external constraints p2, FG2". "Free is really about the person themselves making the decision not someone else in their place p1, FG1". "For me, free means that she knows the answers to give to the interview and says it freely p2, FG1". "For me, free means that she really knows what it entails, what she accepts or refuses p2, FG2". "Each person has the right to autonomy, the right to self-determination p1, FG2". "I would say that enlightened is very much about understanding. [It's] being able to understand the situation p4, FG1". "It is that the person has all the time to think in order to make the decision p12, FG2	Voluntary and free response
	Purpose and interest(ethical, institutional and legal standards)	"I don't think about the consent form while I'm doing my TFC! p1 I1 "In our College of Nursing, we have a lot of articles that say you have to ask for the free and informed consent of the person p1, FG5". "Our code of ethics [says] that we should always get consent. We have certain procedures to follow as well to be compliant with the institution. [...]. I think it was established to respect the rights of the user p1, FG5". "It's mainly at the level of the Charter of Human Rights and Freedoms [...]. The entire legal system is based on this. [...] So everyone has the right to self-determination, regardless of their race, gender and so on. So that's where it comes from, the whole health system is based on that. So, I think it's really based on the Civil Code, on the law p1, FG6"	
	Process	"I go to her, introduce myself, then tell her what I'm going to do p3, FG8". "I try to be in a place of his choice so that there is no pressure p2, FG2". "It's to give all the information for a research, so to say the aim of the research, what the different steps are, what are the conclusions we are going to draw p1, FG2". "I always finish by asking: do you agree? P3, FG3". "Ensure that the person still agrees to continue with p1, FG2".	
Obstacles au respect des normes de CLE	Insufficient tutoring(director and co-director miss time)	"I've had the extremes, one absent and one dictator... It's hell! If they haven't even read them, they don't answer their emails or calls, you leave the manuscripts for weeks and weeks do without feedback. Once the defence is scheduled, there, it's way too much there, too present, too threatening all that, quickly get its management fees. And the management? (Laughs). P1, FG6". "... There were almost fifty of us at his place for the management, how can he follow each of us efficiently? (laughs) P2, FG4 "He didn't know what the essential elements of a CLE were. He told me that it looked good but that he would read it when he had time. For 3 months now, he still hasn't corrected it for me and yet I have stimulated him! I have nothing at all. As a result, on the day of the defence of my TFC in the first cycle, the jury criticised me heavily, almost shouted at me, for not having respected the dignity of the human person. p1, FG6". "They should be really trained on "what is a KEY?" p3, FG1".	Poor supervision

