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sekTOR-HF: A research project for cross-sectoral needs-based care for patients with heart failure and for the development of an alternative remuneration model - Part 1

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inpatient sectors is intended to reduce avoidable hospital stays, prevent multiple examinations and receive beneficial treatment in accordance with national disease management guidelines. The aim is to increase the life expectancy of patients and improve their quality of life. The close coordination between general practitioners, specialists, clinic, nursing facilities and other health service providers will take place via electronic patient records in a web-based eHealth portal (data protection-compliant, telemedical network) and will be coordinated by a specialist-led central network office.³

With each episode of hospitalisation, there is likely myocardial and renal damage, which contributes to progressive left ventricular or renal dysfunction, leading to an inevitable downward spiral. Hospitalised heart failure is associated with unacceptably high post-discharge mortality and rehospitalisation rate. It is important to consider that once hospitalised heart failure patients are stabilised by discharge, most of them should be considered to be in a chronic heart failure state at a significantly high risk for adverse outcomes. By avoiding hospital admissions, resources that are freed up can be used more effectively.

Closely interlinked outpatient and inpatient resources with targeted monitoring and control of the different patient groups, clearly defined service packages and alternative remuneration systems in a cross-sectoral cooperation leads to long-term budget security with the provision of high-quality and quality-assured therapy for HF patients. The main indicator of the quality of cross-sectoral care, therefore, is avoidable hospital admissions of HF patients.

The introduction of the new form of care should reduce the rate of hospitalisations and rehospitalisation's in the model regions by approximately 20 per cent in the long term and thus lead to a considerably lower burden on financing.⁴

PREPARATORY PHASE

As part of the sekTOR-HF project, the following milestones were worked out during the preparatory phase:

- Establishment of a network office (consisting of network manager and network assistance)
- Conclusion of a selective contract with the participating health insurance funds and payers (requirement for patient inclusion and outpatient care)
- Conception of the eHealth portal by the consortium partner Zentrum für Telemedizin Bad Kissingen (ZTM) in close coordination with the project management and the network office
- Obtaining a positive ethics vote from the Ethics Committee of the State Medical Association in Hesse and the Ethics Commission at the RHÖN-KLINIKUM campus in Bavaria
- Development of a data protection concept that defines the handling of personal data and explains this patient-friendly

Seven sub-working groups with the corresponding consortium partners were set up to deal with the aforementioned milestones:

- sub-working group supply network centre
- sub-working group supply Bad Neustadt
- sub-working group supply Marburg
- sub-working group Ethics Request
- sub-working group eHealth portal/technology and data protection concept
- sub-working group Selective Contract

The project logo consists of a heart, an open gate and a radio wave display, which also stands for the network and association characteristic of the project.

The heart symbolises health and human warmth. In the medical context, it stands for patient-oriented medical orientation. The open gate symbolises an invitation to

all actors to participate in a cooperative network, which forms the central element of communication. The radio waves symbolise the most advanced technology, a place that pulsates, creates connections, exchanges ideas and invites the patient to participate.

The selected colours red and blue are based on the scheme of the human cardiovascular system. Green stands for rural areas and forms the visual focus of the brand.

CARE AND MAIN PHASE

A total of 500 patients are included in the period 1 March to 30 November 2021. After the patient's enrolment in the project, a 12-month care phase is carried out by the participating doctors and the network office. With the inclusion in the network, an electronic file is created in the so-called eHealth portal for the patient, in which his or her health and personal data are recorded and stored. At the end of the project-related care and observation period, a 6-month evaluation phase takes place, during which a final survey (review survey) is carried out.

EVALUATION PHASE

After the project is completed, in November 2023, a second part will present the project evaluation and the results.

