German Medical Association

Federation of the German Chambers of Physicians

mHealth in Europe

Dr. Ramin Parsa-Parsi

ZEVA, Tirana, Albania

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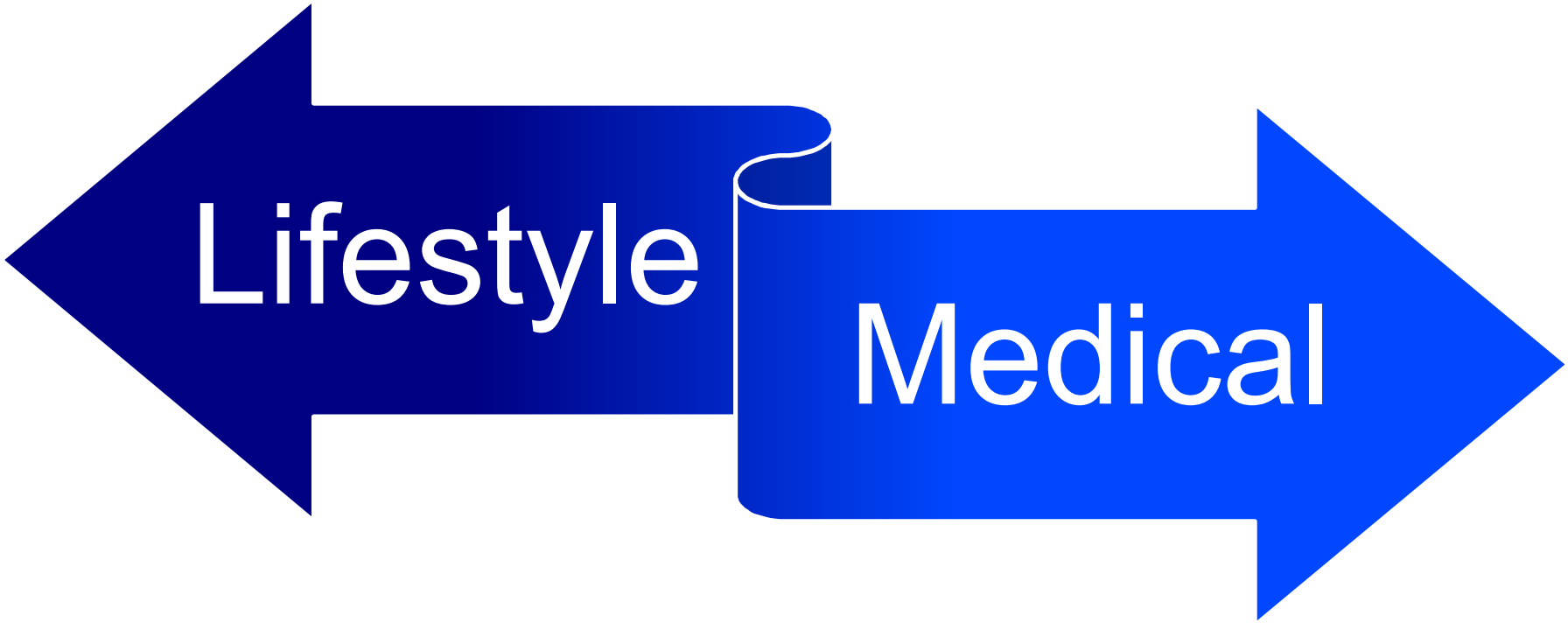
What is mHealth?

