HerzAs: Telemedical care for heart failure patients

DISCLAIMER: This report is a translation of a case study report prepared in German. The German version is the sole authoritative source. All errors and omissions in this translation are the responsibility of empirica and cannot be attributed to AOK NordWest or Gesellschaft für Patientenhilfe.

1. Background

1.1 Introduction to the German healthcare system

Healthcare delivery in Germany is based on the principles laid down by Chancellor Bismarck in the late 19th century, the founder of social health insurance in Germany. The key feature of the German approach is the absence of central government from negotiations between payers and providers of care. Instead, the system relies on elements of "corporatism" or "self-management" (Selbstverwaltung). Health insurance funds are corporations of public law (Körperschaften öffentlichen Rechts) which negotiate the price and volume of care service directly with associations of healthcare professionals. Primary care physicians are self-employed and receive a licence to practice from their respective corporation (Kassenärztliche Vereinigung). Health insurance funds automatically contract with all doctors so licensed, thereby enabling free choice of provider and hospital by the patient. Responsibility for hospital infrastructure financing is shouldered by the Länder (the state governments within the federation). The system is financed through joint contributions by employers and employees, who have free choice of insurance. A complex risk-mitigation fund (Risikostrukturausgleich) redistributes funding between insurance companies, enabling them to contract with every patient, regardless of prior illnesses.

In recent years, efforts were made in the framework legislation on federal level to enable health insurance funds to sign specific contracts (within the above mentioned framework contract) to provide integrated care to chronically ill patients.

Strategic setting in the German healthcare system

Demographic change and the resulting pressures on the German healthcare system have led to high expectations on telemedicine as a new way of delivering healthcare. Related to demographic change is also an expected rise in the incidence of chronic diseases, in particular a rise in cardiological diseases such as heart failure. Telemedicine is particularly promising in light of the regional character of German healthcare and the supply challenge resulting from it. Ensuring sufficient supply of healthcare requires the development of new models of healthcare provision.

The role of telemedicine services will grow in the future. Technically mature telecommunications and telematics solutions allow coordination and communication between patients and doctors across the territory. The multipurpose potential of telemedicine solutions is particularly promising for the delivery of care at and near the home.

The starting point for AOK NordWest

Both demographic and technological trends are a challenge for a large health insurer such as AOK NordWest and require careful economic assessment to judge benefits and costs.

The type of diseases prevalent in a population and the availability of treatments has changed in recent years. The majority of care is delivered today in response to chronic conditions.

Against this background, AOK NordWest identified the diseases of the coronary system as a group of conditions with a particular need for action, not only because of the disease burden for individual patients but also due to its economic implications.

Based on a number of analytical approaches and evaluations, a decision was taken to focus first on heart failure, with a view to offering a new model of care provision which would make use of telemedicine support. This decision was backed up by a cost-benefit analysis. The development of this new care model granted high priority to the complementarity of this additional care with the regular GP care that patients normally receive.

In 2004, AOK NordWest initiated a collaboration with a renowned centre for heart failure care, including close cooperation with local cardiologists in private practice. The goal of the project was to increase the quality of care for heart failure patients.

Results from this pilot project were reassessed in 2011. The reassessment focused on a more targeted use of telemedicine support to achieve better outcomes. Due to a lower than expected number of participating patients in the first pilot, particular attention was paid to the reassessment of processes and the service model. AOK NordWest eventually decided to pursue telemedical services for heart failure patients, but with a new service concept.

The main benefits for the patient, notably:

increased patient mobility and independence,
improved self-care
increased quality of life
should be communicated more clearly.

2. Short description of the service

Heart failure patients require daily monitoring of their body weight, because body weight allows an early detection of water deposits due to the weakened heart muscle. Further relevant clinical information can be derived from the knowledge of co-morbidities and other vital parameters. A dense web of healthcare monitoring is required to react immediately to the slightest deviation from normal parameters.

The tender notice released on a European level in March 2011 for the „HerzAs“ service foresaw the following key service features:

Healthcare monitoring of heart failure patients with a particularly high risk of hospital admission through telephone support, training and counselling as well as the use of a telemetric balance in the home equipped with a data-transmission feature
Healthcare monitoring of heart failure patients with a high risk of hospital admission through telephone support, training and counselling without use of telemetric devices
Key elements of the detailed service component description (and thereby key requirements to any potential contractor) were defined as follows:
Provision of expert personnel trained in medicine or related field (e.g. heart failure nurses)
A service hotline for patients ensuring the availability of medical expert advice
Immediate notification of a healthcare professional upon deviations from the norm
Content of the clinical counselling and training sessions

The contractor will be in charge of the administrative registration of patients as participants in the programme. Prior identification of suitable patients is completed at AOK NordWest through a number of parameters, such as severity of the condition and prior hospital admissions. Participation is on a voluntary basis.

