The three official language versions of the Declaration of Helsinki

RESEARCH ETHICS

The three official language versions of the Declaration of Helsinki: what's lost in translation?

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Background: The Declaration of Helsinki, the World Medical Association's (WMA's) statement of ethical guidelines regarding medical research, is published in the three official languages of the WMA: English, French and Spanish.

Methods: A detailed comparison of the three official language versions was carried out to determine ways in which they differed and ways in which the wording of the three versions might illuminate the interpretation of the document.

Results: There were many minor linguistic differences between the three versions. However, in paragraphs 1, 6, 29, 30 and in the note of clarification to paragraph 29, there were differences that could be considered potentially significant in their ethical relevance.

Interpretation: Given the global status of the Declaration of Helsinki and the fact that it is translated from its official versions into many other languages for application to the ethical conduct of research, the differences identified are of concern. It would be best if such differences could be eliminated but, at the very least, a commentary to explain any differences that are unavoidable on the basis of language or culture should accompany the Declaration of Helsinki. This evidence further strengthens the case for international surveillance of medical research ethics as has been proposed by the WMA.

One issue that has almost completely escaped mention in the debate on a global consensus on bioethical issues is the difficulty presented by linguistic barriers. Here we consider this issue in relation to the Declaration of Helsinki (DoH). This document has been central to the World Medical Association's (WMA's) efforts to achieve consensus on the ethical conduct of medical research and arguably remains the most important international document in this field.[1 2]

Reiterating the organisation's efforts, the Director of Ethics at the WMA, Dr John Williams, has recently issued the challenge that "every effort should be made to internationalise bioethics".[3] Indeed, the challenge of addressing differing ethical standards for research in different parts of the world formed one of the driving forces for the revision of the DoH in the first place.[4] That these issues are still a flashpoint for controversy is amply illustrated in a review of the film version of John Le Carre's novel *The Constant Gardener*, written by Marcia Angell, whose 1997 editorial (in *The New England Journal of Medicine*) helped ignite the controversy.[5] The book and film portray the fictional nefarious actions of a multinational pharmaceutical company. However, Angell uses the opportunity of the review to state again her concerns that medical research standards may differ between countries, and, in particular, that the standards of protection for research subjects are lower in developing countries, and that some researchers continue to exploit these lower standards to conduct studies that would not be ethically permissible in the sponsoring country.

In its most controversial paragraphs (paragraphs 29 and 30), the DoH has sought to address aspects of this issue. The ensuing uproar was such that 4 years of debate culminated first in the note of clarification to paragraph 29 in 2002 and later in the note of clarification to paragraph 30 in 2004.[6]

Yet it also stands to reason that if international statements of ethical standards vary in their content across different language versions, this will be an additional impediment to the achievement of consistent international standards. We raise this question with respect to the DoH primarily because of the document's international prominence and its controversial attempts to go to the heart of these continuing ethical controversies. It also should be pointed out that because the DoH is relatively succinct at less than 2000 words,[7] and exists in only three official languages (compare, for example, the European Union Clinical Trials Directive, which is much longer and must be translated into the 20 official languages of the European Union), it is a less unwieldy starting point for this analysis.

The DoH exists in three official versions, one in each of the official languages of the WMA (English, French and Spanish).[6 8 9] The WMA is the largest global grouping of medical professionals and currently numbers the National Medical Associations of more than 80 nations as its members.[10] Eventually, the DoH will be translated from the official versions into a multiplicity of different languages, and will then likely go on to influence the wording of many other documents, so internationally the stakes are high. The WMA gives no guidance on such further translation and it is up to the organisation that is arranging a translation as to which official version or versions to use as their baseline, and the accuracy of such further translations remains the responsibility of that individual or other organisation.

