FUNCTIONAL IMAGING DIAGNOSTIC DECENTRALIZATION IDEA

Home imaging diagnostic project

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ABSTRACT

Home imaging diagnostic means: a service to satisfy the needs of all those who, for many reasons, have to do radiographs and ultrasounds at home or in private care institutions which got no imaging system. Examples: patients with severe diseases (accidents, after surgery outcome), chronic disease or locomotor system disorders (ex. spine disorders), affected by cardiorespiratory diseases or, also, the ones who cannot move.

So, in the next future, we can see the healthcare facility critical importance for this service, it must be programmed. Now, to activate home diagnostic imaging (hospital or private health care provider), all the criteria is analysed.

INTRODUCTION

"As Aimonino et al" said, is expected world elderly people, in world population, in 2000 year will increase by 6,9% and to 19,3% in year 2050; especially over 85 people, who show faster growth, often delicate and vulnerable.¹

In developing country, ageing people are a fast growing reality for business and health effects, so they show public healthcare further applications and new goals.

Healthcare system technical organizational branch will have to go along quickly to face elderly people challenge current changes and new needs, avoiding hospitalization with preventive and rehab locally activity.² Incapacitates home care growth is possible thanks many factors, for example healthcare technology can be sent home with patients.³ Years ago Ultrasounds and Radiography couldn't be used at home, basic in clinical practice. Thanks to new digital imaging technology, broadcasting systems and to the picture and archiving communication system (Ris-Pacs) is possible to have excellent clinical and diagnostic home imaging, comparable to those by hospital.⁴

Teleradiology is telemedicine service providing for radiological imaging transmission from place to place, whose goal is reporting or reference to improve pa-

tients utility and quality treatment and also healthcare system. We report about that 2011 study in San Giovanni Battista (Molinette) Torino university, carried out in cooperation with 2 Torino Asl and 2 Cuneo Asl. They made a 3 year project, funded by the Ministry of Health named "Teleradiology program for frail patients living at home or in nursing-homes",⁵ whose aim was home diagnostic performance also in general medical practice nursing homes. Another effective interest Tele-radiology example is the testing telemedicine project (telecommunication systems in clinical setting)

Figura 1

¹ "IL TELEMONITORAGGIO NEL PAZIENTE ANZIANO: STUDIO DI FATTIBILITÀ". Isaia Gianluca A.O.U. San Giovanni Battista di Torino, Geriatria

² "L'invecchiamento della popolazione: opportunità o sfida?" Di Lucia Galluzzo et. al.

³ Blog. ESAMI DIAGNOSTICI DOMICILIARI: è possibile effettuarli e avere la stessa qualità clinico diagnostica ospedaliera? <http://www.tmedical.net>

⁴ Mobile radiography services in nursing homes: a systematic review of residents' and societal outcomes. Elin Kjelle et al.

⁵ RICERCA FINALIZZATA 2009 Ministero della Salute – Direzione Generale della Ricerca Scientifica e Tecnologica. PROGETTO: Teleradiology program for frail patients living at home or in nursing-homes. Responsabile Scientifico: Dr.ssa V. Tibaldi

MyDoctor@Home⁶. This test is still developing, based on telemedicine service that can track hospitalized patients physiological parameters in home hospitalized scheme “Ospedalizzazione a Domicilio (OAD)”, patients who have acute heart failure or COPD chronic obstructive pulmonary disease. Research data are sent in real time to the medical facility, using portable devices with bluetooth connection. In so doing is possible to enable also home related echography, venous / arterial echodoppler and radiography.

METODOLOGY AND MATERIALS ACHIEVEMENT GOALS

Plan primary outcome

Feasibility and effectiveness study public home tele-radiology service for elderly people and bedridden.

Secondary outcome

- Radiology process complications reduction (delirium, accidents, pain, behavioral disorders), cost assessment, patient and relatives satisfaction rating.
- medical imaging and other diagnostic practices extending procedure⁷, also home nursing extension (EKG, taking blood samples, post operative medication, specialist visits,...) Art. 22 dPCM 12 January 2017⁸.

