

HOW OFTEN ARE ETHICS APPROVAL AND INFORMED CONSENT REPORTED IN PUBLICATIONS ON HEALTH RESEARCH IN CAMEROON? A FIVE-YEAR REVIEW

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ABSTRACT: WE ASSESSED THE EXTENT OF RESEARCH ethics approval and informed consent reporting in publications emanating from Cameroon and indexed in PubMed from 2005–2009. In our review of 219 full-length articles, we found that 57.53% reported ethics approval, 70.78% informed consent, and 50.68% both ethics approval and informed consent. Reporting these procedures was more common in randomized clinical trials than in other study designs. Also, 59.52% of the articles on vulnerable populations documented ethics approval and 76.19% documented informed consent. This study also identified some structures for ethics review and recommends some next steps for research on the quality of ethics review in Cameroon.

KEY WORDS: Cameroon, ethics approval, informed consent, research ethics committee

Received: July 7, 2010; revised: February 2, 2011

CAMEROON IS A SUB-SAHARAN COUNTRY located in the Central African region. Human research in Cameroon is carried out by investigators in public and private universities and research institutions. The first research ethics committee (REC) in Cameroon was created in 1987 (Cameroon Ministry of Public Health, 1987). Since then, the number of RECs in Cameroon has increased considerably, although

today the exact number is unknown. In 2006, the Network for Ethics on Biomedical Research in Africa (NEBRA) reported that the number of RECs operating in Cameroon was of dubious reliability, based on the available data at the time. Effa et al. (2007) had identified only two RECs in Cameroon, while a recent survey (personal communication) identified 14. Training in research ethics in Cameroon is mainly in the form of workshops; research ethics is not part of the curriculum of universities in Cameroon.

International guidelines (CIOMS, 2002; World Medical Association's Declaration of Helsinki, 2008) strongly advocate the submission of research protocols to a REC for review and approval before the commencement of a research study, and that researchers should engage potential research participants in an informed consent process before enrolling them in any study. The Declaration of Helsinki (paragraph 27) recommends that publishers do not publish articles that fail to respect these procedures. The International Committee of Medical Journal Editors (ICMJE) requires authors of journal articles to state in their publications if the study was done according to national or institutional ethical standards (www.icmje.org). Unfortunately, failure to report these ethical procedures in scientific publications continues to occur (Schroter et al., 2006), and other studies have shown that investigators are not paying sufficient attention to these ethical procedures (Abdur Rab et al., 2008; Sumathipala et al., 2008; Chaturvedi & Somashekar, 2009). Failure by authors to obtain and report ethics approval and informed consent might therefore suggest that they consider these steps as unimportant details or obstacles to their work (Ruiz-Canela et al., 1999).

Recent studies have surveyed some RECs and REC members in Cameroon (Milford, Wassenaar, & Slack, 2006; Nyika et al., 2009; Ateudjieu et al., 2010) with a view toward identifying the needs and capacity of RECs in Africa. However, there is limited information on existing RECs in Cameroon and the Central African region as a whole (Effa et al., 2007), or empirical studies of research ethics in Cameroon. In addition to examining the extent of review and informed consent, we also identify some structures for ethics review in Cameroon.

Method

In this five-year (2005–2009) retrospective study, publications from Cameroon indexed on PubMed were obtained using “Cameroon” and “Cameroonian” as the search terms. Studies that did not require ethics approval and informed consent (Schroter et al., 2006; Bavdekar, Gogtay, & Wagh, 2008) were excluded. Studies involving Cameroonians (as research participants) residing abroad were also excluded, as they were considered likely to obtain ethics approval from the country in which the research was undertaken. The full texts of the articles were obtained using the WHO/HINARI Program (<http://www.who.int/hinari/en/>). The year of publication, study design, population under study, if the study obtained ethics approval and the name of the REC from which it was obtained, and if informed consent was obtained and the type of informed consent (written, oral, assent, or community) were extracted from each article. Data extraction was rechecked by a second reviewer. Full text articles (pdf files) were also searched using: “Ethic”, “approval”, “review”, “committee”, “consent”, and “informed” as the search terms. The data were analyzed using MS Excel 2007 and STATA version 11 (Stata Corporation, College Station, Texas, U.S.).

Results

The PubMed search yielded a total of 1,117 references. Of these, 344 met the inclusion criteria of the study. The full text of 219 of the 344 articles was obtained. These articles were published in 119 different journals, 19 of which had signed the ICMJE policy. We could not get access to the full text of the other articles. However, they were published in 35 different journals, four of which had signed the ICMJE policy.

