ICT-enabled, cellular artificial liver system incorporating personalized patient management and support (d-LIVER)

"d-LIVER" Integrating Project

The d-LIVER project will develop an ICT-enabled bio-artificial liver support system with associated remote monitoring to assist in the treatment and management of liver patients in care settings extending from the hospital to the home. Key emphasis will be on the sensor-based monitoring of patient health status at home and the communication with hospital information systems.

Objectives of the project

Background / Motivation

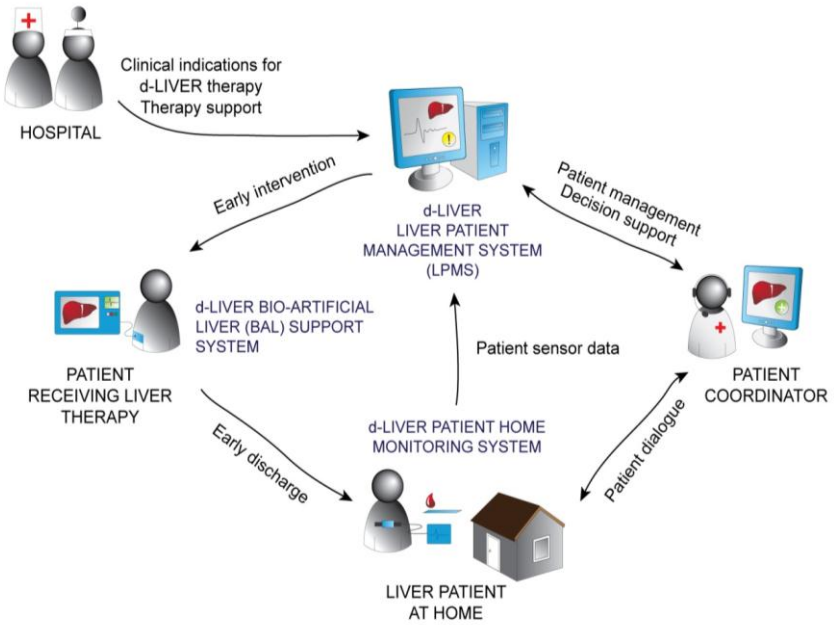
The liver is a complex organ with various vital functions in synthesis, detoxification and regulation; its failure is life-threatening and the only curative treatment is transplantation. Whilst awaiting transplantation, or after major liver resection, patients may need to be supported with detoxification systems which, currently mainly based on filtration, do not support metabolic liver function. This can only be provided by living cells.

Objectives

The d-LIVER project applies a scenario-driven development methodology to address the unmet clinical need for an ICT-enabled bio-artificial liver support system (BAL) for remote management of patients with chronic liver disease outside the hospital.

The aim is to provide safe, cost-effective systems for continuous, context-aware, multi-parametric monitoring of both patient and BAL parameters in order to:

- enhance the quality of medical treatment and management;
- improve the quality of life for patients;
- reduce the incidence and duration of hospitalization and
- consequently reduce the economic burden of chronic liver disease.



Project Description

d-LIVER targets sensor-based monitoring of patient health status at home, concentrating on continuous monitoring of physiological parameters and discrete measurement of a defined set of biochemical species. The project will implement remote monitoring and control of the bio-artificial liver and communication with patient sensor networks and hospital information systems. Systems will be capable of remote, secure communication of the status of both the patient and the bio-artificial liver to central clinical services such that they can schedule swift and beneficial treatment and remedial actions.

In this way d-LIVER will provide fundamental advances in liver support by reducing hospitalisation costs while enhancing quality of care and, at the same time, reinforcing European leadership in Personal Health systems.

In a parallel, high-risk, high reward activity, d-LIVER will identify human pancreatic progenitor cells which can differentiate into human hepatocytes and be cultured into the large numbers of functional cells which can supplement vital liver functions.

