Mobile Medical Applications for Melanoma Risk Assessment: False Assurance or Valuable Tool?

Xavier Chadwick
Dermatology Research Centre
School of Medicine
The University of Queensland
Princess Alexandra Hospital
Brisbane, Australia
x_chadwick@hotmail.com

Lois J. Loescher
College of Nursing and Skin
Cancer Institute
The University of Arizona
Tucson, Arizona
loescher@email.arizona.edu

Monika Janda
School of Public Health and
Social Work
Queensland University of
Technology
Brisbane, Australia
m.janda@qut.edu.au

H. Peter Soyer
Dermatology Research Centre
School of Medicine
The University of Queensland
Princess Alexandra Hospital
Brisbane, Australia
p.soyer@uq.edu.au

Abstract

With the smartphone revolution, consumer-focused mobile medical applications (apps) have flooded the market without restriction. We searched the market for commercially available apps on all mobile platforms that could provide automated risk analysis of the most serious skin cancer, melanoma. We tested 5 relevant apps against 15 images of previously excised skin lesions and compared the apps' risk grades to the known histopathologic diagnosis of the lesions. Two of the apps did not identify any of the melanomas. The remaining 3 apps obtained 80% sensitivity for melanoma risk identification; specificities for the 5 apps ranged from 20%-100%. Each app provided its own grading and recommendation scale and included a disclaimer recommending regular dermatologist evaluation regardless of the analysis outcome. The results indicate that autonomous lesion analysis is not yet ready for use as a triage tool. More concerning is the lack of restrictions and regulations for these applications.

1. Introduction

Advances in mobile phone technology and the ability to run mobile applications (apps) have resulted in thousands of mobile medical apps with functions ranging from medication adherence to first aid. Although simple appearing, these apps involve complex codes that can fail, potentially resulting in detrimental consequences for the user's health [1]. In Australia and the U.S., there currently are no regulations for mobile medical apps, although in 2011, the Australian government issued guidelines for medical devices (apps) that are diagnostic tools [2]. In 2011, the U.S. Food and Drug Administration (FDA) issued guidelines specifically for medical mobile apps [3, 4]. These guidelines were presented to Congress in 2013 with recommendations to consider these apps as medical devices and place them under FDA scrutiny before being marketed [3, 4]. Despite this more recent interest in regulation, there is a dearth of professional literature on mobile medical apps. Given their potential for harm, the lack of information is concerning for consumers and healthcare providers.

Mobile medical apps are available to aid in the detection of skin cancer, which is the most prevalent cancer in Australia and the U.S. The Australian Institute of Health and Welfare reported that in 2012, the most serious type of skin cancer, melanoma, was diagnosed in 12,510 Australians and was the third-most commonly diagnosed cancer in men and women. The age-adjusted incidence rate is 62.7 per 100,000 men and 39.9 per 100,000 women [5]. In the U.S., melanoma was diagnosed in 76,690 Americans in 2013 [6] and continues to be in the top 10 cancers diagnosed in American men and women of all races [7]. The age-adjusted incidence rate is 27.4 per 100,000 men and 16.7 per 100,000 women [6]. Of concern is the increasing incidence of melanoma over the last 30 years. From 2005 to 2009, incidence rates among U.S. whites increased by 2.8% per year [7].

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Early detection of melanoma is critical for survival of this disease [8] and may be accomplished through identification of suspicious pigmented skin lesions. Such detection commonly is guided by the ABCDE algorithm (A=lesion asymmetry, B=border irregularity, C=color variability, D=diameter usually larger in diameter than 6 mm, E=evolving or any change in size, shape, color, elevation, or another trait; or any new symptom such as bleeding, itching or crusting [9]). Most mobile medical apps for skin cancer detection are based on the ABCDE algorithm. These apps are marketed as easy tools for everyone that may facilitate early detection of melanoma. The apps might benefit consumers with limited access to skin assessment resources, such as dermatology services in rural areas, or those who cannot easily travel to a healthcare provider for a lesion examination [10].

