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EDITORIAL

Ethical considerations for leprosy researchers

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The aim of Leprosy Review (LR) is to contribute to the better understanding of leprosy and its control, mainly through publishing reports of research. Some authors are clinicians or field workers rather than being primarily scientists. As a member of a Research Ethics Committee under the UK Health Research Authority (CRB) and a university lecturer in research integrity (RP), and as Associate Editors of LR (both), we hope that this article will help such authors to recognise and manage the ethical aspects of their studies. We begin with commonly accepted statements of ethical principles, the application of these principles to particular circumstances, and then discuss Ethical Review and the issues it would cover; we then consider methods used by editorial boards to ensure ethical standards in their publications. Finally, we highlight some of the potentially difficult issues in leprosy-related research.

Ethical research principles, historical perspective

Research involving human subjects is essential if there is to be evidence on which to base decisions about clinical management of cases, and about public health programmes and policies (including the management of disability, stigmatisation or social disadvantage related to health issues). This has to be done in an ethical manner, however, based on three generally accepted underlying principles of *respect for persons, beneficence and justice*.

One of the earliest modern statements of acceptable standards for ethical behaviour in relation to research involving human subjects was the Declaration of Helsinki,[1] which has, since its original publication in 1947, been through many revisions but is still considered a valuable reference document. Two more recently-compiled authoritative publications, on epidemiological studies and on health-related research involving humans, respectively, are those from the Council of International Organisations of Medical Sciences.[2,3] These offer point-by-point guidelines on how the ethical principles governing the conduct of biomedical research,

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set forth in the Declaration of Helsinki, could be effectively applied, particularly in low and middle income countries (LMIC), taking into account local cultural and physical factors (such as geographical aspects and availability of facilities). An online module is available to facilitate their use.[3] Reaching consensus on detailed implementation of the guidelines can be difficult as researchers involved will have to consider prevailing values in the community concerned. The Nuffield Council on Bioethics has helpfully proposed several principles, including the need to be sensitive to cultural differences, and not to exploit people.[4] The duty of cultural sensitivity arises from respect for persons and does not require compromise of fundamental values: "the principle of equal respect does not imply that we must behave towards others in a uniform manner, since features of individuals and of their circumstances, will differ. Parity of respect requires us to address the specific needs and circumstances of individuals in determining how to behave towards them" (Section 7.10, page 90).[4] Inequalities in power and advantage between researchers and the population targeted present real risks of exploitation: researchers have the responsibility to ensure that – so far as possible – communities in LMIC do actually benefit from the research in which they participate.[4]

Nature and function of an Ethical Review Committee (ERC)

The Ethical Review Committee's oversight ensures that the rights, safety, and well-being of study participants are protected.[5,6] Universities and hospitals often have an Institutional Review Board (IRB) which functions as an ERC, for studies to be carried out under its responsibility. The World Health Organisation (WHO) provides guidance on establishment, maintenance, functioning and governance of ERCs.[7] Committee membership is normally multidisciplinary and consists of a selection of independent professionals and lay members who amongst them have sufficient expertise and who represent a range of community and cultural values.[4] To be ethically acceptable, a study should be scientifically sound, but scientific review by people with appropriate expertise is best kept separate from ethical review.[4] When researchers from one country wish to undertake a study in another country, their choice of location needs to be clearly justified and it is desirable for ethical review to be obtained in both countries.[4] Many LMICs, such as Nepal and Bangladesh, have a national ERC, which has more authority than any Institutional Review Board (IRB). These national committees often have a mandate to ensure that research being done is in the overall best interests of the country. They may also offer to researchers training on ethical aspects of research.

