Author's response to reviews

Title: Patients' perception and actual practice of informed consent, privacy and confidentiality in general medical outpatient departments of two tertiary care hospitals of Lahore

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Author's response to reviews: see over
Comments by: Maria Perez-Carceles

Methods:

1. **The meaning of OPD should be included the first time it is used.**

   This change has been made and the term ‘out-patient department’ now appears in the abstract (material and methods section) as well as in the material and methods section of the main body of the manuscript.

2. **In the third paragraph (page 5) when the authors mention “in the light of existing literature on the subject”, some recent bibliographical references should be included.**

   At least four relevant bibliographical references have been included at that point in accordance with the comments of the reviewer. These are from the years 1993, 2004, 2005 and 2008.

3. **The section should mention the names of the hospitals and point out which are public and which are private.**

   As suggested, the following sentence has been added at the end of the first paragraph of the material and methods section of the manuscript: “Jinnah Hospital was selected from the public sector, while Shalimar Hospital was the private sector hospital included in our study.”

4. **Please give more information on the questions asked to the patients and the possibilities of each of the replies and how they were graded. Also, it would helpful if a better description were given of what he “trained data collectors” evaluated (attitudes, behaviour, etc,) and how the …..were graduated.**

   The three (yes-or-no) questions asked from the patient were whether he/she was satisfied with the doctor’s practice of informed consent, privacy and confidentiality. A yes to all three questions was taken to mean that in the patient’s perception, the ethical principles had been well observed. However, if the patient thought that at least one of the principles had been followed to his satisfaction, (but not all three) the perception was taken to mean that the ethics had been ‘somewhat observed’. This information has been added as the fourth paragraph of the methods section. Response to this question has been presented in Table 3 and compared with the actual practices in Tables 4 and 5.
The actual assessment of these practices was undertaken in a subjective manner by the data collectors who observed each doctor-patient interaction. It was noted whether doctors took (oral) informed consent from their patients before beginning history-taking, beginning physical examination, exposing any part of the body for examination, or discussing treatment options at the end. Confidentiality (informational privacy) was assessed by noting whether there were other people who could potentially overhear the doctor-patient discussion or be told information regarding the patient without prior consent. Taking the patient to another room for examination, or at least taking them behind a screen was categorized as being adequate privacy for the patient.”

5. “Trained data collectors” were health service workers, medical students, or what exactly?

Trained data collectors were medical doctors undergoing training in an MPH program. This information has been added to the third paragraph of the methods section.

6. What was evaluated in “informed consent”? Was it orally given, in written form? What was mentioned – risk, surgery, anaesthesia, pharmacological treatments……?

This has already been described in response to comment number 4. Since the study only covered the Medical OPD, it did not involve taking consent regarding surgery or anesthesia. Therefore, oral consent was considered adequate.

Results:

1. The results section needs more details, avoiding a discussion on the same. The most interesting results should be mentioned.

The most interesting results have been described in the results section as suggested by the reviewer. This is as follows:

"Results of adherence to the practice of informed consent, privacy and confidentiality in each hospital are shown in Table 2. Observance of ethical practices was inadequate or improper in most instances. The practice of informed consent in the private hospital was much better compared to the public hospital (p: < 0.0001). No informed consent was taken at all in 90.3 % cases in the public hospital compared to 53.3 % of the patients in the private hospital. Similarly, confidentiality was adequately practised more often in the private hospital than in the public hospital (p: < 0.0001). On the other hand, the differences in the provision of privacy were not statistically significant."
Table 3 shows the overall patient perception of the way doctors followed these principles in the OPD of each hospital. Compared to the public hospital, more patients in the private hospital believed that the ethical principles had been well observed by the doctors interacting with them (p: < 0.0003).

Tables 4 and 5 compare the patients’ perception, with the actual adherence/non-adherence to these principles as observed by our trained data collector. The results show that there is an association (p < 0.05) between the perception of the patients and conclusion of the data collector in case of the private hospital (i.e. there is greater concordance). On the other hand, the opinion of the patients and data collectors is not significantly associated (less concordance) in the public hospital (p > 0.05). In the public hospital, the patient perception and the data collector’s observation were in agreement in 59.1 % of the cases. However in the private hospital, the patient perception and data collector’s observation were in agreement in 76.3 % of the cases. In other words, patient perception and data collector’s observation were in greater concordance in the private hospital. This difference was statistically significant upon applying a test of two proportions (p: 0.012).”

2. **Mean ages should be include. Standard deviation and age range of the patients in both hospitals, too.**

This information has been included in the results section as suggested by the reviewer: “The mean age of the patients in the public hospital was 34.9 (SD: 15.2, range: 13-79) while that in the private hospital was 37.6 (SD: 15.2, range: 12-79).”

3. **The profession of the patients is interesting and closely related with their educational level. Such information should be included in the sociodemographic variables.**

Information on the educational level of the patients has been included in Table 1 as suggested by the reviewer.

