School of Health Information Science Seminar:

Which computable biomedical knowledge objects will be regulated as a medical device?

Speaker:

Dr. Jeremy C Wyatt

FACMI, FRCP, Emeritus Professor of Digital Healthcare, School of Primary Care, Population Sciences and Medical Education, University of Southampton, Southampton, UK

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10:00AM PT

A key challenge to clinical trust in and use of AI systems is fear of legal liability due to incorrect knowledge base content or software that has not passed regulatory requirements [1,2, 3].

Our aim in this project (sponsored by the UK Mobilising Computable Biomedical Knowledge chapter and the British Computer Society) was therefore to understand which knowledge objects in a computable biomedical knowledge library are likely to be subject to regulation as a medical device in the UK. To achieve this understanding, a briefing paper was circulated to a multi-disciplinary group of 25 people including medical device regulators, lawyers, software engineers, digital health academics, librarians and others with insights into knowledge management and device regulation. A one-day workshop was then convened to discuss key questions relating to our aim. Following wide ranging discussion by participants and further assessment of relevant regulations, a discussion paper was drafted by lead authors, circulated to other authors for their comments and has now been published [4].

This webinar will discuss how UK medical device regulators are likely to treat the different kinds of knowledge objects that will be stored in computable biomedical knowledge libraries used by decision support systems, medical devices, apps, chatbots etc.. While our focus is on the likely approach taken by UK regulators, these regulators contributed to the relevant International Medical Device Regulators Forum (IMDRF) working groups [5], so our analysis will also be relevant to the approaches taken by regulators elsewhere.

We outline the UK criteria for medical devices and the responsibility of device manufacturers, then examine the regulatory implications for knowledge objects that correspond with each of the four knowledge levels described by Boxwala in 2011. We also propose an additional knowledge level for tagged fragments of guidelines etc. that we call level 2b, which is positioned between level 2 and level 3.

Our main conclusion is that if a knowledge object is directly executable and is described or marketed as being intended for a medical purpose to provide decision support, it will be in scope of UK regulation as “software as a medical device”. Conversely, if the knowledge object is not directly executable (eg. it consists of an algorithm, a ruleset, an order set, pseudocode or some other knowledge representation) or the developers make no claim that the object can be used directly for a medical purpose (eg. it is presented as pluripotential, so could be used to support medical research or education), it is not likely to be subject to UK regulation [4].

We expect similar reasoning to be applied in other countries with similar regulatory principles.

(References available in seminar presentation)

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