WHITE PAPER ON CONNECTED HEALTH

The case for medicine 2.0

Withings
Inspire health

Contents

This White Paper was written by the **Withings Health Institute**, which relied on the medical expertise of:

Dr. Eric Topol

Voted as the #1 *Most Influential Physician Executive* in the United States in 2012 in a national poll conducted by Modern Healthcare, Dr. Topol works on genomic and wireless digital innovative technologies to reshape the future of medicine. He is a practicing cardiologist at Scripps in La Jolla, California, where he leads the flagship NIH supported Scripps Health Translational Science Institute, and serves as Chief Academic Officer for Scripps Health and as Professor of Genomics at The Scripps Research Institute. He has published 1100 peer-reviewed articles, has been elected to the Institute of Medicine of the National Academy of Sciences, and is one of the top 10 most cited researchers in medicine. He is also Editor-in-Chief of Medscape and Chief Medical Advisor for AT&T. His book *The Creative Destruction of Medicine* was published in 2012 and his new book *The Patient Will See You Now* will be published in early 2015.

Dr. Nicolas Postel-Vinay

Nicolas Postel-Vinay, a doctor at the Georges Pompidou European Hospital, was head of the communication office of the French Public Health Department. He has also served as chair of Biomedical Innovation at the Collège de France for 18 months. Dr. Postel-Vinay is in charge of telemedicine and therapeutic education programs for public and private hospitals. He is a specialist in medical self-measurement.

Dr. Guillaume Bobrie

Guillaume Bobrie (Georges Pompidou European Hospital), a nephrologist and hypertension specialist, contributed to the French hypertension and chronic renal failure guidelines. He co-founded the French Nephrology Epidemiology and Information Network, recently taken over by the Biomedicine Agency (DIADEM). He has over 20 years of experience in teletransmission and home monitoring of patients. Dr. Bobrie has received several grants for research protocols. In particular, he has demonstrated the benefits of home monitoring of blood pressure over clinical measurement.

INTRODUCTION

In less than two decades, Internet and mobile phones have revolutionized our communication methods. The health sector has eagerly embraced these new technologies. Over 11,000 professional medical journals have been made accessible online through Pubmed, the US National Library of Medicine database. Online access to medical data has facilitated telemedicine exchange protocols, and mobile phones have increased access to medical information among the general public. Over 100,000 smartphone health apps have been released. Today, medical use of new technologies has become a recognized field of scientific research. Engineers, bio-statisticians and clinicians are working together to develop new forms of telemedicine that serve patients and health professionals alike.

Connected devices are the latest innovation in this ongoing revolution. As medical sensors have gotten smaller and the population of smartphone users has gotten larger, there is an increase in the use of connected devices, which makes it easier for people to monitor their health data on the go and share it with medical professionals if they so choose. Connected scales, pedometers and blood pressure monitors have never been so easily accessible. This allows the growing automation in collecting healthcare metrics, such as weight, blood pressure, activity level, heart rate, oxygen saturation, body temperature, blood glucose level, expiratory rate, and sleep.

The expression “connected health”, or “m-health” (mobile health), has come into widespread use to designate a breakthrough that is not just technological, but also social. Until recently, only healthcare professionals monitored patients; now, patients have the tools to take many of their healthcare needs into their own hands.

The number of mobile applications is on the rise, from coaching to prevention, screening, diagnosis, monitoring, therapeutic education, adaptation of care, and orientation toward treatments. For medical practice, the relevance of data gathering varies widely depending on the user profile and on the context.
For example, weight data means something different based on whether it involves a child, an overweight adult or a patient with congestive heart failure. In addition to medical diagnosis, automated data collection has socio-professional repercussions, and raises new questions:

- **How is medical practice impacted?**
- **How does m-health improve patient outcomes?**
- **Should healthcare be re-organized to integrate m-health?**

In a classic medical system, patients make appointments with doctors if symptoms appear and follow their advice until the problem disappears. However, the best type of care for chronic diseases is the exact opposite. Asthma or diabetes patients, for example, are asked to adopt preventative behaviors. They must not only anticipate complications, but also take action immediately if these occur.
They must learn how to assess their own situation in order to decide whether or not to call a doctor. This empowerment of the patient requires a well-supervised therapeutic education. M-health offers new possibilities to perfect home monitoring methods and self-management programs.

Connected health is emerging at a time when connected devices are becoming more necessary, given the increasingly aging population and the soaring rates of chronic diseases. The medical profession should not be apprehensive about patients equipping themselves with connected devices.
On the contrary, a constructive dialogue between both parties should be established. For that, a thorough assessment of the impact of these new tools and practices must be encouraged.

I.
CONNECTED DEVICES: A PRACTICE OF WELL-ESTABLISHED MEDICAL BENEFITS

1. Self-measurement, a practice of well-established medical benefits

Self-measurement, a long established practice, is defined as the measurement of health parameters by the patient himself. In the early 20th century, households started acquiring scales and thermometers, in particular because the scourge of tuberculosis required tracking changes in weight and body temperature. Home monitoring of chronic diseases has been on the rise since the 1980s, when patients were given devices to easily measure their blood glucose level (first with urine strips to check for glycosuria or acetonuria, then with devices to monitor capillary glucose levels), breathing ability (with peak-flow meters) and blood pressure (with electronic blood pressure monitors).

Many studies have shown that these devices are useful in quantifying medical conditions. For example, difficulty in breathing can be accurately evaluated with a spirometer. Increasing numbers of home blood pressure measurements have improved the accuracy of the definition of pressure levels, compared to measurements made exclusively in a medical environment. These devices have also proven their usefulness in monitoring chronic diseases. Data from epidemiological studies and therapeutic trials have demonstrated statistical relationships between the measurements' results and the occurrence of health events. It has therefore been possible to set threshold values of self-measured parameters above which a health risk becomes significant and, consequently, calls for medical intervention.

That is why, in current medical practice, doctors ask their patients with diabetes, asthma or hypertension to keep diaries of their home monitoring results. Recording these values enables doctors to propose prevention plans. **The concept of self-measurement leads to that of self-monitoring and, finally, to that of self-management. This approach gives the patient more room to make decisions with a strong base of scientific rationale.** Digitalization opens the door for smart tools that lead to preventive actions through the collection of data.