Despite these potential advantages, very few studies have addressed the accuracy and safety of mobile medical apps for melanoma early detection [11-13]. Authors of these studies identified concerns about the apps, including (1) the apps go beyond cataloging and tracking skin lesions by providing a specific risk grade and corresponding risk recommendation for the lesion [11], (2) most of the tested apps assessed a disproportionally high number of high risk lesions as low risk [11, 13], and (3) many of the apps were "unable to analyze" lesions despite repeated attempts [12]. Most studies targeted a single app [12, 13] or did not identify the apps tested [11]. Only one study [13] used the app prospectively on suspicious lesions prior to excision. The other studies assessed the app using high-resolution photos [11, 12].

It is not known whether mobile medical apps for melanoma detection have been conceptualized, designed, developed, evaluated and refined in the context of rigorous research targeting consumers [14]. Conceptualization is driven by theory and evidence to improve the chances for success of the efficacy of the app [14, 15]. For example, formative research (e.g., focus groups, technology acceptance surveys) can establish consumers' initial impressions of the app and its usefulness [14, 15]. Consumer feedback is then used for refinement of the app prior to marketing [14]. Affective dimensions of the app—consumers' concerns about privacy, information quality, ability to use the app correctly—are human factors to consider during the development and before the deployment of these apps [16]. Established methods exist for studying these factors in consumers who use mobile phone technology [17]. Mobile medical apps must be devices that respect patient privacy, while also retaining quality data required for their stated purpose. There are opportunities for app-generated data to become lost, damaged, exposed, or otherwise compromised [16, 18]. Consumers may struggle with downloading and using an app, as well as transmitting information to medical personnel [16].

Consumers may not be aware that apps may carry these deficiencies, yet consumers could rely on them to assess a critical medical issue such as detection of melanoma. The aims of our study were to: (1) to identify melanoma apps available for multiple smartphone platforms and are marketed to consumers for independent automated analysis diagnosis, (2) conduct preliminary testing of the accuracy of those apps for melanoma risk assessment, and (3) describe how the apps integrate the ABCDE rule.

2. Methods

2.1. Study framework

The conceptual foundation for this study was the sociotechnical system model for health information technology (IT) safety proposed by the Institute of Medicine (IOM) [19]. The IOM posits that health IT products are not developed or used in isolation. Rather, they evolve as part of a larger sociotechnical system comprised of factors such as persons (e.g., consumers or patients), organizations (e.g., dermatology specialty organizations), processes (e.g., ABCDE rule), the external environment, and technology. Safety emerges from the interactions of these factors—when considering safety of a product one should consider the system as a whole for ways to reduce the likelihood of any adverse health outcome resulting from product use. In the context of a mobile medical app for melanoma detection, an adverse health outcome includes a misclassification of a lesion risk grade (e.g., low, moderate, or high risk)

2.2. App selection

During 2012 we searched the official sites or programs of the four major platforms, Apple iOS (iTunes), Android (Google Play Store), Blackberry (App World) and Windows (Marketplace). We used the following broad search terms to capture potential melanoma apps: melanoma, skin cancer, skin scanner, mole checker, mole scan. Apps were eligible for inclusion if they were English-based and relevant to melanoma and skin cancer or lesion education and/or monitoring. We excluded apps that were solely or primarily cosmetically-oriented. During the review, we formed five categories of apps based on their described purpose:

1. Information/Education about skin cancer only;
2. Facilities for image capture/importation and storage;

3. Facilities for image capture/importation and analysis of photographed lesions, generates report, +/- storage capacity;
4. Facilities for image capture/importation and forwarding to an external service for analysis and report, +/- storage capacity; and
5. Other, including textbooks.

The mobile medical apps that fell into Category 3 best reflected our focus on apps that would provide automated melanoma analysis and diagnosis.

2.3. App testing, integration of the ABCDE rule

The first step in the app testing was the selection of 15 high-quality, full resolution, digital images (.jpg) of melanocytic skin lesions of varying risk (5 melanomas, 10 benign nevi) from the image archive of the study dermatology expert (HPS) to assess the accuracy of the app analysis software. All the lesions depicted by the images had been previously excised and diagnosed histopathologically. The use of an existing, well annotated image data set to test mobile melanoma apps has been used previously [11]. Moreover, this approach is regarded as the standard approach to assess sensitivity, specificity and diagnostic accuracy of pigmented skin lesions using dermoscopy among various observers worldwide [20]. The tester (XC) was blinded to the image diagnoses.

