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WEARABLES FOR AN INCLUSIVE UNIVERSAL HEALTHCARE SYSTEM IN MEXICO (Part II.)

The Competitive Intelligence Unit

Wearables for an Inclusive Universal Health System in Mexico

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ABSTRACT

Wearables are electronic devices that can be worn as clothing, accessories, or body implants. These devices can create, analyze, and report information regarding vital signs and send and receive these data through Internet. They may be used in a variety of alternatives to improve healthcare and wellness in the entire world: they can help to monitor symptoms, and disease diagnose, allowing more effective prevention, maintenance of health, and disease treatment.

Wearables are being used as a tool to increase the efficiency and reachability of healthcare systems in the entire world, being used primarily as gadgets that can continuously monitor, register and analyze various vital signs and parameters of physical activity. Wearables can complement and facilitate the mission of healthcare institutions as well as monitor patients' activities, allowing resources (human and material) to be used in more specialized tasks.

Wearables can also have many other benefits, like helping users with exercise routines, helping to create healthy eating habits and wellness in general. A variety of examples and experiments show the use of wearables is effective for preventing or controlling noncommunicable diseases (also called chronic diseases), which tend to be of long duration and the result of a combination of genetic, physiological, environmental and behavioral factors, as well as communicable diseases, such as COVID-19. An important challenge for the Mexican Health System and, particularly for the Mexican Institute of Social Security (IMSS for its acronym in Spanish), are the noncommunicable diseases (NCDs) that in 2018 caused more deaths than communicable diseases. Besides the increasing number of victims of the NCDs, their treatment causes a major financial impact to the public healthcare system as well as indirect, negative impacts to the economy due to the loss of human capital (deaths and loss of years of healthy life).

Wearables also have been explored to fight the recent COVID-19 pandemic. Some devices can enhance safety for people who have to be at a physical workplace, even with social distancing and physical isolation measures are in place.

A wearable-based strategy can promote physical activity and an efficient monitoring for NCDs. Adopting wearables to monitor patients' diseases and to generate a medical recorsd available for both the treating doctor and the patient could considerably reduce queuing times and medical consultations, allowing human and economic resources to be allocated to other important activities of the healthcare institutions.

Mexican regulation regarding the interoperability of electronic registration, health-related software and exchange of health information is an important step towards a wearables-based strategy. However, the fragmentation of the national healthcare system is a major challenge for its effective implementation.

The digital gap in Mexico, negatively impacts patients and public healthcare infrastructure, which could be addressed with the implementation of a reverse data billing strategy to close this gap and to ensure effective information exchange.

In this sense, to implement a wearables-based strategy for the Mexican Healthcare System, the following recommendations are made:

1. Include a gradual wearable-based strategy in the National Health Plan comprising relevant public and private actors and targeted groups of population considering risk management and cost-benefit analyses.
2. Focus on the use of wearables for preventing and controlling non-communicable diseases, the ones with the highest costs for the healthcare system.
3. Promote effective compliance to interoperability regulations in both the public and private systems.
4. Consider local and private previous experiences to improve existing interoperability regulations.
5. Review and update regulations aimed at ensuring the quality of health data and health-related software contained in wearables (e.g. promote the creation of wearables regulatory sandboxes).
6. Implement a reverse data billing strategy focused on the free provision of data to lower income households, and prepaid users.
7. Promote tax incentives to reduce wearables acquisition barriers and to promote associated software (applications) development.
8. Implement a smartphones-based system for the users and healthcare staff to visualize and analyze data considering the adoption patterns of these devices.

Glossary of Terms and Definitions

Ambulatory Blood Pressure Monitors (ABPM): Devices that allow blood pressure readings to be recorded over a 24-hour period, whether the patient is awake or asleep.

ChiquitIMSS and ChiquitIMSS junior: IMSS's prevention programs servicing kids in the range of seven to nine years and three to six years, respectively.

Comisión Federal para la Protección (COFEPRIS): Federal Commission for Protection against Sanitary Risk responsible for regulating health topics in Mexico, like food safety, pharmaceutical drugs, medical devices, organ transplants, and environmental protection.

Electrocardiogram (ECG): Test that records electrical activity through patches attached to the skin.

Food and Drug Administration (FDA): Federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through control and supervision of food safety, pharmaceutical drugs, vaccines, and medical devices, among other products.

IMSS-Oportunidades: Public program that gives health services to people enrolled in Oportunidades Program.

Information and Communication Technologies (ICT): Refers to a broad set of communication technologies and devices such as wireless networks, smartphones, software, social networks and more.

Information and Communications Development Index (IDT): Index that sizes the development and usage of Information and Communication Technologies.

Information and Communications Development Index Mexico (IDTMex): Adaptation of the IDT to Mexico.

Instituto Mexicano del Seguro Social (IMSS): Healthcare system for workers of the private sector based on contributions by the firms and the workers themselves.

Instituto Nacional para la Salud y el Bienestar (INSABI): Healthcare system for people without social security.

Instituto del Seguridad y Servicios Sociales de los Trabajadores del Estados (ISSSTE): healthcare system for workers of the State.

Non-communicable disease (NCD): a disease that is not transmissible directly from one person to another.

Petróleos Mexicanos (PEMEX): refers to the healthcare system for the workers of PEMEX (state-owned company).

PREVENIMSS: IMSS's fundamental strategy to prevent, detect and promote the timely diagnosis of cancer.

Remote Patient Monitoring (RPM): Use of digital technologies to collect medical data from individuals in any location and electronically transmit it to health care providers in another location.

Secretaría de la Defensa (SEDENA): refers to the healthcare sub-system for people at the army.

Secretaría de Marina (SEMAR): refers to the Healthcare sub-system for the navy.

The Organization for Economic Cooperation and Development (OECD): International organization that works to build better policies for better lives. Their goal is to shape policies that foster prosperity, equality, and well-being.

World Health Organization (WHO): Specialized agency of the United Nations responsible for international public health.

Wearable Blood Pressure Monitors (WBPM): Devices that expands and tightens to take blood pressure readings, in the same way as an upper arm oscillometer machines.

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1. INTRODUCTION

This Working Paper aims to describe the status of the current Mexican healthcare system, its link with technology and, more specifically, to analyze and highlight the benefits of having healthcare public policies which promote the adoption and use of wearables.

Wearables are electronic devices that can be worn as clothing, accessories, or body implants. These devices can continuously monitor, analyze, and report information regarding vital signs and sending and receiving these data through Internet. They may be used in a variety of alternatives to improve healthcare and wellness in the entire world: they can help to monitor symptoms and to diagnose illnesses, allowing a more ubiquitous prevention, maintenance of health and disease treatment.

