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WELLFARESTATE AND EFFECTIVENESS IN HEALTH CARE: THE INTERNET OF THINGHS IN HOSPITALS FROM CHANCE TO CHANGE

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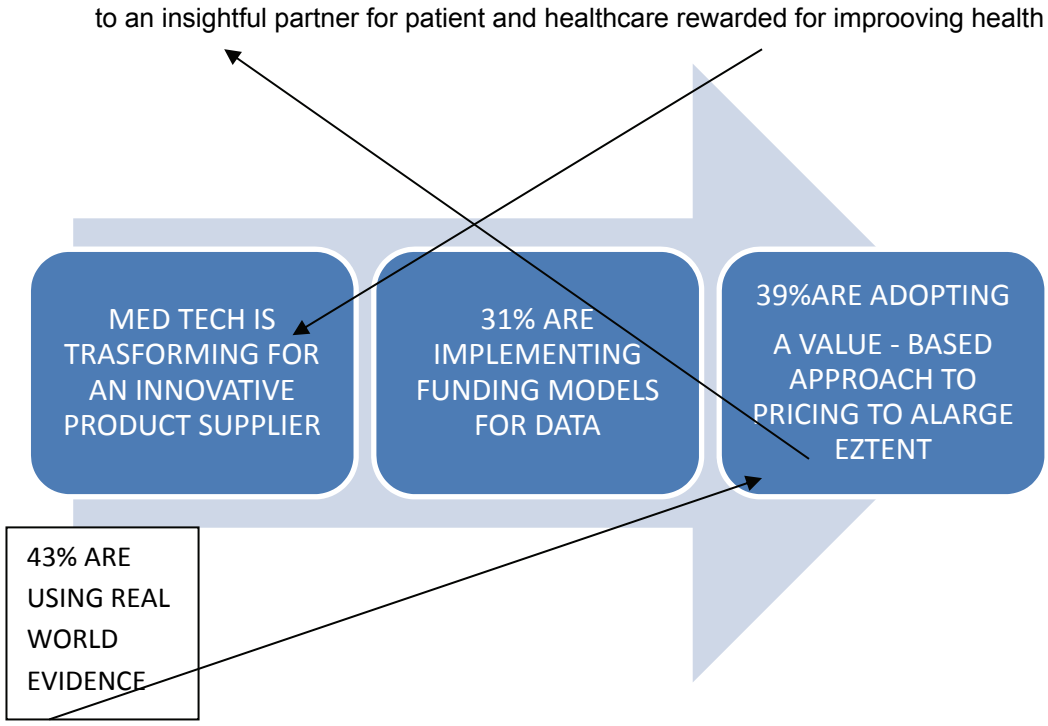
Abstract:
We live in the revolutionary era of electronic waves connecting our everyday gadget. The internet of thinghs (IoT) allows this to happen , through which connected devices communicate each other. Gadget collect, analyze and share data coming in via their sensors, and make certain if consequence of style decisions.A confluence of forces induced healthcare's embrace of digital health, including changing consuler expectations, a new and disruptive reinbursement model, and rising health care cost.
Artificial intelligence and digital assistants (both text based Chatbots and voice based devices) are key components in the smooth operation of IoT networks.The internet of medical thinghs (I o MT) is about a connected infrastructure of medical devices, software applications, wealth system, and services. However, it could extend way beyond the hospital. In the future we can imagine that a smart watch used at home will send back vital signs to a GP's. tablet about a patient, toilets with microchips similar to the MC Io Biostra MPS win monitor urine- so- you won't need to bring your urine sample to doctor any more. Sensors will log movement's patterns, bathroom sensors will follow patterns, of water usage, or digital mirrors with measure basic vital signs, or, we could imagine connected device put in practice: it already allows monitoring patient's sleep patterns mobility and gait, it can pick up on their breathing rates or detect if someone has a fall, it can monitor heart beats and even provide information about their emotional state. What if all that information could be sent back to the hospital for control in the future?

