MOMENTUM

European Momentum for Mainstreaming Telemedicine Deployment in Daily Practice

(Grant Agreement No 297320)

Deliverable 3.2 **Towards a Personalised Blueprint - for doers, by doers:** **consolidated version** **Version 13**	

Work Package:	WP3
Version & Date:	V13 1 December 2014
Deliverable type:	Report
Distribution Status:	Public
Authors:	Ellen Kari Christiansen (NST), Eva Henriksen (NST), Lise Kvistgaard Jensen (Odense University Hospital), Marc Lange (EHTEL), Luís Lapão (EHMA), Rachelle Kaye (AIM), Undine Knarvik (NST), Tino Marti (TicSalut), Bruna Miralpeix (TicSalut), Andrea Pavlickova (NHS24), Michael Strübin (Continua Health Alliance), Peeter Ross (eHealth Foundation), Wenche Tangene (SSHF), Diane Whitehouse (EHTEL/RSD).
With the support of materials provided by:	Giuseppe di Giuseppe (Cardio On Line Europe), Claudio Lopriore (Cardio On Line Europe), Steffen Sonntag (Patientenhilfe), Leonard Witkamp (KSYOS TeleMedical Center).
Reviewed at various stages by:	Silvia Bottaro (HOPE), Gérard Comyn (CATEL), Pascal Garel (HOPE), Eva Henriksen (NST), Lise Kvistgaard Jensen (Odense University Hospital), Rachelle Kaye (AIM), Marc Lange (EHTEL), Rikard Lövström (CPME), Tino Marti (TicSalut), Bruna Miralpeix (TicSalut), Leif Erik Nohr (NST), Peeter Ross (eHealth Foundation), Jean-Baptiste Rouffet (UEMS), Stephan Schug (EHTEL), Robert Sinclair (EHMA), Eva Skipenes (NST), Michael Strübin (Continua Health Alliance), Veronika Strotbaum (ZTG-NRW).
Approved by:	Marc Lange (EHTEL), Coordinator
Filename:	D3.2_v13_Momentum_ConsolidatedBlueprint.docx

Abstract

This report presents the background to the MOMENTUM thematic network. It overviews the drive to scale-up telemedicine deployment in Europe, and outlines the way in which the MOMENTUM has supported this movement. It describes MOMENTUM's aims and scope, and the approaches and methods used by the project. Its main focus is on the 18 critical success factors defined by MOMENTUM. Telemedicine doers need to bear these factors in mind when scaling up their services and deploying them into routine care. Among the key activities are building a deployment strategy; managing organisational change; taking a legal, regulatory and security perspective; and having a perspective on ICT. The report provides a consolidation of the latest work undertaken by MOMENTUM's four special interest groups and the consortium to present it as a consistent and coherent whole.

Key Word List

Assessment of outcomes, blueprint, business plan, champion, change management, communications, compelling need, cultural readiness, decision-makers, eHealth, financing, healthcare professionals, implementation, innovation, interoperability, large-scale deployment, legal and security experts, legislation, legal and security guidelines, legal and security risk assessment, management, market, organisational implementation, patient-centred, primary client, privacy awareness, procurement, resources, routine care, scale-up, security, special interest group (SIG), stakeholders, strategy, technical infrastructure, technology, telemedicine, telemedicine service, toolkit, training.

Change History

Version History:

01	15 September 2014
02	24 September 2014
03	25 September 2014
04	29 September 2014
05	27 October 2014
06	2 November 2014
07	3 November 2014
08	5 November 2014
09	10 November 2014
10	13 November 2014
11	14 November 2014
12	21 November 2014
13	1 December 2014.

Version Changes

01   Initial draft.

02   Details relating to critical success factors extracted from deliverables, D4.2-D7.2.

03   Extract created

04   Context and prerequisites added to text on critical success factors

05   Changes made as a result of input from meeting on 30 September 2014

06   Editorial modifications to contributors and cover page.

07   Relevant sections added throughout, and incomplete sub-sections identified.

08   Modifications made as a result of commentary by Marc Lange.

09   Modifications made as a result of commentary by Luís Lapão, Robert Sinclair and Xristina Karaberi.

10   Changes made as a result of requests made by Marc Lange; abstract, references and abbreviations added and introduction considerably revised.

11   Modifications made to abstract, executive summary, and introduction; small general clarifications; re-structuring of annexes and bibliography; re-pagination.

12   Modifications made as a result of observations by Giuseppe di Giuseppe, Eva Henriksen, Claudio Lopriore, Veronika Strotbaum and Leonard Witkamp. Addition of abbreviations and literature references. Occasional stylistic changes.

13   Quality review, approval in two rounds; Images added and executive summary revised; also taking on board positive feedback from the MOMENTUM fourth workshop held on 26 November 2014 in Brussels.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both. This deliverable consolidates work undertaken in four of MOMENTUM's deliverables, D4.2-7.2.

Consensus statement

MOMENTUM has used a consensus-building approach as stipulated in its Description of Work (p28). It has worked on a consensus basis not only "to create a sustainable network of telemedicine champions in European telemedicine – including 'doers', policy makers and industry" but also to agree on the content of all its deliverables including this one.

The blueprint's main contents were developed as a result of the work of MOMENTUM's special interest groups and the network's wider orbit of organisations. Its contents – particularly its critical success factors – were tested at a wide range of presentations made at public events with the intention of fine-tuning the initiative's outcomes. This test phase culminated in an in-depth workshop held in Kristiansand, Norway, on 27 October 2014, reported on in MOMENTUM deliverables D3.3 and D3.4, and at a final fourth workshop held in Brussels, Belgium on 26 November 2014.

Abbreviations and terminology

This glossary of abbreviations and terminology covers the whole deliverable, D3.2, and the associated attachment describing the seven in-depth cases.

Abbreviation	Name in full and, where appropriate, provisional definition
ABMP	Ambulatory blood pressure parameters.
ADSL	Asymmetric digital subscriber line (ADSL) is a type of digital subscriber line (DSL) technology, a data communications technology that enables faster data transmission over copper telephone lines than a conventional voice band modem can provide.
APS	Australian Public Service.
B2B	Business-to-business.
BSA	*Badalonia Servéis Assistencials*: http://www.bsa.cat/bsaweb/HomeNews.do
CDA	Clinical Documentation Architecture. This is a document mark-up standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients.
CPME	Standing Committee of European Doctors.
CT	Computer tomography.
D2D	Doctor-to-doctor.
D2P	Doctor-to-patient.
DGP	*Deutsche Gesellschaft für Patientenhilfe* (German Society for Patient Assistance) (i.e., Patientenhilfe): http://www.cordiva.de.
DICOM	Digital Imaging and Communication in Medicine.
DSL	Digital subscriber line.
EC	European Commission.
ECG	Electrocardiogram. Electrocardiography is a transthoracic (across the thorax or chest) interpretation of the electrical activity of the heart over a period of time, as detected by electrodes attached to the surface of the skin and recorded by a device external to the body.
EHR	Electronic healthcare record.
EHSG	eHealth Stakeholder Group.
EHTEL	European Health Telematics Association.
EIP AHA	European Innovation Partnership on Active and Healthy Ageing.