It is regularly claimed that the National Healthcare System in Mexico needs large public investments to achieve universal coverage to service the growing population. This certainly may be true, if taken into consideration that total spending in the healthcare sector is equivalent to just 5.5% of the Gross Domestic Product (GDP), while this indicator goes from 9.8% to 12% in other OECD economies, like Canada, UK, Switzerland, Japan, and France, amongst others. [1]

However, the growing fiscal pressure resulting from the current public health and economic crisis, as well as the inefficient tax collection procedures, erodes public investment capacity. The country requires efficient spending strategies.

Mexico is in a transition phase where Non-Communicable Diseases (NCDs) are becoming more prevalent and cause more deaths every year. Mortality for acute respiratory infections or diarrheal diseases is declining while, diabetes, ischemic heart diseases and other NDCs are responsible for more deaths and require more resources for treatment year after year.

[1] OECD. "Health at a glance 2019, Health Statistics" 2019. Available at: https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2019_592ed0e4-en;jsessionid=67bfhqGJgYJ8NKIoaI15fIQM.ip-10-240-5-113

That is why this document proposes an innovative strategy to promote the use of wearables for treating, monitoring, and preventing non-communicable diseases. This approach represents a cost-saving strategy but also an interoperability and connectivity challenge.

This document is structured as follows: the second section presents a literature review regarding the use of wearables in healthcare systems and successful experiments using these devices for healthcare purposes in the world. The third section describes some of the related costs to NCDs in the Mexican healthcare system along with the NCDs implications in the context of the Covid-19 pandemic. The fourth part analyzes the effectiveness of a wearable-based strategy to fight against NCDs by promoting physical activity and remote monitoring, i.e., prevention and control of NCDs with the use of wearables. The fifth part tackles the interoperability challenge, the relevance of connectivity gap in the discussion and other regulatory issues. The last part provides some general recommendations.

This document depicts the magnitude of NCDs problem for the healthcare system in Mexico and provides a general technology cost-effective strategy to address it.

2. Effectiveness of a wearable-based strategy for Mexico

I. *Smartwatches in Mexico*

Back in 2015, Reza Rawassizadeh form Boston University asked: "Has the age of Smartwatches finally arrived?". He explained how a long period of technological developments, highly related to processors design and performance, offered the chance to think watches, wristwatches, as a multifunctional device.[2] Nowadays it is common to see these devices as an opportunity to constantly collect health data without major effort. On the subject, Adam Oldenburg, director of CDW Healthcare Sales stated:

> Smartwatches and other wearables aren´t just for fashion and fitness. Increasingly, they're helping healthcare providers collect and analyze wider swaths of patient data between appointments or after surgery — valuable insights that can inform treatment." (Oldenburg, 2019). [3]

In September 2020, The Competitive Intelligence Unit informed that in Mexico there was about 9.4 million users of smartwatches. This meant an adoption of 9.1% in the Mexican population older than twelve years old. One of the barriers mentioned to expand the use of these devices is the considerably amount of money extra that a user must spend, approximately $4,384 MXN, aside the purchase of a smartphone. [4]

Mexican owners report they use these devices for receiving notifications, listening to music, health monitoring, monitoring of exercise routines and use of alarms.

II. *ICT impact on healthcare in Mexico*

The access to connectivity and to Information and Communication Technologies (ICT) is considered a human right established in the Mexican Constitution. This concept relies on the

[2] Reza Rawassizadeh et al., Wearables: Has the Age of Smartwatches Finally Arrived? Viewpoints, 2015. Available at: https://www.researchgate.net/publication/269410374_Wearables_Has_the_Age_of_Smartwatches_Finally_Arrived
[3] Adam Oldenburg, Smartwatches in Healthcare Drive Insights and Action, Health Tech Magazine, 2019. Available at: https://healthtechmagazine.net/article/2019/10/smartwatches-healthcare-drive-insights-and-action
[4]The Competitive Intelligence Unit, Reloj Inteligente: Pionero de un Mundo de Objetos Conectados, 21/09/2020. Available at: https://www.theciu.com/publicaciones-2/2020/9/21/reloj-inteligente-pionero-de-un-mundo-de-objetos-conectados

importance of ICT for social and economic development: they assist in guaranteeing freedom of speech, information transparency and the education and healthcare services.

For healthcare issues, it has been proven that expanding telecommunications infrastructure has a positive effect on population's healthcare indicators. [5] In Bangladesh and Laos, basic telephone services offer opportunities in delivering timely information on health services to households. In a similar exercise, The Social Intelligence Unit (The SIU) adapted the Information and Communications Development Index (IDT), created by the International Telecommunication Union (ITU), to the Mexican context and at state level (IDTMex). [6] As they tried to understand the relationship of the development and adaptation of technology with healthcare, they found a positive and statistically significant correlation between IDTMex and the life expectancy, a commonly used indicator of healthcare development among countries. The graphic results are pictured in Figure 4 (The SIU, 2020).

This information reveals that an increase of one point of the IDTMex is correlated with an increase of moreover six months (0.56 years) of life expectancy in Mexico[7]. This result aligns with the OECD's Health at a Glance 2019 report where a positive association between health spending per capita and life expectancy is found.[8] It is also coherent with the latest findings of the Federal Institute of Telecommunications (IFT, by its name in Spanish) that found a causal relation in which the increase of one access to wi-fi connection per 100 households means the increase of three days of life expectancy in Mexico.[9] Therefore, is not irrational to think that as a wider index, such as IDTMex develops there are more gains in health.

[5] Micevska, M. "Telecommunications, Public Health, and Demand for Health-Related Information and Infrastructure". ITI Journal 2005. Available at: https://itidjournal.org/index.php/itid/article/view/205

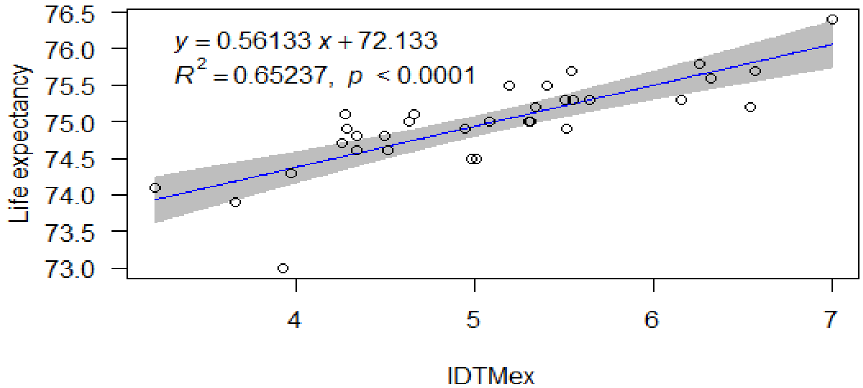
[6] The Social Intelligence Unit. "Índice de Desarrollo TIC para México y Brecha de Desarrollo", 2020. Available at: https://mailchi.mp/theciu.com/distro001-86908

[7] The Social Intelligence Unit. "Salud y Desarrollo TIC: una relación de Complementariedad.

