Author's response to reviews

Title: Teleradiology for remote consultation using iPad improves the use of health system human resources for paediatric fractures: prospective study in a tertiary care hospital in Italy

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Author's response to reviews:

Title: Teleradiology using iPad improves the use of health system human resources for paediatric fractures: prospective study in a tertiary care hospital in Italy

Version: 3 Date: 9 May 2014

Editorial Comment:

A central issue of concern to this editor is the design of the study and its influence on time taken to make a decision. In Phase I a phone message containing the written description was sent. Was this in the form of a direct telephone connection or a voice mail. In either case it did take some time to read out the description which was counted into the time taken to reach a decision. In Phase II, the time was from the sending of the image(s) until a decision was made, BUT the orthopaedic specialist had already heard a verbal description of the case. The manuscript implies that Phase II for each patient immediately followed Phase I. So there are two factors that would favor a shorter time in Phase II - the time taken to read the description over the phone which would increase the time for Phase I and the apparent fact that he or she was already familiar with the case from Phase I which could shorten the decision making time for Phase II. The authors need to address this concern in interpreting the results of their study with respect to time to decision.

*** Time for the verbal description was not included in calculation of Phase I. Time for Phase I was calculated from (after) when the verbal description was completed.
In addition both reviewers raise a number of points that also need to be addressed either by a response to the Editor from the authors or changes in the manuscript. In cases where the reviewers may have misunderstood the description this should be pointed out as a response to the comments.

*** We have addressed all concern of the referees, as described point by point below.

Reviewer: Elizabeth Krupinski

Reviewer’s report:

1) Overall: This paper reports on the use of iPads to view radiographic bone images from kids with fractures by orthopedists. It found that compared to not being able to view the images there was a lowered need to come into the hospital, faster time to treat, and high image quality. It was a very nice study on a practical application yet to be examined.

*** Thank you for the appreciation.

2) Abstract: Fine as written.

*** No action needed here.

3) Introduction: Fine as written. It does a nice job of summarizing the literature on this topic, noting gaps, and thus providing the rationale for this study in the context of the local need for this types of service.

*** Thank you for the appreciation.

4) Methods: A couple of minor points need to be addressed.

Page 7 top: Are these digitally acquired radiographs or scanned in films?

*** These are digitally acquired radiographs (DICOM files).

5) Typically a bone exam acquires more than one image – are all acquired images sent or just the one(s) with critical findings?

*** All images acquired from each patient were sent

6) Page 10 para 4 line 2: What were the characteristics (resolution etc.) of the PACS displays? Did you counterbalance the conditions or did they all view PACS first then iPad or vice versa? How much time was there between sessions? Was viewing in both modes done using the same ambient lighting?

*** PACS is the standard system for viewing digital radiology images used in the hospital, and for this reason it was used as a golden standards to which compare quality of the images as viewed in the iPad. Image comparison was done in parallel, in the same ambient lighting.

7) For the iPad viewing did they orthopedists control the ambient lighting? Was it similar to what the radiologists had in the IQ study?

** Evaluations were generally done from home, in a ambient light that is comparable to the radiologist office.
8) Why didn’t you get IQ & confidence ratings with the orthopedists as it is really them that use the iPad and not the radiologists?

*** We did use radiologists for two reasons: 1) they are the specialists in radiological examination; 2) their opinion was independent from the study.

9) Results: Generally fine with appropriate analyses and good support of the tables & figures. A couple of minor points need to be addressed.

Page 11 para 3 line 3: Did you happen to record whether the fractures were subtle or obvious as this could impact the results?

** There were different types of fractures. We have further detailed this in Table 1. Most fractures were simple fractures (incomplete) and wedge fractures. It’s important to underline that this study did not have the objective to impact the type of diagnosis (fractures were diagnosed by the radiologists), but the need for an in-hospital orthopedic consultation.

10) Figure 1 is a very obvious and clear break not just a fracture and would be visible even on a smartphone without issue!

*** You are very right. However, this picture is not representative of the overall population sample in the study. This picture just want to represent “remote consultation”. In the sample only 2 children had complex fractures.

11) Page 12 para 1 line 2: As there were 3 orthopedists were there any differences between them or were these results typical of all of them?

*** Thanks for this point. We have specified this further. There were not significant differences among the 3 orthopaedics.

12) Conclusions: Fine as written. It does a good job of summarizing the results and discussing in the context of the literature. Limitations are noted.

*** Thank you for the appreciation.

13) References: Fine.

*** Thanks.

14) Tables & Figures: Fine although see point above about Figure 1 – can you show anything less obvious?

*** This is the only picture that we have at the moment.

15) Level of interest: An article of outstanding merit and interest in its field.

