



MOMENTUM

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**ATTACHMENT to
Deliverable 3.2**

**Towards a Personalised Blueprint – for doers, by doers:
MOMENTUM's seven in-depth cases**

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Abstract

This attachment contains the seven in-depth cases of deployed telemedicine services explored by the MOMENTUM consortium and describes how their approach fits with the 18 critical success factors described in the accompanying deliverable, D3.2.

Key Word List

Business plan, change management plan, compelling need, cultural readiness, IT and eHealth infrastructure, leadership, legal and security conditions, legal and security experts, legal and security guidelines, market procurement, patient centeredness, potential for scale-up, primary client, privacy awareness, resource aggregation, service monitoring, stakeholder involvement, user-friendliness.

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Introduction

In this attachment to deliverable D3.2, all seven service cases which the MOMENTUM consortium explored in-depth are described in terms of their fit with the 18 critical success factors. The cases were investigated purely in order to examine and illustrate the 18 critical success factors uncovered by the consortium.

The services should not be considered as “case descriptions” in their own right. Hence, at times, they may contain less information than readers would occasionally desire.

The seven services are: Chronic Disease Management (CDM)¹ (Israel), RxEye (RXE) (Sweden), Teledialysis (TD) (Norway), ITHACA (ITH) (Spain), Patientenhilfe (PH) (Germany), KSYOS (KS) (Netherlands), and Cardio On Line Europe (COE) (Italy). The table below shows how the 18 critical success factors (e.g., cultural readiness) apply to the seven cases.

Table 1: How the critical success factors apply to the seven cases

Short names of critical success factors (CSFs) vs. cases	CDM	RXE	TD	ITH	PH	KS	COE
CSF 1) Cultural readiness	X	X	X	X	X	X	X
CSF 2) Leadership	X	X	X	X	X	X	-
CSF 3) Compelling need(s)	X	X	X	X	X	X	X
CSF 4) Resource aggregation	X	X	X	X	X	X	X
CSF 5) Primary client	X	X	X	X	X	X	X
CSF 6) Stakeholder involvement	X	X	X	X	X	X	X
CSF 7) Business plan	X	X	X	X	X	X	X
CSF 8) Change management plan	X	X	X	X	X	X	X
CSF 9) Patient centeredness	X	X	X	X	X	X	X
CSF 10) Legal and security conditions	X	X	X	X	X	X	X
CSF 11) Legal and security guidelines	X	X	X	X	X	X	X
CSF 12) Legal and security experts	X	X	X	X	-	X	-
CSF 13) Privacy awareness	X	X	X	X	-	X	-
CSF 14) IT and eHealth infrastructure	X	X	X	X	X	X	X
CSF 15) User-friendliness	X	X	X	X	-	X	X
CSF 16) Service monitoring	X	X	X	X	-	X	X
CSF 17) Market procurement	X	X	X	X	-	X	X
CSF 18) Potential for scale-up	X	X	X	X	-	X	X

The MOMENTUM country reports for Israel, Italy, Norway, Spain, and Sweden – the countries where the critical success factors of importance to these in-depth cases were explored – may, as additional background, make helpful reading. They are available at <http://telemedicine-momentum.eu/europe>.

Brief service descriptions of the seven cases are also available on the same website.

Any literature citations made in this document are included in the bibliography located in deliverable D3.2.

¹ This set of short names (e.g., CDM) is used only in the table that follows.

1 Case 1: Chronic Disease Management (Maccabi)

The multidisciplinary Center for Remote Chronic Disease Management in Maccabi in Israel (hereafter referred to as either the Maccabi case or the chronic disease management case) is part of an on-going collaboration between the Gertner Institute for Epidemiology and Health Policy Research and Maccabi Healthcare Services, the second largest Health Plan in Israel. It is the 2012 expansion of an earlier programme that focused on home monitoring for patients with severe congestive heart failure. The service is now operational and is part of a mainstream service offered to patients with heart problems.

The precursor to this service was the Congestive Heart Failure (CHF) home monitoring programme that was implemented in 2008. It was for patients suffering from severe congestive heart failure whose mobility was limited as a result of their condition. This programme initially was a research programme. It had an experimental group, receiving telemedicine services, and a control group that continued to receive conventional care. There were 700 patients in each group – 1,400 patients altogether. With the launch of the Multidisciplinary Center, all 1,400 patients were absorbed into the new telemedicine service.

The objective of the programme was to improve quality of life and patient satisfaction, improve patient security, improve quality of care, and reduce emergency room visits and hospitalisation. Another objective was to make more efficient use of nurse and physician resources.

The main beneficiary of the service is the patient, but it also clearly benefits the particular health plan (i.e., the Maccabi health plan) by enabling it to make more efficient use of professional resources. It thus increases clinical benefits without a parallel increase in healthcare personnel. As there is improved quality of patient care and improved efficiency in the delivery of care, it will also potentially benefit the healthcare system in general.

Much more information on the chronic disease management case is available on the MOMENTUM project website (<http://telemedicine-momentum.eu/chronic-disease-management-il/>). That description contains details on the targeted population, the number of patients, the type of telemedicine service, the set-up that was being replaced, and the outcomes and results expected after introduction.

1.1 Critical success factors for a deployment strategy

Critical success factor 1: Cultural readiness

The importance of cultural readiness is evident in the Maccabi case. Maccabi was one of the first healthcare organisations internationally to implement the use of electronic medical records. It now has a central medical record system that is used by all healthcare providers. As a result, all the relevant Maccabi doctors, nurses, and other healthcare professionals document every encounter with the patient on a central platform which then is accessible to them. An embedded decision support system provides patient-specific alerts and reminders, as appropriate, to each professional. From an international perspective, Maccabi was also one of the early

adopters of telemedicine. The organisation offers a full array of telediagnostic, telehealth and telecare services.

The expanding use of telemedicine is an integral part of Maccabi's strategic vision. Maccabi's strategy is to provide care to its insured members at any time in any place where they are located and need access to services.

Maccabi is situated in the larger culture of a country (i.e., Israel) that welcomes, promotes and rewards innovation. Almost all Maccabi's clinicians and patients are comfortable with telemedicine in its many forms, including accessing medical information on mobile devices.

Critical success factor 2: Leadership

In the Maccabi case, the person who championed the service came from outside the organisation. However, the champion has a long history of collaboration with Maccabi as a result of the various roles he has played in the Israeli healthcare system (from twice being Director General of the Ministry of Health, to being the Chief Executive Officer of one of Israel's largest public hospitals, to his role as founder of the Gertner Institute). He is now director of the Gertner Institute's Division of Health and Society, which is currently co-funding the Maccabi telemedicine centre. The champion has influence, is well respected, and he brought both key operational people and some of the financing to two initiatives: the original Maccabi pilot project, and the currently functioning telemedicine centre.

Although the centre is operated by Maccabi and for Maccabi patients, the champion continues to promote the centre and uses it as a basis for developing and testing further innovative new services.

Critical success factor 3: Compelling need(s)

There are several compelling needs in the Maccabi case: the rapid growth of chronic illnesses (predominantly among old patients, many of whom have mobility limitations), coupled with a shortage of clinical personnel and tight budget constraints. These three factors generated the pressures to find a more efficient, high-quality and cost-effective solution to healthcare provision. They created a fertile ground for the implementation of the champion's vision. The proposed telemedicine service was a 24/7, multidisciplinary, telemedicine centre with high-level professional nurses at its core. The nurses now use computerised clinical protocols and interact proactively with the patients and their families via videoconferencing. The service integrates the care across all caregivers. This solution was perceived as having a distinct advantage over other alternatives.

Critical success factor 4: Resource aggregation

All four of the aspects of pulling together the needed resources – financing, people, information and prioritisation/time – are evident in the Maccabi case.

Financing – The Gertner Institute put up about 50 percent of the financing for the first three years of operation and provided the physical location and equipment for the call centre. The remaining 50 percent of the financing came out of a budget that was dedicated to the continuing development of eHealth and telemedicine in

Maccabi. Due to the persuasiveness of the champion, this particular project received priority above other projects.

People – Another critical element in terms of this case was that Maccabi already had a nurses call centre that was used mainly for routine advice and after-hours care. Maccabi therefore had nurses available who knew how to work with computerised clinical guidelines or protocols. A major asset was a nurse who headed up the pilot project that preceded the establishment of the telemedicine centre – she worked on a telemonitoring project for patients with severe congestive heart failure. She enthusiastically took on the task of implementing and managing the telemedicine centre. She recruited high-quality nurses to staff the centre. A strategic decision in terms of human resources made by Maccabi was to employ the nurses in the telemedicine centre on a half-time basis, enabling them to work for the other half of their time in another clinical service in Maccabi. This half-time approach was very important in preventing burn out on the part of the staff.

Information – The awareness that telemedicine is receiving international attention as a potential solution to increasing service needs was important information for Maccabi. This information was coupled with a situation in which Maccabi was experiencing shrinking resources. Information – on the needs of the population, and on the availability of the requisite infrastructure (internet access, for example) within the target population – was also critical to the design of the programme and the process.

Prioritisation/time – Because this initiative received priority within Maccabi, the time of key people, including clinicians, information technology staff and management, was made available and was dedicated to setting up and running the telephone centre.