Table: Main home monitoring devices and their uses

Measured parameter	Device	Pathology	Description
Capillary glycemia	Glucometer	Type I (insulin dependent) and type II (non-insulin dependent) diabetes	In use since the 1980s. Recommended today by scientific associations and patient organizations, under the condition of users following a therapeutic education comprising the definition of an action plan. Effectiveness is higher for type I diabetes.
Weight	Scale	- Overweight and obesity - Eating disorders (bulimia/anorexia) - Diabetes - Hypertension - Heart failure - Renal failure - Pediatric disorders	Home weight monitoring dates back to the early 20th century. Measurement protocols and interpretation of results clearly differ from one pathology to another. The relation between weight and height allows the calculation of the body mass index (BMI). The scale is the most widespread self-measuring device.
Blood pressure	Electronic blood pressure monitor	- Hypertension	In use since the 1980s. Recommended since the 2000s, subject to compliance with a measurement protocol. Home measurement, considered more accurate than measurement in clinical settings, is advised for screening and monitoring.
Heart rate	- Watch - Electronic oscillometric blood pressure monitor - Heart rate monitor	- Disorders related to a sports practice - Heart rate disorders - Heart failure	Heart rate is monitored in certain physical activities (jogging, cycling, etc.) and cardiovascular situations (disorder symptoms, myocardial infarction, medication intake, etc.), but home measurement is not the most common large-scale practice.
Expiratory rate	Peak-flow meter	Asthma	In use since the 1980s. Recommended since the 2000s, subject to user education as this self-measurement has a complex procedure.

Measured parameter	Device	Pathology	Description
SpO_2 (oxygen saturation rate)	Pulse oximeter (or saturation monitor)	Chronic obstructive pulmonary disease (COPD)	Saturation meters are available for the general public but the interpretation of the results is difficult. Studies on the usefulness of home monitoring of SpO_2 as a means of preventing COPD from getting worse have not yet found positive results.
Number of steps & movement level	- Pedometer - Accelero-meter	- Public health campaigns against sedentary lifestyles - Incitation to walk more for people with diabetes, asthma, obesity, lower limb arthritis and heart conditions	Although pedometers are inexpensive and easy to use, they are still infrequently recommended or used in current medical practice. By helping increase physical activity, they help improve the level of glycated hemoglobin, weight and cholesterol. The long-term persistence of their impact is unknown.
Body temperature	Thermometer	Diagnosis of fever, especially in children	The thermometer has been in very widespread home use since the early 20th century. Used to monitor infectious diseases and to guide people whether or not to call a doctor.

Home monitoring and diabetes

Home monitoring of patients with diabetes has demonstrated its capacity to significantly reduce glycated hemoglobin levels. A meta-analysis of 7 randomized studies of patients with type II diabetes comparing usual treatments to treatments using technologies allowing the teletransmission of glucose levels has shown an average decrease of glycated hemoglobin of 0.5% [(1)]. Mobile phone coaching reduced glycated hemoglobin by 1.2% after 12 months [(2)]. According to a UKPDS study, lowering the glycated hemoglobin level by 1% helps cut the risk of all-cause mortality by 14%, the risk of myocardial infarction by 14% and the risk of microvascular complications by 37%. In addition to transmitting biological data, mobile solutions can include guidelines-compliant educational programs. Experiments on the prospect of direct connection to medical files are in progress.

2. Connected devices: a technological and democratic disruption

A simplified measurement

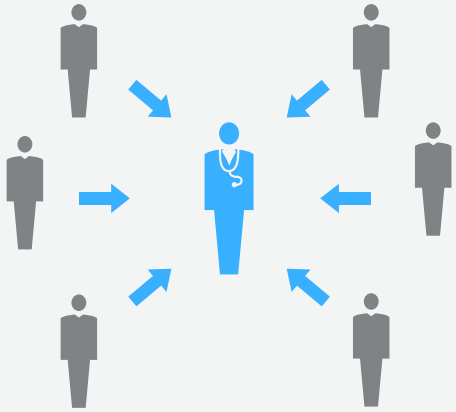
For the first time, individuals using smartphones or tablets as communication gateways are able to compile self-measured records into an easily accessible personal dashboard, allowing them to monitor their health indicators on a day-to-day basis. For example, Withings' Smart Body Analyzer instantly recognizes the person in the household stepping on the scale, and calculates the user's weight, fat mass, heart rate, and body mass index (BMI). All the records are sent to a smartphone/ tablet over a wireless network without any additional effort. For Withings, this simplicity of usage is the recipe for long-term monitoring that will motivate users to make sustainable progress – by managing their weight, watching their blood pressure, or becoming more active.

New data, new relationship to your health

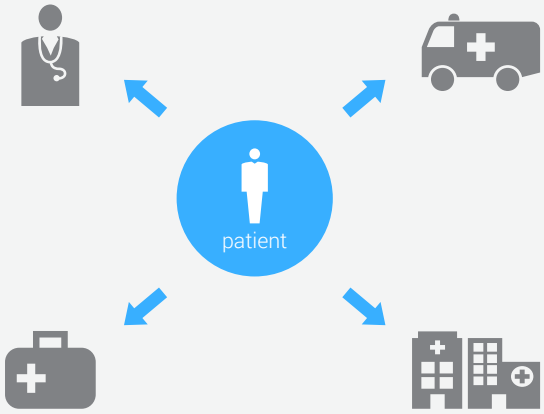
Connected devices generate new knowledge for users. In the past, weight was the only indicator that was widely monitored on a regular basis. **As the use of connected devices becomes increasingly popular, the variety of measurements accessible to the general public is constantly on the rise.** Dr. Eric Topol draws a list of pathologies [(3)] that users can learn to better manage using connected devices:

- **Obesity and nutrition disorders:** the monitoring of weight, activity level, quantity of ingested and burned calories is one of the main m-health applications;
- **Hypertension:** treated better thanks to the dissemination of connected blood pressure monitors, which help increasing compliance and avoiding the "white coat" effect;
- **Diabetes:** connected glucometers allow monitoring glycemia and the hemoglobin level in the blood, for the purpose of adjusting treatments;
- **Sleep disorders:** new monitoring devices, worn on the wrist or placed on the bed, enable patients to learn more about the phases of their sleep;
- **Chronic obstructive pulmonary disease (COPD):** activity trackers and connected oximeters can improve COPD treatment;
- **Asthma:** treated better by monitoring the respiratory rate; the detection of peak flows can prompt patients to use an inhaler before the onset of a new attack.

These technological breakthroughs can help modify one's relationship with his/her health. **Individuals are finally empowered. They are not only involved in monitoring and controlling their health but also in sharing this information with communities of patients and with their doctors.** On the doctors' side, it is becoming harder to ignore patient-generated data. Doctors would benefit from learning how to use this new source of information to enrich and improve their diagnoses.



From passive and limited data collection…



… to active, continuous patient-centric monitoring.

II.
BETTER MANAGE ONE'S HEALTH, RETHINK MEDICAL PRACTICE

1. Tools that reinvent prevention

With Internet-connected devices, users are inventing a whole new relationship to their health. In this new paradigm, health no longer refers uniquely to patients' relationship to their diseases. There is an increasing interest in prevention, not only focusing on treating or curing patients of diseases but helping healthy individuals reach an optimal management of their current health status.

