CTRad Workshop on Outcome Data Collection for Proton Beam Therapy

A meeting was held at The Christie NHS Foundation Trust on 8 July 2013 to discuss outcome data collection for patients treated with proton beam therapy (PBT).

The aims of this meeting were to stimulate discussion and to consider;

- What outcome data should be collected
- How this data should be collated and the
- Requirements for a IT platform suitable for the task

Currently patients are treated with PBT overseas. However there are plans for this service to devolve to the UK in early 2018. We need to capture detailed data on patients currently going overseas for PBT, and also should start collecting outcome data now for photon treatment of tumour sites likely to be treated with PBT in the UK after 2018. The data that we collect also needs to be sufficiently detailed to discriminate important proton and photon differences.

This meeting was attended by clinical oncologists, paediatric oncologists, medical physicists, radiographers, endocrinologists, IT staff, and patient representatives.

The first part of the meeting consisted of a series of presentations.

Outcome data collection and the Proton Programme

Dr Adrian Crellin described the current case mix of patients going abroad for PBT and how this is anticipated to expand once a PBT service is operational in the UK. The justification for PBT in children, who comprise the majority of NHS patients currently receiving PBT, and adults is rather different. For children requiring radical radiotherapy, the justification for PBT revolves around the reduced doses to normal tissues, which are still developing and are more vulnerable than in adults. PBT offers the potential to reduce late normal tissue effects, for example effects on growth, endocrinopathies, neuropsychological effects including on memory and IQ, and second malignancies. This is especially important as children who are cured will have many decades to manifest such late effects. In adults, the justification for PBT can be made where radiotherapy needs to be highly conformal, and where high doses to target volumes close to critical radiosensitive normal tissues are needed. Once a PBT is operational in the UK, up to 1500 patients per annum will be treated, and indications will expand beyond the current list. As well as paediatric tumours, more central nervous system (CNS), head and neck tumours and sarcomas are likely to be treated, as well as a variety of other “difficult cases”. Current outcome data collection is problematic, especially as patients who have received PBT abroad are followed up in many different centres, which inevitably affects compliance and the amount of detail that can be captured with paper returns. Suggestions for how UK data will be collected were made. The VODCA (Visualisation and Organisation of Data for Cancer Analysis) system for radiotherapy allows creation and management of longitudinal patient and outcome databases, for example along with a DICOM server, PACS and radiotherapy data converter which can be tailored for use. Such a system could be linked with existing databases such as the NCIN and RTDS systems. A host site and web based system is needed and soon.

Patient-Reported Outcomes

Dr Caroline Henson presented some examples of how Patient Reported Outcome Measures (PROMs) can be used to assess the impact of treatment on patients in terms of frequency and severity of symptoms. This information is not always recorded by health professionals and the assumption that no reported toxicity equals no toxicity is not always correct. Patient reporting

may go some way to address the under reporting of toxicity symptoms. This requires a standardised system of reporting toxicity with validated tools that are easy to use and acceptable to patients. The use of PROMs at pre-treatment assessments and at agreed time points during follow up must become a routine part of care.

Clinical Outcomes Recording - How to make it happen

Dr Jac Livsey presented the data collection tool used at The Christie by medical and specialist nursing staff to generate meaningful clinical outcomes. The data collection tool is tailored for each disease group so that it is tumour specific, intuitive and generates the maximum amount of information with the minimum number of questions, with drop-down boxes facilitating rapid data entry. The system can produce a front sheet for the patient record and be used to generate clinic letters. We aim to complete these forms for all new patients and by July 2013 more than 12,000 forms had been produced by two-thirds of disease groups at The Christie. This needs to be done by health professionals, who have the appropriate knowledge to collect high quality data. It must therefore be as easy as possible and must feel worthwhile for those concerned. The biggest challenge will be to collect follow-up data at other centres for the PBT patients.

Theragnostics : Integrating clinical outcomes with planning data

Professor Chris Moore presented on "Theragnostics" – integrating clinical outcomes with treatment planning data. A strategy for linking therapeutic and diagnostic data may allow us to match myriad data to outcomes and select best adapted care. Examples of Bayesian Networks (analogous to internet search engines) were discussed, which need very large amounts of data, though not all of it complete. Meaningful data reduction and parameterization will be an essential component of predictive decision support systems of the future. Currently, large multidimensional data (e.g. dose grids from individualized treatment planning and re-planning) are collected but under-exploited. At the moment dose grids are reduced to dose volume histograms (DVHs) to support pre-treatment planning decisions and radiobiological modelling. However, this means the spatial relationships between target, tissues and local dose are lost. An example would be multiple DVHs, for multiple patients, being used to predict post-treatment rib fracture risk, instead of the clinically obvious parameter of rib proximity to the high dose region. Developing online analysis of very large, routinely collected data, which reflects actual clinical practice and patient changes throughout the entire care process, will at the very least assist clinicians to choose best treatment options for their patients from a solid evidence basis.