Abbreviation	Name in full and, where appropriate, provisional definition
EU	European Union.
EXCO	Executive Committee.
FTP	File transfer protocol.
GPRS	General packet radio service. This is a packet-oriented mobile data service on the 2G and 3G cellular communication system's global system for mobile communications (GSM).
GSM	Global System for Mobile Communications. Originally Groupe Spécial Mobile, GSM is a standard set developed by the European Telecommunications Standards Institute (ETSI) to describe protocols for second generation (2G) digital cellular networks used by mobile phones.
Holter	A Holter monitor is a portable device to continuously monitor various electrical activity of the cardiovascular system.
HL7	Health Level Seven. HL7 is the global authority on standards for interoperability of health information technology.
HTTP	Hypertext transfer protocol.
ICT	Information and communication technology.
IEC	International Electrotechnical Commission.
IP	The Internet Protocol (IP) is the primary protocol in the Internet Layer of the Internet Protocol Suite. It has the task of delivering packets from the source host to the destination host solely based on the addresses.
ISO	International Organization for Standardization.
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission.
IT	Information technology.
ITHACA	Intervention of Treatment of Hipertesion Arterial in CAtalonia.
ITIL	ITIL (formerly known as the Information Technology Infrastructure Library.
ITTS	Implementing Transnational Telemedicine Solutions: http://www.transnational-telemedicine.eu.
KSYOS	KSYOS Teledermatology: http://www.ksyos.org/english/
LAN	Local Area Network. A local area network interconnects computers in a limited area such as a home, a clinic, or a hospital.
MRI	Magnetic resonance imaging.

Abbreviation	Name in full and, where appropriate, provisional definition
NST	Norwegian Centre for Integrated Care and Telemedicine: http://www.telemed.no/.
PACS	Picture archiving and communication system.
SIG	Special interest group.
SME	Small- and medium-sized enterprise.
SMS	Short message service.
SNOMED	Systematized Nomenclature of Medicine.
UEMS	Union Européenne des Médecins Spécialistes
UNN	University Hospital of North Norway.
USA	United States of America.
VOIP	Voice over internet protocol.
WP3	Work package 3.
www	World wide web.

Table of Contents

Table of figures

Table of tables

Executive summary

> **Towards a personalised blueprint – for doers, by doers.** This is the first draft of the MOMENTUM Consolidated Blueprint: a holistic European reference document for a telemedicine service framework, and a toolkit for capacity-building among telemedicine doers. It is the result of the collaborative work of the MOMENTUM thematic network.
>
> This draft will be tested and validated by the telemedicine community before it is finalised in the first quarter of 2015.
>
> For more information on MOMENTUM, see http://www.telemedicine-momentum.eu.

What is the MOMENTUM blueprint?

The blueprint examines how telemedicine could be expanded throughout Europe: Europe's healthcare systems are under pressure and require new ways of caring, and of producing and delivering treatments for diseases. Telemedicine tackles a number of current and future societal challenges: to enable people to age healthily, to ensure equal access to health and care, and to reduce the burden of chronic diseases. Telemedicine is both an approach and a technology that can help address these challenges!

In the European Union, international, national and regional initiatives have been underway to explore the potential of telemedicine, especially since 2010. These initiatives show that European policy-makers understand telemedicine's importance. Many initiatives are complementary to the work of the MOMENTUM thematic network, although they differ in their specific orientations.

The blueprint shows what telemedicine is: Telemedicine services mean practicing medicine from a distance. It is "*the provision of healthcare services at a distance*" that "*can help improve the lives of European citizens, both patients and health professionals, while tackling the challenges to healthcare systems*" (EC 2008, p.1). The blueprint contains a number of descriptions of telemedicine services in actual deployment that illustrate its potential.

The blueprint provides help for telemedicine doers: MOMENTUM's blueprint is targeted at everyone who wants to deploy a telemedicine service into routine care and to scale it up. These telemedicine doers includes:

- Leaders in health or care authorities, hospital managers, clinicians or people involved in industry, such as entrepreneurs or business executives.
- All people supporting telemedicine doers, such as public administrators or personnel in innovation agencies and their support organisations.
- All people who are actively involved in deploying and doing telemedicine.

The blueprint captures telemedicine's critical success factors: The 18 critical success factor descriptions cover five areas:

- What each critical success factor means.
- Its underlying objectives.

- The surrounding context, and any prerequisites.

- Lessons learned from seven in-depth cases that MOMENTUM investigated in detail.

- Useful further background information.

Two useful annexes in the blueprint contain tables that include sets of indicators and characteristics to be used by telemedicine doers to examine the critical success factors in their own settings. The tables can be used in a very practical way to validate and test the critical success factors and the blueprint.

The blueprint helps telemedicine doers to "progress with success": These 18 critical success factors form the core of a set of guidelines and indicators that can define an action plan for deploying telehealth in routine care and on a large scale. Several elements help doers to "progress with success" while implementing their telemedicine services, including:

- Critical success factors themselves.

- Lists of indicators and characteristics.

- Illustrations of how the 18 factors have been put into practice in seven concrete cases. The examples are from Germany, Israel, Italy, the Netherlands, Norway, Spain, and Sweden.

The Momentum website http://www.telemedicine-momentum.eu includes many more descriptions of current telemedicine deployments, and welcomes more.

The blueprint describes MOMENTUM's methodology: The methodology used by MOMENTUM was an inductive one. The consortium gathered information on 30 telemedicine services. Most cases made progress on shifting from a pilot phase to deployment at either small scale or large scale. Others are now integrated into the routine delivery of health services. These services were analysed from four perspectives:

- The strategic elements necessary for the initiation of the services.

- The management challenges for successful implementation of the services.

- Important legal, regulatory and security issues.

- Issues from an ICT perspective, including technical infrastructure and market relations.

The blueprint is based on relevant policy documentation: (EC, 2008) "*Telemedicine for the benefit of patients, healthcare systems and society*", Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Commission of the European Communities, Brussels, 4.11.2008, COM(2008) 689.

MOMENTUM's 18 critical success factors

Critical success factors for a deployment strategy

- 1) Ensure that there is cultural readiness for the telemedicine service.
- 2) Ensure leadership through a champion.
- 3) Come to a consensus on the advantages of telemedicine in meeting compelling need(s).
- 4) Pull together the resources needed for deployment.

Critical success factors for managing organisational change

- 5) Address the needs of the primary client(s).
- 6) Involve healthcare professionals and decision-makers.
- 7) Prepare and implement a business plan.
- 8) Prepare and implement a change management plan.
- 9) Put the patient at the centre of the service.

Critical success factors from a legal, regulatory and security perspective

- 10) Assess the conditions under which the service is legal.
- 11) Identify and apply relevant legal and security guidelines.
- 12) Involve legal and security experts.
- 13) Ensure that telemedicine doers and users are "privacy aware".

Critical success factors from an ICT perspective

- 14) Ensure that the appropriate information technology infrastructure and eHealth infrastructure are available.
- 15) Ensure that the technology is user-friendly.
- 16) Put in place the technology and processes needed to monitor the service.
- 17) Establish and maintain good procurement processes.
- 18) Guarantee the technology has the potential for scale-up.