PATIENT CARE PATHWAY

The new care model, sekTOR-HF, is available to patients with confirmed suspicion or diagnosis of HF in NYHA stages I–IV according to the severity classification of the New York Heart Association (NYHA). Eligible participants are between 18 and 85 years of age and live in the selected regions in Bavaria and Hesse (residents within 100 km of the clinic locations Bad Neustadt an der Saale and Marburg) and insured with a participating health insurance company. Depending on the severity of the HF, the patients are

directed to a guideline-compliant and suitable process, which is either the inpatient or the outpatient service. HF patients with NYHA I–II are treated and cared for on an outpatient basis, and those with NYHA III–IV are treated and cared for as inpatients (see Figure 1). This means that the costs are not increased but rather postponed owing to needs-based treatment.

A patient is accepted into the new care model by an outpatient or inpatient service provider participating in the project, which the patient visits because of a (suspected) heart problem. A standardised questionnaire is used to check whether the patient meets the inclusion criteria for cross-sectoral care. In the event of a positive result and on obtaining the patient's agreement, an electronic patient file with all relevant data is created in the eHealth portal. In the portal the network office has a view of the collected patient data, such as vital parameters or health information, and in the event of any abnormalities it can consult a doctor and contact the patient subsequently. So the eHealth portal is the basis for the monitoring of all therapeutic and diagnostic steps by the network office in the further cross-sectoral treatment of the patient.

As shown in the graphic (Figure 2), HF patients with a relatively low degree of disease severity (NYHA stages I–II are treated primarily on an outpatient basis by resident doctors and accompanied by the network office (outpatient care). As a result, patients who can be cared for on an outpatient basis and have a low need for care with a mild HF (NYHA I–II)



Figure 1: Project logo — sekTOR-HF

Source: Walter D., Simon I., Zehe D., Arnold M., Divchev D., Wolter A., Korfhage T., Griewing B. (2020).

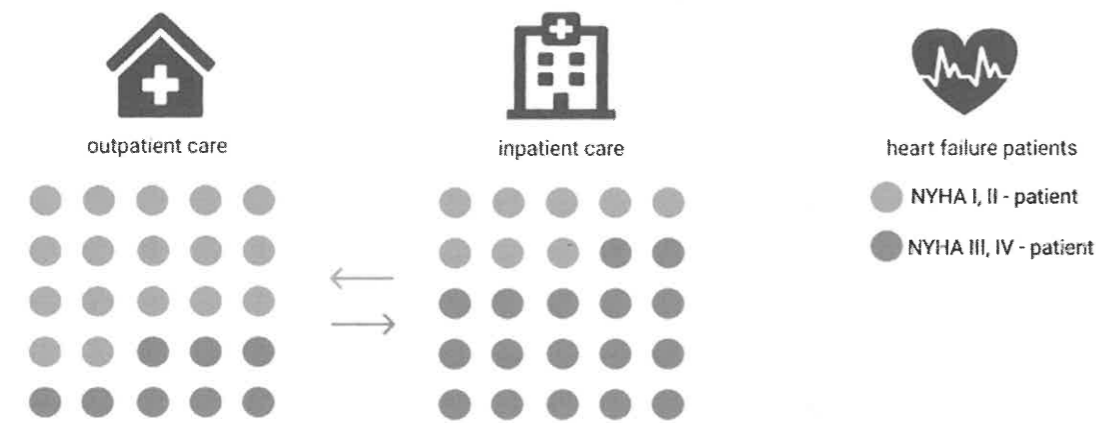


Figure 2: Patient and cost shift
Source: Walter D., Simon I., Zehe D., Arnold M., Divchev D., Wolter A., Korfhage T., Griewing B. (2020).

