CGWG advice regarding use of Apps in Medicines Information

It is the role of the Clinical Governance Working group (CGWG) to advise on suitable resources for provision of an MI service. In recent years, due to widespread availability of smart phones, there has been an explosion in availability of medical apps. The CGWG has been asked to provide advice on suitability of these as part of their remit on resource advice.

Background

Over the past decade, there has been an exponential growth in use of mobile apps in healthcare for a variety of purposes ranging from capturing health data directly from patients to presenting healthcare information and delivering or shaping interventions [1].

A Bing search of "medical apps" returned 1,210,000 results; restricting to UK and English returned 144,000 results (16/10/17). Reviews have yielded disturbing conclusions regarding the quality, scientific basis and safety of a great number of apps [2]. A study published in 2015 found many apps included in the NHS Health Apps Library failed to provide adequate protection for patient data [3].

Throughout the EU, including the UK, all apps that meet the definition of a medical device are required to be CE marked in line with EU Medical Devices Directives and Regulations. Those apps governed by medical device legislation have to register with MHRA, provide clinical data, and are obliged to conduct post-marketing surveillance. If there is an adverse reaction, it has to be reported. The obligation to decide whether or not it is a medical device falls on the manufacturers [4]. Some companies may put a disclaimer that the product is not a medical device, but this does not exempt them from the legislation. Different guidance issued by the FDA applies in the US.

Health related apps and software that are not medical devices fall outside the scope of the MHRA. NHS Digital has developed a Digital Assessment Questionnaire (DAQ) and assessment review process to assess health related apps and software that are not medical devices. This process, designed to ensure only trusted, high quality apps are made available via the NHS Digital Apps Library, is currently being tested via a beta site. The site links to a selected number of healthcare apps that have each been through the assessment process [5].

Public Health England (PHE) guidance also requires health app developers to show how they meet the technical criteria set out in the DAQ before PHE will endorse a public health digital product. The guidance states this will eventually be required by any national health body commissioning a health app developer's product or service [6].

In addition, an app developer must register with CQC if their app provides a health or social care service that fits in one of 14 regulated activities [7].

In April 2015, the Royal College of Physicians (RCP) produced a factsheet providing guidance on use of medical apps in conjunction with the MHRA and the General Medical Council. The factsheet explains what is and what is not a medical app, what to do if you are using or developing a medical app, and how to report issues or problems with apps. The guidance underlines two key pieces of advice:
- You should not use medical apps, including web apps, that do not have a CE mark.
- Always exercise professional judgement before relying on information from an app.

The factsheet [8] states *"The RCP has no plans to endorse particular medical apps (in the same way that it would not endorse a particular drug), although it is centrally involved with other organisations in establishing quality criteria for apps."*

It also defines what is meant by a medical app *"Briefly, apps that diagnose, support diagnosis or clinical decisions, make calculations to determine diagnosis or treatment, or are used for any medical purpose are classed as 'medical devices'. For example, users of the Mersey Burns app (a CE-marked app) can input the parts of a patient's body that have been burned and it calculates the percentage of skin damage and their fluid balance requirements. A medical app does not need to link to the patient's records or capture the patient's name or NHS number; if it uses patient-specific information, it is a medical app and it needs a CE mark."*

Relevance to Medicines Information Professionals

Those apps that are of interest to MI professionals are less likely to be categorised as a device and more likely to be a different presentation of a currently available resource. However, even if the app is based on a well recognised and widely used resource, the way the data are presented is likely to look different and as such could present risks. An app can also reduce risk, for example, with the use of colour coding (BNF - compare interactions information via medicines complete with that via the BNF app).

So how would an MI professional know whether an app they use in their day to day work can be trusted? The answer is in much the same way as when assessing a new resource including websites (see Medicines Learning Portal Internet and medicines). The BMJ suggests the following (adapted) checklist [9]:

> *Questions to ask before downloading and using an App may include:*
> - Is it a Medical Device? Does it have a CE mark?
> - Has it been assessed by PHE, NHS Digital or NHS Scotland?
> - Is it produced by a trusted publisher?
> - Is it regularly updated?
> - Is it properly referenced?
> - Are the authors listed?
> - Is it possible to give feedback?
> - Is the content peer reviewed?
> - Is its primary purpose to inform health professionals?

Conclusion

UKMi are aware that various 'Apps' are available for health information resources. UKMi will not review the content or functionality of such Apps. However, if an 'App' is available as another platform for an already endorsed UKMi resource, this may be highlighted as being available.

References

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