4. **Since the discussion mentions that there were differences between both hospitals and that they could be justified by differences in the sociodemographic characteristics of the patients, a statistical test should be applied to ascertain whether statistically significant differences existed.**

The income and educational profile of patients in both hospitals is difference and this result reaches statistical significance. That has been indicated in Table 1.
5. It is not clear from Table 1 which hospital is private and which public.

This information has now been included in Table 1 as suggested by the reviewer.

6. Given that the BMC Medical Ethics is an international publication, perhaps some idea should be given of the value of the currency mentioned is, as this might help threaded understand the socioeconomic profile of the patients.

$1 = Rs. 67. This information has been added to table 1 in order to help the reader better understand the socioeconomic profile of the patients.

7. Tables 4 and 5 mention “observed and graded”; however the term “graded” would be best omitted since only observed and non-observed data are included.

The term “graded” has been removed from both the tables in line with the comments of the reviewer. It has also been removed from the results section where the text refers to tables 4 and 5.

8. In the same tables (4 and 5), a statistical treatment should be applied to ascertain whether there were significant differences between “actual adherence concluded by data collector” and “patient perception”

A chi square test has been applied to both tables generating p values that have been included in each table. Further description has been provided briefly in the results section. The results show that there is an association (p < 0.05) between the perception of the patients and conclusion of the data collector in case of the private hospital (i.e. there is greater concordance). On the other hand, the opinion of the patients and data collectors is not significantly associated (less concordance) in the public hospital (p > 0.05).

Discussion:

I think that the results should be contrasted with those obtained in other countries.

As suggested by the reviewer, international references have been added to the discussions. These include studies from USA, Canada, Germany, Lithuania, South Africa, Japan, Malaysia, Kashmir (India) and Hong Kong. The total number of references has thus increased up to 38.
Comments by Helena Leino-Kilpi:

Purpose of the study and reason to report this in an international journal remains unclear.

This seems to be nationally important and gives reasons to national developmental work in this field in Pakistan – but what is the meaning for international audience?

Please, clarify the purpose, particularly for international audience.

(All research needs to have an international meaning. Even this was interesting to read, it is not enough)

It is agreed that the study is of utmost importance to Pakistan where few studies have been carried out on ethical issues, and even fewer that actually compare these practices between public and private hospitals. However, the reasons for submitting this manuscript to an international journal are as follows:

1. Like Pakistan, many other developing countries are also likely to face similar issues of poor application of ethical principles in their clinical practice. However, very little work has been done on the practices of informed consent, confidentiality and privacy in a medical out-patient setting. Most work focuses on informed consent before research, or before a surgical procedure. Furthermore, most works simply assesses the attitude/knowledge of physicians, but does not compare actual doctor-patient interaction. By publishing in an international journal, the authors wish to highlight this problem and encourage researchers/governments in other countries to carry out similar projects at a larger scale if possible.

2. Ethical guidelines like the Helsinki Declaration have been prepared to safeguard medical ethics in the research setting. This declaration has been signed and recognized internationally. On the other hand, such agreed “guidelines” have not been formally endorsed for ethics involving medical practice. Governments are not bound by any direct international law to assure observance of medical ethics in clinical practice.

Although ours is a small study, we hope that it can highlight the importance of this issue.

3. As stated in our article, ethics do not form a significant part of our national medical education curriculum. The degree to which this is included in the curriculum is dependent on the individual medical college. Pakistan Medical and Dental Council (PMDC) is the regulatory body in our country and needs to ensure its inclusion in the curriculum. At the same time, there needs to be coordination between such bodies internationally to bring the teaching of ethics to a globally acceptable level through a united concerted effort.

4. Many hospitals in the developing world are currently applying for recognition by international organizations that certify the quality of health care offered by that hospital.
However, such organizations hardly ever view or observe the actual doctor-patient interaction. Through an international journal, we hope to reach out to these organizations in stating that they need to look at the ethical issues as well, while inspecting the hospitals for quality in health care.

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**Introduction**

There are relevant international references mentioned in the introduction.

The situation in Pakistan, however, is very shortly mentioned. I was missing of any references (preferably in English –if there are).

A more detailed discussion on the situation in Pakistan has now been included in the last paragraph of the introduction section in line with the comments of the reviewer. At least seven references from Pakistan are now cited in this paragraph.

Also, you mention, that there are some efforts to create ethical guidelines – what are these? It would be important to know the national situation better, for understanding the results.

The following sentence has been added to the last paragraph of the introduction: “However, most of this work focuses on research ethics and is currently limited to individual institutions or some non-governmental organizations.”

**What about, for example, the ethical education of physicians and other health care workers?**

This information has been mentioned in detail in the second last paragraph of the discussion section: “It is noteworthy, that there are also some other reasons for inadequate ethical practices in Pakistan. For example, PMDC does not include education in bioethics as a major component of the medical curriculum. It follows that very few medical colleges in Pakistan impart formal training in bioethics. Such education is also largely omitted from postgraduate training programs.”