In 2014, Withings conducted an unprecedented study on the impact of connected devices on health. The study analyzed data from a representative sample of scale, blood pressure monitor and activity tracker users. The findings outline the positive effects of using these connected devices on improving weight and blood pressure control, and on increasing physical activity.

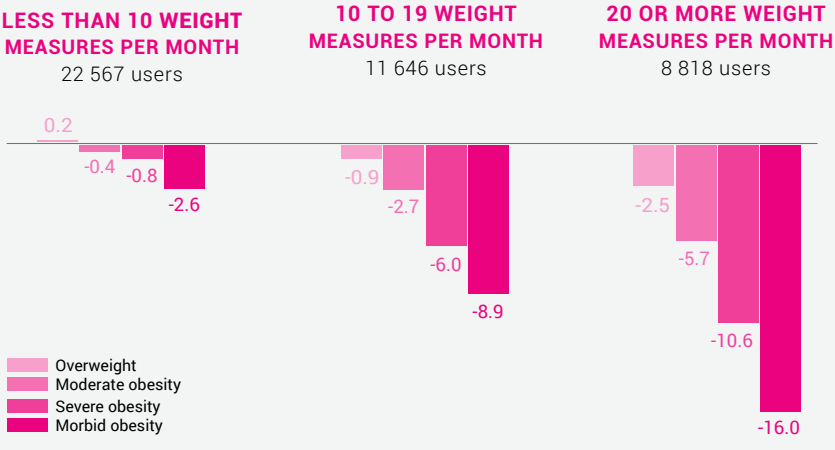
Weight control

Users suffering from obesity who weigh themselves on a regular basis lose, on average, much more weight than those who do not. For example, the Withings study shows that users with very severe obesity who used their scales 20 or more times a month lost six times more weight than those who used their scales less than 10 times a month.

Average weight evolution according to the frequency of weight measures

in lb, over a 12-month period

Sample of overweight or obese users 20 to 79 years old, having used both the scale and the BP monitor in the 12-month period May 13 to April 14. Weight evolution computed as the difference between 12th and 1st month averages; weight measure frequency as the average number of measures per month over the months of utilization of the scale in the period; BMI class according to WHO classification and as the average at the 1st month of utilization of the scale in the period. $p < 0.001$.

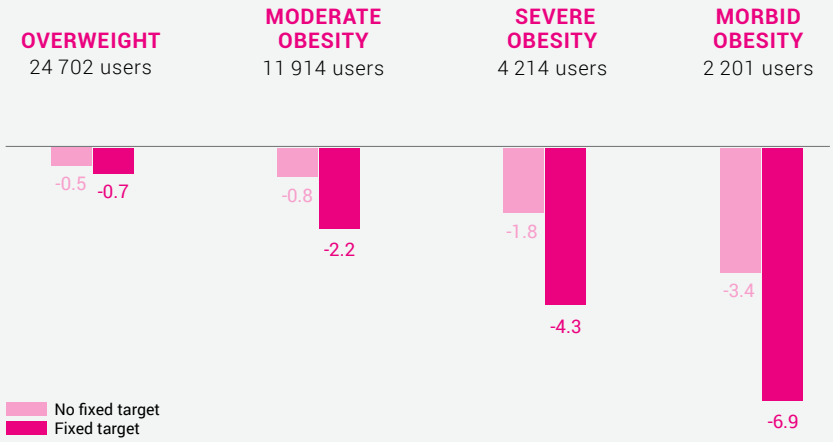


The study also showed that **setting weight targets on the mobile app with automatic reminders is correlated with weight loss.** On average, users with very severe obesity who set a target weight lost 6.9 lb over a year, twice as much as those not having set a target weight (3.4 lb).

Average weight evolution according to the existence of a fixed weight target

in lb, over a 12-month period

Sample of overweight or obese users 20 to 79 years old, having used both the scale and the BP monitor in the 12-month period May 13 to April 14. Weight evolution computed as the difference between 12th and 1st month averages; BMI class according to WHO classification and the average at the 1st month of utilization of the scale in the period. $p < 0.001$.



The scientific literature reveals similar findings. For example, a study published in JAMA [(4)] analyzed 69 overweight or obese people above 50 years old who were on a diet. The group was divided into two subgroups, one with mobile coaching and the other without mobile coaching. The study showed that after six months, the group coached by mobile phone cues lost an average of 8.6 lb more than the group following standard treatment. Additionally, 41% of the mobile group reached the goal of losing at least 5% of their weight versus 11% for the others.

“With Internet-connected devices, users are inventing a whole new relationship to their health.”

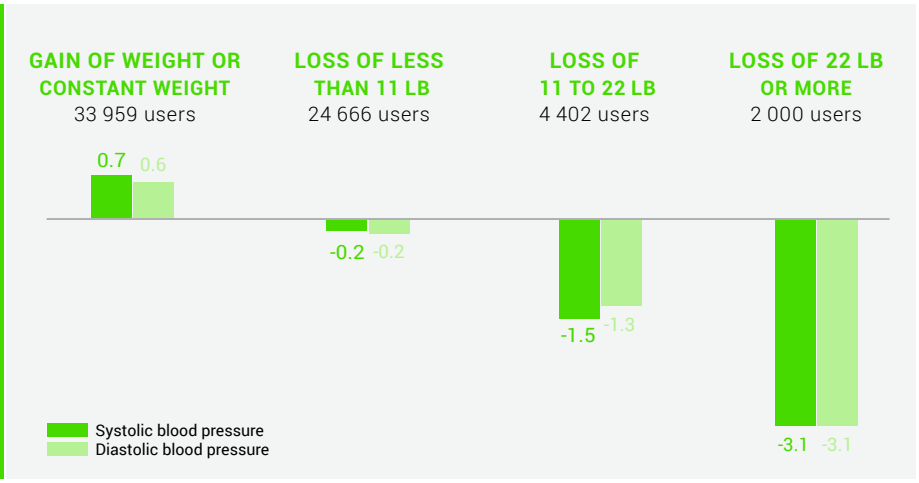
Blood pressure control

This is also a **high correlation between weight loss and lowering blood pressure.** Users in the Withings study who lost 22 lb or more over the period of a year also lowered their systolic and diastolic pressure by 3 mmHg.

Average blood pressure evolution according to the corresponding weight evolution

in mmHg, over a 12-month period

Sample of users 20 to 79 years old, having used both the scale and the BP monitor in the 12-month period May 13 to April 14. Weight and blood pressure evolution computed as the difference between 12th and 1st month averages. No information about the consumption of hypertension drugs by the users. $p < 0.001$.



