## Vietri, Roberto Michele

## Master's thesis / Diplomski rad

2014

Degree Grantor / Ustanova koja je dodijelila akademski / stručni stupanj: University of Zagreb, School of Medicine / Sveučilište u Zagrebu, Medicinski fakultet

Permanent link / Trajna poveznica: https://urn.nsk.hr/urn:nbn:hr:105:898204

Rights / Prava: In copyright/Zaštićeno autorskim pravom.

Download date / Datum preuzimanja: 2024-04-25



Repository / Repozitorij:

Dr Med - University of Zagreb School of Medicine Digital Repository





# UNIVERSITY OF ZAGREB SCHOOL OF MEDICINE

**Roberto Michele Vietri** 

# Mobile Health: current state and possible future developments

# **GRADUATE THESIS**



Zagreb, 2014

This graduation paper was made at Chair for Medical Statistics, Epidemiology and Medical Informatics, University of Zagreb School of Medicine under supervision of Prof. dr. sc. Jadranka Božikov and it was submitted for evaluation in the academic year 2013/2014.

# **ABBREVIATIONS**

BNF:	British National Formulary
CHW:	Community Health Worker
eHealth:	Electronic Health (also written as E-Health)
EHR:	Electronic Health Record
EMR:	Electronic Medical Record
FDA:	US Food and Drug Administration
GNI:	Gross National Income
HbA1c:	Haemoglobin A1c
HCP:	Health Care Provider
HIPAA:	Health Insurance Portability and Accountability Act
HONCODE:	Health on the Net Foundation Code of Conduct
HUILODD.	
ISO:	International Organisation for Standardisation
ISO:	International Organisation for Standardisation
ISO: IT:	International Organisation for Standardisation Information Technology
ISO: IT: mHealth:	International Organisation for Standardisation Information Technology Mobile Health (also written as M-Health)
ISO: IT: mHealth: NFC:	International Organisation for Standardisation Information Technology Mobile Health (also written as M-Health) Near-Field Communication
ISO: IT: mHealth: NFC: OS:	International Organisation for Standardisation Information Technology Mobile Health (also written as M-Health) Near-Field Communication Operating System
ISO: IT: mHealth: NFC: OS: PDA:	International Organisation for Standardisation Information Technology Mobile Health (also written as M-Health) Near-Field Communication Operating System Personal Digital Assistant
ISO: IT: mHealth: NFC: OS: PDA: PHR:	International Organisation for Standardisation Information Technology Mobile Health (also written as M-Health) Near-Field Communication Operating System Personal Digital Assistant Personal Health Record

## CONTENTS

INTRODUCTION	1
THE CURRENT STATE OF MOBILE HEALTH	5
Early Adopters and the current mHealth Market	5
M-Health Applications	9
Current Unique Uses	
Diabetes	13
The fight against counterfeit drug manufacturing using mHealth technology	14
Mobile Health in Disaster Zones	16
Wireless ECG Monitoring	
Online Appointment Scheduling	19
E-Learning Tools for Medical Professionals and Medical Students	
Health Specific Calculation Applications and Other Miscellaneous Applications	
Financing Healthcare in Developing Nations	
Regulations and Approval Bodies	24
When is a Mobile App a Medical Device?	24
FDA	
MHRA and EU Regulations	25
Relevant Regulations in Europe	
The Future	
Factors Hindering mHealth Growth	
Poor Integration of IT Systems	
IT Skills	
Public vs Private Healthcare Sectors	
Data Protection and Trust	
Safety of Applications and Dubious Claims	
Exciting New Technologies and Trends	
Google Glass	
Personal Health Records (PHRs)	
Prescribing Apps	
Other Up and Coming Trends	
Discussion	
Conclusion	
Acknowledgements	40
References	41
Biography	45

## SUMMARY

Title: Mobile Health - current state and possible future developments

Keywords: mHealth, eHealth, mobile technology, mobile health, mobile phones

Mobile Health (mHealth) is an exciting new field of Electronic Health (eHealth) with continual and massive developments at all levels of the stack, from the devices themselves at the lowest level to the operating systems and the software at the higher levels. We look at the origins of mHealth and its initial development as well as the reasons for that. The current state of mHealth varies significantly by geographic region and economic status. We look at the current role of mHealth worldwide and it's relation to the development of mobile technology. mHealth has also been used in many unique roles in disaster areas and in disease outbreaks, we have a look at a few of these unique usage cases such as mHealth use in diabetes, Dengue Fever and malaria. We also look at some remote application uses such as wireless ECG monitoring and the potential for change that has as well as the cost effective role it is playing in ensuring genuine drugs that are not tampered with reach the end users. We look at the role medical professionals and students are utilising mHealth for, and the many different areas where it is developing in education. We then move on to futuristic trends and developments and look at the factors hindering mHealth growth as well as up and coming technologies which are only now starting to hit the market and give a taste of what we can expect from mHealth in the future.

## INTRODUCTION

"When we talk about mobile health, we are talking about taking the biggest technology breakthrough of our time and using it to take on one of the greatest national challenges of our time." said Kathleen Sebelius (Sebelius 2011), the then US Secretary of Health and Human Services, during her Keynote Address at the 2011 annual mHealth Summit in Washington DC.

Mobile Health, hereafter referred to as mHealth, is the use of mobile technologies (information, devices and communication technologies) to support or improve medical and public health, and the provision of healthcare (MHealth Evidence 2014). The field includes different applications in developed and developing nations that tend to vary, and this contrast will be thoroughly explored later. These devices typically include mobile phones but may also include other specialised devices such as wireless monitors, PDAs, smart watches, body devices, etc. These mobile applications and services can include remote patient monitors, video conferencing, online consultations, personal healthcare devices, wireless/mobile access to patient records and information, education and awareness, disease and epidemic tracking, healthcare worker training and many more (Dolan 2010).

mHealth is considered as a subset or narrowed down topic within eHealth. eHealth covers a wide range of services such as EHRs and telemedicine, and while there is much overlap, there are also many distinctive features worth noting. Overall far more people have access to a mobile device than a desktop. This difference is more pronounced in developing nations where mobile devices significantly outnumber desktop devices. Tech savvy under 30s drive a lot of this growth where their SMS and music usage for smartphones still outpaces Internet usage (mHealth Alliance 2014). mHealth relies more on telecommunications equipment and costs than eHealth, and these telecommunication costs, especially data, are often significantly more expensive in developing nations (ITU 2013). A lot of the mHealth development is coming out of

poorer nations whereas eHealth development is mostly coming from more developed countries (Mhealth Alliance 2014).

A common use for mobile devices is that for mLearning which falls under the category of eLearning and is defined as the learning across multiple contexts, through social and content interactions, using personal electronic devices (Crompton 2013). While not part of the core definition of mHealth, it is a popular trend worth mentioning. M-Learning is an increasingly popular field for mobile devices and besides the massive amount of currently available medical reference tools and medical learning apps, there is also an increasing uptake in remote learning. While formally mostly restricted to major tertiary learning institutions, increasingly free online learning with institutions such as Coursera, Khan Academy or Apple's iTunesU are becoming very popular especially with the endorsement of celebrities and some of some of the top universities in the world. These can be studied anywhere in the world at any time where one can find some Internet connection, in many cases, even offline without a connection.

The International Telecommunication Unit report highlights the continued increase in global mobile device penetration with 6.8 billion global mobile-cellular subscriptions in 2013 (ITU 2013). Global penetration is now over 100% in four of the worlds' six regions, and the current estimate is that 2.7 billion or approximately 39% of the worlds population was using the Internet by the end of 2013. While mobile broadband costs continue to decline worldwide, there is still a stark comparison between Europe with the cheapest mobile broadband at just less than 2% of average GNI per capita versus well over 50% in some developing nations.

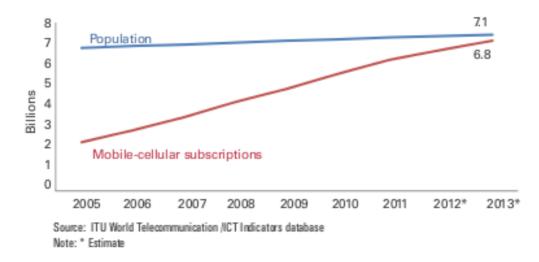


Figure 1 - Mobile subscriptions over time vs Population

One of the differences between mHealth and eHealth is that mHealth is more personal. The more personal nature has led to an explosive growth both on the software and hardware front allowing the mHealth consumer to get access to their own health information and to empower them to make decisions based on this. Health promotion apps and devices are now used to measure vital signs such as heart rate, blood pressure, blood glucose level, body temperature and even brain activity. This information is now combined with other information such as body fat, weight, activity measuring software (pedometers and sport trackers) and even food tracking apps that not only measure calories but even vitamins, minerals and protein or fat requirements. All this information can be seen in most cases instantly off a smartphone, or in many cases with cloud-connected apps or devices, off the web browser on any device anywhere in the world. This same information can be shared with friends, family and of course, healthcare professionals.