3. Detailed description of the project and procurement process

3.1 Strategic planning

The strategic planning for the tendering process of the telemedical service was the result of complex statistical analysis at AOK NordWest. Preparations began in September 2010 and ended with the release of the tender notice in March 2011. Experience from prior piloting projects was also available.

The starting point for the analytical work at AOK NordWest was the desire to optimise the HerzAs service with regard to the subjective utility for the patient and to be able to offer a geographically widespread telecardiological service, complementary to the existing service offer. Simultaneously, such a service should contribute to higher acceptance of telemedical solutions with patients and healthcare professionals alike.

The following questions were at the heart of the in-house analytical work:

How can patients with a heightened risk of heart failure be identified?

What kind of care model needs to be offered to patients to improve their situation

Is it possible to measure (at pre-defined endpoints) the effects of the care delivered, e.g. reduced hospitalization?

What kind of economic evidence can be identified?

For each risk-group in heart failure, specific recommendations for care were formulated. Patients with a very pronounced heart failure condition were identified as possible candidates for intensive telemedical monitoring, based on a statistical algorithm.

To determine the feasibility of offering such a service to insurees of AOK NordWest, detailed market intelligence talks were held with several firms with the necessary service expertise, in full respect of procurement law. The results of these talks were fed into the analytical work at AOK NordWest. The questions put to companies included every aspect of service delivery, ranging from the capacity of the telephone support centre to the certification of devices.[1]

3.2 Service development

3.2.1 Clinical aspects

A review of expert literature on heart failure revealed that the use of a telemetrical balance would promise more utility to the patient than the use of a mobile ECG. Previous projects by AOK Schleswig Holstein, which had made use of a mobile ECG, had concluded without clear success.

From the patient's perspective the installation of the balance is possible without technical expertise. The easy to use devices transmit health status data on a daily basis. Via a small monitor, patients respond to simple questions such as: "Did you need an additional cushion tonight?"Or "Do you feel more tired today than previously?" The information flowing from the balance and these interviews allows clear determination of a health status. [2]

Treatment by a patient's GP or cardiologist continues unchanged. They are immediately informed about important changes to their patient's health status.

In addition, coaching and support conversations take place between the patient and the staff at the HerzAs service centre at regular intervals.

3.2.2 Organisational changes

Within AOK NordWest t a dedicated project team was set up and supplemented with specialist expertise as required. Legal advice was available in-house, with procurement support provided by the legal experts at the AOK Bundesverband (federal association of AOKs). Informatics expertise was equally available in-house (IT-Service) and was supplemented during the course of the project with experts from the gkv-informatik, an association of computing centres set-up jointly by several German health insurance companies.

The personnel structure over the whole course of the project can be illustrated as follows:

Conceptual and analytical work phase (April-June 2010):

Eight full-time equivalents (FTEs) and a project leader, full-time until June 2010

From July 2010:

Five project staff and a project leader

[1] We would like to thank AOK NordWest for making the questionnaire available.

[2] Description adapted from the German „HerzAs – das Gesundheitsprogramm für ausgewählte Herzpatientinnen und –Patienten", verfügbar auf http://www.aok.de/nordwest/leistungen-service/leistungen-HerzAs-189372.php

At two days per week (40% of weekly working hours)

From January 2011:

Six project staff and project leader

Three of which for one day per week (20% of weekly working hours)

The others at two days per week (40% of weekly working hours)

End of project: 30.09.2011

3.2.3 Legal framework

The implementation of the above mentioned predecessor pilot project (starting in 2004) was launched without a European tendering process. This situation changed in 2010 with a formal ruling of the European Court of Justice, which declared the German "corporations of public law" equivalent to any public procuring authority. This ruling made health insurance companies in Germany subject to European procurement law.

The tendering procedure was designed as a negotiated procedure with prior participation contest[3].

3.2.4 Data protection

The tendering notice required a data-protection policy from tenderers. A detailed documentation of this concept and other related documents were a part of the required tender documentation to be submitted by every bidder.

With regard to the first contact with patients, AOK NordWest followed a resolution of the "76. Konferenz des Datenschutzbeauftragten des Bundes und der Länder" [conference of data-protection experts at Länder and federal level]. This resolution enshrined, in particular, the requirement that only health insurance companies themselves could identify and approach patients for programmes designed to modify health behaviour.[4]

3.2.5 Economic and financial aspects

From the perspective of AOK NordWest the following economic/financial expectations towards the project were formulated:

Increasing quality of care at the same level of cost

Or: providing the same quality of care at lower cost

The selected bidder for the service „Gesellschaft für Patientenhilfe" receives a capitation payment per patient per year for the services. No up-front payments or further bonuses are paid.

---

[3] German legal provisions corresponding to the European requirements were in particular: GWB, VgV and the second section of VOL/A nach den § 1 Abs. 2 VOL/A- EG i.V.m. Kategorie 25 in Anhang 1 Teil B, § 3 Abs. 3 VOL/A-EG

[4] See: „Steuerungsprogramme der gesetzlichen Krankenkassen datenschutzkonform gestalten", Entschließung der 76. Konferenz der Datenschutzbeauftragten des Bundes und der Länder am 6. und 7. November 2008 in Bonn, kindly made available by Ms. Erichsen, AOK NordWest.

