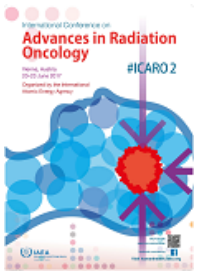

Contribution ID: **274** Type: **Oral Presentation**

IT safety requirements in the Radiation Therapy field: risks and solutions all over the process

Wednesday, 21 June 2017 12:00 (10 minutes)

Introduction

An impressive evolution of the Information Technology (IT) tools and systems since the invention of computers has radically modified Radiation Therapy. From standalone systems with limited and dedicated functionalities, to networks of all equipment through a common system, all these developments have resulted in a tremendous enlargement of the IT area, of the data transfer capacities and of the interactions between modalities (linacs, software, imaging devices).

Maintaining this growth over the last half-century has been successful thanks to safety and security methodology. From aviation to nuclear power plants, from pharmaceutical process to surgery, from basic manual manufactures to complexes automatic industries, ⋯everywhere checklists have been introduced to ensure an optimal level of process quality achievement.

On the way to improve safety and efficiency in our Radiation Oncology department, we initiated an in-house software development in 2004. The need emerged from the sharp increase in complexity when IMRT was introduced as a routine treatment. The need was to keep a constant overview of the workflow as well as the detailed "to do lists"to be completed, at the right time and in the right order.

A permanent flow of information is exchanged between systems, requiring specific quality control procedures of the accuracy of these transfers.

Material and methods

A web-based, open-source software has been developped, which is able to display the list of all the patients currently supported in the Radiation Oncology department. The system is called iTherapy Process (iTP, figure 1). The patients are distributed in various steps of the process (from the first consultation to the last radiotherapy session). Each step consists of a checklist relative to the process. Each step has also a colour code indicating which group of staff is in charge (for example planning in orange for physicists, or contouring in green for physicians). Whenever a step is completed, the person in charge validates it, and the name of the patient appears in the next step. This allows for immediate warning of the next person in charge that the file is ready to progress (from simulation to contouring for example).

Some steps consist of checklist to verify the accuracy of digital data transfer. This is considered an efficient safety measure in a domain where risk is frequently underestimated.

The different key points of the development story of this open source (AGPL Licence) software will be discussed, focusing on the pros and cons. The current challenges and our needs for the future will also be addressed.

Results

This software entered in production in 2005; it has been completely redesigned in 2012, and is called now iTherapy Process (iTP). Patient workflows are deeply detailed and frequently brought up-to-date by an ad-hoc department standing working party (the iTP committee).

Next to the workflow management by checklists, several iTP steps contribute to automatize, standardize and centralise control tools (existing in the past as separate "Excel"sheets), like in-vivo dosimetry, brachyther-

apy sources management, patient delivery quality assurance, eNal protocol, communication book, incident reporting system, team planning, breakdown database and downtime calculation, ⋯

From the CT-scan room, where the Hounsfield Unit (HU) must be well known and calibrated, to the treatment delivery, our daily activities are supported by the digital world (IT) which has, in the end, an impact on the treatment delivery itself and his quality.

The safety and quality of the treatments is a permanent goal but a perpetual challenge. We face today a high level of complex process. The checklists help to keep the teams on the right track.

Discussion and conclusions

Working on a complex process within a multi-disciplinary team calls for a very well organized "information transfer system".
Interaction between systems (TPS, OIS, Image viewer, linacs, ⋯) usually works fine. But what is the safety level of those data transfers? How far can we trust the standard protocols (Dicom-RT, HL7, ⋯), our storage areas, the modules used to transfer dosimetric information? Trustable data exchange protocols, automated and cross-check tools, standardizations, are currently lacking or are insufficient.
iTP is an attempt to help the user to verify, after data transfer from a system to another one that the data have been transferred appropriately. But, in the long term, solutions to strengthen the big data world still need to be developed.

Different area like aeronautic, chemistry, nuclear industry, banking or pharmaceuticals have developed (from the business as well as the legal point of view) a strong "safety and QA"oriented on the data transfer side. The medical world just starts to think about it. With all the technologies at our disposal, we must open our minds to new risks, to new challenges and also to new ways of working.

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Session Classification: Session 11b - Quality in Radiotherapy: various dimensions

Track Classification: QA/QC