		"The director needs to come to some sort of agreement with himself. p1, FG2 "Dear Thinkers: STOP! p3, FG7	
	Late and insufficient learning of ethical standards in research	"Besides, we are at the end of our cycle; we still haven't had any training on research ethics! p1, FG2 "But afterwards, when you have the TFC, the dissertation, the thing, a lot of the paperwork for the internship report, I think it's not essential! p2, FG3".	
	Lack of rigour in the validation of the ethical part in the TFC or dissertation	"He didn't know what the essential elements of a CLE were. He told me that it looked good but that he would read it when he had time. For 3 months now, he still hasn't corrected it for me and yet I have stimulated him! I have nothing at all. As a result, on the day of the defence of my TFC in the first cycle, the jury criticised me heavily, almost shouted at me, for not having respected the dignity of the human person. p1, FG6". "Yes, but it's good that they're getting us back to work. P3, FG5 "They don't agree with each other when there are two of them (director and co-director) so frankly... (Rolling his eyes). P2, FG6". "It's all very well to ask us for things when you haven't tested them yourself! I would like to see a consent form from the TC and SSA X.Y. It's easy to ask us for quality consent forms without having done it! p3, FG6". "That, (KEY) in the appendix of the brief, it's so that there's something in our brief (laughs). It's a fashionable thing to have an ethical point in your brief. But when we defend our elders (laughs), we notice that readers don't even read. In the end, we wonder what all this bullshit is for! p3, FG2".	
	lack of neutral validation	"As far as validation is concerned, I see that it is not only effective during the production (by the director and co-director) but also once it is finished. It would be important that a validation in advance, i.e. before the defence of my dissertation, be done by someone outside the dissertation p1, FG2 "	
	Unclear written explanatory material.	"If students are not excited about the KEYS, they should stop sticking to these tracks and consider other tracks. They should listen to us a bit more. P4, FG3 "There was another long reminder which I don't think serves any purpose, which only touches on the subject of the consent form in general without going into any real depth on these essential elements. p1, FG1". "There's a document that explains the outline of the thesis and what we have to put in the ethical part. But finally, if you read it (the ethical part), it's a sort of generic note with terms that mean everything and nothing, empty terms that define what you're supposed to put in and how to put it in. It's not very intelligible. P3, FG1".	Clearer written explanatory material.
	Lack of personal motivation	"We've lost this habit of writing and finding it in old syllabuses and notes, it takes time. P2, FG4. "I find it burdensome to start it because I know it will take hours and hours and hours ... Once it's started, its fine, butto start it, well .... P1, FG5 "	
Proposition pour l'amélioration	Research ethics training in the research methodology course	"Besides, we are at the end of our cycle; we still haven't had any training on research ethics! p3, FG2 "But afterwards, when you have the TFC, the dissertation, the thing, a lot of the paperwork for the internship report, I think it's not essential! p3, FG3". "Faced with these difficulties in producing consent forms, we often organise ourselves to have the accompaniment of our elders (finalists) who sometimes explain to us in their own way and, this is not enough, we need a good training in what! p1, FG3 "	Not late and not insufficient preparation in research ethics
	validation by a neutral person	"As far as validation is concerned, I see that it is not only effective during the production (by the director and co-director) but also once it is finished. It would be important that a validation in advance, i.e. before the defence of my dissertation, be done by a person outside the dissertation p1 , FG2 " ".... Often, during the defence of the memoirs of our elders, we see too much criticism of the ethical part, but this part has been read and re-elected by the director and codirector, so why not have it read by people from outside the management team, perhaps it (an outside person) will give a plus what! p2, FG4 " "can be created a team that has to deal with the correction of this ethical part before its publication p3, FG5 ".... We are still waiting for this evil (poor quality KEY application form) to be done to criticise us, why not prevent this evil by supervising us in the production of our consent forms, there are no expert teams for that? p3, FG4".	Need for an institutional ethics committee.

Source: Based on the field research results of our qualitative study from 19 May 2021 to 10 March 2022

According to this table n°2, Sub-theme 1: perception of CLE: the participants in our study present a diversified perception of the notion of CLE. Some mentioned the ethical principles (autonomy, etc.) in making decisions to participate in the research, while others equated it with the process of giving voluntary responses after a period of reflection.

Sub-theme 2: Obstacles to achievement and respect for standards: The interviewees claim to be victims of poor supervision. They are victims of late and insufficient learning of research ethics, insufficient tutoring and demotivation during the work defence activities, which the evaluation team does not take seriously.

Sub-theme 3: Proposal for improvement: Need for an institutional ethics committee for validation of CLÉ. Presence and completeness of free and informed consent forms attached to TFCs or briefs

Nomenclature	Number of KEYs (in %)	
	Completeness of ELCs in TFC appendix or brief	
	Completeness -	completeness +
FG1	100	0
FG2	100	0
FG3	100	0
FG4	100	0
FG5	100	0
FG6	100	0
FG7	100	0
FG8	0	10
E1	0	10
E2	0	10
Average	700	30

Number of KEYs (in %) according to completeness (presence of the 21 essential elements) completeness + if 21/21 and completeness - if less than 21.

Source: Based on the field research results of our qualitative study 19 May 2021 to 10 March 2022

With regard to the results obtained in Table 3, we note that the analysis of the appendices of the participants' final reports and dissertations showed a predominance of finalists who were not up to date with their CLÉ (70%), despite a significant participation in the coaching sessions, calculated at 100%. Indeed, the coaching sessions represented the first contacts with the writing and correction of the consent form, a copy of which is included in the appendix of each final report.

DISCUSSION

Our study was initiated with the aim of identifying the perception of Respect for Ethical Standards in Free and Informed Consent (FEC) in Midwifery Practice by the Finalists of the Higher Institutes of Medical Techniques of the DR CONGO and consequently, to understand the difficulties of these participants in producing FECs respectful of Good Clinical and Ethical Practices.