Also, it would be very welcome to explain, why only medical doctors are included in the study? (There must be a national explanation for that) In many Western countries, nurses are involved in informed consent process and they –in collaboration with physicians- take care of the information to patients, or they check, that the patients have been informed.

Most of the hospitals in Pakistan are extremely understaffed as far as the nurses are concerned. In a typical public hospital, for example, there is generally only 1 nurse for 60 patients at night, and approximately 2 or 3 for 60 patients during the day. Furthermore, there are few quality training institutes for nurses and nurses do not enjoy as much trust of the patients as doctors in our country. In such a setting, it is almost always the doctors
that take informed consent from the patients. This is especially true for the medical outpatient department where, unfortunately, the role of nurses is even more limited. A brief explanation to this effect has been included in the third last paragraph of the methods section. This appears as:

“In Pakistan, the nursing departments are often understaffed so that the role of nurses in the outpatient departments is limited and it is almost always the doctors who obtain informed consent from the patients regarding their examination/treatment. Therefore, nurses were not included in the study.”

Material and methods

There are not, however, any research questions presented. It would be important to have them, because empirical data is easier to understand, if the reader knows, what questions were presented.

This information has been added in the 4th and 5th paragraphs of the methods section. They appear as follows:

“The assessment of these practices was undertaken in a subjective manner by the data collectors who observed each doctor-patient interaction. It was noted whether doctors took informed consent from their patients before beginning history-taking, beginning physical examination, exposing any part of the body for examination, or discussing treatment options at the end. Confidentiality (informational privacy) was assessed by noting whether there were other people who could potentially overhear the doctor-patient discussion. Taking the patient to another room for examination, or at least taking them behind a screen was categorized as being adequate privacy for the patient.

At the end of the OPD visit, subjects were asked questions on whether they were satisfied with the way these principles were followed by the doctors interacting with them. The three (yes-or-no) questions asked from the patient were whether he/she was satisfied with the doctor’s practice of informed consent, privacy and confidentiality. A yes to all three questions was taken to mean that in the patient’s perception, the ethical principles had been well observed. However, if the patient thought that at least one of the principles had been followed to his satisfaction, (but not all three) the perception was taken to mean that the ethics had been ‘somewhat observed’.”
Also, I do not find the criteria of hospital selection (there was one public and one private- but how were these selected? Just give a short explanation for this)

The following description of hospital selection has been included in the first paragraph of the results sections in line with the comments of the reviewer:

“The sample was selected using multistage random sampling. In the first stage, public and private tertiary care hospitals of Lahore were listed separately. One hospital was then selected from each list using simple random sampling.”

Results

Results are presented in 5 Tables, all rather clear. Results are not, however, described at all in the results section. This is up to the Journal, but I would miss at least a short description of all tables, not only listing them!

A short description of the tables has been provided in the results section as suggested by the reviewer. This is as follows:

“Results of adherence to the practice of informed consent, privacy and confidentiality in each hospital are shown in Table 2. Observance of ethical practices was inadequate or improper in most instances. The practice of informed consent in the private hospital was much better compared to the public hospital (p: < 0.0001). No informed consent was taken at all in 90.3 % cases in the public hospital compared to 53.3 % of the patients in the private hospital. Similarly, confidentiality was adequately practised more often in the private hospital than in the public hospital (p: < 0.0001). On the other hand, the differences in the provision of privacy were not statistically significant.

Table 3 shows the overall patient perception of the way doctors followed these principles in the OPD of each hospital. Compared to the public hospital, more patients in the private hospital believed that the ethical principles had been well observed by the doctors interacting with them (p: < 0.0003).

Tables 4 and 5 compare the patients’ perception, with the actual adherence/non-adherence to these principles as observed by our trained data collector. The results show that there is an association (p < 0.05) between the perception of the patients and conclusion of the data collector in case of the private hospital (i.e. there is greater concordance). On the other hand, the opinion of the patients and data collectors is not significantly associated (less concordance) in the public hospital (p > 0.05). In the public hospital, the patient perception and the data collector’s observation were in agreement in 59.1 % of the cases. However, the patient perception and data collector’s observation were in agreement in 76.3 % of the cases. In other words, patient perception and data collector’s observation were in greater concordance in the private hospital. This difference was statistically significant upon applying a test of two proportions (p: 0.012).”
Discussion

Discussion is rather long and I find it interesting. Here also some results are presented.

Also this text in Discussion – as in the whole manuscript – stays only nationally in Pakistan. It would be important to draw some more general conclusions and compare, if there are similarities in international literature. For example, there seem to be differences between public and private hospitals – this difference maybe seen also in other countries, but authors do not seem to know the situation in other literature (or at least they do not mention anything about that). It would be important to compare the results with possible existing international literature (as is the case usually in scientific reporting).

There is existing literature in the realization of informed consent and privacy in literature and I suggest that the authors use also it.

As suggested by the reviewer, international references have been added to the discussions. These include studies from USA, Canada, Germany, Lithuania, South Africa, Japan, Malaysia, Kashmir (India) and Hong Kong. The total number of references has thus increased up to 38.