*** Thank you for the appreciation.

16) Quality of written English: Acceptable

17) Statistical review: Yes, and I have assessed the statistics in my report.

18) Declaration of competing interests: I declare that I have no competing interests
Reviewer: Erik Ranschaert

Reviewer's report:

Major Compulsory Revisions

Article: Background

“There are many unsolved normative and technical problems that hamper its implementation.”

This is not correct: most technical problems have been solved, and the EU legal framework is also very clear and transparent. For teleradiology there are not many remaining barriers, certainly not when it is not cross-border teleradiology. A clarification should be made on how the final diagnosis is made and who’s responsible for it.

For using mobile devices there is no legal limitation at this moment, in most countries there is no legislation for using these devices for diagnostic purposes. The legal implication is even less if the device is being used for clinical conferencing/consultation/communication instead of for making a final radiological diagnosis and report. Therefore it should be clarified who is making the final diagnosis and who’s responsible for that: radiologist or orthopaedic surgeon? For Radiology it’s usually the radiologist, so if the diagnosis is made on PACS and dedicated workstation than the radiologist is responsible for the primary diagnosis and the role of the iPad is not relevant in this process. If the orthopaedic surgeon is looking at the images from outside the hospital this is not a primary diagnosis but a “second opinion” or “clinical consultation”. Doing this on a mobile device is not legally “hampered”.

*** You are right. The sentence was actually very generic. We have deleted it.

Although a number of pilot experiences exist, teleradiology for on call specialist services in Europe is not a widespread practice. This is not correct. In Europe this type of consultation is widely implemented especially in the countries with high PACS coverage where radiologists can login into the hospital PACS from distance. In some countries where PACS is less available such as Greece and France this is less frequently used, but for other countries it’s done very often.

*** This sentence was unclear and we have revised it. We are referring here to on call orthopaedics. In our country teleradiology using mobile devices for on call orthopaedics is not an established practice.

The Health Insurance Portability and Accountability Act (HIPAA) and other existing regulations, require that the images are transferred securely and are accessed only by authenticated users.

HIPAA is only valid in the USA, not in Europe. There is other specific European legislation applicable on patient safety which is more relevant in this paper since the hospital is in Europe.

*** You are right, we are now referring more explicitly to the European regulation as well.
“In Phase I they were given only the written report from the radiologist, by phone, as usual for routine care.” Who’s giving the written report to whom? Why is it written if it’s by phone? Is the radiologist calling or someone else?

*** This was already described on page 5, two bottom lines “When a child is diagnosed with a fracture, the paediatrician in charge in the emergency department phones the orthopaedic on call, and describes the clinical case and the radiological findings as from the written report of the radiologist.”

We are talking here of orthopedic on call, they are outside the hospital.

We have further made all steps of this process explicit in the text.

Are the images visible for the paediatrician or not?

*** According to our system it is the orthopedic who has to decide on orthopedic cases.

Was there any comparison between the orthopaedic diagnosis and radiology diagnosis? Or was the orthopaedic decision mad on iPad compared with the orthopaedic decision based upon viewing the images on PACS in the hospital?

When comparing decision without X-ray vs decision with X-ray on iPad: what is being studied? Did the orthopaedic surgeon go to the hospital to verify his/her decision after having viewed the images on iPad?

*** The diagnosis is already made on the X-ray is made by the radiologist.

The orthopaedic has to decide whether to come immediately for treatment or not. This is what we are evaluating in this study.

How was the decision made to go (or not to go) to the hospital? Or was the decision to go or not to go to the hospital discussed with someone (e.g. other orthopaedic surgeon) who did see the images?

*** The decision to go or not to go to the hospital is taken by the orthopedic on call solely.

How did the orthopaedic surgeon make the decision, based upon what information: only viewing the images?

*** This was already described in page 9 in the method section, and we have further detailed it. Briefly, in phase I they only had the radiological report, in Phase II they also had the X-ray image.

Was any analysis made about the circumstances in which the orthopaedic surgeons looked at the images (location where images were looked at)?

*** Most evaluations were done from home.

How did the radiologists use the iPad: was it before or after the consultation with the orthopaedic surgeon that they compared the image quality, or was this done in a separate study at a separate moment? If there’s only 1 iPad available, then who was using it during the on-call consultation, the radiologist or orthopaedic surgeon?
The evaluation of the image quality was done by independent radiologists, to avoid bias in the evaluation. This was done in a separate moment (usually the morning after). This is described in page 10, last paragraph.

**Statistical Analysis:** On what was the priori hypothesis based, how was this estimation made?

**When this study was designed, we were unable to find similar studies evaluating this outcome. Most studies just evaluated image quality, while we decided here that we wanted to evaluate the relevance of using remote consultation for the use of health resources in the health system. This estimate was based on local experience, showing that in many cases orthopaedics were coming to the hospital to see the X-ray, without a real need to manage the patient urgently.**

Teleradiology needs to be defined better: this is a form of remote consultation and not primary image interpretation, so that should be mentioned.

