

Brussels, January 23, 2013

Concerns:

Position PRISMA-RT Network Belgium in relation to the letter from the Belgian Federal Government Service concerning 'Communication reporting and learning systems of incidents and near incidents'

Dear PRISMA-RT member,

As you may know, the Belgian Federal Government for Health, Food chain Safety and Environment, recently sent out a letter announcing the usage of a single portal for reporting incidents and near incidents in Belgian Health Care Organizations.

Hereby we would like to clarify some ambiguities that have arisen recently.

The College has been developing the incident report and analysis project in parallel with the reporting system of the Ministry of Health for a number of reasons:

1. As radiotherapy users, we report both to the Ministry of Health (radiotherapy is Health Care) and to the AFCN/FANC (radiotherapy is using ionizing radiation). We therefore need to comply with two separate regulations, one being Federal (Health) and one being European (radiation, see directive EURATOM 94/7).
2. PRISMA-RT is a reporting tool, as other systems, but it is also a tool for root-cause analysis, cause classification and above all a tool to compare and learn from analysis. The combination of these factors is unique.

In hospitals where an institutional incident declaration system already exists, PRISMA declarations need to be transferred to the institutional database. Data with incident details remain in the hospital database in all cases. The company Adheco will care for the link between the radiotherapy declaration system and the institution declaration system (there are no incompatibilities).

Coordination is therefore mandatory between each radiotherapy department and its own institutional safety organization. The ultimate goal is to benefit from the specificities of the PRISMA-RT tool while collaborating with the institutional system of incident declaration.

Last but not least, any future exchange between RT departments on their own analysis of PRISMA registrations will be entirely voluntary, with a guaranteed anonymity and protection of original incident data (name of patient, name of declarant, name of institution).

With regard to the Belgian PRISMA-RT Network

Objectives

- Register specific radiotherapy (near) incidents occurred in Belgian radiotherapy centers.
- Analyze the data through the retrospective PRISMA methodology.
- Classify the results through the Eindhoven Classification model.
- Add certain context variables to the results to enforce a more qualitative dimension to the interpretation of the classification codes and gain more insight into the root cause of the (near) incidents.

All these results provide more insight into weaknesses in current work processes and give the opportunity to set out targeted improvement actions before serious incidents develop, as well on an individual center base as well as on a collective national level.

Principles

- Data are stored safely and secured on the web (see annex 1& 2).
- At all-time individually data are the property of and are managed by each individual radiotherapy center.
- Exchange of data between hospitals is entirely voluntary. Each center decides whether or not to exchange data with the benchmark point.
- Collective data are owned by the College of radiotherapists & oncologists. These data will be managed by the PRISMA-RT Steering Committee, yet to be composed. This Steering Committee will consist of mandated representatives from the institutions of the PRISMA-RT Network and will oversee the confidentiality in accordance with a specific privacy protocol.
- At NO time third parties have access to the data, own the data or manage the data.

Methodology

1. Each radiotherapy center collects its own data and stores this data into its own database (DB) (dedicated server 1), secured and only accessible by the center itself. Each center is owner of its own data.
2. Files are analyzed locally (per center) by using the PRISMA methodology. Successively, these files are classified by the Eindhoven Classification model; context variables are also added.
3. The results of these classifications and their context variables (thus only codes, no information on individual incidents) are exported into the benchmark environment (dedicated server 2); confidential data are NOT exported and remain in the DB of the center. Moreover, these data can at all-time be made anonymous by removing or changing confidential information into an anonymous string.

4. In each radiotherapy center one or more PRISMA analysts are trained in order to apply the same PRISMA methodology and analyze data consequently in a uniform way.
5. The analyzed data and their context variables are anonymously transferred in the benchmark environment; each center has a dynamic anonymous profile so no center is recognized by another.
6. Results are put into a national statistical analyze tool, compared and displayed in a global and individual (anonymous) way. Each center can consult the global and individual (anonymous) data and compare its own results with the national results.
7. Finally centers can connect to each other and share their experience. At this time the involved centers get to know each other, otherwise they cannot share their experience and/or start improvement actions.

Structure

See annex 3

With regard to the recent letter by the Federal Government and the collection of PRISMA-RT data

We would like to clarify the position of the PRISMA-RT Network Belgium with respect to the communication by the Federal Government.

- The PRISMA-RT Network is fully funded by the National Cancer Plan, Initiative 16.
- The PRISMA-RT system is fully compatible and satisfies all the conditions imposed by the Belgian Federal Government concerning the WHO taxonomy, its import and export of data. I.e. standard formats (XML, CSV, ...) to import / export data are fully respected. Moreover, these conditions are partially based upon the properties of inter alia the Clinical Risk Management System used by the PRISMA-RT Network.
- Data are collected by preference directly through the web application provided by the PRISMA-RT Network or can be collected throughout other reporting systems.
- Within the PRISMA-RT system there is a two-way communication:
 - Data from other digital information systems can be imported into the PRISMA-RT environment.
 - Data collected in the PRISMA-RT environment can be exported to other digital information systems.

In order to import PRISMA analyzed data and their context variables registered in other digital reporting systems into the PRISMA-RT Network, at this moment specific XML export protocols are planned to be developed for defining the specific mappings of these registration systems.

In the meantime, centers using already their own registration system, are advised to continue to register and analyze their data through PRISMA and add the context variables through their existing reporting system. This way, in a second time, these data can be put into the PRISMA-RT benchmark environment and be used to compare individually and/or collectively.

With regard to the WHO taxonomy and the Belgian PRISMA-RT Network

Belgium is the first country to register (near) incidents through the WHO taxonomy. This registration provides especially quantitative data to compare i.e. at the level of incident categories.

The Belgian PRISMA-RT Network is the first Clinical network in Belgium that uses systematically and in a uniform way the root causes of radiotherapy (near) incidents data, adds context variables and creates qualitative insights into root causes.

Combining data from the WHO taxonomy registration and the results from the PRISMA-RT Network, could provide radiotherapy centers an even more powerful database for individual and collective learning and by this means improve safety and quality of patients and staff.

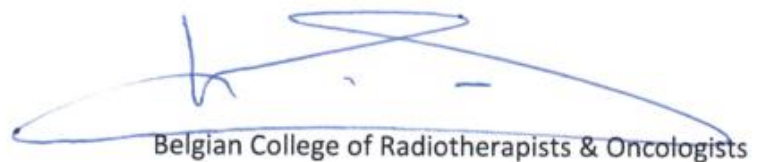
We hope to have informed sufficiently.

Should you have further questions, please contact us through info@prisma-rt.be or The Belgian College of Radiotherapists & Oncologists.

Kind regards,



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Annex 1 – Subscription conditions

Annex 2 – TPSC Cloud Infrastructure Specifications

Annex 3 – Figurative presentation of the PRISMA-RT Structure