METHODS

We undertook a detailed comparison of the English, French and Spanish versions of the DoH. In each case, this was initially undertaken by doctors on our authorship team who grew up in contexts where they were fluent in both of the languages (NHG for the French–English comparison and LMP for the Spanish–English comparison) and who have used both of the relevant languages extensively in a professional context. To reduce the subjectivity involved in this process, we obtained three translations of each of the French and Spanish versions of the DoH into English. The translators were all language

Abbreviations: DoH, Declaration of Helsinki; WMA, World Medical association

Table 1 The three official versions of second sentence of paragraph 1

English[6]	French[8]	Spanish[9]
1. … Medical research involving human subjects includes research on identifiable human material or identifiable data.	1. … Celle-ci comprend également les ètudes réalisées sur des données à caractère personnel ou des échantillons biologiques non-anonymes	1. La investigación médica en seres humanos incluye la investigación del material humano o de información identificables.

teachers and were not previously aware of the content of the DoH. These back-translations were used to verify the differences detected on initial analysis. Full texts of these translations are available through a separate internet link.[11]

RESULTS

A detailed comparison of the English, French and Spanish texts of the DoH reveals, not unexpectedly, many grammatical and stylistic differences between the versions. Although in many cases these changes were not dictated by rules of language syntax or any obvious aesthetic advantage, most differences did not affect meaning. For example, in paragraph 5, the English and Spanish versions state, ''In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society''. The French version reverses the syntactic logic; ''In medical research on human subjects, the interests of science and society should never take precedence over the well-being of the human subject''.

The main concern of our discussion, however, is the small number of paragraphs where something important seems to be ''lost in translation''. Here we outline five that we consider of particular importance.

(1) True opposites or a risky assumption? (paragraph 1)

The English and Spanish versions use ''identifiable'', whereas the French version states ''non-anonymes'' (non-anonymous) to define the kinds of studies using data or tissue samples that are covered by the DoH guidelines (table 1). Ethical dimensions regarding protection of privacy of personal information in epidemiological and tissue sample studies have long been an issue for debate, but the 2000 revision is the first occasion when the DoH has explicitly referred to such issues.[7 12] The question of an ethically relevant difference in meaning hinges around whether there is any difference between ''non-anonymous'' and ''identifiable'', or put another way, whether ''identifiable'' and ''anonymous'' are exact opposites of one another. Clearly, if the researchers know the identity of the research subject, then data are ''identifiable''. On the other hand, if all possible re-linking of data with the person providing the data has been eliminated, then data are ''anonymous''. What about the intermediate situation where a code held by a third party separates the identity of an individual from the data used by the researcher? These would seem to be ''non-anonymous'' in that, if the right steps were taken, individual and data could be re-linked. But are they ''identifiable''? Certainly they are not identifiable to the researchers and this may be considered to be the ethically important point. So we see that a grey area emerges that could possibly lead to different interpretations of the French version from the Spanish and English versions. Given that ''non-anonymous'' would be perfectly acceptable in the English version (and ''no anónimo'' in the Spanish), or that ''identifiables'' would be a valid adjective to use in the French version, we argue that this difference is unnecessary under the rules of the languages concerned and introduces an unnecessary risk of an ethically relevant difference in interpretation.

(2) Whatever happened to ''quality''? (paragraph 6)

Without explanation, the French version omits the word ''quality'' from the list of criteria by which medical methods should be evaluated (table 2). This is of particular concern because internal discussions subsequent to the adoption of the 2000 version of the DoH raised concerns that ''safety'' was not explicitly included in this list. It was concluded by the WMA's Medical Ethics Committee in May 2002 that ''the aspect of safety is sufficiently addressed by the term 'quality', which is already mentioned in paragraph 6''.[13]

(3) Three languages, three standards in the control arm? (paragraph 29)

This paragraph (table 3), along with paragraph 30 (discussed below), has been one of the most controversial in the DoH. Both of these paragraphs, after lengthy word-by-word debate about their meaning, have had notes of clarification appended to them. In paragraph 29, a major controversy relates to the appropriate standard of comparator in an active-control trial. Should it be the best available anywhere in the world or the best that was available to the population in which the trial was conducted?[14] The change from ''best current'' (English) to ''best existing'' (''mejores existentes'' in Spanish) and ''in use'' (''en usage'' in French) is arguably the most significant difference we discovered between the three versions. Although we recognise that there may be semantic overlap, the French ''en usage'' carries some implication of a localised availability. However, the 1996 French version used the word ''courantes'' (''current'') in the paragraph dealing with placebo and the change to ''en usage'' paradoxically seems to move the translation further away in potential meaning. On the other hand, the Spanish version is suggestive of a universal standard of care for the control group. The debate over the standard of comparator arm is not fully resolved. In this paragraph, the difference between the three language versions illuminates the debate but, of course, does not resolve it.

