EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health programme and chronic diseases

Luxembourg, 16 Jan. 2019

NOTE OF THE MEETING

STEERING GROUP ON HEALTH PROMOTION, DISEASE PREVENTION AND MANAGEMENT OF NON-COMMUNICABLE DISEASES

SUBGROUP ON PROTON THERAPY CENTRES

22 OCTOBER 2018, LUXEMBURG

Welcome and Introduction

The meeting was chaired by the Deputy Head of Unit for the Health Programme and Chronic Diseases, Director-General of DG Health and Food Safety (DG SANTE) and co-chaired by the Lead Health Economist at the European Investment Bank (EIB) Life Sciences Division.

The participants were the nominated representatives of 12 Member States, as well as of Norway and Iceland. Colleagues from DG ENER and the Joint Research Centre also attended. Expert input was further provided from the European Reference Network EURACAN and the European Particle Therapy Network. An additional three Member States as well as DG RTD indicated their interest to contribute to the effort of the subgroup, but presented their excuses for this meeting.

The Chair welcomed the participants to this first meeting of the group. He reminded them it was set up as a temporary subgroup of the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases with a mandate to examine the current state of play of availability and use of proton therapy centres across the EU and identify options for willing Member States to cooperate sustainably to improve information exchange and avoid duplication of efforts. Its work is to support the European Investment Bank (EIB) in developing a better understanding of the needs for proton therapy treatment and centres in Europe. It is an example of how the Commission seeks to improve its working and decision making processes, aligning approaches across silos and budgets, consulting and involving Member States at an earlier stage.

The co-chair explained the EIB has already invested in several proton therapy centres, all of which include a research dimension. The Bank has recently seen a considerable increase in requests to invest in proton therapy facilities, also for treatment purposes. The EIB seeks to gather the latest evidence and knowledge to inform balanced decision making and possibly revise current lending guidelines. Dialogue with Member States' health authorities and DG SANTE is expected to provide valuable insights into national and regional health systems contexts, and opportunities for cross-border collaboration.

Update on EIB mapping and fact finding exercise

The co-chair elaborated on the EIB's motivation and need to gather evidence on clinical effectiveness, demand and running costs. As a European institution, the EIB invests in projects that deliver high quality and affordable services to general populations, in support of equity of access across the EU. As a bank, the EIB invests long term, and according to a set of appraisal guidelines that address technical areas, but also creditworthiness and ability to pay back.

Before deciding whether to expand its lending to proton therapy treatment centres the EIB seeks to answer several key questions. These centre on capacity needs for the EU; costs and reimbursement; referral systems to ensure equity of access and cross-border operation; technology; and project management.

The EIB will commission a consultant to draft a mapping report on the current availability and use of proton therapy centres across the EU. This will be a technical document that may facilitate relevant analysis by the EIB and the Member States. It will not provide political recommendations on national competences such as access or reimbursement of healthcare services. Rather, it will address current evidence-based indications, features and clinical value currently available, potential future indications, human resources and skills required, and research priorities. This fact finding will be followed by an additional analysis of cost-effectiveness, reimbursement schemes, and issues related to geographical distribution.

The review and update on clinical evidence is envisaged to start by the end of this year, the mapping and market study will run in the first half 2019. The consultant will be informed of any expertise gathered via the subgroup, and the subgroup will be approached for comments on the draft report.

Tour de table

This meeting focussed on sharing of evidence, studies and reports on the usefulness and efficiency of the technology. All Member State participants reported on the current state of affairs in their respective countries. From this a hugely varied picture emerged as regards current availability, size and purpose of therapy facilities, their geographical spread across Europe, and the role of the private sector.

Several countries with a decentralised health system shared examples of specific collaborative processes to facilitate more central decision making on (clinical) criteria for eligibility, equitable access, reimbursement, and joint funding for more central facilities.

It also became clear how complex it currently is to gather information about cost-effectiveness of proton therapy. Patient populations are very small in size. Some evidence is lacking and there is a need to broaden the existing knowledge base via international research efforts.

There seems to be consensus about good clinical outcomes in treating paediatric cancers, skull-base or spine rare tumors and -to a lesser extent- head and neck cancers. It was mentioned that the added value of proton treatment for other cancers is not proven. However, this may change quickly as innovation continues and less costly infrastructure becomes possible. Quantifying clinical demand remains a challenge and the estimate of 5-15% of all cancer patients as potentially benefitting from a proton therapy option was

discussed several times. In parallel, it was noted that patient demand has also been pushed by -increasingly active- private providers who raise ungrounded expectations about outcomes. Geographical factors also have an impact on planning. Some countries currently treat cross-border patients. Once treatment becomes available in the countries of origin of these patients, this kind of demand will dry up.

Existing and planned facilities vary with regard to number of treatment rooms, flexibility of how the facility is used (research and/or treatment), and whether the facility is linked to a specialised or university hospital of public or private status. These factors may impact on operating costs but also on quality. Making reliable estimations of running costs is further complicated by rapid innovations that enable the development of less expensive facilities.

