This is a repository copy of *Ensuring app safety*.

White Rose Research Online URL for this paper:
http://eprints.whiterose.ac.uk/116154/

Version: Accepted Version

**Article:**

Click contribution Feb 2017

Dr Linda Milnes

Associate Professor in Children and Young People's Nursing, School of Healthcare, University of Leeds. Chair of RCN Research in Child Health National Group.

**Digital mhealth: Ensuring quality, reliability and safety of information**

Healthcare apps provide health related information or can be used to collect patient data and support diagnosis and treatment. An app falling into the latter category would most likely be classed as a 'medical device' and be required to meet the Medicines and Healthcare products Regulatory Agency (MHRA) regulations (MHRA 2016) – as indicated by a CE mark on the device. The MHRA regulation is written to guide professionals and lay people but in the first instance the user needs to distinguish between a medical and a non-medical device (mhealth app). To support this decision making process the MRHA provide examples of a medical device as:

*'Those which calculate medicine doses for you to take /inject '*

*'Those that tell you that you have a medical condition or disease or give you an individual percentage risk score of having one.'* *(MRHA 2016 page 5)*

In addition a decision making flow chart is available which helps users and developers to identify which type of device they are working with (MRHA 2017).

Ensuring the safety, reliability and quality of mhealth apps is equally important because they provide healthcare related information for children, young people and their families. Therefore, the European Union Commission have undertaken a stakeholder consultation and developed mHealth App Assessment Guidelines are due to be published 2017.

To ease the process of assessing the quality and safety of apps' by the public the Governments National Information Board (GOV.UK 2015) – workstream 1.2 - is focused on the provision of endorsed NHS and social care apps.

Medicines and Healthcare Products Regulatory Agency (MRHA) (2016) Medical Device Stand-Alone Software including Apps. Online https://www.gov.uk/government/publications/medical-devices-software-applications-apps. (Accessed Feb 2017).

MRHA (2017) Is your App a medical device? It's healthy to know: regulator issues updated guidance. Online. https://www.gov.uk/government/news/is-your-app-a-medical-device-its-healthy-to-know-regulator-issues-updated-guidance (Accessed Feb 2017).

Gov.uk (2015) National Information Board Available online https://www.gov.uk/government/publications/national-information-boards-workstreams (accessed Feb 2017)