This massive surge in mHealth and mobile use in general has been due to its many advantages. mHealth allows for early diagnosis and better treatment (Taconi et al 2008; Collins 2012), it empowers patients to care for themselves, the emphasis is on prevention and therefore saving lives, it is more efficient and sustainable, and creates time savings both in collecting the information as well as analysing it. This all leads to an overall cost saving both in obtaining information but also in the saving of healthcare

professional time. Mhealth is aiding more in the sphere of preventative medicine that is overall more effective, as well as cheaper in most circumstances, but not all (Williams 1974). Naturally there is an initial cost and time involved with all new technologies and much uncertainty especially with non-uniformity in standards. The medical field has long been viewed as the realm of medical professionals, and mHealth is shifting some of the decisions and information out of the hands of doctors to that of the layperson, that has naturally led to some resistance.

The term mHealth was only coined as late as 2005 by Robert Istepanian in his book when he defined it (Istepanian et al. 2006). Despite being such a new field, it has seen much growth and excitement with annual conferences dedicated to it, big name investors pouring funds into it and payers putting their money down and driving development towards the next big thing with mHealth. Mhealth has already made substantial differences in homes, healthcare settings and even disaster zones. The continual growth of the mobile market, the increased emphasis on preventative medicine, the increased use and reliance on technology in medicine and a younger more tech-savvy generation are all combining to ensure that this field continues to grow exponentially and become increasingly important to ensure both quality healthcare and access to healthcare for everyone on the planet.

## THE CURRENT STATE OF MOBILE HEALTH

#### Early Adopters and the current mHealth Market

Developing countries have a massive disadvantage when it comes to healthcare, but these same healthcare handicaps are a driving force for mHealth use and development. The big handicap in developing nation is access to healthcare due to numerous factors such as lack of transport, long travelling distances, inadequate doctor to patient ratios, etc. Luckily this is something that mHealth is very capable in helping to alleviate and is doing just that. This contrasts to developed nations where the primary driver of mHealth is cost cutting. The biggest telecommunication cost cuts and mobile growth have happened in these developing nations which has helped fuel this explosive mHealth growth (ITU 2013).

Year on year, both smartphone and phone sales have continued to increase. With each year, smartphone features have increased especially due to competition between the major smartphone OS makers namely Apple with iOS, Google with Android, Microsoft with Windows Mobile OS and RIM with Blackberry OS. RIM, once a powerhouse in the smartphone category and an old name to many has been unable to keep up with the likes of Google and Apple and has continually lost market share. This is evidenced in *table 1* below.

Worldwide Smartphone S	ide Smartphone Sales to End Users by Operating System in 3Q13 (Thousands of		ousands of Units)	
Operating System	3Q13	3Q13 Market	3Q12	3Q12 Market
	Units	Share (%)	Units	Share (%)
Android	205,022.7	81.9	124,552.3	72.6
iOS	30,330.0	12.1	24,620.3	14.3
Microsoft	8,912.3	3.6	3,993.6	2.3
BlackBerry	4,400.7	1.8	8,946.8	5.2
Bada	633.3	0.3	4,454.7	2.6
Symbian	457.5	0.2	4,401.3	2.6
Others	475.2	0.2	683.7	0.4
Total	250,231.7	100.0	171,652.7	100.0

#### Table 1 – Worldwide smartphone sales to end users by OS in 3Q13

Source: Gartner (November 2013)

Features that were once considered luxuries are now considered standard, almost every smartphone now has motion sensors, as do smart watches, which more and more top manufacturers are producing. Apple recently further improved this with a dedicated chip which they have named the M7, which has the sole function of processing motion information, greatly improving accuracy, capabilities and power saving (Ritchie 2014). If this was not enough to convince everyone that Apple is taking the sport and health capabilities of its devices seriously, Apple has recently gone on a hiring spree of experts in biomedicine from companies such as Vital Connect, Masimo Corp, Sano Intelligence and O2 MedTech (Farr 2014b). All of this advancement in common consumer devices is bringing mHealth technologies right into the home as an expected feature and changing peoples viewpoint on health by giving them access to health technologies always there with them, which were once expensive and specialised devices.

These same features which are now considered standard in smartphones such as motion sensors, GPS, high speed data/Internet connectivity, cameras and even security technologies like fingerprint sensors allow the creation of very versatile mobile health applications without requiring any additional hardware and, therefore, very cheaply. Any single feature can be used in a multitude of different ways. The GPS feature, for example, can be used to accurately obtain the location of the user for use in an emergency for the healthcare services to locate the user or for someone like an allergy sufferer, accurate pollen information for their area. The Medical University of Vienna, for example, has released a free application which relies on data published by the various countries and allows pollen sufferers to get a sort of pollen weather report. Even more useful is that it can even send automatic notifications to the smartphone should a pollen threshold be reached in the local area. This same GPS feature is also used extensively by the various activity tracking and sport applications for speed and distance calculations and tracking

While bulk production and decreasing costs of electronics are helping to drastically reduce the pricing of mHealth devices, the research involved especially with more advanced or specialised technology still costs large amounts of money. On the consumer device side, the competition between manufacturers, combined with the expectation of the consumers is encouraging that research and paying for those devices. But what about on the more commercial devices and software?

One recent high-profile acquisition was that of the iTriage application made by iTriage LLC. iTriage LLC is a company started in Denver, Colorado by two emergency medicine physicians in 2008. By 2011, it was mentioned by the White House, and by the end of 2011 it had been bought out for an undisclosed sum by the Aetna Group, a major American medical insurance and disability seller. This little application, which was recently started from humble beginnings has now been downloaded over 11 million times, has 115 employees, over 600 hospital partners and thousands of physician partners (iTriage LLC 2014).

This acquisition is important as it marks the major purchase of one of the first highprofile mobile health startups. The application itself is a market neutral application available to all consumers, payers and providers which allows the user to input symptoms and then find treatment providers in their area. It also gives them cost estimates and allow them to book an appointment in the application. The primary motivation for using iTriage is the cost saving to the consumer, as well as helping the consumer navigate the healthcare landscape which is becoming increasingly more complicated (Dolan 2011). More importantly for mHealth though, other than the massive consumer and provider numbers interested in this application, is the fact that major companies are now willing to invest large amounts of money into new and innovative and therefore risky mHealth services. Companies are willing to invest now in what are considered positive trends in heath, right now these are the aging population and baby boomers, people living longer with chronic diseases, obesity and diabetes epidemics, technological advances and personalised medicine. Now that big money is involved, mHealth is taken more seriously and both major advances and deployments can now occur.

Amongst different countries, even with the same development status and language, distinct mHealth usage differences can be seen. In the case of the USA and UK there is a noticeable different in mHealth adoption. The US has seen much greater growth in mHealth than the UK has and doesn't seem to be changing quickly. The reasons for this difference in adoption rates is the type of health markets in the two countries. In the USA, the health market is consumer-driven as health is either financed by the consumer or through private medical insurance for now although this is beginning to change with national insurance being implemented. In the UK, however, almost all healthcare is government financed in the form of the NHS and this has lead to the consumers not expecting to pay for their health. In the US the mHealth market is also driven by the healthcare payers as they see it as a way to reduce costs, however in the UK there is little to no push by the UK government or NHS to increase mHealth adoption. The NHS is under heavy financial pressure now leading to more private healthcare funding which may lead to increased mHealth adoption in the UK in the near future, reducing the difference between the two countries (Davis 2014). A report by the Center for Technology Innovation at Brookings did a comparative study of mHealth adoption between the USA and China. Both countries had many similar trends such as increasing mHealth adoption, mobile device adoption and importantly, annual health cost. The mHealth market in China has been exponentially increasing and is now just shy of half that of the US, 5.9 billion US \$ versus 2.5 billion US \$. The authors did come away with four ideas to help speed up mHealth growth in these two countries based on current problems encountered (Xiaohui et al. 2014). These being:

• Policy makers should encourage the use of mobile devices in healthcare whether mobile phones, tablets, PDAs, etc.

- Public officials should reimburse medical professionals who make use of mHealth devices for remote consultations, diagnostics or treatments.
- Reminder messages should be sent to patients via SMS or other texting medium
- Figuring out what works and doesn't work is one of the biggest problems currently in mHealth. Government should assist with this both in terms of financing and policies

Investment in mHealth has now reached new record breaking highs this year with technology companies getting over \$700 million USD in the first three months of 2014 which is an 87% increase compared to the same quarter last year. These investments were in everything from secure HIPAA compliant texting to health analytics and telemedicine companies (Bresnick 2014). Crowd funding of mHealth companies is also a new trend which is proving to be very successful with many extremely successful projects starting from humble crowd-sourced roots. Crowd funding companies are coming into their own and booming themselves, not just in the domain of health. All of the big brands have released health related products over the last year including the likes of Google, Apple, Samsung, Withings, Greylock Partners, etc. It is worth noting that the healthcare industry is a much bigger industry than the technology industry and therefore healthcare has the potential to have a massive influence on the technology market and its size (Finn 2014).

#### **M-Health Applications**

Both the Apple and Google play contain tens of thousands of health applications. Apple has called the category "Health & Fitness" and it's here where a big problem with mHealth applications begins. While there are tens of thousands of apps related to health in someway out there, the explosive growth and lack of desire by these large companies to give them special treatment or extra regulation/curatorship has lead to highly specialised professional applications being lumped together with unscrupulous snake-oil applications. To illustrate this with an example, a very popular app called Medisafe by Medisafe Project, that can be found in the Google or Apple stores for free, self-proclaims itself as the top rated medication reminder application. While it contains links to everything from Fox News to Med City News in the description, the UK store only

has 4 user reviews, none of which can be verified. The application itself has gone through no audit or regulation process. There is no privacy statement viewable and yet many users are happy to trust this application to manage their drug taking as well as provide it data that is patient health information without knowing any security details.

