AIOTI

ALLIANCE FOR INTERNET OF THINGS INNOVATION

Report

AIOTI WG07 – Wearables

2015

Executive Summary

In the future wearables will become much more pervasive in our lives. While many technological challenges have been overcome (near field communications, energy use, miniaturization etc.) others remain, many of which are not technological. The technological advances mean that a large scale pilot project is feasible now but outside the technology sphere, end-user concerns remain (who has access to the data, who owns the data etc.). Barriers to the adoption and acceptance of wearable devices must be identified and overcome if the benefits of large scale deployments are to be achieved. Evidence from the US and elsewhere shows that a third of users stop using their wearable within 6 months. Overcoming barriers to adoption but also barriers to the continued use of adopted wearables is one such objective, one focus of the wearable LSP must be to identify bottlenecks/roadblocks in the wearable domain and propose methods to overcome them.

The purpose of this LSP is to create a test platform across many sites and Member States with different levels of technological sophistication and different cultural norms to fully identify and address barriers to adoption and use. The recommended domain for this LSP is in the area of well-being and healthcare. One of the major challenges facing the EU has been identified as an aging population and this LSP is an opportunity to test wearables that can enable healthcare and well-being solutions that facilitate independent living (thereby taking pressure off scare health resources) and which can prolong the productive lives of the population generally.

Wearables are most effective when they move beyond the collection of data and the simple monitoring of data readings to actuating and ultimately to the creation of a closed loop system. Already there is a large scale example of LED lighting being used to create pain relief, this being triggered when the device receives the appropriate signals from the wearable [1]. Such a system has the backing of insurance companies who can see the benefit not only for the individuals concerned but this also keeps people in productive work when they would otherwise not. The use therefore of closed loop systems that can demonstrate a clear benefit to end-users and/or to firms and/or society in general and which are likely to be self-sustaining from a business perspective should be favoured. Creating products that end-users want and that create value for the suppliers and users will ensure viable business cases.

It may also be that the device being tested could perform more than one function addressing different interest groups – for instance medical sensors which can take or recommend an action based on readings taken might also serve as a security verification which might open doors to restricted areas depending on the user’s level of security clearance. Such multifunctional devices are more likely to garner support from the different user groups involved and their continued use is also more likely.

There is significant room for economies of scale and scope in wearable deployments leveraging existing technology and systems should help to release those benefits. There should be strong links to the horizontal Work-Groups 3 and 4 on policy and standardisation respectively but also with WG5 on Aging well and WG8(Smart Cities).

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1 Scope and focus of WG7

1.1 Vision

In a near future, wearables of different types are likely to become a pervasive and integrated part of our lives.

Wearables are integrating key technologies (e.g. nano-electronics, organic electronics, sensing, actuating, localization, communication, energy harvesting, reconfigurable cognitive antennas, low power computing, visualisation and embedded software) into intelligent systems to bring new functionalities into clothes, fabrics, patches, aids, watches and other body-mounted devices. As such, they may be to some extent “hidden” to the end-user and the end user may be more or less aware of the wearable device. This provides enormous opportunities for new applications and services but also raises a number of concerns (privacy, security, dependability and so on) that must be understood and mitigated in order to encourage adoption and usage.

One area of particular interest in the proposed LSP should be on the nexus of healthcare and well-being with applications applied in different contexts such as active and health ageing, mental health, medical monitoring (children, elderly, drivers), safety interventions (firemen, police…) but also in workplace environments (e.g. worker well-being and safety in harsh environment) or (connected/autonomous) automotive (driver and passenger interaction during travel). The general trend in health care is to move from a reactive to a proactive P4 approach (predictive, personalized, preventive and participatory). There will be two major challenges to achieving this P4 health care and wellbeing—technical and societal—and the LSP needs to address both. Therefore, the LSP need to bring patients, physicians and members of the health-care community into alignment with the enormous opportunities of P4 medicine. In this sense, the LSP should focus on two flavours of P4:

Firstly, the LSP need to address the first three Ps (predictive, personalized, and preventive) by means of wearable technologies for the general population. A question that must be addressed is how far off-the-shelf wearables can address the first 3Ps for large groups of users, particularly for a large part of the elderly population.

Secondly, the LSP should also look at the last P (participatory) where clinically validated wearables and wearable systems may be needed. One challenge here is the degree of clinical validation needed and the process for this validation on medical device risk classification. For this, the LSP may need to include clinical centres and, eventually, patient-advocate groups. Another approach would put affordable mass-market wearables e.g. for well-being, safety and convenience of living at the centre of the project.

Another important objective might be related to offices and to white collar workers, in order to improve the employees’ working conditions and help to simulate the growth of the silver economy particularly in the area of participation.