Workforce issues also emerged as a major factor for planning: high quality proton therapy facilities require highly specialised personnel. There already is a shortage of such specialist doctors, dosimetrists, radiation technicians and nurses. Unbalanced growth of proton therapy services could also result in photon therapy staff shortages. In addition, this may affect the supply of specialised workforce for conventional radio therapy facilities.

Concrete examples

Participants were informed about the experiences with moving proton therapy forward in England by the NHS England National Clinical Lead for Proton Beam Therapy. Following clinical consensus (in 2007) about the relevance of proton therapy for some patients it was recommended to set up a mechanism for treatment overseas while also exploring the business case for establishing UK based facilities. Since 2008, approximately 1600 patients, the majority of them paediatric cases, have been treated via the NHS England Proton Overseas Programme. They are referred through a national electronic portal that also serves the health authorities (and patients) in Scotland and Northern Ireland. Referral numbers go up steadily each year. This may in part be caused by investments in health care/surgery quality.

The first high energy National Health Service proton therapy centre in the UK will open in Manchester late 2018, another one is under construction in London. There are also several commercial centres in England. The increasing role of the private sector raises questions as regards quality and equity. It was suggested that they may target different patient populations, sometimes raising unrealistic expectations among them.

The speaker concluded that there is an urgent need to build and broaden the existing evidence base, including through clinical control trials. International studies may provide the best context for this. Following an exchange with participants, the chair suggested that contributions to the evidence base could be a requirement for the financing of new centres, especially those centres that are funded via public resources.

Participants then heard from the Department of Clinical Sciences of the University of Barcelona about the outcomes of Spanish evidence reviews from an HTA perspective. Between 2009 and 2018 three such reviews were carried out. In 2014 this also included an analysis of the facilities planned or working in Europe. The insufficiency of the existing evidence stood out, as most reviewed studies were retrospective case series. No Randomized Control Trial (RCT) study directly comparing proton and photon therapies was identified. Choosing proton therapy is reasonable in cases where the evidence is

sufficient (i.e. particularly in paediatric cancers) but otherwise gathering new evidence via RCT should be advocated.

The review also highlighted how different European countries apply different criteria to estimate patient demand, resulting in certain countries being more restrictive than others. Translating these criteria to the Spanish population resulted in wide ranging patient numbers. This raised questions among policy makers about the validity of methods to quantify patient need and plan for therapy centres. In the specific case of Spain, the decentralised health system also is a key factor. At the moment it is not viable to offer a publicly funded facility in each region.

The Coordinator of the Department of Radiotherapy at the Centre Leon Berard in Lyon shared information about the European Reference Network (ERN) on rare adult solid cancers (EURACAN). This brings health care providers from 17 European countries together with associated partners that include patient advocacy groups. One of its main objectives is to produce guidelines for diagnostic and treatment, shared via key international professional organisations and contributing to harmonising existing guidelines across Europe. EURACAN also promotes high-level research through pooling of patients and resources, and develops training and education. To support ERNs in cross-border diagnosis and treatment a web-based application has been developed. EURACAN will start to pilot this Clinical Patient Management System in the coming months.

Experience from this ERN supports the observation that large prospective studies are lacking to improve our knowledge on proton therapy and the type of patients it would benefit. Sharing patient experiences and other expertise would help, as would prospective evaluations and long-term follow-up.

It was suggested the ERN model could be useful for European initiatives on proton therapy. As ERNs consist of centres that are already designated by their respective countries, (future) proton therapy centres could be linked to ERNs. Integrating such centres into existing major cancer centres would be advisable.

The Head and Chairman of the Proton Therapy Center of the Paul Scherrer Institute in Switzerland informed participants about the European Particle Therapy Network (EPTN). This set up in 2015 as task force of European Society for Radiotherapy and Oncology. The network seeks to advance work on issues such as clinical effectiveness, quality assurance and health economic aspects of particle therapy. It also has a specific working group on education and training. It is foreseen that EPTN will launch a prospective database Q1-Q2 2020 with the help of the European Organisation for the Research and Treatment of Cancer (Brussels, BE) within the framework of the E2RADIatE project.

In conclusion, there are not sufficient studies with relevant patient numbers to assess the added value of particle therapy in all cases. Reviewing cost effectiveness requires more RCT trials, creative study designs and international collaboration, also across medical specialists focusing on specific types of cancers.

Discussion and next steps

The co-chair thanked all participants for a very rich and interesting exchange. Revisiting the EIB's priority questions it was discussed how the expertise shared during the day

helped to provide more clarity, also on key challenges and existing knowledge gaps. The chair concluded on the advantage of reinforcing the knowledge basis. International collaboration is essential given the still very limited number of patients, and it could be recommended that all new proton therapy should contribute to reinforce the international knowledge base.

In closing, the chair invited all participants to share any additional information and suggested how this could inform the upcoming EIB study. Once the terms of reference for this study are defined the subgroup members will be invited to contribute comments and additional expertise. It is envisaged that then the draft report will be shared for further comments and clarifications. The report will be discussed at a second meeting of the subgroup –most likely in the second trimester of 2019- where possible suggestions to the Steering Group on Prevention and Promotion will also be on the agenda.