Overhaul of European and US medical device safety recommended by leading diabetes associations

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Two major diabetes associations have joined forces to recommend a comprehensive overhaul of medical device safety, involving regulators, manufacturers, doctors and the associations themselves. The recommendations come from a joint committee of the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) and will be published simultaneously in Diabetes Care, the journal of the ADA, and *Diabetologia*, the journal of the EASD, on Monday, March 16. The authors include Professor John Petrie, Institute of Cardiovascular and Medical Sciences, University of Glasgow, UK, and Professor Anne Peters, Keck School of Medicine of the University of Southern California, Los Angeles, CA, USA.

The number of people using insulin pumps (continuous subcutaneous insulin infusion) worldwide is estimated to be around 1 million, but accurate data are scarce. Most pump users have type 1 diabetes, but some patients with type 2 diabetes are also using pumps. The total number of pump users is continuously rising.

The authors highlight shortcomings of the current regulatory framework, saying that the bar is set too low for 'like me' devices to be approved, provided they are similar in functionality to those already on the market. The problem is more acute with the European Union (EU) Notified Bodies system than it is with the US Food and Drug Administration (FDA) system. However, in neither case are device manufacturers

obliged to do follow-up studies relating to 'real life' use.

"Technology is evolving rapidly for treating diabetes," says Dr Anne Peters, Director of the University of Southern California Clinical Diabetes Program and one of the lead authors on the statement. "While that's certainly a good thing, we don't have very good post-marketing surveillance for devices such as insulin pumps, particularly in Europe where manufacturers often introduce products prior to releasing them in the United States. We need to make sure we have sufficient data about how the devices are working once they hit the market, so that we can support patients by helping them understand how to prevent errors in using them."

Furthermore, this EASD and ADA joint review suggests that the reporting system for adverse events related to insulin pumps (whether these were mechanical, human or other cause) in both the USA and Europe could be substantially improved (especially in Europe). The authors say: "We found that useful information held by the manufacturing companies is not currently shared in a sufficiently transparent manner. Public availability of adverse event reports on the FDA's MAUDE (Manufacturer and User Facility Device Experience) database is potentially a rich source of safety information but is insufficiently utilised due to the current configuration of the system; the comparable database in Europe (European Databank on Medical Devices, EUDAMED) is not publicly accessible."

The authors say that data on 'real world' use "could provide vital information to aid healthcare teams in educating and supporting users, thereby preventing future adverse events. As well as requiring more from the manufacturing companies, we call for public funding of more research addressing clinically important questions in relation to pump therapy: both observational studies and clinical trials. At present there are significant differences in the regulatory systems between the US and

EU at both pre- and post-marketing stages; improvements in the European system are more urgently required."

They conclude: "This Position Statement aims to contribute to the improvement of pump technologies by stimulating the adoption of a more rigorous, standardised and transparent approach to safety."

Provided by Diabetologia