The mere fact that there are tens of thousands of healthcare apps, and more by the day, doesn't necessarily bode well for mHealth. While quantity is good, quality quantity is better. A report by the IMS Institute for Medical Informatics analysed about 44,000 applications on the English US iTunes store and almost immediately excluded approximately 20,000 of them as they made bogus claims. Of the remainder analysed on a scale of 0 to 100, more than 90% of applications scored 40 or lower. The report also took user-friendliness into account and further rated the applications by category (Aitken 2013). What this report does highlight, is the need for consumers to be wary of applications they use or download, especially if non-free. It also highlights how difficult it can be to differentiate the useful from non-useful or even worse, dangerous.

A company called Happtique (<u>www.happtique.com</u>) tries to solve this problem by having their own list of applications which doctors can digitally prescribe to their patients which they receive by SMS or E-Mail, sorted by detailed category and condition. Happtique also had their own certification program which was very slow and worse yet, was suspended in December 2013 when basic security flaws were discovered in 2 of their 16 certified applications which once again highlights the difficulty in certifying health applications. The app prescription part of the service still exists though as they have even created a proprietary algorithm called the Happtique Engagement Score which they say objectively analyses apps using key components—including psycho-social considerations, persuasion and education tools, and content validity—that have empirically shown in studies to promote or influence behavior change. There are no research papers or reviews on this algorithm though to show how effective it is.

Some countries such as Brazil differ from more developed countries in that they have most of their mHealth development coming from Universities (56%) and Health Units (32%) rather than from commercial companies. The survey of research initiatives (Iwaya et al. 2013) also pointed out that this has lead to an interesting situation where the majority of applications are targeted at physicians (55%) and Community Health

Agents (33%). The latter being an important part of the Brazilian Governments national health programme. Only the minority focus on specific disease while the majority focus on general health (57%). Worryingly for mHealth development is that 52% of the mHealth projects lacked security mechanisms that could put health information at risk and is an important consideration in mHealth technology deployment. This factor alone could hinder adoption of the various technologies until resolved.

There are many categories of heath applications all with unique defining characteristics, a few of the major categories and defining characteristics of mHealth applications can be seen in the flowchart in *figure 2* below:

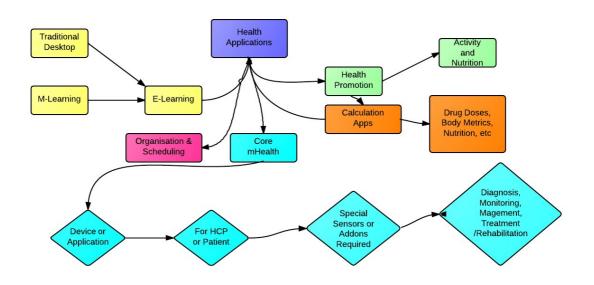


Figure 2 – mHealth defining categories & characteristics by Roberto Vietri

As already mentioned, categorisation and rating of applications is extremely difficult. Based on research from numerous sites such as the health category in app stores, apps certified on Happtique and other sites such as imedicalapps.com, a selection of the most popular medical apps in the world which are designed with professional collaboration and are highly respected in the medical community are listed in *Table 2* along with categorisation columns as per *Figure 2*.

App Title	Free/ Paid	Category	HCP/ Patient	Add-ons required	Purpose	Regulatory
UpToDate	Paid	E-Learning, Reference	HCP & Patient	No	Management, Treatment	No
Medscape	Free	E-Learning, Reference	НСР	No	Management, Treatment	No
MedCalc	\$1.99	Calculators	НСР	No	Management, Treatment	No
EyeMD	Free	Calculators/T ools	НСР	No	Monitoring	No
MyFitnessP al	Free	Health Promotion	Patient	Optional	Monitoring	No
Lifesaver	Free	E-Learning	Patient	No	Learning	No
AliveCor	Free (Device: \$199)	Disease Detection	Patient & HCP	Yes	Monitoring	FDA Approved
iHealth Wireless Pulse Oximeter	Free (\$69.95 for device)	Calculators	Patient	Yes	Monitoring	FDA Approved, CE Approved
New England Journal of Medicine	Free (Paid add-ons)	E-Learning	НСР	No	Learning, News	No
Radiology 2	Free	E-Learning	НСР	No	Learning	No
Diabetes Manager by Welldoc	Free (required paid add- ons)	Disease Management	HCP & Patient	Yes	Monitoring, Management	FDA Approved

 Table 2 - Self compiled summary of mHealth applications

#### **Current Unique Uses**

#### Diabetes

Diabetes would seem an ideal area for mobile devices which can analyse blood glucose, store or transmit the data and then finally send it to a server or service for tracking and analysis. This can then be analysed by primary health care providers or specialists instantly without the patient so much as making an appointment. Diabetes is also an increasingly common disease and the fact that it's more common in affluent countries such as the USA vs developing countries make it an even easier target for funding, especially personal funding. Diabetes is a disease which requires lifestyle modification as well as blood sugar monitoring and medical drug management. mHealth technologies are capable to assist in all these areas to improve overall health outcomes. There are obviously economic hurdles that need to be overcome which is a common issue with mHealth projects, as well as the fact that few mHealth apps or devices for diabetes have been rigorously tested. Outcome studies of the use of mHealth for diabetes from the literature have shown the potential for benefits, but higher-quality studies are needed (Klonoff 2013). The safety and efficacy of a device intended for a disease such as diabetes is obviously important due to the life threatening complications that can occur both acutely and chronically especially in type 1 (insulin dependent) diabetes.

A systematic review of 18 different studies from 1985-2008 found that wireless devices can improve diabetes self-care, and that pedometers were effective lifestyle modification tools however the authors concluded that additional controlled trial studies were needed focusing on both existing and novel technology and the health outcomes associated with diabetes (Russell-Minda et al. 2009). One platform which is well researched and clinically proven to improve health in diabetics is the DiabetesManager platform by Welldoc. The Welldoc platform requires a per user month-to-month subscription which collects information such as blood glucose, food information broken down by category and ties this in with meal time data. This cost is not insignificant but two health insurers have already agreed to pay \$100 a month for patients to use the platform. This data is instantly sent to the platform where it can be analysed by HCPs and corrective action can be taken where necessary. More effective diabetes management is important as only a small minority of patients reach combined HbA1c goals and blood pressure goals. A randomised control study on the Welldoc platform found both statistically significant improvements in A1c controls as well as both patient and HCP satisfaction with the system (Quinn et al. 2008). mHealth technology is already making measurable improvements in diabetes care however further advancements such as wireless sensors which automatically transmit the data without user intervention as well as improved statistical algorithms and increased familiarity by both patients and HCPs is likely to lead to increased efficiency and health outcomes by the system. This global blood tracking market is estimated to be worth about \$12 billion USD by 2017 according to the research firm GlobalData. While mHealth applications are currently focusing on manual input from users, the new breakthrough multiple large companies such as Apple, Google and Samsung are looking at is non-invasive blood sugar monitoring. Non-invasive technology could take many forms. Electricity or ultrasound could pull glucose through the skin for measurement, for instance, or a light could be shined through the skin so that a spectroscope could measure for indications of glucose. Apple has poached multiple executives and bio-sensor engineers from firms such as Masimo Corp, Vital Connect, and the now-defunct glucose monitoring startup C8 Medisensors. "All the biggies want glucose on their phone," said John Smith, former chief scientific officer of Johnson & Johnson's LifeScan, which makes blood glucose monitoring supplies. "Get it right, and there's an enormous pay-off (Farr 2014a)."

With all new technology, consumers should be wary of buying into applications or devices that don't have solid evidence behind them both in terms of their safety and efficacy. Diabetes medical apps which measure blood sugar would fall under current US and EU regulations for compulsory regulation and therefore have more stringent checks than many apps in the field currently have.

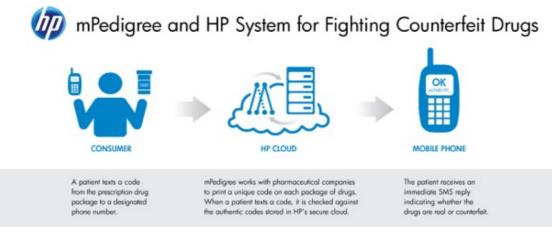
#### The fight against counterfeit drug manufacturing using mHealth technology

Unfortunately the reality is that it is far easier to counterfeit a \$50 pill than it is to counterfeit a \$50 bill. It's for this reason that a large number of SPAM e-mails received are trying to peddle drugs like Viagra and Cialis. Online pharmacies such as Indian Generic Meds and Canada Pharmacy Online are a dime a dozen and of course most are willing to ship anywhere in the world that people are willing to pay for them at prices

often far below what the genuine pharmacies sell them for, and for good reason. Counterfeit drugs used to mainly be the problem of developing nations where studies of anti-infective treatments in Africa and Asia have shown that 15-30% are fakes, and the UN estimates that half of the anti-malarial drugs in Africa, worth approximately \$438 million USD a year, are counterfeit (The Economist 2010).