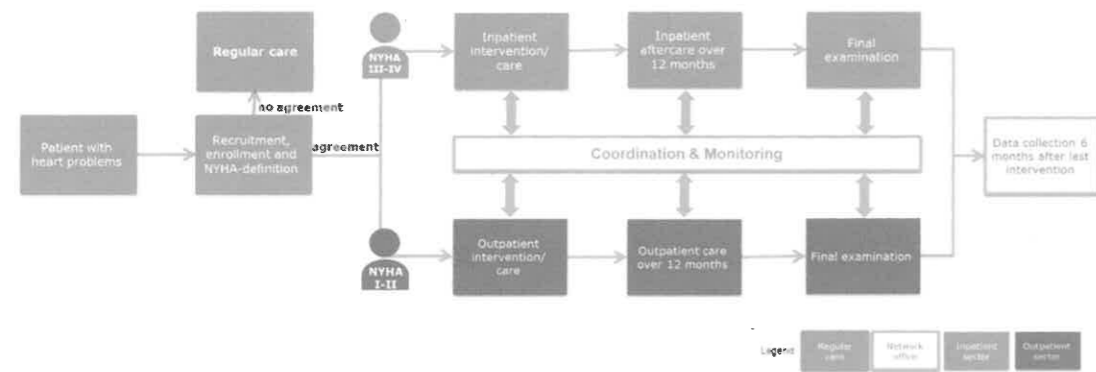


Figure 3: Care process of patients in sekTOR-HF
Source: Walter D., Simon I., Zehe D., Arnold M., Divchev D., Wolter A., Korfhage T., Griewing B. (2020).

are no longer treated in systematically more expensive structures of the hospital (diagnosis and therapy). The network office, which monitors the patient continuously for 12 months from the moment they are included in the care concept, will initiate adequate, guideline-based treatment at the appropriate care level in close coordination with the general practitioners in the event of impending decompensation (Figure 3).⁵

Outpatients who have previously been undersupplied and have a high need for care with severe HF (NYHA III-IV) are referred to the inpatient service provider or admitted to the emergency room.

After discharge from the hospital, these patients receive 12 months of specialist

follow-up care by the hospital, also supported by the network office and outpatient telemedical measures (Monitoring), with the aim of recognising decompensations timely and preventing rehospitalisation. The provision of necessary services is directed centrally by the network office and is thus provided independently of the sectors. All patients will be part of the project for 12 months. From the 13th month onwards, patients are treated again within the framework of standard care.

NETWORK OFFICE

The concept of the network office is based on the approach of the accountable

care organisation (ACO) and network medicine.⁶ They are formed when healthcare organisations — like behavioural health, substance use treatment and other specialty care providers — merge into integrated centres of care.

In sekTOR-HF a coordinating network point accompanies both patient groups throughout the entire project period. Care is provided by a specialist doctor and specially trained staff by telemedicine or in the patient’s home environment. In coordination with the outpatient and inpatient doctors involved, the network office ensures that the patient receives the best possible care at all times. Monitoring requires the collection, structuring and evaluation of all outpatient, clinic and post-inpatient treatment-related data centrally in the eHealth portal.

The vital data of the patients are also continuously recorded by telemedicine and regularly evaluated by the specialist and functional staff of the network office, taking into account the patient’s history, the doctor’s letters and the laboratory values provided by the outpatient doctors according to established evidence-based algorithms. Should the values deteriorate and symptoms and clinical signs appear that indicate an incipient decompensation, the network office can derive tailored measures and coordinate individual treatment recommendations with the doctors involved.⁷

The patients are therefore cared for as seamlessly as possible over the defined period, even outside the period of service of the resident doctors.

The network office creates continuity of care through telemedical support and regular training elements, the effects of which can be transferred to the reality of care beyond the care period of 12 months. One of the main tasks of network management is to strengthen and support the patient and his empowerment.

The network office consists of the network assistance and the network manager.

The network assistant is responsible, among other things, for house calls and briefing the patient in telemedical devices. It initiates telemedical measures, monitors them and supports data collection.

The network manager takes on the coordination of health care. He structures and evaluates all the treatment-relevant data collected in the eHealth portal and conducts a telemedical consultation.

ALTERNATIVE REMUNERATION MODEL

Depending on the severity of the condition, treating patients with heart disease requires both ambulatory and stationary care. The sectoral divide between the ambulatory and stationary care system in Germany is characterised by distinct reimbursement arrangements between care provider and insurer. Stationary care services are reimbursed by a fee-for-service type system, the so-called German Diagnosis Related Group (G-DRG). Ambulatory care relies heavily on capita lump sums plus individual service fees for a dedicated list of services, with a global budget restriction for both. Both reimbursement systems impose distinct and non-aligned incentives onto care providers. Bundled payment arrangements aim to reimburse the specific episode of care rather than each individual activity independent of the place of service delivery. As such, they may help to harmonise incentives by providing a consistent reimbursement framework for hospitals and ambulatory care providers.

