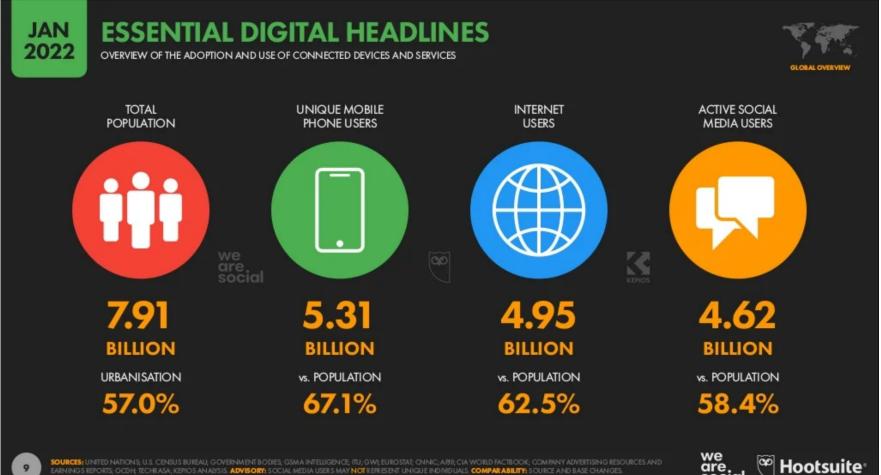




## mHealth, Internet of Things, and telemedicine systems

Sara Marceglia

#### The app world



we are social 🥙 Hootsuite<sup>,</sup>

#### The app world

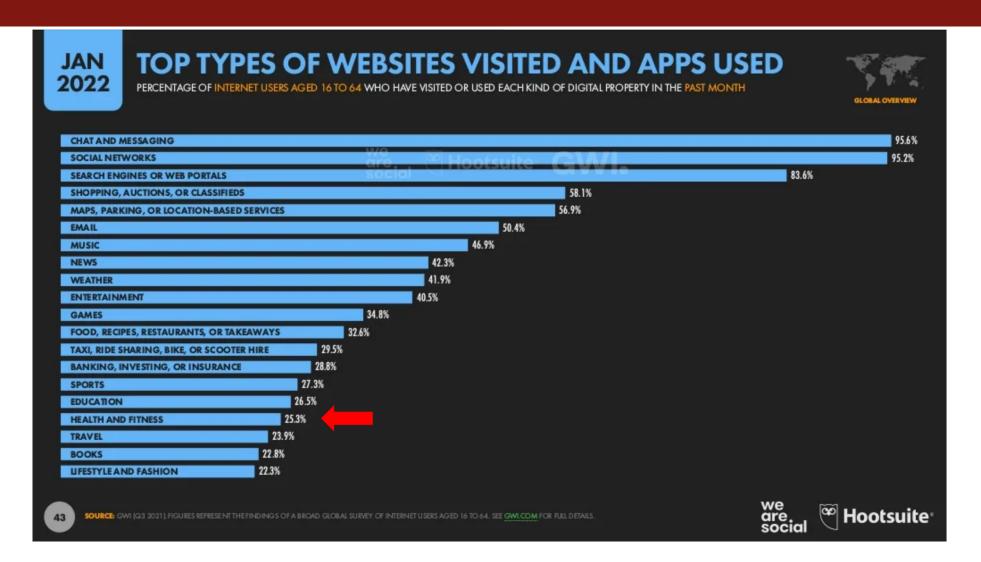
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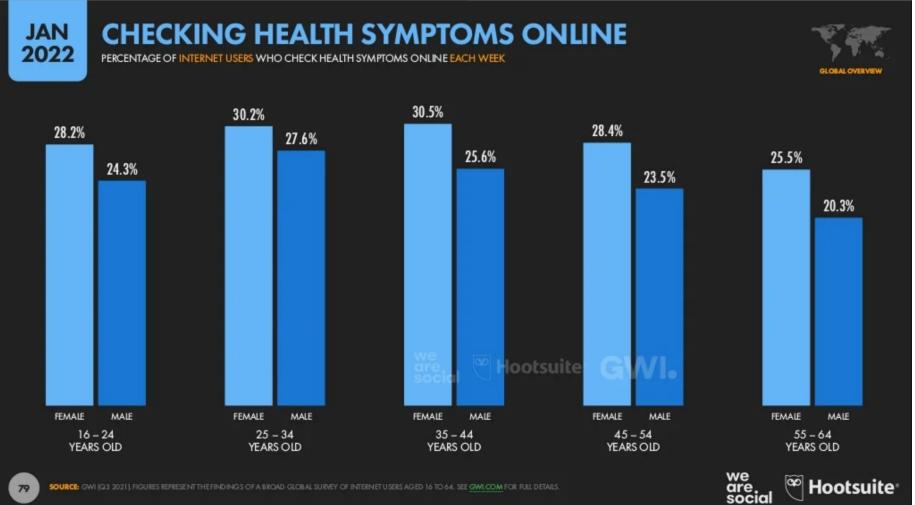
SOURCES: UNITED NATIONS; U.S. CENSUS BUREAU; GOVERNMENT BODIES; GSMA INTELLIGENCE; ITU; GWI; EUROSTAT; ONNIC; ARII; CIA WORLD FACTBOOK; COMPANY ADVERTISING RESOURCES AND EARNINGS REPORTS; OCDH; TECHRASA; KEPIOS AN ADVISORY; DUE TO COVID-19: RELATED DELAYS IN RESEARCH AND REPORTING, FIGURES FOR INTERNET USER GROWTH MAY UNDER REPRESENT ACTUAL TRENDS. SEE NOTES ON DATA FOR MORE DETAILS. SOCIAL MEDIA USERS MAY NOT REPRESENT UNIQUE INDIVIDUALS. COMPARABILITY; SOURCE AND BASE CHAINGES.