Many technological and other solutions have been attempted to combat this counterfeiting. While almost any anti-counterfeiting technique can eventually be overcome, the idea of course is to make it too expensive and therefore unprofitable for the counterfeiters so that they'll resort to counterfeiting products other than pharmaceuticals where it would be easier. Many big names in the IT industry have assisted in this role, Oracle has created a program called Pedigree to assist the drug manufacturers in tracking drugs while IBM and other firms have gone with an RFID solution which allows for both tracking and tampering detection. While these solutions are far more effective than the simple holograms which were used in the past and are now relatively easily replicated, they can be impractical and costly in developing nations who have neither the infrastructure nor funds for these methods.

HP and mPedigree have come up with a solution initially targeted at Nigeria and Ghana, where the mPedigree social enterprise network has its roots. The system is relatively simple and free to the consumer. A scratch off label is applied to the pharmaceuticals by the manufacturer with a unique code. This code is then scratched off by the consumer and sent via SMS to a free number when an immediate reply is received confirming the product as genuine or not (Zax 2010). All the genuine numbers are stored on cloud servers run by HP in Frankfurt, Germany. The system, while relatively simple, is both cheap and effective and takes advantage of the fact that almost everyone in Ghana and Nigeria has a mobile phone of some form which doesn't need to be a smartphone.



ELIMINATING COUNTERFEIT DRUGS COULD SAVE 700,000+ LIVES A YEAR.

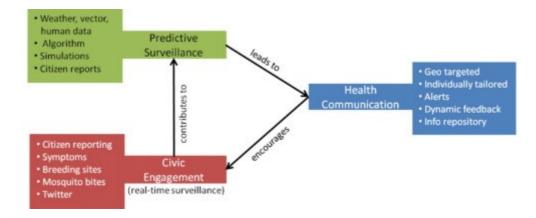
#### Figure 3 – mPedigree

### Mobile Health in Disaster Zones

Haiti experienced a major earthquake in January 2010 and on 21 October 2010, the CDC confirmed an outbreak of cholera. This was despite cholera outbreaks seeming highly unlikely as they hadn't been experienced in Haiti for decades. Cholera also requires two conditions to spread in a population: (1) There must be a severe breakage in hygiene systems such as water and sanitation and (2) Cholera must be present in the population (CDC 2010). Mobile phones specially programmed by Nokia were brought in to assist with the epidemic. Both the Cholera victims as well as the supplies required such as soap, clean water, bleach etc. needed to be tracked in real-time due to the remote location of many villages, some of which took hours of traveling by foot in order to submit reports. Accurate and up to date information was very important in fighting the Cholera. An interface was created on the mobile phones in Haitian Creole which allowed HCWs to input the data and transmit it instantly in the local language to the national coordination center (Lincoln 2010). Following the successful use of the mobile phones during the Cholera epidemic, they were rolled out again in Haiti to be used by Haitian water technicians to track chlorine usage in two thousand households, later to be expanded to 40,000 households (Kaye et al 2012).

An interesting use of mobile technologies was used to assist in the treatment of paediatric malaria outpatients in Kenya. A randomised control study was setup in which the intervention group of HCWs received one way text messages daily for six months reminding them to follow proper treatment guidelines in artemether-lumefantrine use, a drug used in malarial treatment. This included texts such as "Check ALL sick children <5yrs for any severe signs! Also check for fever, cough, diarrhea, pallor & any other problem." Intention-to-treat analysis showed that correct artemether-lumefantrine management improved by 23.7 percentage-points (95% CI 7.6-40.0; p=0.004) immediately after intervention and by 24.5 percentage-points (8.1-41.0; p=0.003) 6 months later (Zurovac et al. 2011). This simple and effective one directional communication intervention showed both immediate and long-term health benefits.

mHealth technology has also been used in other countries with mosquito caused problems such as with Dengue fever, also known as "breakbone fever" in Sri Lanka. Dengue fever is a disease caused by the dengue virus which uses the mosquito as a vector. There is no current vaccine and only supportive therapy. There is a wide range of severe symptoms which can lead to life threatening conditions such as dengue hemorrhagic fever and dengue shock syndrome. A platform known as "Mo-Buzz" has been created to combat Dengue. It consists of three integrated components. The first being predictive surveillance which uses computer analytics to give advanced warning to the public and HCPs about future outbreaks. The second being civic engagement which utilises social media to engage the public and allow them to communicate with HCPs by reporting symptoms, mosquito bites and breeding sites using mobile devices. The third component is health communication which allows for the sending of customised health messages to aid in both prevention of future infections and to increase knowledge in the general population (Lwin et al. 2014).



(Lwin et al., 2014) - Reproduced with permission (license 3385901319982) Figure 4 - Mo-Buzz platform to combat Dengue

#### Wireless ECG Monitoring

Atrial fibrillation is a common cause of stroke and can increase the risk of having one up to about 5 fold. Atrial Fibrillation is often asymptomatic leading to a large pool of undiagnosed patients who therefore don't receive any therapy. Alivecor has released a simple mobile device case which wirelessly attaches to the phone or other mobile device and allows for single lead ECG analysis. Initially the system only allowed for manual remote reading by cardiologists but not includes automated algorithms which can give a result in seconds without human intervention. The device currently retails both online and over-the-counter for approximately \$199 USD and has recently been FDA approved. This is currently only available in the USA both for online order as well as over the counter. The case is simply touched with both hands and records the ECG which it then transmits to the AliveECG app on the device via ultrasound at 19KHz which is then sent to a cloud based secure storage which can be retrieved by the user at any time. This is simple enough to be used by the layperson and the elderly. The results of both the readings as well as the newer automated algorithm have been validated in studies (Table 2) and the device allows the user to submit his personal readings to aid in future research and further fine-tuning of the system.

This low-cost and quick system allows for mass population screening for atrial fibrillation even in locations such as pharmacies and GP clinics, where it would usually

have been missed. The financial saving according to Alivecor is estimated to be about \$4,000 USD as measured by QALY, and \$20,700 USD if a stroke is prevented. Given the high rates of undetected AF in the aging population at risk and the effectiveness of anticoagulation in reducing stroke, widespread screening to detect sub-clinical AF using a smartphone and an automated algorithm could have a substantial impact on reducing the stroke burden (Lau et al. 2013).

Table 3 – Performance of single lead iPhone ECG for detection of AF

	Sensitivity	Specificity	Accuracy	Kappa
Learning set (n = 109)				
Cardiologist A	100%	90%	94%	0.87
Cardiologist B	95%	94%	95%	0.88
Original algorithm	87%	97%	94%	0.86
Optimized algorithm	100%	96%	97%	0.94

Reproduced from (Lau et al., 2013)

#### **Online Appointment Scheduling**

Appointment scheduling is not technically an mHealth app but falls under the general organisers category of applications with specific functions designed purely for the health sector. It is still worth mentioning due to its direct influence on all aspects of health services. While NaviGo Health has recently released a compatibility tool for finding doctors which may make one think they're using Match.com instead, other scheduling applications have taken a somewhat more traditional approach. DocASAP is one such platform which has recently been released for the US market and allows customers to search on any device for a specialist or primary health care provider in their area by ZIP code and the insurance they accept, and then make an appointment online. This system still allows the physician to manage their free time as they wish while helping attract new patients as well as fill up free time slots which would've otherwise been vacant (Baum 2013). Increasingly patients are becoming frustrated at long waiting times of weeks and sometimes months to see a specialist, this system helps dramatically reduce these times while giving patients additional information such as information about their doctors qualifications and even reviews by other patients. Bill Sonn, UCH's senior director of marketing, communications and media relations, said doctors were initially reluctant to open up their already-busy schedules to patient perusal, but have since come to understand that they still have complete control over who they see, and can much better manage patients, cancelled appointment and no-shows through the portal (Wicklund 2014). DocASAP is further expanding the reach of their online platform with applications soon to be released for iOS and Android.

A similar app developed and used on the other side of the ocean is Dodo (http://www.dodo.hr) in Croatia made by Digital Europe Ltd in Zagreb, Croatia. The name itself is derived from the Croatian for good doctors and it is exactly this which is the slogan and marketing line of the system. Similar to DocASAP, it allows for the searching of doctors by specialty and city and then booking the appointment online. A fundamental feature of the system is the ability to both view and rate the professionals online which include not only doctors but also dentists and even biochemists. It also includes some additional miscellaneous features such as a page where one can find discounts or specials for various procedures. A system like this in Croatia is more noteworthy as Croatia's medical system is mostly public with health insurance covered by the government health insurance agency HZZO and as such, is appealing to a much smaller portion of a much smaller country than the likes of the USA with their significantly larger and more private healthcare sector.