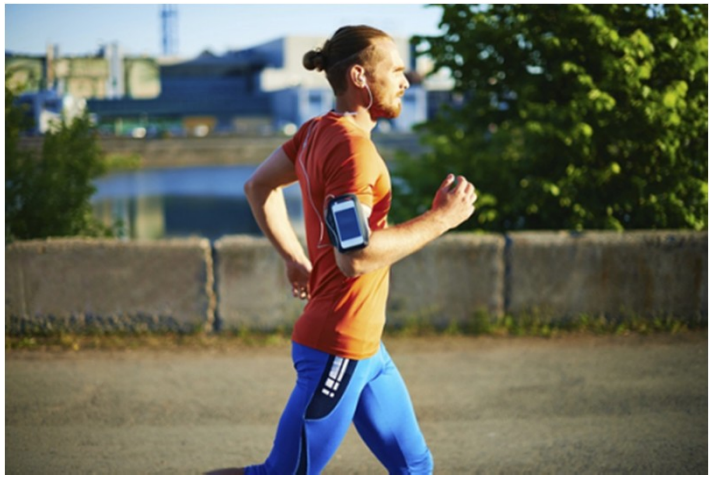
- mHealth = mobile health (a form of eHealth)
- "Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices." WHO Global Observatory for eHealth series – Vol. 3 (2011)
- Generally involves the **measurement** or **input** of medical, physiological, lifestyle, activity or environmental data

What is mHealth?



Purpose of mHealth: Lifestyle

- Mobile devices used to track health-related behaviors and indicators
- Marketed to everyday consumers
- Results in collection of large amounts of data:
  - Data collected by device sensors
  - Data inputted by user
  - Information sourced by device from internet



Purpose of mHealth: Lifestyle

- Device sensors collect data on sleeping patterns, heart rate, blood pressure, blood sugar
- Health promotional purposes, personal interest in biofeedback
- Measurement of calorie intake, alcohol/tobacco consumption
- Fitness apps (encourage and register exercise)
- Incentive schemes based on lifestyle apps already used by some health insurers/employers (rewards for healthy behaviors)

Purpose of mHealth: Lifestyle

- Devices source health-related information based on, e.g. environmental factors in locality, UV level, air pollution, exposure to allergens
- App to measure the noise level and warn
- App to register the sleep phases and wake up the user during best moment
- App that helps to determine the ovulation times and fertility

Purpose of mHealth: Medical

- Mobile devices used to assist medical practice (patients can be fitted with devices)
- Used by health professionals
- For purpose of:
  - Disease monitoring
  - Diagnosis
  - Public health promotion
  - Treatment compliance
  - Consultations between medical professionals

Purpose of mHealth: Medical

- Reminder for medicine intake and updates for the doctor (Insufficient compliance is said to be responsible for up to 200.000 deaths per year in Europe)
- App to train the eyes for visually impaired (prescribed by doctors, paid by insurance)
- Diagnosis of the fundus of the eye. An attachment that cost 4 Euros replaces a device that costs 20.000 Euros and difficult to transport. Early diagnosis of eye diseases in remote areas and transmission of results to clinics
- Pics of skin rash or eczema sent to doctor
- App for total hip replacement that accompanies patients from the first physician encounter to the end of rehabilitation (explanations of each step, treatments, tips and videos for physiotherapy exercises)
- Vaccination Reminder App of WHO

Why is it important to address mHealth now?

- Technological innovation → increasing number and range of mHealth technologies available,
  - 100 000 mHealth applications (each month another 1.000 are added)

- Increasing affordability & network coverage = public has more access & affinity to mobile technologies
  - 85% world's population covered by commercial wireless signal.

- New, fast growing & largely consumer driven market

→ ***Impact upon medical practice & relationship with patients***

EU legislation on mHealth

- Relevant EU legislation currently under revision:
  - Medical devices directives, incl. 93/42/EEC
  - In vitro diagnostic medical devices directive 98/79/EC
  - Data protection directive 95/46/EC

- EU Green Paper on mobile health (Apr. 2014)
  - Public consultation: April-July 2014
  - Draft directive expected in 2015?
- Commission Staff Working Document on EU law for lifestyle and wellbeing apps (Apr. 2014)
  - Highlights regulatory gaps and room for interpretation in mHealth legal framework

Regulatory gaps

- No rules setting out objective criteria to differentiate between lifestyle mHealth and medical devices