Next the apps were uploaded onto one of two compatible smartphones: (1) a Sony Xperia Arc running Android 4.0.4 and equipped with an 8.1 megapixel camera and (2) an Apple iPhone 3GS running iOS 4.2.1 equipped with a 3 megapixel camera. When available, the paid/premium versions of the app were tested to take advantage of the full features. If the app allowed, the digital images were submitted for analysis. When direct analysis was not possible we used the phone's camera to photograph a high-resolution printed version of the lesion image. If the app had an option to provide a history of lesion change, we left this at the default setting for all lesions. Some apps did not successfully return an analysis score for all lesions; therefore each lesion was resubmitted until we achieved a successful risk assessment. If the app failed to provide an analysis after 10 attempts, it was deemed "unable to analyze". Each lesion image was submitted to each app for analysis. A result was considered positive if a melanoma lesion received a grade of high risk or a benign lesion received a grade of low or moderate risk. The grades were analyzed descriptively. Accuracy was determined by sensitivity and specificity analysis, based on the first lesion allowed for analysis by the app. To determination integration of the ABCDE rule, we noted what input was required for each criterion during our own testing.

3. Results

3.1. App selection

The search terms yielded 1,437 apps. Apps that were not relevant (e.g. the keyword "Skin Scanner" returned a large number of police scanner apps) or were duplicates under search terms were omitted from further assessment, yielding 132 applications that met the eligibility criteria. Of those, 73 were sorted into the 5 categories. Apple had the greatest proportion of apps (n=48; 65.8%) followed by Android (n=15;20.5%), Blackberry (n=6;8.2%) and Windows (n=4;5.5%). Of those, eight apps focused on automated assessment (met Category 3): Apple (n=3), Android (n=4), and Windows (n=1). These apps were *Dr. Mole* [21] (Android and Windows), *SkinScan* [22] (Apple), *SpotMole Plus* [23] (Android), *MelApp*, [24] and *Mole Detective* [25] (the latter 2 apps were available on both Apple and Android platforms), yielding 5 unique apps for analysis. *MelApp* and *Mole Detective* were tested on the Sony Xperia Arc due to its camera's higher image quality.

Each of the apps included a disclaimer stating that the software was to be used as a guide only, did not substitute for a professional dermatological evaluation, and recommended regular health checks. Most apps included recommendations based on assigned grade of the lesion, with the exception of *MelApp* which gave the grading alone and no recommendation. Table 1 summarizes the app recommendations.

3.2. App testing, integration of ABCDE rule

Table 2 lists the results of the lesion risk analysis for each lesion as assessed by each app. *SkinScan* and *MelApp* most consistently gave a low/moderate risk grade to all five melanomas (high risk), and also consistently gave low/moderate risk grades to benign naevi, thereby not allowing any differentiation between naevi and melanomas. All apps that were able to analyze lesion 11, which was a melanoma < 6mm in diameter, graded it as low or moderate risk. *Mole Detective*, *SpotMole Plus*, and *Dr. Mole Premium* consistently gave three low-risk benign lesions (1, 12, 14) a higher risk grade. Only *SpotMole Plus* classified benign lesion 15 as low risk. Three benign lesions (1, 12, and 15) dropped their grade from high to low risk simply by removing the diameter input from the calculation.

Table 3 lists the sensitivity and specificity of each app for melanoma risk analysis based on the

assessments of the 15 test lesions. The sensitivity ranged from 0% to 80% and the specificity ranged from 20% to 100%. We attempted to perform a second analysis of the images without diameter input to investigate the value placed upon this parameter by the app program. However, only *Dr. Mole Premium* allowed for reanalysis of the same images (Table 4); all other apps featuring a diameter input required a second image to be captured. In *Dr. Mole Premium*, for lesion 4, a melanoma, dropping the diameter lowered the grade from high to moderate. Thus, reliability of the diagnosis of *Dr. Mole Premium* could not be assured (Table 4). Table 5 lists how each app integrated each criterion of the ABCDE rule.