1   Introduction

Working collaboratively and transparently over a three-year period, MOMENTUM has held consultations with stakeholders and the wider public to achieve three objectives. The first two objectives were pursued in order to achieve the third – the personalised European telemedicine deployment blueprint:

- **Foster stakeholder engagement and build consensus:** MOMENTUM has solicited the views of stakeholders – healthcare professionals, health insurers, industry and patients – to arrive at a consensus-based approach to its work.

- **Build and disseminate a library of good practices:** MOMENTUM has worked together with a wide range of telemedicine actors – what the initiative calls doers – to build a European resource of good practice examples of telemedicine deployment.

- **Develop a European telemedicine deployment blueprint:** This personalised blueprint is the result of the collaborative work of the MOMENTUM network. Its ambition is to act as a toolkit for capacity-building. Although its approach has been structured, it was never intended to be a scientific exercise.

This document provides a first overview of this holistic European reference telemedicine service framework. Its strategic, organisational, legal and security, technological and market-related content shows how telemedicine doers can support telemedicine to move into mainstream use in Europe.

In this general introduction, the following elements are described: MOMENTUM's background, telemedicine development in general, the different types of telemedicine explored by MOMEMTUM, and the general scope of the project.

1.1   Background to MOMENTUM

The strategic, organisational, legal and market value of telemedicine services is beginning to be recognised by European, authorities, and a variety of national and regional administrations and clinical authorities.

In many cases, however, telemedicine has yet to gain its place in routine healthcare delivery. To date, the field has been dominated by trials and pilots. Telemedicine is now in a transition phase. Many key European actors are seeking to bring telemedicine services into routine healthcare at regional or national level and in particular areas of healthcare. Many scientific trials have delivered evidence of the benefits of telemedicine services. Deploying telemedicine services promises to yield powerful benefits: on the one hand, for the quality of life of patients living with chronic conditions or who are receiving social care services; on the other hand, in rectifying financial efficiencies.

Significant roadblocks – strategic, organisational, legal and regulatory, technological and market-related – have remained until recently. Where efforts have been driven by individual champions, sometimes efforts have collapsed after their departure.

Organisational difficulties have also played a role, even if they have occasionally been under-estimated. The introduction of telemedicine services requires changes in clinical and social care practice: in the past, when deployment was driven top-down, or without consultation and buy-in from all the stakeholders, it has all too often failed.

Telemedicine has also raised knotty legal questions about professional responsibility, liability, security and privacy. These challenges have at times been over-emphasised, although at others have been difficult to address or even to overcome.

Technical problems have sometimes led to frustration, and market relations were classically neither clear nor smooth. Telemedicine may supplement existing service provision with its own infrastructure rather than being integrated, so that multiple infrastructures operate in parallel. In turn, this limits not only telemedicine's impact but also overall service sustainability and scale-up.

As a result, pilots and trials have tended to dominate the field until now.

To deploy telemedicine services into routine care – so that it becomes part of the daily care delivery process – means using tools and methods. While such methods already exist or are under development, much of this activity has been taking place in an uncoordinated manner. A variety of telemedicine initiatives exist at local, regional, national levels and also at that of the European Union (EU). This variety results in limitations in large-scale deployment or inefficiencies. These methods may indeed suffer from scope limitation, lack of robustness, difficulties in their actual use or a lack of professional acceptance.

MOMENTUM seeks to address these developments. It is a thematic network that has been committed to concentrating on the needs of what it calls telemedicine doers, a group that includes:

- Leaders in health or care authorities, hospital managers, clinicians or people involved in industry, such as entrepreneurs or business executives.
- All people supporting the telemedicine doers, such as public administrators, and personnel in innovation agencies and support organisations.
- All people who are actively involved in doing and deploying telemedicine.[1]

MOMENTUM has focused on building stakeholder consensus on how precisely deployment can take place effectively at scale, how good practices can be gathered together and disseminated, and how a personalised European telemedicine deployment blueprint[2] can be developed. This document is the product of these three combined activities.

1.2 Telemedicine development

Today's healthcare requires the introduction of new ways of producing and delivering treatments of diseases and means of caring. These innovative methods will help to address a number of current and future societal challenges, such as healthy ageing, equitable access and the burden to society of chronic diseases. Telemedicine is seen as an approach and technology that has the potential to address these challenges.

Five years ago, in the United States of America (USA), researchers, R.L. Bashshur and G.W. Shannon (2009), with contributions from 20 other researchers, presented an analysis of the

---

[1] Doers are people who are actively involved in doing things rather than simply thinking or talking about them (cf. Merriam-Webster http://www.merriam-webster.com/dictionary/doer), accessed 27 October 2014.

[2] A blueprint is a "detailed plan of work to be done, or a guide or model provided by agreed principles or by conclusions from earlier experiment" (experiences) Chambers (1998) *The Chambers Dictionary*. Edinburgh: Chambers Harrap Publishers Ltd. A blueprint can therefore be thought of as guidelines that can help facilitate implementation.

problems facing the American healthcare system and the potential role of telemedicine in addressing and alleviating them. Their analysis showed that, over the past several decades, telemedicine systems have demonstrated the capacity to:

- Improve access at the three levels of healthcare – primary, secondary, and tertiary – for a wide range of conditions and services. The conditions included, but were not limited to, heart and cerebrovascular disease, endocrine disorders such as diabetes, cancer, psychiatric disorders, and trauma. The services included radiology, pathology and rehabilitation.

- Promote patient-centred care at lower cost and in local environments that also contributed to stabilising local healthcare and economies.

- Enhance efficiency in clinical decision-making, prescription ordering, and mentoring.

- Increase the effectiveness of chronic disease management in both long term care facilities and in the home.

- Promote individual adoption of healthy lifestyles and self-care.

The conclusion reached in the report was that, while telemedicine is not a panacea, it offers significant opportunities to address the three possible areas of inequity – access to care, cost containment, and quality enhancement. Telemedicine has its costs and benefits. However, the benefits that accrue to clients, providers, and society at large far exceed the costs (Bashshur & Shannon, 2009).

At the same era, the European Commission adopted a policy to encourage the development of telemedicine. In its Communication (EC, 2008, p.1) on *telemedicine for the benefit of patients, healthcare systems and society*, it outlined Europe's changing demographics and growth in multiple chronic conditions. It also identified the ways in which telemedicine services might assist patients, particularly those living in remote areas or experiencing conditions or specialities that might not be treated as easily or as often as they need. It cited specific benefits such as improving access to healthcare, compensating for reductions in healthcare expertise, improving patient quality of life, and – organisationally and practically – helping to shorten patient waiting lists, optimising the use of resources, and enabling productivity gains (Ibid, p.1-2).

Together, the economic and financial crisis, ageing of the population, and the increasing number of people with chronic diseases, have highlighted the urgent need for reforms that promote service redesign and new ways of working, increase efficiency and create innovative new solutions to deliver care in Europe. Telemedicine is perceived as an opportunity to support people and give them greater choice and confidence in their care; enable safer, effective and more personalised care; and help generate efficiencies in clinical decision-making. Telemedicine can also help to intensify cross-border cooperation in the medical, health and care fields. As a consequence, medical staff will gain more and more experience with its deployment and use.