#### The app world



#### **App and Health**



79

#### **HEALTH AND SOCIAL MEDIA**







**ISTITUTO DI RICERCHE** FARMACOLOGICHE MARIO NEGRI · IRCCS

Istituto Ricerca Forma

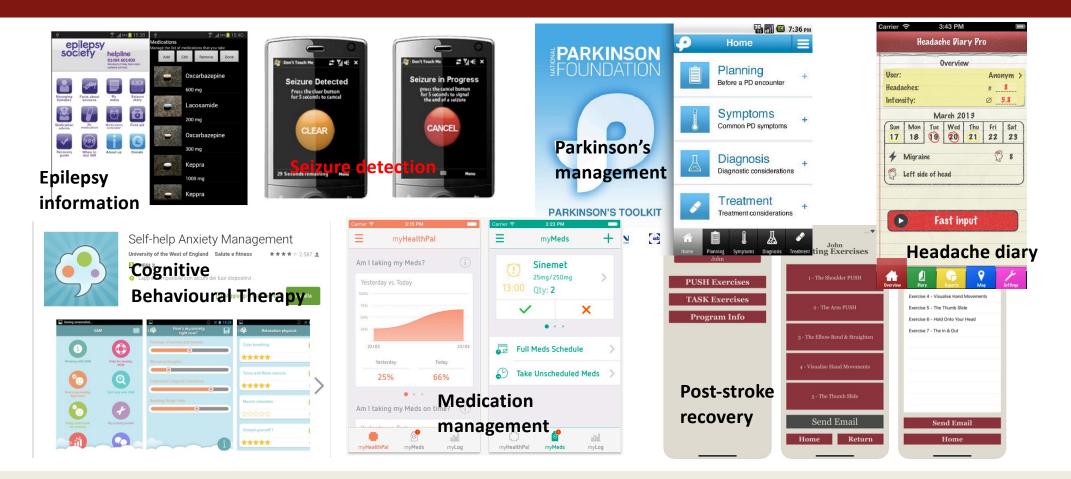
#### Coronavirus: attenziop alle bufale su social e c

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ONLINE

#### **Example: Health apps for neurology**





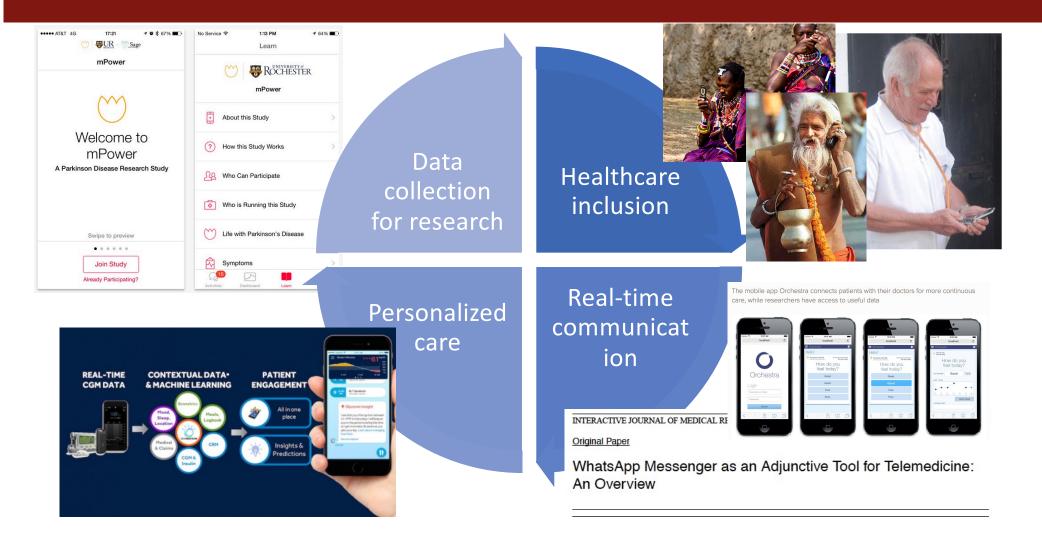


#### mHealth

#### m-Health $\rightarrow$ the use of mobile technologies to deliver e-Health



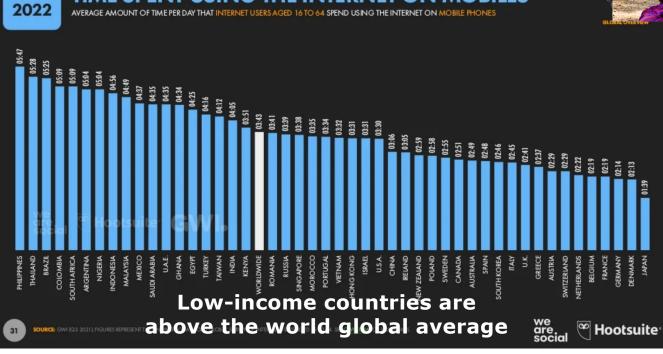
#### **Expectations**



#### WHY MOBILE: HEALTHCARE INCLUSION

- Digital inclusion also of developing countries
- Distributing healthcare benefits across society (equity)

JAN



USING THE INTERNET ON MOBILES



#### WHY MOBILE: REAL-TIME COMMUNICATION

INTERACTIVE JOURNAL OF MEDICAL RESEARCH

Giordano et al

Original Paper

WhatsApp Messenger as an Adjunctive Tool for Telemedicine: An Overview

The mobile app Orchestra connects patients with their doctors for more continuous care, while researchers have access to useful data









The app helps doctors get information about their acute kidney failure patients to enable faster diagnostics in situations where time is of the essence.

The app uses 'breaking news' alerts to make sure doctors' attention is directed to the patients who need it the most in the moment.