4. Discussion

Mobile medical apps are easy-to-use programs that have the potential to empower consumers to take a greater responsibility in their care, or to prioritize patients and streamline consults in areas with low access to specialist care [26]. However, overwhelmingly, the apps evaluated in this study were unreliable and incurred risks to users in the form of underdiagnosis of melanomas, which potentially are life threatening. The app analysis also contributed to overdiagnosis of benign naevi, which leads to unnecessary medical follow-up and a drain on dermatology resources [27]. Although each app had a disclaimer warning users to seek medical attention for any potential diagnosis, previous research demonstrates low adherence to follow-up recommendations for skin lesion screening even among persons at high risk of melanoma [28-30]. Thus, it is not known whether users may take the recommendations of the app at face value, despite the disclaimer.

Inherent with mobile medical apps for melanoma detection is a degree of inconsistency in diagnosis from the captured images. Each time a lesion is captured, the variations in position and lighting caused the programs to interpret the lesion size and color differently with each new image. This issue, which was a phenomenon observed during our data collection has been briefly addressed in one previous study [13]. Of all the apps tested, *MelApp* was the most inconsistent because it was unable to analyze six of the 15 images, a failing also noted by Robson [13]. This issue may have been due to the resolution power of the camera; use of a dermoscopic attachment might have elicited better data. However, the app did not specify such an attachment as a requirement.

The apps assessed in this study relied on the ABCDE algorithm for lesion analysis. This rule pertains only to pigmented lesions such as naevi. However, the diameter criterion is particularly problematic in that small, thin lesions potentially are missed by the 6 mm diameter cut-off—possibly the ideal time to recognize them from a prognostic standpoint [31, 32]. Furthermore, de Giorgi et al. recently demonstrated that even in clinical examination it is difficult to assess lesions with a diameter <6mm, as some may not display classic dysmorphic features until they have reached this size, adding weight to this method of stratification [33]. How each app integrated the ABCDE criteria also was variable (Table 5). *Mole Detective* allowed for the input of diameter under 3 categories: "<6mm", "about 6mm" and ">6mm", while *Dr Mole Premium* used a sliding scale that showed a progression from low-to-moderate risk at 4mm to high risk at 6mm and above. *SpotMole Plus* allowed for the input of a numeric value for diameter. It was not possible to test the effect of an altered input diameter on the risk generated by *Mole Detective* or *SpotMole Plus* because the input values could not be altered once the lesion had been analyzed, and consistent diagnosis could not be assured if a new image was captured and reanalyzed. The results gathered from the comparison of diagnoses show a decline in sensitivity when the diameter input was removed (Table 4). Lesion 11, with a diameter of < 6mm, was the only melanoma image consistently not identified by the apps.

Both *MelApp* and *SkinScan* failed to identify any high-risk lesions and, therefore, did not detect any of the melanomas in the test set. *SkinScan* is now *SkinVision*, which advertises improved algorithms and user interface (new version not tested in this study). *Mole Detective* correctly identified four of the melanomas, and gave the fifth melanoma a moderate risk grade (still directing the user to see a dermatologist). However, it also classified 12 of the 15 test lesions as high risk, impinging on its specificity. *Dr Mole Premium* had the same score for melanoma identification but graded eight of the 15 lesions as high risk, as did *SpotMole Plus*. The problems concerning lesion accuracy of apps for skin cancer detection were identified in detail by other authors. For example, Wolf et al. [11] conducted a study of four melanoma-detecting apps (unspecified) available for two smartphone operating platforms (unspecified) and determined that the accuracy of these apps for assessing melanoma risk was highly variable. Ferraro et al. [12] evaluated the *SkinScan* app and concluded that the app's low sensitivity of melanoma detection could be substantially harmful. In our study, the highest sensitivities produced were by *Mole Detective*, *SpotMole Plus* and *Dr Mole Premium*, each achieving 80%. This is comparable to clinical examination without the use of a dermatoscope, which has a reported sensitivity of between 60%-90% [20] However, in the case of clinical examination, the patient is in the hands of the examiner, and a clear

conversation will support the patient's understanding of the findings and subsequent steps needed.