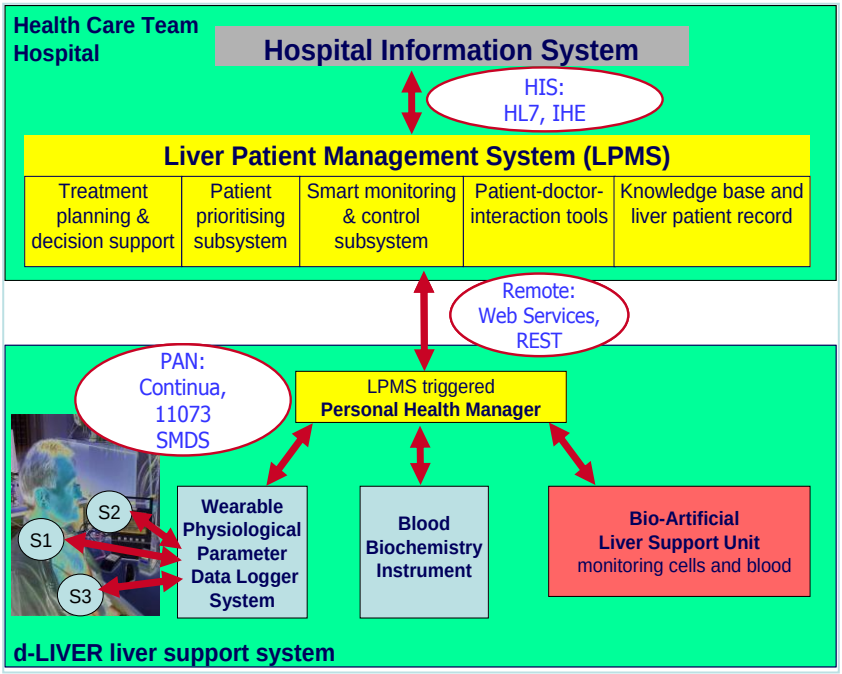
The project includes benchmarking and validation studies to demonstrate the clinical utility of the d-LIVER system in the remote environment.

CASE STUDY: John is a 56 year old taxi driver living 75 km west of Newcastle, UK who has chronic liver disease. Recently he felt weaker than normal and within the last few days his condition deteriorated further. Hence John was admitted to Newcastle hospital and was diagnosed with an acute decompensation of his disease. "Your liver is overworked, and needs time to regain capacity", Dr Jones said. After a few days of hospital treatment, John improved and was offered management using the d-LIVER system which enabled him to be discharged early and for his progress and treatment to be monitored and refined at home. Before being discharged John was trained to use the instrument correctly. Each morning the instrument displays instructions which John follows so that measurements such as weight and blood tests can be carried out. He doesn't mind pricking his finger with a small needle in order to place a drop of blood in a measurement cartridge and finds the d-LIVER system easy to use. When done, "measurement complete " is displayed on the main screen. The cartridge is then ejected from the instrument, and John throws it in the bin. The system allows Dr Jones to monitor John remotely ensuring that his treatment is effective and safe. Each Friday, Dr Jones forwards a brief assessment of the status and recovery progress for John to read on the main screen. John feels reassured that his condition is being closely monitored and loves being back home.

Results & Impacts & Preliminary Results Expected

The d-LIVER project is based on four inter-linked scenarios, defined by clinicians, which will drive ICT and sensor technology development, namely: Chronic liver failure, Chronic cholestatic itch, Bridging therapy before liver transplantation, and Acute liver failure.
The resulting d-LIVER patient monitoring system is expected to provide:

- Indication/ decision/ timing/ planning for bio-artificial liver support sessions
- Basic remote monitoring during d-LIVER bio-artificial liver support therapy
- Evaluation of therapy success after liver support / detoxification
- Remote monitoring of patient liver function/ toxin level/ general condition until the indication for the next session
- Actual recommendations for patients at home regarding personal life-style and behaviour based on patient data monitored by the LPMS



The expected project impacts, societal & economic benefits can be summarised as follows:

- Reduced hospitalisation and improved disease management and treatment at the point of need, through more precise assessment of health status and quicker transfer of knowledge to clinical practice
- Economic benefits for health systems without compromising quality of care
- Reinforced leadership and innovation of the industry in the area of Personal Health Systems and medical devices
- New business models for health service providers and insurance sectors
- Demonstrated potential for patents and spin-offs
- Improved links and interaction between patients and doctors facilitating more active participation of patients in care processes
- New ICT-based environment for biomedical research
- Accelerating the establishment of interoperability standards and of secure, seamless communication of health data between all involved stakeholders, including patients.

Regular updates on results will be published through workshops, news publications and through the d-LIVER website.

d-LIVER

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- Charité - Universitätsmedizin Berlin (Germany)
- Centre Suisse d'Electronique et de Microtechnique (Switzerland)
- Fraunhofer Gesellschaft zur Förderung der angewandten Forschung e.V., FhG-IBMT (Germany)
- Institut für Mikrotechnik Mainz GmbH (Germany)
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- Universitat Rovira i Virgili (Spain)
- AT4 wireless, S.A. (Spain)
- Stem Cell Systems GmbH (Germany)
- 4M2C Patric Salomon GmbH (Germany)
- STAR Healthcare Management GmbH (Germany)

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Instrument: IP (Integrating Project)

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KEYWORDS

e-Health, end-stage liver disease, chronic liver disease, patient, hospital, ICT, healthcare, communication, information, personal health, personalized monitoring, transplantation, detoxification, wearable sensor, biochemical sensor, bio-artificial liver, home.