Since about 2010, a number of interesting European, national and regional initiatives have been underway to resolve these challenges. Among those that can be cited are the Competitiveness and Innovation Programme – in particular its Policy Support programme[3] –

---

[3] http://ec.europa.eu/digital-agenda/en/ict-policy-support-programme, accessed 27 October 2014.

and specific pilots or projects such as Renewing Health[4] and United4Health,[5] Digital Agenda for Europe,[6] Horizon 2020,[7] the European Innovation Partnership and its first partnership on Active and Healthy Ageing (EIP AHA)[8], including its action group with a focus on telemedicine use, the 2008 European Commission communication on telemedicine (EC, 2008), and the 2012 European eHealth Action Plan (EC, 2012). In addition, there is the 2008 EHTEL briefing paper entitled "Sustainable Telemedicine: paradigms for future-proof healthcare" as well as various studies focusing on good practices and indicator development, and a growing tendency to explore the implications of integrated care and its technological support.

Telemedicine has emerged as one of the key solutions to resolving both contemporary and future challenges in healthcare and social care. Unsurprisingly, therefore, there are a number of other initiatives and activities working on the same or a similar domain as that of MOMENTUM. In all cases, they are an indicator of the importance of the topic of telemedicine deployment. Many are completely complementary to MOMENTUM, although they all differ in their specific orientation.

For example:

- High-level models that identify enablers of innovation and promote continuous learning about those enablers on the part of an organisation's strategic leadership (EFQM, 2012).[9]

- Guidelines on stakeholder engagement in analysing and understanding jointly the barriers to large-scale implementation of telemedicine solutions (Centre for Telemedicine and Telehealthcare, 2014).[10]

- An implementation resource for telehealth commissioners, provider organisations and individuals that focuses on telecoaching, telemonitoring and teleconsultations for people with long-term conditions, that is to be updated on an on-going basis (Yorkshire & Humberside HIEC, n/d).

- A toolkit that provides a structured approach to delivering the business objectives implicit in telemedicine (Brownsell & Ellis, 2013).

- A small pamphlet outlining the ten issues considered key to designing a telehealth service (Merck, Sharp & Dohme Ltd., 2013).

- A collection of telemedicine case studies (COCIR, 2011).

- A collection of telehealth testimonials collected by the Campaign for Telehealth in

---

[4] http://tinyurl.com/Renewing-Health-Final-Report, accessed 27 October 2014.

[5] http://www.United4Health.eu, accessed 27 October 2014.

[6] https://ec.europa.eu/digital-agenda/, accessed 27 October 2014.

[7] http://ec.europa.eu/programmes/horizon2020/en, accessed 27 October 2014.

[8] http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing, accessed 27 October 2014.

[9] The aspiration underlying this generic model is for European organisations to raise themselves to a level of excellence on the global stage.

[10] This was an initiative that emerged from a European Commission co-financed project called RICHARD, that was a regional ICT-based cluster for healthcare applications and research and development integration: http://www.richardproject.eu, accessed 27 October 2014.

---

support of Integrated Care, an initiative of Brussels-based organisations started in 2011.[11] A wide range of organisations was involved in the initiative; editorial support was provided by Intel. [12]

1.3 Telemedicine and its types

Telemedicine services mean practicing medicine at a distance. Telemedicine refers to the use of ICT to provide health services so as to overcome a spatial distance between patients and physicians or other healthcare professionals, or between several doctors or people from different types of healthcare professions. As identified in policy documents by the European Commission (EC, 2008, p.1) – which place an emphasis on the benefits to be garnered by telemedicine services – it is suggested that it is "*the provision of healthcare services at a distance*" that "*can help improve the lives of European citizens, both patients and health professionals, while tackling the challenges to healthcare systems*".

The growth of telemedicine was typified by some very early experiences that used first generation telecommunication systems, such as the radio or the telephone. Yet it is the current expansion in information and communication technology (ICT) that has brought a wave of innovations in the telemedicine field.

Today, telemedicine refers to the provision of a medical service in situations where the healthcare professional and the patient do not necessarily meet face-to-face. Rather, they meet in a 'virtual' encounter mediated by some type of telecommunications system. These technologies can range from the most basic – like a telephone, letter or fax – to the more technologically advanced – such as emails, text messages, the internet or a video conference.

Telemedicine can be classified into three types – telediagnosis, telemonitoring and teleconsultation:[13]

- **Telediagnosis** – when the patient undergoes some type of diagnostic examination, and the professional interpretation of the results of the exam are done at a distance. The results of the x-ray, ultrasound, CT, MRI, ECG or Holter examinations are sent digitally from the diagnostic device to the appropriate health professionals. These professionals then interpret the exam, determine the diagnosis, and send their interpretation or diagnosis digitally to the referring physician or diagnostic clinic.

- **Telemonitoring** – when the results from devices that measure patients' vital signs are followed by a professional monitoring centre, clinician, or even a website to enable on-going monitoring of the patient's condition. As a rule, the recipient of the transmitted data uses clinical guidelines to identify any aberrations from what is considered usual for that patient. Embedded algorithms, written guidelines or professional knowledge can all support this process. If an unusual event occurs, the

---

[11] http://telemedicine-momentum.eu/testimonials/, accessed 27 October 2014.

[12] The organisations included the International Association of Mutual Benefit Associations (AIM), the European Health Management Association (EHMA), the European Patients' Forum (EPF), COCIR [Sustainable Competence in Advancing Healthcare], the Continua Health Alliance, the European Health Telematics Association (EHTEL), and the European Hospital and Healthcare Federation (HOPE).

[13] Other observers also like to add teletherapy – when treatments, especially psychological therapies, are provided at a distance.

monitoring process generates a response: for example, an alert, contact between a clinician and a patient, or some form of online guidance given to the patient.

- **Teleconsultation** – means that a virtual visit or dialogue takes place instead of, or in addition to, a physical encounter.[14] Two common types of teleconsultation exist:
    - Between a clinician and a patient.
    - Between two or more clinicians[15].

MOMENTUM has covered all three types of telemedicine in its investigations. It is anticipated that the blueprint outcomes can be applied to all three forms.

1.4 The purpose and scope of MOMENTUM

The MOMENTUM initiative has had two main purposes.

- First, its consortium has aimed to understand the kinds of challenges faced by telemedicine doers when they work to implement telemedicine successfully as a part of a routine service.
- Second, as a result, the initiative has identified the critical success factors needed to take telemedicine from the pilot phase to large-scale deployment and thus aiming to integrate it into the healthcare delivery system.

MOMENTUM has focused on a personalised blueprint that is intended to be useful to telemedicine doers as soon as they take the decision to deploy telemedicine further.

MOMENTUM has concentrated on the needs of telemedicine doers, viewed from the perspective of doers who themselves have experience in scaling up initiatives. It has focused on the importance of mutual learning and feedback. Therefore, it has placed its emphasis on lessons learned through experience rather than via the available literature or academic investigation.[16]

1.4.1 Out of the scope of MOMENTUM

Several elements of telemedicine deployment have been considered to be out of the scope of MOMENTUM. These include small-scale initiatives and (research) projects; evaluation and assessment; maturity models; and phasing and timing of scaling.

