

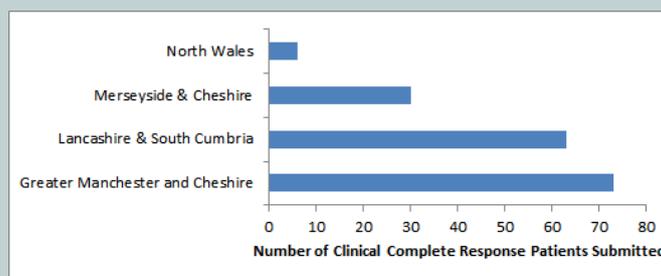
Rectal Cancer Complete Response Research Database Winter 2017/18 Newsletter

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Issue 3

2017 Achievements & Update

Thanks to the support from the 26 participating centres from around the North West of England and Wales, the Rectal Cancer Complete Response Registry continued to develop in 2017, with a total of 172 patients with a clinical complete response submitted to date - making it one of the largest datasets in the world, second to only to the Sao Paulo series.



Breakdown of Patients submitted to the OnCoRe registry to date

This updated dataset resulted in numerous key presentations during 2017, including the Tripartite meeting in Seattle & the ACPGBI meeting in Bournemouth, where the outcomes after salvage treatment for local re-growth in cCR patients were presented. The findings from this updated cohort supported the oncological safety of management by Watch & Wait and importantly showed that there was no compromise to subsequent surgical resection, with the majority of re-growths amenable to salvage surgery with a high R0 rate.



In this issue:

2017 Achievements & Update 1

Registration as a Research Database 1

Patient Consent 1

Patient & Public Involvement / Engagement 2

World Rectal Conference on Organ Preserving Perspectives 2

Initial Projects for OnCoRe 2

Registration as a Research Database

Towards the end of 2017, the decision was made to convert the OnCoRe Registry into a Research Database registered with the Health Research Authority (HRA) & with Section 251 approval from the Confidentiality Advisory Group (CAG). This will allow us to continue to add patients and follow up data to further investigate the oncological outcomes of these patients.

In December 2017, we received full ethical approval for this project from the HRA and CAG until at least November 2021. Thanks to funding from the NIHR Manchester Biomedical Research Centre grant, the database will be fully supported until this time. In addition, we are currently applying for inclusion of the database within the CRN Portfolio. We are therefore pleased to announce that The OnCoRe Research Database is now ready to launch.

Patient Consent



A key requirement resulting from the registration of the research database is that all future patients included are to give informed consent before their data is added. The Confidentiality Advisory Group have agreed that it is not necessary for patients already added to the registry to provide consent under Section 251 approval. Please see the included Patient Information Sheet and Consent Form for use when recruiting patients.

NHS
National Institute for
Health Research

Manchester
Biomedical Research Centre

MANCHESTER
1824

The University of Manchester

NHS

The Christie
NHS Foundation Trust



Steering committee

Professor Andrew Renehan,
Colorectal Surgeon, The Christie
NHS Foundation Trust &
University of Manchester

Dr Simon Gollins, Clinical
Oncologist & Chair of the NCRI
Colorectal Cancer Trials Group,
North Wales Cancer Treatment
Centre

Dr Mark Saunders, Clinical
Oncologist, The Christie NHS
Foundation Trust

Mr Nigel Scott, Colorectal
Surgeon Royal Preston Hospital

Dr Shabbir Susnerwala, Clinical
Oncologist, Royal Preston
Hospital

Professor Arthur Sun Myint,
Clinical Oncologist, Clatterbridge
Cancer Centre, Liverpool

Professor Sarah T O'Dwyer,
Colorectal Surgeon, The Christie
NHS Foundation Trust

Mr Fraser Smith, Colorectal
Surgeon, The Royal Liverpool

Prof Richard Emsley, Biostatistics,
Institute of Population Health,
University of Manchester

Contact Details

Lee Malcomson
Research Associate

The Christie NHS FT
Wilmslow Rd
Withington
Manchester
M20 4BX

Tel: 0161 446 8417

Fax: 0161 446 8593

E-mail:

lee.malcomson@nhs.net

Patient & Public Involvement / Engagement

The OnCoRe Database has been discussed at two PPI/E meetings and has been consulted with a total of 25 patients & members of the public. The overall feedback was very positive, with all attendees stating that they would be happy for their data to be included within the database - with some specifying that they would prefer to give informed consent beforehand. The project will be reviewed at annual PPI meetings in the future.



World Rectal Conference on Organ Preserving Perspectives

In November 2017, the 5th World Rectal Conference on Organ Preserving Perspectives took place in Leiden, The Netherlands. During this meeting, experts in the field (including surgeons, radiation oncologists, radiologists and trailists) from around the world met to discuss the endpoint of organ preservation in trials. There were two key outputs:



- 1) Clinical Complete Response is now considered to be classified as two distinct types:
Opportunistic - after stand (chemo)-radiotherapy treatment
Intentional - where standard pre-operative treatment is modified to improve the chance of a complete sustained response.
We currently believe that the follow up protocol should be the same for each type and that there is an equal risk of local regrowth.
- 2) There is to be on-going work to develop clinical guidance on the best follow-up practice

Initial Projects for OnCoRe

There are two international projects that the OnCoRe data will initially contribute to:

- The International Watch and Wait Database (IWWD) is a Dutch based site with data collected for over 800 patients on a Watch & Wait Pathway, to which OnCoRe is a key contributor.
- InterCorRe is an individual Participant Data (IPD) meta-analysis initiated by Dr Sami Chadi, a Toronto based surgeon and supported by Professor Angelita Habr-Gama (Brazil) & Professor Steve Wexner (USA). This project will investigate high-quality data for over 600 complete response patients from 10 key centres in addition to the OnCoRe data. This analysis will allow us to determine the influence of factors on local re-growth rates while taking account of other unmeasured, study-level (residual) factors. This project has been successfully registered on the PROSPERO International Prospective Register of Systematic Reviews and a manuscript is in early preparation.