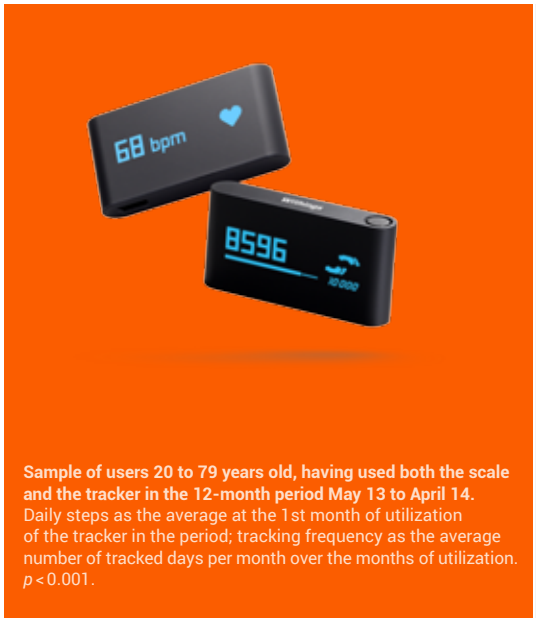
Likewise, a study by the Center for Connected Health on the use of connected blood pressure monitors, published in May 2013 in the *Journal of Diabetes Science and Technology* [(5)], concludes that **wireless blood pressure monitoring has a positive impact on users' adherence, on clinical results and on the operational efficiency of telemedicine.** Participants in a wireless blood pressure monitoring program took their blood pressure more often and transmitted more data than those who were connected by modem (0.46 compared to 0.01 data transmissions per day, respectively). The conclusions are also positive for the control of blood pressure levels: the wireless blood pressure monitoring program had the effect of reducing the participants' systolic pressure by 6 mmHg and diastolic pressure by 2 mmHg. **According to the study, a decrease of 5 mmHg reduces the heart attack mortality rate by 14% and the heart disease mortality rate by 9%.**

Stimulation of physical activity

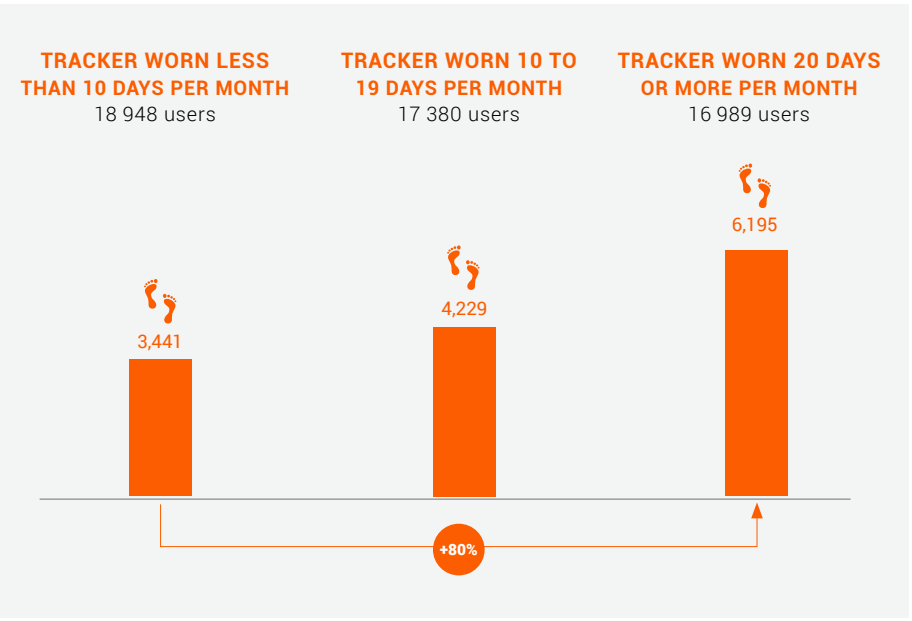
Lastly, the study conducted by Withings examined data from activity trackers. One of the main conclusions of the study is that **the regular use of a connected tracker is correlated to a higher level of physical activity.** Users who wore the tracker 20 days or more during the first month of use walked an average of 6,195 steps a day, 80% more than the average of 3,441 daily steps recorded for users who wore it less than 10 days a month.

Average number of daily steps according to the frequency of utilization of the tracker

in number of steps per day



Sample of users 20 to 79 years old, having used both the scale and the tracker in the 12-month period May 13 to April 14.
Daily steps as the average at the 1st month of utilization of the tracker in the period; tracking frequency as the average number of tracked days per month over the months of utilization.
$p < 0.001$.

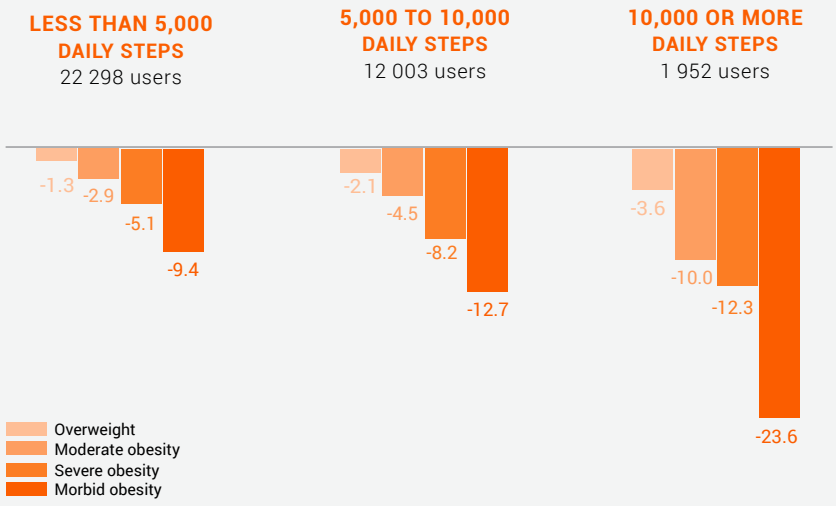


These figures confirm the findings of scientific studies such as the one published in 2007 in JAMA on the impact of pedometers [(6)]. The study showed that **people who monitor themselves with a pedometer walk an average of 2,000 additional steps a day, and record a drop in their blood pressure of 3.8 mmHg.** Similarly, the Withings study shows that **the most active users were also the ones that lost more weight.**

Average weight evolution according to the number of daily steps

in lb, over a 12-month period

Sample of overweight or obese users 20 to 79 years old, having used both the scale and the tracker in the 12-month period May 13 to April 14. Weight evolution computed as the difference between 12th and 1st month averages; daily steps as the average at the 1st month of utilization of the tracker in the period, BMI class according to WHO classification and as the average at the 1st month of utilization of the scale in the period. $p < 0.001$.



" The regular use of the connected tracker is correlated to a higher level of physical activity."