#### **E-Learning Tools for Medical Professionals and Medical Students**

Not part of mHealth, E-Learning is changing the way medical professionals and students learn and find medically relevant information. Historically using a mobile device such as a phone around a patient or even a nurse was frowned upon, the immediate assumption was that one was doing personal work, disinterested or worse. These days, tablets and phones are common place and even encouraged, both in developed and developing countries. The days are fast disappearing where medical students had to find lab coats with big enough pockets to hold a collection of mini books for quick reference of the myriad of medical conditions, drug information and dosages and to make notes. Not only can almost all the popular books be found in app form for most devices now, but they even automatically update to the latest version. While this may be slightly less important for a reference book such as Oxford

Handbook of Clinical Medicine which is a firm favourite of medical students in the UK and Croatia, it is very important for reference items such as drug information and dosages which change often. A popular example of this is the BNF in the UK which is available in app form in both versions (adult and children) for free to all NHS employees and students. This is not only more up to date than the paper-based versions usually are but its ease of use and availability allows for quick drug interaction checking leading to increased patient safety and satisfaction. In the United Kingdom there is now a large push towards using digital references. Most Hospital libraries have subscriptions to various journals with online access, subscriptions to services like UpToDate and of course access to all local published treatment guidelines and any other Internet resource. UpToDate is an online platform worth mentioning in it's own right due to it's size and worldwide usage. It is used by more than 850,000 physicians in 164 countries to provide the latest evidence based peer reviewed treatment guidelines (Uptodate Inc 2014). Needless to say, just having the tools on hand doesn't mean that they are providing for better healthcare or improving outcomes however in this case more than 30 research studies confirm widespread usage of UpToDate and its association with improved patient care and hospital performance. One study published in the Journal of Hospital Medicine found that patients admitted to hospitals using UpToDate vs hospitals not using UpToDate had shorter length of stays, lower risk-adjusted mortality and finally, hospitals with UpToDate had better quality performance for every condition on the Hospital Quality Alliance metrics (Isaac et al. 2012). This is a tool which can be accessed on any smartphone, tablet or desktop anywhere in the world for the latest information. This is not unique to UpTodate as other studies have confirmed that when HCPs use library and information resources, up to <sup>3</sup>/<sub>4</sub> of them said they had definitely or probably handled aspects handled aspects of the patient care situation differently as a result of the information (Marshall et al. 2013).

The application landscape goes far beyond purely reference tools though for students and HCPs. Educational resources such as 3D anatomy applications allow students to visualise the human body in ways impossible on a 2D medium such as paper. Some medical schools such as University College London and Leeds are starting to trial ways of giving out textbooks on smartphones. Welsh Foundation Doctors are trialling iDoc, a searchable version of four Oxford handbooks with the British National Formulary (BNF) to help with the transition from medical student to F1 which is the first year post medical school graduation for medical students in the UK (Kimpton 2014). For the students in upper or clinical years. applications such as Prognosis test you on patient treatment by giving simulated cases which the user then has to deal with and get live feedback on from the application. Applications such as Almostadoctor allow for quick reference of common conditions in a very simplified form with all the major pertinent points which allows for quick brushing up during ward rounds on conditions which are no longer as familiar as they should be.

#### Health Specific Calculation Applications and Other Miscellaneous Applications

Higher level applications for doctors can be found everywhere. Everything for CliniCalc which includes a calculator for almost every single medical formula imaginable to ultrasound learning applications. The applications are becoming increasingly more specialised and with many of the creators now doing evidence based research and getting regulatory approval, they are also a lot more professional than the gimmicky applications which initially flooded the app marketplaces. Some which particularly stand out are applications like Lifesaver made by the Resuscitation Council of the UK and a production company UNIT9. The application is available on both smartphones and tablets and immerses the user in a cinematic scene filmed by real actors where they have to make life and death decisions based on the latest first aid CPR guidelines to effectively treat and hopefully save the simulated patient. This once again leverages the unique advantages that these devices offer to aid in educating the public in ways which are both fun and improve recall of what they've learnt. This application has been made available for free. Other applications such as CPR Tempo are designed for actual resuscitation and act like a metronome in order to help the provider do compressions at the exact recommended rate, something which laymen and even professionals often struggle with.

#### **Financing Healthcare in Developing Nations**

Mobile banking and even payments are becoming more popular in developed countries with the UK recently introducing Paym, a service which allows the linking of a bank account to a mobile number and therefore anyone to send and receive payments from any bank in the UK while only giving their mobile, creating a completely bank neutral system. However Kenya's M-Pesa has taken the crown title of being the biggest mobile banking platform in the world with over 13 million active customers. This unique platform allows for payments and savings for people who would not normally have access to banking infrastructure which allows them to not only pay for medicine but also save securely towards any future health needs.

A more direct use of this mobile payment technology and health though is by an agency known as Pesinet in Mali. Pesinet takes mobile technology and combines the health aspects with payments and insurance. Families pay a monthly fee and in return they get checkups and half the cost of any medications required covered. The HCWs also use mobile phones and enter the checkup data into a customised application which is all sent to a central database. This database is reviewed by doctors and if anything noteworthy is found, the HCWs get a notification alert on their mobile phones (Lincoln 2014). All of this mobile technology aiming to tackle Mali's extremely high infant mortality with an infant mortality rate of 110 per 1000.

## **Regulations and Approval Bodies**

#### When is a Mobile App a Medical Device?

As simple as this question sounds, it is a fundamental one which is causing problems for application developers and even the users of such applications worldwide. Medical devices themselves are highly regulated worldwide with strict legal frameworks and representative bodies. The FDA being responsible for this in the USA, but mobile applications themselves tend to have little to no regulation worldwide, and at best tend to have security checks done in virtual stores such as the Apple Store and Google Play Store. To further add to this complexity, certain applications may be an intermediary step between a controlled medical device such as an electronic blood pressure cuff and the mobile phone which could be used to send the information to the patient's doctor.

Development of mobile applications for healthcare applications is relatively expensive compared to simpler and less scientific applications. This lack of certainty in the regulations can hinder application development investment and therefore, mobile application development worldwide. Worse still, providing an easier market for unprofessional and lower quality applications to flood the marketplace. The lack of strict regulations, on the other hand, does give application developers more leeway to develop as they wish, where more strict regulations may stifle the rapid development currently seen in health related mobile applications.

#### FDA

One of the most famous medical regulatory agencies in the world is the FDA which regulates mHealth applications in the USA. In July 2012, the U.S. Congress passed The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), which directed the FDA to come up with a proposed strategy and recommendations within 18 months. It directed the FDA to create a risk-based regulatory framework pertaining to

health IT that promotes innovation, protects patient safety, and avoids regulatory duplication (Litt 2014).

In September 2013, the FDA released their guidelines that are available from the FDA.GOV website. This 46 page guidance aimed at Industry as well as FDA staff contains a lot of non-binding guidance and definitions. It is written with many examples to try and help the staff separate apps that are definitely not regulated from those that are, while leaving a grey area in the middle. In grey areas, where the FDA guidance still provides no clear answer, the agency has said it will exercise discretionary enforcement, essentially leaving open regulatory options if they believe the situation warrants it. The document does specifically mention categories of applications which are excluded from the definition of medical applications and are, therefore, not regulated by the FDA, this includes things such as electronic versions of textbooks and Electronic Health Record (EHRs) applications.

#### **MHRA and EU Regulations**

The Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, is the body responsible for the regulation of medical devices in the UK. While regulation is set at a European level under the Medical Devices Directive, the MHRA is the Competent Authority for the UK and therefore has responsibility for interpreting and enforcing legislation transposed into UK law

The Medical Device Directive 93/42/EEC (MDD) is the primary source of regulation governing health apps across European member states. In essence, the directive defines what constitutes a medical device, how medical devices should be regulated according to different classifications, and how devices should be marked to demonstrate their conformity. It is important to note that under most circumstances, EU directives do not have direct effect: they only come into force when implemented in national legislation (Devices 4 Limited 2012)

The MHRA also attempted to define exactly what a mobile device is under Article 1 of the MDD as well as attempting to define and cover the treatment of mobile health apps. Despite numerous pages dedicated to precisely this, it leaves much room for further clarification and is ambiguous in many areas. Whether applications are regulated and fall under the MHRA is still a thorny one which Devices 4 (Devices 4 Limited 2012) has tried to give some guidance on in figure 5 below.



Source: Devices 4 Analysis

Figure 5 – Likelihood of an application being classified as a medical device

## **Relevant Regulations in Europe**

Beyond the Medical Devices Directive (MDD) which is the primary legal framework for mHealth, many other frameworks are relevant to application developers such as Liability for defective products (1985/374/EC &1999/34/EC), General product safety (2001/95/EC), Data Protection (1995/46/EC) etc.

Of special importance worth noting is that there is no central registry of manufacturers or medical devices in the EU and therefore this makes both registration and verification of registration more difficult. Under the MDD, each member nation has a specific Competent Authority which is responsible for registration and issuing of the CE mark before a medical device can be approved. Once it is approved in one member state, it is automatically approved in all member states. Competent Authority requirements and regulations may and do vary by state and therefore different medical devices or applications may meet different requirements depending on where they are registered which poses additional problems as well as creating potential loopholes for manufacturers and developers to exploit. Hopefully more coherent regulations and registries will be developed in the future.

In the EU, there are no binding rules as to the delimitation between lifestyle and wellbeing apps and a medical device or in vitro diagnostic medical device. Since January 2012, in order to help software developers and manufacturers identify whether their products fall or not under the Medical Devices Directive or the in vitro diagnostic medical devices Directive, the Commission's services have issued some guidance on this issue, which will be continuously updated. According to this guidance, depending on their intended purpose, apps may fall under the definitions of a medical device32 or of an in vitro diagnostic medical device and consequently will have to comply with the relevant provisions of the aforementioned directives (European Commission 2014). This has not yet been clarified by any binding rules and therefore there is still a lot of room open for interpretation.

## **The Future**

#### **Factors Hindering mHealth Growth**

A major influence on the growth of mHealth is of course the issues with the applications or devices, or even the perceived issues with them. The lack of IT skills is a major problem worldwide with IT growth often exceeding IT skills supply. Other important problems worth mentioning are the lack of inter-operable standards between devices, communication technologies and data from the applications. There is also the different markets to consider whether private or public and the different funding and needs for them. Luckily work is being made in all of these areas but due to the fact that mHealth is still a very unregulated territory, it still remains difficult for the public to separate the good from the bad.