1.2 Critical success factors for managing organisational change

Critical success factor 5: Primary client

In the Maccabi case, there is more than one primary client. On the face of it, and from a strictly business point of view, Maccabi itself would appear to be the primary client as it expects to see benefits in improved quality, effectiveness and efficiency of care which will result in clear economic benefits over time: these are indeed its incentives for implementing the service. However, in order for the Maccabi service to be successful, it must serve at least one other primary client – the primary care physician. The doctors are “clients” as they are the gateway to the service: i.e., if the doctors do not perceive a benefit from the service, they will not be willing to refer their patients to the Maccabi service.

Critical success factor 6: Stakeholder involvement

In the Maccabi case, doctors (both general practitioners and specialists) were involved in the design of the service. They continue to be involved in the service’s on-going development.

Decision-makers were also involved: in fact, in this case, the chief executive officer of the organisation made the decision to implement the service and continues to

monitor its development and on-going assessment personally.

Critical success factor 7: Business plan

In the Maccabi case, all components of a business plan were prepared. The overall concept was presented: it included the anticipated outcomes in quality of care, patient satisfaction, and economic indicators (such as reduced emergency room visits and reduced hospital days). However, by and large, these outcomes were not quantified at this early stage. A budget for expenditures was prepared which was presented to both Maccabi and Gertner, the supporting organisation, and approved by both. The budget served as the basis for a contract between the two organisations that specified who was responsible for what services and how the costs for set-up and on-going operation were to be divided between the two.

Critical success factor 8: Change management

In the Maccabi case, the decision to foster a close collaboration with the primary care physician was a key element of the initiative. It included the decision that no patients could be admitted to the programme without the recommendation or consent of their general practitioner. The shared electronic medical record, which is transparent to all of the healthcare providers as well as to the centre's multidisciplinary staff, was a key factor in mediating the information exchange and communication which is critical to the success of the service. The core elements that lie behind this success factor are: the clear responsibility for the service, and the support of senior management in managing the change.

For the Maccabi service, training and capacity-building were clearly viewed as important. Stringent criteria were developed for the eligibility of the nurses to serve in the centre: they had to be registered nurses, and have a bachelor's degree, at least three years of experience of working with chronically ill patients, a subspecialty in at least one of the relevant chronic diseases, and high-level communication skills. Each candidate was interviewed in depth: many were rejected. Those that qualified and were accepted to work at the telephone centre then underwent 300 hours of intensive training in all the skills required to care for chronically ill patients using telemedicine.

The communication strategy included presenting the new centre at all levels of the organisation, and holding working meetings with those parts of the organisation likely to be affected by the centre. Primary care physicians were invited to visit the centre physically, and many of them did.

Critical success factor 9: Patient-centeredness

The Maccabi service is human-centred insofar as it promotes a strong personal relationship between the case-manager nurse in the telemedicine centre and the patient. All nurses have their own group of assigned patients for whom they are responsible. The individual nurse is also responsible for coordination with both the patient's primary care physician and the specialists who care for the patient. The patients are still free to make face-to-face appointments with their doctors (and most do). Thus, the service enhances and strengthens the therapeutic relationship with the healthcare team and does not replace it. It is intended that the service

reduces the burden on both the general practitioner and the specialist while giving the patient a sense of security and safety. Patients know that they have access to their nurse (or another nurse on the team who is familiar with their history) on a 24/7 basis.

The strategic decisions made by Maccabi in going to large-scale deployment were: to strengthen the proactive relationship between the nurse and the patient via videoconferencing; to bolster this with multidisciplinary back-up; and to use telemonitoring only on selected patients where it provides actual value-added.

1.3 Critical success factors from a legal, regulatory and security perspective

Critical success factor 10: Legal and security conditions

The Maccabi case illustrates a situation in which the legality of telemedicine provided by the company was never questioned. All the relevant ethical, privacy and security issues had already been dealt with in earlier versions of Maccabi's telemedicine services.

Critical success factor 11: Legal and security guidelines

Legal and security guidelines were applied during the process of working on the Maccabi case. Guidelines for the central electronic medical record were clear to both the medical personnel and the patients. Since ethical, privacy and security issues had already been dealt with in earlier Maccabi-developed telemedicine services, these guidelines were available and the system has been confirmed as being compliant with them.

Critical success factor 12: Legal and security experts

Ethical, privacy and security issues had already been dealt with in earlier Maccabi-related telemedicine services. Therefore, legal, ethical, privacy and security expertise was not needed when the Maccabi service was established. The already-existing guidelines for the central electronic medical record (which was transparent to both the medical personnel and the patients) were adapted to fit the new context. Hence, this was not considered as a critical success factor for this service. All Maccabi personnel are indeed familiar with these various guidelines and know, understand, and have been using them for some years.

Critical success factor 13: Privacy awareness

Patients' consent to access to their electronic medical record by the relevant Maccabi personnel involved is a condition for patients' subscription to the Maccabi service, which in turn is voluntary.

"Privacy awareness" is needed both for doers and for telemedicine users. It is very important, certainly from an ethical point of view.

In Maccabi, privacy awareness was addressed by making sure that everyone directly involved in the scheme (including patients and doctors) knew that access to the electronic medical record was essential for the nurses and multidisciplinary staff at the telemedicine centre.

1.4 Critical success factors from an ICT perspective

Critical success factor 14: Information technology (IT) and eHealth infrastructure

The Maccabi chronic disease management service is based on technological features that help to show that the initiative is a modern healthcare case.

The Maccabi example encompasses the use of an electronic healthcare record system that is used with other Maccabi applications, a computerised central medical record, a computerised call centre management and patient management infrastructure, computerised clinical protocols embedded in the electronic healthcare record, and a videoconferencing and telemonitoring system to communicate with patients who are at home. Together, all these technological elements act as a comprehensive telemedicine service for delivering high-quality care to patients with chronic conditions.

The interoperability of the infrastructure is critical for the Maccabi institution and its healthcare professionals so as to facilitate transitions of care and to integrate the full cycle of care whether the care is provided face-to-face or virtually.

Critical success factor 15: User-friendliness

User-friendliness is a critical success factor in the Maccabi service as the target patient population is not necessary tech-savvy. For instance, the tablets used for videoconferencing between patient and nurse have only one use. Hence, the patients have only to touch one button to connect with their nurse. Those patients who do not have tablets contact their nurses by telephone.

Critical success factor 16: Service monitoring

In the Maccabi case, IT service monitoring is critical to the long-term sustainability of the service. It is mostly done by Maccabi's IT department. External providers, like the company that is providing the tablets (Avaya) as well as a telephone company, support Maccabi's maintenance team.

Critical success factor 17: Market procurement

Maccabi's procurement department experience enabled it to procure the array of services needed by means of a set of clear contracts that defined the appropriate deliverables, schedules, maintenance and responsibilities. Clarity in the procurement process (what is expected and what will be provided) was considered to be critical to the success of the implementation of the service.

Critical success factor 18: Potential for scale-up

The service was scaled up within the Maccabi organisation after a pilot phase involving 1,400 patients. It reached 10,171 patients after two years of service in July 2014. The fact that the large-scale deployment did not require a new health information integration or a new technological environment helped to enable the completion of the scaling-up process in only several months.

2 Case 2: RxEye

RxEye service is a business-to-business (B2B) online service for sharing competences and resources relevant to medical imaging.

Using an e-marketplace concept, it is the brokering service between intermediate imaging reporting service providers and customers. Its aims are to improve the collaboration between different actors in the care process, patient security and the quality of care by carrying out diagnostics more effectively, and to increase diagnostic quality in radiology and pathology. The RxEye service is a secure web solution where healthcare providers can offer and purchase all types of radiological and pathology reviews. Since the technical platform is common to all functions and products used, all that is needed is a single infrastructure installation.

RxEye does not provide an actual radiologists' or pathologists' service: rather, it aims to mediate between those who need radiological reporting and those who have the competence to produce such reports. RxEye does this through a brokering IT platform and a contract library.

More information on the RxEye case is available on the MOMENTUM project website (<http://telemedicine-momentum.eu/rxeye-se/>). That description contains details on the targeted population, the number of patients, the type of telemedicine service, the set-up that was being replaced, and the outcomes and results expected after introduction.

2.1 Critical success factors for a deployment strategy

Critical success factor 1: Cultural readiness

The RxEye service aims to provide new business processes in the medical imaging domain, particularly in terms of image reporting. A pre-requisite for this kind of change is the acceptance that market rules can operate in the healthcare domain. The need for the acceptance of market rules in healthcare in turn requires cultural readiness on the part of the various parties in the healthcare value chain, who need to be open, for example, to the purchase of a commercial reporting service. The current situation in most countries is not favourable to trade in imaging services. Most healthcare providers, including radiologists, are still not willing to open up their reporting procedures to bidding processes.

Thus, the relative lack of cultural readiness of the healthcare sector is a critical factor in terms of whether this specific form of service can progress further. In the RxEye case, the lack of cultural readiness hinders the potential of the service to grow further.

Critical success factor 2: Leadership

The RxEye service was planned and deployed by two individuals who clearly believed in this medical imaging brokering service. They established the company and started the service. Finding customers for the service remains – to quite a large extent – an activity that is dependent on the relations built by the founders of the company

themselves. Thus, these two individuals are themselves the champions of this particular initiative.