Preparing to undertake health-related research

Almost all types of medical research require prior review by an ERC. Exceptions include any analysis or review of already published material such as a systematic review or meta-analysis, studies involving the analysis of aggregated data from a secondary source, such as leprosy data from the Weekly Epidemiological Record (WER); or from publicly-available reports of a national disease control programme, outcome of audits, and occasionally where an authorised person conducts epidemiological analysis of a data collection mandated by public health regulations.[2] However, if the primary purpose of the data collected was to provide clinical care to a patient, then the study must be approved by an ERC first, before this data can be secondarily used in a research study (New South Wales Guidelines, s 1, q 4, p 4).[8] Local regulations (including data protection legislation) should be consulted to identify studies which might be exempt from ethical review.[8]

COMPETENCE OF THE RESEARCH GROUP

One of the first things an ERC will consider is the capability of the research group to achieve its goals in an ethical manner. Apart from their professional qualifications, "Good Clinical Practice" (GCP) training for key members of the research team would be one type of evidence of suitability for their level of responsibility. Certificated short GCP courses can be accessed on-line (in some cases, free of charge, for example from the Global Health Network[9] – or from academic institutions). WHO recommends that "to the extent possible, the principles of GCP (originally designed for pre-registration pharmaceutical studies) should apply to all clinical research involving human participants, not only clinical trials",[7] and "Good clinical practice (GCP) standards should be applied meaningfully, but proportionately to suit the ethical and scientific requirements of the study".[10]

Informed consent

Ethical approval for a trial or any study involving human subjects depends on several factors, one of which is the process of seeking consent for participation. Potential participants in studies will usually be asked to give voluntary "informed consent" (and to confirm this with a signature or witnessed thumbprint), only after receiving adequate information (about the reasons, the requirements and the risks of the research) and opportunity to ask questions. A participant information sheet should clearly state what benefit the person can expect to receive and what he/she should not expect. If there is to be any personally identifiable information published, including any photograph, video-recording (or quotation from an interview which might be recognisable/attributable) this should be specified in the informed consent form. When highly sensitive issues are to be investigated, perhaps by an in-depth interview, the potential participants should be informed about this before giving consent, and reminded that they may opt out of some questions or the whole interview, at any time.

Very rarely, and with suitable precautions, the need for prior informed consent may be waived by an ERC, for example, when testing an intervention to be used in an emergency situation when the subject would not at the time be capable of giving consent (this is unlikely to be needed in leprosy research).[3,11] Having consented to participate it is important that the participants know in advance they can still withdraw at any time without having to give an explanation and without any penalties.

Before an individual can be approached for informed consent, it may be necessary to involve the community. Where the culture favours a less individualist approach to decision-making, prior to inviting individuals to participate in a study it is appropriate to ask assent from a community leader or head of the family.[4] In the context of a leprosy vaccine trial in Venezuela, researchers had to offer information first to leaders then to the group before checking whether individuals' understanding was adequate for them to be approached with invitations to participate.[4] When the research will involve minors, a parent or guardian will be asked for informed consent, but children should be offered age-appropriate information and have a chance to give assent to their participation.

If there is to be a control group receiving alternative treatment, whether a placebo is used or "standard care" alone, participants should be made aware of this and of any randomisation procedure to be used before asking for their consent. The control group should not receive less than the usual standard of care in the national public health system, and preferably should be offered the best available treatment for their condition.[3,4,8] 'Interventional quality activities comparing one intervention with another should not involve provision of care

inferior to the benchmark "standard of care"'. One example from the leprosy field would be the TENLEP study comparing prednisolone courses of 20 weeks or 32 weeks for new nerve function impairment, in which subjects allocated to the control arm received 12 weeks "placebo prednisolone" after 20 weeks real prednisolone.[12] If a novel intervention is found to be effective, it might be offered to the control group after trial completion – mention of this possibility in the participant information sheet would be appropriate.

Leprosy Review also accepts case reports and case series, which are potentially valuable contributions to the evidence base relating to leprosy diagnosis and management, but do not fall under the purview of an ERC. When submitting such studies to a journal, if there is any identifiable information or image included, an author should obtain, from the patient(s) described, specific permission for publication. This relates to some kinds of specific personal characteristics (such as demographics) as well as to images. Some journals have a patient permission form for authors to complete.

RESPONSIBILITY FOR DATA

Generally, a research ethics committee would also consider who has access to personal medical records and to the research data (including consent forms) and how the data is stored. For studies using data from medical records, when sensitive material may be revealed, personal records should be accessed only by members of the clinical care team who already have a duty of confidentiality, or by research staff who have specific permission. Identifiable personal information provided by the participant for other purposes (such as access to benefits), should not be used for research without his/her consent. Researchers need to ensure they have adequate protection in place for both paper records and soft copies of confidential data. This will include measures such as anonymisation of data, use of strong passwords, encryption, secure depositories with separate storage of identifiable information, and compliance with national data protection regulations.