#### WHY MOBILE: PATIENT-CENTERED MEDICINE

- Patient inclusion in healthcare delivery
- Increased education capability
- Services for non-patients (wellness, healthy lifestyle)
- Moving some health responsibilities to patients

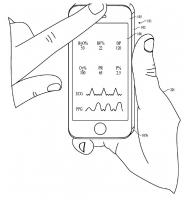


Cochlear Limited launches FDA-cleared, Apple-compatible cochlear implant By Jeff Lagasse



#### Newly granted Apple patent shows ways to turn an iPhone into a health sensor





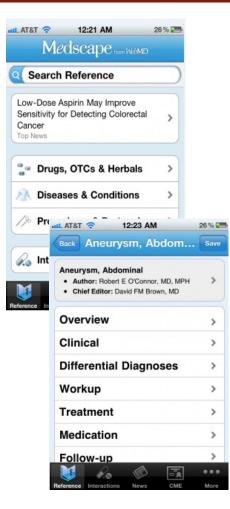
#### WHY MOBILE: MEDICAL PRACTICE

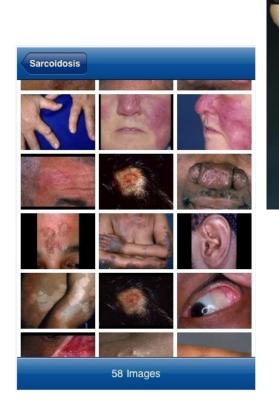


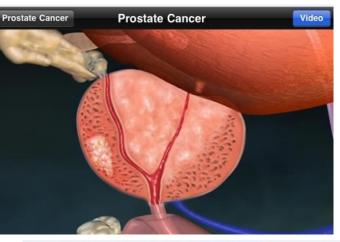


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#### WHY MOBILE: MEDICAL EDUCATION









#### WHY MOBILE: COLLECTING DATA FOR RESEARCH

#### **Crowdsourcing for research**

A Wandering Mind Is an Unhappy Mind

Science Matthew A. Killingsworth\* and Daniel T. Gilbert

We solved this problem by developing a Web application for the iPhone (Apple Incorporated, Cupertino, California), which we used to create an unusually large database of real-time reports of thoughts, feelings, and actions of a broad range of people as they went about their daily activities. The application contacts participants through Large DNA study using 23andMe data finds 15 sites linked to depression

### Collecting data for epidemics

Boston research company collecting COVID-19 data in new app

## Coronavirus: NHS contact tracing app to target 80% of smartphone users

By Leo Kelion



#### Collect digital data for advanced analytics

Evidation Health's technology platform and services enable healthcare companies to partner with patients and consumers who are engaged in understanding and improving health outcomes.



#### Sanofi and Evidation Health to work together to understand, treat disease By Jeff Lagasse | August 1, 2017

Medicines aren't the only tools that biopharma companies like Sanofi are using to help patients. Information technology has become a key tool in every part of Sanofi's business, and among the most important digital tools are data and analytics; they enable the company to apply insights gained from real world evidence to the discovery, development and delivery of new medicines. To advance that...

#### Brigham and Women's partners with Evidation Health to research impact of digital tools in clinical trials

By Heather Mack October 21, 2016

The innovation arm of Brigham and Women's Hospital has partnered with efficacy-focused digital health company Evidation Health to collaborate on a project measuring the real life impact of digital health solutions on clinical and financial outcomes. The idea is to combine forces to develop methods of creating direct-topatient trials of digital health solutions, leveraging the research...

#### **CAVEATS (1): Content reliability**

literature are not those available in stores



- Internet search engines like **Google** are the 3rd source of information (51,4%), **Facebook** is the **fifth** (43,7%).
- Among younger people:
  - First: Facebook (71,1%)
  - Second: Google (68,7%)
  - Fourth: YouTube (53,6%)

#### User Reviews





Apps are chosen based on the review of other users but there are no recognized systems for app review

#### **CAVEATS (2): Privacy and security**

- Individuals may have a limited or incorrect understanding of when data about their health is protected by law, and when it is not → some health-related information are stored in places that usually treat non-health information (e.g., Twitter, Facebook, etc) → HIPAA rule does not apply
- Health information collected in different places without consistent security standards may pose a cybersecurity threat (of which individuals may be unaware)
- Medical device manufacturers may not be covered entities or business associates under HIPAA. This leaves a health care provider using a medical device with potentially greater responsibility for assuring privacy and security protections for health information created and shared by the device





#### **CAVEATS (3):** Risks for the users

Cyberpsychology, Behavior, and Social Networking, VOL. 19, NO. 11 | Original Articles

normal

#### The Facebook Experiment: Quitting Facebook Leads to Higher Levels of Well-Being

Tromholt Morten

Published Online: 1 Nov 2016 | https://doi.org/10.1089/cyber.2016.0259

#### SI FFP

Getting worked up with anxiety or envy from what we see on social media keeps the brain on high alert, preventing us from falling asleep



"If we direct all of our attention toward capturing the best shots for our social media followers to admire, less will be available to enjoy other aspects of the experience in real time,"

#### Gen Z is quitting social media in droves because it makes them unhappy, study finds

March 09, 2018 by Oliver McAteer, Campaign

It's the most socially savvy generation, but many are leaving multiple platforms and marketers need to know why.



Guidance for the Clinician in Rendering Pediatric Care

Clinical Report—The Impact of Social Media on Children, Adolescents, and Families

#### **RESPONSES TO CAVEATS (1): regulatory bodies**



DH

FDA Pre-Cert



**Mobile Medical Applications** 

#### Guidance for Industry and Food and Drug Administration Staff

Document issued on February 9, 2015.

This document supersedes "Mobile Medical Applications: Guidance for Food and Drug Administration Staff" issued on September 25, 2013.

This document was updated to be consistent with the guidance document "Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" issued on February 9, 2015.

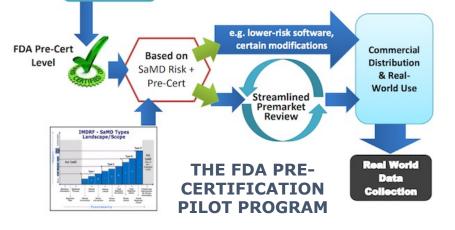
For questions about this document regarding CDRH-regulated devices, contact Bakul Patel at 301-796-5528 or by electronic mail at <u>Bakul Patel@fda.hks.gov</u> or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication. Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402Sotware e app mediche sono "dispositivi medici" e dovranno avere il marchio CE. La sentenza della Corte di Giustizia Europea

La Corte ha stabilito che "un software è di per sé un dispositivo medico quando è specificamente destinato dal fabbricante ad essere impiegato per una o più delle finalità mediche stabilite nella definizione di dispositivo medico" e partendo da tale assunto hanno dichiarato che il software può essere dispositivi medico anche senza impiego "sull'uomo". <u>LA SENTENZA</u>