- Onus upon manufacturer to declare intended purpose of a product
  - Declaration as medical device not mandatory
  - If not declared a medical device must not conform to safety and performance requirements
  - Often fail to clearly indicate intended purpose if not medical device
- Adaption of devices can change intended purpose, products can be used in ways other than their intended purpose
- Updates may alter functionality and data security

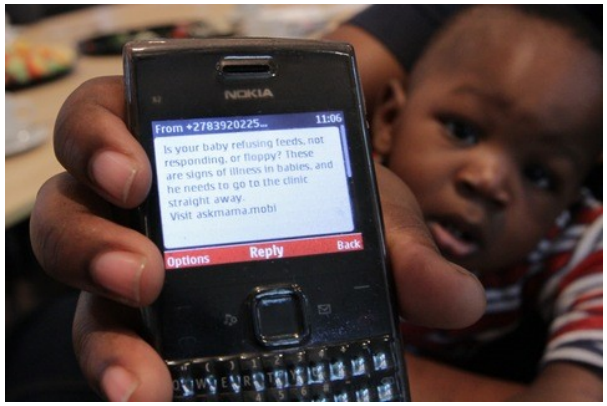
Data protection

- EU Directives: Data collected for mHealth cannot be further processed for commercial purposes without informed specific and explicit consent of user

BUT:

- Consumers often unaware of types of data collected
- Consumer consent for processing, storing and accessing data often not appropriately obtained
- Apps/app developers may alter the purposes or types of data collected without seeking further consent from the end-user.
- Parties involved in the development and distribution of apps often unaware of legal obligations
- Data beyond that necessary for function of mHealth collected & processed without consumer knowledge

Opportunities



- Improved **efficiency** of healthcare provision
- Better healthcare **access**
- Facilitates contacts between physicians and patients (in remote areas)
- Supplements traditional ways of managing health and delivering healthcare
- Expanded **diagnosis** and **treatment** options
- Patient **empowerment** and **motivation**
- Increased **public awareness** of health issues
- Potential uses of **big data**

Concerns

- mHealth can’t replace in person doctor-patient consultations
- Lack of evaluation of effectiveness and cost effectiveness
- Data collection, security, secondary use, misuse & anonymization
- Insufficient regulations on safety and performance
- Hygiene

Concerns

- Unclear distinction between lifestyle & medical
- Low cost market. Target group consists of consumers not HCP. Consumers have no obligation to use certified medical devices for medical purposes.
- Market rather than needs-driven development
- Lack of interoperability
- Not appropriate for all users / regions

Limitations on use of mHealth by physicians

- Hygiene
- Data security
- Data protection
- Patient rights
- Functionality
- Intended use, e.g. as medical device
- Liability

Recommendations

- Improve regulation, esp. of mHealth services that require medical expertise. Apps and devices must be certified and regulated even though the manufacturer/developer does not declare them to be medical devices.
- Undertake regular, comprehensive evaluation to assess effectiveness and safety
- Introduce measures to protect user data & better consent procedures for use

Recommendations

- Develop schemes to improve interoperability, reliability, functionality and safety
- Clarify physician reimbursement & liability when using mHealth
- A clear legal framework to address the question of identifying potential liability from the use of mHealth technologies.

Conclusion

- mHealth has huge potential to supplement traditional healthcare & collect research data

BUT:

- Must not be used to replace in-person treatment by a physician
- User data must be protected. It must be transparent how personal data is collected, stored, protected and processed and consent must be obtained prior to any disclosure of data to third parties.
- Take into account the risks of excessive or inappropriate use of mHealth (e.g. psychological impact)

Conclusion

→ Medical profession must take an informed position to ensure opportunities and risks sufficiently addressed

→ “WMA Statement on Mobile Health” up for discussion and approval at the forthcoming WMA General Assembly in October 2015

One World
One Medical Profession

Thank you!