#### **Poor Integration of IT Systems**

IT Systems are often a mash of different programs specifically designed for a purpose. A GP (primary health care) system for example has very different needs and design to a tertiary hospital ward management system which once again is different from a radiology department film management system. To make matters worse, device manufacturers such as those of X-Ray machines or CT scanners often make their own systems and then worse still is that these are built on top of different stacks including different operating systems and these are designed to work on different devices.

The end result is often a mix and match of different systems with different logins, interfaces and more importantly, data storage. This often means that while something like all the patient information and results are in one system, the patients x-ray is in a completely separate and incompatible system and these often vary by hospital or region making it pretty common to have personnel assigned to purely obtaining information from other hospitals, GPs and various other sources and then importing them into the

system where it is needed, causing delays and extra costs. Just 53% of doctors say that the mHealth applications and services they use work with their organisation's information technology (IT), and even fewer say they are integrated with technology in other parts of the health system (Cooper 2013). Unfortunately the rapid development of technology also has a downside in this regard and that is that continual development of new systems and rapid changes mean that systems often struggle to keep up.

This lack of interoperability has led to a term known as "medical bridges to nowhere" coined by Patrick Soon-Shiong when he described the complete waste of money and resources in creating various systems which aren't inter-operable (McCann 2014). In particular he noted the rush to create Electronic Medical Record (EMR) systems due to legal changes but with no middleware allowing them to communicate to each other. This lack of interoperability can be found throughout the EU, with organisations such as the Continue Health Alliance working to improve this by creating interoperability standards.

Ensuring interoperability in eHealth is complex. For instance, millions of terminologies and vocabularies are required to describe and code health data48. This complexity is compounded by the wide heterogeneity of health information systems in the Member States (implemented by health authorities, hospitals, or doctors etc.). The eHealth Network, established under Directive 2011/24/EU on Patient Rights, is leading the development on EU eHealth guidelines. It aims to enhance interoperability among electronic health systems and to ensure access to safe and high-quality healthcare (European Commission 2014).

#### **IT Skills**

IT Skills and professionals are currently at a severe shortage right now meaning that companies and the end-user is less likely to adopt new technology. New technologies in big corporate environments require a lot of time and expert resources in order to allow for a smooth transition and to not hit any major snags further down the road. One of the biggest IT system roll-outs in history, that being the healthcare.gov website for the new

"Obamacare" in the USA, experiences a series of major software bugs significantly delaying the roll-out and costing significantly more money (Acosta 2014). This IT skills shortage include the likes of HCPs who usually have done very little IT training. There is of course a time and cost factor to train HCPs up to the level required to satisfactorily and efficiently use eHealth systems, and this needs to be weighed up in cost vs benefit before any eHealth deployments.

#### **Public vs Private Healthcare Sectors**

The varying needs of the public and private healthcare sectors can have a major influence on funding and design of the IT systems. Governmental systems are often nationally oriented and very structured with everything being all-encompassing. Private healthcare sector systems don't need to be and therefore can and are more likely to be on the cutting edge. More so, there is very little overlap or shared funding between the two sectors meaning that there is often no compatibility between them either.

#### **Data Protection and Trust**

Confidentiality of patient health information is considered one of the core requirements of the Hippocratic oath and in this stead, the notes we take whether written or digital need to protected. This is pretty simple with written notes as they can just be locked away but with digital notes it's not that simple, as even a password on the device or software does not guarantee confidentiality. A design of the healthcare system from the ground up with privacy in mind has to be done. This often requires specific advanced skills in secure system design and encryption systems. Even when all this has been done, there have been numerous security breaches in multiple countries in the past with medical professionals or administrators taking confidential data home or to other locations using portable devices or Internet accessible systems. If either the healthcare professional or patient are unable to trust systems to keep the inputted data safe, then they are far less likely to be used and trusted especially now with additional laws being added to further enhance the protections for data security as well as the repercussions for breaches thereof. Dr Mike Sevilla points out that during his talks to patients, they are very sensitive to their health information, especially the less technology savvy ones (Sevilla 2014). Furthermore, mHealth manufacturers are often unaware of the legal and medical framework of the systems they design, especially the smaller manufacturers.

According to a Financial Times investigation, 9 of the top 20 health-related apps have been found to transmit data to one of the dominant companies tracking details about people's mobile phone use.

Apple recently announced their up-and-coming Healthkit framework in the new iOS 8 which will have the potential to do things like two way communication of user health data to Mayo Clinic and Epic hospitals. There is no mention of HIPAA compliance or how secure all this health data is on the phone itself.

### **Safety of Applications and Dubious Claims**

Healthcare apps are flooding the Internet and the application marketplaces daily. The minority of which are professional and properly designed. With apps claiming to do anything from diagnose diseases just by taking pictures to others allowing for selfdiagnosis or crowd sourced information, there is a serious risk of misdiagnosis and incorrect health information. While this is not limited to technology itself as issues such as black-market prescription drug ordering and quack therapies have continually been an issue, this does bring a multitude of new opportunities for bad health information and tools directly to an individuals home. This being many scales worse than the patient who still sees his GP after coming to the conclusion he has an unlikely rare disorder due to something he read on the Internet. Unfortunately software for private use has little to no regulation right now and it's instantly obtained for free to low-cost. The low quality of many applications, the many dubious ones out there and the lack of regulation contribute to a general negativity towards encouraging end-users or patients to use medical software, devices or applications that aren't officially prescribed or from a limited specific resource. One research study found that electronic blood pressure monitors connected to smartphones available now often gave readings which were too high or too low (Mottl 2014). Consumers need to be assured that these mHealth devices are giving values which can be relied on and that they aren't swapping out physician time for inaccurate devices if these devices are not yet adequate to replace face to face interactions with a HCP. Apple has specifically mentioned electronic blood pressure monitors sending notifications to Mayo Clinic if the blood pressure was too high in their recent Healthkit demonstration (Sevilla 2014). What they didn't mention is what would happen with erroneous results either due to machine or user error. One paper also points out that "There may be a need to assess the legal issues arising from the use of lifestyle and wellbeing apps, in view of the potential safety risks they may pose to citizens' lives (European Commission 2014)."

### **Exciting New Technologies and Trends**

#### **Google Glass**

Google Glass is a pretty high profile product which has slowly been making it's way into the mainstream helped along with a large number of news reports and unique uses. One area where it is increasingly found is in medicine, this is despite the privacy concerns inherent with camera equipped eye-wear. The device itself looks similar to a regular pair of spectacles except for the one eye missing a frame and a noticeable little device attached to the right frame.

While Google Glass has been pioneered by many individuals in medicine such as broadcasting surgeries live while wearing the equipment, a more large scale uptake has occurred at the University of California, Irvine. The first major unique difference between UCI and other medical institutions taking up Google Glass is that every medical student gets to use the device during their studies, while not all will receive one themselves. First and second year medical students will use the device in anatomy and clinical skills classes while upper year students will use it during clinical rotations (Kerr 2014). UCI has also been testing the device in operating rooms, intensive care and the emergency department. This device allows all the information needed to be displayed right in front of the physician with a simple gesture rather than having to hunt through computers of manual medical records.

### Personal Health Records (PHRs)

Electronic Health Records are already becoming pretty common place in many developed countries however a technology which has been relatively slow to take off up to this point is PHRs. PHRs have a significant defining factor to that of Medical Health Records and that is that PHRs are compiled and maintained by the patient which is a stark contrast to the traditional records compiled and maintained by various HCPs. This increased control and accessibility by the user fits perfectly into the common trend we are seeing in mHealth apps which are increasing both of these. There are numerous free PHR systems which can be either desktop based or web based. Despite all these benefits and even a free price tag, the uptake is really slow and this can be mostly attributed to

user concerns over privacy and security. When polled, a total of 91% of Americans stated they were very worried about the privacy and security of their health information (Kaelber 2008). A review of free web accessible PHR privacy policies found that most privacy policies of PHR systems do not provide an in-depth description of the security measures that they use. Moreover, compliance with standards and regulations in PHR systems is still low (Señor et al. 2012). The lack of usage currently is a pity as PHRs can provide the user with numerous advantages such as saving the HCP time and money as all the healthcare information can be viewed clearly and in one place which saves a lot of repeated history taking and testing while at the same time giving more insight and more accurate information. This same data can be sent to the HCP by the patient without even scheduling an appointment which can avoid unnecessary appointment scheduling and healthcare visits. For these benefits to be realised, the PHR needs to be accurate, reliable and complete. It should give the user control over how the information is used and disclosed and the user should always have complete access to the whole PHR. Apple has recently announced a new Health App and HealthKit for their yet unreleased iOS 8 mobile operating system which created a relatively simple PHR system on an iOS device. This PHR can store information from various other apps and devices such as calories burned and sleep tracking but can also include more detailed medical information such as lab results, vitals and medications which can be sent to or viewed by HCPs. It even includes an emergency card function where important information can be viewed at a glance in an emergency such as medical conditions and allergies. This easy to use PHR push by Apple may be all that is needed to start seeing a large uptake and usage of PHRs in the near future by both consumers and application manufacturers.