There is a grey zone of Apps that are not medical devices and fall outside the regulation Reclassification of mobile medical apps for smartphones and other mobile devices  $\rightarrow$  generally risk class IIa, but under certain conditions can be risk class IIb or III. (Rule 11 in Annex VIII MDR)





#### **RESPONSES TO CAVEATS (1): regulatory bodies**

## Healthcare **IT** News

TOPICS

**Global Edition** Medical Devices

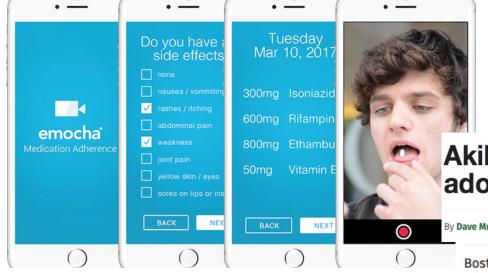
## FDA hopes draft guidance on device software will offer 'clarity, simplicity'

The new document, published this past week, takes stock of a fast-changing technology environment – and would replace the agency's previous medical device guidance, first issued more than 16 years ago.

https://www.healthcareitnews.com/news/fda-hopes-draftguidance-device-software-will-offer-clarity-simplicity

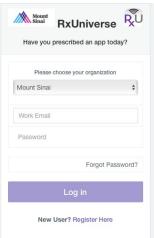
#### **RESPONSES TO CAVEATS (2): companies moving forward**

## With \$1.7M NIDA grant, emocha will evaluate its app for treating opioid addiction



## Mount Sinai launches RxUniverse, a system-wide platform to prescribe medical apps

By Heather Mack (/content/heather-mack) November 03, 2016



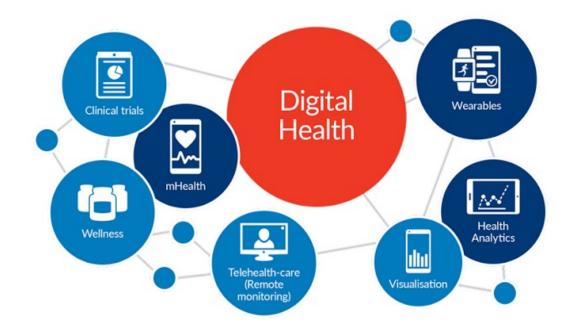
## Akili preparing FDA bid following strong results of adolescent ADHD trial

By Dave Muoio December 04, 2017

Boston-based **Akili Interactive Labs** has announced positive results from the largest clinical trial of its video game-based pediatric ADHD treatment yet. In light of these data, the company announced that it now plans to file AKL-T01, also known as Project: Evo ADHD Treatment, for FDA clearance as a novel treatment for children and adolescents with ADHD



#### **Internet of Things**



"Interconnection of sensing and actuating **devices** providing the ability to **share** information across platforms through a unified framework, developing a common operating picture for **enabling** innovative applications. This is achieved by seamless ubiquitous sensing, data analytics and information representation with Cloud computing as the unifying framework."

#### Apps, wereable & implantable devices

SHARE <

Hollywog launches smartphone-controlled pain management wearable





SOWATCH: lo smartwatch che previene l'ictus





THIM, il primo wearable al mondo "migliora-sonno" | Video The number of devices connected to the Internet was 12.5 billion in 2010, making the number of connected devices per person >1 (1.84) for the first time in history. Now they are 25 billions



Hodei Technology helps hospitals use Google Glass for surgical collaboration; rural telemedicine

 Image: State in the state

Medtronic implantable device for treating chronic pain by delivering neurostimulation at the spinal cord is connected to a Samsung Galaxy Tab S2, to allow data capturing and IPG controlling



#### IO(h)T

#### Apple Watch adds gym equipment integration, builtin Bluetooth





"Apple Watch is designed to help you live a healthier life," CEO Tim Cook said, "and people are absolutely loving the fitness capabilities, the health capabilities, the quick access to information, and even the ability to swim with it."

The biggest update to the Apple Watch health and fitness suite was an integration between the watch and fitness equipment at the gym. Brands like LifeFitness, Matrix, TechnoGym, Star Trac, Cybex, Schwinn, and StairMaster, which sell 80 percent of the country's fitness equipment, will start to roll out Apple Watch-integrated equipment this fall.

#### **SENSORS AND DRUGS**

## In-Depth: How digital sensors could change the face of pharma

Earlier this week, Proteus Digital Health and Otsuka Pharmaceuticals announced that Abilify MyCite, a new, sensorenabled version of Otsuka's drug for schizophrenia, **had received FDA approval** for mental health conditions including schizophrenia and bipolar disorder.

The Proteus digital medicine platform is a medication management and adherence system that includes sensorenabled pills, a peel-and-stick biometric sensor patch worn on the body, and a companion smartphone app. The patch records when a pill is ingested and can also track other things like sleep patterns and physical activity levels.

#### A historic clearance

For those who have been aware of Proteus for a long time, the importance of this latest regulatory win might not be obvious. It's far from the first FDA nod for the startup, which saw its patch first cleared in 2010 and its pill first cleared in 2012. Proteus has also been using its technology in small hospital deployments for some time. Representation of the sensor o

mobihealthnews

Nonetheless, this is something new and potentially game changing. For one thing, previous clearances went through the FDA's medical device pathway and didn't allow the system to be prescribed the way the Abilify's clearance eventually will.

#### **Telemedicine and Telehealth**

#### TELEMEDICINE

• Integration, monitoring and management of patients, as well as education of patients and healthcare professionals using systems and technologies allowing a prompt communication with experts and an effective access to patient's information, independent from where the patient is or the information are stored" (EC commission, 1990)

#### TELEHEALTH

• Delivery of health care services, where patients and providers are separated by distance. Telehealth uses ICT for the exchange of information for the diagnosis and treatment of diseases and injuries, research and evaluation, and for the continuing education of health professionals. Telehealth can contribute to achieving universal health coverage by improving access for patients to quality, cost-effective, health services wherever they may be. It is particularly valuable for those in remote areas, vulnerable groups and ageing populations (WHO)

#### Telemedicine

## Syncronous telemedicine

#### **Real-Time**

Provider and patient communicate via live videoconferencing. Used often in telepsychiatry, telehomecare, telecardiology and remote consults (teleconsults) with specialists, primary care physicians, counselors, social workers and other health care professionals.

