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EDITORIAL POINT OF VIEW

mHealth. Attention!

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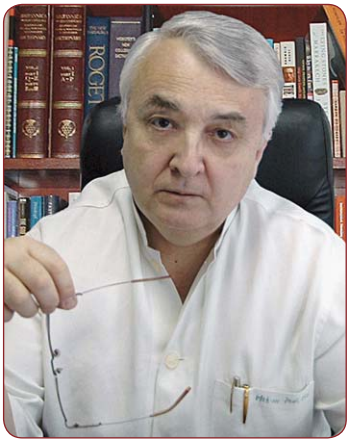

Recently, at the 24th meeting of the Central and East European Chambers of Physicians held in September 2015 in Tirana, Albania, a report from Germany underlined that more than 2000 (two thousands!) mobile devices are currently used for medical purposes. „Their classification and the consecutive rules of approval for secure use seem not to be appropriate", the German delegate said. Let us have a look to the problem.

mHealth is derived from eHealth. eHealth is the larger segment, defined as using information and communication technology for health services and information (1). mHealth reffers to the practice of medicine and public health using mobile devices. This definition is complex, because it includes:

- collection of clinical health data
- collection of community health data
- delivery of healthcare information to practitioners and researchers
- delivery of healthcare information to patients
- real-time monitoring of patient vital signs
- affordance of health care

All these elements of definition include devices which collect clinical signs, software to transmit and store data, most often on computers/servers belonging to eHealth systems and information given to doctors and especially to patients. We may say that eHealth is the backbone of mHealth. But mHealth is the more complicated issue, because in the domain of collecting clinical signs and in the information provided to the patient there is a huge overlap between medical and non-medical devices, between medical and pure marketing information. The regulation of the appropriate use of these devices and information constitues a real challenge in mHealth.

Both United States and Europe did develop regulation in this field (2,3). The FDA regulations seem to be larger and more detailed and are summarized and commented in the issue "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Commu-

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They define the basic non medical equipment of mHealth by a mobile platform (mobile phone, tablet or other mobile computer with or without wireless connectivity) which runs a mobile application (software). The Mobile Medical Application – a specific medical software – may transform the mobile platform into a Regulated Medical Device. Here comes the interesting philosophy of FDA which complicates the issue. If the Mobile Medical App only is used as an accessory to the device, FDA intends only to exercise what is called enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act – the basic act under which FDA impose severe rules to approve a drug, a medical device, a food additive etc. – (4). In this way, FDA only takes notice of that device, but does not apply its general rules of approval. On the contrary, if the software does transform the mobile device in a medical one, as defined by FD&C Act, the severe rules of FDA approval are applied.

Examples of general purpose tools which necessitate only ”enforcement discretion” are medical calculators for: Body Mass Index (BMI), mean arterial pressure, APGAR score, Glasgow Coma Scale score and many similar others. Very important, in this field there are also many information to the patient, such as advices for smokers trying to quit, advices for addictors in recovery or for pregnant women. Other very interesting information may be those given to asthmatics about presence of allergens in their environment, information for those who want to take plant products as therapy about possible interactions with drugs or video information or games to motivate patients to perform their indicated daily physical activity. In the FDA documents there are tens of such examples of so called intermediate conditions, which are not neglected by the FDA, but are included in the softer procedure of ”enforcement discretion” (2).

The European regulations are not so detailed. In the Green Paper published in 2014 (3), the definitions are however clear. mHealth covers „medical and public health practice supported by mobile devices” as well as „personal guidance systems, health information and medication reminders provided by SMS and telemedicine”. There are two categories of mHealth applications: a) for the purpose of diagnosis, prevention and treatment of diseases and b) for the purpose of lifestyle and fitness. The regulation dedicated to mHealth is included in the Medical Devices Directive (93/42/EEC) and the In Vitro Diagnostic Medical Devices Directive (98/79/EEC), both under revision (5). The considerations on this subject are numerous and in an attempt to clarify, in 2014 in the documents of EU appeared a manual to classify medical devices (6).

All these data show how complex is the problem of mobile health care. Non-medical industry does produce monthly tens of new devices dedicated to consumers and showing numerous measurements in direct linkage with body activity. These may be medically important and the producers do not submit their device to medical certification. There are monthly tens of medical advices spread by the most different channels, mostly by electronic ones. These are often not revised by doctors, nor approved by a regulatory body, are only consumer directed.

In an era of some 5 billion mobile phone subscribers in the word from a total of 7 billion (about three quarters of the word population) and a network territory coverage of more than 80%, in the era when new sensors are developed every year (such as accelerometers, GPS, new light detectors, barometers, gyroscopes etc.) regulation of all the new devices by the medical authorities is almost impossible. It is the task of doctors to be very attentive to the information given to their patients by the devices, especially from those consumers dedicated and to check the medical advices spread by mass media. It is their task to correct all the dangerous consequences of a wrong information produced by a wrong device or a wrong adviser, but which are very quickly adopted by patients, so sensitive to the internet and media information.

This is a difficult task in an era when the time to talk to the patient is more and more limited.

However, this is a major duty for the doctor of today!

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