

NHS BLOOD AND TRANSPLANT

CARDIOTHORACIC ADVISORY GROUP

APPLICATIONS FOR DATA - APPROVAL PROCESS

INTRODUCTION

- 1 There is currently an established route for access to NHSBT held cardiothoracic transplant data through a data application to the CTAG Clinical Audit Group. Applications are only considered by the Audit Group in their meetings and this can add significant delay to the process. Also, considerable statistical time is taken to prepare bespoke datasets when approval is given.
- 2 By contrast, the Liver Advisory Group now have, and the Kidney Advisory Group are developing, an established process involving more timely release of an agreed core transplant dataset, with some stipulations about who has access.
- 3 It is proposed that the CTAG also adopts this process, which has been welcomed by the Advisory Groups, the statisticians and researchers requesting data. This paper explains the proposed new process whereby a standard cardiothoracic dataset can be released, without the CTAG Clinical Audit Group approval, for data applications fulfilling certain criteria.

PROCESS

- 4 A standard cardiothoracic transplant data set will be created for provision in response to data applications. It is suggested that the following criteria are used and, if met, would allow automatic release of the cardiothoracic transplant dataset without the CTAG Clinical Audit Group approval. The criteria are as follows:

The standard cardiothoracic dataset can be automatically released where:

- a) All required data are included in the standard transplant dataset

AND

- b) The request is from one of the following:

- 1 A current cardiothoracic transplant unit in the UK (with consultant level support)
- 2 A group with funding through an NIHR grant (or equivalent peer review funding stream)
- 3 A public health or government body

AND

- c) No statistical support is required from NHSBT

- 5 Data applications not meeting these criteria will continue to be reviewed by the CTAG Clinical Audit Group. The group will also receive brief details of all studies for which the standard dataset has been issued. This will be provided at the group's meetings.
- 6 An application can be made using the current process of completing an *Application for Data* form (http://www.odt.nhs.uk/doc/uktr_application_for_data_form.doc) (see

Appendix A) and sending to statistical.enquiries@nhsbt.nhs.uk. If approved, a Data Release Agreement is also required (**Appendix B**).

- 7 It is proposed that the contents of the standard national cardiothoracic transplant dataset include the following information: All cardiothoracic transplants performed in the UK - donor characteristics, recipient characteristics, transplant information, graft and patient survival times and censoring indicators, follow up information. There would be no centre indicators or patient identifiable information.

Action

- 8 Members are asked to endorse this proposal so that the data application process is more transparent, timely and effective.

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