At the end of the present study, it was observed that there was ambivalence in the knowledge of the concept of free and informed consent (FIC). Some did not know it, others were hesitant. Some knew only the first part, i.e. consent, "it is a response that is voluntary p1, F 2". "It is that the person gives their consent without feeling constrained, whether by other stakeholders, whether by the researcher, whether by their family. "[It is] the opportunity [given to the research participant] to say yes or no without external constraints p2, FG2". Definitions differed between finalists. Finally, for the majority of finalists interviewed, the 'informed' and 'free' parts of consent were not understood. On the notion of "free", the finalists defined it in several ways: "free, it is really that the person himself makes the decision, not someone else in his place p1, FG1". "For me, free means that she knows the answers to give to the interview and says it freely p2, FG1". The notion of 'enlightened' was experienced differently by the finalists: 'I would say that enlightened is very much about understanding. [It's] being able to understand the situation p4, FG1". "It is that the person has all the time in his or her possession to reflect in order to make the decision p12, FG2".

The majority of the finalists characterised the concept of "CLE" as only a voluntary response by the participant that originates in the code of ethics. Others did not know how to define it in its free and informed component and process.

This result is in line with that of Bushby, K., Chan, J., Druif, S., Ho, K., and Kinsella, E. A. (2015) on "Ethical tensions in occupational therapy practice: A scoping review" who, in their findings, observed that situations of non- compliance with the essential elements of the ELC are conducive to the emergence of ethical issues [6].

Considering that these issues may have negative consequences for human subjects participating

in research, as well as for finalists, it is important to address them in the context of obtaining and respecting human subjects' ELC during research.

Finally, the participants in our study state the solutions to the obstacles in these terms: "[Faced with these difficulties in producing consent forms, we often organise ourselves to have the accompaniment of our elders (finalists) who sometimes explain to us in their own way and, this is not enough, we need good training in what! p1, FG3]". [As regards validation, I see that it is not only effective during the production (by the director and co-director), but also once it is finished. It would be important that a validation, in advance, i.e. before the defence of my thesis, be done by a person outside the thesis p1, FG2]".

"[Besides that, we are at the end of our cycle, we still haven't had any training on research ethics! p3, FG2]". "[A team can be created to take care of the correction of this ethical part before its publication p3, FG5]". These results highlighted the need to introduce the professional ethics course in the first years of graduation and the research ethics course early in the training of health personnel in the ISTMs in the Congo, i.e. in the second year of the baccalaureate or graduation (in the initiation to research course) and the first licence or master 1 (in the research methodology course) on the one hand, and on the other hand, the creation of institutional ethics committees to provide ethical support for researchers and the protection of participants in research Indeed , Delany, C. M. [3] describes three mandates of an institutional ethics committee: (1) to examine research protocols involving subjects to ensure that they comply with internationally and locally recognised ethical principles; (2) to monitor the conduct of studies; and (3) to participate in follow-up and monitoring once the studies have been completed, if necessary. The functions of this Institutional Ethics Committee will be to: (i) identify and assess the potential risks and benefits of the research; (ii) evaluate the procedures and documents (printed or otherwise) that will be used to obtain informed consent from participants; (iii) evaluate the methods of recruiting subjects and the incentives, if any, offered to them; (iv) assess the risks to the confidentiality of participants' information (and the related dangers of discrimination) and the adequacy of confidentiality safeguards; and (v) consider any other issues that may affect the ethical acceptability of the research.

Our work could also be affected by selection bias, as the study participants were selected from only official ISTMs, which are active in the field.

We therefore recognise, through the limitations outlined above, that our work does not have absolute objectivity. Despite all these limitations, we believe that they make this work original and unique.

CONCLUSION

Any consent collected and signed outside any quality approach (which respects the autonomy and protects the autonomy of vulnerable subjects) and completeness of information would be questionable.

Despite the above-mentioned limitations, the results of this study establish for the first time ever in an African population, in particular in academic circles in the DRC, the lack of understanding of the CLE and its emphasis, the strong discrimination and the chaotic restriction of freedom of opinion guaranteed by the United Nations Charter of Human Rights in this area.

Outlook

Our study advocates for the promotion of ethical principles and standards through the imminent creation of an Ethics Committee in all medical education institutions (ISTM and Universities) in Congo with a guaranteed legal framework.

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