PROFESSIONALS INVOLVED

- **Radiologist:** head of the radiology facility, art. 2 comma 2 lett. B, D.Lgs 187/00.
- **Qualified Expert:** also Biophysician could be better (he will also do quality tests), who will carry out the technical investigation to respect the applicable current ratified legislation: drawing up a detailed radiological asset report. Produced by in charge radiologist ahead of project and relevant report art. 61 comma 2 D.Lgs. 230/95 of qualified expert in care of it. Sending in 30 days, before holding the radiology unit, “the practice prior communication”. Art. 22 D.Lgs 230/95 signed by the operator.

TSRM

What kind of diagnostic service is offering you?

- Routine radiological exam (TX)
- Plain abdominal X-ray
- Skeletal system X-ray (Pelvis, knee, femur)

Diagnostic Accuracy

As we said before makes sense to be doing home radiography only if it will have the same hospital quality. Skeletal system X-ray and TX (chest X-ray the most popular) have good imaging quality. New digital radiography systems especially, latest generation, ensure great imaging quality.

Medical and Legal aspects

The service will operate according to the hospital organisational requirements. As regards authorization it will be necessary to notify first art. 22 D.Lgs 230/95 s. m. i., enclosing the qualified advance report.

1. GDPR, general data protection regulation UE 2016/679
“relative to the protection of physical persons in the matter of processing their personal data, and the free circulation of this data 95/46/CE (General Data Protection Regulation)”, in Accordance with the provisions of the General Data Protection Regulation (GDPR), effective 24 May 2018, introduces the person in charge of personal data. (art. 37-39)
2. the said regulation provides for an obligation on the data officer “the processing is carried out by a public authority or body, except for courts acting in their judicial capacity” (art. 37 section 1, A)⁹.

EQUIPMENT REQUIRED

Image processing system:

- internet network for remote diagnosis and live reporting (4G network).
- pictures print system or CD (only when images are to be delivered in the short term to the hospital structure).
- portable X ray tube with vertical holder support system.
- X ray cassette or flat panel detector.
- personal protective equipment (lead vest) for radiographer and lead apron (lead protection) for patients.

Figura 2

⁶ Servizio di teleassistenza domiciliare di Telecom Italia. Nato nel 2008 dalla collaborazione tra Telecom Italia (TI), l'Azienda Ospedaliero-Universitaria (AOU) San Giovanni Battista di Torino e l'Istituto Superiore Mario Boella (ISMB).

⁷ <http://www.salute.gov.it/portale/lea/dettaglioContenutiLea.jsp?lingua=italiano&id=4706&area=Lea&menu=socioSanitaria>.

⁸ <https://www.medicoeleggi.com/argomenti000/italia2017/409077-22.htm>

⁹ http://tsrmvolontari.it/a90_gdpr-regolamento-europeo.htm

INVESTMENT PLAN

As the publicly available sources¹⁰ says, the “bankrol¹¹” ,on the radiology imaging manufacturers¹¹ estimates basis from information retrieved, for a new device (iva, warranty & assistance) is split as follows:

- Van/truck.
- X ray source (generator), CD and FDA certification. Convenient and easily to move thanks to foil flight case, 2 kW power 40-100 kV 30 mA (max) 0,3-50 mAs.
- Gadolino or Cesium Digital/Flat panel wireless from 25x30 to 43x43, lightweight and durable with carbon fibert inserts to improve impact resistance.
- Laptop, display 15.6” (customized according to your needs) high resolution for great images.
- Software features: autocrop, auto grid deletion, auto stitching, auto tag (labeling), auto-rotate, multiple layouts.
- Internal setup.
- Remote trasmission system.

Total amount, about 80000e, may be different according to the company needs, to the catchment area and also according to the payment formula (ticket SSN, private or freewill offering).

DIAGNOSTIC PROCESS

It is divided into the following phases:

JUSTIFICATION: refers to Dlgs. 187/2000 ,amended by 39/2002¹² law. Before the X-ray execution medical inquiry must be assessed (diagnostic modes,review requested,clinical question,...) , in order to avoid inappropriate and unjustified examinations, that add nothing to the medical query. These incorrect tests exposes patients to the damage radiation risk without good sake, and there is waste of resources¹³.