Table 2 The three official versions of the second sentence of paragraph 6

English[6]	French[8]	Spanish[9]
6. …Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality	6. …Les méthodes diagnostiques, thérapeutiques et de prévention, même les plus éprouvées, doivent constamment être remises en question par des recherches portant sur leur efficacité, leur efficience et leur accessibilité	6. …Incluso, los mejores métodos preventivos, diagnósticos y terapéuticos disponibles deben ponerse a prueba continuamente a través de la investigación para que sean eficaces, efectivos, accesibles y de calidad.

Table 3 The three official versions of the first sentence of paragraph 29

English[6]	French[8]	Spanish[9]
29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. …	29. Les avantages, les risques, les contraintes et l'efficacité d'une nouvelle méthode doivent être évalués par comparaison avec les meilleures méthodes diagnostiques, thérapeutiques ou de prévention en usage. …	29. Los posibles beneficios, riesgos, costos y eficacia de todo procedimiento nuevo deben ser evaluados mediante su comparación con los mejores métodos preventivos, diagnósticos y terapéuticos existentes. …

(4) Differing standards for use of placebo controls? (note of clarification to paragraph 29)

The English version, in the second of the two clauses defining acceptable conditions for the use of placebo where proven therapy exists, makes the requirement that there be no ''additional risk of serious or irreversible harm'' (table 4). In the French version, we find ''des risques supplémentaires de dommages significatifs ou durables''. ''Durables'', which translates most closely as ''long-lasting'', would seem to have a different meaning from ''irreversible''. The adjective ''irréversible'' is available in French, or the English could be changed to ''long-lasting'' depending on what the intent is. The Spanish version uses ''irreversible''. However, the ethical demand does need clarifying. If a harmful outcome of a study potentially lasted several years (but was eventually reversible), would that really be acceptable? Our suggestion is that it would not and therefore that either the French version is preferable, or all three versions should refer to ''long-lasting or irreversible'' in this paragraph.

(5) Requiring the impossible? (paragraph 30)

This paragraph (table 5) has also been the subject of considerable controversy and, in October 2004, had a note of clarification appended.[6 8 9] The English version calls for patients to be ''assured of access'', whereas the French requires that patients be ''assured of benefit''. This seems to be beyond what any ethical code can require. It is only the potential benefit (through assurance of access) that can be required. Perhaps a wording that combines the two versions could read ''should be assured of access to the potential benefit of…''. The note of clarification to paragraph 30, added in 2004, may partially address this problem by speaking of ''access'' (accès) rather than benefit, but the difficulty with the wording of the paragraph itself still stands.

''Must'' or ''should''?

Debate continues about whether normative ethical guidelines such as the DoH, which do not have the status of legal documents, are best seen as pragmatic (and thus able to be followed in every case) or as aspirational (thus setting the direction but recognising that not every case will achieve every aspiration). Interestingly, the versions may differ in this regard. The Spanish (''deber'', and its conjugates, rather than the conditional ''deberia'') and French (''doivent'' and its conjugate ''doit'' rather than ''devrait'') consistently use words more closely equating to ''must''. English, on the other hand, uses ''should'' 16 times and ''must'' 5 times where the Spanish ''deber'' and French ''doit'' are used. The one exception is paragraph 4 of the DoH where the English (''research … must rest in part on…'') is translated in French as ''peuvent imposer de recourir'' (ie, ''may require recourse to…''). However, this sentence could be considered descriptive of a fact rather than a statement of an ethical guideline and thus is not a true exception to the statement above.

It is not possible simply by analysing the text to understand what to make of this, eg, whether the Francophone or Hispanophone worlds see a set of normative ethics differently from the Anglophone world. Nor is it clear why the English version switches between ''should'' and ''must''. Further conjecture is therefore beyond the scope of this paper. It remains, however, an intriguing difference that should be explored in further studies.

