EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Promotion, disease prevention, financial instruments

Minutes

MEETING OF THE PROTON THERAPY SUB-GROUP- 21 OCTOBER 2020 (14:30-17:00)

Web-based meeting

Attendees: DG SANTE, DG RTD, JRC, EIB, 11 Member States' health authorities (The Netherlands, Sweden, Belgium, France, Slovenia, Czechia, Lithuania, Spain, Italy, Denmark and Hungary), and the consultants reporting to the EIB.

EIB and DG SANTE opened the meeting by welcoming the participants and setting up the aim of the meeting – to inform the participants about the state of play of proton therapy availability in EU and the scientific evidence of its effectiveness, collect feedback and validate the main conclusions.

Slovenia shortly presented the overview of national conventional radiotherapy centres and the openness to discuss the possibility to build a proton therapy centre and the possible advantages of a catchment area spanning several countries; the evaluation of the cost-effectiveness is ongoing.

The **EIB consultant team** noted the record of effectiveness of proton therapy in some cases (e.g.: better dosage control and better-localized treatment) but also the not so well identified side effects. The review of the available literature up to 2019 that was carried out has not provided such evidence. It was also mentioned that are 286 studies ongoing in this area that may in the future add to the pool of quality evidence.

A rapid increase in new proton therapy centres has occurred from 2005 (when eight centres were identified) to 2020 (34 centres in 14 countries); presently, four are under construction and nine are being planned. This will lead to almost 50 centres by 2025.

This is happening despite the lack of evidence on the relative effectiveness of the technology. Any investment in new and expensive technology should be backed by adequate evidence of its effectiveness and superiority to conventional treatment.

An important blocking factor for the improvement of the evidence base has been the lack of an European registry of proton therapy patients.

On reimbursement schemes, there is information from 13 centres but there are no general clinical guidelines.

Addressing the identified issues will require:

- obligation to store and share data on the clinical outcomes of Proton Beam Therapy (including both private and state centres) in a EU repository. This would help to carry out randomized studies;

- obligation to store and share data on photon therapy and conventional radiotherapy in order to have the possibility to compare the two;

- collecting information on national reimbursement policies.

EURACAN highlighted the importance of the collection, sharing and centralisation of data and proposed that the current leaders in proton therapy implementation would also to offer leadership in collaboration.

The Netherlands pointed out that the major obstacle for advancing research in the proton therapy area is funding. There is no specific financial instrument for proton therapy research and this should be improved, including at EU level.

Belgium informed about the data centralisation on treated patients in Belgium, performed in co-operation with the national cancer institute.

The **European Particle Therapy Network** called for the increased and improved networking of the centres.

The **EIB consultant team** pointed out the importance of improving the studies' design.

The Netherlands added that randomized control trials studies are not always adequate for assessing new technologies as they are being introduced. Alternative, robust and fit-for-purpose methodologies must also be considered. It was also noted that some side effects may only be detected after 10-15 years of use of the technology.

The **JRC** informed about the Commission's support to European Reference Networks, namely in the area of cancer, and on the knowhow and expertise of the JRC in setting up and/or pooling EU registries.

The **EIB** informed about the possibility of to proceed in the future with a more complete mapping of centres in Europe. It also noted the important role that conditionality can play to help move forward: support to investments in the sector can be linked to commitments to increase collaboration in data sharing, research and networking. The EIB encouraged Member States to submit additional feedback by 6 November.

DG SANTE and the EIB summarized the outcomes of the meeting:

There was agreement on the need for improved study design, metrology, and networking between centres, and patient registries and databases, in order to increase the knowledge and evidence bases.

The same consensus applied to the need to use 3 routes with EU dimensions to resolve the situation: i) supporting research; ii) promoting collaboration between centres; and iii) using conditionality in investment support.

It was decided that the Steering Group would be reported on the above to help define the next steps.