Keywords: E-Health, public health, effectiveness, heath stewardship

1. HOW DIGITAL TECHNOLOGY ARE ENABLING PATIENT CENTRICITY

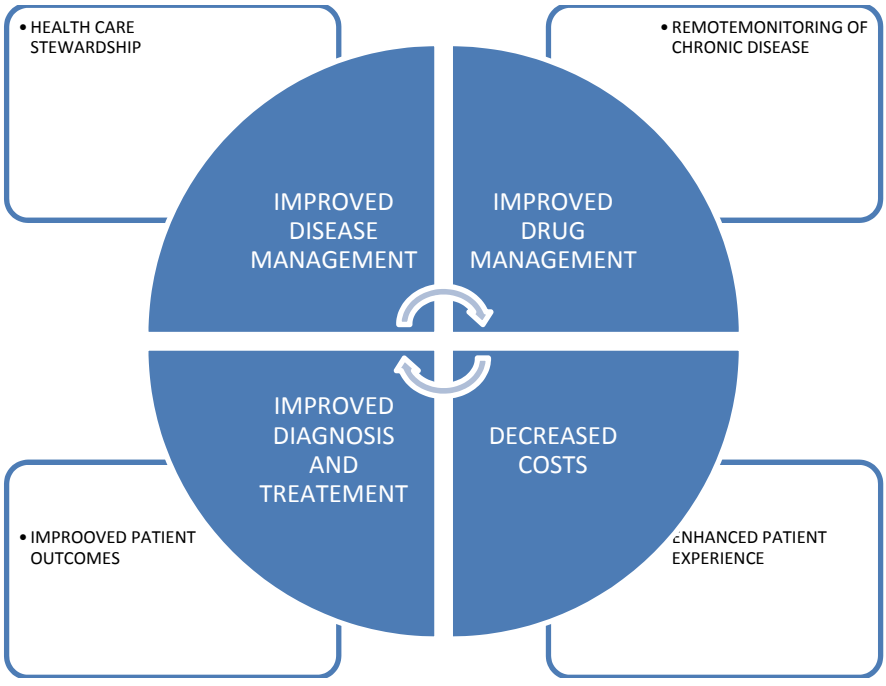


2. IoT AND HEALTH CARE

Connected sensors measuring and sharing crucial data started to spread around in hospitals, in the GP. S office and throughout the medical and pharma supply chain.
The Accentur 2017 internet of health survey emphasized that almost three - quater of health care executives say IoT in health will be disruptive within the next three years at first of all in three areas:
1 Remote patient monitoring care
2 Remote patient monitoring- wellness.
3 Preventionand safety, - where the health sensors and wearables come into play - and healthcare operations, such as managing inventories of medical supplies in sum, Accenture expects in 2020 to reach a $ 163 billion market.
Health IoT could help optimize medication management processes, guarantee the accuracy of prescriptions, support remote monitoring of patients, doctors, nurses, etc. keep an eye on the levels , of basic eqipement on wards or recorder when new stock is needed .
The multifaced nature of connected networks comes in handy, and their possible areas of use seem to be endless. Here, we .
Monitoring in patient's health.
Sensors could track and monitor patient from the moment, they arrive in a hospital or even in the home before that. With real - time data automatically added to patient records without the need for nurses to take readings or update charts.
Hospital beds are the first choice for sensors placed in the closest proximity to the patient. For example , to avoide pressure ulcers from stayng in bed for too long.. SMI manifactures pressure sensors wich can allow the mattress to inteigently redistribute force to minimize the occurrence of this type of ulcers . Im December 3008 , Hill Room announced that it equips its new hospital beds with heart and respiratory rate sensors. Using early sense "A. I Techmology they continuously monitor patient's vital signs and alert nurses if a change is detected.
IoT networks could also help patients get back the feeling of control for example , NYU Langono, newly opened hospital offers my wall which lets patients manage. Daily needs like ordering meals and viewing entertrainment via a tablet , patients can also learn about their care team, plan and adjust room light or temperature . Optimizing care processes a busy hospital is a place where tracking patients, doctors, nurses, expensive medical equipment, the right medication sought after resources, and even hospital beds is an over whelmingly complex and challenging task, not doing it. In time, could even endanger patient's lives, Some years ago there was a case of a patient found dead in the stair well of a California Hospital , so, thath's what