Quality controls in medical publishing

We would like to highlight three different quality controls. First, in the interests of transparency, nowadays it is a requirement for any clinical trial (whether of an investigational medical product or other intervention) to be registered on a publicly available database, so that the protocol and other key information can be checked. This reduces selective publication and prevents unnecessary duplication of studies. Observational studies and even literature reviews should ideally also be registered.[1] The World Health Organisation's International Clinical Trial Registry Platform lists approved registries.[13] Since 2005, Editors of scientific journals (including Leprosy Review) normally ask for proof of this before considering publishing a paper about a trial.[14,15] Second, Leprosy Review follows International Council of Medical Journal Editors' (icmje) guidelines. There are widely-accepted minimum standards for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals.[16–18] Third, the traditional system of peer review by unpaid independent experts helps Editors to maintain high standards in deciding which manuscripts to accept for publication, considering their importance, originality and clarity, plus relevance to the remit of that particular journal.[19]

When a manuscript on original work is received by a journal such as Leprosy Review the Editor will consider not only the findings but also the scientific justification, design and conduct of the study, besides any ethical aspects which might cause concern. To obtain a fair and unbiased assessment of the strengths and weaknesses of the manuscript it is standard

practice to use a system of peer review.[14,20] The Leprosy Review policy when assessing every manuscript is to consult two or more independent reviewers, whose names are withheld from authors. Their suggestions often help authors to improve the quality of the paper at revision. The value of peer review was critically assessed by a UK parliamentary committee,[21] which concluded that while it is an important part of good practice which gives a measure of quality assurance, it does not explicitly assess the integrity of research and will not provide a guarantee of scientific validity. If reviewers notice in the manuscript under consideration any evidence which might suggest fraudulent activity (such as fabricated data), they should bring it to attention of the Editor for appropriate action to be taken. Plagiarism (attempting to pass off as one's own, the thoughts or writings of someone else) might be suspected where there are sentences exhibiting a very different style of writing to the rest of the paper, but are not presented as properly referenced quotations. Leprosy Review (like many other journals) has an online plagiarism checker, which can be used when an infringement seems to be a possibility. The Committee on Publication Ethics (COPE) is a source of advice in difficult cases.[18,19] Occasionally it is necessary to publish a correction to a previously published paper, and very rarely a complete retraction is required if new evidence becomes available about the authenticity of a paper.

Scientific integrity

Scientific integrity includes intellectual honesty, transparency and accuracy, accepting responsibility, and appropriate dissemination. Violation of research integrity can produce harm to the public as it leads to wrong policy decisions.[22,23] In addition to ethical aspects of implementing a research study, there are numerous ethical aspects to publication decisions (those taken by researchers and those taken by journals).[24] One is the importance of faithfully reporting both negative and positive findings.[14,15] This is mentioned in the Declaration of Helsinki, 2013 point 36 and should be specified in the protocol.[2] Data from well-designed studies with adequate sample size, which produce negative or inconclusive findings do warrant publication as much as those with positive results: their findings may prevent unwarranted duplication of effort for other researchers or continuing exposure of patients to ineffective management. Furthermore, their data might still help answer important questions, especially if combined with that from other studies through meta-analysis. Publishing only favourable results introduces bias into the scientific records. Description of methodology should be sufficiently clear and detailed to allow replication of the study by others: if similar results are obtained elsewhere this adds to confidence in the findings.

A complex issue is determining who is accountable for the paper and who receives credit for the work. There are generally accepted guidelines on authorship:[14,24] broadly speaking, all those who made major contributions to conception/design, collecting or analysing or interpreting data, drafting or revising the paper should be named as co-authors and these should all have approved the final version thus accepting responsibility for it. The traditional allocation of "honorary" authorship (e.g. naming the head of department even if he/she was not intimately involved in the study) has recently been challenged.[23] Generous use of the Acknowledgements paragraph is encouraged to thank people who have contributed but are not named as authors. Nowadays, it is common practice for Editors to expect a statement of the various contributions made by different authors named on a manuscript, and to expect (as in Leprosy Review criteria) that studies carried out in endemic countries should include at least one author from that country. Declarations of interest are normally required,[14] to alert readers to any possible bias they might introduce, which is especially important if there is

a question of potential intellectual property rights or a possibility of commercial advantage arising from the study. The scientific community needs to find ways to give recognition to the original researchers when data is reused by others.[4]