*** We have fully revise the paper. Now it should be more clear that we are refering here to remote consultation.

**Results:** The time for decision-making was shortened with “teleradiology”: was it based upon the fact that no transportation was needed? Or was it based upon a better diagnosis or easier communication? How did it affect the management? How did the treatment of patients improve, e.g. did it only improve the waiting time or also the type of treatment? How was this measured?

*** If you are an orthopaedic on call probably it is useful to see the X-Ray of the patient immediately, rather than coming to the hospital to see it...

The analysis of image quality by radiologists is a separate study, which should be described/published separately. It is not part of the focus of this study which is more related on the impact of the iPad on the orthopaedic treatment (or management of orthopaedic surgeon)

*** The evaluation of image quality and diagnostic confidence was considered important in this study, as it complements other results. It was felt that it was important to evaluate image quality and diagnostic confidence using iPad. This was a separate outcome, but included in the the same study.

**Discussion:** In this study teleradiology through an iPad halved the number of in-hospital orthopaedic consultancies for paediatric fractures and sped up the decision-making on case management and organisation of care. How was this result achieved – only by reducing the time for the orthopaedic surgeon to come to the hospital, or by improving the communication? In what sense was the availability of iPad different compared with the “classical” communication between paediatrician/radiologist/orthopaedic surgeons? How did this affect the outcome for the patient, or was only the treatment TIME measured and not outcome of treatment (treatment errors with/without Xray on iPad)?

*** As described in the paper, the “classical communication” does not include the
provision of the X-ray to the orthoped on call (see page 3 third paragraph; page 4; page 5 fourth and fifth paragraph). This results was achieved by providing the X-ray to the orthopedic on call.

Outcomes of the study are reported on page 10. Results are reported on page 11 and 12.

Discussion: “Although teleradiology is a very rapidly growing field, to the best of our knowledge, there are no other studies in orthopaedics on systems for teleradiology ensuring adherence to international standards on data privacy, image quality, and data integrity.”

This is incorrect. It all depends on the definition of teleradiology, which actually in this study is only image transmission. Teleradiology is a well-studied discipline (see European white papers of ESR and ACR white papers on teleradiology). The legal issues regarding patient privacy and other issues are well known. Orthopaedics is just a part of teleradiology in general and radiologists are responsible for providing a primary reading (final report). Orthopaedic surgeons are not responsible for teleradiology services.

*** We were referring here to experimental studies on mobile devices for remote consultation for orthopedics on call. We have specified this better now.

Another limitation of this study is that, even if Aycan OsiriX PRO complies with most international standards, actual European regulations forbid the use of tablets for the purpose of formal diagnosis (final authenticated report). The European X-ray Ordinance and other regulations stipulates specific workstations for viewing and diagnostics.

This is irrelevant. There are no regulations that forbid the usage of tablets for making a diagnosis in Europe. There are no regulations either that forbid consultation (clinical conferencing) with orthopaedic surgeons. The radiologists are making the final authenticated report and this is not relevant in this study since the iPad is used by the orthopaedic surgeon to make a decision about going to the hospital or not.

*** We have deleted this sentence.

“The European legislation is complex and most Member States do not have legal instruments dealing specifically with teleradiology; only a few have regulations or guidelines.” This is not correct: please verify the recent ESR statement / teleradiology white paper update. The legal framework is clear.

*** This was an official statement from ESR in 2013 (not too long ago!).

Although now improvement have been made in the European regulations, not all member states still have implemented a clear regulating in respect to all these issues. This process will probably require a little bit more time.

However, we have deleted this part as not strictly relevant (see following point).

The European Society for Radiology (ESR) in January 2014 issued a white paper on teleradiology proposing best practice guidelines for teleradiology usage. In
summary, the ESR is calling for a future European legislation providing the following: a) Definition of teleradiology as a medical act in its own right; b) Establishment of EU-wide accreditation criteria for teleradiology providers; c) Emphasis on the importance of delivery of high-quality health care; d) Application of international quality standards including monitoring of service providers; e) Regulation of teleradiology as a responsibility of the member state where the patient undergoes the imaging procedure; f) Full information of patients and informed consent about usage of teleradiology.