Wearable devices should also seek to perform more than one function where possible and in particular they should interact with the environment and the context they operate in. An example might be medical sensors that might also serve as a security verification which could open doors to restricted areas depending on the user's level of security clearance. Multifunctional devices are more likely to garner support from the different user groups involved.

If there is a specific focus on wearables that are clinically validated and tested, as part of a decision support system it should be noted that there will be trade-offs in terms of time to validation and also the cost of the end user device which will need to be set against a non-validated (and therefore challenged results) and likely cheaper/more -accessible device group.

Any LSP should be driven by concrete business cases and user requirements, taking into account data protection and liability concerns. They should involve the actors of the entire innovation value chain and aim at demonstrations in real world settings. The number of users involved should be sufficient to ensure statistical significance in impact analysis. Multifunctional devices are also likely to have a broader range of users and are more likely to persist with users than single function devices. Accessibility/affordability will be an important consideration to building a large community of users and a viable business case.

The 'silver economy' allows the rich ageing-well population to invest in wearable technologies for fitness, pain relief, depression management, safety, nutrition/hydration, which can then create viable services to a wider population for the EU. Aging populations also create opportunities for extending the length of the working life either by an improvement in general health and well-being or through the use of specific wearable solutions to monitor and manage existing conditions [2].

An aging population in Europe creates a range of opportunities which includes problems such as dementia which can be due to a lack of control over nutrition that better management can control hypertension management for vascular dementia (using for instance the DASH Diet) and going beyond DASH for high risk familial Alzheimer's populations. Wearables can be a key technology for management of activity and sleep, and for the discovery of the lost heritability of dementia population genomics (APOE) which can be vital to managed cognitive decline. It can also be used to reduce stress and depression risk in families' of dementia sufferers.

The appropriate handling of the data and the medical classification of the device will be dependent on the user, data analysing and use case, for example data sharing within communities in a social network (family, "patients like me" support group) could be one of the benefits. Another use-case can be for assisted living care for increasing silver generation independence, to enable independent living at their own environment which they interact with in a carefully monitored way.

Being part of so-called 'persuasive technologies', wearables can close the feedback loop (with smart information, signals,..) and increasingly enable users to monitor and adapt behaviour towards healthier and a more sustainable lifestyle.

Seniors should also be addressed as members of heterogeneous populations, citizens, workers, families and patients. In this case, a larger geographical scope such as a city, would be suited to measure impact and interdependency of different interventions.

The wearable technology market in Europe remains an emerging market. The relative novelty of these wearable technologies has not allowed a significant increase in the number of players for this market and the cost of products remains relatively high. Nevertheless, the wearable technology market in Europe is expanding across numerous sectors which may suggest some economies of scale or economies of scope might be achieved in the coming years. Proposals should seek always to achieve enhanced EU competitiveness by leveraging these effects.

1.2 Objectives

General Objectives

Demonstrating a closed loop wearable ecosystem.

At a higher level this LSP should be a platform to link industry, society and research. It should seek to create a demonstration of a closed-loop, interoperable wearable eco-system. The creation of a wearable ecosystem which not only collects data but also uses that data collected to take action is central to this LSP e.g. from individuals, family members, carers/doctors, care operators etc. Particular attention should be devoted in the LSP to actuating functions providing whenever feasible fully automated closed- loop solutions.

The LSP should seek to demonstrate innovative wearable solutions and services that are integrated in interoperable IoT ecosystems. For instance, existing IoT environments (e.g. smart homes, smart buildings) may usefully interact with the proposed wearable solution.

One example pertaining to the safety and security aspects could include use of wearables to track the location of particular population e.g. children, elderly or disabled people, detect their hazardous condition or situation, and call the authorities (police, hospital) for help automatically.

Another more specific example in the medical domain might be for the management of health and nutrition for the metabolic syndrome population with hypertension risk of dementia [3]. The at-risk familial AZ population needs health care system innovation to manage the risk of cognitive decline and reduce burden of dementia in the population [4]. The closed loop does not necessarily have to act itself, it may simply authorise an action.

Usability and interaction design: Interaction of a user moving between different environments.

The LSP should seek to support the EC in further actions in the IoT domain and specifically it is felt that there is a strong case for working with the WG5 group looking at Aging Well.

The LSP should provide a platform to discuss related topics and should develop recommendations in certain areas.

It should also support inter-use-case communication such that specific gaps in one group might be covered by tweaks in the other group's activities.

Specific Objectives

A primary objective must be to identify specific use-cases for the LSP.

The use case should look at demonstrating the interoperability between wearable devices & environments and should address seamless service & resource discovery.

Trust between different environments should be demonstrated so that the wearable interacts with a range of environments e.g. home, workplaces, buildings, cities, cars and public transport modes but always in a way which is absolutely secure. The use case should seek to have a scope that incorporates as many of the mentioned actors as possible and is tested in an environment as close as feasible to a real life situation.