All of the apps except *MelApp* provided recommendations for follow-up of analyzed lesions based on grades (Table 3). One grade option in the *Dr. Mole Premium, Mole Detective*, and *SkinScan* apps was "Moderate", with an accompanying, but conflicting recommendation ranging from "consult a specialist" to "continue to track." Those recommendations would have been problematic for melanoma lesions 4 and 11 in our study. We contend that a lesion is either worrisome or not, and dichotomous grading as used by the *SpotMole Plus* app may be a less confusing recommendation for a user.

A limitation of the apps is their questionable ability to assess lesions that are not pigmented. There could be a mistaken assumption among consumers and health care providers that the apps are useful for this purpose.

Another limitation is the inability to upload quality, high-resolution .jpg photos for analysis. *SkinScan* was the only app that allowed this direct uploading of digital images. Studies of the ability to upload .jpg files would be useful in further establishing accuracy of the app. The nature of the current technology dictates that all images are digital by the time the app programs analyze them. As such, it likely makes little difference whether the images are captured directly or imported in digital form, provided that the quality of photography is similar. The only difference is when a print medium is used.

Similar to other studies [11, 12] our analysis was performed on high-resolution printed images. We acknowledge that the print medium possesses different optical properties and lacks the three dimensionality achieved when directly photographing the lesions. This is an aspect that should be investigated before printed image analysis studies can be validated as analogous to *in vivo* images. Our findings using *SkinScan* gave the best representation of *in vivo* testing results. However, we note that the authors of the sole evaluation of an app's (*MelApp*) ability to assess lesions *in vivo,* reported that the app was unable to assess 40% of prospectively photographed lesions [13].

These findings lead to further concerns about the issues involved in conducting a prospective study of assessment of *in vivo* pigmented lesions using apps. Receiving ethics clearance for such a study could be challenging, given that so little is known about the sociotechnical factors involved in app development. A study would have to build in concomitant histopathologic testing to validate app decisions, meaning that some lesions may be unnecessarily biopsied. **Manufacturers in collaboration with dermatology researchers might consider conducting such prospective studies as part of the app development and evaluation.**

5. Conclusion

In this small study we sought to determine the accuracy of the "mobile melanoma detecting apps" currently easily and inexpensively available at the app markets of the various platforms. None of the tested apps appear ready for such a task, either due to their inconsistency and inaccuracy or bias towards large lesions. Reliance of the apps on the ABCDE algorithm may be problematic based on current evidence. Before any of these apps could be implemented as an adjunct to face-to-face consultations, prospective studies of efficacy and safety would have to be performed. Yet the question of who funds and conducts such a study remains unanswered. There is little doubt that as the processing power and camera resolution quality of mobile phones increases, the abilities of detecting melanomas with these apps may improve, thereby elevating the apps' potential role in triaging of suspicious melanocytic lesions. However, according to the proposed FDA guidelines, each of these apps transforms or makes the mobile platform into a regulated medical device [4]. Before such a role can occur, these apps deserve the same attention to safety and efficacy as all medical devices, both during the development life cycle and after release [1].

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Table 1. Recommendations for follow-up of assigned lesion grades provided by each app* (apps are listed in alpha order).

App	Risk Recommendations		
	Low Risk Grade	Moderate Risk Grade	High Risk Grade
Dr. Mole Premium	No recommendation; reminded user to always consult a specialist as "no tool can guarantee the knowledge and expertise of a professional."	Consult a specialist.	Consult a specialist immediately. None
Mole Detective	Mole shows few signs of melanoma, continue to monitor but do not schedule an extra appointment with the dermatologist.	Mole shows some "symptoms of melanoma." Continue to track and schedule annual dermatology appointment. If this mole changes, call dermatologist.	Mole shows several "symptoms" of melanoma. Contact dermatologist to have it evaluated.
SkinScan	Archive and keep track of lesion evolution.	Keep track of lesion evolution.	None
SpotMole Plus	Okay (low grade): Consult a doctor if any doubts.	None	Problematic (high grade): Consult a doctor.

