Author’s response to reviews

Title: A health app developer's guide to law and policy: A multi-sector policy analysis

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Miguel López-Coronado
Editor, BMC Medical Informatics and Decision Making

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RE: Response to reviewers
Dear Dr López-Coronado:

Thank you so much for the opportunity to revise manuscript MIDM-D-17-00190, A health app developer’s guide to law and policy: A multi-sector policy analysis. Our response to each critique is included below under the headings “Authors’ response.” The line numbers refer to the clean version of the revised manuscript.

Thank you again for your time in consideration of this manuscript.

Sincerely,

Lisa Parker
Tanya Karliychuk
Donna Gillies
Barbara Mintzes
Melissa Raven
Quinn Grundy

Reviewers’ comments:

ANTÓNIO DOURADO CORREIA, PhD (Reviewer 1): The paper presents an interesting work, made by an interdisciplinary team. The issue addressed is important.

The authors developed basically a questionnaire to help apps developers to care about the certification issues of health applications and devices. Call it an application can be exaggerated. However it is useful for decision making.

The geographical span of the regulations used by the authors does not include (if I am not mistaken) Asia and Africa, where most of the population lives. If possible, some information should be included.

Authors’ response:
Thank you for this comment. We used a case study approach to this study, with Australia as our focus, not only because of the high level of smartphone penetration, but because state and federal governments and national organisations are actively promoting the use of health apps. As such, we sampled purposively for polices that were explicitly relevant to Australia, or likely to be influential in Australia. However, during policy source extraction and analysis, we came to realise the largely global nature of regulation in the health app field and identified multiple international influences on Australian policy, and as such we have drawn from international policy as well. Although the majority of these policies were from Western, English-speaking countries, one policy was authored by the International Medical Device Regulators Forum, which includes Brazil, Russia, China, and Japan as members, amongst others. This influential, international body aims to address and accelerate international medical device regulatory harmonisation, thus likely reflects current regulatory climates in multiple countries.

We note, however, that the reviewer’s critique is a limitation of this study as the countries that have the highest number of app downloads are largely located in countries where English is not the official language. (See: Grundy QH, Wang Z, Bero LA. Challenges in Assessing Mobile Health App Quality: A Systematic Review of Prevalent and Innovative Methods. American Journal of Preventive Medicine 2016;51(6):1051-1059.) There has been very little research both on the content of apps in these countries and their policy context. We have added a comment in the Discussion calling for further work in this space (lines 637-639).

Reviewer 1: The main text describes extensively and in detail the work done. This text can be reduced substantially. The content of many paragraphs is well known, many common-sense statements are there. The reader knows that. Keep to the essential, namely to novelty of your work. The Supplementary Material 2 (App developer’s guide to law and policy) should be included in the main text, at least most part of it. Without this, the main text will have a low interest for readers.

Authors’ response:
We have substantially edited the Results, cutting down on well-known material or extraneous detail. Within the Results section, under each of the headings corresponding to the 7 regulatory domains, we have added a Table that provides relevant excerpts from the App Developer’s Guide to Law and Policy (Supplementary Material 2) as an exemplar from the Australian jurisdiction on how our findings can be translated to app developers. The corresponding text explains the regulatory principles and concerns for each domain, which is intended to translate our findings to an international audience. The tool in its entirety has now been published and is publicly available through the Australian Communications Consumer Action Network. We have added these details to the manuscript Introduction (line 103-105).
Jos Aarts, Ph.D. (Reviewer 2): The authors have written an overview of regulatory oversight of mental health apps and proposed a set of guidelines for app developers. The authors conducted a well designed literature review of both published papers and policy documents. They identified seven key regulatory domains that they found relevant for the developers. In terms of health policy they find that mental health apps do not meet the strict definitions of medical devices and therefore not subject to oversight by regulatory bodies; they propose that a new regulatory entity will be set up. Making policy recommendations for oversight is a tricky business, because foremost it must proved that health apps cause harm, or at least may potentially cause harm. Another reason may the regulation of markets. There is no documented evidence that mental health apps have caused harm or are disrupting markets.

Authors’ response:

As you note, there is limited evidence about harm associated with the emerging market of health apps, and certainly it is more challenging to make policy recommendations without this kind of firm empirical evidence. However, neither has the nascent field of health apps been proven safe (or efficacious, with a sprinkling of minor exceptions). There is substantial public and academic discussion around the potential for harm, as we have noted in our Introduction, which is not restricted to health-related harm, but includes loss of privacy, theft or identity fraud, and financial harm. We consider, therefore, that it is relevant to discuss principles, challenges and opportunities for policy development across sectors as it relates to health apps.

Reviewer 2: This is not to say that the app market is completely free. Data protection and patient privacy laws most likely prevent that patient data can be shared without consent. Also legislation may be in place that prevent suppliers of health apps to make false health claims.

Authors’ response:

We certainly agree that we found regulation applicable to health apps stating that apps must not share user health data without consent, and must not make false claims. However, a key finding of our analysis was that many health apps do not follow these requirements (e.g. see manuscript references 10 (Kaye, 2014), 11 (Lohr, 2016), 31 (FTC, 2015) and 32 (FTC, 2017)). For example, the Federal Trade Commission in the United States has recently settled with a number of health app developers over allegedly false marketing claims. Our analysis shows that health app regulation exists in multiple, often siloed sectors, and it may be that some rules are unknown, or at least unfamiliar to health app developers. Hence, the chief outcome of our analysis was the creation of this developer guidance tool to help address these knowledge gaps.
Reviewer 2: As this paper focuses on a guide how to incorporate (health) law and policy in the development of apps, it seems less appropriate to make recommendations for regulatory oversight. This belongs to the public and political domain, and is often country specific.

Authors’ response:

Thank you for this, and for your overall comments about recommending regulation. Certainly we acknowledge that recommendations about regulation should not be made lightly, and should always be accompanied by substantial justifications. In this paper we propose several possible solutions to bridge the regulatory gaps in the health app field. One of them is more market-driven: a guidance document for health app developers who are incentivised to create legally compliant, safe and secure products. Others however, are more policy-driven: that with new and emerging markets may come the need for new and emerging regulatory structures. We think that this point is worth briefly raising given that we identified a number of gaps existing policy addressing health apps, which we have incorporated as matters of “professionalism” in our guidance document. Although analysis of major regulatory changes is beyond the scope of this paper as the reviewer notes, we believe some preliminary suggestions warrant discussion.

Reviewer 2: However, the authors can address the question whether health apps can or should be considered as a medical device in the light of definitions currently used by the European Union or the United States (see e.g. Magrabi F, Aarts J, Nohr C, Baker M, Harrison S, Pelayo S, et al. A comparative review of patient safety initiatives for national health information technology. Int J Med Inform. 2013;82(5):e139-48). Note that the UK is still part of the European Union and thus bound to European Union directives that have the power of law. That may change in 2019.

Authors’ response:

We have provided more detail on how app developers might determine whether or not their health app is likely to be a medical device by providing an example of regulatory law and guidance within the context of Australian policy (Table 7). Our work was informed by policies from a variety of jurisdictions, including the UK and the EU. Even though the UK is, as Reviewer 2 notes, still part of the EU, we included the UK guidance document about medical devices in our sample for policy analysis because it carries different information to the EU documents, and because the close historical and legal ties between the UK and Australia mean that UK policy is likely to be influential for the purposes of our Australian case study.
Reviewer 2: The paper is well written, but the authors are advised not to use the improper style of enumeration of firstly, secondly, thirdly, fourthly, etc (page 15), but just first, second, etc. or avoid it altogether (page 19).

Authors’ response:

We have emended or deleted the improper uses of enumeration throughout the manuscript.

Editorial Policies:

In accordance with BioMed Central editorial policies and formatting guidelines, all manuscript submissions to BMC Medical Informatics and Decision Making must contain a Declarations section which includes the mandatory sub-sections listed below. Please refer to the journal's Submission Guidelines web page for information regarding the criteria for each sub-section (https://bmcmedinformdecismak.biomedcentral.com/).

Where a mandatory Declarations section is not relevant to your study design or article type, please write "Not applicable" in these sections.

Response:

We have included all of the mandatory Declarations, noting the following as “Not applicable”: Ethics approval and consent to participate; Consent for publication. We have included statements for the remaining Declarations.