DISCUSSION

Guidelines for WMA translations are not published. However, both Dr Delon Human, the Secretary-General of the WMA at the time of the revision, and Dr John Williams, the current Director of Ethics at the WMA, affirm that the translations should be as close as possible to one another, recognising that some differences may be imposed by the syntactical rules or the cultural framework of the languages (Personal communications, 2004). Translation difficulties are an enormous communications challenge faced by any establishment dealing with people who speak different languages, and the WMA is no exception. We accept that there are complex philosophical and linguistic questions about the nature of language, translation and meaning that remain among the biggest issues in contemporary philosophy.[15 16] Steiner asserts, ''each human language maps the world differently''.[17] This is a simplified statement of a well-recognised theory within the study of linguistics and anthropology known as the Sapir-Whorf hypothesis, which contends that culture and ethics are so bound up in the language used that they can only be fully understood from within that linguistic system.[18] To the extent that this is true, not only will the translations always contain differences, but also some differences will never be apparent to those trying to investigate them.

On the other hand, as Peter Kay has pointed out, cultural differences may be much more significant than linguistic differences and may lead to very different world views between speakers of the same language.[19] This is especially relevant in view of the worldwide distribution of the three official WMA languages: Spanish would be an important language for ethical discourse in settings as diverse as Madrid, Montevideo and Havana, French in Port-au-Prince, Paris and Montreal, and English in Glasgow, Gabarone and Auckland.

Table 4 The three official versions of the relevant portion of the note of clarification to paragraph 29

English[6]	French[8]	Spanish[9]
…where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.	…lorsqu'une méthode prophylactique, diagnostique ou thérapeutique est mise à l'essai pour une affection bénigne et que la participation à l'essai n'expose pas à des risques supplémentaires de dommages significatifs ou durables.	…Cuando se prueba un método preventivo, diagnóstico o terapéutico para una enfermedad de menos importancia que no implique un riesgo adicional, efectos adversos graves o daño irreversible para los pacientes que reciben el placebo.

Table 5 The three official versions of paragraph 30

English[6]	French[8]	Spanish[9]
30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.	30. Tous les patients ayant participé à une étude doivent être assurés de bénéficier à son terme des moyens diagnostiques, thérapeutiques et de prévention dont l'étude aura montré la supériorité.	30. Al final de la investigación, todos los pacientes que participan en el estudio deben tener la certeza de que contarán con los mejores métodos preventivos, diagnósticos y terapéuticos probados y existentes, identificados por el estudio.

Some might argue that there is no empirical evidence for differing standards as a result of these translation issues within the DoH. We invite those who would contend this to consider both the difficulty in gathering such evidence (given linguistic difficulties), the long time-frame before those differences would be noticed empirically, and most importantly to consider whether we really want to find out about such systematic differences after the fact.

It is by no means our intention to suggest that any of the three official languages should become dominant in determining the wording of the DoH, or in any other debate regarding issues of international importance in medical research ethics. One of the major drawbacks of our study is that analysis of the results has been in English only. Ultimately, in the absence of a universal language, there is no way around the fact that discussions of meaning must take place in one language or another. The use of English is dictated by the provenance of this work.

The existence of discrepancies that could lead to a difference in interpretation is worrying. That we have demonstrated the existence of such discrepancies in the case of the relatively succinct DoH, across only three languages, gives rise to questions about other key international documents that are longer and have many more official language versions. So what is to be done?

In the first instance, the WMA should address these differences either by way of explanation or by way of the necessary amendments to the DoH to harmonise their meaning. Given the intense word-by-word debate and analysis that occurs both in WMA meetings and in the subsequent literature about the DoH, attention to these differences between the three official versions is vital. The DoH remains too significant an international instrument to leave these inconsistencies unattended.