2. A paradigm shift in medicine

Mobile phones, the Internet, and connected devices are having a major impact on healthcare professionals. Mobile phones have already revolutionized the access to emergency care, and the Internet has proven its usefulness in terms of health-related education and information to patients. Today, **connected devices reinforce physicians' adherence to long-term monitoring and limit therapeutic inertia regarding chronic diseases.** Most importantly, **they foster a new relationship between the patient and the doctor** who will increasingly have to take into account this new source of information. Indeed, a growing number of EMR (Electronic Medical Records) are now integrating mobile apps' data, coming from connected objects.

An effect on monitoring adherence and on therapeutic inertia

It is already established that sending automatic SMS reminders raises the odds that patients will take their medication when they should. Several acknowledged studies with have demonstrated its positive impact regarding malaria treatment [(7)], anticoagulant therapy after myocardial infarction [(8)], and diabetes medication [(2)]. Smoking cessation programs have demonstrated the most significant impact. Similarly, combining coaching through SMS with relaxation programs available on the Internet has proven to be effective [(9)]. There are already many Internet programs aiming to help people lose weight and to encourage them to exercise.

Text messaging can help to prevent and manage chronic diseases

Sending automated SMS to help monitor chronic diseases has already proven its usefulness in various scenarios. Experiments have shown positive results, especially in helping people quit smoking or lose weight. For example, experiments have allowed patients with type II diabetes to better control their glycated hemoglobin levels, and to better follow a drug treatment (antimalarial and diabetes medication, and anticoagulant therapy after a myocardial infarction). There is no lack of interesting studies but those with rigorous methodology are not numerous (4 randomized studies including 182 participants according to a 2012 Cochrane review (10)), and there are negative experiments. Medical use of SMS also involves prevention, for example in monitoring pregnancy or the intake of vitamin C (11). Although there is a gap between a sometimes too-enthusiastic communication and the availability of proofs, medical use of SMS constitutes an element in favor of the development of the m-health.

M-health encourages patients' adherence and limits doctors' therapeutic inertia. Follow-up studies of hypertension patients treated by telemedicine show for example how teletransmission of blood pressure levels not only boosts patients' adherence, but also influences doctors to adapt treatments more actively.

Impact of blood pressure home monitoring on therapeutic inertia

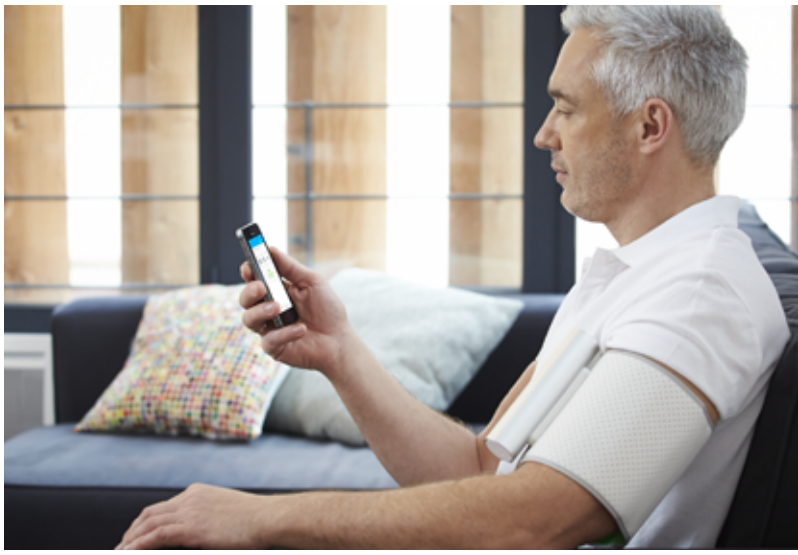
A randomized telemonitoring study [12] involving 401 patients has shown that combining home monitoring of blood pressure with telemonitoring of the results by nurses helps control hypertension better. The best result (4.3 mmHg for systolic and 2.3 mmHg for diastolic pressure) is obtained when doctors telemonitor their patients. Teletransmission led them to increase treatments more often than for the group with traditional care. However, this advantage is offset by a higher cost of care.

Likewise, a smartphone app has proven its ability to influence the behavior of patients being treated for alcoholism. An alert warns users when they come near a usual place of alcohol consumption, whose location has been recorded beforehand. Another case worth mentioning is that of connected bracelets used for GPS monitoring of patients with Alzheimer's disease, which have the effect of delaying their admission to specialized residences. Today, these types of connected devices are commonplace.

Geolocation combined with support programs to assist patients being treated for alcoholism

Smartphones can combine various functions such as access to multimedia information, geolocation, and SMS. All of them have been brought together in an app to support patients undergoing treatment for alcoholism. In a randomized clinical trial [13], patients who were trying to stop drinking were connected, with sharing of geolocation data. All the usual places where they went drinking were recorded in the app beforehand. When they approached one of these places, the app automatically sent a message asking the user if he or she "really wanted to be there". The app also offered relaxation programs and allowed the user to contact a support person. A scientific evaluation demonstrated the app's effectiveness.

“Connected devices reinforce physicians’ adherence to long-term monitoring and limit therapeutic inertia regarding chronic diseases.”



A new doctor-patient relationship

Broader access to medical information is changing the doctor-patient relationship. For example, a survey conducted in 2013 on 1172 Withings users revealed that in France, nearly 25% of connected blood pressure monitor users over 60 years old communicate their data to their doctors. This figure reaches 42% in the United States and 31% in Germany. Sharing information has become a common practice.

For the improvement of the patient-doctor relationship

Tools that allow to easily exchange data

42%

of American Withings Blood Pressure Monitor users over 60 **share their data with their doctor.**

Source : Survey conducted on 1172 senior users in December 2013.

Simpler home monitoring is reshaping the patient-doctor relationship, which now extends beyond the medical consultation. **Technological change is a vector of sociological change, as it becomes easier to know what happens to patients between consultations.** This change of paradigm is particularly noticeable for chronic diseases.

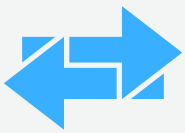
Reshaping the patient-doctor relationship

For a better management and prevention of chronic conditions

Doctor

Data sharing

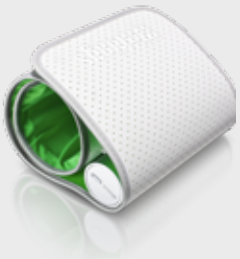
Disease management



Patient

Withings Pulse Activity Tracker

- Motivates patients to stay active.
- Combats the effect of metabolic syndrome.
- Monitors resting heart rate.



Wireless Blood Pressure Monitor

- Easy and precise self-measurement.
- Helps patients maintain healthy blood pressure levels between consultations.
- Helps adjust dosing requirements based on circadian rhythm patterns.

Smart Body Analyzer

- Effortless weight, body mass and heart rate monitoring.
- Motivates patients to lose and maintain a healthy weight.
- Helps congestive heart failure patients monitor their fluid status.