the concept of autobed system goes against . It was developed by GE, and introducedin the Mount Sinai Hospital . Autobed is an algoritm that uses the admitting nurses's triage reccomendation and real time data of wich hospital beds are available (using real time location awareness devices like radio frequecency identification, Tags - infrared and computer vision.
To figure out as fast as possible on wich bed to put an incoming patient. The metod proved to be highly effective: Mount Sinai decreased waiting times by 50% of their emergency room patients . NY based start up ,Inspiren concentrates on mitigating patient neglect . Using computer vision , deep learning , and natural body recognition movement, their Io T Device, in, detects staff presence and assesses environmental safety risk while simoultaneously collecting and aggregating data from other medical devices such as EKGG/ vital monitors and from environmental sensors detecting temperature, noise, brighteness, ETC.. The BY product is an intelligent system that gains insight into the care environment and mitigates the risk of human error . The data analitics engine then uses A. I to create predictive algorithms to prevent injuries and medical errors. There are expected more similar solutions to appear on the market to monitor medical errors. More similar solutions to appear on the market to monitor medical staffand patient behavior to enhance the healing process.
Indoor GPS and Medical Devices in the operational process of large hospital , enough attention should be paid on the inventory and maintenance of medical devices. Io T networks could mean an immense help in both areas. For example , RFID Technology could be used for tracking medication and medical equipement, via the unique via the unique identifier placed on the specific item . Another method is the real time location system (RTLS) used to provide immediate or real time tracking and management of medical equipement, staff and patients within all types of patient care environments while the technology differs from using location data captured by satellite trilateration, it can be throught of Asatype of "indoor GPSfor Hospitals. It works similarly to the RFID Technology in the sense that the system includes location sensors that are attached to various assetts be it a patient, a staff member or a piece of equipement. However, it's not enough to find a device or a medical equipement. Doctors needS to have that in optimal working conditions. That's what it needs to solve with e- Alert system , which monitors medical hardware and alerts hospital staff in case of a problem. More over , it takes a proactive approach to analyze the actual state of equipement and notifyng users in advance of emerging issues.

3. THE BENEFITS OF THE Io MT



4.CRITICISM

Hurd less of Io T ; security concerns and lack of standards. While there's no medical field where connected networks cannot have a positive impact on patient outcomes , most hospitals , and medical institutions which introduced IoT system so far are still in the experimental phase, and thus , serious problems could arise. One of the most terrifyng stories regarding the power of EHRS and computer administered medication management was the story of teenager Pablo Garcia who received 38,5 times the dosage he should have received due a setting error in the EHR system. Beyond errors arising from managing IoT networks or unfortunate system design flows.Two main hudles hamper the adoption of connected medical devices in higher number and both should be solved before going forward with the spread of the technologies.
At first concern is security as the internet of healthy thinghs is expanding the points of vulnerabilities keep multiplyng throught a swarm of end points, networks and channels. Some analyst say medical devices in particular have been identified as highly vulnerable and hacked medical devices may now be the single bibbest threat to health care IT.
The expansion in the use of health technology carries its own challenges:
1-Quality and safety of care,medical e practice
2- Cyber security and patient medical record
3- Privacy and ownership of the data
4-Cross borders standardisation; interoperability and data exchange.
5- Health spending
The governance of health technologies is generally shared among different agencies. For example , in the United Kingdom , the medicines & health care products regulatory agencies oversees drug safety, medical devices, (including apps), and blood regulation and safety.
Another agency , the national institute for health care excellence (NICE) has functions that include technology appraisal, guidance through the review of clinical and economic evidence of new pharmaceutical products, as well as devices, procedures and diagnostic agents.
While regulation meet the block of a new technology FDA appears to be making steps towards speeding up the process digital health companies undertake to get their products certified in 2017. FDA launched digital health action plan wich brought new guidance on implementing legislation touching on digital health and clarify wich product fell under IYS Jurisdiction as well as debuting a pre - certification program for certain developers that program aimed at low risk products made by companies "who demonstrate a culture of quality and organizational exellence based on objective criteria . Apple, Samsung and Verity have all joined.
In Europe there's more legislation on the horizon. The medical devices Regulation (MDR) is due to come into force in 2020; and will revamp the legislation digital health products are governed by, in particular IT classifies and broadens the definition of a medical devices, software and Apps and strenghtens the traceability of medical devices. .
F.D.A model
In January 2019 F.D.A. published :" Developing a software pre - certification program : a working model " In this paper the FDA pre certification program is envisioned as a voluntary patway that embodies a regulatory model more tailored than the current regulatory paradigm to assess the safety and effectiveness of software technologies without inibiting patient access to these technologies. The program goal is to provide more steamlined and efficent regulatory oversight of software.based medical devices from manufacturers who have , mitigate o prevent disease or other condition's are medical devices under federal law. This software based technologies, including mobile medical Apps, are what FDA and other regulators call software as medical deviceSaMD demonstrated a robuste culture of quality and organizational excellence (CQOE) and are committed to monitoring real world performance "but momentum toward a treat, diagnose, cure , mitigate o prevent disease or other conditions are medical devices under federal law. This software based technologies, including mobile medical apps, are what FDA and other regulators call software as medical device SaMD. An agyle regulatory paradigm is necessary to accomodate the faster rate of development and potential for innovation in software products while ensuring that existing standards of safety and effectiveness are met or exceeded. The software precertification program is envisioned as a voluntary patway that enbodies a regulatory model more tailored than the current regulatory paradigm to assess the safety and effectiveness of software technologies without inibiting patient access to these technologies .
Conclusion- The FDA activity aims to ensure effectiveness : the right things, adequate to accomplish a purpose producing the intended or expected resultant efficent or performing in the best possible manner with the least waste of time and effort.
Regulatory (EU) 746
on invitro diagnostic medical devices and repealing directive 98/79/EC and Commission decision 2010/227 (text with EEA relevance)
In vitro Diagnostic Medical Device