[8] OECD. "Health at a Glance 2019 Chartset", 2019. Available at: https://www.slideshare.net/OECD_ELS/health-at-a-glance-2019-chartset

[9] IFT. "El Uso de las TIC Genera un Impacto Positivo Directo en el Ingreso y la Salud de los Mexicanos", 2020. Available at: http://www.ift.org.mx/sites/default/files/comunicacion-y-medios/comunicados-ift/comunicado106ift.pdf

Fig. 4 Correlation between IDTMex and Life Expectancy



Source: The Social Intelligence Unit, 2020. * Each circle in the figure represents a state.

As stated, in Mexico, some of the barriers that people face to access healthcare services are non-universal coverage, inefficiencies associated with its fragmentation, and the high costs of NCDs treatment. The use of ICTs, such as wearables, for NCD prevention and monitoring might address these barriers.

It is important to identify related risk factors because: "The fight against NCDs involves being aware of the determinants and the causes, since people's lifestyles have an influence on their health".[10]

III. *PREVENTION*

According to the WHO Global Strategy for the Prevention and Control of Noncommunicable Diseases, four diseases (cardiovascular, cancer, diabetes, and chronic respiratory) are responsible for the majority of deaths caused by NCDs and are largely caused by four shared behavioral risk factors: tobacco use, harmful alcohol use, physical inactivity, and unhealthy diet.[11] The Pan

[10] Op. cit., WHO (2020). P.21.

[11] WHO. "Scaling up action against noncommunicable diseases: How much will it cost?", 2011. P.10

American Health Organization estimates that 81% of deaths in the Region of the Americas are caused by NCDs.[12]

To select the appropriate policy to deal with these diseases, the WHO came up with a "best policy" proposal, that is, policies that are not only cost-effective but also low-cost and appropriate to implement within the constraints of the local healthcare system.[13]

The most important recommendation is promoting physical activity and healthy diet by generating public awareness to prevent NCDs prevalence. It has been proven that the level of physical activity is associated with a lower risk of diseases such as hypertension, cardiovascular disease, diabetes, and cancer.[14]

Mexico has a long tradition of disease prevention policy implementation. IMSS declares that the greatest challenge within the prevention policy is to ensure that the people at risk carry out at least one yearly general check-up. To reduce the opportunity cost for patients, PREVENIMSS programs at schools, universities, and companies reached students and workers in their workspaces to perform health check-ups.[15]

Meanwhile, an assessment of ChiquitIMSS and ChiquitIMSS junior[16] programs servicing kids in the range of seven to nine years and three to six years, respectively, found that the weight and height monitoring contributed to a 3.2% decrease in the prevalence of obesity in children under the age of five and a 12.8% decrease in children aged five to nine years.[17]

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[12] Organización Panamericana de la Salud. "Enfermedades no transmisibles".2020. Disponible en: https://www.paho.org/es/temas/enfermedades-no-transmisibles#:~:text=Las%20enfermedades%20no%20transmisibles%20(ENT,muertes%20por%20ENT%20cada%20a%C3%B10.

[13] Op.Cit., WHO (2011). P.11

[14] Hafner M., et al. "Incentives and physical activity: an assessment of the association between Vitality's Active Rewards with Apple Watch benefit and sustained physical activity improvements". Available at: https://www.rand.org/pubs/research_reports/RR2870.html

[15] In 2018 1,078,895 students and 1,624,807 workers were reached.IMSS, "Report to the Federal Executive and to the Congress of the Union on the Financial Situation and Risks of the Mexican Institute of Social Security. Mexico", 2019. p.143.

[16] Program providing training to children focused on the practice of physical activity, accident prevention and other topics.

[17] *Op. Cit.* IMSS. P.144.

However, prevention campaigns have not been able to influence patients' lifestyles to improve their health. Some of the possible explanations, according to the IMSS, have to do with the limited time that is devoted to each patient at PREVENIMSS modules.[18]

> It is observed that the current strategies are not effective enough to generate changes in the lifestyle of the user population when seeing results of the information systems where the different age groups have high levels of obesity and overweight. [19]

This does not suggest that prevention is not valuable. Prevention, in the case of cervical cancer and breast cancer, as an example, has helped reduce death rate from malignant tumors by 7.4% from 2005 to 2018.[20]

One of the most popular recent campaigns of the Ministry of Health in Mexico was "Chécate, Mídete, Muévete" in which the population was encouraged to generate habits such as physical activity and monitoring their health status. This campaign managed to reach a high percentage of the population using ICTs. However, there still are no available impact assessments showing a reduction of diseases such as obesity. The strategy reached 11% of the adult population and only a third of this group "understood the message" of the campaign.[21]

Healthcare programs may require the implementation of technology to improve their efficiency and effectiveness.

As stated in this document, the promotion of physical activity along with the use of wearables is a more effective strategy than only promoting physical activity. An alert system integrated to wearables has proven to be an effective invitation to physical activity.

IV. *REMOTE MONITORING*

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[18] *Id.* P.146

[19] *Ibid.*

[20] *Id.*p.167

[21] Salazar, Araceli A. et al. "Knowledge and level of understanding of the Chécate, Mídete, Muévete campaign in Mexican adults. Salud Pública de México", 2016, vol.60 no.3. http://dx.doi.org/10.21149/8826

Although the benefits of preventive campaigns for NCDs are visible, the question regarding the possible benefits of preventing overcrowding of the health system infrastructure remains pending.

In the Mexican context, in 2018, heart disease and diabetes mellitus ranked first and second, respectively, among the main reasons for consultation at IMSS Family Medicine Units. Emergency consultations were placed fourth and ninth, and in specialties consultations, fifth and seventh, respectively.[22]

Likewise, in the United States, a series of 2006 surveys for the Markle Foundation[23] revealed that 88% of people consider that one way to reduce the number of tests and repeated procedures in their treatments would be to have online access to their medical records.[24]

Adopting wearables to monitor patients' diseases and to generate a medical record available for both the treating doctor and the patient, could considerably reduce queuing time and medical consultations. An example of the reduction of visits to the doctor using ICTs is the experiment of Rossi, A. et al. for cancer patients, previously mentioned.

IMSS, in addition to preventive campaigns, has special campaigns to monitor NCDs. The idea behind this it is that complications of diabetes can be avoided with opportune detection and proper control of the people suffering an NCD. IMSS has special modules for glucose control and, since 2018, it has been possible to control the glucose of 50% of the insured population.[25]

Monitoring also allows the timely control of risk factors that, if taken care of, can reduce complications and, therefore, the use of health services infrastructure.

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[22] Op. Cit. IMSS. p. 339

[23] Since its inception in 1927 by John and Mary R. Markle, the Foundation has worked "to promote the advancement and diffusion of knowledge among people of the United States, and to promote the general good of mankind." Available at: https://bit.ly/2XQSug9

[24] Lake Research Partners and American Viewpoint. "Survey Finds Americans Want Electronic Personal Health Information to Improve Own Health Care", 2006. Available at: https://bit.ly/2AoOoTt

[25] Ibid.p.166

If monitoring were to expand and be accessible to a larger population using ICTs, it would be reasonable to expect that the population would have fewer complications and, consequently, that the demand for health services would decrease.

3. Challenges: Interoperability, Connectivity and Other Regulatory tasks

To develop a healthcare system that can effectively take advantage of wearables technology, some challenges need to be addressed.

Interoperability and connectivity allow the obtention and management of data collected from wearables. Moreover, data quality management and regulatory requirements for these devices will help users to assimilate the health information and take data-driven decisions in a timely manner.

I. *Interoperability in Healthcare System*

Interoperability, according to the Institute of Electrical and Electronics Engineers (IEEE), refers to the capability of two or more systems to exchange information and use the exchanged information.[26]

This characteristic in the healthcare system ensures that the patients' health data is exchangeable no matter if this data was generated by any device (including wearables), management system or others. The benefit of interoperability is that allows data integration from different computer systems, even if they have:

> ...different programming languages, communication protocols, operating systems, data standards, units of measurement units, identifiers o patients, and electronic interfaces... [27]

As an example of the relevance of interoperability, health authorities require timely information regarding contagion and hospitalization rates to take decisions to fight against Covid-19 pandemic and to promote transparency about the disease dynamics. In Mexico, there have been discrepancies between states and federal registries triggering social confusion.

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[26] IEEE Computer Society. Standards Coordinating Committee. "IEEE standard computer dictionary: a compilation of IEEE standard computer glossaries", 610. New York, NY, USA: Institute of Electrical and Electronics Engineers; 1990.

[27] WHO et al. "Revisión de Estándares de Interoperabilidad para la e-salud en Latinoamérica y el Caribe".

According to the Health Ministry, this is caused by deficiencies in notifications at state-level to the federal authority.[28] Interoperability for an efficient information exchange between the states and the Health Ministry would provide an important input for health authorities to take accurate decisions to prevent contagions.

In Mexico, the General Directive of Health Information - NOM-024-SSA3-2012 Electronic Registry Health Information Systems (NOM-024) -applicable for the whole National Health System (private and public)- is in charge of regulating the Electronic Registry Health Information System (SIRES by its acronym in Spanish), and establish mechanisms for healthcare providers register, exchange and consolidate patients' information.[29]

This regulation (NOM-024) considers the following:

- Creation of a Technical Framework Health Information Exchange of Health among SIRES
- Definition of data sets for people identification
- Definition of Health Information Exchange Guides for specific scenarios.
- Information security and data protection

This regulation is an important step towards the interoperability for the Mexican healthcare system, however there are important challenges. First, the fragmentation of the system in social security institutions, public institutions for people with no social security, and private healthcare services increases the coordination cost for implementing interoperability among all healthcare institutions. Second, the regulation (NOM-024) lacks general enforcement although is mandatory for the National Health System (public and private institutions).

Currently, the NOM-024 includes 11 guidebooks providing technical details to implement health information exchange. These guidebooks include international standards however, a more specificity level is required to implement interoperability.

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[28] El Financiero, "Discrepancia en cifras nacionales y estatales de COVID-19, por desfase en la notificación: López-Gatell". Available at: https://www.elfinanciero.com.mx/nacional/discrepancia-en-cifras-de-covid-19-se-deben-a-desfase-en-la-notificacion-lopez-gatell

[29] DGIS. "Intercambio de Información", 2055- Available at: https://www.gob.mx/salud/acciones-y-programas/menu-intercambio-de-informacion-dgis?state=published

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II. *INTEROPERABILITY FROM THE LOCAL PERSPECTIVE*

In a review prepared for Latin America and the Caribbean, the Pan American Health Organization collected several local experiences implementing interoperability standards.[30] These experiences include the implementation of a web-based system developed by the Universidad Autónoma de Querétaro and Sociedad Mexicana de Radiología for exchanging medical images. [31]

The Colima state has carried out efforts to develop an electronic health record at public system level. According to reported experience of the involved stakeholders, this action improved the reporting mechanisms for the two main healthcare programs in the State.[32]

The increasing production of images of the Instituto Nacional de Rehabilitación (INR) required "the existence of a system of transfer, storage and visualization to ensure the integrity of the information, optimize image quality and allow the immediate availability of it". Therefore, a solution was designed to allow a more efficient view and exchange of images from magnetic resonance, nuclear medicine, computed tomography, and computed radiology.[33]

Although it is possible to rely on federal level guidance through NOM-024-SSA3-2012, it is relevant to review the executed local experience. The interoperability challenge must be

[30] eHealth in Latin America and the Caribbean: interoperability standards review ISBN 978-92-75-11881-8, 2016. Available at: https://iris.paho.org/bitstream/handle/10665.2/28188/9789275318812_spa.pdf?sequence=1&isAllowed=y

[31] Palma A, Aguilar J, Perez L, Alvarez A, Muñoz J, Omaña O, et al. "Web Based Picture Archiving and Communication System for Medical Images". Ninth International Symposium on Distributed Computing and Applications to Business Engineering and Science (DCABES) IEEE. 2010.: 141-4.

[32] Hernandez-Avila JE, Palacio-Mejia LS, Lara-Esqueda A, Silvestre E, Agudelo-Botero M, Diana ML, et al. "Assessing the process of designing and implementing electronic health records in a statewide public health system: the case of Colima, Mexico". J Am Med Inform Assoc. 2013 Mar-Apr; 20(2): 238-44.