Projects for testing or for implementing telemedicine usually come about as the result of some level of perceived need or value that is combined with an opportunity to access resources to carry out the project. As a rule, such initiatives are accompanied by a level of assessment. This assessment feeds into the decision-making process that occurs at the end of the project period whether to continue to operate the service, expand it, or integrate it into routine healthcare delivery.[17, 18]

---

[14] Teleconsultation at times includes also telediagnosis. In some jurisdictions, telediagnosis on its own is currently either not permitted or restricted.

[15] Elsewhere in this deliverable, the expressions doctor-to-patient and peer-to-peer are used.

[16] Nevertheless, of course, the consortium has paid attention to the literature in the telemedicine field (see in ANNEX to this document as well as lengthy bibliographies available in deliverables D4.1, D5.1, D6.1 and D7.1).

[17] See the shamrock model notion that is described in the following chapter. Nevertheless, evaluation and assessment did feature in the findings reported in deliverable D4.1 as an outcome of the results of the MOMENTUM 2012 survey.

The MOMENTUM consortium considered that at least two important items should simply be taken as given: the consortium members assumed that these activities had already taken place before the blueprint guidelines come into play. These two activities are: an information technology (IT) systems design, and the evidence-base on which the intervention has been based.[19]

At times, the MOMENTUM consortium would have been particularly motivated to explore in greater depth issues related to the maturation process of telemedicine ("maturity models"), and issues related to the timing and phasing of telemedicine deployment. Its members nevertheless recognised that these are issues currently under investigation by other European Commission co-financed studies and projects, and initiatives such as the EIP AHA, and hence restricted its activities in this area.[20]

Last but not least, no in-depth analysis of other guidelines was undertaken by MOMENTUM (for example, Brownsell & Ellis, 2013; Centre for Telemedicine and Telehealthcare, 2014; Merck, Sharp & Dohme, Ltd., 2013; Yorkshire & Humberside HIEC, n/d).

MOMENTUM is, of course, a thematic network, limited in its scope, size and resources. Besides the development of these guidelines, its role lay equally in fostering stakeholder engagement, generating consensus, and building and generating a library of good practices. As a result, several activities that would have been typical in a more scientific, academic or conventional project or study were not attempted. MOMENTUM did, of course, use a particular methodology in approaching its work. That approach is described in ANNEX.[21]

1.4.2 Potential for future steps following the end of the MOMENTUM project

The more work MOMENTUM did, the more the consortium found that there are areas where further guidelines would be useful. Examples include:

- The guidelines that are developing out of the 18 critical success factors.

- A set of indicators – the generic questions developed to test the blueprint with TREAT[22] – to be used to define an action plan for deploying telehealth in routine care and on a large scale.

- Benchmarking the MOMENTUM blueprint in comparison with other deployment guidelines that are emerging in parallel.

---

[18] Many of the same factors that originally influenced the decision to undertake a telemedicine project in the first place also play a critical role in the decision to continue to operate the service and to expand it to large-scale deployment as a part of routine service delivery.

[19] See the explanation of these items in the chapter of this report covering the overview of the critical success factors.

[20] See, however, some observations on these issues particularly around the legal, regulatory and security issues covered in this report.

[21] Further details are available in the ANNEX on methodology.

[22] TREAT is method developed in the context of the Renewing Health project (see http://tinyurl.com/Renewing-Health-Final-Report for the project's final report, accessed 27 October 2014). TREAT stands for **T**elemedicine **RE**adiness **A**wareness **T**ool. Preliminary work undertaken by MOMENTUM in this context is described in two of MOMENTUM's other deliverables, D3.3 and D3.4.

- Creating a bridge between the MOMENTUM telemedicine deployment guidelines and other tools that exist (e.g., tools to assess the impact of a service, develop a business model, run a cost-benefit analysis, or certify a service).

- Developing a set of guidelines and indicators could be useful to define a deployment strategy and its planning.

- Developing guidelines to monitor an operational system – by identifying key performance indicators and creating a learning system – that would provide input to define and enhance the system further.

All these elements are, however, out of reach of the ambition of the MOMENTUM project itself. Instead, they could become the subject of one or more new initiatives, actions or projects.

2 Overview of critical success factors

This chapter explains the definition of a critical success factor, the general background to the work undertaken in MOMENTUM, in particular with regard to the shift from general data-gathering to an investigation of the critical success factors implicit in deploying telemedicine in routine care.

The chapter presents an overview of all the possible critical success factors that may apply in any given telemedicine service. Each service, site or case is unique. Not every critical success factor is intended to fit every single service or setting. The participants involved in each case will find that different critical success factors are applicable to it.[23] The blueprint is therefore ready to be tailored, individualised or "personalised" for the specific telemedicine doers who are involved. The blueprint does not imply a set of step-by-step guidelines. It certainly enables self-assessment.

Ultimately, MOMENTUM is an enabling process and the work of a collective group that focuses on telemedicine deployment at scale. The process integrates a set of tools, training, workshops, and support by example cases.

There may, in addition, be some overlap among critical success factors.[24]

2.1 A working definition of critical success factors

The MOMENTUM consortium operated with a working definition of a critical success factor. MOMENTUM took a critical success factor to be:

- The term for an element[25] that is necessary for an organisation or project to achieve its mission.

- An element that is vital for a strategy to be successful.

- A factor that drives a strategy forward, and it makes or breaks the success of the strategy (hence, it is "critical").[26]

The fact that success factors are "critical", i.e., that they are factors that are crucially important for the success of an initiative, implicitly means that they must be beneficial or advantageous. The resulting benefits might accrue to the healthcare system, region or organisation. Ultimately, there will be benefits for end-users too.[27]

---

[23] This observation was particularly supported by the three example cases that featured in MOMENTUM's fourth and final workshop: Kristiansand (Norway), NHS24 (Scotland), and the international pharmaceuticals company, Merck.

[24] Where the MOMENTUM consortium has been aware of these overlaps, it has identified them. The consortium has not, however, attempted to explain the overlaps in detail or to reduce the volume of success factors from 18 to a smaller number.

[25] An element can be understood as a condition or an action or a factor that is either internal or internal to the organisation.

[26] This definition is similar to the work of Hardaker & Ward (1987). Other similar materials are available on Wikipedia (see http://en.wikipedia.org/wiki/Critical_success_factor accessed 27 October 2014) with particular reference to work done by John Rockart, Andrew Boynlon and Robert Zmud.

[27] The benefits and beneficiaries of the 30 or so services investigated by MOMENTUM were identified and described in some detail in deliverable, D3.1.

For a telemedicine doer, the underlying aims of examining critical success factors are that:

- A doer can create a common point of reference to help direct and measure the success of the business or initiative.

- Using the factors as a common point of reference, everyone on the team can be helped to know exactly what is most important.

- Having a general understanding of these factors helps people to do their own work in the right context and pull together towards the same overall aim(s).