Key elements are:
1- Supervision or notified bodies,
2-Risk classification,
3- Conformity, assessment procedures,
4-Performance evaluation and performance studies
5 -Vigilance and market surveillance
Should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding in vitro diagnostic medical devices should be introduced to improve health and safety to take into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide and to facilitate trade in particular in the provisions on unique device identification general safety and performance requirements, technical documentation , classification rules, conformity assessment procedures and clinical evidence. Software is necessarly clarify that in its own right , when specifically intended by the manifacturer to be used for one or more of the medical purposes set out in the definition of an in vitro diagnostic medical device.
Conclusions
Medical device
EU Regulation
EU Consumer right Directive, a Regulation is a binding legislative act . It must be applied in its entirely across the EU. For example when the EU wanted to make sure that there are common safe guards on goods imported from outside the EU.
The Medical Device regulation (MDR) 93/42/EC
The full EU MDR Regula Medical Device definition : "Medical Device means any instrument, apparatus appliance, software implant, reagent, material or other article intended by the manufacturer to be used alone or in combination for human beings for one or more of the following specific medical purposes
-Diagnoses,prevention, monitoring ,prediction, prognosis, treatment or alleviation of disease
- Diagnosis, monitoring , treatment, alleviation of or compensation for, an injury or disability
-investigation, replacement or modification of the anatomy or a phisiological or pathological process or state.
-Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations .
-and wich does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but wich may be assisted in its function by such means.
The following products shaw also be deemed to be medical devices.
-Devices for the control or support of conception
-Products specifically intended for cleaning, disinfection or sterilization of devices as referred to in Article 1 (4) and of those referred to in the first paragraph of this point.
Accessory of a Medical Device means an article which, whilst not being itself a medical device (s) to be used in accordance with its/their intended purpose (s) or to specifically and directly assist the medical functionality of the medical device (s) in terms of its/their intended purpose (s).
Article 1 (4) EU MDR 2017/745
2For the purpose of this regulation medical devices, accessories for medical devices and product listed in annex XVI to which this regulation applies pursuant to paragraph 2 shall here in after be referred to as devices word "Device" referred :
-Medical
Accessories
-Products from Annex XVI
Veterinary medical evices are not rewarded at the european level, but by each National Autority..