Critical success factor 3: Compelling need(s)

Overall in RxEye (<http://www.rxeeye.net/en/>), the demand for imaging and image reporting in the medical field is increasing on both the supply side and the demand side. On the supply side, the two compelling needs in the RxEye case are: first, the increasing number of radiology and pathology examinations; and second, the lack of radiologists and pathologists who are able to report on such exams. On the demand side, the compelling need comes from the customers (examples include a hospital board, or the Chief Executive Officer of a reporting company, i.e., people who are looking for more efficient service provider). The service is a cost-effective and timely solution to providing interpretation of imaging examinations without requiring an increase in the number of radiologists and pathologists.

Critical success factor 4: Resource aggregation

Once the RxEye service's primary way of attracting customers was determined, the resources for the service were described in detail in the company's business plan. As a critical success factor, therefore, because the financial resources were already accounted for in advance, pulling together the resources needed for deployment did not constitute a major challenge to initiating the service.

However, the availability of human resources, such as radiologists willing and able to perform the interpretation of the imaging tests, was a critical resource. Personnel (i.e., human resources) are indirectly needed on the customer side to integrate the RxEye platform with the local information system and to upload referrals and images to the portal. This has required only minor changes to take place in the local reporting process.

2.2 Critical success factors for managing organisational change

Critical success factor 5: Primary client

In RxEye, it is possible to identify both the primary client and the reason for the client's interest in the particular telemedicine service.

The primary client can be identified as healthcare managers who are in need of additional medical imaging reporting capacity. These managers have a clear business objective. The main concern of these healthcare administrators is the lack of personnel (i.e., radiologists, pathologists or other medical imaging specialists in their healthcare institution) and the deficit in certain other imaging subspecialists. This lack of reporting capacity causes long delays for patients. The managers are responsible for the effectiveness and efficiency of the healthcare organisation, but they are not the provider of the service.

The primary client cannot replace the contemporary radiological imaging reporting service. They are looking for new ways to provide the service without unduly changing the current workflow. Healthcare administrators would often like to use the institution's own human resources alongside the external resources.

Critical success factor 6: Stakeholder involvement

The main groups of healthcare professionals affected by the RxEye service are radiologists, pathologists and other medical imaging professionals. RxEye clearly differentiates between two subgroups of radiologists that have different expectations and incentives. The first group is radiologists who are working for the local healthcare provider which is going to outsource the reporting service. The second group is teleradiologists who provide the reporting service from a distance and do not belong to the local organisation. For RxEye, it was crucial to find incentives that appealed to both groups of professionals. Local radiologists are offered: i) subspecialty readings, if appropriate; and ii) backup in case of vacancy, sick leave, or a temporary increase in workload. Teleradiologists are provided with: a) access to a wider market, and b) the opportunity to increase their income.

RxEye managed to introduce the service while making only minor changes in imaging and reporting processes.

From the point of view of medical image reporters (i.e., radiologists and pathologists), the design of the RxEye service has the potential to re-engineer the current workflow and disrupt the “comfort zone” of the employees, requiring new and different behaviours from them. Therefore, when implementing the RxEye service, one should also consider the benefits that accrue to medical image reporters: RxEye offers opportunities such as the possibility to be substituted for when on vacation or sick leave, or to be able to concentrate on more specific work such as paediatric, trauma or other specific fields of radiology.

In the RxEye case, the needs of healthcare decision-makers are addressed by offering them more diagnostic capacity and increasing the daily output of the organisation. In addition, the fact that the healthcare provider could obtain better access to specialised diagnostic sources – improving the overall diagnostic quality of the service – is a clear incentive for the decision-makers.

Critical success factor 7: Business plan

RxEye prepared its business plan with a focus on providing a service for a certain market segment. RxEye knows its market segment and customers well: for example, it is aware of the pressure on imaging service providers to be more effective, while experiencing increasing budget deficits and having little opportunity to increase the budget. RxEye has identified the business opportunity deriving from the distance between hospitals in isolated, rural areas and university hospitals, where much of the radiological diagnosis traditionally takes place, and the shortage of healthcare professionals. Its business plan includes a clear description of the service components and information flow.

RxEye is an enabler in two ways. On the one hand, it enables healthcare providers (i.e., hospitals) to speed up their reporting time, and physicians to provide a good service to their patients. On the other hand, it enables radiologists and pathologists to provide their services in a multi-organisational environment based on market rules. The service aims to address the uneven distribution of radiologists and pathologists among hospitals.

All components of a business plan, including technology investments and milestones, were described in order to raise financing from investors. For the time being the costs and the estimated benefits of the service are not publicly available, however, the technology costs were not very significant.

Critical success factor 8: Change management

The RxEye service changes imaging specialists' routines as little as possible. It offers a simple and secure solution to contract with remote reviewers of images. RxEye facilitates the image interpreting service using external radiologists or medical imaging experts for care given for internal purposes. Teleradiologists/pathologists can offer their reporting services to other companies through an automatically generated invoicing system. The RxEye service supports clinical flow processes fully so as to minimise the need for administration on the part of both clients and reviewers. Only minor changes are needed in the routine workflow for the imaging department. RxEye forms a part of the existing and reimbursed image reporting service. It is a mature service, well integrated into the whole health information chain.

RxEye customers are different hospitals and physicians groups who need only a little training in support of the service. Therefore, there is no universal RxEye change management plan for healthcare professionals. All training is addressed according to the needs of the particular case.

Critical success factor 9: Patient-centeredness

User-centeredness was not a critical factor for RxEye, since RxEye provides a doctor-to-doctor service and because patients do not use the services directly themselves.

A successfully deployed service speeds up the medical imaging reporting process, which enables the patient to get quicker access to results from the service. Even if patients are only involved indirectly in the RxEye service, the communication of the opportunity to obtain quick access to results on the part of patients plays a very important role in RxEye's public broadcast channels.

2.3 Critical success factors from a legal, regulatory and security perspective

Critical success factor 10: Legal and security conditions

The legal framework was considered very important for RxEye. The service was designed to comply with all the relevant provisions set out by the legal framework on teleradiology services. Hence, the RxEye service operates within the current legal framework for these kinds of services.

Contracts are the main enablers that ensure the provision of this brokerage service for medical image reporting. One of the components of the service is to provide customers with model contracts. These models are prepared according to the appropriate legal framework. In this case, especially in case of the provision of cross-border services, accordance with the relevant legal framework is critical.

Critical success factor 11: Legal and security guidelines

The reliability of the RxEye radiological service was discussed at an early stage of service development. The conclusion was that RxEye provides a proper way to conduct a radiological service, as long as the patients' rights are taken into account. Both the European (European Society of Radiology, 2014) and North American (American College of Radiology, 2013) societies of radiology have issued white papers which address the principles of good teleradiology practice. The RxEye service follows the principles outlined in these white papers.

Critical success factor 12: Legal and security experts

The Swedish RxEye service represents a new, and different, teleradiology service. Thus, legal consultancy and/or the presence of a lawyer were necessary. The lawyer who was involved ensured that the service complied with the relevant legal framework.

Critical success factor 13: Privacy awareness

The Swedish RxEye service de-identifies radiology-related referral letters and images. Privacy awareness is important because RxEye believes that patients should know where and by whom their medical data (including radiological images) are viewed.

2.4 Critical success factors from an ICT perspective

Critical success factor 14: IT and eHealth infrastructure

Because RxEye is a Swedish eHealth solution designed to provide radiological knowledge and advice from a distance, the system was built to serve different clients. It consists of a web platform for transmission and radiology image reading and reporting. It relies on the available broadband infrastructure and uses standard data communication systems over the net, both hypertext transfer protocol (HTTP) and file transfer protocol (FTP).

The quality of the teleradiology reporting service depends on the availability of digitalised referral letters, clinical data, previous imaging reports and images, current examinations, and other reports. An existing eHealth infrastructure is mandatory for teleradiology to achieve a similar quality of service as on-site radiology.

In terms of interoperability, the nature of this radiology-related service required it to be connected with customers' picture archiving and communication system (PACS), using the Digital Imaging and Communication in Medicine (DICOM) standard, and radiology information systems.

Critical success factor 15: User-friendliness

The RxEye service depends critically on the fact that the teleradiology service should not change routines in the radiology department which is outsourcing reporting. RxEye service does not require major changes in local software or hardware setup. The technical platform is common for all the functions and products. The teleradiology customers should create a single infrastructure installation and integrate it within their own information system.

Critical success factor 16: Service monitoring

Service monitoring has a double role in the case of RxEye. From an IT perspective, this service, which involves the outsourcing of radiology diagnosis, requires a joint effort. On the one side, RxEye needs to be available to receive radiological images and send diagnostic reports to its healthcare clients. On the other side, the client IT system has to be able to store and send radiological images and receive, store and integrate radiology diagnostics into its health IT infrastructure. Therefore, good collaboration with the customer's IT governance team(s) is important so as to deliver a good level of service.

Critical success factor 17: Market procurement

RxEye dealt with the contracting process as a provider rather than as a client. As a telemedicine service provider, RxEye has relied on flexible and secure online contracts to guarantee the level of service provided and data protection. RxEye is providing customers with the software to send and receive referral letters, images and reports, to buy and sell medical image reporting, and to make contracts between parties. In this regard, RxEye is a vendor: according to its service level agreement and other contractual conditions, it provides support, maintenance and development of the system.

Critical success factor 18: Potential for scale-up

The RxEye brokering platform has properties which will enable it to be scaled up further as it interoperates with customer information system in a non-intrusive way, exchanging radiological image and reporting results. The expansion and profitability of the service depends extensively on the number of transactions made when using the platform.

In fact, the service has already been scaled up inside Sweden and abroad, as it has become a provider to Danish customers.