DISSEMINATION OF FINDINGS

Firstly, it is important to publish the results of a study. It is justifiable to request participation by human subjects in research studies from which those individuals can expect to receive no personal benefit and may even risk suffering some inconvenience. Subjects are often motivated by an altruistic hope of furthering the cause of science, expecting that results of the study to which they contributed will help others in future. If findings of a well-designed study which was successfully completed are never appropriately published, this is unethical. Choosing a suitable journal to which to submit one's paper can be difficult for inexperienced authors. Reputable journals will provide information on ownership, management, policies and scope of the journal along with clear Instructions to Authors. One must be wary of the proliferation of maverick on-line "journals" which appear to have very low thresholds for acceptance of a paper.

Open Access publishing means that publications are accessible on-line, free of charge, for everybody to read (whether or not affiliated to an academic institution).[1] Institutions and donors sometimes require this.

However, where Open Access publication transfers costs of journals from readers to researchers this has implications for scientific research integrity[23] which should be openly addressed. The high cost to the author, unless covered by a research grant, can discourage submission to reputable journals by individuals with less resources, unless they are able to utilise fee-waiver policies offered by some journals. Leprosy Review – which is owned by Lepra and financially supported by a number of ILEP members – is fully open access and does not charge for publishing papers. Its website (https://leprosyreview.org) displays the journal's policies as well as other information and instructions for authors, consistent with standards advocated by the Committee on Publication Ethics[25] (see Box 1).

Box 1 Role of LR in facilitating dissemination of research findings

To fulfil its mandate to contribute to better understanding of leprosy, Leprosy Review requires of authors to ensure that all items published in the journal meet its ethical standards. These include

(1) statement of approval by an authorised ERC (or justification for exemption),
(2) where applicable enough information to show that the participants in a study were enrolled only after voluntary informed consent,
(3) evidence of informed consent from the patient for any clinical photographs or use of identifiable information,
(4) the authors' statements regarding their funding sources,
(5) their respective contributions and any conflict of interest they may have,

[1] Infolep can help researchers to obtain copies of important papers on leprosy which are not open access. Infolep is the international knowledge centre for access to (digital) information resources on leprosy and related subjects; go to https://www.leprosy-information.org/Infolep-Services or contact info@infolep.org.

Box 1 Continued.

(6) inclusion of at least one local author, if the study is carried out in an endemic country,
(7) the possibility of access to the database, if any query arises about its authenticity,
(8) a transparent, balanced account of the conduct and findings of the study
(9) a conclusion justified by the results.

Researchers are encouraged to offer study participants feedback on the results of the study (CIOMS 2021, 5.2 recommendations p 70, CIOMS 2009 GL 5 point 7, p 46, 48).[2,10] It might be in a different format (not a published document), for example, verbally at a stakeholders meeting. ERCs will ask about this and perhaps mention of it should be included in published papers.[26] Participants will find it gratifying to learn the outcome of the research to which they contributed.

Specific ethical considerations related to the study of leprosy

In relation to leprosy, the ethical issues are often compounded by the fact that the potential subjects are patients for whom the researcher has clinical responsibility, or beneficiaries receiving support from a rehabilitation project, or otherwise in a position where they might be vulnerable to exploitation or coercion. Leprosy-affected people are peculiarly vulnerable to the risk of coercion from service providers as they often have little or no choice of where else to go for help with their acute or long-term problems, and so may rely heavily on services offered by the team which is inviting them to participate in research. Categorising them as vulnerable is no reflection on their cognitive ability, but recognises "they may have insufficient power, education, resources, strength … to protect their own interests" (CIOMS 2009, Guideline 13, p 68) or "some feature of the circumstances … in which they live makes it less likely that others will be vigilant about, or sensitive to, their interests" (CIOMS 2016, Guideline 15, p 57). Therefore, specific protections should be reviewed and applied to safeguard the rights and welfare of these individuals.[2,3] These will include considerations of privacy – for example, a recognisable research team undertaking a home visit for follow up might lead neighbours to guess that the house includes someone affected by leprosy.

