Reviewer’s report

Title: Teleradiology 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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Reviewer: Erik Ranschaert

Reviewer’s report:

Major Compulsory Revisions

1 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 is 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”.

2 Although a number of pilot experiences exist, teleradiology for on call specialist services in Europe is not a wide-spread 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.

3 The Health Insurance P 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.

4 “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? Are the images visible for the paediatrician or not?

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? 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?

How did the orthopaedic surgeon make the decision, based upon what information: only viewing the images? Was any analysis made about the circumstances in which the orthopaedic surgeons looked at the images (location where images were looked at)?

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?

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

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

7 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?

8 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)

9 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)?

10 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.

11 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.

12 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.

13 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.

Minor Essential Revisions

1. 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.

2. 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?

3. Article
   Background
   14 “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?

   15 “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)?

16 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

17 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.

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

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

20 Patients and study design:

“Every patient served as his/her own control.” – what does this mean?

21 “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.

Images

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

Level of interest: An article of limited interest

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