3 Case 3: The Norwegian Teledialysis case

Patients receive haemodialysis in their local health institution supervised by a nurse and sometimes also by a nephrologist from the University Hospital of North Norway (UNN) via videoconferencing, as part of the doctor's round. The nephrologist participates only in videoconferencing to those units that they do not visit or when their expertise is needed due to the patient's condition. If necessary they solve patient problems by phone. UNN is the unit that is responsible for the treatment of dialysis patients in its area.



Figure 1: A Teledialysis patient and a healthcare professional in discussion

Hence, UNN uses videoconferencing technology to communicate with remote hospitals, health centres and wards that are without nephrologists but which still provide dialysis. At UNN both specialists and nurses participate in providing the service – indeed, sometimes, it is only nurses. At the local hospital/healthcare centres there are both nurses and patients.

More information on the Norwegian Teledialysis case is available on the MOMENTUM project website (<http://telemecine-momentum.eu/teledialysis-no/>). That description contains details on the targeted population, the number of patients, the type of telemedicine service, the set-up that was being replaced, and the outcomes and results expected after introduction.

3.1 Critical success factors for a deployment strategy

Critical success factor 1: Cultural readiness

In general, technology use in Norwegian healthcare is considered useful.

The Norwegian Centre for Integrated Care and Telemedicine (NST), the organisation which has assisted University Hospital of North Norway in establishing this service, is a department in a university hospital. Videoconferencing was generally well known in the hospital and already widely used prior to the specific service being introduced. Together with the identification of the compelling need (see the third critical success factor discussed below), this general openness to technology, and videoconferencing specifically, created the necessary cultural readiness for the telemedicine service to be introduced.

Both patients and local health personnel wanted to have this teledialysis service. The patients felt that they would feel secure, as a result of being supervised by highly

qualified health professionals. This provision of the service by highly qualified professionals would, in turn, strengthen the patients' confidence in the quality of the service. The service made both patients and local health professionals feel safer.

Patients and health professionals were comfortable with the idea of using teleconferencing, particularly as it saved them travelling time and expense.

Critical success factor 2: Leadership

The initiator of the Norwegian Teledialysis service was a department or a team of individuals rather than an individual: the department was the nephrology department of a specialist healthcare hospital in the specific region of Norway.

There were several champions who operated at different levels both inside and outside the renal unit/nephrology department:

- The head of the medical department at the hospital (who is a doctor) believed in telemedicine, and related ideas, and he made the required resources available.
- The head nurse at the renal unit at the hospital recognised the need for the service and motivated the staff and the patients.
- The project manager at NST (who is a technologist) was responsive to the clinicians' wishes and was good at facilitating their visions.

Critical success factor 3: Compelling need(s)

For the Norwegian Teledialysis service, the compelling need was to provide a safe and high-quality dialysis service to small local hospitals. The advantage and unique benefit of the teledialysis service is that it meets these needs with the added benefit of reducing both travel time and costs for patients and doctors.

Critical success factor 4: Resource aggregation

In the initial phase of the Norwegian Teledialysis service, the hospital renal ward allocated the appropriate professional personnel to the service. Equipment, devices and the project leader were financed through project funds.

Teledialysis is now a routine service publicly financed through the specialist healthcare hospital's ordinary budget. The personnel working on it are nurses in local hospitals/healthcare centres, and nephrologists (medical doctors who are specialists in kidney care) and nurses in the specialist healthcare hospital that provides the videoconferencing service.

3.2 Critical success factors for managing organisational change

Critical success factor 5: Primary client

The initiator of the Norwegian Teledialysis service was the nephrology department at a specialist healthcare hospital. The funds for the routine service come from the hospital budget. The incentive for the hospital to start up the service was to avoid its own staff travelling and, at the same time, to provide patients with the same quality

dialysis service as patients who receive teledialysis at the university hospital in Tromsø.

From this perspective, the primary clients of the teledialysis service were the nephrologists responsible for the dialysis. They re-engineered their work around the teledialysis service in such a way that they were able to minimise travel from one hospital to another. The medical staff members in remote locations were also the primary clients insofar as they were ready to accept teledialysis as a new way to help patients with renal failure.

Critical success factor 6: Stakeholder involvement

The Norwegian Teledialysis service involves nurses in local hospitals and healthcare centres, doctors who are mainly nephrologists, and nurses in specialist healthcare hospitals. Healthcare personnel consider the service as an improvement on the previous service it replaced. The personnel involved describe it as inspiring and exciting.

In the Norwegian Teledialysis service, the healthcare professionals were considered to be more important than the decision-makers in the implementation phase of the service. They were the people who knew the routines and “the internal life” in the hospital, and had well-founded and highly qualified opinions on what would work and what would not. They were very important supporters of the initiative when adaptations and practical solutions were discussed.

A pre-requisite for the service’s implementation and routine use was that it was supported by both the clinicians and the management of the hospital. The head doctor and the head nurse were initiators of the service and were involved throughout the whole process, together with the project manager at NST. The health professionals continued, and continue, to be involved in all stages of the service development.

No information was provided on how patients were involved in the service deployment.

Critical success factor 7: Business plan

In the Norwegian Teledialysis service case, economic indicators were not quantified in detail at the service development and implementation stage, but a simple economic analysis was calculated. The implementation decision was based on the perception that: the service was wanted, it would improve the quality, and it would work on to be less costly to operate in the long run (i.e., investment costs were taken into account, and both patients and nephrologists’ travel time was avoided).

Critical success factor 8: Change management

In the Norwegian Teledialysis service case, the new telemedicine service is fully integrated in the ordinary routines of the organisation, for example, by setting up schedules for use of the service.

In terms of change management, the main emphases in this case were on training, the communication strategy, and the scaling-up of the service.

With regard to training, technical training was given on how the monitoring devices and/or system(s) and videoconference equipment were to work. From the teledialysis service implementation point of view, on-going training of the staff is crucial. There is a need for: updates of the initial training and possible new elements of work, and training of new staff (such as the checking and updating of routine descriptions, basic training in dialysis, and training in the use of videoconferencing in particular). Nurses received training in professional conduct via videoconferencing.

The communication strategy can be classified into internal strategy and external strategy. However, no internal strategy was worked out as the service was initiated in the hospital's renal department which is a well-known unit. The external strategy included presentations at conferences and at meetings for nephrology nurses. There was widespread publication of papers or articles in professional journals and reports too.

The service was exported to other countries, including Scotland. It was also included in some international projects such as Implementing Transnational Telemedicine Solutions (ITTS) and Competitive Health, both of which are European Union co-financed projects.

No information was provided on how patients were considered by the change management plan.

Critical success factor 9: Patient-centeredness

The aim of the Norwegian Teledialysis service is to deliver good quality service to patients with kidney failure who live in areas where there are no nephrologists.

The teledialysis service avoids unnecessary travel on the part of patients. Thus, it saves a remarkable amount of patients' time and resources that would otherwise be needed for travel to receive conventional services.

3.3 Critical success factors from a legal, regulatory and security perspective

Critical success factor 10: Legal and security conditions

The circumstances under which the Norwegian Teledialysis service was or could be legal were queried and clarified at several stages of the development and deployment of the service. Liability and responsibility issues were the main focus and had to be defined and described. The fact that the roles and the work-related tasks of the staff changed due to the way dialysis was reorganised were also assessed in the light of the legal framework for such services.

Critical success factor 11: Legal and security guidelines

Appliance of legal and security guidance was of great importance. Guidelines for telemedicine and responsibility/liability matters issued by the Norwegian government (HOD, 2001) were taken into account. Based on these guidelines, the service was described, the roles and responsibilities of the healthcare personnel were defined, and the protection of the patients' rights was secured.

The Norwegian Code of Conduct for information security in the healthcare, care, and social services sector (Helsedirektoratet, 2014), issued by the Norwegian national

health authorities, was applied. This code of conduct was developed by representatives from the health and social services sector, and comprises the two sectors' view of how to ensure information security. In addition to developing the code of conduct, the Norwegian health authorities have produced a set of short practical guidelines and several fact sheets on how to meet the individual requirements in the code.

The code represents a holistic approach to an information security policy for all organisations within the sector. Since 2006, this code has emerged as an important tool in the process of deploying telemedicine.

Norwegian legislation requires regular risk assessments. According to the legislation in force, risk assessments shall be repeated when changes have an influence on information security (FOR-2000-12-15-1265, 2000). According to the Norwegian Code of conduct (Helsedirektoratet, 2014), risk assessment should be conducted regularly. The International Organization for Standardization (ISO) standard for information security risk management (ISO/IEC 27005 2011) states that "information security risk management should be a continual process" (International Organization for Standardization, 2008).

Critical success factor 12: Legal and security experts

In the Norwegian Teledialysis case, an information security risk assessment was conducted at the outset so as to comply with Norwegian legal requirements.

Measures to secure the quality, reliability and security of the service were also discussed and implemented. Local guidelines were worked out in these three fields in close cooperation with the telemedicine doers. Routines for documenting the service were also adapted to the Norwegian legislation in force.

In Norway, the telemedicine users – who are medical staff members – know who they can ask if problems arise or if they are worried about a particular legal or security issue. These are lawyers and security staff at the NST, as well as the data protection supervisor at the relevant hospital.