Special care is needed where the researchers are functioning in a cross-cultural situation.[2] Inequalities between the teams of researchers and sponsors based in wealthier countries and the teams who will implement studies in resource-poor situations create the risk of exploitation with failure to give proper weight to the interests of local research colleagues as well as of subjects. Insensitivity to cultural perspectives on health matters is one potential misuse of power.[4] "Researchers from high-income countries taking advantage of the low-cost, under-regulated environments of low- and middle income countries (LMICs)" has been perceived as a problem (CIOMS 2021, s 1.4, 4.3.1).[10] Where a study is to be carried out in a resource-poor community, there should be congruence with the national health needs and priorities, plus an expectation that knowledge gained from the study will benefit the health of the population in which it was obtained, and that conducting the study will contribute to strengthening research capacity of the host country,[2,10] perhaps by providing a platform for enhancing the skills of scientists in those developing countries (CIOMS 2009, Guideline 20, CIOMS 2021, s 2.3). Field work in a resource-poor setting, which primarily benefits others elsewhere (perhaps in terms of career-progression or utilisation of findings) could be unethical, but true partnership

would benefit both sides. Engagement in research encourages national medical staff to practise evidence-based medicine. Consultations with the local community are important[3,10] and special attention should be paid to appropriate levels of any payments to participants for loss of income during time spent on research activities, travel costs or other incidental expenses. Researchers need to be careful to avoid any risk of scarce health care resources being diverted from routine work toward research work. The indemnity arranged should be suitable to the situation (CIOMS 2021, s 4.2.2).[10]

Many papers submitted to Leprosy Review report social science studies and there are several aspects of good practice in this field that should be heeded. If a study is focusing on a sensitive topic such as stigmatisation, discrimination or mental well-being, extra care should be taken to minimise any distress caused. First, note that persons affected by leprosy – in order to avoid stigmatisation – might not have informed their spouse, family members or neighbours about their condition.[27,28] Hence when inviting persons affected to participate in a study, this should be done with tact and respect for their privacy. Though very rare nowadays, persons affected by leprosy might be unaware of their own condition; some health workers might have withheld the diagnosis, intending to "protect" the patient.[29] Second, the researchers who interact with the participants need very good communication skills. Adequate training at the start and continuous supervision during the fieldwork are important. It can, for example, be helpful to discuss with the study participant preferred terminology for their condition. Interviewees might prefer "skin disease" (or in certain contexts "Hansen's disease"), over the term leprosy. Third, it is vital to allow breaks during long in-depth interviews or questionnaires and to reserve time at the end to answer questions from participants. For example, a questionnaire about causes of leprosy might leave participants puzzled about the etiology: it is important to address these questions to avoid misconceptions and concerns. Fourth, appropriate arrangements should be made to handle any distress incurred. This might be by immediate simple counselling (at an in-person encounter), or referral to locally available services (useful for on-line assessments), or working together with a local psychologist or mental health specialist to whom study participants can be referred if needed. Fifth, when interventions are implemented, some unexpected and unintended consequences can be anticipated and therefore implementation studies need to be systematically evaluated for such consequences.[30] These should also be reported if likely to be of importance to participants, or for interpretation of results, and may lead to adjustments in the interventions.

Finally, it is important to consider the well-being of members of the research team; offering time to share, reflect and process upsetting experiences they have heard from the study participants, may be helpful.

Conclusion

Research studies on human subjects such as people affected by leprosy, as well as being grounded in sound scientific principles and a balanced understanding of the scientific literature, should comprehensively comply with accepted ethical principles, and any study should be followed by accurate reporting and submission for publication.

All research has to deal with the challenge of ethical considerations and in the field of leprosy there are aspects that require our specific attention. There are a wealth of resources available now, that can help us. Nevertheless, there might still be unique situations that require careful thought and discussion both within research teams and with the wider community where the research is to be done. Our advice would be to keep in mind the principles described in the International Ethical Guidelines of CIOMS when making decisions, and to continue

engaging in dialogue with fellow-researchers about ethical challenges so we can learn together as a community.

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