#### **Prescribing Apps**

"Improve your health in a mobile minute" is the tag-line of Health-e-Apps part of the eHealth strategy of the University of British Columbia, Canada ("Health-e-Apps" 2013). While we are used to seeing prescriptions for medications and perhaps even physical therapy, a prescription for an application probably hasn't crossed most peoples mind. Dr Kendall Ho, an emergency physician and Vancouver General Hospital hopes to change that. "There are now on the market a lot of great apps that can help people achieve better health and really reach excellence in health," said Ho. "Some of those apps are actually free yet they're very, very useful (Shaw 2013)." In particular he makes

mention of My Fitness Pal (a calorie and fitness tracker), Heart Rate (an application to measure ones pulse) and Sleep Time (an app to monitor sleep and wake you up depending on whether you're in deep or light sleep). Dr Ho uses them as a physician in treating patients as well as personally in improving his own health. This is likely to be a continued trend with more physicians encouraging the use of apps such as these to assist their patients in dealing with and taking responsibility for their health.

### **Other Up and Coming Trends**

While all the latest developments and trends could fill books due to not only the development of existing areas of mHealth but also the creation of entirely new categories, a few interesting trends are worth mentioning. One such area if telemedicine where the improvements in the field of communication and robotics now allow for surgeons to complete an entire procedure from beginning to end from the other side of the planet. A related field is telemedicine diagnostics where ambulances now are often equipped with sophisticated tools such as ECGs and now even CT in ambulances. Specialised stroke ambulances in Germany known as VIMED STEMO carry a portable CT scanner and point-of-care laboratory. The CT data can be transmitted over encrypted 3G and 4G connections to trauma centers or emergency rooms (Stomp 2012). This allows for stroke therapies to be commenced before the patient even arrives at a hospital, allowing for the use of an extremely successful and time sensitive intervention.

Some uses which have already been mentioned but will see continued development and worldwide usage include areas such as in support on long term conditions (eg: diabetes self management), pharmaceutical supply chain monitoring and patient safety systems (eg: Sproxil and mPedigree), remote healthcare worker communication and training (such as Malaria SMS systems) and health promotion and and community mobilisation systems (eg: mHealth systems in Sri Lanka for Dengue Fever).

### Discussion

Future technological trends are notoriously difficult to predict. Famous quotes by leading names in the field such as Bill Gates with his 640KB memory (Lai 2008) and then later, the whole IT industry completely downplaying the potential for the mobile device, specifically tablets, completely not expecting the tablet revolution, and how it has changed day to day interaction with technology and the Internet. That being said; there are a few trends which are obvious and important. Namely mobile devices and applications are increasing in number and this is due to their decreasing cost, improving features and enthusiastic uptake in both developing and developed nations (ITU 2013). A question that can be asked is whether mHealth will broaden this divide or narrow it. Without a doubt, mHealth is beneficial to health in both markets however if trends continue, wealthy people will have access to advanced diagnostic tools, top specialists and continual monitoring right in the comfort of their home while at the same time, developed nations will still be using mHealth technologies to fight basic diseases and to just get basic access to healthcare.

The third and perhaps most important topic that needs to be discussed and perhaps rectified sooner rather than later is the issue of mHealth regulation, review systems and feedback processes. The lack of professional reviews, categorisation and concern of privacy and security of mHealth applications as discussed, is having a major effect on the uptake of mHealth worldwide. Further to this, while not seemingly a concern at this stage, is the safety of mHealth apps in dealing with patient advice and disease (Mottl 2014). While the danger may not seem as obvious as an unsafe defibrillator, the danger is just as real and without interventions worldwide to enforce the same level of quality and review which medical devices have to undergo, there will be negative effects on both morbidity and mortality due to the use of dangerous mHealth applications. Legal

issues also need to be evaluated in terms of liability for any repercussions due to use or failure of these applications (European Commission 2014)

The Internet has connected the world together and given instant access to information, as well as mHealth applications. In this vein one needs to fight against the temptation to view mHealth as the responsibility of nations to police, but rather a global problem where bigger bodies such as the EU or WHO need to get involved in creating universal policies and discussions to help steer mHealth in the right direction.

### Conclusion

Mobile devices and the technology involved have come a long way and continue to do so. Mobile devices have already overtaken traditional fixed line devices and they continue to become "smarter" giving us additional functionality that is quickly taken up by mHeath application developers. Smart devices which integrate with mobile devices such as the many we have mentioned (electronic BP cuffs, ECG sensors, etc.) are further turning mobile devices into high end professional machines which were once only found in hospitals. However despite all these advancements and continual upward trends including in health applications in general and mHealth apps. What they do not show is that mHealth applications have not kept up with the physical/device side of development. More than that, the current application stores are ill-prepared to even categorise health applications appropriately let alone review them for things as basic as security and safety, let alone even looking at the medical side of the applications. The national bodies responsible for regulating mHealth and health-related applications in general are only now starting to release guidelines in some countries, which as discussed, lack clarity, are non-binding and don't even attempt to provide strict regulations. Where third parties have attempted to step in and provide their own certification, they too have failed and given up for now. These same factors are hindering mHealth growth more than any other factors. As new and improved frameworks are put in place to deal with all these new developments, mHealth will finally begin to realise its potential.

In the near future (next ten years), the current trend of HCPs and health institutions changing from paper-based records to EHR will go one step further with EHRs and PHRs becoming cloud-based. Accessible from anywhere at any time by anyone the user chooses whether that be the HCP, family or emergency services. All backed up and secure with fine-grained access control which can be set by the user. These same records will be able to be updated by hospitals, GPs and the user himself using a myriad

of mHealth devices and applications giving an accurate and comprehensive view of health which has never been possible before. This same system will give improved health outcomes, time saving and cost reduction. Analytics will be possible and immediate notification of irregular events can be sent to the user or a designated HCP. The integration of cloud computing with mHealth will then give access to all steps, which include monitoring, data collection, alerting, automated management, decision support systems, diagnostic and therapeutic use.

These are exciting times for mHealth, but it is a brand new technology and the world still needs to catch up, as well as both the HCP and patient mentality. Its use in disaster zones and against epidemics have proven to be effective but things like E-Prescriptions for drugs, as well as health applications, will soon become more commonplace and greatly aid in improving healthcare in the future. Medical student training in both IT skills in general and mHealth will greatly add in the success of mHealth in the future. The ability to independently appraise mHealth apps is currently an important skill until proper curated and professional health specific application stores and review systems are finalised. Hopefully the software giants like Google and Apple, who are beginning to push health applications more than ever now, also assist with the advancement in their quality and appropriate review systems. The next few years will tell.

# Acknowledgements

I would like to personally thank Prof. dr. sc. Jadranka Božikov for agreeing to be my mentor on this thesis and for her assistance in this regard. I would also like to thank all my mentors and teachers throughout my medical career who have passionately shared their knowledge and experience with me and given me this opportunity to use these skills in the service of mankind.

# References

Acosta J (2014, March 31) Website issues on Obamacare enrollment deadline day. http://politicalticker.blogs.cnn.com/2014/03/31/website-issues-on-obamacareenrollment-deadline-day/ Accessed 6 April 2014.

Aitken M (2013, October) Patient apps for improved healthcare: from novelty to mainstream.

http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a

Baum S (2013, September 5) Physician finder and scheduling tool raises \$800,000. http://medcitynews.com/2013/09/physician-finder-and-scheduling-tool-raises-800000/

Bresnick J (2014, April 8) MHealth, health IT investment break records in Q1 of 2014. http://ehrintelligence.com/2014/04/08/mhealth-health-it-investment-break-records-inq1-of-2014/

Carrión Senor I, Fernández-Alemán JL, Toval A (2012, Aug 23) Are personal health records safe? A review of free web-accessible personal health record privacy policies. J Med Internet Res. 14(4):e114.

CDC (2010, October 22) Cholera Confirmed in Haiti, October 21, 2010. http://www.cdc.gov/haiticholera/situation/

Collins F (2012) How to Fulfill the True Promise of "mHealth". Scientific American, 307(1), 16-16. doi: 10.1038/scientificamerican0712-16

Cooper P (2013) Emerging mHealth: Paths for growth. http://www.pwc.com/mx/es/industrias/archivo/2012-06-emerging-mhealth.pdf

Crompton H (2013) A historical overview of mobile learning: Toward learner-centered education. In Z. L. Berge & L. Y. Muilenburg (Eds.), Handbook of mobile learning (pp. 3–14). Florence, KY: Routledge.

Davis T (2014, March 28) MHealth in the US and UK: Two countries divided by a common language. http://www.mhealthnews.com/blog/mhealth-us-and-uk-two-countries-divided-common-language

Devices 4 Limited (2012) Regulation of Health Apps: A Practical Guide. http://www.d4.org.uk/research/regulation-of-health-apps-a-practical-guide-January-2012.pdf Dolan B (2010, February 19) Six differences between mHealth and eHealth. http://mobihealthnews.com/6624/six-differences-between-mhealth-and-ehealth/ Accessed 4 May 2014.

Dolan B (2011, December 16) Mobihealthnews. http://mobihealthnews.com/15324/why-aetna-acquired-itriage-app-maker-healthagen/

European Commission (2014, April 10) Green Paper on mobile health ("mHealth"). http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth

The Economist (2010, September 2) Fake Drugs: Poison Pills. The Economist. http://www.economist.com/node/16943895 Accessed 10 May 2014.

