

Background

One of the key aims of InTBIR is to promote data sharing across the TBI research field and to facilitate collaboration between laboratories and interconnectivity with other informatics platforms. Accordingly, the collection of common data elements and the establishment of open-source databases for easy storage and analysis of collected data was a mandatory component of the funding agencies' call for research proposals under the InTBIR Initiative.

Intraconsortia and cross-border data sharing is possible in principle where patients have given signed consent to data transfer. To do so they must be explicitly informed that their deidentified data may be transferred outside of the study consortium and/or country; be aware of the reasons for data transfer (for specific and/or more general research and/or commercial purposes); and be given assurances that the level of data protection is guaranteed.

Purpose

As a first step towards implementing a data sharing policy, a survey was conducted of the content of the information sheets given to TBI patients and the informed consent forms signed by them in each of the InTBIR projects. The aim was to determine whether and to what extent data sharing is possible with the content currently adopted by the InTBIR consortia, and to propose common content, based on adaptation or extension of currently used wording.

Results

Seven out of the eleven PIs responded to the survey. The details included in the InTBIR consortia's information sheets and informed consent forms varied considerably among the consortia, among countries, and even within countries, due in part to local ethics committee/IRB requirements. The majority of consortia did not specifically envisage the transfer of data to other groups or other countries, although consent was implied in many cases.

Conclusions

The question of data sharing is often overlooked by research consortia and, generally, the content of patient information sheets and informed consent forms makes no specific provision for data transfer. This is often the result of oversight on the part of the consortia and not part of a deliberate policy. In future studies it will be important to make clear arrangements for data sharing that patients can explicitly sign up to.