Did you know ?

- The University Hospital of Toulouse uses Withings devices to help adjust the treatment of type 2 diabetes patients (Project Educ@dom). → ***http://economie-numerique.blogspot.fr/2013/11/congres-antel-educdom.html***
- UCSF's groundbreaking *Health eHeart* study uses Withings devices. → ***http://www.health-eheartstudy.org***
- Activity trackers tend to motivate users to walk an extra 2,000 steps a days on average (Source : *Using Pedometers to increase Physical Activity and improve Health,* JAMA. 2007 ; 298 (19) : 2296-2304).
→ ***http://jama.jamanetwork.com/article.aspx?articleid=209526***

New home monitoring possibilities are not only changing telemedicine in its existing framework; they are also contributing to its generalization. The popularization of connected devices reduces the cost of home monitoring chronic conditions, as each patient is able to use these technologies with his or her smartphone, and to send the resulting data directly to his or her doctor.

In addition to economic gains, telemedicine can improve the comfort and quality of life of patients suffering from a chronic disease. It can reduce travel time, shorten the length of a hospital stay, lower the number of doctor appointments and raise the patient's level of therapeutic education.

Connected devices make it easier to know what happens to patients after they leave the hospital or between two medical consultations. This is particularly true regarding obesity surgery, where patients are equipped with connected scales and blood pressure monitors. For heart operations, activity trackers can be used to monitor patients after the intervention. Home monitoring using activity trackers also proves to be useful in cases of hip replacement surgery, to facilitate physical reeducation and detect intervention needs, in time to avoid re-hospitalization. This benefits the patient and also helps cut healthcare costs. **With connected devices, doctors have access to new health data, which can be used to improve the control of patients' health conditions outside consultations.**

Examples of telemonitoring uses of connected devices

Measures	User Data	Applications
Weight, BMI & Body Fat Percentage	Gender, **Age**, Family situation, Living area, Medical condition, Frequency of measures	• Diabetes prevention & pre-diabetes management • Management of post-bariatric surgery conditions
Blood Pressure (diastolic and systolic) and **Heart Rate**		• Heart failure tracking • Hypertension diagnosis • Assessment of diuretics' effectiveness
Activity (steps, elevation, calories)		• Cardiovascular risk detection • Respiratory diseases tracking
Sleep phases (light, deep, awaken)		• Sleep disorders tracking • Sleep apnea detection

3. Changing the healthcare organization

A new split of roles and responsibilities

M-health leads to a greater delegation of doctors' tasks, in particular in the monitoring of drug therapies and of hygiene and dietary treatments. Tasks tend to be delegated to the patient, but also to other health professionals – nurses, pharmacists, telemedicine assistants, etc. As an example, studies showing the benefits of connected glucometers involve nurses in the adaptation of insulin doses to patients with type I diabetes.

Overall, the organization of healthcare is influenced by the interpretation of the connected devices' results: for example, an abnormal result will prompt users to make an appointment with a doctor, while a reassuring one will encourage them to postpone their appointments.

A new momentum for telemedicine

The integration of connected devices into telemedicine is still in its beginning stages, both for prevention and for the monitoring of declared diseases. More detailed medical-economic evaluations are needed, in order to establish the medical relevance and the potential for healthcare costs optimization of these devices. Many implementations in the United Stated and Europe have already shown encouraging results.

- In the United States, the Saint Vincent Health organization has set up a telemonitoring system in Indiana for patients with chronic heart failure and with chronic respiratory failure. After two years, results show that the readmission rates to the hospital have fallen to 5%, a 75% drop compared to the American average. In France and Germany, the Cardiauvergne and Alere programs aim to showcase similar results.

- In 2013, researchers at the Scripps Translational Science Institute launched a clinical study [(15)] to show connected devices' direct effects on healthcare spending: 200 participants with common chronic diseases – diabetes, hypertension or cardiac arrhythmia – received a Withings blood pressure monitor and an iBGStar glucometer. Results will be compared to those of a control group not equipped with connected devices.

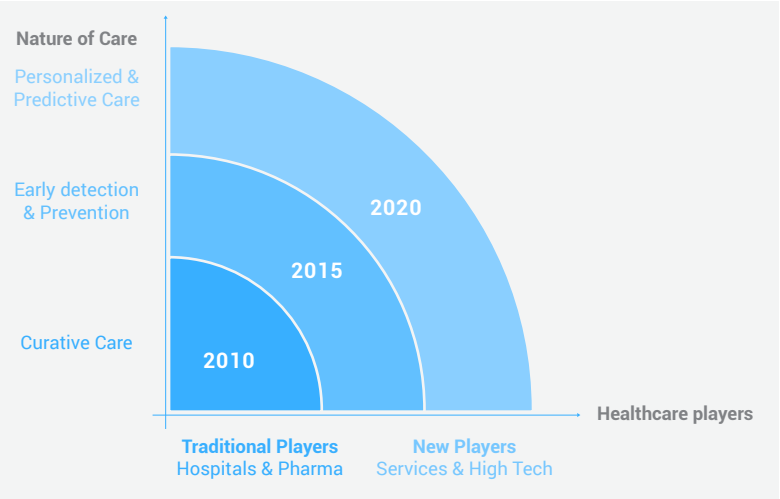
A study carried out by Myriam Le Goff, a professor and researcher at Télécom-Bretagne, in association with the consulting firm JALMA [(14)], estimates that the deployment of telemedicine for four chronic diseases (diabetes, hypertension, heart failure and kidney failure) could generate up to €2.6 billion in healthcare savings in France. Similarly, in 2013 PricewaterhouseCoopers assessed at €99 billion the total of healthcare savings for the European Union that could be attained by 2017 [(16)].

From preventive to predictive medicine, from doctors to data scientists

Connected devices do more than just produce data for users, patients and doctors as part of individual care. They also generate a collective intelligence thanks to the mass of data that can be aggregated to analyze overall trends. For Google founder and CEO Larry Page, **the use of health data for the advancement of medical research "will save hundreds of thousands of lives"**. The mass of collected data opens the door to much more accurate analyses of the healthcare system – with the purpose of optimizing it – and ultimately to a shift from preventive to predictive medicine. With Big Data providing several new tools to prevent and predict pathologies, the data scientist role emerges, suggesting an evolution of the medical profession itself.

Expected evolution of healthcare

Source : *Santé : Horizon 2020*, JALMA ; Withings



There are numerous perceptible signs of this evolution. In Great Britain, for example, the General Practice Research Database [17], an anonymized database of medical records created under the authority of the NHS, has already served as a basis for nearly 1,200 academic studies. These studies have, for example, improved clinicians' understanding of the causes of rheumatoid arthritis, and helped them to better dose anticoagulant drugs in atrial fibrillation treatments. The following table shows some examples of how Withings connected devices are being used in medical studies in universities or hospitals.