Again this is irrelevant in this context: all depends on who’s making the final diagnosis. In this paper the iPad is used by the orthopaedic surgeon to make a decision about coming to the hospital or not. The radiologist makes the primary diagnosis. Furthermore the analysis of the white paper to which is referred is incorrect. The latest publication (Insights into Imaging, January 2014) should be studied thoroughly. There is no more call for a future legislation, the white paper has 5 main messages:

- TR describes provision of radiological services remote from the site where images are obtained (this is not relevant in this paper since the orthopaedic surgeon is using an iPad)
- TR should be part of and integrated with the wide spectrum of radiology services and not a tradable commodity
- Quality of TR reports and services should not be less than those of local radiologists (irrelevant in this study since radiologist’s interaction is not changed)
- International quality standards need to be established
- Patients need to be fully informed when teleradiology is used (was this the case in this study? This is not mentioned in the methods)

It is also incorrect to state that ESR demands “Regulation of teleradiology as a responsibility of the member state where the patient undergoes the imaging procedure”. The European legislation is clear at this point: the radiologist needs to be registered in the country of activity and as long as the radiologist is an EU-trained radiologist living in a EU member state this is no problem.

*** We have deleted all the discussion on the legal framework of telemedicine as not strictly relevant.

*** All ethical aspects, including patients’ information, were already explicitly reported on page 6 under “Ethical approval” (separate paragraph, as requested by BMC).

Minor Essential Revisions

Abstract:

Background: The question is not clearly defined. What do you mean with “impact on”? Is it impact on correct diagnosis or impact on treatment and/or quality of services? Or impact on communication between radiologists and clinicians? etc.
Methods: First sentence needs to be rephrased, difficult to understand: “Children from…eligible for enrolment”

What does mean “every patient served as his/her own control”?

Who did interpret the images on iPad, how did radiologists interpret images?

iPad were used to provide the X-ray to the orthopaedic for remote consultation.

Article
Background
“the emergency department staff contact an orthopaedic specialist for support and advice. Usually, this remote support relies on a verbal description made by the emergency department staff, or on a written description made by the radiologist.” How exactly is the radiologist involved? Who looks at the images? Is the radiologist available for advise? Is the report made immediately? Are the images and report quickly available on PACS?

“description of the X-ray is not enough for a proper decision making in orthopaedics, and often does not substitute for viewing the actual images”. Why is it only description? Does a radiologist look at the images, and is the report immediately available? Is it impossible for the orthopaedic surgeon to login into the PACS (in hospital or outside hospital) and look at the images from distance? Is there a PACS in the hospital or not? Is it only for cases when there’s no orthopaedic surgeon available in the hospital to look at the images, eg. During on-call times (out-of-office times)?

It seemed to us that this was already clearly written (see background, page 6 last sentence of the first paragraph. We quote this sentence here “Before this current study there was no routine system for providing the X-ray images to the orthopaedic specialist on call for remote consultation.”

“In this prospective study we evaluated the impact of teleradiology using an iPad on orthopaedic consultations for children with bone fractures in a tertiary care paediatric hospital in Italy

See remarks made about Abstract, regarding clarification of question”

Methods: In the first part (“setting”) a lot of background information is provided that should be mentioned in the “background” part of the paper (see questions above). Methods should be restricted to the way the study has been performed. It is not described how the radiologists look at the image, how and how quickly the
report is provided by the radiologist (telephone or PACS …), if the paediatrician has access to the images at the emergency department or not. It is not mentioned who’s making the final/primary diagnosis (radiologist or orthopaedic surgeon). It’s not mentioned if radiologists are available for interpreting the images during on-call services.

*** The background defines the general problem of X-ray remote consultation for orthopedics outside the hospital, as this is common to many settings. In the methods section details are given in regards to our specific setting. We still believe that providing these details here is important. We have also added several specifications to this part, as requested by the referee.

It is of notice that no similar issues were raised by the other referees in regards to this part.

It’s not mentioned what kind or PACS is being used (brand).

***We have added this in the method section .

Training: what are the technicians trained for? How are the radiologists involved? Who did the training? What were they trained in?

*** They were trained in using Aycan OsiriX PRO. See details added in the text.

Patients and study design:
“Every patient served as his/her own control.” – what does this mean?

*** This part was rephrased.

“Children from 0 to 18 years with a bone fracture diagnosed by the radiologist on the X-ray during the hours when orthopaedic service is provided only call”

Sentence should be rephrased, is not clear.

*** This sentence was rephrased.

Images Image 2: radiologist on left side is “sharp” but screen iPad is not. Picture is not really relevant.

*** The Referee must have mistaken the image number. It seems he refer here to image 1. This picture is not providing results, but just illustrating how the system was operating.

Level of interest: An article of limited interest

*** This is a very different judgment from the judgment of the other referee.

In this study remote X-ray consultation through an iPad halved the number of in-hospital orthopaedic consultancies for paediatric fractures and sped up the decision making on case management and organisation of care. We believe that this is not irrelevant in a health system perspective.

As we have stated in the background/discussion, there is very limited literature on this particular aspect of health care.

Quality of written English: Needs some language corrections before being published
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests