



FDI POLICY STATEMENT

Dentistry and Oral Health Related Apps

**Adopted by the FDI General Assembly:
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CONTEXT

Humanity is now living in the era of information and communication technology. There is increased access to information and use of mobile devices as well as coverage of internet networks around the world. A growing trend is the development of mobile applications (mobile apps), which has led to the point where there is an app for almost any purpose.

There have been some major advances in the utilization of smartphones to seek oral health related information and assistance – countless applications for mobile platforms in the field of dentistry and oral health are downloaded from virtual stores every day. Some deliver dental information to the public, patients, or the dental profession; some provide dental organizations a means of serving their members; some support the use of oral hygiene products, and others are just gimmicks.

As in many other areas of innovation, new regulations arise as the technology develops. It is necessary to establish principles and guidelines that guide users on the safety and reliability of apps related to oral health. At the same time, the principles should be the frame of reference for developers, manufacturers, and regulatory authorities.

SCOPE

This policy statement is relevant to the general public, developers, manufacturers, regulatory authorities and certifying bodies and provides basic guidelines when developing oral health related mobile applications. It covers all mobile oral health applications on topics such as: content, advertisement, safety and reliability.

DEFINITIONS

Mobile platform: commercial off-the-shelf computing platforms with or without wireless connectivity that are handheld in nature. Examples of these mobile platforms include mobile computers, such as smartphones, tablet computers or other portable computers¹.

(Mobile) app: software application that can be run on a mobile platform, i.e. a handheld commercial off-the-shelf computing platform with or without wireless connectivity or a web-based software application that is tailored to a mobile platform but is executed on a server¹.

Personal data: any information relating to an individual, natural person that can be used to identify that individual, directly or indirectly, such as a name, an identification number, location data or one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

PRINCIPLES

The user's rights have absolute priority. Oral health-related apps must be developed ethically without compromising the health and welfare of users and must always respect the local and national regulations.

POLICY

FDI recommends that:

- oral health-related apps should be designed to better inform and guide the user with the best available research-supported information delivered in an informative and easy-to-read manner;
- apps should be developed following strict rules and standards of engineering, security and design to protect its users' personal data, and the storage should be in the best encryption possible to prevent accidental or intended hacks or phishing attacks;
- the protection of the users' data must always be sought. The acceptance forms should preferably be in the language of the country in which the application is used. The app must be designed so that it will not share user data with third parties unless it has warned users of this possibility and has obtained user permission to do so. Users should be notified in case of modifications to the terms and conditions of use of the application;
- the content of apps should be fully vetted and reviewed by oral health professionals or have the approval of recognized professional, academic or regulatory entities and be supported by independent scientific literature before being available to users;
- the content or use of apps should not intend to cause harm or misinform the users. In case the application does not work as intended, the potential for harm to the user's health should be minimal or nil;
- any app that is used for diagnosis and treatment of a disease or that modifies the health status of a person should be considered a medical device and should be subject to all regulations that exist for such a device;
- the user must be made aware that an application is not an alternative to seeking qualified professional diagnosis and treatment;
- apps be free from advertising. If advertisements are to be displayed, then the developer should ensure that there is no promotion of objectionable or unhealthy content. These advertisements should be easily identifiable, so

that the message of the advertiser is not confused with the content of the application and thus does not confuse the users;

- any app must clearly and visibly express financial interest of the developers and show who is behind the promotion of the application, as well as who to contact in case of a complaint, how to report content errors, etc. The developers should also be responsible for constant app updates regarding the content as well as security patches integral to the operating system.

KEYWORDS

mobile apps, oral health, health promotion.

DISCLAIMER

The information in this policy statement was based on the best scientific evidence available at the time. It may be interpreted to reflect prevailing cultural sensitivities and socio-economic constraints.

REFERENCES

1. US Food and Drug Administration. Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff. 2015 Available from <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>. Accessed December 2017.