The MOMENTUM team modified these ideas, so that they can be applied more specifically to the field of telemedicine, from materials available from the University of Washington in the USA.[28]

2.2 Background and purpose to MOMENTUM's work

The purpose of the MOMENTUM project has been to determine how to enable service deployment in the field of telemedicine/telehealth. As a result of MOMENTUM's work, 18 critical success factors were defined that are directly pertinent to enabling that service deployment.

These 18 factors were formulated as a result of in-depth work by MOMENTUM's four special interest groups (SIGs), the professional experience and expertise of the groups' members, the groups' focus on a set of real-life case studies, and the members' understanding of the underpinning theory in the telemedicine, service, and management fields.

Four domains have been covered by the consortium (see Figure 1 below):

---

[28] https://depts.washington.edu/oei/resources/toolsTemplates/crit_success_factors.pdf, accessed 27 October 2014.

Figure 1: The MOMENTUM triangle

Each of the four domains contains four or five critical success factors. For the time being, in Figure 2 – that follows – each of the critical success factors is accompanied by a number (1-18). These numbers represent the numbering that was originally given to the critical success factors when they were originally developed by the MOMENTUM consortium in early summer 2014.

The list of 18 critical success factors follows, classified under the four domains renamed by the consortium in Athens in May 2014:[29]

2.2.1 Critical success factors for a deployment strategy[30]

   1) Ensure that there is cultural readiness for the telemedicine service.
   2) Ensure leadership through a champion.
   3) Come to a consensus on the advantages of telemedicine in meeting compelling need(s).

---

[29] In undertaking its work, MOMENTUM has mostly avoided making reference to the timing or sequencing of these 18 critical success factors, although these can be located especially in relation to factors that are pertinent to the legal, regaulatory and security perspective. At a number of MOMENTUM workshops and meetings, questions have been posed by attendees in audiences about whether some form of chronology or sequencing could be anticipated in terms of the relative importance or timing of the critical success factors.[29] Instead, it is recognised that in parallel with MOMENTUM's work other studies examining the nature of maturity models and the phasing of telemedicine deployment work are being undertaken in other European Commission co-financed projects and especially in the context of the European Innovation Partnership on Active and Healthy Ageing (EIP AHA).

[30] The original names of the four domains were strategy and management; organisational implementation and management; legal, regulatory and security issues; and, at different stages of the project, either technology and market relations or technical infrastructure and market relations.

4) Pull together the resources needed for deployment.

2.2.2 Critical success factors for managing organisational change

5) Address the needs of the primary client(s).

6) Involve healthcare professionals and decision-makers.

7) Prepare and implement a business plan.

8) Prepare and implement a change management plan.

9) Put the patient at the centre of the service.

2.2.3 Critical success factors from a legal, regulatory and security perspective[31]

10) Assess the conditions under which the service is legal.

11) Identify and apply relevant legal and security guidelines.

12) Involve legal and security experts.

13) Ensure that telemedicine doers and users are "privacy aware".

2.2.4 Critical success factors from an ICT perspective

14) Ensure that the appropriate information technology infrastructure and eHealth infrastructure are available.

15) Ensure that the technology is user-friendly.

16) Put in place the technology and processes needed to monitor the service.

17) Establish and maintain good procurement processes.

18) Guarantee that the technology has the potential for scale-up.

2.3 Towards a more dynamic display of the 18 critical success factors

A table (below) shows how the work undertaken by the four MOMENTUM SIGs can be categorised within the shamrock model later developed by the consortium. The four categories of strategy, organisation, legal and security, and technology are shown according to the categories of context, people, plan and run. Telemedicine – the core of the shamrock – is omitted.

---

[31] The term legal, regulatory and security framework is preferred by some commentators.

Table 1: Layout of the work of the special interest groups compared to the outline of the shamrock

	Context	People	Plan	Run
Strategy	1) Cultural readiness 2) Compelling need	3) Leadership.	4) Resource aggregation.	
Organisation		6) Stakeholder involvement. 9) Patient centeredness.	5) Primary client. 7) Business plan. 8) Change management plan.	
Legal & security			10) Legal and security conditions.	11) Legal and security guidelines. 12) Legal and security experts. 13) Privacy awareness.
Technology		15) User friendliness.	18) Potential to scale up.	14) IT and eHealth infrastructure. 16) Service monitoring. 17) Market procurement.

Through MOMENTUM's progressive development of its work, the consortium has now shifted in its orientation towards an even more dynamic illustration of the importance of the critical success factors. The 18 critical success factors are portrayed visually using the image of a trefoil – three-leaved – plant, more commonly called a shamrock. The use of a shamrock is intended to indicate the holistic and organic character of the various critical success factors, and the way in which they are firmly grounded in a context. A shamrock plant typically has three main leaves and a stem.

The diagram that follows (see Figure 2) illustrates each of the domains first shown in Figure 1 (strategy, organisation, legal and security, and technology and market).[32, 33] It uses four colours (yellow, pale green, dark green and red):

---

[32] The diagram also uses very short texts to identify the MOMENTUM critical success factors. Two simple examples, shown in the figure below, are "cultural readiness" and "compelling need".

[33] First, each of the critical success factors is described in sections 3-6 of this deliverable in a less abbreviated way than this simple use of a noun and adjective. For example, in the full descriptions of the two critical success factors, "cultural readiness" and "compelling need", MOMENTUM refers to the fact that a telemedicine doer should *ensure that there is cultural readiness for the telemedicine service* and *come to a consensus on the advantages of telemedicine in meeting compelling needs*. A similar expansion of all the wording and descriptions of the other 16 critical success factors is equally evident throughout the deliverable.

- Strategy (yellow).
- Organisation (pale green).
- Legal and security (dark green).
- Technology and market (red).
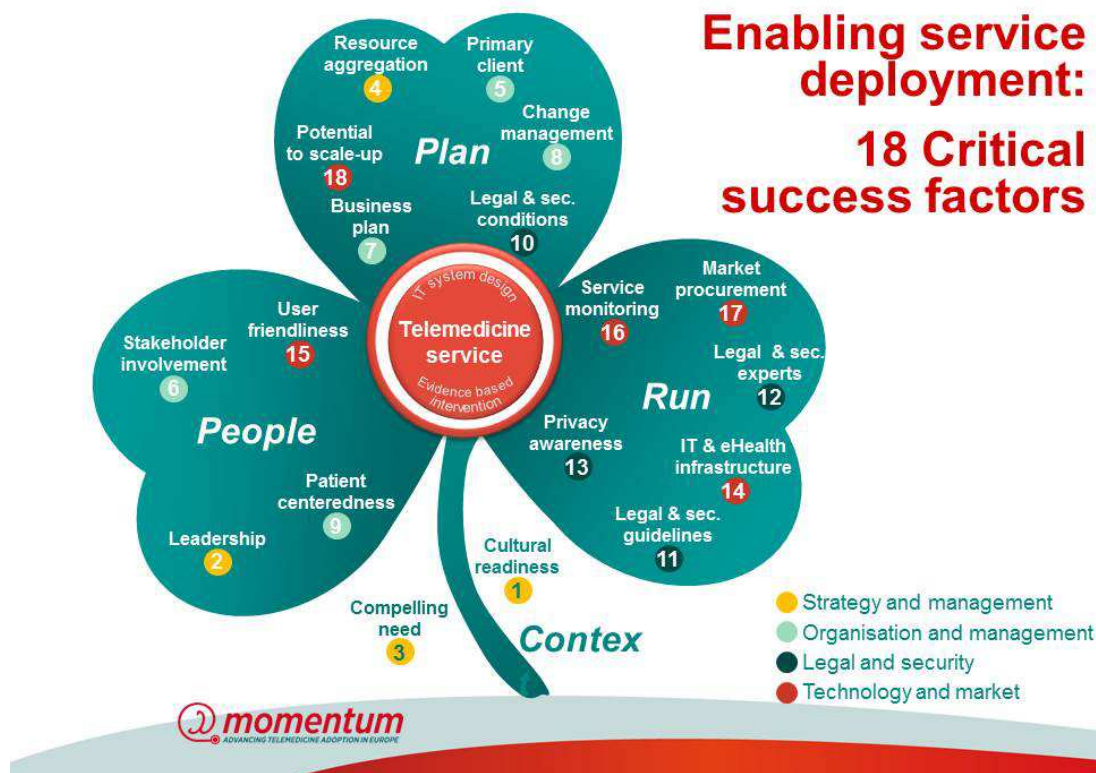
Figure 2: Enabling service deployment - 18 critical success factors