The wearables deployed in the use case should also be as multifunctional as possible e.g. whatever its primary use it can also perform secondary actions such as validate security and open authorised doors. The wearable device might also display context awareness, detecting that context and adapting to a suitable user interface e.g. a display may pause or change medium as the user moves from a car to a house. Other examples might be smart watches that are also be used for actuation with identification and verification leading to a payment event. Also, health patches might not only sense and monitor but might move to analysis and actuation (e.g. pain detection leading to LED light treatment). Hearing aids might also be a wearable device which could be adapted to perform more functions. Other than adapting its own behaviour, the wearable can provide information which will trigger the environments to adapt themselves e.g. home automation system may switch to various modes e.g. convenient for sleeping, or power saving.

Smart watches and other wearables could enable safety/precaution service for the guardians of children, elderly and vehicle drivers, by means of the wearables' positioning, communication and sensory capabilities.

In order to ensure trust and acceptance across all users (for example, the elderly but also the carers ranging from practitioners up to family and friends, through relevant social/medical platforms) within the LSP, particular attention should be given to the data owner's means for deciding and setting-up the data access entitlements. As indicated, the challenges facing adoption are not only related to collecting data but also to sharing and acting on the data which implies the connection or intervention of external stakeholders (practitioners/carers). This need to exchange and share data at some level and the fact that events will occur based on that data, suggests a necessity for all relevant stakeholders' to be involved in designing the pilot: patients/end-users, medical practitioners, sociologists, software engineers, service providers (for storage of data, use of data, device maintenance…), insurance companies, local/regional/national authorities might be involved in the targeted medical/care process. In the medical domain, medical companies can sometimes develop devices which medical professionals are unhappy with; which suggests the LSP might benefit from medical professionals being involved in designing the LSP (and device) right from the start. Ensuring broad participation to build an ecosystem of trust will be important to adoption and use whatever the domain.

One important part of IoT is related to interaction (which includes acting, sensing and physical connectivity) not only with objects but also with end-users. As the LSP includes people, industry and developers need to develop user-friendly applications and services taking into account user experience, psychological, and even some philosophical concepts. End-users must readily know how to use their connected objects, how to consume services provided by these objects and how to personalize all of that interaction. It will be necessary to support the integration of adaptive and multi-modal interfaces for a richer and user-friendly interaction. This will allow users with different competence levels to improve their interaction with IoT networks.

A key issue for an LSP testing health wearables is acceptability of the device to medical staff and 'patients'. Medical professionals need to be comfortable with the idea that a device will be providing data for them to act on, or indeed for the device itself to act on. Patients also need to have confidence in the device. An LSP should probe these concerns to see how this can be achieved.

User adoption: Addressing the "late majority"

While still in its infancy, there is already some evidence in the market that wearable technologies split users into two categories. On the one hand, the enthusiasts are early adopters eager to engage with different monitoring activities such as sleep, heart-rate, steps and calories consumed. In many cases this category of users is already engaged with a "healthy lifestyle". This is in sharp contrast to the second category of users, the rejecters, who can be categorized as the "late majority" where some of these users can be categorized as "couch potatoes" that would benefit the most from a healthier lifestyle supported by, for example, self-tracking.

What are the barriers that need to be overcome in order for wearables to reach and be accepted by the mass market rather than the early-adopter community? This is a critical issue to be addressed in any pilot project.

A secondary issue, which in ways is even more important is to address the prolonged use of the wearable. There is evidence that within 6 months, as many as one-third of consumers owning a wearable product stops using it. The pilot should have a medium to long-term perspective for its users so that they remain engaged or at least do not resist the benefits that wearables can deliver. Identifying the reasons for ceasing to use the devices and the means to encourage prolonged use will be important to the success of the pilot and suggests a need for an early integration of usage assessment protocols within the LSP.

Issues of data protection and privacy may undermine acceptance of the wearable device and affect its credibility. There may also be a perception risk that using wearables is most advantageous to the service deliverer e.g. there might be a view that the device owner is collecting data for its own use rather than for the end-user and this may undermine adoption and use. Clear communication with respect to device use, the project objectives and the anticipated benefits can underpin support for adoption and continued use after adoption. For instance with respect to the dementia issue mentioned earlier, the usefulness of continuous hypertension measurement for the population at risk needs to be established to enable lifestyle management of sleep activity and diet. If the benefits are well communicated then these potential benefits may promote the product's acceptance. An understanding of the broader social benefits offered by using the device could also help in user acceptance and other IoT exercises (for example tracking city-bikes for better management [5]) can act to support acceptance and continued use of wearables. Similarly, allowing the ever increasing silver generation to live independently in their own home and productively in their own environments will help not only with productivity but will also help to control healthcare budgets in a context of potentially increased needs.

