

# Potential harm from medical instruments not made clear in studies

July 4 2019

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The potential harm from medical instruments is not made clear in academic studies, according to research by the University of York.

The researchers say too many studies use "inconsistent terminology" and poor reporting when describing the potential adverse effects, which makes identification of these studies challenging.

The wide variety of terms are used, include: complication, safety, failure, problem, side effect, adverse event, loosen, removal, migration.

The authors of the report say part of the problem could be that the regulatory requirements for [research evidence](#) on the safety of new devices is less stringent than those for medicines.

## Health policies

Researchers argue that it is essential that potential harms are made clear in medical reviews to fully inform [medical practice](#), health policies, and ultimately, patients.

Medical devices are defined as equipment, instruments, software or related articles intended for use in healthcare. They cover a range of procedures, from high-tech equipment used in complex heart surgery to medical grade mattresses and hearing aids.

Medical devices have been linked to 1.7 million injuries and nearly 83,000 deaths over the last decade in the UK.

As part of the research the University of York team analysed nearly 2,000 studies on [medical devices](#), looking for [adverse side effects](#).

## **Regulatory requirements**

Dr. Su Golder, a Research Fellow with the National Institute for Health Research (NIHR) in the University of York's Department of Health Sciences, said: "Whilst much attention is paid to the side effects of drugs, it is just as important to consider the potential harm of medical devices.

"We only have to look at the news to see stories of the potential harm they can produce. However, regulatory requirement for medical devices are less stringent than for drugs and less research is undertaken."

## **Appropriate advice**

Finding the research that has been undertaken is also difficult, even for academics, and the researchers recommend the development of bespoke search filters.

"Search filters may be useful not only for librarians and information professionals but also for clinicians, researchers and policy makers. A relatively efficient method of retrieving useful information would enable decision making in clinical practice to generate appropriate advice on the benefit or harm of medical devices," Dr. Golder added.

Further research on larger datasets is required in order to measure the precision of searching for adverse effects of medical devices and to test

the suggested search filters with more rigour.

Provided by University of York

Citation: Potential harm from medical instruments not made clear in studies (2019, July 4)  
retrieved 17 July 2024 from <https://medicalxpress.com/news/2019-07-potential-medical-instruments.html>

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