Critical success factor 13: Privacy awareness

In the Norwegian Teledialysis case, the duty of professional secrecy is important for the healthcare staff. If patient information goes astray due to insufficient technical security measures and/or unsatisfactory routines for handling patient information it might be considered a breach of duty on the part of the health professionals.

In this case, brief guidelines for secure conduct were therefore worked out in advance, to be used by both the parties who take part in the dialysis-related videoconferencing. The guidelines were established in order to create best practice in this field, thus preventing patient information from going astray.

3.4 Critical success factors from an ICT perspective

Critical success factor 14: IT and eHealth infrastructure

The Norwegian teledialysis service is a telemedicine service based on synchronous video and audio two-way communication linking the main hospital to other regional

hospitals and health centres. It required a pre-established broadband network to allow real-time communication. The Norwegian broadband network was mature at the time of the teledialysis service implementation and this thus helped the service to be rolled out without problems.

The videoconference solution adopted by the teledialysis service was off-the-shelf equipment (Cisco TelePresence System Edge 95) which brought reliability and reduced implementation risks.

Interoperability was involved when accessing the electronic health record available during doctor-to-patient consultation and in recording documentation of the treatment. Initially, the staff in the local units and in the university hospital documented the patient treatment in the same electronic healthcare record. Later, the local units installed new dialysis machines with a documentation system incompatible with the electronic healthcare record system at the university hospital. Therefore, they stopped documenting patient treatments in the same system.

There also turned out to be some legal barriers: this was because the (then) newly passed Norwegian Health Register Law prohibited employees in one health institution from documenting patient treatment in another health institution's electronic healthcare record.

Critical success factor 15: User-friendliness

The technology deployed in Teledialysis is not complicated, and it was – through its own design – user-friendly from the outset. The system is flexible in the sense that, while not all its possibilities are used at all times, they are adapted to the actual needs of the end-users.

Critical success factor 16: Service monitoring

The IT system involved in Norwegian teledialysis is based on three main technological elements:

- A videoconferencing system over internet (VOIP) protocol.
- Medical equipment capable of being used with the assistance of a local nurse or physician assistant (e.g., ultrasound, an electronic stethoscope and a dialysis machine).
- A health information system to store and access patient data (in the electronic health record).

Therefore, service monitoring has to ensure the maintenance of all three types of technologies – videoconferencing, medical equipment, and the health information system – which involves a diverse maintenance team. In this case, it is the same organisation which monitors and supports all IT systems at the hospital.

Critical success factor 17: Market procurement

The teledialysis managers had access to experts from NST on videoconference equipment that helped define the necessary requirements for the “package” that was acquired (a configuration of solutions and procurement knowledge). They also had access to general procurement expertise at the hospital.

Critical success factor 18: Potential for scale-up

Regional scale-up (with more local health centres being connected to the hospital) would require the redesign of the organisation and routines, according to how many simultaneous videoconferences the renal department should and can handle.

As for a broader scale-up (i.e., connection with new hospitals or regions), no particular problems are foreseen as the communication technology used is standard.

4 Case 4: ITHACA

ITHACA – which stands for “Intervention of Treatment of Hipertensión Arterial in Catalonia” – provides telemedicine services for chronic hypertensive patients in the Catalan region. Badalonia Serveis Assistencials (BSA) is an innovative public organisation with a certain management autonomy – it is a hybrid model of public healthcare organisation. It has a history and tradition of initiating innovation in health services, including technological innovation. ITHACA was conceived as a consortium venture in which three different organisations brought together their capacities to build a new telemedicine service for patients with blood pressure disorders.



Figure 2: Poster for the ITHACA programme

4.1 Critical success factors for a deployment strategy

Critical success factor 1: Cultural readiness

BSA has been a pioneer organisation in Catalonia, Spain, when it comes to health technology and information systems innovation. Initiating and welcoming innovation are crucial aspects of cultural readiness. In ITHACA, this readiness was particularly strong inside the executive team and in some clinical departments.

Critical success factor 2: Leadership

The clinical lead in BSA pushed for the implementation of this service and led it. A pharmaceutical firm, Novartis, was also a strong partner in the initiative. The company not only championed the launch of the service but also brought various resources to the initiative. There was no single champion who was responsible for successful adoption by the organisation. Rather, it was a champion management team that made it possible. The team is a multidisciplinary one that combines a set of skills and knowledge coming from clinicians, managers and IT staff.

Critical success factor 3: Compelling need(s)

In ITHACA, the compelling need was clearly a clinical need: high blood pressure patients. The increasing number of patients with chronic hypertension, the need for improvement in the quality of care, and the need to reduce costs and increase satisfaction were the main compelling needs that lie behind this service. The ITHACA programme now meets these needs in an efficient and cost-effective manner.

The design of ITHACA made it possible to monitor patients with high blood pressure as well as educate them about healthy behavioural habits through different services that are provided at a distance. As a result, a reduction in (ordinary) service use was observed while quality indicators improved.

There are two unique advantages of the programme: it is strongly supported by a strategic partner – Novartis – that also provides financial support. This programme also forms part of the Catalan national strategic plan.

Critical success factor 4: Resource aggregation

In the ITHACA programme, staging of the service and its developing maturity are important. Two different aspects of this staging need to be distinguished in the way in which they affect resource aggregation: deployment and sustainability.

In the deployment phase, the interests of three partners: BSA, as the host health organisation; the pharmaceutical company, Novartis, as promoter; and Indra were aligned. Novartis secured sufficient resources to enable a successful deployment. It made external funding available, and continues to finance the service. BSA provides the clinicians and the professional staff that operate the programme.

As far as sustainability is concerned, financial commitment in the long run has not yet been agreed. Currently, there is no guarantee that there are enough resources available to continue with the programme. This last fact underlines the importance of identifying resources for the successful deployment and sustainability of the initiative and planning how to mobilise these resources.

The level of dependency on external support should also be considered.

4.2 Critical success factors for managing organisational change

Critical success factor 5: Primary client

The primary clients were: the public healthcare provider, BSA; the pharmaceutical company, Novartis; and the technology partner, Indra. While the incentives of these three primary clients were different, all were motivated to start the telemedicine service. Their aim was to promote the adherence to treatment of chronic hypertension patients.

Critical success factor 6: Stakeholder involvement

The ITHACA service included the intense involvement of both healthcare professionals and decision-makers from the very beginning. Healthcare professionals were involved in the deployment as they could envisage a reduction in visits and consultations due to the services provided by ITHACA.

Critical success factor 7: Business plan

In the ITHACA case, BSA initially drafted a functional plan to describe the intervention design to set the patient target, inclusion and exclusion criteria, and the size of the service requirements. The joint initiative with Novartis and Indra required a detailed business plan that was built on that original functional plan. Novartis helped to refine the document that was finally approved by the steering committee.

Despite the fact that there is no tradition of working using this type of business document in Spanish public healthcare services, the business plan was seen by BSA as a constructive initiative that helped to define the roles of the partners along the development journey.

Critical success factor 8: Change management

The ITHACA partners did not call their plan a change management plan. However, they actually did everything that would be included in such a change management plan. A particular emphasis was paid to training and communicating throughout the whole project. This included: training different groups of end-users, and disseminating activities both internally (through meetings) and externally (through public presentations).

Since the service was co-designed by the health professionals, some change management activities were encompassed implicitly in the design process.

Critical success factor 9: Patient-centeredness

The multimodal design of the ITHACA service – based on communication via web, phone, and paper – supports the inclusion of all sorts of patients regardless of their level of computer skills. The telemedicine service is intended for chronic hypertensive patients, so as to improve patient satisfaction and treatment adherence. In order to achieve these objectives, patient-centeredness was a key feature for all the partners involved in the project. Patients' health and personal needs were taken into account in the design process and throughout its deployment.

4.3 Critical success factors from a legal, regulatory and security perspective

Critical success factor 10: Legal and security conditions

In general in Spain, telemedicine is a legally approved, and undisputed, service; it is not perceived as an inferior service or as “second-class medicine”. As a complement to traditional healthcare, it is seen as posing little threat.

ITHACA is run in the community of Badalona in Catalonia. The circumstances under which the ITHACA service could be organised in a legal way were assessed. The service operates in strict compliance with the Spanish Personal Data Protection Act (Ley Orgánica, 1999). The Spanish law complies with the Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (EC, 1995). No concerns arose regarding the legality of the services included in the ITHACA initiative.

Collaboration agreements were set out between all three organisations involved: BSA, Novartis and Indra. All three are independent companies. The three organisations signed bilateral and multilateral agreements to carry out the project and to give ITHACA a binding strength.

Critical success factor 11: Legal and security guidelines

Guidelines were considered useful and important in the ITHACA case. The service builds on the Catalan clinical guideline (Amado Guirado, 2003), which is based on international guidelines for treatment of hypertension (Chobanian et al, 2003; Chalmers et al, 1999). It is assumed that security advisors follow appropriate technical guidelines. No specific legal guidelines were used apart from procurement guidelines.

Critical success factor 12: Legal and security experts

Legal services were involved in the collaboration agreements which were contracts composed of service level agreements. The project details were scrutinised by the ethical committee on the initiative of its promoters and they were validated. Privacy and security advice was provided by Indra, one of the three organisations involved, to guarantee health-level compliance with the Spanish Personal Data Protection Act.

Critical success factor 13: Privacy awareness

Patients signed an informed consent document before being registered to use the service. The health professionals (telemedicine doers) are aware of privacy issues as they are accustomed to work on electronic clinical records that have the same level of privacy protection.