Other issues which could be addressed on the technology side include energy management for nomadic devices which could include a demonstration of innovative solutions for energy scavenging (e.g., based on kinetic, thermic and solar energy sources), batteries and smart batteries/power management. Overall, comprehensive energy management could exploit cognitive schemes to dynamically adjust application logic, optimize the use of available hardware resources and adapt communication parameters, including antenna patterns. This would lead to increased battery duration and possibly even to completely self-powered wearable devices, positively impacting on user adoption and promoting seamless user experience.

Semantic interoperability could be examined and may be important to ensure interoperability targets are met.

Privacy & Security:

The LSP should understand and find solutions for the privacy & security concerns of end-users and ensure that users understand and trust the wearable platform. To achieve this, the wearable platform should have clear and transparent definitions of input modalities and consider limited displays/output capabilities and side channels.

Particular attention should be paid to third party aspects, e.g. the use of data in apps and services that need access to this data while mitigating privacy risks. Risks to bystanders could exist and if so, how do we protect bystanders and mitigate the perceived risks (consider concerns with Google Glass in this context). The pilot should address how security is to be monitored and upgraded or dynamically adapted as necessary; how security updates and patches can be implemented as needed in a simple way for users.

The LSP will need to determine the sort of authentication that will be required and how often: cyber-physical authentication, bio authentication? How will this impact on the user experience and acceptance? Again, clear communication has a very important role to play in this area. Research from Boston Consulting Group 2012 [6] found that consumer willingness to share and make available personal data was related directly to the extent to which they felt they had control of their own data – the greater the control the greater the willingness to share. The LSP will need to consider what kind of user data controls will be considered and the kind of authorization framework that will be needed to dynamically share subsets of personal data. The authorization framework should include security and privacy components in order to allow an anonymous share of personal data in addition to the usual security features.

Degree of clinical validation

A key issue in the WG discussions concerned the degree of clinical validation that will be needed for different types of wearables within the LSP. It is clear that new sensors need a long time for development and even more time for approval so there was a consensus that the core technology should be proven and mature but allowing some innovation to take place. However, it remains to be determined what should be the clinically validated threshold for wearables (from class 1 outside the body to class 3 within and class 2 (a) and class 2(b) being somewhere between).

For instance it may be that a fully validated device will be required where the domain is fully healthcare orientated but less so when the wearable is more well-being focussed. However a high degree of accuracy and dependability suggests something closer to fully clinically validated might be appropriate. The discussion on this point looked at the trade-offs in terms of time to achieve clinical validation even for proven technology and the associated cost increment on the devices for users versus the reliability and acceptance of the recorded results.

The degree of clinical validation needed for a device in such large scale projects will depend on the specific use case(s). In many cases, a full validation of the device may not be required. Moreover, a device, which is not certified for a medical use, can be integrated into a healthcare oriented LSP provided it is agreed by an ethical committee. Indeed, limiting the healthcare oriented LSP to already clinically validated devices could restrict the innovation to the combination of existing products into new services or applications which could be too restrictive.

The LSP should seek further input from AIOTI WG4 group looking at Policy Issues and WG3 group looking at IoT Standardisation. This may be relevant particularly in the context of including security and privacy in the early stage of the design process (e.g. for the targeted products/services).

Support Certifications

The LSP should identify the needs & opportunities for further certification in the platform – this will depend on the use case.

Business-cases

The LSP should seek to understand how we can bridge the ‘second valley of death’ – after the technology was certified to see how to get the technology to market at scale to test its viability etc.
This includes both devices (sensors and other hardware that measures and generates data) and apps/software (diagnose or support of diagnosis).

The LSP should consider how start-ups and SMEs might alter traditional business cases to bridge this valley of death. It could be that part of the objective of the LSP would be to take a wearable solution without full clinical validation to scale and thereby bridge this ‘2nd valley of death’. An LSP is a very good opportunity to perform clinical validation or finalize developments of devices that are not yet fully validated: the devices and processes are used in a controlled environment - and they can be monitored by an ethical committee. This approach will in particular help innovative start-ups and SMEs bridging this “second valley” of death.

Legislation

The pilot should consider what legal obstacles arise in the case of specific business cases. It may be that there are existing rights for the individual for assistance by professional services (for instance aids to intervention to avoid the consequences of a poor diet and lack of exercise, and aids to help remain fit) and how will these rights be impacted by the LSP.

Other legislative frameworks also exist which the pilot will need to take cognisance of and adhere to as appropriate. For example, data protection, data storage, data mobility issues arise specifically in healthcare applications (can data be shared with third parties, under what circumstances etc.). In particular, inconsistency across legislative regimes or gaps in the legislation should be identified.

Guarantee of service / quality of service

The LSP should demonstrate dependability (especially for closed loop systems) where the service or use-case requires real time availability and quality of sensor data.

The pilot should examine how mixed priorities are handled in the use case and how should trade-offs be managed between different priorities (for example a health service should have priority over convenience aspects).