Such appreciation is up to the radiologist that, will communicate to the TSRM, after the patient (also relatives or medical booking) home performace booking. The medical request, in the booking stage, will be sent to the radiologist on duty who will assess the needs and benefits.TSRM will still be able to call the radiologist for further explanations (example: wrong elements in medical history,anamnesis, compared to those reported to the radiologist in the booking) before doing an X-ray.

INFORMED CONSENT¹⁴

“Informed Consent is the decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of

Figura 3

¹⁰ <http://consultatsrm.altervista.org/acquisto-di-apparecchiature-radiologiche-radiologia-domiciliare-quesito-2/>

¹¹ <https://www.ibisray.it/prodotti/umani/easy/>

¹² Decreto Legislativo 26 maggio 2000, n. 187. Attuazione della direttiva 97/43/ EURATOM in materia di protezione sanitaria delle persone contro i pericoli delle radiazioni ionizzanti connesse ad esposizioni mediche. Modificato dall'art. 39, Legge 1 marzo 2002, n. 39.

¹³ https://www.unipd.it/rpx/Legislazione/DLgs_187_26.5.00.pdf

¹⁴ DECRETO LEGISLATIVO 17 marzo 1995, n. 230. Attuazione delle direttive 89/618/Euratom, 90/641/Euratom, 96/29/Euratom e 2006/117/Euratom in materia di radiazioni ionizzanti. (GU Serie Generale n.136 del 13-06-1995 - Suppl. Ordinario n. 74). Entrata in vigore del decreto: 28-6-1995. <https://www.gazzettaufficiale.it>

Figura 4

giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of particular workstations at least one witness may be given in exceptional cases, as provided for in national legislation.”

EXECUTION AND SENDING OF IMAGES

Once the radiological examination has been performed in compliance with the guidelines¹⁵, the T.S.R.M will provide for the transmission of the images to the referring physician.

This phase is divided into several steps:

- Patient registry entry in RIS¹⁶.
- Generation of digital request.
- Acceptance of digital request.
- Processing and transmission of the exam.
- Acceptance from the hospital FIREWALL and recall from the radiologist doctor's reporting station (fig.5).

REPORTING AND COMMUNICATION OF THE REPORT

X-ray radiologist report (F1-2) have to be done from a thus made workstation:

4 GB RAM HD 500 GB, graphic card 512mb, 2 high resolution displays (3k x 3k for X-ray), 21” colour monitor 1280x1024 pixel and triple video output graphic card that can manage 3 screens giving the depth of the right color. This is necessary to use teleradiology for X-ray.

Monitor brightness must be high, 300 cd/m. All the radiologist have a smart card, that has a subscribing digital certificate, through which the owner can digitally sign his documents.

Digital sign¹⁷ represents the regular signature and it provides the following features:

- authentication, ensures subscriber identity
- integrity, ensures that the report hasn't been modified after subscription
- legal validity, gives signed report full value.

Reporting procedure

In RIS we select patient name from executed exams and after we go to the report. In the next screen we go in images and the X-ray will be on the screens thanks to DICOM e-film 4.2.0 viewer. The image shall include patients data (surname, name, sex, date of birth, ID) and also how the image as been done (date, time, X-ray type [kind], body parts orientation example L/R patient position- supine, prone, compression ratio and algorithms). All these data are in the DICOM header.

The radiologist provide for writing, saving and publishing (with his own password) and last signing the report (using again his own password).

The Report is now available in the report signed page. TSRM can now print the report, selecting print icon and can send the image to burning on DVD, clicking on CD and selecting portable burner.

The project is also for ultrasounds. Steps are the same, the only difference is that radiologist does all the work, as it is an operator dependent examination.

RADIOPROTECTION

Main problem about home radiology/tele-radiology is security, safety radiation protection for patient and radiographers. Protection system states that the rules 187/2000 and 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180,

¹⁵ Codice Deontologico TSRM ver. agg.2007, cap2. Linee d'indirizzo sulle attività di radiologia domiciliare – TSRM. <http://www.tsrn.org/wp-content/uploads/2015/10/R@dhom-FNCTSRM.pdf>

¹⁶ Sistema informatico radiologico. https://it.wikipedia.org/wiki/Sistema_informatico_radiologico

¹⁷ Firma Digitale, riferimento legislativo, articolo 15, comma 2, della legge 15 marzo 1997, n. 59 e successive modificazioni. <http://www.interlex.it/testi/dpr51397.htm>.