4.4 Critical success factors from an ICT perspective

Critical success factor 14: IT and eHealth infrastructure

Indra was the venture partner responsible for IT development. It is a Spanish IT and defence systems company with broad experience in developing complex IT solutions for a range of different industries including healthcare.

The solution developed by Indra had to be integrated with BSA's health information systems. The interoperability of this connection became mission-critical in so far as it needed to avoid duplications in computerised physician order entry – i.e., there should not be two health records – and reduce clinical workload. Ultimately, ITHACA's solution was successfully integrated with the BSA current electronic health record in one direction, extracting data from BSA's electronic healthcare record so as to display it within ITHACA systems. ITHACA is fed by BSA electronic healthcare record data so that clinicians do not have to feed data manually into the ITHACA system.

ITHACA is a solution based on telecommunications standards for data exchange (such as the world wide web (WWW) and smart messaging service (SMS)) and voice communication (GPRS).

Critical success factor 15: User-friendliness

Inspired by its patient-centred framework, ITHACA is a user-friendly solution. Patients may access ITHACA services in different ways, including via letters, telephone, or interactive web-based services. The service's user-friendliness has been validated by various satisfaction surveys.

Critical success factor 16: Service monitoring

Services maintenance and monitoring were outsourced to Indra, the technological partner in the ITHACA venture. Indra is used to large technological projects in different sectors. In the case of ITHACA, it has provided excellent service maintenance to date and has developed new features of the web platform needed by BSA.

Critical success factor 17: Market procurement

Good vendor relations were secured through contracts and agreements among the three partners in the telemedicine initiative, BSA, Indra and Novartis. The impetus to formalise agreements came from all three partners as the potential for scalability was foreseen by each. For instance, Novartis envisioned extending the ITHACA system to other pathologies related to its therapeutic lines in the fields of cardiovascular, respiratory or endocrinological conditions. Indra was comfortable acting as a technological provider for ITHACA and being able to export the solution to new customers.

In terms of consultancy about market procurement, BSA obtained legal advice from its procurement department which it used to draft and issue service contracts to support healthcare delivery. Novartis and Indra were also assisted by their own legal departments.

Critical success factor 18: Potential for scale-up

From a technological point of view, ITHACA is ready to be scaled up both geographically and functionally: for example, in other areas in the Catalonia autonomous region and to be used for other health conditions, such as diabetes.

This scale-up has not yet occurred, however, as it has so far not been possible to develop and sign a further scale-up agreement due to the divergent interests among the three ITHACA partners. Actually, all three partners want to scale up the service, but in different ways. BSA would like to extend the service to more chronic care patients, while Novartis and Indra would like to offer ITHACA to other healthcare organisations worldwide.

5 Case 5: Patientenhilfe

ALERE's German subsidiary "Patientenhilfe", an innovative diagnostics business, offers the Cordiva service. Cordiva provides near-patient diagnostics. It uses devices that cover such domains as cardiology, endocrinology, nephrology, infectious diseases, toxicology and intensive care. The service involves point-of-care measurement, connects patients and providers, is supported by analytics, and is linked to health management.

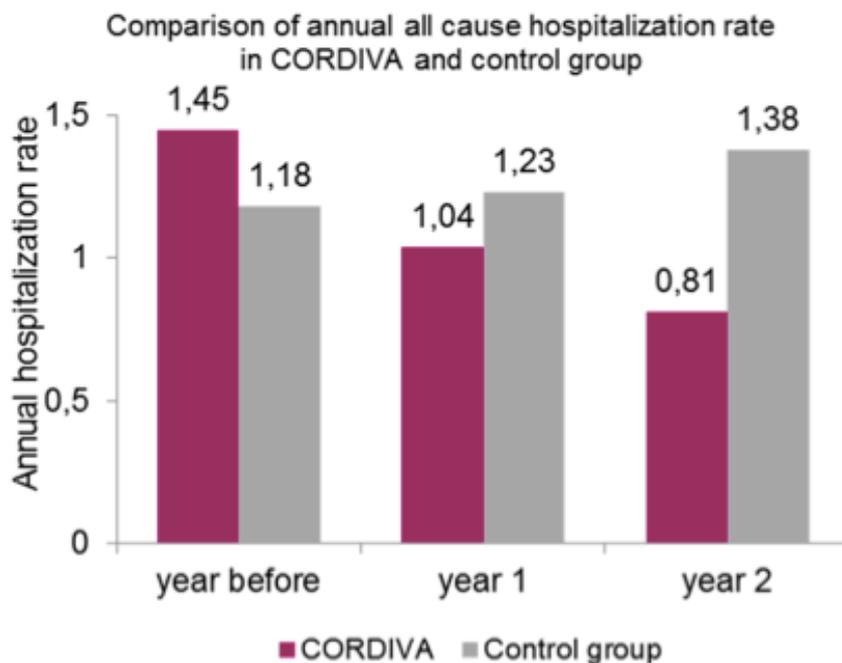


Figure 3: Evidence of Cordiva's effectiveness

5.1 Critical success factors for a deployment strategy

Critical success factor 1: Cultural readiness

Cultural readiness is important here, as it took some time to reach the cardiologists who, only after a deeper debate on the subject, joined the initiative.

Critical success factor 2: Leadership

The chief executive officer of the company struggled until he finally established the business.

Critical success factor 3: Compelling need(s)

It can be inferred from the impact statements that support the German Patientenhilfe Service that the compelling need that drove the development of this service and its success was the increasing number of hospital admissions and deaths from chronic diseases that, with appropriate monitoring and early detection, could be avoided.

Critical success factor 4: Resource aggregation

The German Patientenhilfe Service is a commercially-sold service that is making a profit. At the current time, it is sustained by its income from sales of the service. MOMENTUM has no direct information about how the service was started and who made the initial investment.

5.2 Critical success factors for managing organisational change

Critical success factor 5: Primary client

The primary client of the German service, Cordiva, is an insurance company. The initial agreement was made between Patientenhilfe and the insurance company to agree on the reimbursement conditions of the telemedicine service. This agreement paved the way for Patientenhilfe to build a business case and to start up this service for cardiovascular disease patients.

Critical success factor 6: Stakeholder involvement

The German Patientenhilfe service addressed decision-makers on the level of financial decisions made by the health insurance company. Only after agreement was reached on the decision-maker level about reimbursement criteria for the service did the service design start.

The telemedicine service provider employed healthcare professionals who were mainly nurses. It provided them with clear work descriptions and understandable workflows which made the healthcare professionals interested in the actual work.

To secure adoption on the part of general practitioners – in the event of their daily routines being interfered with by a surplus of information about home monitoring – the service provider made an attempt not to interrupt their information flow. For instance, reports are sent to the practitioners, according to an agreed schema and data-set, by fax instead of in digital format in order to avoid data overload. Hence, the doctors can read the important data that comes from the home monitoring service at times which suit them rather than experiencing any major interruptions in their work.

Critical success factor 7: Business plan

In order to strengthen the Patientenhilfe service, the telemedicine service provider addressed the need for clarity by specifying targeted eligibility conditions, inclusion and exclusion parameters, and the periods of time needed to do the work involved. There are clear benefits for the insurance company in reducing the number of costly hospitalisations. Most of the time, the services offered by Patientenhilfe are clearly defined. The implementation plan includes clear success and failure parameters: these are linked to eligibility, size of the targeted population that are linked to the budgeting, screening and inclusion procedures, intended patient flows, exclusion procedures and follow-up offers.

Critical success factor 8: Change management

Specific evidence is not available on a change management plan. However, it is clear from the Patientenhilfe case documentation that the service did modify specialist, general practitioner and nurse behaviours. For the doctors, it did so as little as possible.

The programmes available in the Patientenhilfe service form part of standard healthcare processes operated in cooperation with inpatient and outpatient facilities where general practitioners and specialists operate. Physicians are alerted whenever a patient requires an intervention above the level of nursing care, thus alleviating their workload but keeping them in the information loop.

The service provides seamless implementation of the telemonitoring service into the existing workflow, which places exceptionally high demands on development and implementation. Only necessary, actionable information is delivered to the healthcare professionals. Additional details are given on request. Hence, the system is one of management by exception, at least for the clinicians and general practitioners involved: their normal – older or former – workflow has not been interrupted by the introduction of the new service.

Customisable guideline-based rules stratify patients, based on the patients' prognosis regarding their psychosocial stressors: the guidelines or rules provide individually tailored care. Nurses follow up by phone, so as to ensure that patients comply with their care plan and avoid higher acuity. Patient-specific alerts are subject to rule-based management.

Critical success factor 9: Patient-centeredness

The Cordiva service complements face-to-face meetings with primary care doctors. There are several benefits. Individualised care is available, and patients are stratified according to their health status. The results of the service prove that the patient benefits considerably from the service – it is reported that, in the first year of the service being provided in Germany, 46 percent of deaths were prevented, up to 40 percent of hospital admissions were avoided, and there was a 25 percent gain in cost savings.

5.3 Critical success factors from a legal, regulatory and security perspective

Critical success factor 10: Legal and security conditions

Legal and security issues were not mentioned at all in relation to this case; the background to this context is still under investigation and appears to relate more to security compliance.

Critical success factor 11: Legal and security guidelines

In terms of guidelines, Deutsche Gesellschaft für Patientenhilfe (DGP) is certified for data security based on an audit according to the ISO 27001 standard. This certificate includes a confirmation that Patientenhilfe obeys the specific regulations for health and social data. Furthermore, since it is a legal requirement for every company's website in Germany, the service has also declared that it conforms with the general

German federal law on data protection to which there are two German regulations which apply.