On a broader note, however, this study shows one possible source of variation in ethical practice regarding research in different parts of the world. It raises the much bigger question of how to detect and act upon research standards that vary in unacceptable ways in different geographical settings (we accept that some variations, eg, greater emphasis on verbal consent than on written consent in different cultures, may be acceptable). One possible way forward was suggested by Dr Kgosi Letlape of South Africa, currently president of the WMA, when he made his speech as president-elect in Tokyo in October 2004. Dr Letlape mooted the creation of a surveillance unit to monitor coherence with the standards of research in various parts of the world.[20] Unfortunately, this aspect of his speech was neither reported in the written summary,[21] nor does it appear to have been taken any further by the WMA.

The last 50 years has seen the widespread recognition of two lines of defence for protection of people participating in research: voluntary participation through appropriate consent and the establishment of independent ethical review committees. What is lacking now, especially in the context of increasing multinational studies, is some system to ensure that standards worldwide do not fluctuate outside ethically acceptable parameters of variation. Dealing with the issue of linguistic harmonisation of ethical guidelines would ideally fit within the work of such a surveillance unit. However, harmonisation of the three official versions of the DoH need not, and should not, wait for its establishment.

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REFERENCES

1 **Macklin R**. *Double standards in medical research in developing countries*. Cambridge: Cambridge University Press, 2004:5.
2 **Lewis JA**, Jonsson B, Kreutz G, *et al*. Placebo-controlled trials and the Declaration of Helsinki. *Lancet* 2002;**359**:1337–40.
3 **Williams J**. The promise and limits of international bioethics: lessons from the recent revision of the Declaration of Helsinki. *J Int Bioethique* 2004;**15**:31–42.
4 **Macklin R**. *Double standards in medical research in developing countries*. Cambridge: Cambridge University Press, 2004, 13–14, 18–19..
5 **Angell, M**. The body hunters. *The New York Review* 6 Oct, 2005:23–5.
6 **World Medical Association**. *Declaration of Helsinki*, www.wma.net/e/policy/b3.htm (accessed 2 May 2007).
7 **Carlson RV**, Boyd KM, Webb DJ. The text of the Declaration of Helsinki: past, present and future. *Br J Clin Pharmacol* 2004;**56**:695–713.
8 **World Medical Association**. *La Déclaration d'Helsinki*, www.wma.net/f/policy/b3.htm (accessed 2 May 2007).
9 **World Medical Association**. *La Declaración de Helsinki*, www.wma.net/s/policy/b3.htm (accessed 2 May 2007).
10 **World Medical Association**. *List of members*, www.wma.net/e/members/list.htm (accessed 2 May 2007).
11 **Carlson RV**. Comparison of the 3 official language versions of the Declaration of Helsinki. www.cvs.med.ed.ac.uk/research/cvs_content.asp?SubCatID=28&pID=26 (accessed 2 May 2007).
12 **Riis P**. Perspectives on the fifth revision of the Declaration of Helsinki. *JAMA* 2000;**284**:3045–6.
13 **World Medical Association**. *Workgroup report on the revised Declaration of Helsinki*, MEC/WG/DoH2000/May2002.Unpublished report presented to Medical Ethics Committee of World Medical Association, May, 2002.
14 **Macklin R**. *Double standards in medical research in developing countries*. Cambridge: Cambridge University Press, 2004:38–49.
15 **Gadamer HG**. *Reason in an age of science*, (Transl by Frederick G Lawrence). Cambridge, MA: MIT Press, 1981:4.
16 **Van Hoozer KJ**. *Is there a meaning in this text*? Grand Rapids, MI: Zondervan, 1998:16–17.
17 **Steiner G**. *After Babel: aspects of language and translation*, 3rd ed. Oxford: Oxford University Press, 1998:xiv.
18 Gumperz JJ, Levinson SC, eds. *Rethinking linguistic relativity*. Cambridge: Cambridge University Press, 1996:25.
19 **Kay P**. Intra-speaker relativity. In: Gumperz JJ, Levinson SC, eds. *Rethinking linguistic relativity*. Cambridge: Cambridge University Press, 1996:110–111.
20 **Letlape K**. Acceptance speech of the President-elect of the World Medical Association. World Medical Association Annual Assembly: Tokyo, October, 2004.
21 **Anonymous**. Meeting of the WMA General Assembly, Tokyo, 9 October 2004. *World Med J* 2004;**50**:108–9.