

# Insights

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## TELEMONITORING TO COMBAT HEART FAILURE

Heart failure patients with left ventricular assist device (LVAD) need sophisticated after-care to lower the high risk of life-threatening complications that accompanies this kind of device therapy, which is becoming more common these days. The international Medolution project is seeking to enhance long-term survival rate of LVAD patients by means of remote monitoring.

Heart failure is a major public health problem. For terminal heart failure the treatment of choice used to be heart transplantation during the last three decades. But this is changing, largely due to a decreasing supply of donor organs: “The alternative therapy nowadays is the implantation of a left ventricular assist device (LVAD),” states Prof Dr Nils Reiss, Head of Clinical Research at Schüchtermann-Klinik in Germany. “With the exponential increase in the use of LVADs, caregivers now face a higher frequency of readmissions because of serious complications occurring out of hospital such as thrombosis of the LVAD pump, right heart failure, arrhythmia, driveline infection or bleeding – all of which are associated with high costs for the healthcare system,” Reiss says.

### **'Telemonitoring can prevent complications, readmission and cost-intensive treatment'**

Readmissions and late interventions in LVAD patients are expensive. A severe pump thrombosis, for example, can make it necessary to replace the LVAD completely, ranging from €70,000-80,000 for the device only. “Detecting pump thrombosis early by means of telemonitoring can prevent such a scenario,” heart surgeon Reiss points out. Reiss is the German project co-ordinator for ‘Medolution’, an international telemonitoring project aiming to apply long-term monitoring and real-time decision support for the diagnosis, treatment and further monitoring of LVAD patients in reactive and preventive cases. The project is not only about costs. “Detecting LVAD-related complications early by means of telemonitoring can also improve patients’ quality of life significantly,” Reiss continues, as he outlines the vision and potential of the project.

To make this happen, a multidisciplinary consortium was installed consisting of 19 partnering companies and institutes across five countries including the Netherlands, France, Germany, Turkey and Canada. Their expertise ranges from medical big data management, security, interoperability and up to system integration. Supported by ITEA, the EUREKA Cluster programme supporting innovative, industry-driven, pre-competitive R&D projects in the area of Software-intensive Systems & Services (SiSS) ‘Medolution’ is run with an overall budget of €22.7m and terminates in May 2019.

As for the German consortium with its six partners, the main focus is on the development of the telemonitoring system. German sub-project leader Schüchtermann-Klinik in Bad Rothenfelde addresses the long-term secondary prevention of LVAD patients. The long-term aim is to establish a telemedical service centre for LVAD patients. Until now, patients after LVAD implantation had to come for routine check-ups every three months.

***The patient app provides access to basic data, graphs and allows the user to contact the telemedical service centre in case of emergency.***

The telemonitoring within ‘Medolution’ however facilitates continuous surveillance and decision support in smart environments that bundle all relevant professional and user-created information from different data sources into one platform.

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The telemonitoring system provides a comprehensive overview of a patient's situation. In the background, big data analyses run permanently in order to detect abnormalities and correlations: "We survey pump and hemodynamic parameters, impedance, anti-coagulation, cardiac rhythm and drive-line wound," says the project co-ordinator. "Along with the sensor measurements on power and preload pressure transferred by the LVAD, the patient app provides driveline pictures and analyses the data for complications like suction or thrombosis." All results are then processed within the cloud-based platform with on-board decision support and notification system and will eventually be forwarded to the app of the physician.

### **Data circulation between patient app, cloud and physician app**

Once collected, the data of LVAD patients is transmitted to telemedical service centres and reviewed around the clock by medical experts who may extend the access to external caregivers such as an ambulatory cardiologist. Reiss explains further: "Value limits of the diverse parameters can be defined for each patient individually in the decision support system. When they vary tremendously or exceed the limits, this triggers an alarm signal in the user interface or even the mobile phone of the treating physician or LVAD co-ordinator". While the physician app allows you to adjust the limits and offers direct patient-contact options, the patient app provides access to basic data, graphs and allows the user to contact the telemedical service centre in case of emergency.

### **Enabling discharged patients to return to an (almost) normal life**

The clinical outcome of 'Medolution' could be huge: "With this kind of sophisticated telemonitoring, LVAD patients can really return to an almost normal and safe life – permanently monitored and controlled by our telemedical services," states the project co-ordinator. Today, LVAD patients, once discharged from hospital, face complex self-management. Reiss points out at the burden of multiple medical visits, utter dependence on the infallibility of their medical device, strict adherence to medication plans and, not least, the psychological impact ranging from medical and financial worries related to complications up to an altered body image, anxiety or even depression.

*"This patient simulator allowed us to test sensor integration, data transfers and evaluation as well as notification functions," says Prof Dr Nils Reiss, Head of Clinical Research at Schüchtermann-Klinik in Germany*

This burden might come to an end considering the potential advantages that medical experts see in the telemonitoring of LVAD patients: "Not only does it allow for fewer clinical visits reducing time, effort and money of the all the more mobile patient, it also detects patient- or device-related problems and immediately alerts the clinicians which eventually will also add to the patient's psychological well-being," Reiss says.

## **Clinical studies for a future successful implementation**

So when will LVAD telemonitoring actually become part of regular care? At the moment, the 'Medolution' project partners are still in the testing phase. Specific technical, structural and legal requirements must be met before the developed telemonitoring system can be used with patients routinely. To prepare and ensure a successful implementation, the German project partners have initially set up a mock loop circulation system to generate test data *in vitro*. "This patient simulator allowed us to test sensor integration, data transfers and evaluation as well as notification functions," he reflects.

By now, the first studies with LVAD patients using smartphone applications have already been carried out to examine usability aspects. Furthermore, Germany plans for another clinical study conducted at Schüchtermann-Klinik Bad Rothenfelde in 2019 in order to investigate the implementation into clinical routine and to evaluate the system with regard to its benefits for patients, physicians and the health insurance companies. If the results of this follow-up study are convincing and financial reimbursement by the healthcare system is ensured, this might actually leverage telemonitoring of LVAD patients in the daily clinical routine.

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