Association of Anaesthetists Data Sharing Principles

Introduction

The Association of Anaesthetists (the Association) expects all of its funded researchers to maximise the availability of research data with as few restrictions as possible. The concept of 'open data' is in the interests of all stakeholders in the research process, including researchers. Access to data is increasingly demanded by funders, policy makers, public and patients and it has become a basic principle of data management that data should be made openly available unless there is a compelling reason not to do this. Data sharing is also in the interests of the primary researchers as it allows secondary verification of interpretation of the data and therefore validation of the original findings.

The drive for open data needs to be balanced against the overriding right of patients and the public to confidentiality. Adequate anonymisation/pseudonymisation of datasets, the use of 'airlocks' to provide a 'wall' between researchers and primary data, and analysis rules for minimum analysis sizes will be important in this respect.

The drive for open data must also be balanced against the needs of the primary researchers to be able to capitalise, through scientific publications and other research outputs, on the process of project origination, development and delivery that led to the acquisition of the dataset concerned.

It is important to distinguish between datasets where the Association is the data owner and datasets where they are the funders or the data handlers acting for other data owners. The following principles are aimed at scientific datasets derived from projects such as clinical trials, surveys, audits and database studies. They do not apply to internal Association data such as the membership database, membership surveys or other information collected for internal or operational purposes. It is important to note that the Association will not be an owner of patient data.

Principles

1. This data policy will be consistent with the relevant legislation as well as relevant customs and practice (such as the six Caldicott principles). It will be reviewed periodically to ensure that it remains up-to-date and consistent with relevant legislation. It also recognises the policies of the National Institute of Academic Anaesthesia.

2. All those seeking Association funding will be required to consider, at the research proposal stage, their approach for managing and sharing data, and to include a statement outlining their policy in the funding application. This issue is likely to have been considered as part of the ethical approval process, depending on the type of study.

3. It is important that these principles inform all elements of the research process including the design of the project, consent process and documentation (e.g. to acknowledge the 'open

data' policy), maintenance of confidentiality including anonymisation/pseudnomymisation methods, analysis plan including provision to avoid identification of individuals, and reporting.

4. Researchers may wish, for a reasonable period of time, to deliver on the primary research aims and any subsequent analyses before data are made open. This period should be defined in advance for each dataset. The criteria for 'reasonable period of time' will vary from project to project. A clear definition should be specified for each project based on a defined duration of time following a clear start-time. The default start-time is likely to be the time the dataset is closed and cleaned and therefore ready to use for analysis. The duration of time will depend on the project but is unlikely to be less than six months and a clear justification would be expected for duration greater than two years.

5. The presumption will be that collaborative research is encouraged, unless there is a compelling reason not to. For some projects a 'lock-out' may be specified in which some or all of the data will not be 'open', for example where there is reason to believe that the ability to collect the primary data may be substantially compromised by a requirement to meet open-data policies subsequently.

6. Data owners, handlers and other stakeholders should be clearly identified for each dataset before project initiation.

7. For all scientific datasets for which the Association is the data owner, it will keep a 'Register of Data Holdings' with relevant metadata including the source, size and scope of the dataset, identity of the data owners/guardians, identify of the data handlers, 'open data' policy and any special provisions of data governance (e.g. the project data governance policy).

8. All Association owned projects as defined above will require a data governance and sharing policy, consistent with principles laid out in this policy.