[33] Gutierrez-Martinez J, Nunez-Gaona MA, Aguirre-Meneses H, Delgado-Esquerra RE. "Design and implementation of a medical image viewing system based on software engineering at Instituto Nacional de Rehabilitación". Pan American Health Care Exchanges, PAHCE 2009 IEEE. 2009:15-9

addressed from a local perspective and look into private efforts to include them in a gradual national interoperability strategy. These experiences, once united, become crucial for the construction of an interoperability effort at national level.

III. *REQUIREMENTS FOR HEALTH DEVICES AND DATA QUALITY*

In Mexico, the Federal Executive, through the Ministry of Health, establishes the requirements for the manufacturing process of medical devices to guarantee their quality and functionality.

The Ministry of Health exercises sanitary control in the manufacturing establishments, warehouses for conditioning and distribution of medical devices following the criteria established in the standard NOM-241-SSA[34], which addresses the issue of good manufacturing practices for medical devices providers.

This standard defines the requirements that processes of medical devices commercialized in Mexico must meet, including installation, development, procurement, preparation, mixing, production, assembly, handling, packaging, conditioning, stability, analysis, control, storage, and distribution. Some of the most important requirements are:

- **Information:** Design and production methods of medical devices must be documented in accordance with current regulations. In addition, user manuals must be clear and precise to be used, when required, by personnel who do not have any previous training.
- **Safety:** Manufacturers must be aware of potential risks of devices before being use on patients, users or third parties.
- **Performance:** Medical devices must achieve the intended use or performance characteristics established by the manufacturer.
- **Quality:** Devices must provide equal safety and performance characteristics as prototypes or design devices.

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[34] NORMA Oficial Mexicana NOM-241-SSA1-2012. Available at: http://dof.gob.mx/nota_detalle_popup.php?codigo=5272051

Efficient regulation of medical devices should guarantee access to high quality and effective products; in addition, it ensures benefits to public health and safety of patients, health workers and communities. As such, technological advances confirm the need to update regulations, adapting them to a market that is evolving day by day, offering new alternatives for making diagnoses and treatments faster and precisely.

The new regulatory and surveillance needs to consider other essential requirements that previously were not considered mandatory, such is the case of pre-market evaluation of a medical device, to guarantee general safety and performance of these devices. That is, regulation must be impartial and include independent institutions to obtain objective results.

Therefore, one important aspect of COFEPRIS (Federal Commission for Protection against Health Risks), the institution in charge of protecting population against health risks caused by use and consumption of goods, services and health supplies, is the improvement of the regulatory framework, as wearable technology is introduced into the Mexican health system. Currently, there is a sanitary registration process, duly established and regulated, that categorizes and classifies medical devices according to their risk of use.

For medical device's compliance, COFEPRIS establishes "techno-surveillance" [35] (a device's surveillance mechanism), which indicates the procedure to follow to collect all information on adverse events that may occur during a device's use[36]. Its objective is to guarantee that medical devices in the market operate in accordance with the manufacturer's intended use. Manufacturers' corresponding actions are taken to correct and decrease the probability of recurrence of adverse incidents, improving the protection of health and safety of users.

The techno-surveillance system is in force as mandated in NOM-240[37], which improves the evaluation of risk obtained from adverse incidents reported by the manufacturers, users and

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[35] COFEPRIS. "Tecnovigilancia". Gobierno de México, December 31, 2017. Available at: https://www.gob.mx/cofepris/acciones-y-programas/antecedentes-tecnovigilancia

[36] José Alonso Novelo, head of COFEPRIS, revealed in 2019 that the institution has a backlog of 13,815 permits for allopathic drugs, medical devices and pesticides: https://www.eluniversal.com.mx/nacion/cofepris-revela-retraso-de-13-mil-815-permisos

[37] NORMA Oficial Mexicana NOM-240-SSA1-2012, Instalación y operación de la tecnovigilancia. Available at: http://dof.gob.mx/nota_detalle.php?codigo=5275834&fecha=30/10/2012

operators to the Ministry of Health, reducing the probability of recurrence or not addressing consequences of any incidents.

All actors involved in the production, marketing and use of medical devices must be involved in techno-surveillance, such as the institutions of the public, social and private sectors of the National Health System, as well as their professionals, technicians and auxiliaries. It also includes the holder of sanitary registries of medical devices, distributors, marketers, establishments, and users of medical devices. Therefore, any individual can report adverse incidents arising from the use of medical devices. This transparency is essential to carry out techno-surveillance.

IV. *SOME WEARABLES ARE NOT CONSIDERED MEDICAL DEVICES*

The rapid expansion of mobile technology such as smartphones and smartwatches elevate the consuming of mobile apps of all kind, including medical apps. Nevertheless, due to their nature, this apps are regulated depending on the characteristics it has and the effects it proclaims it generates.

Medical devices in the United States and Europe Union are strongly regulated by the Food and Drugs Administration (FDA) and the European Medicines Agency, respectively. To give an example, the FDA stablishes three classes of risks for medical devices (Class I; II; III) and only oversight the Class III (high-risk) devices. Apps that promote self-management of diseases or conditions without providing specific treatment suggestions are considered of medium-risk and does not require, in most cases, any regulatory enforcement.[38]

Additionally, exists unions like the International Medical Device Regulators Forum in which representants of the UE, US, Canada, Japan, Australia, and Brazil gather to harmonize and simplify medical device regulation. Other countries, such as China or India do not have any regulatory framework on medical devices.[39]

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[38] For an exhaustive list of each class applications see: FDA, Device Software Functions Including Mobile Medical Applications, FDA, 2020. Available at: https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications#b

[39] Anand M, Akshay et al., Global Regulatory Approach Towards M-Health, International Journal of Drug Regulatory Affairs, 2016, 4(1), 6-12. Available at: https://www.researchgate.net/publication/307476545_Global_Regulatory_Approach_Towards_mHealth

It is important to mention that wearables such as smart watches and exercise wrist bands are not considered as medical devices per se. However, technology evolution has allowed the development of health-related apps to be used on these wearables that, as mentioned, can help to complement medical healthcare. Nevertheless, applications on this type of wearables are an informative complement, and they are not intended to replace the medical treatment provided by a specialist.

