Poor medical data access could lead to erroneous clinical decisions

October 21 2015

Researchers from the University of East Anglia are calling for medical trial data to be kept in national repositories.

A *BMJ* study published today reveals how a series of barriers stopped researchers from reviewing the effects of heart failure drugs such as beta blockers on patients.

Now they are calling for greater transparency in research and recommend that access to data should be a mandatory requirement of

funding.

They warn that the risks of not doing so, could lead to "erroneous clinical decisions".

Lead researcher Dr Robert Fleetcroft, from UEA's Norwich Medical School, said: "Current NICE guidelines on drug treatments for heart failure are heavily based on evidence from patients with severe symptoms. However most patients only have minor symptoms and these drugs might be less effective.

"We wanted to carry out a systematic review of the effectiveness of heart failure drugs - such as beta blockers, angiotensin converting enzyme inhibitors and angiotensin receptor blockers - for patients with minor symptoms.

"We found 30 studies that looked at the effect of these drugs on heart failure. But none of the studies included enough data to assess outcomes for patients with minor symptoms."

The research team set out to request the additional data by contacting the authors of each study.

Authors from only 24 studies could be contacted because of difficulties finding up to date email addresses. Of these, one of the authors had passed away, and three had left their institutions, but contact details were found on the internet for two of the latter. In total, only six authors replied from the 24 authors contacted.

Three authors said that data were not available, one said that only one class of heart failure patient had been included in their study, one author refused the data on the grounds that such analyses were not appropriate and may lead to misleading results, and one author recommended getting

in touch with a co-author.

Dr Fleetcroft said: "We were surprised at the difficulties we faced, even though the majority of studies were published between the 1990s and 2010 and four had been published since 2010.

"Difficulty accessing data from clinical trials means that only part of the evidence base is available and this may lead to erroneous clinical decisions.

"Many funders and institutions now recommend data sharing. Benefits of access to patient data include that it can enable researchers to answer new questions with existing data, validate findings, and combine the power of individual studies. It may also prevent selective reporting and research fraud.

"The next stage is for mechanisms of data sharing to be developed. Finding a solution will require coordinated actions from funders, journals, ethics, committees, and national guideline developing bodies.

"We need central national repositories for trial data based in the country of trial sponsor," he added.

Dr Fleetcroft argues that bodies involved in national guidelines have a role to play.

"It is unacceptable for NICE to make decisions about new drugs based on clinical effectiveness data that are not in the public domain. Such transparency is essential to bolster trust in the process of evaluation of new treatments.

"We also recommend that research ethics and funding committees should make future access to data a mandatory requirement. Funders

should cover the costs of archiving data and journals could require evidence of archived data."

More information: 'Difficulty accessing data from randomised trials of drugs for heart failure: a call for action' is published in the *BMJ* on October 21, 2015. www.bmj.com/cgi/doi/10.1136/bmj.h5002

Provided by University of East Anglia