2 Mapping of existing initiatives in the relevant area of the WG

There are a number of areas where previous activities relevant to AIOTI WG 7 (Wearables) have been carried out already. Beside industrial standardisation activities, many EU funded projects have been or are currently being carried out in this area (see Appendix 1). AIOTI aims to integrate these activities and to provide a platform for exchange to enhance interoperability and increase take-up of these technologies.

The LSP should seek input from the AIOTI WG4 group that is looking at Policy Issues and the WG3 group that is looking at IoT Standardisation. Without prejudice to the work of WG3, the LSP should seek to support multiple IPR licensing regimes as much as possible e.g FRAND based standards (ETSI, 3GPP etc) and FRANDz based standards (OIC) which support both the free license and the fair and reasonable model.

The European Commission has funded many collaborative projects developing or testing solutions based on wearable devices in different frameworks. For example the Trans.Safe project [7] in the AAL-JP is a wellbeing@work service that provides a better quality of working conditions to the employees, monitoring his/her stress status and suggesting intervention strategies. The stress conditions of the user are described using both wearable sensors (PPG, EMG, EEG, Inertial, GSR and Temperature) and environmental sensors (including data from the truck). Important focus on user acceptability more than medical certification of the devices. The cloud service is based on algorithms that collect data and returns an indication of the stress level of the user, suggesting an intervention strategy (light shower, breathing exercises...).

In the EIT-HW Action line, the Personal Health and Wellbeing Self-management Service (Phaser) project [8] is a wellbeing@home service prototype focused on prevention of cardiovascular diseases. A wearable PPG sensor detects the amount of physical activity performed by the user through the cardiac activity and sends medical validated suggestions to improve the quality of life of the user, in a gamification scenario. Parameters like blood pressure and weight are detected using clinically validated wireless devices.

In the H2020 BonVoyage project, the smartphone is used to identify the transportation means of the user and encourages her/him depending on behaviour to use more sustainable and healthy transport (cycling, walking) for reaching a destination. This development is incorporated within the BonVoyage platform to offer a full service in terms of cost (e.g. renting a bike) and access to the transport mode (e.g. the location of a bike rental shop). This illustrates that for quantified self and well-being, an extension could be made to other activities that are not categorized as sport or physical activities as such, but which contributes to healthy lifestyles. This dimension may be highly relevant when considering a dedicated population (e.g. elderly) integrating healthy lifestyles in a different dimension of life and not only through the sport/physical activities which may thereby avoidstigmatisation and rejection among the targeted individuals.

In the EIT Digital Action Health & Wellbeing, the Fit2Perform project aims to make driving safer and healthier providing driving solutions for risk-prone professionals & individuals. This is enabled by monitoring and predicting the drivers' fitness-to-drive and incentivising them to drive as long as they are fit to. The usage of a wearable device and data coming from the car, significant data is collected about the drivers' wellness status and driving style. This information is shared with the driver to make her/him aware about his/her fitness to drive and to support him/her during the driving experience. The data can also be shared with the driver's insurance company for a personalization of the insurance policy.

Other projects were funded autonomously by private companies. An example is Fisio@Home: a telemedicine project focused on the knee-rehabilitation. The service allows doctors and physiotherapists to remotely monitor the condition of patients with neuromotor or orthopedic problems. The system uses wearable inertial sensors that assists the patient in the execution of the rehabilitation exercises at home. A Cloud platform is used for data collection and statistics visualization.

3 Investigation of the technological dimension for the large scale pilot

Advanced sensors take a long time to be developed. There was a strong view that the core technology must therefore be relatively mature for the LSP regardless of the degree of clinical validation associated with the device; on the other hand, the development of new services/application domains around existing wearable hardware can happen much faster. However, the innovation does not have to be limited to the development of services for existing wearables and technology or system innovation can be part of the LSP so long as the core technology is proven.

- Relevant combination of available wearables solutions (watches, patches, shoes, hearing aids, textiles) can give access to innovative services and new functions in the detection of physiological status (e.g. stress or fatigue). This makes use of sensors and biosensors.
- Consumers define the type of wearable and function to be targeted
  - For example, in the case of active and healthy ageing, for participants aged between 60 and 70 the LSP might focus on leisure and quantified self, for participants aged between 70 and 80 solutions should addressed social interaction and safe/secured home, while for those over age 80, the medical aspect might be the main focus. Wearables should become a tool for easier interaction with an instrumented environment (home, car…).
- Data from wearable is a source of services (nutrition recommendations, adaptation of care level…)
- Wearable devices may be worn by users in support of, for example, entertainment, sports, wellness and medical applications. Such devices should coexist with potentially many others in the future IoT environment. A real-world, mixed use scenario is envisioned. Dependable service must be maintained in the presence of many different users and devices, across heterogeneous networks. Priority for medical applications must be respected.
- The use of wearables is not only for individuals but also for defining the person's environment (air quality…), up to the crowd environment (safety…).
- Investigate the different needs of users on using wearable devices on in-patient and out-patient treatment of diseases.
- Security & privacy
  - Cryptography, reliability, confidentiality, secured cloud
  - security architecture that preserves devices and information against cyber attacks

The Security & Privacy framework should ensure to the whole system these five services: (1) authorization, (2) authentication, (3) key management, (4) identity management and (5) trust and reputation management.

