Using apps in clinical practice

Important things that you need to know about apps and CE marking

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Protecting your patient and yourself

Smartphones, tablet computers and websites are widely used by clinicians to support patient care and by patients to inform and help themselves. Apps range from tools that help in diagnosis, staging or treatment (for example, to calculate fluid requirements for burns patients) to the many wellbeing apps that help to manage diet and/or fitness. Many people are excited about using and developing apps to help patients and clinicians.

There are important European regulations about medical apps and you should know where you stand. A CE mark is the assurance that an app meets essential criteria, works and should be clinically safe (rather like an MOT for a car in the UK). **You should not use medical apps, including web apps, that do not have a CE mark.**

Best practice is continually improving. Unfortunately, even if an app has a CE mark, that does not mean that it meets best practice, has been tested for accuracy or benefits in clinical use, or is applicable to the patient/decision for which it is being used. **Always exercise professional judgement before relying on information from an app.**

The medical app market is evolving rapidly, and the Royal College of Physicians (RCP) is monitoring it closely. 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.

What is a medical app? Which apps need a CE mark?

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. >>>

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What is NOT a medical app?

Apps that have only administrative functions, eg to book an appointment or request a prescription, are unlikely to be classed as medical apps. Apps that give general guidance or support training, such as books that you read or MRCP(UK) test questions that you answer on your smartphone, are not medical apps as such. Equally, apps that are not marketed as medical apps, such as a generic calculator on your mobile phone (which could be for general use in offices or at home), are not medical apps, even if you use them at the bedside. Apps that do not provide personalised advice are unlikely to be considered medical apps.

What to do now if you use apps

If you rely on an app for your professional work, you should check that it has an official CE mark. If there is no CE mark, you must urgently ask the app's developers to obtain one; meanwhile, you should stop using the app.

We recommend that you try to use the app with your device set to flight-safe mode to see how the app copes without Wi-Fi – many apps use Wi-Fi in the background.

Always make sure that all the information you are using is for the right patient (some apps will keep data from the last time they are used).

Any medical app approved for use in Europe must carry a CE mark. Information about the CE mark status should be available with the app, possibly in the 'About this app' section or in the app's description in the online app store. Be aware that it is possible for the app store to say that an app has a CE mark, but this may not refer to the version that you have. You should check that the actual version you are using has the CE mark. Of course, it is important to keep your apps up to date, to ensure that you benefit from any fixes to glitches or bugs. If an app acquires a CE mark, your version of the app should gain the CE mark on its next update.

If you are using an app that should have a CE mark but it is missing, then you are leaving yourself open to problems and possible litigation. Always exercise your professional judgement, whether or not an app has a CE mark.

Many apps are developed and used all over the world. Even if they have been approved for medical use in other countries, such as the USA, they need a CE mark before they can be used or sold in Europe. Even if the app is free to download, it still needs a CE mark.

Reporting issues or problems with apps

The Medicines and Healthcare Products Regulatory Agency (MHRA) can only investigate problems of which it is aware. If you know of any problems with apps used for medical purposes (such as calculation errors), please report these to the MHRA online at www.mhra.gov.uk/safetyinformation/reportingsafetyproblems/devices

Finally, what to do if you are developing apps

If you develop an app that is intended for use in any medical context in Europe, it will need a CE mark, whether it is free to download or not.

Throughout the EU, including the UK, all medical devices and apps placed on the market must meet the requirements of the Medical Devices Directives and Regulations. The requirements are determined by the classification of the device or app, which in turn is determined by its complexity and functions. Many apps will be so-called Class I devices, which require their manufacturer or UK representative to register with the MHRA and to self-certify compliance with a list of essential requirements. Complex apps may additionally require the involvement of a notified body to assess them before the CE mark can be granted. Full details are available from the MHRA at www.mhra.gov.uk/howweregulate/devices

We would like to hear from you if you have examples of problems caused by apps, or of best practice.

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