Farr C (2014a, May 05) Apple on medical tech hiring spree, a possible hint of iWatch plans. http://www.reuters.com/article/2014/05/05/us-apple-hiring-insight-idUSBREA4409020140505

Farr C (2014b, June 23) Apple, Google, Samsung vie to bring health apps to wearables. http://www.reuters.com/article/2014/06/23/us-tech-healthcare-mobilephone-insightidUSKBN0EY0BQ20140623

Finn T (2014, January 16) Healthcare Matters. http://hcmatters.com/2014/01/investments-healthcare-startups-skyrocketed-outsidersbeating-insiders-punch/

Health-e-Apps (2013) http://ehealth.med.ubc.ca/resources/resourcesmobileapps/ Accessed 19 May 2014.

Isaac T, Zheng J, & Jha A (2012) Use of UpToDate and outcomes in US hospitals. J. Hosp. Med., 7(2), 85-90. doi: 10.1002/jhm.944

Istepanian RS, Laxminarayan S, & Pattichis CS (2006) M-health: Emerging mobile health systems. New York, NY: Springer.

Itriage LLC (2014) About our Company. http://about.itriagehealth.com/about/

ITU (2013) ICT Facts and Figures [Brochure]. http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2013-e.pdf Accessed 4 May 2014.

Iwaya L, Gomes M, Simplício M, Carvalho T, Dominicini C, Sakuragui R, ... Håkansson P (2013) Mobile health in emerging countries: A survey of research initiatives in Brazil [Abstract]. Int J Med Inform, 82(5), 283-298. doi: 10.1016/j.ijmedinf.2013.01.003

Kaye J, Holstius D, Seto E, Eddy B, Ritter M (2012) Using NFC phones to track water purification in Haiti. In CHI '12 Extended Abstracts on Human Factors in Computing Systems (CHI EA '12). ACM, New York, NY, USA, 677-690. doi: 10.1145/2212776.2212839

Kerr D (2014, May 14) Google Glass handed out to medical students at UC Irvine - CNET. http://www.cnet.com/news/google-glass-handed-out-to-all-medical-students-at-uc-irvine/

Kaelber DC, Jha AK, Johnston D, Middleton B, Bates DW (2008) A research agenda for personal health records (PHRs). J Am Med Inform Assoc. Nov-Dec; 15(6):729-36.

Kimpton G (2014) 'Appy Days. http://www.medscape.com/viewarticle/823344\_6

Klonoff DC (2013) The Current Status of mHealth for Diabetes: Will it Be the Next Big Thing? J Diabetes Sci Technol, 7(3), 749-758. doi: 10.1177/193229681300700321

Lai E (2008, June 23) The '640K' quote won't go away -- but did Gates really say it? http://www.computerworld.com/s/article/9101699/The\_640K\_quote\_won\_t\_go\_away\_b ut\_did\_Gates\_really\_say\_it\_

Lau JK, Lowres N, Neubeck L, Brieger DB, Sy RW, Galloway CD, ... Freedman SB (2013) IPhone ECG application for community screening to detect silent atrial fibrillation: A novel technology to prevent stroke. Int J Cardiol, 165(1), 193-194. doi: 10.1016/j.ijcard.2013.01.220

Lincoln C (2010) Cell Phones Fight Cholera in Haiti. http://www.mobiledia.com/news/114015.html Accessed 10 May 2014.

Lincoln C (2014) Reducing Infant Mortality With Phones. http://www.mobiledia.com/news/121877.html

Litt A (2014, March 26) When is a mobile app a medical device? The future of healthcare may depend on the answer. http://blogs.computerworld.com/healthcare-it/23701/when-mobile-app-medical-device-future-healthcare-may-depend-answer

Lwin MO, Vijaykumar S, Fernando ON, Cheong SA, Rathnayake VS, Lim G, ... Foo S (2014) A 21st century approach to tackling dengue: Crowdsourced surveillance, predictive mapping and tailored communication [Abstract]. Acta Tropica, 130, 100-107. doi: 10.1016/j.actatropica.2013.09.021

Marshall JG, Sollenberger J, Easterby-Gannett S, Morgan LK, Klem ML, Cavanaugh SK, ... Hunter S (2013) The value of library and information services in patient care: Results of a multisite study. J Med Libr Assoc : JMLA, 101(1), 38-46. doi: 10.3163/1536-5050.101.1.007

McCann E (2014, January 15) MU creates 'medical bridges to nowhere' http://www.healthcareitnews.com/news/mu-creates-medical-bridges-nowhere

mHealth Alliance (2014) Frequently Asked Questions. http://mhealthalliance.org/about/faq Accessed 4 May 2014.

MHealth Evidence. (2014). https://www.mhealthevidence.org/ Accessed 4 May 2014.

Mottl J (2014, May 27) The imperative of safety in mHealth and why it can't be ignored. http://www.fiercemobilehealthcare.com/story/imperative-safety-mhealth-and-why-it-cant-be-ignored/2014-05-26

oAfrica (2013, Dec 7) African smartphone usage driven by savvy young South African, Kenyan, and Nigerian consumers. http://www.oafrica.com/mobile/african-smartphone-usage-driven-by-savvy-young-south-african-kenyan-and-nigerian-consumers/ Accessed 4 May 2014.

Quinn CC, Clough SS, Minor JM, Lender D, Okafor MC, Gruber-Baldini A (2008) WellDocMobile Diabetes Management Randomized Controlled Trial: Change in Clinical and Behavioral Outcomes and Patient and Physician Satisfaction. Diab Tech and Therap, 10(3), 160-168. doi: 10.1089/dia.2008.0283

Ritchie R (2014, April) Apple M7. http://www.imore.com/apple-m7 Accessed 6 May 2014.

Russell-Minda E, Jutai J, Speechley M, Bradley K, Chudyk A, & Petrella R (2009) Health Technologies for Monitoring and Managing Diabetes: A Systematic Review. J Diabetes Sci Technol, 3(6), 1460-1471. doi: 10.1177/193229680900300628

Sebelius K (2011) MHealth Summit Keynote Address. NCI Cancer Bulletin, 8(24), 4-4. http://www.cancer.gov/ncicancerbulletin/121311/page4

Sevilla M (2014, June 20) A doctor is skeptical about Apple's HealthKit. Here's why. http://www.kevinmd.com/blog/2014/06/doctor-skeptical-apples-healthkit-heres.html

Shaw G (2013, July 18) Take these apps and call me in the morning: Mobile apps as the new health prescription | Calgary Herald.

http://blogs.calgaryherald.com/2013/07/18/take-these-apps-and-call-me-in-the-morning-mobile-apps-as-the-new-health-prescription/

Stomp W (2012, June 6) Specialized Stroke Ambulance Features CereTom Portable CT Scanner to Reduce Time to Treatment. http://www.medgadget.com/2012/06/specialized-stroke-ambulance-features-ceretom-portable-ct-scanner-to-reduce-time-to-treatment.html

Tacconi D, Mayora O, Lukowicz P, Arnrich B, Setz C, Troster G, & Haring C (2008, January) Activity and emotion recognition to support early diagnosis of psychiatric diseases. In Pervasive Computing Technologies for Healthcare, 2008. PervasiveHealth 2008. Second International Conference on(pp. 100-102). IEEE.Chicago.

Uptodate Inc (2014) About us. http://www.uptodate.com/home/about-us Accessed 12 May 2014.

Wicklund E (2014, April 11) Online scheduling fitting right in with consumers and doctors. http://www.mhealthnews.com/news/online-scheduling-fitting-right-consumers-and-doctors

Williams A (1974) The cost-benefit approach. Brit Med Bull, 30(3), 252-256. http://www.med.mcgill.ca/epidemiology/courses/EPIB654/Summer2010/CBA/CB %20approach%20Williams.pdf

Xiaohui Y, Jiadong D, Liurong W, Cheng L (2014, March 12) MHealth in China and the United States: How Mobile Technology is Transforming Healthcare in the World's Two Largest Economies (Rep.).

http://www.brookings.edu/~/media/Research/Files/Reports/2014/03/12%20mHealth %20China%20United%20States%20Health%20Care/mHealth\_finalx.pdf

Zax D (2010, December 6) Fighting Counterfeit Drugs With Mobile Technology | Fast Company. http://www.fastcompany.com/1707667/hp-and-mpedigree-fight-counterfeit-drugs Accessed 10 May 2014

Zurovac D, Sudoi RK, Akhwale WS, Ndiritu M, Hamer DH, Rowe AK, Snow RW (2011) The effect of mobile phone text-message reminders on Kenyan health workers' adherence to malaria treatment guidelines: A cluster randomised trial. The Lancet, 378(9793), 795-803. doi: 10.1016/S0140-6736(11)60783-6

## **Biography**

Roberto Vietri was born in Cape Town, South Africa where he graduated from High School and worked for 10 years in IT and volunteering as a paramedic while studying psychology and computer science via correspondence at the University of South Africa and University of Cape Town. In 2008 he started Medicine at the University of Zagreb School of Medicine in Croatia where he plans to graduate in July of 2014. He has a passion for IT and Medicine, in particular emergency medicine. He has been a lecturer at the Emergency Medicine Summer School in Dubrovnik, Croatia in 2012, 2013 and 2014. He has also been a member of the Zagreb chapter of the European Medical Students Association from 2011-2014.