Table: Examples of medical use of Withings connected devices

Institution	Description	Types of connected devices used
Scripps Wired for Health Study	200 participants with common chronic diseases – diabetes, hypertension or heart arrhythmia – have been given a Withings blood pressure monitor and an iBGStar glucometer. Results will be compared to those of a control group not equipped with connected devices.	Blood Pressure Monitors
North Norway University & NST Telemedecine center	The *Norwegian Center for Integrated Care and Telemedecine*, in partnership with the Northern Norway Hospital, is equipping a number of cohorts of patients suffering from heart failure with Withings connected scales, with the objective of generating automatic alerts for these patients.	Scales, Blood Pressure Monitors
Stanford	Prof. David Michael Axelrod uses "Baby Scales" at the hospital of the Stanford University for his pediatric, pediatric cardiology and general cardiology studies.	Scales
UCD	Withings blood pressure monitors, scales and trackers are being used in a study of pregnant women suffering from type 2 diabetes.	Scales, Blood Pressure Monitors, Activity Trackers
Cornell	David A. Levitsky (Stephen H. Weiss Presidential Fellow Professor of Nutrition and Psychology) uses Withings scales for his research around nutrition.	Scales

Institution	Description	Types of connected devices used
CHU Toulouse Hôpitaux de Toulouse	The Educ@Dom project aims at equipping around 100 type 2 diabetes patients with connected devices to be used at home (scales, blood pressure monitors and trackers). These devices would allow generating alerts for an early medical intervention.	Scales, Blood Pressure Monitors, Activity Trackers
American Medical Group Association Measure Up Pressure Down	Withings blood pressure monitors are used to monitor blood pressure levels as part of the national campaign “Measure Up, Pressure Down.”	Blood Pressure Monitors

III.
LEVERS TO SPEED UP THE DEPLOYMENT OF M-HEALTH

1. Encourage adoption by doctors

Investing in experimentation and evaluation

An evaluation and certification effort is still necessary to convince healthcare professionals and authorities to adopt innovation more readily. The evaluation studies should be set under a pragmatic framework, instead of being uniquely based on classic methodologies for clinical trials. Of course, the hypotheses and results tested must be relevant, the study population well characterized, and the methodology free of bias. The sample of study subjects also needs to be large enough to allow for relevant demonstrations. All these requirements come naturally with a cost. Investing is research is necessary.

The digitalization of medical and prescription records has mobilized considerable expertise in the past 30 years. It is also the case of telemedicine, with experiments applied to disease management in the context of home monitoring. So far, these implementations have not fully succeeded to demonstrate a cost-effectiveness potential. **The economic challenge of mobile health in the context of connected home monitoring will be to offer solutions that are less expensive than telemedicine practices currently employed by the medical profession.**

The integration of connected devices into existing EMR/EHR (Electronic Medical Record/Electronic Health Record) software should be accelerated. This would not only enrich the database of electronic medical records, but also prompt doctors to adopt m-health. With players such as Apple and Google now pushing for the integration of patient generated data into EMR, change is coming faster than expected.

Training doctors

Doctors generally agree on the health benefits of new technologies. A survey carried out in 2011 by Accenture [(18)] shows that over 70% of physicians in France, and nearly 60% in the United States, believe these technologies improve access to quality data for clinical research, allow better coordination of treatments and reduce medical errors. However, a generation gap has been observed, as physicians over the age of 50 show themselves more skeptical.

New digital technologies are better perceived after a practice and appropriation stage. Based on this information, it is essential to train doctors on how to use new technologies. It should be the role of medical schools to raise awareness among the medical community, taking into account the generational gap to tailor its teaching programs. This requires focusing on both the continuous training of doctors, with the introduction of new courses on m-health and connected devices, and the initial education of medical students with a curriculum comprising dedicated courses on these subjects.

Training patients

Medical relevance of data coming from connected devices may vary depending on the circumstances of usage of these devices. **In this context, it is also important that users be trained to follow a protocol of usage.** Doctors should be able to set up an ergonomic evaluation of devices (sensors and applications) depending on each relevant target class of users. This approach, already used in pharmacology and therapeutic education, must be extended to mobile health.

2. Reassure about devices, reassure about data

Certifying medical devices

In some situations, the usage of connected devices has strong medical implications. It is the case for cardiac arrhythmia detectors, pulse oximeters that serve to monitor respiratory failure, or glucometers that calculate insulin doses for diabetics. In these cases, technical flaws or shortcomings are likely to result in potentially serious diagnostic or therapeutic errors. **In order to protect consumers, devices with a medical use must be certified before being introduced on the market.** An example is the Withings blood pressure monitor, a medical device approved by the FDA in the United States and holding the CE label in Europe.

More generally, **the certification of m-health applications constitutes a challenge for health authorities.** The dynamism of application publishers points to an increasingly larger number of applications being launched. How should the algorithms associated with the software be certified? When this software supports a medical prescription or decision, its evaluation would not only be complex but also need to be updated on a regular basis as new versions come out and scientific knowledge develops. One could imagine an approach of regular surveillance after introduction on the market, similar to that in place today for prescription drugs.

If rigorous certification is needed in cases of high-risk medical use, it becomes irrelevant for connected devices used in a non-medical context, such as for wellness or fitness purposes. However, the line between these two classes is not always clear. For example, should the use of a heart rate monitor by a patient who has recently suffered from a myocardial infarction be supervised?