Critical success factor 12: Legal and security experts

(No information pertinent to this critical success factor is available.)

Critical success factor 13: Privacy awareness

(No information pertinent to this critical success factor is available.)

5.4 Critical success factors from an ICT perspective

Critical success factor 14: IT and eHealth infrastructure

The service is supported by a web portal and a call centre.

Critical success factor 15: User-friendliness

(No information pertinent to this critical success factor is available.)

Critical success factor 16: Service monitoring

(No information pertinent to this critical success factor is available.)

Critical success factor 17: Market procurement

(No information pertinent to this critical success factor is available.)

Critical success factor 18: Potential for scale-up

(No information pertinent to this critical success factor is available.)

6 Case 6: KSYOS

KSYOS develops, investigates and implements telemedicine services in routine healthcare. KSYOS is a health institution that delivers healthcare by means of telemedicine which began by offering teledermatology services.

The KSYOS TeleMedical Centre was founded in 2005: it was the first virtual hospital in the Netherlands. The centre has since been recognised for payment by health insurers just like any other hospital, since teledermatology was integrated in regular healthcare in the Netherlands.

KSYOS is not an IT company. Instead, as a health institution it provides regular and extensive health services to patients using expert teleconsultation among clinicians.



Figure 4: KSYOS's teledermatological on-screen images

The KSYOS package includes the medical description of the service, contracting with health workers and organisation in the region, software and hardware, and the education of contracted health workers. It also includes administration and finance, liability agreements, contracts with health Insurance companies, a helpdesk for patients and health workers and the evaluation of the efficiency of teleconsultations by measuring satisfaction, productivity and quality.

6.1 Critical success factors for a deployment strategy

Critical success factor 1: Cultural readiness

KSYOS TeleConsultation as a medical service emerged from both the vision of its initiator and the readiness of the market. KSYOS checked out the then cultural readiness towards teleconsultation before starting its own service.

Since the KSYOS service was a frontrunner in its field, at the beginning of the process there was mainly support from innovators among health workers, health institutions and health insurers, which is precisely why KSYOS focussed initially on this group. By using its Health Management Practice model, KSYOS gradually collected evidence

from the increasing numbers of health workers involved in the service of the quality and efficiency-improving potential of teleconsultation.

This initial level of cultural readiness was strengthened by three notions during the design of the service: putting the doctor at the centre of the service and not – immediately – the patient; focusing on getting all the relevant people on board; and translating the vision and mission into a business plan.

Critical success factor 2: Leadership

In general, KSYOS has ensured leadership in its field. Starting with itself as an innovative healthcare institution, it has taken the risk to invest and focus on its own vision and mission that was translated into a business plan. This leadership was initially limited.

The champion in the KSYOS service was the founder of the service, Leonard Witkamp, who is a dermatologist by background. He began the service as a research and development project, and then championed the expansion of the project into a teleconsultation business in the field of dermatology. He is an entrepreneurial champion, and he has continued to expand the service to include additional teleconsultation services.

Currently, the KSYOS model is increasingly promoted by health insurers, government and interest groups.

Critical success factor 3: Compelling need(s)

The compelling needs for the service were: a very high proportion of referrals from general practitioners to dermatologists; long response times on the part of dermatology consultants; long wait times on the part of patients waiting for a diagnosis; high costs for consultations; and the need for better cooperation between general practitioners and dermatologists. The service had clear benefits for all the parties involved insofar as it provided a rapid, cost-effective and user-friendly solution to address these problems.

Critical success factor 4: Resource aggregation

KSYOS started as a research foundation in 2001, set up by its director. In the early stages of the business, KSYOS thus depended heavily on research grants. The service is now being sold, like any other health service, on a fee-per-use basis in the Netherlands. Research and development is now financially sustained by income derived from its medical turnover. KSYOS has focused on public-private cooperation, and has therefore benefitted from both public trust and private flexibility.

6.2 Critical success factors for managing organisational change

Critical success factor 5: Primary client

At the beginning of the service provided by the KSYOS TeleMedical Centre, the primary clients were dermatologists. Once dermatologists had adjusted the service to their needs, a second group of primary clients was identified: this was general practitioners. In order to scale up the KSYOS service outside the Netherlands, the

company director commented that the primary clients should be identified according to each local situation.

Critical success factor 6: Stakeholder involvement

KSYOS has contracted general practitioners and other specialists who provide clinical content to the telemedicine service. The type and content of the work is organised in a manner that includes sufficient incentives for in-house healthcare professionals. In relation to the healthcare professionals in the institutions that are using the KSYOS service. Rather than competing with the healthcare professionals, KSYOS attempts to find a mutually beneficial way of working.

Critical success factor 7: Business plan

Preparation of a business plan was part of KSYOS service implementation. The organisation's founder highlighted that it was important to translate the company's vision and mission into that business plan.

Critical success factor 8: Change management

KSYOS implemented telemedicine services incrementally so as to avoid resistance on the part of general practitioners and other specialist doctors.

The change management started with the introduction of this new diagnostic service to dermatologists. After initial feedback, and adjustment of the service according to dermatologists' advice on the acceptability of the system's use, the new teledermatology service was launched for general practitioners.

A similar change management method was used by KSYOS to introduce other new telemedicine services, in telecardiology, teleophthalmology, and other fields.

Critical success factor 9: Patient-centeredness

Patients from the KSYOS service experience various benefits. The service aims to avoid unnecessary visits to general practitioners or specialists. The patients start with a visit to their general practitioner's office where the necessary images are taken or tests made. This ensures physical contact with the healthcare provider. Images and test results are consulted by specialists who use the telemedicine solution. The ensuing report is provided remotely. The results show that, when using the KSYOS telemedicine service, after careful selection of the appropriate patients by general practitioner, 74 percent of all live referrals are prevented. The average response time is 4.6 hours only, there is a learning effect in over 90 percent of the teleconsultations, and the short-term cost savings are 20-40 percent.

6.3 Critical success factors from a legal, regulatory and security perspective

Critical success factor 10: Legal and security conditions

According to the founder of KSYOS, legal and security issues were handled in the early development process of the service although not all legal issues were fully worked out. This permitted the service to get rapidly underway, and without too many delays.

Critical success factor 11: Legal and security guidelines

KSYOS's founder indicated that the application of relevant legal and security guidelines was important in what he calls the scale-up phase of this service. Applying the legal and security guidelines was handled relatively late in the process of the development and dissemination/scaling-up of this commercial service.

Critical success factor 12: Legal and security experts

KSYOS has yearly audits by independent auditors for adherence to Quality Standards for TeleMedicine (Dutch Normalisation Institute, NEN 8028).

Critical success factor 13: Privacy awareness

In the KSYOS case, in connection with the topic of contractual arrangements with health workers and health payers, the founder of the service emphasised that telemedicine doers and users have to be privacy aware (specifically there has to be informed consent). As a health institution, KSYOS has to adhere to legal privacy requirements.

6.4 Critical success factors from an ICT perspective

Critical success factor 14: IT and eHealth infrastructure

To ensure deployment of KSYOS's own system, both IT and eHealth infrastructures were critical to the delivery of these telemedicine services. KSYOS understands criticality as the appropriate combination of a reliable IT infrastructure and the capacity to interoperate with customer's information systems to reduce workloads and increase quality and customer satisfaction.

KSYOS considered IT infrastructure at two phases of development: in its second phase, when usability research was performed, and in its fourth phase when the company scaled up its solutions.

Critical success factor 15: User-friendliness

User-friendliness and safety were two aspects particularly encompassed in the second phase of KSYOS's development: when it undertook internal and external testing and usability research. The goal was to assure end-users – both general practitioners and hospital specialists – that they would feel comfortable using KSYOS interfaces, and ensure that they would engage immediately with its functionalities. Any potential steepness in the adoption learning curve was reduced through KSYOS's enhanced user-friendly design.

Critical success factor 16: Service monitoring

KSYOS paid attention to the quality of service monitoring in its fourth phase of activity during which its services were scaled up to routine care with a large customer base. For KSYOS, scale was a determinant of the back-office infrastructure that is needed to guarantee an uninterrupted service. KSYOS executives adopted a proactive approach to maintenance, actively monitoring the service performance to improve user experience.

Critical success factor 17: Market procurement

KSYOS acts as a health institution that contracts health insurance companies as a vendor rather than as a client. KSYOS developed a telemedicine service that is marketed jointly with other medical diagnostic and consultation services.

As a result, good procurement practices were scoped during KSYOS's fourth phase of development. In this phase, it scaled up its services and offered them to various medical groups through a set of different contracts and agreements that covered both the near-term and long-term time horizons.

Critical success factor 18: Potential for scale-up

KSYOS follows a Health Management Practice model that has four phases. These phases are: service development, usability research, efficiency research, and scale-up. The scale-up phase focused specifically on deploying KSYOS services to new clients and larger organisations.

From the very first phase, when the service was designed and developed, KSYOS already took scale into account. Scaling-up was outlined in the KSYOS business plan. It was considered that technology infrastructure must be supported by growth in terms of the number of patients, health workers and services in fields such as teleophthamology, telecardiology, teledermatology, and telepulmonology. Expansion models and service adaptation were defined at the very beginning of KSYOS service extension.