In this aspect, in Mexico, the current regulation does not require such wearables to be registered as medical devices neither applications nor software. For example, software is listed under number 1918 of the COFEPRIS -"AGREEMENT by which the list of health supplies considered as low risk for the purposes of Obtaining the Sanitary Registry"- as one of the products that due to their nature, characteristics and use is not considered as health supplies and therefore do not require a sanitary registry; software is considered as an accessory to medical equipment without requiring a sanitary registry.[40]

According to the economic theory there exists a relation between Research and Development (R&D) with regulatory policies. This means that the regulatory framework can foster or hinder innovation. Usually an excessive regulation would lead to inefficient market results where there is less competition and fewer innovation.[41] Specifically, John A. Vernon has found that strong regulation in the pharmaceutical market, an essential part of the medical market, leads to diminished R&D.[42] This information suggests that a non-regulatory approach would help for promoting a greater development of medical apps for wearables that for being highly accessible would expand the adoption of this kind of technology, specially in developed economies.

V. *Data Quality*

[40] SEGOB, AGREEMENT by which the list of health supplies considered as low risk for the purposes of Obtaining the Sanitary Registry, DOF, 2014. Available at: https://www.dof.gob.mx/nota_detalle.php?codigo=5376857&fecha=22/12/2014

[41] For more details see: Klapper, Leora et al. , Entry regulation as a barrier to entrepreneurship, Journal of Financial Economics, 2006, 82(3), 591-629. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0304405X06000936

[42] Vernon, John A. and Golec, Joseph H., Pharmaceutical Price Regulation: public perceptions, economic realities, and empirical evidence, The AEI Press, 2008, Whasington, D.C.

Worldwide, addressing data standards and privacy concerns will require collaboration with regulators. It will be imperative to maintain transparent communication with them on the trial design plan to have downstream acceptance of the outcome data. At the same time, an efficient implementation of wearables in healthcare industry will need collaboration with academics, technologists, and patients to turn all these newly accessible data streams into meaningful, actionable, and useful knowledge.

Because of the demonstrable benefits of using wearables in the healthcare industry, there is a need to simplify the information obtained from them as a healthcare tool. This is necessary for both patients and doctors, as easy access and understanding of information is vital for wearables adoption. The development of new devices and applications to be used will highly depend on the added value they can provide.

For this, is essential that algorithms and machine learning programs gather all data, make sense of it and then present the valuable information to health workers in a way that aligns with their workflows.[43] In other words, dumping enormous amounts of data from wearables, by itself, is of no use to patients who won't understand the data they receive. The same can be said for the health worker who would have to pull together all the individual pieces of data for each patient.

Additionally, data comes in many different formats and from a vast variety of vendors, leading to cognitive overload for providers. In the same manner, lack of knowledge may lead patients to collect information that is not useful. Simplicity and easy access to information play a vital role in the success of wearables in healthcare. Nevertheless, a lot of data is wasted, especially when providers change, leaving users without an opportunity to retrieve their datasets from "dead" systems.[44]

The need for better trust, collaboration and transparency is a requirement to attain community and societal value. There is also a legal issue as a too- rigid approach (restrictions on sharing and use of data) in privacy policies found in mainstream products or services. Those

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[43] Sukel Kayt. "How physicians can get useable data from wearables", July 29, 2019. Medical Economics. Available at: https://www.medicaleconomics.com/news/how-physicians-can-get-useable-data-wearables

[44] Estrada-Galiñanes, Vero and Wac, Katarzyna. 'Collecting, Exploring and Sharing Personal Data: Why, How and Where'. 1 Jan. 2019 : 1 – 28.Avialable at: https://content.iospress.com/articles/data-science/ds190025

restrictions do not allow the design of innovative solutions for managing diversity of personal data sources throughout a human lifetime. Modernizing this area requires consideration of technological, financial, legal, institutional, and behavioral factors.[45]

Other challenges that must be overcome include a decrease quality in data (because of potential large quantities of volume), how accurately data is interpreted, as well as accuracy risks: "Transforming activity data into meaningful outcomes that translate into significant treatment benefits to patients is work that still needs to be done."[46]

Since datasets are not generated to test specific hypothesis, data tend to be messy and difficult to analyze. Measurement error can arise from the inaccuracy of sensors in estimating quantities of interest. Missing data is another challenge since individuals do not always wear their devices. Selection bias can also occur, as individuals may not represent the gender, age, geographic location, socioeconomic status, or ethnicity of the population of interest.[47]

Medical research has been undertaken towards this objective. There are studies that developed an activity tracker to provide patient engagement, data quality, and operational efficiencies in clinical trials. This will allow capturing patient data and integrating it with other traditional clinical data, including labs, vital signs, medical history, and adverse events.[48]

Despite these challenges, wearables in the industry have already provided many benefits. These devices have not been exclusive to disease treatments, in fact, wearables are already being used as diet, exercise, and socioeconomic indicators that may prevent the potential arise of problems for the user.

VI. *THE RELEVANCE OF CONNECTIVITY SERVICES AND DEVICES*

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[45] *Ibid.*

[46] Robinson, Robin. "Wearables in Clinical Trials", June 2015. Pharma Voice.com. Available at: https://www.pharmavoice.com/article/wearables-0615/

[47] Hicks, J.L., Althoff, T., Sosic, R. et al. Best practices for analyzing large-scale health data from wearables and smartphone apps. npj Digit. Med. 2, 45 (2019). https://doi.org/10.1038/s41746-019-0121-1

[48] *Ibid.*

In Mexico, an Internet connection is available only for 52% of households, while 77% access internet through mobile services. This gap needs to be closed so information exchange through wearables becomes a reality.

Currently, the following internet access policies aim at universal coverage in Mexico at federal and state levels:

- Free internet access in public spaces strategy developed by the Ministry of Communications and Transportation (SCT by its acronym in Spanish).
- The public-private effort known as the "Shared Network" deploying a wholesale telecommunications network which must provide coverage to 92.2% of the population by 2024. As reported, this network currently covers 61.47%.

These strategies are still insufficient not only because the digital gap is still wide among citizens, but because there are more than 11,281 healthcare centers, hospitals, Family Medicine Units, and other public healthcare infrastructure with connectivity requirements in Mexico.

Considering the connectivity gap and the considerable amount of connectivity services in the public healthcare system, the use of reverse data billing where beneficiaries of healthcare services are provided of credits for mobile internet service are an option. These systems provide toll free numbers for telephone calls where the hospital, insurance companies, or social security institutions receiving the calls pay back the service tariff.

Prepaid services users report a low average spending and, therefore, limited internet use, but they account for 82.1% of total lines. Reverse data billing focused on servicing prepaid scheme users will ensure that poorer households receive most of the benefits from a tele-health wearable-based strategy.

On the other hand, the adoption pattern of smartphones (121.5 million) representing 91.6% of the mobile lines is conducive to a wearable-based policy since data generated by wearables is usually visualized on these devices through a synchronization process.

