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Abstract:

This commentary addresses the emerging market for health-related smartphone applications. Specific to dermatology, there has been a significant increase not only in applications that promote skin cancer awareness and education but also in those meant for detection. With evidence showing that 365 dermatology-related applications were available in 2014--up from 230 in 2012--and that 1 in 5 patients under the age of 50 have used a smartphone to help diagnose a skin problem, there is clearly a large subset of patients participating in this growing trend. Therefore, we are obligated to take a closer look into this phenomenon. Studies have shown that applications are inferior to in-person consultations with one study showing that 3 out of 4 applications incorrectly classified 30% or more melanomas as low-risk lesions. Although the FDA gained regulatory oversight over mobile health applications in 2012 and recently released their statement in 2015, their reach only extends to cover a selected portion of these applications, leaving many unregulated as they continue to be marketed toward our patients. Dermatologists should be updated on our current situation in order to properly counsel patients on the risks and benefits of these applications and whether they are acceptable for use.

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Challenges to smartphone applications for melanoma detection

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Abstract

This commentary addresses the emerging market for health-related smartphone applications. Specific to dermatology, there has been a significant increase not only in applications that promote skin cancer awareness and education but also in those meant for detection. With evidence showing that 365 dermatology-related applications were available in 2014--up from 230 in 2012--and that 1 in 5 patients under the age of 50 have used a smartphone to help diagnose a skin problem, there is clearly a large subset of patients participating in this growing trend. Therefore, we are obligated to take a closer look into this phenomenon. Studies have shown that applications are inferior to in-person consultations with one study showing that 3 out of 4 applications incorrectly classified 30% or more melanomas as low-risk lesions. Although the FDA gained regulatory oversight over mobile health applications in 2012 and recently released their statement in 2015, their reach only extends to cover a selected portion of these applications, leaving many unregulated as they continue to be marketed toward our patients. Dermatologists should be updated on our current situation in order to properly counsel patients on the risks and benefits of these applications and whether they are acceptable for use.

Keywords: smartphone, melanoma, dermatology, mobile apps, mobile health

Discussion

With the boom in health care technology and the rise

in smartphone programming, it was only inevitable that both have merged to create a new market for health-related mobile applications. Specific to dermatology, there has been a significant increase not only in applications that promote skin cancer awareness and education but also in those meant for skin cancer detection. Nearly 230 dermatology-related applications were available for download in 2012 with that number rapidly expanding to 365 by 2014 [1,2]. It appears that this number continues to grow. Of the available programs, most are free and predominately geared toward patients. Although no data exists for the exact number of users, it was found that one of every 5 patients under the age of 50 used a smartphone to help diagnose a skin problem [3]. Clearly, this demonstrates an emerging market.

Many applications can analyze a picture of a pigmented nevus and/or electronically transmit it to a dermatologist. Because of this, the first question that comes to mind is whether they can be trusted. Several studies have concluded that applications were inferior to in-person dermatologists and dermatopathologists in determining the likelihood of malignancy [4,5,6,7]. Results by Wolf et al. even showed that 3 out of 4 applications incorrectly classified 30% or more of melanomas as low-risk lesions [7].

Is this level of inaccuracy acceptable? And who determines what is 'acceptable'? Until recently, no governing body regulated these applications. Without any requirements, there remained a gross lack of oversight for several years. In 2012, congress eventually approved the Food and Drug

Administration (FDA) Safety and Innovation Act, which gave the FDA authority to monitor a select subset of mobile medical applications. However, it was not until 2015 that the FDA issued a detailed statement [8]. Relevant to melanoma applications, those that analyze lesions using algorithms to provide risk assessment were now considered to be medical devices and subsequently fell under FDA oversight. However, those that transmit images to dermatologists were not required to follow regulations if intended to supplement a description for consultation. Although such applications tout the involvement of dermatologists, there is no requirement for the quality of their credentials. Therefore, many questions remain on how effective the FDA will ultimately prove to be and if it will further extend its reach.

There exists a high level of uncertainty with these applications. Results may be misinterpreted, which can place an unjust burden on users. When they are incorrectly reassured that a lesion is safe, they may miss a short window when early treatment of melanoma is significantly more responsive--thus delaying or even preventing care. The opposite case--when normal lesions are reported to be high-risk--may at first be interpreted as beneficial since users would ideally seek professional care. However, the emotional and psychological toll may be unfair and excessive until they are able to see a dermatologist, which may take weeks to months.

The most important question that needs to be asked is: Are we doing 'good'? At first glance, detecting possible melanomas may be seen as a victory, especially in areas that are rural, predominately uninsured, unsaturated with dermatologists, and/or prone to long patient wait times. However, relying solely on an application to screen for melanomas and alleviate any concerns that a lesion may be malignant is extremely flawed. Missing an early diagnosis for this severe disease could have drastic consequences in therapeutic options. Additionally, applications hold zero liability when they are incorrect, which--unbeknownst to most users--is usually stated in their terms of use.

At this time, physicians should not recommend these applications, since the possibility for harm far

outweighs any benefit. In diagnoses that are serious and urgent, there remains little room for error. As gatekeepers of the field, dermatologists must hold patient safety above all else. There is certainly the potential for applications to improve patient outcomes in the near future. However, we should advocate for their safe and effective implementation to allow for the most benefit but least amount of risk to our patients.

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