## Asyncronous telemedicine

#### Store & Forward

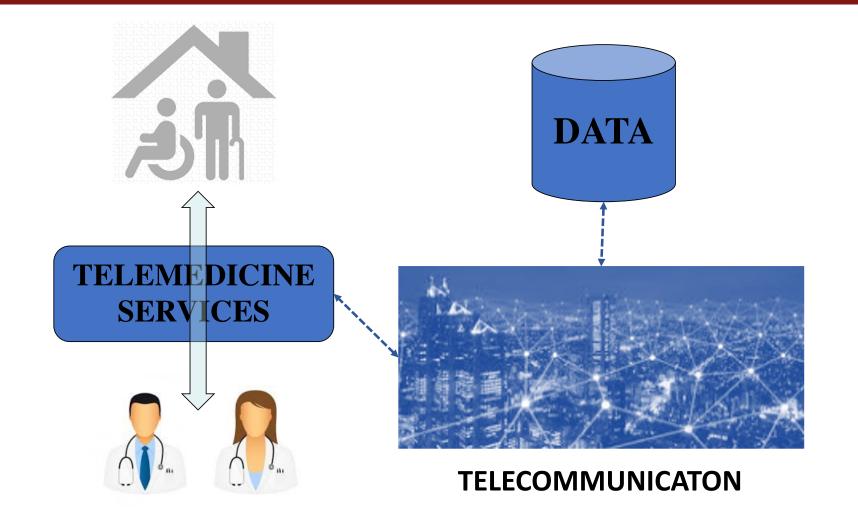
Digital images, video, audio, clinical data are captured and stored on a patient's computer or mobile device and then transmitted securely to a provider for later study or analysis. Used often in teledermatology and telepathology.

#### Telemonitoring

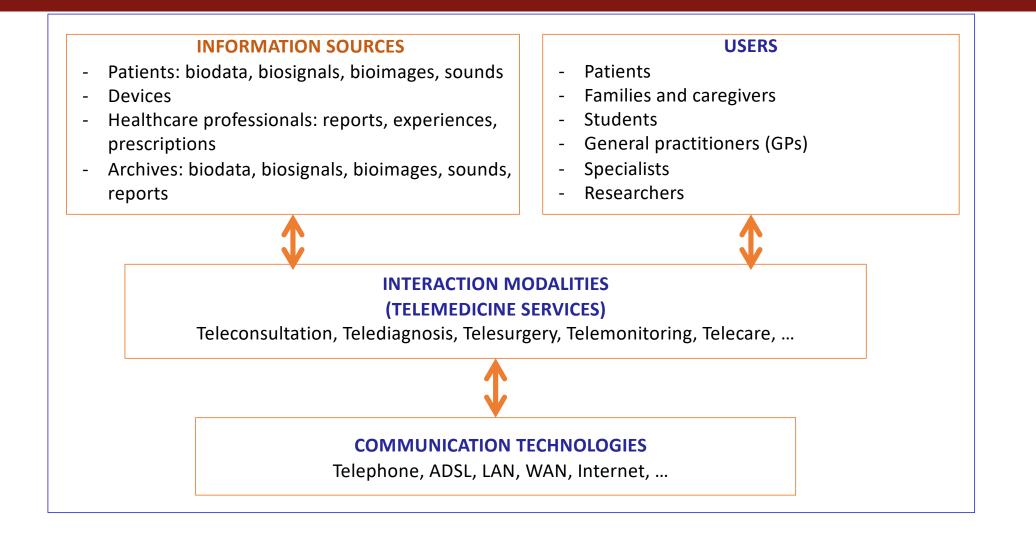
#### **Remote Monitoring**

Patient uses a system that feeds data from sensors and monitoring equipment to an external monitoring center so that health care professionals can monitor a patient remotely. Used to monitor chronic conditions such as heart disease, diabetes and asthma.

#### **Application scenario**

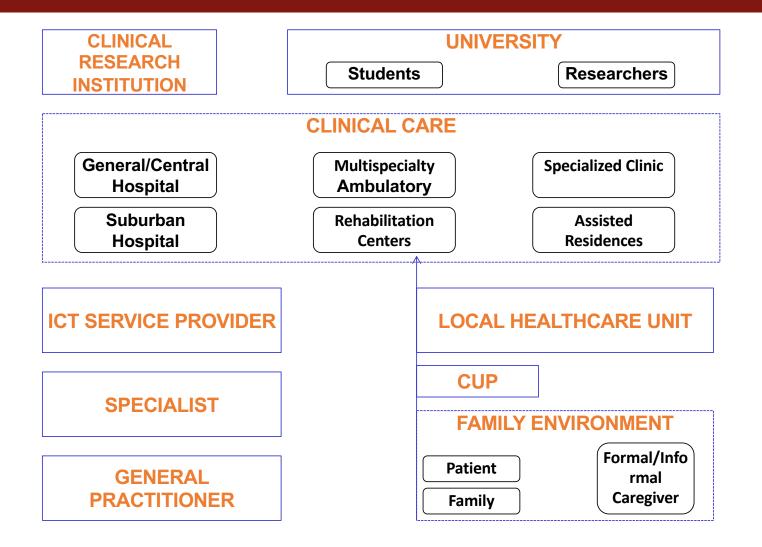


#### A general model for telemedicine



29

#### **Actors involved**



30

#### **Telemedicine classification by service**

#### Tele-reporting

ullet + ullet the reports are created and visualized remotely

#### **Tele-consultation**

 $\cdot 
ightarrow$  a second opinion is asked remotely

#### Tele-explanation

 $\bullet 
ightarrow$  from a specialized to a non-specialized physician

#### Tele-psychology

•  $\rightarrow$  to provide comfort to the patient/family

#### Fele-monitoring

 $\bullet \rightarrow$  remote monitoring of patient's clinical condition

#### Tele-prescription

 $\bullet \rightarrow$  remote prescribing (drug, therapies, rehabilitation, activities, exercises,..)