Working group discussion

Four working groups, led by Dr Anna Cassoni (sarcoma), Dr Yen-Ch'ing Chang (paediatrics), Dr Lip Lee (head and neck) and Dr Gillian Whitfield (CNS), and representing the main diagnostic areas anticipated for the UK PBT service in 2018, were asked to discuss the following:

- What needs collecting?
- How would we structure this?
- Who else do we need to involve?
- How soon and when operational?

Summary: a way forward

A summary of discussions by each group was presented to the group as a whole. Prof Bleddyn Jones gave a short presentation, in which he recommended storing 3-D linear energy transfer (LET) maps, as well as 3-D dose maps, and recording normal tissue outcomes in relation to each of the International Commission on Radiation Units and Measurements (ICRU) defined target volumes, because of uncertainties in relative biological effectiveness (RBE) at the present time. Dr Ed Smith, clinical lead for PBT at The Christie, led a summing up.

- The Service Investment Framework states we must "ensure that proton therapy in the UK has evaluation as a core principle of the service". It is going to require the efforts of a broad range of clinicians, medical physics, external suppliers, informatics, finance and business development to achieve this.
- The presentations throughout the day were well received and the general consensus was that the approaches outlined in the various presentations were a good way of collecting the information we need in relating outcomes to treatment (and other variables).
- Informatics will need to be prioritised to produce a web-based management system for clinical patient information. Decisions need to be taken on the key requirements of a platform for this, e.g. ease of use, access by health professionals across the UK, and data mining.
- The Christie and UCLH as the future PBT centres will need to collaborate on IT requirements, and must start progressing that work within the next three months.
- The outcomes groups (Paediatrics, Sarcoma, Head and Neck, CNS) need to explore and refine their requirements for outcomes data collection, with the aim of starting data collection prior to the opening of a UK Service (both photon and proton).
    - All groups to produce the outcome data requirements for their specialism (what needs to be collected and how often). Review in a year's time of the outputs of that work and how they can be combined. Some work will need to be done to consider diagnoses not discussed today. The paediatrics' group is already well advanced in this, thanks to efforts by the CCLG led by Dr Michelle Kwok-Williams.
- Aim to meet for presentation of work done up to that point.

Actions from Meeting

1. **Site Groups**
    a. **Groups to review their membership (additional views/expertise needed?)**
    b. **Develop Outcome parameter needs by next year**
    c. **Further disease sites needed? Group Leads/SED/GW**
2. **Schedule Update Meeting – GW/SED**
3. **Informatics requirements – AC/Trusts**
4. **Funding – AC/Trusts**

Agenda

09:45 Registration and coffee

10:15 Introduction: Aims of the day & why we are doing this – Dr Gillian Whitfield / Dr Susan Davidson, Consultant Clinical Oncologists, The Christie, Manchester

10:25 Outcome data collection & the Proton Programme - Dr Adrian Crellin, Consultant Clinical Oncologist and Director of the Proton Overseas Programme, St James' Institute of Oncology, Leeds

11:00 Patient-Reported Outcomes - Dr Caroline Henson, Clinical Research Fellow & SpR in Gastro-enterology, The Christie, Manchester

11:25 Clinical Outcomes Recording - How to make it happen – Dr Jac Livsey, Consultant Clinical Oncologist, The Christie, Manchester

11:50 Theragnostics : Integrating clinical outcomes with planning data – Prof Chris Moore, Consultant Clinical Scientist / Medical Physicist, The Christie, Manchester

12:15 Lunch

13:00 Working groups:

- Sarcoma - Dr Anna Cassoni (Consultant Clinical Oncologist, University College London Hospitals)
- Paediatrics - Dr Yen-Ch'ing Chang (Consultant Clinical Oncologist, University College London Hospitals)
- Head and Neck - Dr Lip Wai Lee (Consultant Clinical Oncologist, The Christie, Manchester)
- Central Nervous System (CNS) - Dr Gillian Whitfield (Consultant Clinical Oncologist, The Christie, Manchester)

What do we need to do?
Who here can do some of this?
Who else do we need to involve?
Funding?

14:30 Tea / coffee

14:45 Presentation from the Working Groups (4 x 10 mins)

15:25 Summary: A way forward – Dr Ed Smith, Consultant Oncologist, Clinical Lead for Proton Beam Therapy Development at The Christie - to lead the discussion

Finish by 16:00