Reporting REC Approval

The proportion of articles that reported obtaining research ethics approval varied over the study period (Table 1), although this was not statistically significant. Ethics approval was reported in just 58.33% of studies on people living with HIV and in 70.97% of studies on children (Table 2). All publications on randomized controlled trials (RCTs) documented ethics approval, whereas only 54.59% of cross-sectional studies documented ethics approval (Table 3). A total of 126 (57.53%) articles reported ethics approval from an institution in Cameroon (117) (Table 4) or abroad (7) or both (26). Ethics approval was also obtained from such administrative units as the Ministry of

TABLE 1. Documentation of Ethics Approval and Consent According to Year.

Year of Publication	Number of Articles	Documented Ethics Approval (%)	Documented Consent (%)
2005	35	16 (45.71)	27 (77.14)
2006	40	24 (60.00)	28 (70.00)
2007	38	25 (65.79)	26 (68.42)
2008	46	21 (45.65)	27 (58.70)
2009	60	40 (66.67)	47 (78.33)
Total	219	126	155

TABLE 2. Reporting of Ethics Approval and Consent According to Vulnerable Groups.

Vulnerable Group	Number of Articles Reviewed	Documented Ethics Approval (%)	Documented of Consent/Assent (%)
People living with HIV	60	35 (58.33)	39 (65.00)
Children	31	22 (70.97)	26 (83.87) Assent 2 (6.46)
Pregnant women	18	11 (61.11)	16 (88.89)
Total	109	68 (62.39)	81 (74.31)

TABLE 3. Documentation of Ethics Approval and Consent by Study Design.

Study Design	Number of Articles	% of Total Articles Reviewed	Documented Ethics Approval (%)	Documented Consent (%)
Routine data analysis	12	5.48	1 (8.30)	0 (0)
Case reports	7	3.20	0 (0)	1 (14.29)
Case series	2	0.91	0 (0)	1 (50)
Cross-sectional studies	129	58.90	70 (54.59)	94 (72.86)
Qualitative studies	27	12.33	18 (66.67)	22 (81.48)
Cohort studies	27	12.33	22 (82.90)	23 (85.18)
Randomized control trials	14	6.39	14 (100)	13 (92.86)
Case control studies	1	0.46	1 (100)	1 (100)
Total	219	100.00	126 (57.53)	155 (70.78)

TABLE 4. Ethics Approval in Cameroon and/or Abroad.

N° RECs Documented in Study (number of times cited)	RECs in Nkwescheu's List (year of creation)
1 National Ethics Committee of Cameroon (62) National Ethics Committee of the Ministry of Public Health (11) Human Use Committee, Cameroon Ministry of Public Health (2) Ethics and Scientific Committee of the Ministry of Public Health (1) Ethics Committee of the Ministry of Public Health (1) Ethics Review Committee of the Ministry of Public Health (1) National Ethical Committee for Ethical Review (1) Research Ethics Committee of Cameroon (1) Ethics Committee of Cameroon (1)	Comité National d'Ethique du Cameroun, Yaounde (1987)
2 Ethics Committee of the Tropical Medicine and Research Station, Kumba (1) IRB of the Tropical Medicine and Research Station, Kumba (2)	Institute of Medical Research and Study of Medicinal Plants IRB Annex, Kumba (1994)
3 Ethics Committee of the Faculty of Medicine and Biomedical Sciences (2) IRB of the Faculty of Medicine and Biomedical Sciences (1)	Faculty of Medicine and Biomedical Sciences IRB, Yaounde (2001-2002?)
4 Cameroon Baptist Convention Health Board IRB (1)	Cameroon Baptist Convention Health Board IRB, Bamenda (2004)
5 University of Buea Ethics Committee (4) IRB of the University of Buea (1)	University of Buea IRB, Buea (2008)
6 Cameroon Bioethics Committee (1)	NA
7 Ethics Committee of the University of Yaoundé I (1)	NA
8 Research Ethics Committee of IFORD (1)	NA
9 IRB, Delegation of Public Health, South West Province (1)	NA (in the process of creation)
10 University of Douala, Use of Human Subjects (1)	NA (in the process of creation)
11 NA	Cameroon Bioethics Society, Douala (1990)
12 NA	Research Foundation in Tropical Diseases and Environment (REFOTDE) IRB, Buea (1998)
13 NA	Institute of Medical Research and Study of Medicinal Plants Yaoundé IRB, Yaounde (2004)
14 NA	Bamenda Provincial Hospital IRB, Bamenda (2004)
15 NA	Ethics Review and Consultancy Committee of the Cameroon Bioethics Initiative (CAMBIN), Yaounde (2006)
16 NA	Comité d'Ethique du Centre International de Référence Chantal Biya, Yaounde (2006)
17 NA	Biotechnology IRB, Nkolbisson, Yaoundé (2007)
18	IRB University Teaching Hospital, Yaoundé (-)
19	IRB General Hospital of Yaoundé (-)

NA: not available; -: year of creation not available.