#### Tele-contro

ightarrow possibility to remotely change what is monitored

#### Tele-booking

•→ remote booking of visits, exams, ...

#### Tele-administration

• → remote control of administrative procedures

#### Tele-education

 $\bullet \rightarrow$  training, support, and even examination in a remote fashion

#### **Examples**

# Televisits Image: Stress str

#### Il tuo dottore ONLINE

Con DaVinci puoi consultare facilmente un dottore o uno psicologo tramite videochiamata dove e quando è più comodo per te

PARLA CON UN DOTTORE



#### **COVID boost of telemedicine and telehealth sysetems**

#### JAMA Neurology August 2020 Volume 77, Number 8

VIEWPOINT

The Coronavirus Disease 2019 Crisis as Catalyst for Telemedicine for Chronic Neurological Disorders

#### Vol. No. 2020

Journal of Pain and Symptom Management 1

#### **COVID-19** for Fast Track Publication

#### Telemedicine in the Time of Coronavirus

Brook Calton, MD, MHS, Nauzley Abedini, MD, MSc, and Michael Fratkin, MD Division of Palliative Medicine (B.C., N.A.), Department of Medicine, University of California, San Francisco (UCSF), San Francisco, California; and ResolutionCare (M.F.), Eureka, California, USA



Kevin E. Lai, MD, Melissa W. Ko, MD, Janet C. Rucker, MD, Jeffrey G. Odel, MD, Linus D. Sun, MD, PhD, Kimberly M. Winges, MD, Arko Ghosh, BS, Shruthi Harish Bindiganavile, MD, Nita Bhat, MD, Sydney P. Wendt, BS, Jackson M. Scharf, BS, Marc J. Dinkin, MD, Nailyn Rasool, MD, Steven L. Galetta, MD, Andrew G. Lee, MD

#### PERSPECTIVES IN HOSPITAL MEDICINE

#### Keep Calm and Log On: Telemedicine for COVID-19 Pandemic Response

Ameet Doshi, MD, MBA\*, Yonatan Platt, MD, John R Dressen, MHA, Benji K Mathews, MD, FACP, SFHM, Jerome C Siy, MD, MHA, SFHM

Department of Hospital Medicine, HealthPartners, Bloomington, Minnesota

#### Comment on this paper From Isolation to Coordination: How Can Telemedicine Help Combat the **COVID-19 Outbreak?**

Yunkai Zhai, 💿 Yichuan Wang, 💿 Minhao Zhang, 💿 Jody Hoffer Gittell, Shuai Jiang, Baozhan Chen, Fangfang Cui, Xianying He, Jie Zhao, 💿 Xiaojun Wang doi: https://doi.org/10.1101/2020.02.20.20025957

This article is a preprint and has not been peer-reviewed [what does this mean?]. agement It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

#### Ruggero Capra<sup>1</sup> · Flavia Mattioli<sup>2</sup>

Virtually Perfect? Telemedicine for Covid-19

Judd E. Hollander, M.D., and Brendan G. Carr, M.D.

medR<sub>χ</sub>iv

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**Epilepsy & Behavior** 

**BMI** Yale

journal homepage: www.elsevier.com/locate/yebeh

Epilepsy & Behavior 111 (2020) 107282

HOME | AE

Search

Review

Telehealth in pediatric epilepsy care: A rapid transition during the COVID-19 pandemic

Shifteh Sattar<sup>a</sup>, Rachel Kuperman<sup>b,\*</sup>

#### Accelerating Telemedicine for **Cerebral Palsy During the COVID-19** Pandemic and Beyond

Hilla Ben-Pazi<sup>1,2,3\*</sup>, Liana Beni-Adani<sup>1,4</sup> and Ron Lamdan<sup>1</sup>



#### **Telemedicine use**



Rapporto ISS COVID-19 • n. 12/2020



versione 13 aprile 2020

Indicazioni *ad interim* per servizi assistenziali di telemedicina durante l'emergenza sanitaria COVID-19

Ministerc della Salute

TELEMEDICINA Linee di indirizzo nazionali

2014

#### **Services**

CLASSIFIC	CLASSIFICAZIONE		PAZIE	RELAZIONE	
	TELE VISITA		Può essere rivolta a	Presenza attiva del Paziente	B2C B2B2C
TELEMEDICINA SPECIALISTICA	CONSULTO sanitario	sanitario	patologie acute, croniche, a situazioni di post-	Assenza del Paziente	B2B
	TELE COOPERAZIONE SANITARIA		acuzie	Presenza del Paziente <i>, in tempo</i> <i>reale</i>	B2B2C
TELE SALUTE		sanitario	E' prevalentemente rivolta a patologie croniche	Presenza attiva del Paziente	B2C B2B2C
TELE ASSISTENZA		socio- assistenziale	Può essere rivolta ad anziani e fragili e diversamente abili		

\* B2B: individua la relazione tra medici

B2B2C: individua la relazione tra un medico e un paziente mediata attraverso un operatore sanitario

B2C: individua la relazione tra medico e paziente

#### **Telemedicina specialistica**

Dipendentemente dal tipo di relazione tra gli attori coinvolti, le prestazioni della Telemedicina Specialistica si possono realizzare secondo le seguenti modalità:

#### Televisita

La Televisita è un atto sanitario in cui il medico interagisce a distanza con il paziente. L'atto sanitario di diagnosi che scaturisce dalla visita può dar luogo alla prescrizione di farmaci o di cure. Durante la Televisita un operatore sanitario che si trovi vicino al paziente, può assistere il medico. Il collegamento deve consentire di vedere e interagire con il paziente e deve avvenire in tempo reale o differito.

#### Teleconsulto

Il Teleconsulto è un'indicazione di diagnosi e/o di scelta di una terapia senza la presenza fisica del paziente. Si tratta di un'attività di consulenza a distanza fra medici che permette a un medico di chiedere il consiglio di uno o più medici, in ragione di specifica formazione e competenza, sulla base di informazioni mediche legate alla presa in carico del paziente.