4. Conclusions and General Recommendations

This document recommends the implementation of a wearables-based strategy in the healthcare system. The features and applications developed for wearables in the healthcare sector make them an ideal complementary tool in the control and prevention of NCDs, which are the diseases with the highest incidence and costs for the Mexican healthcare system.

Wearables promote physical activity and an efficient monitoring for NCDs and to fight against Covid-19 pandemic and facilitates the mission of healthcare institutions as well as allows resources (human and material) to be allocated in more specialized tasks.

Mexican regulation regarding the interoperability of electronic registration and exchange of health information is an important step towards a wearables-based strategy. However, the fragmentation of the national healthcare system, the lack of regulation enforcement and technical specifications represent a major challenge for its effective implementation.

Connectivity plays a fundamental role so that information collected from wearables can reach healthcare staff and patients.

In this sense, to implement a wearables-based strategy for the Mexican Healthcare System, the following recommendations are made:

1) Include a gradual wearable-based strategy in the National Health Plan comprising relevant public and private actors and targeted groups of population considering risk management and cost-benefit analyses.

2) Focus on the use of wearables for preventing and controlling non-communicable diseases, the ones with the highest costs for the healthcare system.

3) Promote effective compliance to interoperability regulations in both the public and private systems.

4) Consider local and private previous experiences to improve existing interoperability regulations.

5) Review and update regulations aimed at ensuring the quality of health data and approval devices such as wearables (promote the creation of wearables regulatory sandboxes).

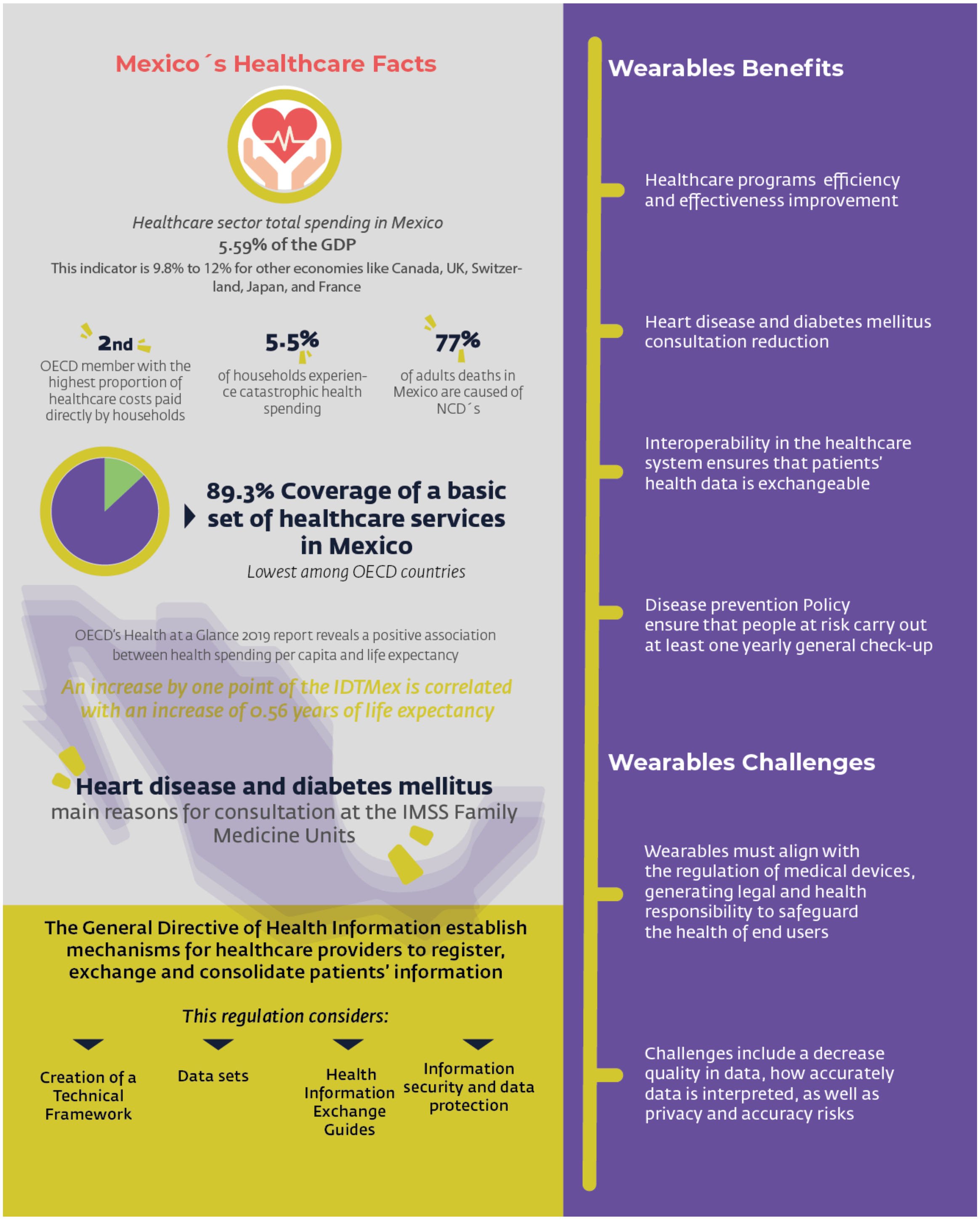
6) Implement a reverse data billing strategy focused on the free provision of data to lower income households, and prepaid users turn out to be a good guide.

7) Promote tax incentives to reduce wearables acquisition financial barriers and to promote the adoption of mobile devices and associated software (applications) development.

8) Implement a smartphone-based system for the users and healthcare staff to visualize and analyze data considering the adoption patterns of these devices.

The Mexican healthcare system is facing important challenges to guarantee universal coverage. The implementation of a wearable-based solution may represent an opportunity to alleviate the financial pressure and increase the reach of the system as mandated by the Constitution.

Fig 5. Mexico´s Healthcare



Source: The CIU, 2020.

5. APPENDIX: WEAREBALES IN HELATHCARE SYSTEM, A LITERATURE REVIEW

Focusing on Patient Management, Chen et al. showed that wearables can be used to monitor heat stroke risk, alerting users, and therefore preventing harm.[49] Nguyen, N. H. et al. found that wearable technique programs have the potential to provide effective, intensive, home-based rehabilitation, which represent an opportunity to reduce hospitalization costs.[50] By doing this, patients will be safer if they use these devices as a method to track their health.