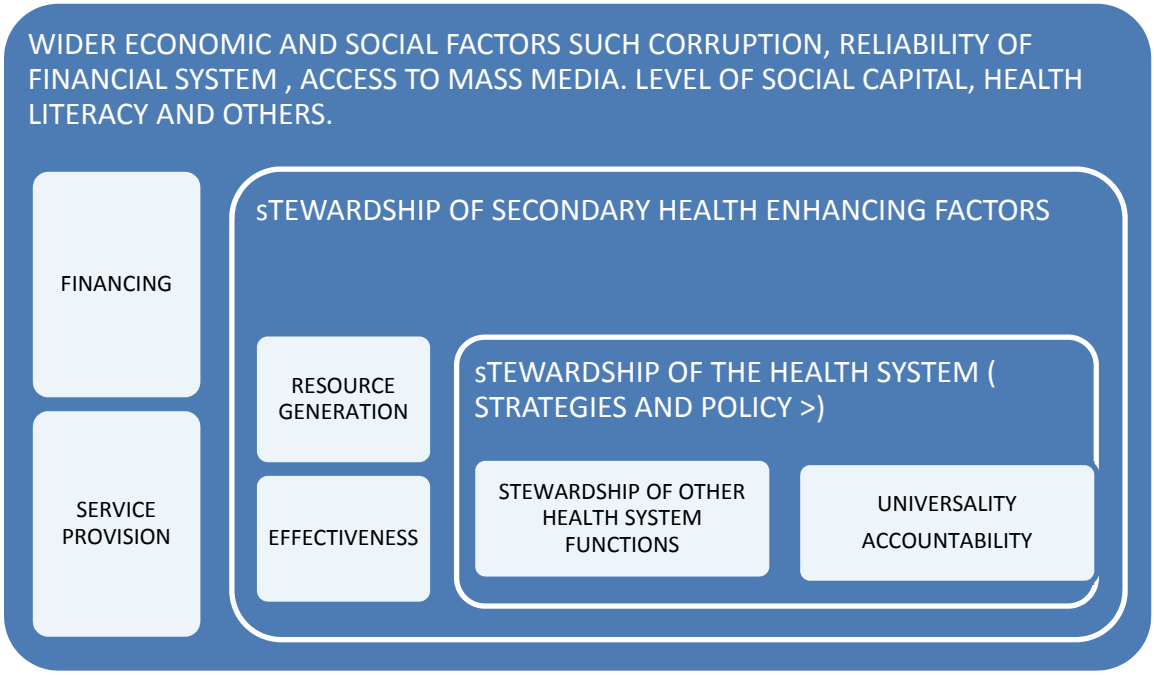
5. FDA DEFINITION OF MEDICAL DEVICE

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article , including a component part, or accessory which is.
1)Rrecognized in the officia national formulary , or the United States Pharmacopea or, any supplement to them.
2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals
3) Intended to affect the structure or any function of the body of man and other animals , and wich does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes . The term "device" does not include software functions excluded pursuant to section 520 (0)

6. CONCLUSION

We can see that there is a major difference between the EU and US Medical device definition.
1) First in USA a medical Device is for human or other animals, so veterinary products and human products are considered similar.
If you run a veterinary business in Europe, you should be careful regarding the requirements as its different than what you would expect.2) Then software functions are excluded from this definition
3) In USA there's only three classes.
BRAZIL ANVISA
Brazil Anvisa is the health autority that is regulating medical devices.
Brazil define medical device as :
Medical product, health care product , such as equipement, devices, materials, articles, or systems for medical, odontological or labory use or application intended for prevenction, diagnosis, treatment, rehabilitation or anti- conception and that does not use pharmacological, immunological, or metabolic means to full fill in its main function in human beings , but, we can have its functions assisted by such means.
Obliviously it looks not so different than the other countries, this definition is shorter, but includes al the specificity of a medical device. We only see that the word software is not mentioned. It also includes the distinction with a borderline product (medicaldevice or pharmaceutical).
In Brazil there are four classes of medical devices Class I, II, III, IV.

CHINA CFDA
In China CFDA. China food and drug administration is regulating the health care industry. Here is the official CF DA Medical Devices definition.
Medical Device as defined in these regulations refers to any instrument, apparatus, appliance, material, or other article whether used alone or in combination , including the software necessary for ITS.proper application , it does not achieve its principal action in or on the human body by means of pharmacology, immunolgy, or metabolism , but which may be assisted in its function by such means ; the use of which is to achieve the following intended objectives:
1) Diagnosis, prevention, monitoring, treatement or alleviation of disease.
2) Diagnosis, monitoring, treatment, alleviation of or compensation of an injury or handicap conditions.
3)> Investigation, replacement or modification for anatomy or a physiological process.
4) Control of conception
For China is similar vocabulary used is the same as for the european Union . It also is specific to humans . For the classification they use three class 1-2-3. Logically the definition of medical device are in majority similar in most of the main countries. The main aspects are:
The category of products
-The main intended use should not be by a pharmacology, Immunology or a metabolic means.
- The medical function
However there also differences , the definitions are not all aligned on the "softwares" , and only the United States are considering veterinary products in the definition of medical devices.
Finally, the class of products are not similar. Maybe to keep some specificity for each country.
There are still some problems you will see, if you are dealing with some health authorities , this can hurt business as each party don't
Understand the same vocabulary to avoid any interpretation on a medical device definition . The European Union up dated the new EU MDR 2017/745 to include a clear vocabulary.
It helps the manifacturers and the health authorities to speak the same language and provide the best support to patients.
The new MDR 2017 /745 created a surprise by creating a specific annex to some products that were not considered medical devices before because the intended use was nt specifically matching the definition , but when you look at those device for sure they should be considered as medical devices.
TAVOLA 3.
Stewardship of different factors influencing health



7. FINDINGS

The Industry future's will depend on its ability to demonstrate to providers and payers how connected Medical Devices contribute to the new value based paradigm. This paper highlights the most important barrier against the process of market's internationalisation;there are lack of standardization and different Regulations. At last the findings support software firms and policy makers to stewardship strategies for export missions.

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