#### Telecooperazione sanitaria

La Telecooperazione sanitaria è un atto consistente nell'assistenza fornita da un medico o altro operatore sanitario ad un altro medico o altro operatore sanitario impegnato in un atto sanitario. Il termine viene anche utilizzato per la consulenza fornita a quanti prestano un soccorso d'urgenza.

#### Telesalute

La registrazione e trasmissione dei dati può essere automatizzata o realizzata da parte del paziente stesso o di un operatore sanitario.

La Telesalute prevede un ruolo attivo del medico (presa in carico del paziente) e un ruolo attivo del paziente (autocura), prevalentemente pazienti affetti da patologie croniche, e in questo si differenzia dal Telemonitoraggio. La Telesalute comprende il Telemonitoraggio, ma lo scambio di dati (parametri vitali) tra il paziente (a casa, in farmacia, in strutture assistenziali dedicate,...) e una postazione di monitoraggio non avviene solo per l'interpretazione dei dati, ma anche per supportare i programmi di gestione della terapia e per migliorare la informazione e formazione (knowledge and behaviour) del paziente.

#### Telemonitoraggio

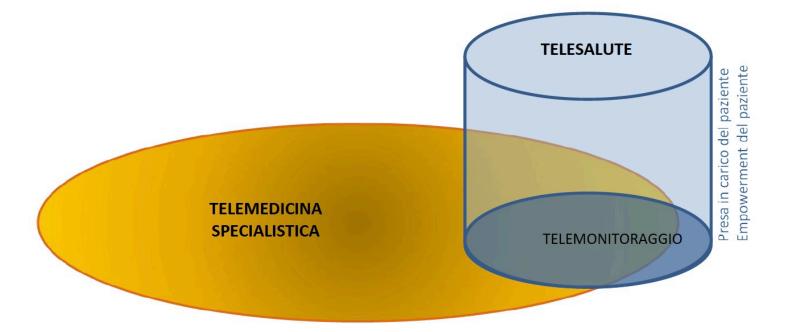
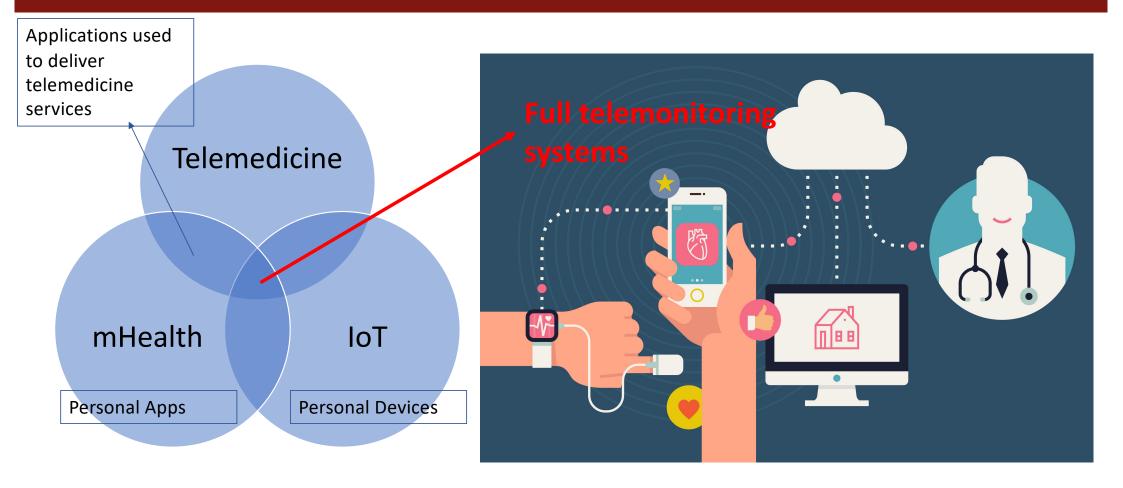


Figura 2.1 Rappresentazione schematica dei rapporti tra Telemonitoraggio, Telemedicina Specialistica e Telesalute. Si evidenzia il ruolo attivo del Paziente (Empowerment) e del Medico (presa in carico) nel caso della Telesalute, che espande il concetto del curare nella direzione del prendersi cura (medicina di iniziativa).

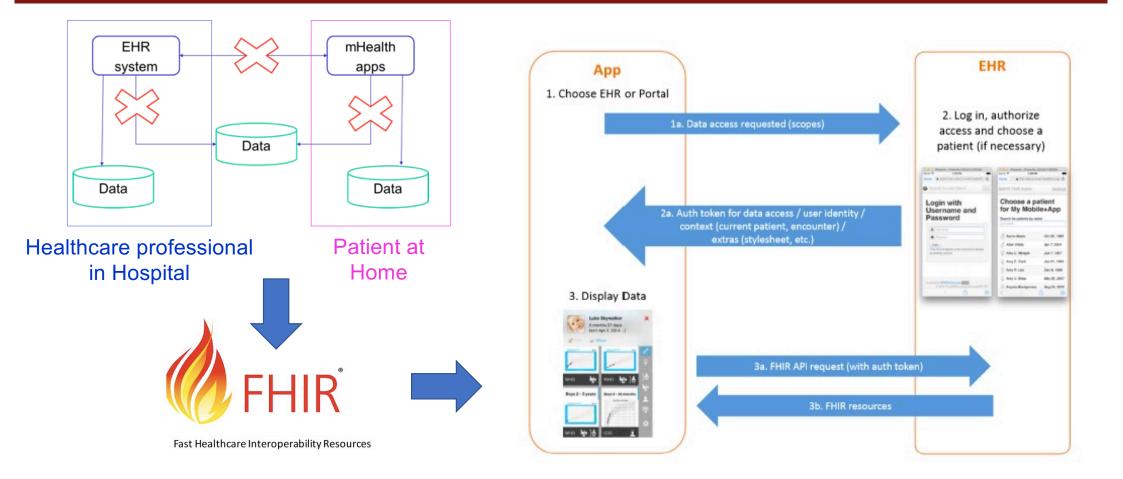
#### Teleassistenza

Per Teleassistenza, si intende un sistema socio-assistenziale per la presa in carico della persona anziana o fragile a domicilio, tramite la gestione di allarmi, di attivazione dei servizi di emergenza, di chiamate di "supporto" da parte di un centro servizi. La Teleassistenza ha un contenuto prevalentemente sociale, con confini sfumati verso quello sanitario, con il quale dovrebbe connettersi al fine di garantire la continuità assistenziale. Non rivolgendosi all'ambito sanitario, ma a quello socio-assistenziale, non sarà oggetto di queste Linee di Indirizzo.

