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National mHealth applications assessment framework

AMA submission to Australian Digital Health Agency (ADHA) consultation

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The AMA sees the evolving mHealth apps landscape as an area of opportunity for improved outcomes for clinicians and patients alike, but also an area of caution, where a balance needs to be struck between the usability of these applications and their clinical safety and utility.

To effectively balance the risk and benefits, it will be crucial that the assessment framework is established in such a way that is not tokenistic, but rather a deep study of apps safety, data security, and their reliability.

Patients place their trust and confidence in clinicians to recommend the best course of action to ensure quality health outcomes. In return, doctors must be confident that, when recommending health apps to their patients, the products they are recommending are of high quality. Furthermore, there must be assurances put in place for doctors that they will not held liable for any weaknesses in apps developed by vendors, be it data security, app safety or any other feature that may result in negative outcomes for patients. Neither should they be liable for the incorrect use of apps by patients.

The AMA commends the ADHA for taking a proactive role and undertaking this initiative to develop an assessment framework. As a trusted Government organisation, ADHA is uniquely positioned to undertake this important work.

Scope of a national mHealth applications assessment framework

It is the AMA view that the scope of the assessment framework should include all those listed in the consultation paper: intended usage of the app, target user groups for the apps and the technology type/platform.

Risk of harm to the users should be the baseline criterion for risk assessment. Characteristics of the person that the app is aimed at must also be taken into consideration. For example, an app that may be targeting consumers who wish to maintain healthy lifestyles or reduce weight might

be harmful for younger people, by perpetuating wrong image of what constitutes a 'healthy' look or a healthy lifestyle.

The AMA supports aligning the assessment framework with the risk assessment approach applied by the TGA (Therapeutic Goods Administration), to ensure the two frameworks complement each other. Although the TGA risk approach focuses mainly on the risk of harm for consumers/patients, the AMA does not see this as something that should be contradictory to the Assessment Framework proposed in this consultation. The Framework could be broader than the one applied by TGA, while at the same time being aligned with it and complementary to it. The doctors would like to be able to easily access the information on what mHealth apps will fall under the remit of the TGA and accordingly those that will be assessed and listed in the register under the proposed assessment framework.

Furthermore, the AMA suggests that for the future of usability framework, app vendors will need to be able to understand where their app fits, whether it is under the TGA remit or under the assessment framework. Education of all those involved in this space will be required in the future.

The AMA also sees merit to the risk-based approach to triage of apps prior to assessment. However, the consultation paper also indicates that application vendors would be expected to request an assessment if they wish their app to be listed among those assessed under the framework. The consultation paper does not provide enough detail how this would be resolved. For example: if a vendor submits a request for their application to be assessed, and it is deemed low risk under the framework, would the application in that case not be considered? While this approach may support effective use of resources, it may deter vendors from applying for assessments, and at the same time undermine the relevance of the library of apps assessed under the Framework. The AMA suggests that a possible solution could be to maintain the list of those apps who are deemed low risk, along with the list of fully assessed apps.

Preliminary assessment framework

The AMA supports the proposed Preliminary national mHealth apps assessment framework, as outlined in the consultation paper. The five domains outlined are seen as reasonable to guide the Framework.

The AMA notes that under effectiveness domain there is an expectation that the apps should be critically evaluated and accepted by health practitioners. The consultation paper however does not provide information on whether health practitioners will be included in teams conducting the evaluation, whether the evaluation process will entail testing the usability of the apps in the clinical setting, and if so what type of clinical evidence would be required under the framework.

The AMA contends that apps that are recommended for use in clinical settings should be tested and evaluated in clinical settings, to demonstrate their usability. This way medical professionals. for example, would be assured that the product they are using and recommending to their patients has been proven to work. Furthermore, the Framework does not resolve the issue of continuous updates to mHealth apps and the need for reassessment (if any) following the updates.

The AMA also suggests more robust requirements around Developer transparency/credibility criterion. The current definition requires that "the developer has not been found guilty of any wrongdoing, misleading claims or misuse of information." The presumption here is that the guilty

finding would have to came from a judicial institution, however such findings may only happen after years of data misuse. The recent example of Australian Competition and Consumer Commission and Google court case is a stark example[1]. Therefore, criteria and definition on what constitutes developer transparency/credibility should be broadened in the AMA view.

Assessment process

The AMA broadly supports the proposed design features for the operation of the Framework. The AMA would like to see more information around the national network of independent assessors and, as stated previously, the apps intended for use in clinical setting being tested in clinical setting. Ideally, evidence of the app workability would need to be provided in the form of evaluation by consumers and health professionals alike. In that sense, the AMA would like to see the Framework being more robust in terms of the evidence that would be required in the assessment process. The AMA disagrees with the proposition that increased requirements would stifle innovation; quite the opposite, obtaining clinical usability evaluation of their product might incentivise developers to improve and innovate. Furthermore, knowing that apps have been rigorously tested would give clinicians the confidence to recommend specific apps to their patients.

The AMA's preferred approach to conducting assessments would be to involve multidisciplinary assessment teams with a mix of skills, including those with clinical skills and experience, who can test the apps in clinical settings.

Organisational arrangements

The AMA is in favour of role of the auspice organisation being awarded to a Federal Agency or a State and Territory Health Department. In this way access to clinical settings during app evaluation periods would be more easily facilitated and multidisciplinary teams would be more easily mobilised.

The AMA supports the governance arrangements proposed in the consultation paper, with the national approach to Government involvement. It is the AMA view that ADHA is appropriately placed to operate the national mHealth apps assessment process.

User charging arrangements

Recovering the costs associated with the assessment of the mHealth apps will be one of the key issues that will enable appropriate functioning of the framework as well as provide for investment in education of those accessing the mHealth app database.

The AMA is aware that in some countries, including Germany[2], after passing the relevant legislation, health apps are now available for prescription. The framework should give consideration to this option in the future, understanding that for many patients the cost of apps may be prohibitive and cause further health inequities between those who can afford apps and smartphones and those who cannot. An option for consideration should be funding for prescribed

[1] https://www.accc.gov.au/media-release/google-misled-consumers-about-the-collection-and-use-of-location-data
[2] https://thejournalofmhealth.com/germany-allows-firsts-healthcare-apps-for-prescription/

apps (like prescribed medication), to ensure health equity for all. If prescribed, apps must be accessible and available to all patients regardless of their ability to pay.

Conclusion

The AMA again commends ADHA for undertaking this important work. Key issues when developing the Framework for the AMA will be its ability to provide confidence to clinicians using the apps and recommending apps use to their patients, its capacity to balance the risks and benefits, alignment of the Framework with the TGA's regulation of medical devices and testing of apps in clinical settings.

The AMA also suggests that an evaluation after the first year of Framework implementation might be advisable, to inform and guide any improvements necessary. Finally, the AMA calls for an allocation in the budget for Framework implementation for its promotion among stakeholders, primarily clinicians. Like the past activities on promoting My Health Record, a segment of the promotional campaign should be directed via colleges, peak medical bodies, Primary Health Networks, and others.

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