MOMENTUM began to present this shamrock model at a number of events in autumn 2014, culminating in its fourth (final) workshop. Here is an example of MOMENTUM project coordinator, Marc Lange from EHTEL, speaking in Paris on 16-17 October 2014:

Second, these lengthier titles are accompanied by much longer descriptions of the factors themselves, their objectives, their contexts and any prerequisites that might be necessary for them to function.

Figure 3: MOMENTUM project coordinator, Marc Lange, presents the shamrock model

2.4 Explanation of the shamrock model and its relation to the 18 critical success factors

In Figures 2 and 3, the notion with regard to the shamrock is that there is a "core" to the shamrock which identifies a number of prerequisites that are needed *before* larger-scale telemedicine service deployment can start. There is a main stem that underpins the plant, accompanied by three important leaves (or fields).

2.4.1 Core of the shamrock

In a real shamrock there is no core, however, this is not the case with this virtual shamrock. At the heart of this shamrock lies a big red circle. In this circle, space is allotted to **information technology (IT) systems design** that is based on the need for **evidence-based intervention**. This circle symbolises the fact that, even before thinking about deployment, telemedicine doers need to have a service that is ready for deployment. It stipulates what the various prerequisites should be. These prerequisites are, of course, not critical success factors in their own right.

The diagram implies that before large-scale service deployment occurs:

- A new innovative service (or a new set of clinical pathways) has been defined.
- The necessary evidence has been obtained that this service will deliver benefit (i.e., the intervention is evidence-based which means that it is an evidence-based intervention).
- The necessary supporting information technology (IT) system has been defined and tested (i.e., information technology systems design has taken place).

Telemedicine doers should not anticipate that the MOMENTUM critical success factors are able to assist them with regard to these prerequisites.[34] Rather, support is provided by other tools and methods, such as the **M**odel for **AS**sessment of **T**elemedicine (MAST).

2.4.2 The stem (or base) of the shamrock

The description of this shamrock continues with the issues that are at its foundation (its base or stem). At the stem of the shamrock lies the all-important issue of the **context** in which the specific telemedicine service is being designed and deployed, and its contextual attributes. Two particularly important factors that form part of that basic content relate to **cultural readiness** and creating a consensus around a **compelling need** (or needs). These contextual issues are especially related to strategy and management.

2.4.3 The leaves of the shamrock

The description of the shamrock branches out into the other 16 critical success factors. Each of these critical success factors is displayed on the three leaves/fields of the plant. The three leaves/fields relate to people, plan and run.[35] These three areas move generally and logically from the more strategic, managerial and organisational to more operational levels.

The "people"-related critical success factors are all those that relate to leading people, involving people interacting with the telemedicine service, putting people at the centre, and designing systems and equipment so that they are people-friendly.

The "plan"-related critical success factors are all those that relate to setting up the necessary resources, determining who is the primary client, putting in place and following a business plan, and ensuring that there are mechanisms underway for change management, determining what the surrounding and appropriate legal and security conditions are, and setting out the plans so that the technology involved has the potential for scale-up.

More fundamentally, the management or operational-related critical success factors under the title of "run" are related either to the legal and security issues or the underpinning technology concerns that are key when preparing the operationalisation of large-scale telemedicine service deployment. The first set are, for example, legal and security guidelines and having access to legal and security experts, and being aware of the privacy needs of patients in particular. The second set refers to IT and eHealth infrastructure, service monitoring and market procurement.

At this stage of the MOMENTUM project, the implications of these three categories of "people", "plan" and "run" are being investigated further by the consortium members.

---

[34] Nevertheless, in deliverable D4.1 of MOMENTUM, some insights were provided into a number of methods of evaluation that telemedicine deployment sites have undertaken to assess the success of their intended services.

[35] "Run" is used here in the sense of manage or operationalise the large-scale deployment of the service.

2.4.3.1 People

The people leaf/field contains a description of four critical success factors:

- Leadership.[36]
- Stakeholder involvement.
- Patient-centeredness.
- User-friendliness.

2.4.3.2 Plan

The plan leaf/field contains a description of six critical success factors:

- Resource aggregation.
- Primary client.
- Business plan.
- Change management.
- Legal and security conditions.
- Potential for scale-up.

2.4.3.3 Run

The run leaf/field (which is about management and/or operationalisation) contains a description of a further six critical success factors. The critical success factors described in this field constitute a mix of factors that relate to legal and security issues, and technology and market issues:

- Legal and security guidelines.
- Legal and security experts.
- Privacy awareness.
- IT and eHealth infrastructure.
- Service monitoring.
- Market procurement.[37]

In the four chapters that follow, each of the 18 critical success factors are explained step-by-step. The critical success factors are described in terms of the four original categories in which they were initially laid out, i.e., according to the deployment strategy, the way of managing organisational change; from a legal, regulatory and security perspective; and from an ICT perspective.

---

[36] Each of these short titles is an abbreviated version of the longer titles used by the MOMENTUM special interest groups (SIGs) to name the 18 critical success factors.The abbreviation of these "short titles" means that telemedicine doers are always recommended to read the full title of the critical success factors accompanied by their full detail.

[37] This is elsewhere described as "good procurement processes".

3 Critical success factors for a deployment strategy

This chapter describes systematically each of the critical success factors relevant to the deployment strategy. It covers the four critical success factors relating to:

- Cultural readiness.
- Leadership.
- Compelling need.
- Resource aggregation.

Each description covers the following five domains: first, the general background to the critical success factors i.e., what each critical success factor means; second, its underlying objectives; third, the surrounding context, and any prerequisites; and, fourth, lessons learned about that specific critical success factor from the in-depth cases investigated. Fifth, if appropriate, useful further background information is included.

3.1 Critical success factor 1: Ensure that there is cultural readiness for the telemedicine service

This critical success factor is about the issues surrounding the assessment of cultural readiness and the need to facilitate changes that generate it. The need for cultural readiness is directly related to telemedicine deployment scale-up.