Reassuring people about the safety and the confidentiality of data

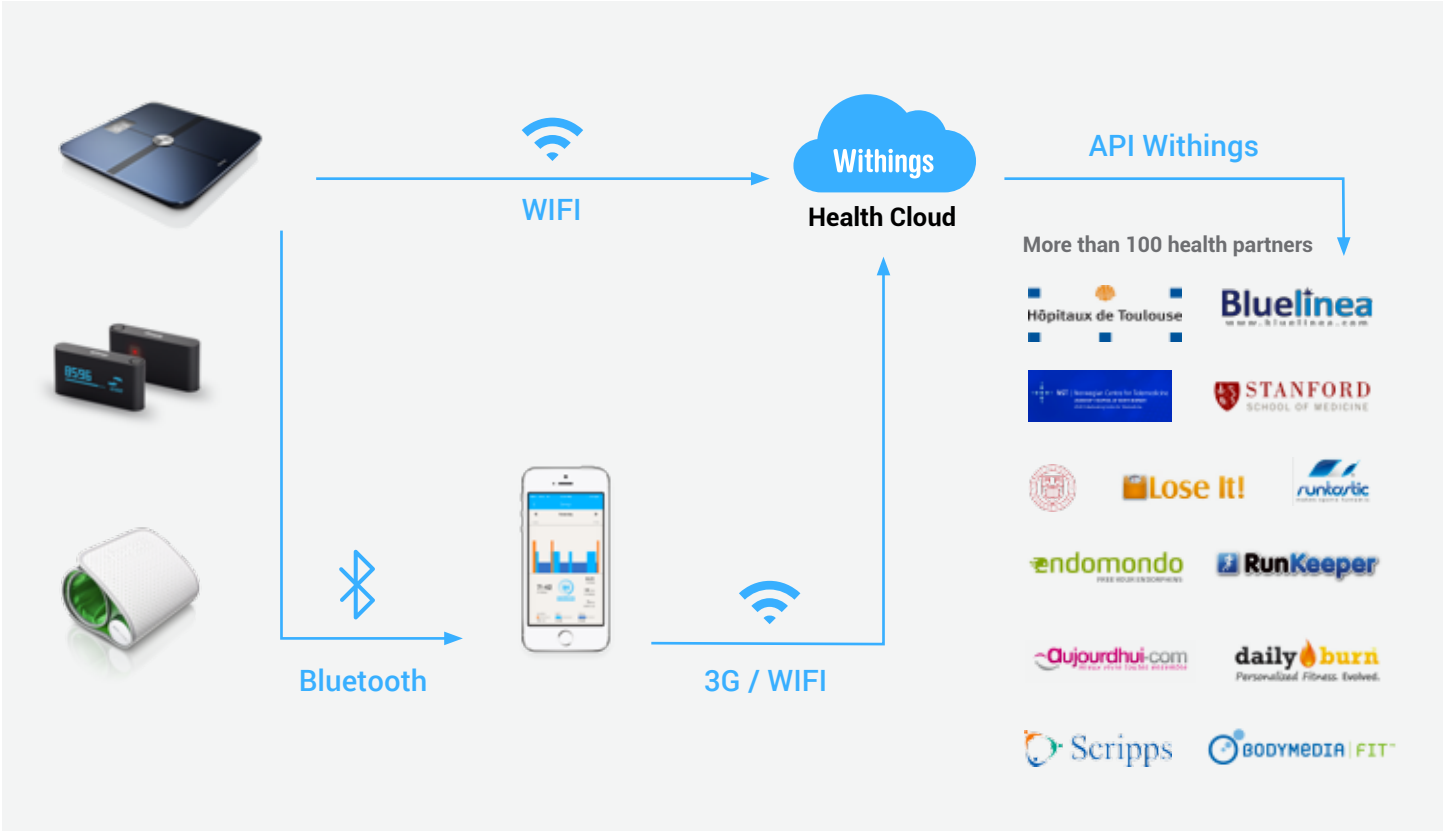
Connected devices collect personal data, which in a medical context of usage can become sensitive data. That is why it is essential to reassure users and physicians about the security of data flows.

The status of data changes depending on whether the device is used for recreational purposes, in which case it is personal data, or in a medical context, in which case it

requires conformity to specific hospital norms. The relevance of the collected data is not the same depending on whether the individual uses it himself or not. In the first case, it is the patient's own responsibility. When a doctor uses data, he is held responsible for it and for the diagnosis he generates based on it. In this case, **an accredited hosting of health data becomes necessary.**

Example of Withings API

Real-time data sharing through the API



3. Adapt the financial and regulatory framework

Large-scale deployment

Despite the rising number of studies showing the positive impact of connected devices and solutions, the regulatory context and the health insurance organization are today an obstacle to their wide-scale adoption. The main challenges involve re-imbursing patients for the devices and rethinking the way doctors are paid. In the absence of large-scale experimentation and national pilot programs, experiments are rolled out locally, relying on regional funding.

Rethinking the funding of prevention and of m-health

As connected devices open the door to a new model of prevention, the question of healthcare funding arises. **If today a disease treatment is reimbursed, why not imagine funding good health itself in the future?** In less provocative terms, is it possible to imagine funding something that keeps people from getting sick?

Today, billing for medical care does not sufficiently encourage early detection and home monitoring. To change that, it is necessary to study models where novel funding methods are used:

- **New compensation methods for doctors, based on the size of the patient pool and on the number of monitored patients with long-term illnesses should be considered.** With the rising incidence of chronic diseases, this new compensation system should optimize patients care depending on priorities.

- **Similarly, hospitals should promote tele-care of post-surgery patients**, to shorten hospitalizations and avoid patients coming back.

Lastly, sick patients and healthy people alike lack incentives to adpot prevention tools. A sedentary lifestyle, smoking habits and lack of exercise increase the odds of cancer and cardiovascular diseases. **In this context, a system rewarding healthy behaviors could be imagined.**

The corporate world: a new payer for healthcare?

The real potential for prevention may lie in the workplace. Businesses in England, Switzerland and the United States have already adopted a “corporate wellness” approach that may lead the way, where **companies fund prevention programs around the usage of connected devices.** Workplace wellness not only has an impact on productivity or absenteeism; it also ensures good health conditions on a long-term basis.

CONCLUSION

M-health and connected devices are not only going to impact medicine, but the entire healthcare system and, consequently, the role and positioning of public and private health insurers, and pension funds.

The purpose of this White Paper is to raise awareness on the impact of m-health and detail the changes that arise with m-health in general and connected devices in particular. In this new paradigm, healthy individuals also become the focus of healthcare, not with the purpose of treating or curing them, but to help them manage their health better. Since Antiquity, medicine has always been divided into two facets: Hygieia (prevention) and Panacea (treatment). With m-health, prevention and early detection tools are reshaping medical practices.

M-health and connected devices have opened the way for a second revolution: Big Data. Connected devices generate an unprecedented mass of data, and consequently create a new knowledge. In this new context, the value of health data lies in aggregation and sharing. The creation of huge databases on physical activity, weight and blood pressure of populations who voluntarily monitor themselves and agree to share their data for research purposes can spur considerable advances in medical research. Big Data analysis will show its full potential when these data can be crossed with other sources, such as insurance data, patient databases and even genetic information.

With connected objects, individuals can be treated earlier, and adopt preventive behaviors. However, benefits will only be fully achieved with the support from physicians, healthcare providers and public health decision-makers.

In this perspective, this White Paper has put forward a series of proposals to accelerate the adoption of connected health, focusing on three areas:

Encouraging the use of connected objects by the medical profession, through

- investment in research and experimentation;
- doctors education and training;
- patients' awareness on the use of these new tools.

Reassuring people about connected devices and data, through

- protection of personal data;
- certification of medical devices;
- guarantees on security and confidentiality of data.

Adapting the financial and regulatory framework, through

- creation of a high-level set up favorable to the implementation of m-health experiments;
- rethinking of the funding model for prevention and for m-health;
- encouraging of corporate wellness programs.

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