Research shows that the degree to which users can control their data influences the extent to which they are willing to share their data and participate actively in the generation of data [6].

In relation to ongoing projects (H2020 ICT30, etc.) in the domain of wearables, smart objects may share a common trust relationship related to its owner's identity where security and privacy are their main features. The notion of a **Personal Bubble** may be introduced to describe this group of devices. This can ensure the security and the privacy between the devices belonging to the personal bubble and with the cloud services that could enable the storage of personal information, a set of functions should be deployed.

The system should deal with heterogeneous radio channels, for example, Bluetooth 4.2, RFID, IEEE 802.15.4, UWB, 3G/4G, Ethernet…, and their associated communication protocols. Each new smart object authorized to join the bubble will follow a secure bootstrapping procedure to be authenticated as a device belonging to the bubble. The key management component will provide and maintain the cryptographic keys to ensure the security of the data exchanged over the air and on the infrastructure. Cryptographic functions implementing both symmetric and asymmetric cryptography should be integrated in each device according to its resources, its capabilities, its communication stack, the security protocols supported. Generally, block cipher functions as AES are used for symmetric cryptography to guarantee the confidentiality of the data exchange. A hash function could be added to guarantee both the authentication and the integrity of the message. Elliptic curve cryptography could also be used for the most constrained smart objects to provide security primitive for the key negotiation phase. Adaptive security mechanisms could be also adopted to support power management strategies.

The management of energy within the devices remains a field where improvements can bring significant added value by allowing longer lifetime and data collection and transmission. Ideally, energy management is studied from the conception of devices to integrate optimisation at the different level (from sensors to system). The current trends in connected objects also pushes for flexibility in this energy management to be able to manage different functioning modse depending on the context (e.g. opportunistic access to communication via other IoT components for data transmission, continuous monitoring or on-demand monitoring). Adaptive and context aware security mechanisms could also be adopted to support power management strategies while ensuring the proper level of security.

Several persons may want to share information or resource from their personal bubble with selected users. They can create a community of personal bubbles and new services as member registering and management to provide the access to the user’s shared services or devices could be introduced in this case.

A new kind of bubble or community based on a specific set of security policies and created spontaneously when specific circumstances or relationships conditions arise may be defined as an **Opportunistic Bubble**. This could be the case in a family group for instance. While data will likely need to be shared at some level (though in a closed loop system this may be more autonomous) issues of anonymonisation may also be relevant.

In the resulting context, radio localization technologies could play a key enabling role for the LSP. Novel scenarios could be implemented exploiting adaptive and cooperative localization based on standardized wireless technologies (e.g. Bluetooth and UWB). Cognitive algorithms could be used to define energy efficient solutions. Localization accuracy and robustness could also benefit from the cooperation among different devices and the use of low cost inertial MEMS.

Different issues are related to the actual sensors on the market: accuracy, usability, reliability, security and privacy. The development of new sensors is an activity to be encouraged, but it requires a lot of time (design, development, testing). The core technology to be tested in a LSP has to be mature and usable. The aspects to be underlined could be:

- Integration: not all the sensors needed for a specific application are present in a single device. And each device producer comes to the market with its own platform to collect data. In this scenario, interoperability becomes a primary aspect to underline. Data formats and ontologies would need to be properly considered.

- Privacy & Security: data from wearables can describe precisely the users' lifestyle. From a commercial point of view, this information is relevant to provide personalized services. At the same time, it is important that the final user has given an explicit consent to the storage and processing of this kind of data. Each LSP should specify how to manage the issue of privacy and security of sensitive data coming from a wearable system, from the point of view of transmission and storage. Encrypted communications and usage of a secure cloud system should be encouraged.

- Usability: according to a study by Endeavour Partners [12], one-third of American consumers who have owned a wearable product stopped using it within six months. There are no particular reasons to think that in Europe the statistics are different. That means that the investigation of the user acceptability of a wearable system is fundamental for a LSP, together with a strategy on how to enforce long-term engagement of the user with the wearable devices under test.

- Accuracy and Medical Acceptance: clinical validation of a wearable device could be a key factor for a service. This is fundamental for services in the field of telemedicine (i.e. telemonitoring, telerehabilitation), but it could be important even for applications (i.e. wellness) that do not require at first stage a high accuracy of data. For this reason, a LSP should encourage the activities related with the clinical validation of a wearable device or a device with a very high degree of accuracy. However, due to the long and expensive clinical validation process this could be a barrier to mass adoption; therefore a sensible validation policy with respect to use case must be developed.