**MelApp* did not provide recommendations.

Table 2. Lesion risk grades for each lesion as assessed by each app (platform). Inaccurate gradings are in bold.

Lesion Number	*Skin Scan* (iOS)	*Mel App* (Android)	*Mole Detective* (Android)	*Spot Mole Plus* (Android)	*Dr. Mole Premium* (Android)	Confirmed Diagnosis *
1	Low	Low	**High**	**High**	**High**	Benign naevus
2	Moderate	Low	**High**	Low	Low	Benign naevus
3	**Low**	**Low**	High	High	High	Melanoma
4	**Low**	**Moderate**	High	High	High	Melanoma
5	**Moderate**	**Low**	High	High	High	Melanoma
6	Moderate	UA	Low	Low	Low	Benign naevus
7	**Low**	**Low**	High	High	High	Melanoma
8	Low	Low	**High**	Low	Moderate	Benign naevus
9	Low	UA	Low	High	Low	Benign naevus
10	Low	UA	**High**	Low	Low	Benign naevus
11	**Low**	**UA**	**Moderate**	**Low**	**Moderate**	Melanoma
12	Moderate	UA	**High**	**High**	**High**	Benign naevus
13	Low	Low	**High**	Low	Moderate	Benign naevus
14	Low	UA	**High**	**High**	**High**	Benign naevus
15	Moderate	Low	**High**	Low	**High**	Benign naevus

***The diagnoses were confirmed by histopathologic examination.

Table 3. Sensitivity and specificity of each app based on assessment of 15 test lesions.

		Skin Scan	*MelApp**	*Mole Detective*	*SpotMole Plus*	*Dr. Mole Premium*
Melanoma detection	True Positives	0	0	4	4	4
	True Negatives	10	5*	2	6	6
	False Positives	0	0	8	4	4
	False Negatives	5	4*	1	1	1
	Sensitivity	0%	0%	80%	80%	80%
	Specificity	100%	100%	20%	60%	60%

*MelApp was unable to provide a risk assessment for 6 lesions, including a melanoma.

Table 4. *Dr. Mole Premium* risk grades with and without diameter input. Inaccurate ratings are in bold.

Lesion Number	With Diameter	Without diameter	Confirmed Diagnosis
1*	**High**	Low	Benign naevus
2	Low	Low	Benign naevus
3*	High	Moderate	Melanoma
4*	High	**Moderate**	Melanoma
5*	High	Moderate	Melanoma
6	Low	Low	Benign naevus
7*	High	High	Melanoma
8	Moderate	Moderate	Benign naevus
9	Low	Low	Benign naevus
10	Low	Low	Benign naevus
11	**Moderate**	**Moderate**	Melanoma
12*	High	Low	Benign naevus
13*	Moderate	Moderate	Benign naevus
14*	**High**	Moderate	Benign naevus
15*	**High**	Low	Benign naevus

* Indicates any lesion which was >6mm in diameter.

Table 5. ABCDE rule integration by mobile melanoma apps for melanoma detection

App name	(A) Asymmetry	(B) Border	(C) Color	(D) Diameter	(E) Evolution
SkinScan	Analysis by inbuilt pattern recognition software.		Analysis by input comparison algorithms.	No input.	No input.
MelApp	Analysis by inbuilt pattern recognition software. Area could be limited to focus the analysis.		Analysis by input comparison algorithms.	Manual sliding scale input.	Manual sliding scale input.
Mole Detective	Analysis by inbuilt pattern recognition software.		Analysis by input comparison algorithms.	Manual input of <6mm, ~6mm or >6mm.	No input for analysis. Reminder can be set for future use.
Spot Mole^{+}	Analysis by inbuilt pattern recognition software. Manual adjustment of lesion border available.		Analysis by input comparison algorithms.	Manual input of numeric value.	No input for past history of change. Can perform serial analysis of lesion images.
Dr Mole Premium	Analysis by inbuilt pattern recognition software. Comparison of lesion quadrants for asymmetry.		Analysis by input comparison algorithms.	Manual sliding scale input.	Manual input of "none", "slow" & "fast" with time frames for each.

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