

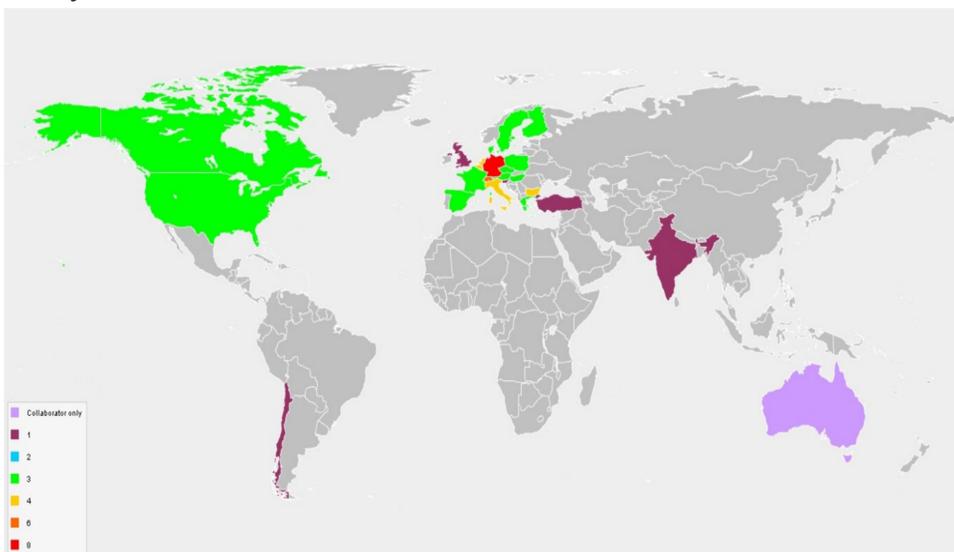
Ethical Implications of Sharing Individual Patient Data for Prognostic Meta-analysis

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Introduction

Meta-analysis of data from prognostic studies is challenging. It has been suggested that an individual participant data (IPD) approach is preferable to using aggregate data as it enables many of the challenges to be better addressed. We formed an international collaborative (Predicting Infectious Complications In Children with Cancer; PICNICC) as part of an MRC funded Research Training Fellowship. PICNICC has constructed prediction models using anonymous un-linked patient data to identify clinical characteristics that predict the outcome of children and young people presenting with febrile neutropenia. Febrile neutropenia is a common and potentially fatal complication of cancer therapy.

As part of this we undertook an investigation into the ethical and regulatory considerations involved in sharing such information. Using clinical trial IPD within meta-analyses that address the same clinical questions is usually considered exempt from ethical review. This is because individual consent has already obtained for using the data. However, the ethical position remains unclear regarding the use of data that has been obtained outside research studies, or where the meta-analysis has different aims.



Methods:

The PICNICC Collaborative IPD review collaborators, and those who expressed an interest in the project but did not ultimately submit data, were surveyed by email to find if they had approached a research ethics committee (REC) for permission to share data from their primary study. They were asked to provide information on which committee they had approached or to explain why such an approach was unnecessary. The outcome of their experiences was also sought.

Discussion:

A consultation exercise by the UK National Cancer Research Institute (NCRI) found most patients believed material and data collected should be used, without identifiable information, as broadly as possible and that retrospectively seeking consent was inappropriate (1). The European Treaty on Biomedical Ethics permits the use of data without specific consent where there is minimal risk and potential benefit to similar persons (2). On reviewing policy statements and guidance, it was considered data sharing would require REC agreement, and similar processes applied in Australia, New Zealand, and Canada. Other locations (such as Germany or the United States of America) stated such data sharing was exempt from the need for formal REC approval.

This project has demonstrated that despite a variety of legislative frameworks, large-scale international collaborations can effectively share data without obstruction or significant delay. Most service users wish to see care improved, and science advanced, and desire that the broadest possible use be made of their information. With a clear protocol, a sound ethical argument and appropriate requests to regulatory authorities, we believe that other studies, regardless of the age of their participants or the nature of the medical condition of interest, should also be able to progress their objectives and may seek to use our experience and data to support their work.

Country	Study type(s)	Research Ethics Committee review requirements
Belgium	Prospective study	Two University Hospital review agreements were required
Bulgaria	Prospective study	Review unnecessary as consent already given to primary study
Canada(a)*	Prospective study	Review unnecessary as consent already given to primary study
Canada(b)*	Prospective study	Review required by Institutional Review Board
Chile	Prospective study	Review unnecessary as consent already given to primary study
Germany	Prospective study	Review unnecessary as consent already given to primary study
Italy	Prospective study	Review unnecessary as consent already given to primary study
Netherlands	Prospective study	Review unnecessary as consent already given to primary study
Slovenia	Prospective study	Review required by National Medical Ethics Committee
Switzerland	Prospective and retrospective studies	Review required by University Hospital review board
Turkey	Audit	Review unnecessary to share such data
UK	Audit	Review required by NHS REC
USA	Retrospective notes review	Review required by Institutional Review Board
USA	Prospective studies	Review unnecessary as consent already given to primary study

* Two Canadian groups had different answers

Results:

The collaborators came from sixteen countries in North and South America, Europe and the UK as shown in the figure. The Table shows the position taken by RECs from the collaborating groups regarding the need for ethical review.

To our knowledge, no potential collaborative group had their request to share such data declined.

References:

1. NCRI, National Cancer Intelligence Network, onCore UK: **Summary of responses to consultation on 'Access to Samples and Data for Cancer Research'**. In *Summary of responses to consultation on 'Access to Samples and Data for Cancer Research'* London; 2009.
2. European Treaty on Biomedical Ethics; <http://bit.ly/17Zmp3X>