7 Case 7: The Cardio On Line Europe case

Cardio On Line Europe is a service that enables electrocardiogram (ECG) checks to be performed electronically. It has a telemedicine centre that is continuously staffed by operators, technicians and cardiologists 24 hours a day and 365 days a year. The staff members are ready at all times to receive and report in real time using a 12 lead ECG standard. They receive electrocardiograms from any ambulance, first aid post, or other location in the Puglia regional 118 emergency system.



Figure 5: Cardio On Line Europe's telephone centre

Cardio On Line Europe also receives Holter Cardiac or ambulatory blood pressure parameters (ABMP) from some socio-health districts located across the Puglia region and recorded by chronic patients who need a periodic check-up or follow-up.

7.1 Critical success factors for a deployment strategy

Critical success factor 1: Cultural readiness

Both patients and the regional, Puglia, 118 emergency service have been happy to use the Cardio On Line Europe telecardiology system: its prompt cardiological response provides a valid form of support for both the patients and for any medic who needs to make a cardiological decision.

In its first month of activity, from 11 October 2004 onwards, 601 ECGs were recorded. Today, in comparison, Cardio On Line Europe receives more than 10,000 ECGs a month. This shows the growing cultural readiness to use telemedicine in the cardiological field.

The foundation of the Cardio On Line Europe service a decade ago is indicative of the fact that telemedicine was and is viewed positively and is embraced by all its service users, including the company's employees. The aim of Cardio On Line Europe is, however, not to limit itself to expansion to only one region i.e., Puglia, but to extend the same service to other Italian regions once policy-makers and cardiologists agree that this should be done. This ambition is an indication of the cultural readiness for this service: it reflects the support and acceptance of the service, the value attributed to it, and the conviction that policymakers and cardiologists can be brought on board.

Critical success factor 2: Leadership

(No information pertinent to this critical success factor is available.)

Critical success factor 3: Compelling need(s)

The compelling need in the Cardio On Line Europe service was to reduce mortality from heart failure by increasing the efficiency of the emergency services. This was done by making sure that patients with chest pains are taken to the appropriate hospital, and that treatment has already started while the patient is en route, i.e., within the so-called golden hour.

Critical success factor 4: Resource aggregation

The service was – and continues to be – financed and operated by the Puglia region in Italy as an integral part of its Emergency Services System.

7.2 Critical success factors for managing organisational change

Critical success factor 5: Primary client

The primary client in the Puglia telecardiology service is the public emergency service. Through this telecardiology service, it achieved instant feedback from cardiology specialists on ECG results.

The hospital cardiologists also play an important role as a client since, in receiving the ECGs, they can organise their services better and provide faster responses to more serious cases of illness or emergency.

Critical success factor 6: Stakeholder involvement

The Puglia Cardio On Line Europe service was designed and implemented in close cooperation with ambulance doctors and cardiology specialists. The overall aim of the telecardiology service is to support ambulance doctors in their daily routine activity when dealing with cardiac emergencies. The telecardiology service offers 24/7 support to ambulance doctors by providing them with ECG readings from specialist cardiologists based in the Cardio On Line Europe centre. These reports are based on a mix of clinical findings and remote ECG reports. Both professional groups participated in a series of meetings that defined the functionalities of the system. The system was tested before it went online to be sure that it worked as required.

The Puglia region was one of the initiators and early supporters of telecardiology services. Thus, decision-makers were also involved in the implementation process. The Puglia Cardio On Line Europe service has proven itself to be cost-effective through hospital referral of only those patients who are in need of hospital intervention. Therefore, the system helps to avoid unnecessary hospitalisations. Cost-effectiveness increases the interest of decision-makers in the telemedicine service.

The parties involved in the Puglia telecardiology service are the public healthcare service, Cardio On Line Europe and all regional hemodynamic centres. They all contributed to the deployment of the service.

Critical success factor 7: Business plan

The Puglia telecardiology service was started with the help of sponsors. However, once it was proven to be cost-effective, Cardio On Line Europe continued its provision of the service.

Critical success factor 8: Change management

During the analysis process, there was no opportunity to collect evidence about the change management plan in the Puglia telecardiology service.

Critical success factor 9: Patient-centeredness

The Puglia telecardiology service provides patients with immediate ECG interpreting using a telemedicine solution. This avoids unnecessary visits to emergency departments or other forms of specialty care. Even more importantly, the results show that the telecardiology service improves patient outcomes and ensures access to proper intervention and treatment.

7.3 Critical success factors from a legal, regulatory and security perspective

Critical success factor 10: Legal and security conditions

Great efforts were made to ensure the quality, security and legality of this cardiology service in accordance with the legal framework in force in Italy. The device and software is certified by the Italian Ministry of Health. The application is manufactured in Israel, and has licenses for its use and sale.

Every ECG is signed by a specialist cardiologist. The system has an integrated certification for information security management system, ISO/IEC 27001, in telemedicine (International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) (ISO/IEC), 2013). It is also certified in terms of its quality, ISO 9001 (International Organization for Standardization (ISO), 2008). All the system's software and devices are certified as medical devices.

Critical success factor 11: Legal and security guidelines

In terms of Puglia's Cardio On Line Europe case, great efforts were made to ensure that the adopted service was approved by the relevant bodies.

Critical success factor 12: Legal and security experts

(No information pertinent to this critical success factor is available.)

Critical success factor 13: Privacy awareness

(No information pertinent to this critical success factor is available.)

7.4 Critical success factors from an ICT perspective

Critical success factor 14: IT and eHealth infrastructure

The telecardiology system of Cardio On Line Europe definitely pays particular attention to IT infrastructure, as it depends on it to deliver timely urgent care.

The service has the most recent hardware technology (Cardiovox P12 and Cardiolink), while the software used for the heartline receiving system works on an Oracle database. In 2013, Oracle developed a new hardware product with features that meet the scope of this task. This Oracle database application ranks in one of the top places in terms of performance on a scale of values.

Cardio On Line Europe has three levels of networks that are synchronised with its database. Electricity and telephone dashboards are tested daily by technical staff. The service also has a dedicated room in the same office that houses a central telecardiology backup system.

The output file of an ECG report can be downloaded in real time from the internet as a jpeg or pdf file. The heartline receiving system data files and database are interoperable with the health information systems.

In Cardio On Line Europe's case, because the IT infrastructure must always be functional, this critical success factor is closely associated with another critical success factor – service monitoring.

Critical success factor 15: User-friendliness

In terms of user-friendliness, the telecardiology system is easy to use. The platform enables viewing of all the electrocardiograms online. The standard 12-lead ECG is recorded in the place where the intervention of the public emergency system is needed. It is transmitted by a normal telephone to a central specialist who, in real time, analyses the track and issues a report, based on anamnesis i.e., the patient's history, and communicated by the ambulance doctor. The operations centre of reference for the ambulance decides where to refer the patient.

The ECGs used in the Cardio On Line Europe case – which are Aerotel medical system Cardiovox P12 – are extremely easy to use and have a user-friendly design.

By pressing only one button, the doctor records and sends a standard 12-lead standard ECG, within a few minutes. The transmission involves acoustic coupling. The sound produced can be transmitted by every telephone system, from the ambulance's or the doctor's phone or from the patient's home, or from any other device capable of making a phone call.

Cardio On Line Europe is aware that other communication systems exist. Yet the company also knows that every signal transmitted by the internet or any other digital system must be electronically transmitted from start to end. If not, the trace cannot be recognised. For this reason, the company has opted for an analogue solution, because the sound produced by Cardiovox P12 can be transmitted through any transmission mode.

Critical success factor 16: Service monitoring

The telecardiology services offered by Cardio On Line Europe in Puglia region are supported by an IT infrastructure that needs to be fully functional on a 24/7 basis to receive, read and transmit ECGs. Due to the medical criticality of this support, service monitoring is crucial. More than a third of the ECGs sent are received during night shifts, and 12 percent of patients reported have serious diseases.

Cardio On Line Europe has a dedicated section in its customer satisfaction survey to check the customers' satisfaction with the service. The section contains questions considering the needs of users. These questions range from issues around instructions for use to technical assistance.

Cardio On Line Europe guarantees the replacement of devices within 24 hours from any call requesting support. Devices are tested frequently. Every five years, the equipment is collected and sent to check-up centres, which is what the law stipulates.

Critical success factor 17: Market procurement

Cardio On Line Europe regards good practice with vendors from a similar position as that of KSYOS and RxEye. All are providers of a telemedicine solution, so they handle this critical success factor differently from several of the other MOMENTUM cases.

Cardio On Line Europe delivers services to the public healthcare system in the Italian province of Puglia as well as to private hospitals with which it has signed collaboration contracts. Therefore, the Puglia region acts as the procurer of the services. In these contracts, service levels are specified that Cardio On Line Europe has to meet.

Critical success factor 18: Potential for scale-up

For some years, the Cardio On Line Europe service has been directed not only towards the emergency sector but also to either the severity or chronic character of the condition. Many patients need care and regular health checks, so the Puglia region decided to make the same technologies – i.e., ECGs and Holter – available to those individuals who experience an emergency event.

The aim of Cardio On Line Europe is not to stop at scale-up in only one region, but to extend the same service to other Italian regions. This scaling-up occurs when policy-makers and cardiologists agree on it, as was the case in the Puglia region.

As an indication of its growth as a service, in 2014, Cardio On Line Europe moved offices and more than tripled the size of its premises.