Within this project, we explore bundled payments as a potential reimbursement mechanism for heart failure in the context of the German healthcare system. As a first step, we conduct a systematic assessment of the existing evidence, which will inform the current state of knowledge and identify knowledge gaps. Next, we invite national reimbursement experts into a workshop that aims to identify regulatory and organisational

boundaries in Germany and agree on quality criteria for the evaluation of potential bundled payment variations. This is followed by additional workshops with international experts on reimbursement systems and experience with bundled payments with the aim of identifying best practice examples that can be adopted by the German health system. With this combination of workshops between national and international experts, we aim to ensure that the best practices are feasible and practicable and that evaluations are based on transparent criteria.

After potential candidates have been identified, we use a simulation modelling approach to test and evaluate. The simulation approach specifically aims to

1. test variations of episode length and index patients,
2. explore the influence of comorbidities and cost drivers in each variation,
3. assess critical factors — or 'bundle breakers',
4. estimate the cost of the bundle, and, finally,
5. recommend a bundle definition on the basis of quality criteria agreed on with international and national experts.

We use claims data from German statutory health insurances to predict the value of each bundled payment.

This simulation approach will be one of the first applications using real-world data to assess the feasibility and explore practical implications of bundled payments for heart disease in Germany. By using a simulation approach and retrospective data, we establish a first point of reference and benchmark for a future experimental introduction of bundled payment in the German healthcare system.

The view of a Statutory Health Insurance (SHI)

In Germany, 73 million people are insured under statutory health insurance (SHI). By law, they are entitled to health care that is

adequate, appropriate and economical. The health system is facing a major challenge on account of the continued increase in chronic diseases, including heart failure. New care models can establish a needs-based treatment and comprehensive and easily accessible medical care at a high level.

With the aim of promoting healthcare research projects and new healthcare approaches that go beyond the standard benefits available through SHI thus far, the innovation fund was introduced in 2015 by the German government with §92 German Social Code, Book Five (SGBV). The funding from the innovation fund will enable projects like sekTOR-HF to build efficient structures with a new care model and to make the German health system sustainable, for example by ensuring cross-sectoral treatment.

The aim of the SHI is to transfer those new care models to basic and customary care after a successful evaluation and a proven significant effect on the patient's health status and well-being as well as a cost-benefit analysis. For the evaluation two sources of routine data will be used: one source will be the sample of the Institute for Applied Health Research Berlin (InGef) Research Database, which comprises anonymised routine data of approximately 6.3 million insured persons from around 60 German SHI.⁸ Another data source will be a set of pseudonymised secondary data of four relevant SHI in Germany. For the evaluation a propensity score matching will be used that allows the creation of a comparison group and enables the evaluation of effects and the cost-effectiveness of the new care model.⁹

Another important point that can be implemented in basic and customary care is a knowledge of possible obstacles and hurdles. A qualitative survey will need to be implemented to ask the patients and care providers about this. These results may help to increase later acceptance through appropriate measures and adoptions of the new care model and can also be used for the further development of the eHealth platform.

Patients will only use digital solutions, if these will offer a recognisable added value for them, and therefore these questions will also be added to the evaluation. The telemetric recording of vital data and the telephone or digital care of the patients is seen as a relevant part of the sekTOR-HF project and can offer people with heart failure a valuable opportunity for better care. The development of an alternative remuneration model within the framework of the project could help to harmonise incentives by offering hospitals and outpatient service providers a uniform reimbursement framework.