Public Health (cited in 8 articles), Ministry of Research and Innovation (cited in 1 article), the delegations of Public Health in Buea (cited in 8 articles) and Bamenda (cited in 1 article), and the Yaoundé central hospital (cited in 1 article).

Reporting of Informed Consent

Informed consent was documented in 155 (70.78%) articles, 41 written, 1 "tacit" consent, and 17 from parents or guardians. Oral consent and community consent was documented in 15 and 2 articles, respectively. Informed consent from family heads was reported in 2 articles and "explicit" consent in 1 article, while 76 of the articles simply reported that consent was obtained. Informed consent was not reported in 1 article on RCTs. Assent

was documented in just 6.46% of studies on children (Table 2). Informed consent was documented in 111 (88.10%) of the 126 studies that reported ethics approval ($P = 0.0001$), whereas it was documented in only 44 (47.34%) of the 93 studies that did not report ethics approval.

Discussion

This study reflects the state of research review and informed consent in a developing country with very little legislation governing health-related research. A majority of articles from Cameroon did not report ethics approval and informed consent. Although this does not amount to proof of failure to obtain ethics approval and informed consent, it might actually be the case.

Our findings are, however, less worrying than those of Chaturvedi and Somashekar (2009), who reported a failure rate of 74% and 36%, respectively, for ethics approval and informed consent in articles published in the Indian psychiatry journal. However, the failure rate in our study is likely to be an underestimation, given it is restricted to journals listed on PubMed, thereby excluding several African biomedical journals.

Over the years under study, reporting ethics approval and informed consent remained almost unchanged, contrary to growing international awareness of the value of incorporating these ethical issues into the execution of health research. This implies that Cameroon is still lagging behind the global community in reporting these important ethical components of health research. Authors of articles reporting analysis of routine data, case reports, and case series significantly failed to document ethics approval and informed consent compared to RCTs, cohort, and cross-sectional designs (Table 3). Researchers may not always be aware that some of the less-intrusive research designs tend to carry more potential risks than might be anticipated at first glance.

Reporting the type of informed consent was not a common practice, as vague statements such as “consenting individuals” and “consent was obtained from each participant” were used quite frequently. Very few (6.46%) articles of studies on children documented assent. It is important that researchers not only obtain informed consent from parents or guardians of children they enroll in a study, but also ensure that the children give their assent, as far as they are capable, to being a part of the study. Community consent was documented in one article. Although this is an acceptable cultural practice, it is recommended that such community approval be accompanied by informed consent from each research participant (Krogstad et al., 2010). Informed consent was more likely to be obtained for studies that had ethics approval than for studies that did not obtain ethics approval (88.10% and 47.34%, respectively).

Many authors obtained research ethics approval from structures that apparently are not RECs and lack research ethics review capacity, such as the provincial delegation of Public Health and the Ministry of Public Health, which instead are charged with administrative approval and supervision of health-related research. There is therefore a blurred demarcation between ethics and administrative approval among some researchers in the country and even among some administrative health units.

Some of the RECs identified in this study may have been duplicated because authors stated their names differently. For example, the “University of Buea Ethics Committee” and the “IRB of the University of Buea” could be one and the same REC (Table 4). It is an intriguing question as to why authors would refer to the same REC using different

appellations. This paper therefore identifies a total of 19 RECs in Cameroon, contrary to the two documented by Effa and colleagues in 2007 and the two that are officially recognized by the Ministry of Public Health. The state of RECs in Cameroon remains chaotic. In Nigeria (<http://nhrec.net/nhrec/news.html>, 10/01/2011) and South Africa (www.doh.gov.za/docs/factsheets/guidelines/ethnics/sec3.pdf, 10/01/2011), RECs are accredited and listed by name on websites. It would be desirable for the Ministry of Public Health to put together a more comprehensive list of RECs in Cameroon and make it publicly available to the various stakeholders involved in health-related research.

Research Agenda

This study highlights the need to explore a number of issues concerning research ethics in health research. These include:

- The frequency of reporting of these matters in published research in Cameroon.
- The knowledge, attitude, and practices of Cameroonian researchers on research ethics.
- Survey of editors of African journals on their perspective regarding the need to document ethics approval and informed consent in articles to be published in their journals, versus their simply being informed of these details by authors.
- The understanding and clear description of the actual procedures employed in obtaining informed consent. For example, did the investigator provide truly informed consent by offering a clear explanation and check for comprehension, or simply engage in a bureaucratic procedure of asking participants to sign a consent form?

Acknowledgment

We are grateful to Dr. Nkwescheu Armand of the Division of Operational Research, Ministry of Public Health, Cameroon, for providing us with the list of RECs in Cameroon, recognized even if not approved by the Ministry of Public Health. And to the Cameroon Bioethics Initiative (CAMBIN) for the facilities placed at our disposal during the study period. We equally thank the two anonymous reviewers for the comments they made, which contributed to improving the quality of the paper.

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