- There is a link to WG5 (Smart living environment for ageing well), WG3 (standardization), WG4 (Policy Issues) and link to WG8 (Smart Cities).

The LSP could encompass the study of wearables and the interoperability between a set of personal devices (e.g. smart phone) and/or the IoT framework of a dedicated place.

4 Recommendations for the testing of business models and of user acceptability

Overall, three dimensions should be addressed by the individual players in the LSP

- Users acceptability of the technological solution as such (leaving business aspects such as pricing etc. aside)
- Business model acceptability and sustainability
- Level of validation (Data fidelity and usefulness)

There should be clearly defined use-cases with integration of service providers as necessary and with strong end-user involvement. A good way to generate this type of use case would be with a large-scale data-driven living-lab approach in multiple countries. This type of research would also benefit from the adoption of co-creation mechanisms to involve the relevant stakeholders of the considered ecosystem and promote the definition of innovative business models and partnerships, while enabling the design of more highly accepted technological solutions.

An evaluation should be carried out and should consider the social/societal benefits on the end-user level and at a macro group level (acceptance, usability, satisfaction, ..) and on the macroeconomic level what are economic benefits, direct and indirect (new as well as the business & service models enabled by IoT etc.).

In order to achieve that evaluation, an analysis of the impact, costs and benefits for all relevant stakeholders on the following levels should be conducted:

1) At a personal level, persons involved (users of wearables, personal-trainers, physiotherapists, doctors): What inconsistencies and benefits arise from the use of wearables and what anxieties arise for these persons? How can different use-cases interact without overloading the user? What support is needed to ensure a high level of acceptance and prolonged usage?
2) At a system level (service providers, integrators, public health providers): Are systems better informed with the available data and hence operate more efficiently? Who distributes & maintains the devices? What potential legal questions have to be addressed?
3) At an economic level (service providers, social insurance providers, public health providers and public bodies): What monetary rewards or savings due to more efficient processes, economic viability of deployed business models, etc. are attainable (in which countries)?

To address these questions not only are technological and psychological expertise needed for the evaluation but also social and (health) economic specialists.

The aim should be for a high level of sustainability of the technologies being rolled out through the LSP value chain. In order for this to make sense, it is important to address these dimensions properly and to rule out introducing short term effects. With this aim in mind, the recommendation is that the LSP should involve each participant for a period of at least 6 months.

In addition to different business models, also differing motivation (feedback) strategies could be analysed in such an LSP. By setting up evaluation sites in different countries, cultural influences (privacy concerns, technological acceptance, etc.) can be analysed.

The global cost of deployment should be considered and not only focus on one specific device or on one expected functionality but integrate as many as possible in a more global framework and support/address other societal challenges (e.g. transport, working environment, social inclusion…). This approach would ensure higher sustainability and stimulate the adoption of the developed technologies to create novel services.

Beyond the end-users, other involved groups such as medical, organisational staff will be quantitatively involved in the business model evaluation in order to identify shortcomings and potential problems.

5 Investigation of the operational dimension for the large scale pilot

Service providers in the target regions for the initial and secondary trials need to be prepared for the study of operational issues that provide the most rapid form of deployment of the health IoT across the EU according to the silver economy model. Regions with a high commitment based on funded programmes for the introduction of health care technologies need to be part of the operational dimension of the large scale pilot.

Regions that are making significant investment in dedicated health areas (e.g. genomic mapping of the origins of dementia in the population) should be given priority for pilots looking at targeting the corresponding population (e.g. dementia).

Europe is constituted of a series of national health system where interoperability is being implemented, but, on a practical level, the EU remains fragmented. In the case of active and healthy ageing, several stakeholders (public: cities, region, government – and private: insurance companies, residential housing…) are not involved and do not share the same direct objectives. Implementation of a LSP should therefore include representatives from the different systems in Europe and take into account this variety of systems including the different types of stakeholders. This could facilitate a more coherent business model and ultimately allow the creation of a new organisational scheme for the meaningful and optimal integration of wearables in our environment.

This approach can be translated in particular for the medical and care context for health and well-being. The LSP should encourage and support testbeds gathering such communities of end-users and stakeholders to face problems locally before wider scale deployment.

In the wild evaluations for-and-with IoT and wearables

It should be noted that many evaluations of IoT and related wearable applications should be done in realistic environments, as doing this in controlled lab environments does not offer a representative insight on user experience. Such evaluations are often referred to as “in the wild” and are part of the methodologies found in the area of Living Labs. Wearables should themselves be used as an integral part of an “in the wild” evaluation strategy. Indeed, a combination of IoT data and bio data emanating from wearables can be a powerful mix to perform “in the wild” evaluations of IoT and wearable prototypes.