Evaluation concept

To understand the mechanisms of sekTOR-HF and its consequences for patients and healthcare institutions, the project will be scientifically evaluated. This evaluation will be conducted by the *RWI — Leibniz Institute for Economic Research*, an independent research organisation that specialises in economic impact evaluations. The main goal of the evaluation is to test whether the project has a significant effect on the patient's health status and well-being and to run a cost-benefit analysis. It includes the evaluation of the following seven hypotheses about how the 12-month sekTOR-HF programme might affect participating patients with HF:

1. reduction in avoidable hospital admissions
2. reduction in emergency service operations
3. reduction of avoidable hospital readmission
4. improved quality of life
5. improved ejection fraction
6. improved ability to care for oneself
7. improved NYHA status

Hypotheses testing will rely on two different estimation strategies: *First*, whenever feasible with available data sources, a quasi-experimental approach will be used that allows the ex-post

estimation of causal effects (hypotheses 1, 2 and 7). Thereby, sekTOR-HF patients (treatment group) are compared with individuals who did not participate in the programme (comparison group), with a view to separating the treatment effect from underlying confounders such as age or health effects.

A large administrative claims data set from multiple SHI providers in Germany makes it possible to draw a comparison group that is very similar to the treatment group with respect to health outcomes and socio-economic characteristics. Inference is based on a combination of difference-in-differences estimations and propensity score matching. This combination provides a double robust estimation that controls for sample composition as well as for different outcome levels in the pre-treatment period.¹⁰ *Second*, comparisons of outcomes before and after treatment are used to provide descriptive evidence on sekTOR-HF-related changes whenever causal inference is not feasible. This is the case for all outcomes not reported in administrative SHI data, making comparison groups unavailable (hypotheses 3, 4, 5 and 6).

The project aims to analyse at least 400 different individuals in the treatment group. The individual-related data is collected in an electronic health portal that can be accessed by patients, physicians and assistants. While medical outcomes are provided primarily by physicians, patients are frequently asked to answer specific survey questionnaires on their socio-economic background and well-being.

Besides hypothesis testing, the evaluation will include a detailed analysis of patient's subjective assessment of the project and interviews with experts on the German healthcare system. This mix of quantitative and qualitative evidence aims to provide policymakers with a full picture of the consequences of sekTOR-HF compared with treatment of patients with HF under status quo regulations.

CONCLUSION

By developing a regional cross-sectoral care model, the sekTOR-HF project represents an innovative approach to ensuring a needs-based care for patients with heart failure. With the help of a telemedical network and alternative remuneration models such as bundled payments, the separation of care, remuneration and culture that prevails in the health system is overcome. By focusing on the entire value-added chain and coordination between healthcare providers in the outpatient and inpatient areas, hospital stays can be avoided and the patient's life expectancy and quality of life improved.¹¹

The patients included are between 18 and 85 years of age, live in selected regions in Bavaria and Hesse and are insured with a participating health insurance company. The patient is directed to the outpatient or inpatient care on the basis of the severity of the heart failure (NYHA stages I–IV) via monitoring of the patient data and parameters stored in the eHealth portal by the network office. The network office, consisting of network assistant and network manager, monitors the patients for 12 months, attends to them by telemedicine or in the patient's home environment and coordinates health care.

The development of a remuneration model such as bundled payments, in which specific episodes of care are reimbursed independently of the location of the service delivery, is aimed at guaranteeing a consistent reimbursement framework for care providers.

Regulatory and organisational boundaries in Germany as well as best practice examples are determined in expert workshops, and quality criteria for the evaluation of potential bundled payment variations are agreed. Using a simulation modelling approach, the feasibility is assessed using real data, and the practical effects of bundled payments for heart failure in Germany are examined.

The project is evaluated using a quasi-experimental approach, in which a

comparison group is formed by using a data set from the public health insurance and an ex-post estimate of causal effects is carried out. In addition to the quantitative data, experts and patient interviews are conducted in order to obtain a subjective assessment of the project and a comprehensive picture of the effects of sekTOR-HF.

The project aims to provide important insights into cross-sectoral care and alternative forms of remuneration and thus lay the foundation for the necessary changes to the structures in the German healthcare system, which needs to focus on a more effective use of available resources as well as needs-based care and patient empowerment.

Part 1 describes the initial situation and concept for the start of the project in 2020. Patient inclusion began in March 2021. After the project has been completed, in November 2023, a second part will present the project evaluation and the results at this point.

There is a conviction that remuneration incentives and supply incentives must be consistent.

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