When it comes to operability, mobile health (mHealth) apps must be able to install, load and run in a way that gives the user a reasonable experience on mobile and web platforms, according to guidelines that aim to ensure patients and physicians get the most out of this technology.

And it is equally important that the mHealth apps have interoperability with electronic health records and personal health records (PHRs) so that physicians and patients can take chronic disease management and other care to the next level.

The guidelines were developed by Xcertia, an independent nonprofit that the AMA, the Healthcare Information and Management Systems Society (HIMSS) and other major health and technology organizations founded. HIMSS continues the critical work of developing these mobile app guidelines with the support of the other founders.

When developers comply with the Xcertia mHealth App Guidelines—which include sections that address privacy, content, security, design and operability—it helps provide a level of assurance that a mHealth app delivers value to patients, physicians and other users.

The operability section of the guidelines tells developers that they must address important elements such as whether the app loads properly and runs consistently.

“I’ve had the experience with an app where it opens, but then it closes immediately. It’s very frustrating. Is it the app? Is it an update in the operating system that caused an incompatibility?” said Michael Hodgkins, MD, AMA senior adviser for digital medicine.

The guidelines also advise developers on a crucial piece for patients and their care teams—interoperability.

“If I’m your doctor and I’m telling you to use this app as part of how we are going to manage your hypertension, but I can’t get the data in a usable form from you, then the data that you are collecting...
in the app isn’t any better than if you had written it down on paper,” Dr. Hodgkins said. “That doesn’t make the app very helpful and that is frankly an area where most of these apps fall down rather dramatically.”

Today most apps are independent silos of information that can’t effectively share information with the health care team, he said, particularly when it comes to sharing it with the EHR.

“Over time, that information can be shared another way. But today, for better or worse, electronic health records are what are used and being able to interoperate with the electronic health record is important,” Dr. Hodgkins said.

**Ensuring mHealth app operability**

The operability portion of the Xcertia guidelines details requirements in these seven areas that developers need to consider to provide mHealth app users with an optimal experience.

**Onboarding.** The app installs, launches and runs consistently on its target devices and operating systems.

**Connectivity.** If applicable, the app connects consistently to any and all peripheral or accessory devices, such as Bluetooth, as well as third-party mobile applications or software needed to operate the app or marketed to use in conjunction with the app.

**Access to app publisher.** Users have a way to contact the app publisher for technical support.

**Documenting and detailing releases.** The app publisher has a history of updates, including details of changes, over time.

**Operability with EHR.** The app has a secure and operable data exchange with EHR systems optimized for mobile devices or apps for certified EHRs.

**Connectivity with PHR.** An app intended to connect with a PHR lets users send and retrieve patient information between a mobile device and does it in a secure manner.

**Medical device status.** If applicable, the app publisher certifies that it is not a medical device or certifies that it is a medical device as defined by the Food and Drug Administration (FDA), has ascertained its correct classification and complies with all applicable FDA regulatory requirements.

AMA involvement in Xcertia stems from a 2016 policy recommended in an AMA Council on Medical Service report. HIMSS, the American Heart Association and the digital health nonprofit DHX Group co-founded the effort to improve trust in, and the value of, mHealth apps.


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