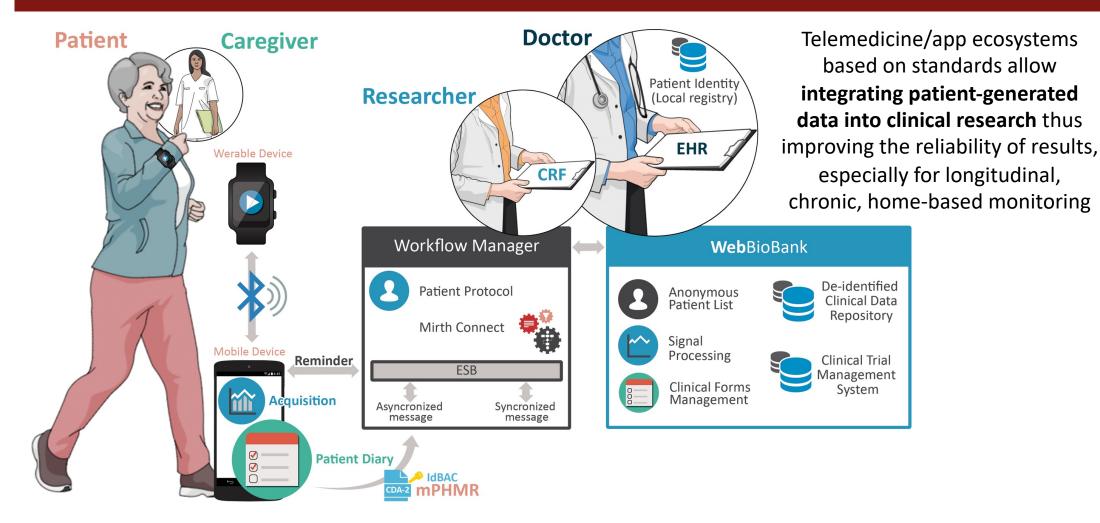
#### **Internet of health things ecosystems**



#### **Connecting apps to telemedicine services: HL7-FHIR standards**



#### mHealth-IoT-telemedicine ecosystem for clinical trials: an example



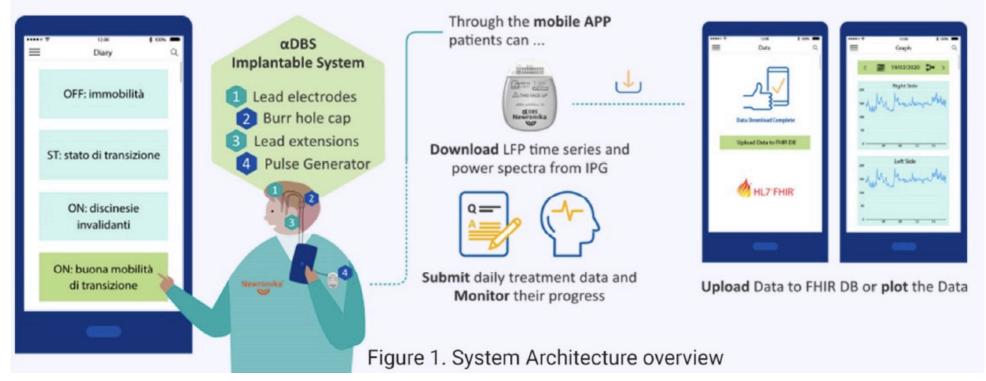
#### mHealth-IoT-telemedicine ecosystem for clinical trials: an example

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Patient List - Ospedale Maggiore Policlinico - U.O. di Neurofisiopatologia Clinica, Neurochirurgia Show 10 V entries Search:																		
IdEHR	↓↑ IdBAC	↓† Data	1 Protocols		ļţ.	Code	ţ₽	Surname	ţţ	Name	↓† s	ex ↓†	DateOfE	Birth	\$1	TaxCo	de	ĴĴ
3317	11461	10/07/2017 23:02:48				722												
3321	11465	18/10/2017 17:41:39				P004												
3316	11460	10/07/2017 23:01:40				122												
3320	11464	13/07/2017 16:57:25				123												
3318	11462	11/07/2017 11:39:04				812												
3319	11463	11/07/2017 17:30:14				890												
3323	11467	19/10/2017 15:36:11				P001												
3322	11466	19/10/2017 15:23:06				P002												
3324	11468	21/10/2017 16:48:32				P003												
98	42	22/10/2011 17:49:37																
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#### mHealth-IoT-telemedicine ecosystem for clinical trials: an example

Notifications	
Prossima attività	
3	

#### Apps and bi-directional computer interfaces: adaptive DBS



- Adaptive Deep Brain Stimulation (aDBS) devices can record neural signals and adapt the neuromodulation therapy accordingly, thus being fully bi-directional computer interfaces
- It is now necessary to study brain dynamics 24/7, and to define optimized algorithms for providing personalized stimulation
- A data management ecosystem

- mHealth apps are increasingly adopted, together with wearable and IoT devices
- There are no recognized review systems for health-related apps that are not certified as medical devices
- A full Internet of Health System including telemedicine (communication technologies), apps, and devices could be an effective way to exploit the full potentials of apps
- There are medical informatics standards (HL7-FHIR) that enable the connection of apps to electronic health records and hospital systems
- The use of apps can boost medical research thanks to the possibility to collect data in ecologic environments and to include patient's generated data
- The COVID-19 pandemic boosted the adoption of apps and telemedicine opening the way for its adoption also in non-emergency situations