Figura 5

9.7.1997, p. 22) are respected, also “protection of the health of workers and the general public against the dangers from ionising radiation” D.Lgs n.230/95 and D.Lgs 241/00 and D.Lgs 257/01^{<7>}.

Radioprotection analysis is essential, especially if we think about all the security devices in a traditional radiodiagnostic room that are not found in the house of the patient.

Struttura complessa fisica sanitaria hospital molinette (Chief: dott R.Ropolo) review, noted that the exposure risk is low for patients and radiographers¹⁹.

Main radio protection safety standards, ensured by the radiographers are:

- always wear dosimeter at work
- minimize the number of present people
- ensure that there are no minors or pregnant women
- wear the lead vest to any person who necessarily assist the home patient
- do the Xray at the maximum possible distance from the patient
- check that on the direct X-beam there are no other people, besides the patient
- minimise Xray beam aperture to the useful area
- immediately report any inconvenience found to the radiologist.

DISCUSSION AND RESULTS

Telemedicine and teleradiology today are part of health care management.

There are many good points for patients:

- saving time, avoiding waiting before the examinations and wait for the report, which is given directly to the patient or to his doctor

- high quality services allow the treating doctor to be informed quickly about patient health
- elderly and immunosuppressed people are protected from nosocomial infections (hospital infections)
- home environment gives safety to the patient, for a better cooperation for a better radiography,...
- relationship between patient and radiographer is better, with both great advantage and satisfaction.

Exposure risk for radiographers and patients is low, provided that the rules are respected.

High satisfaction because the people don't go to the hospital or medical center.

Cut-off criteria

- urgent need radiography within 24h and home non executable or RSA non executable
- hospital catchment area cognitive study lack, that can show the effectiveness of the project.

This service in Italy is done only by private medical studies, exception for associazione nazionale tecnici di radiologia medica volontari (Messina 2002 and Andria 2009), who do this service for free, working with ASL locali and LIAOU San Giovanni Battista di Torino and L'ATSV-ONLUS (associazione TSRM volontari) throughout the territory of Brescia and province. It is worth recalling that home radiology service is complementary and not an hospital radiology substitute, because the only X-rays we can do are the ones for which technological limitations do not cause decrease in quality²⁰

^{<7>} <https://www.camera.it/parlam/leggi/deleghe/testi/00187dl.htm>

¹⁹ RICERCA FINALIZZATA 2009 Ministero della Salute – Direzione Generale della Ricerca Scientifica e Tecnologica. PROGETTO: *Teleradiology program for frail patients living at home or in nursing-homes*. Responsabile Scientifico: Dr.ssa V. Tibaldi

²⁰ https://it.wikipedia.org/wiki/Radiologia_domiciliare

As Kjelle²¹ and Lysdahl²² says in article “Mobile radiography services in nursing homes: a systematic review of residents and societal outcomes”, health policies requires efficiency and organisation changes, in addition to the use of new technologies and telemedicine to lowerspecialist healthcare stress. It is necessary to have a sound cost effectiveness analysis on larger areas of many countries; also are needed searches to find telemedicine obstacles in sanitary system. Home radiography service have the same hospital X-rays quality for nursing homes patients and have clear potential benefits. Mobile radiography

unit reduced the hospital patients amount, increasing the performances numbers and facilitating the early diagnosis, also the access to treatment.

Further research is needed to formally assess potential improvements in healthcare and efficacy-price²³.

COVID-19²⁴ will do a big change in people practice routine, also in many work activities, showing that they can be distributed (decentralized) outside the hospital (smart working).

So you could start think about the real chance to bring many hospital services at home or nursing home.

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²⁴ IL COVID-19 (abbreviazione di coronavirus disease 19), o malattia respiratoria acuta da SARS-CoV-2 o più semplicemente malattia da coronavirus 2019, è una malattia infettiva respiratoria causata dal virus denominato SARS-CoV-2 appartenente alla famiglia dei coronavirus. I primi casi sono stati riscontrati durante l'Epidemia di COVID-19 del 2019-2020. definizione presa da <https://it.wikipedia.org/wiki/COVID-19>.

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