The use of Electrodermal activity (EDA) (the amount of sweat produced by the skin) or Heart-rate variability (HRV) (the variability of the periods between heart beats) has an established track record in detecting both positive and negative affective responses as a result of human activity (e.g. [9], [10]). An example of a negative affective response would be a user experiencing frustration because of a badly designed user interface. An issue with bio-data like EDA and HRV is that they are highly dependent on the context of use in which they occur. Indeed, a change in EDA may be due to the affective response to a software prototype, but may also be caused by the user moving a lot. IoT infrastructure, both the sensors and the backend-technologies, can be instrumental in providing the context data to analyse the user’s response and isolate the required results from other data produced by the context of use. In order to allow this to happen, analysis software must be made available that can collect, store, analyse and visualise all relevant data to allow research by the people performing the evaluation.

This would require the availability of an IoT infrastructure that can interact with the wearables used to perform the evaluation. Indeed, such an infrastructure, deployed at the scale of a natural human environment, would allow “in the wild” testing for many types of applications. Furthermore, it would introduce economies of scale for its operation and allow developers to build-up expertise in how to use the available technological means.

Another component may be the need for a database of user characteristics that would allow both the selection of the optimal user profiles to be invited to the evaluation as well as the analysis of the resulting data. The analysis must be combined with demographic and other types of information that will allow the formulation of better statistical inference to support the evaluation (e.g. comparing early adopters to the late majority in a field trial).

Finally, an application may be used to motivate and engage users in “in the wild” evaluations. Such an application would gather data (bio-data, IoT data, app log data) on the actions of users, and would send out polls to inquire on the state of the user, as is common in the practice of experience sampling.

6 Next steps

In order to disseminate the findings among public and private stakeholders it is suggested that there be active participation at a number of public workshops, information days and conferences.

The ICT 2015 Conference in Lisbon https://ec.europa.eu/digital-agenda/en/ict2015-innovate-connect-transform-lisbon-20-22-october-2015 is clearly relevant and some of the networking sessions looks especially topical (e.g. Avoiding a digital health divide with wearables Room 5C, 21/10/2015 (14:00-14:45) or IoT: How to counteract the coming security disaster? Room 12, 21/10/2015 (09:00-09:45))

Other events that should be considered include :

- Conferences, symposia and workshops
    - IoT360 (http://iot-360.eu/2015/)
    - eHealth360: http://ehealth360.org/2016/
    - 1st EAI International Conference on Ambient Assisted Living Technologies based on Internet of Things, http://aal-iot.org/2016/show/home
    - HealthyIoT (http://healthyiot.org/2015/show/home)
    - International Symposium on Medical Information and Communication Technology (ISMICT), http://www.cwins.wpi.edu/ismict16/index.html
    - Body Sensor networks (BSN), https://www.pinterest.com/vandypandy/bsn-2016/
- Standardisation bodies
    - ETSI: SmartM2M, SmartBAN, eHealth
    - IEEE: IEEE802.5..x, IG Dependability
- Platforms
    - Wearable Technologies (http://www.wearable-technologies.com/)

7 References

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[3] http://www.alzheimers.org.uk/site/scripts/documents_info.php?documentID=102

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[11] A. Sano and R. W. Picard, "Stress recognition using wearable sensors and mobile phones," in Affective Computing and Intelligent Interaction (ACII), 2013 Humaine Association Conference on, 2013, pp. 671–676.

[12] http://endeavourpartners.net/the-future-of-activity-trackers-part-3-the-secret-to-long-term-engagement/

Appendix 1

- Architecture
    - Continua (http://www.continuaalliance.org/), includes a WAN Mobile-Ready Interface for Personal Connected Health
    - UniversAAL (www.universaal.org), Universal AAL Middleware
- Interfaces
    - BLE
    - NFC
    - ZigBee
    - ANT+
    - IEEE 1451
    - IEEE 802.15.4
    - UWB
    - 6LoWPAN
    - CoAP
    - MQTT
- Projects
    - FIWARE (http://www.fiware.org)
    - iCore (http://www.iot-icore.eu)
    - COMPOSE (http://www.compose-project.eu)
    - Upcoming H2020 ICT30 projects
- Certification
    - ISO 13485 (medical devices)
- Other
    - EPoSS
    - IPSO Alliance
    - Green Paper on Mobile Health by EC Health & Well-Being unit
- EIT Health http://eithealth.eu/
- National initiatives/policy? (e.g. Silver Eco national policy in France, Innovate UK's IoT Smart Cities Demonstrator in UK)
- By technologies: Open standards / open access (e.g. Open Interconnect Consortum (OIC) Healthcare Charter)

Chair: Kit Lam - Samsung

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