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The CHRONIOUS Project

An Open, Ubiquitous and Adaptive Chronic Disease Management Platform for COPD and Renal Insufficiency

Launched in Venice on February 1, 2008, CHRONIOUS is a highly innovative Information and Communication Technology (ICT) research project that aims to implement its vision for ubiquitous health and lifestyle monitoring of people with chronic diseases at a European level. CHRONIOUS is partially funded by the European Commission (under the 7th Framework Programme) and expected budget counts up to 10,598 million euros. The European Commission's expected contribution is 7,250 million euros. The project will last for 42 months.

The CHRONIOUS team is a consortium of internationally renowned research labs in Europe, hospitals, universities and private companies.

CHRONIOUS consists of designing and implementing a wearable platform, based on multi-parametric sensors processing, for monitoring people suffering from chronic diseases.

In particular CHRONIOUS will be tested with patients suffering from chronic obstructive pulmonary disease (COPD) and chronic kidney disease (CKD) in their home. These two pathologies have been chosen because they are widespread and highly expensive in terms of social costs.

Project Reasoning and Development

CHRONIOUS's primary goal is to define a European framework for a generic health status monitoring platform schema, addressing people at risk or with chronic health conditions. This goal will be achieved by developing a multidisciplinary, sophisticated, and adaptive chronic disease platform that integrates state of the art sensors and services in order to cover both patient and healthcare professional needs.

Data will be collected at home using monitoring sensors, mostly wearable, that continuously control vital parameters, sounds and activities performed by patients suffering from COPD and CKD. A Bluetooth network will link environmental monitoring, wearable devices, patient interface and sensor data management. Every abnormal health condition will be noticed and reported by the system. In particular this system has the main objective of reporting deviations and all conditions differing from those that are expected.

The main elements of the project that have to be highlighted are:

- a) Development of wearable sensors in order to monitor parameters concerning health status, environmental context and social context;
- b) Very simple and friendly interfaces as expected users are old people with very limited technological knowledge and abilities;
- c) New algorithms and methodologies for assessing information coming from the monitoring device; new decision mechanisms and instruments aiming at enhancing both patients' and physicians' possibilities in deciding in real time how to react;
- d) Collection and management of appropriate, shared and validated medical knowledge, and
- e) Interoperability with existing ICT systems based on common standards to exchange useful information.

Once the CHRONIOUS wearable monitoring prototype and the general infrastructure are ready, the resulting innovative device will be tested by implementing specific clinical trials in Italy and Spain.

Ethical and Legal Issues

CHRONIOUS is highly sensitive to what is considered to be the ethical use of human beings by the scientific community and confidentiality issues with specific reference to information on patients.

The legal aspects related to CHRONIOUS project concern regulations regarding medical devices, clinical trials and privacy protection of personal data. The Declaration of Helsinki, the European directives and all related national laws passed in Italy and Spain are being taken into consideration in designing and implementing the Chronious system. Full compliance with these rules is requested to address the protection of

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human dignity; the related controls are assigned to local ethical committees.

The first problem concerns the anonymity of users. It means that the information concerning personal or material circumstances can no longer, or only with a disproportionate amount of time, expense and labour, be attributed to an identified or identifiable individual.

A second important issue concerns wearable medical monitoring applications and how not to disclose the information collected about the user. Since the user would like the data collected to remain private, the data will be encrypted and made physically secure.

But simply wearing the device may disclose to the user's employer/ insurer/ acquaintances that the user is suffering from a medical condition and in more cases it is not desirable for the patient. In order to reduce risk of such disclosure, the wearable monitoring device is being designed to be as unobtrusive as possible. The use of encryption technologies and the use of closed networks for the transfer of personal health data are some of the additional measures that the CHRONIOUS system is considering.

Moreover, the system will be designed to ensure that the CHRONIOUS elements are safe to use and do not generate any adverse effect to the human body. The device will comply with the international quality system standards and all EC directives, which apply to the manufacture and use of the product.

Also transparency in decision mechanisms can help all actors involved and make them aware of what the system is and how it evolves. For this reason an advisory board on ethical issues has been constituted and will pay attention to respect international and national rules dealing with the protection of subjects involved in the clinical trial. The first task of the advisory board on ethical issues has concerned the preparation of an appropriate template for informed consent for the distribution of questionnaires among patients in order to properly address user requirements issues.

Benefits Expected

- Raising quality of life and providing highly qualified and efficient, holistic healthcare services to all EU citizens (e.g. through disease prevention, ubiquitous and seamless to the user monitoring, adaptive interaction based on user characteristics and context of activity, reduction of unnecessary visits to hospitals and complexity of self-care especially for patients with chronic diseases);
- Advancing medical research through the provision of advanced disease prediction and diagnosis tools and the exploitation of the vast pool of monitored parameters (e.g. vital signs recorded for various user groups under diverse contexts and conditions) for the production of new diagnostic models and protocols;
- Reducing formal care burdens, and hence improved formal care (e.g. through the reduction of patients' visits for routine examinations, the prevention, diagnosis and in some cases prognosis of diseases, immediate intervention in emergency or time-critical situations);
- Penetrating neighbouring future markets and creating new business opportunities by integrating various actors (e.g. microelectronics industry and telecommunication providers or research institutes) and reinforcing competitiveness;
- Improving informal care effectiveness without increasing intrusion;
- Reducing the cost of informal care, which is particularly high for people suffering from chronic diseases, and
- Involving the care recipient in health promoting activities and decision-making.

Impact on patients' life Non-invasive monitoring; Reduces routine visits to hospitals for diagnostic purposes;

Provides more tranquillity thanks to the reduction of time of intervention in time-critical situations;

Integrates an alert and reminder service linked to particular behaviours such as drug intake, eating and activities performed;

Requires an active participation of patients both in monitoring and decision-making, and

Needs availability of adequate ICT equipment at home and a friendly approach to new technologies by patients and their families.

Impact on health institutions and professionals:

Reduction of acute events and related hospitalisation costs up to 20-30%;

Significant rationalisation of medical prescriptions for diagnostic routine examinations;

Stronger integration with home care service providers both in terms of shared clinical pathways and technological interoperability Sensible growth in cooperation and multi-actor approach to chronic diseases, and Enhancement in ICT investments.

While depicting the testing framework and outlining the related scenarios, a prototype of the CHRONIOUS wearable monitoring device is being developed.

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Once it is ready, it will be possible to assess in a more concrete manner all potentialities and problems concerning the project.

Author:

Roberto Rosso, Coordinator of

the CHRONIOUS Consortium,

Italy - Email: rosso@tesan.it

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