3.2.6 Technical aspects

Technical aspects of the service focused on the security certificates for the balance device and usability criteria. CE certification for the balance was a requirement. Other aspects concerned the design of the display (readability) and the user manual for the device.

3.3 Preparation and execution of procurement

Through the detailed preparations and analysis work described in section 3.1, the actual procurement process and conclusion of contract were concluded within six months. The typical process of application evaluation is documented in an annex to this report.

3.4 Implementation and use of the service

The identification of eligible patients is done by AOK NordWest based on billing data.

The administrative registration of patients into the programme through a registration and consent form is managed by the service provider, which is also responsible for the send-out of the balance to the patient.

3.5 Monitoring

Current monitoring of the project is intended to accompany patients on their care pathway.

3.6 Quality assurance

Currently, weekly telephone conferences are held between AOK NordWest and the service provider. A monthly controlling report, comprising number of participants and other indicators is part of the quality assurance process.

3.7 Evaluation

A detailed evaluation of the project is envisaged after two years of operation. An economic assessment will most likely be part of this evaluation.

4. Procurement phase

Six months after the publication of the tender notice in the official journal of the European Union, a successful bidder could be identified. This time span does not include the detailed preparatory work. See in particular the description in section 3.1.

- From an initial ten bidders, five were selected for a detailed negotiation procedure. These bidders were allowed to present their service concept at AOK NordWest headquarters in Dortmund in the presence of the CEO and members of the project team. This first round of negotiations was in line with procurement rules. The entire procedure was scheduled according to a legally prescribed calendar which had been communicated to bidders.

- The evaluation of the individual bids was carried out according to a detailed catalogue of criteria. The offers were assessed and weighted accordingly. Each criterion evaluation was done at a 100% measure and then weighted according to importance:
    - Administration 5 %
    - Patient care and support 20 %
    - Documentation 5 %

- Personnel 15 %
- Device features and functionality 10 %
- Software 20 %
- Quality management 10%
- Controlling 5%
- Concept development 10 %

- In a second round of negotiations, two of the five bidders were admitted, based on the assessment criteria mentioned above. In this second round, details regarding the service content and questions of service pricing were addressed. Upon submission of the final offer, the two bidders were eventually assessed. The award decision was published in the Official Journal of the European Union[5].

5. Results and success criteria

AOK NORDWEST has identified the following planning and project success criteria for the HerzAs service:

a) Careful up-front planning of the procurement process, in particular with regard to the requirements catalogue
b) Independent and flexibly adaptable project team with specific legal and informatics knowledge
c) Availability of all necessary data for the identification of the condition and service participants „in-house“
d) Clear but flexible requirements catalogue for negotiation with the bidders and stepwise refinement thereof during the negotiations
e) Integration of a conceptual development clause for the service during its initial runtime
f) Close contact with the board of AOK NORDWEST to ensure swift decision-making. This contact was ensured through bi-weekly reports during the preparatory phase of the project

In particular with respect to point d) experience showed that data requirements and data quality assurance are a time consuming affair and require close coordination with the IT department.

6. Recommendations for other projects

General recommendations for action can be directly derived from the preceding analysis:

- Detailed analysis of market environment
- Clear, but flexible requirements catalogue
- Dedicated project team
- Early integration of legal expertise into the team
- Integration of information technology expertise

[5] - The release of the award notice was done on 08.09.2011 in the official journal of the European Union ABI.EU 2011/S 172-282602.

- Short decision-making procedures and close contact with top-level management
- Data protection considerations need to be integrated systematically throughout the project

7. Sources

This report was drafted following an interview with senior management at AOK NordWest on the 5th of August 2012 in Dortmund. Further documentation was subsequently provided by AOK NordWest.

8. Annex

Schematic process of bid assessment

All participants are reminded of their duty to confidentiality

The bid documentation envelops are checked for integrity, opened and recorded in the meeting minutes

Bids are checked against the requirements as published in the call for tender:

Completeness check of required documentation by the tendering authority

Where applicable, checks on the bidder's domain competence where evidence on qualifications are submitted

Missing documentation may be requested within a specified delay by the tendering authority

An evaluation based on the listed criteria begins to identify suitable bidders, with a view to identify a maximum of five:

Subsequently a comparative evaluation is carried out to determine which bidder is more suitable, based on the documentation provided and possibly additional information collected through additional requests by the contracting authority. The contracting authority is not required to ask for additional information.

A further evaluation is then carried out with regard to the professional qualities of the project leader presented by the bidder.

Both evaluation steps are weighted equally. Evaluation results are documented in prose. In case of doubt, a final decision is taken by lot.

The unsuccessful bidders are notified. Successful bidders receive detailed tendering documentation and an invitation to direct talks.

All evaluation session documentation is dated and signed.