Physical activity lower risks of various major non-communicable diseases, while improving wellbeing and mental health at the same time. In this regard, Hafner M. et al. prove that the use of smartwatches, and proper incentives for its acquisition, promote physical activity, reducing inactivity and sedentary lifestyles.[51] Furthermore, technology innovation keeps adding more tools to these devices, for example, some smartwatches added blood oxygen measurement capabilities with an integrated health sensor, able to measure it in only 15 seconds, while periodically storing user information in the health app.52

Frank, Jacobs, and McLoone used wearable device-based systems with vibration capabilities to remind students of taking breaks after long sessions of sitting, to change (and investigate) students' posture.[53]

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[49] Chen, Sheng-Tao & Lin, Shin-Sung & Lan, Chein-Wu & Hsu, Hao-Yen. "Design and Development of a Wearable Device for Heat Stroke Detection", 2017. Sensors (Basel, Switzerland). 18. 10.3390/s18010017. Available at: https://www.researchgate.net/publication/322024732_Design_and_Development_of_a_Wearable_Device_for_Heat_Stroke_Detection

[50] Nguyen NH, Hadgraft NT, Moore MM, et al. "A qualitative evaluation of breast cancer survivors' acceptance of and preferences for consumer wearable technology activity trackers". Support Care Cancer. 2017;25(11):3375-3384. doi:10.1007/s00520-017-3756-y. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28540402

[51] Hafner M., Pollard J., and van Stolk Christian. "Incentives and physical activity" Rand Corporation 2018. Available at: https://www.rand.org/pubs/research_reports/RR2870.html

[52] CNET. "Apple Watch Series 6 now measures blood oxygen, but it's not a medical device". Available at: https://www.cnet.com/news/apple-watch-series-6-now-measures-blood-oxygen-but-its-not-a-medical-device/

[53] Frank HA, Jacobs K, McLoone H. "The effect of a wearable device prompting high school students aged 17-18 years to break up periods of prolonged sitting in class". Work. 2017;56(3):475-482. doi:10.3233/WOR-172513. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28282846

In a similar way, and with an effort to reduce the frequency of patient visits to medical centers, Choo, Dettman, and Dowell proposed a rehabilitation system that combines wearables devices and motion-sensing cameras for support and assessment of patients with chronic breathing difficulties. [54]

Regarding prevention of diseases, González, S. et al. used a wireless tri-axial accelerometer bracelet to detect walking patterns in elderly people, to prevent disruptive events such as falling and seizure onset.[55] In the same direction, Hsieh et al. developed a fall detection system using an accelerometer device on the waist with about 99% accuracy in identifying falling events.[56]

For mental status monitoring, Setz, C. et al. showed that even simple electrodermal activity sensors have the capacity to identify stress levels.[57]

For breast cancer patients, the Cancer Council Victoria conducted a study with women diagnosed with breast cancer who finished treatment. By using wearable activity monitors (via accelerometers) to measure their physical activity, they found that women in the intervention group increased their physical activity by 70 minutes per week and decreased their sitting time by 40 minutes a day, in comparison with women without any intervention during the evaluation period. Increasing physical activity proved to be beneficial for woman who had suffered breast cancer.[58]

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54 Choo, D., Dettman, S., Dowell, R., & Cowan, R. "Talking to toddlers: Drawing on mothers' perceptions of using wearable and mobile technology in the home". In A. Ryan, L. K. Schaper, & S. Whetton (Eds.), Integrating and connecting care: selected papers from the 25th Australian National Health Informatics Conference (HIC 2017) (Vol. 239, pp. 21-27). (Studies in Health Technology and Informatics; Vol. 239). Amsterdam, Netherlands: IOS Press. Available at: https://researchers.mq.edu.au/en/publications/talking-to-toddlers-drawing-on-mothers-perceptions-of-using-weara

55 Gonzalez S. et al., "Features and models for human activity recognition". Neurocomuting 2015. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0925231215005470

56 Hsieh CY, Liu KC, Huang CN, Chu WC, Chan CT. "Novel Hierarchical Fall Detection Algorithm Using a Multiphase Fall Model". Sensors (Basel). 2017;17(2):307. Published 2017 Feb 8. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28208694

57 C. Setz, B. Arnrich, J. Schumm, R. La Marca, G. Tröster and U. Ehlert, "Discriminating Stress From Cognitive Load Using a Wearable EDA Device," in IEEE Transactions on Information Technology in Biomedicine, vol. 14, no. 2, pp. 410-417, March 2010, doi: 10.1109/TITB.2009.2036164. Available at: https://ieeexplore.ieee.org/document/5325784

58 Lynch, Brigid. "Wearable technology and breast cancer survivors". World Cancer Research Fund International. Available at: https://www.wcrf.org/int/research-we-fund/what-we-re-funding/using-wearable-technology-activity-monitors-increase

Similar experiments have been held to monitor cardiovascular activity in patients. Ear wearables can be used as an alternative monitoring system, no matter the place or situation a specific patient is going through. Da He, D. et al. developed an ear-worn portable ballistocardiogram with this objective. [59]

In a similar path, Goldberg, E. M., and Levy, P. D.[60] demonstrated that wearable trackers have the potential to improve hypertension control and medication adherence through ambulatory blood pressure measuring and medication reminder alerts.

In terms of disease detection, researchers from University of Michigan developed a wearable device that detects cancer in circulating blood. This device, which is in testing phase, "scans" cancer cells. This innovation might replace traditional biopsies[61] for cancer detection which are invasive to the body and generally uncomfortable to the patients.

Wearables are also being used as a tool to help tackle the COVID-19 epidemic. Stanford Healthcare Innovation lab launched a study exploring how data collected from wearables can be used to predict infectious diseases before symptoms start.[62] Stanford Medicine researchers are seeking a series of algorithms that indicates the behavior of the immune system and how it is acting. If the algorithms succeed, the team expects to be able to contribute to curb the spread of viral infections, like COVID-19.[63]

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[59] D. D. He, E. S. Winokur and C. G. Sodini, "An ear-worn continuous ballistocardiogram (BCG) sensor for cardiovascular monitoring," 2012 Annual International Conference of the IEEE Engineering in Medicine and Biology Society, San Diego, CA, 2012, pp. 5030-5033, doi: 10.1109/EMBC.2012.6347123. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4384813/

[60] Goldberg, Elizabeth & Levy, Phillip. (2016). New Approaches to Evaluating and Monitoring Blood Pressure. Current Hypertension Reports. 18. 10.1007/s11906-016-0650-9. Available at: https://www.researchgate.net/publication/301734559_New_Approaches_to_Evaluating_and_Monitoring_Blood_Pressure

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[63] *Id.*

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