Figure 4: Cultural readiness.

3.1.1 What cultural readiness means

Cultural readiness in a healthcare system or organisation has three components:

- a set of **beliefs and perceptions** that influence establishment of priorities;
- **attitudes and norms** that affect behaviour including decisions, ideas and practices that determine how a person, organisation, society will respond to the environment;
- **values and current needs** that determine whether telemedicine will be viewed positively or negatively, and will be embraced, rejected or just ignored.

Cultural readiness applies both to telemedicine generally and to the modification of care processes, particularly those supported by health ICT.

It is useful to bear in mind a set of characteristics for cultural readiness. In addition, there is also an important relationship with the compelling need that underpins the telemedicine deployment (for more on this issue, see therefore critical success factor 3 later in this sub-section). Identifying and creating an awareness of a compelling need bears a close relationship with cultural readiness, since it points to a willingness to do things differently in the service or organisation because the way things are done today is not working.

Characteristics: The characteristics of cultural readiness for telemedicine include:

- Doctors and healthcare professionals are ready to share clinical information with each other and with the patient i.e., among the stakeholders, there is a level of trust as well as "openness of spirit", cooperation, and willingness to modify their working habits.[38]

- Patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).

- Financial and other incentives are aligned with the service to be deployed.

- There is an underpinning culture that embraces technology, that welcomes and even promotes change and innovation, and that shows an openness to new ideas.

- For commercial services there is market readiness, i.e., the service provider can sell and commercialise the service.[39]

These characteristics for cultural readiness range over such fields as the surrounding culture, the culture and level of trust of professional groups and their relationships with their clients, and – commercially – market readiness.

Cultural readiness is multifaceted and exhibits itself in very different ways in different places. From the perspective of telemedicine doers, this implies that there is no simple formula or uniform set of circumstances that indicate the presence or absence of cultural readiness. Instead, doers need to be sensitive to the unique nuances in each situation. This context awareness will help to determine where to focus first to get the process going or what values need to be emphasised for the person, the service and its rationale to gain acceptance. Being aware of the phasing or scaling of the initiative is therefore also important.

Another important factor in cultural readiness is the self-image or self-perception of the organisation or system. Self-perception on the part of the initiative, project or even the

---

[38] This success factor is relevant in both provider-provider services and provider-patient services. However, in a provider-provider service, the willingness to share information with the patient is less important.

[39] Although focused on Canadian companies and chiefly on innovation, Canada's International Center for Innovation Technology Transfer (IFCITT) regards market readiness as being dependent both on technology readiness and market-related demand for the particular technology on http://www.icfitt.com/index.html, accessed 27 October 2014. Many technology readiness level assessment mechanisms are available. Most have originated from North America and relate to either large-scale corporations or prominent national agencies associated with the defence, space, and energy fields:
http://en.wikipedia.org/wiki/Technology_readiness_level, accessed 27 October 2014.
The telemedicine equivalent of these readiness levels or methods is the TREAT method (see MOMENTUM deliverables D3.3 and ultimately D3.4). in terms of healthcare readiness levels, these appear to have been mainly explored in the fields of emerging economies and developing nations. EHTEL's Innovation Initiative is currently exploring the notion of service readiness levels.

---

champion as an innovator or a pioneer would appear to be a very strong indicator of cultural readiness. This is particularly the case when it is perceived positively by the external environment, as is seen in the cases of both ITHACA and Maccabi. Therefore, cultural readiness can be created, or at the very least facilitated, and may well be more of a process than a static condition.

3.1.2   Objectives underlying cultural readiness

Cultural readiness is a critical success factor because, without it, the adoption of a telemedicine service will not occur. This requires that telemedicine doers actively address culture, in order to verify that the stakeholders concerned (including individuals, professional groups and or organisations) are open to the value and benefits of telemedicine, and can be convinced to adopt it. Building such cooperation is an important element in the organisational restructuring that is part of telemedicine deployment.

To take on board this critical factor, telemedicine doers will need to:

- Assess the level of cultural readiness in the system or organisation for developing and/or deploying the specific telemedicine service.
- Determine what steps can be taken to either
  (i) facilitate or stimulate cultural readiness, or
  (ii) increase and strengthen the level of cultural readiness for telemedicine deployment.

Two types of awareness-raising on telemedicine activities can be incorporated – the first is awareness in society as a whole[40], while the second is more focused directly on telemedicine-relevant groups such as clinicians and patients. Involvement of the main actors in the health life-cycle will ultimately be needed at different stages of decision-making on telemedicine deployment.

Steps to facilitate cultural readiness may include such actions or activities as the training of healthcare personnel.

3.1.3   The context surrounding cultural readiness

The issues surrounding cultural readiness are the social, political and technological context in a particular country, region, city or organisation. Cultural readiness will also be influenced by whether the specific environment where telemedicine is to be deployed is public sector or private sector, and whether the organisation concerned is a public service or a commercial enterprise (in which case the focus may be more about the readiness of the market).

Prerequisites: Prerequisites underlying cultural readiness may include:

---

[40] Telemedicine doers, on their own, have perhaps limited influence on this societal level. However, some participatory initiatives taking place in the health systems, and the regions of Europe, indicate how this awareness-raising may be achieved with citizens at large, and with the recipients of integrated care in particular, e.g., the Kent Innovation Hub exercise and the Scottish Living it Up initiative , accessed 27 October 2014.

- The absence of legislation or political action that would impede, prevent, or act as a significant barrier to telemedicine deployment.[41]

- Sufficient flexibility or freedom in the system for leaders to make and implement necessary decisions.

- Awareness in society as a whole of the added value and convenience of using technology to support healthcare.

3.1.4 Lessons learned from the cases on cultural readiness

The lessons that can be learned from the case studies on which MOMENTUM has focused are:

- Cultural readiness for telemedicine can be at least partially achieved by promoting other aspects of health ICT, such as electronic medical records (Maccabi, ITHACA).

- The inclusion of technological innovation in general and telemedicine in specific in the strategic vision of an organisation or system is a powerful force for cultural readiness (Maccabi, ITHACA).

- The expectation of "reward" from the external environment is also an important factor in cultural readiness (Maccabi).

- RxEye appears to be a telemedicine service that succeeds despite only limited cultural readiness, in their case – market readiness. Hence, the entrepreneurs who initiated it were "culturally ready" (they saw the lack of radiologists in the country involved as an opportunity that would enable them to provide an innovative solution to a compelling need). However, the service is still struggling to grow to meet the needs of the potential client population.

- A technology-friendly environment with widespread use of the particular telemedicine technology for other purposes – as is the case with videoconferencing in the Norwegian Teledialysis case – is indicative of cultural readiness in terms of both the environment and also the specific type of solution.

- The pioneering spirit of the organisation, and the value it places on innovation, is an important factor in cultural readiness (ITHACA).

- In some senses, KSYOS is reminiscent of RxEye insofar as the "cultural readiness" at the initial stage of the initiative was limited, but needed to be built by the initiator of the service. The KSYOS case is a good example of how telemedicine doers go about creating cultural readiness. The KSYOS doer did this in several steps. First, he created the "service" as a research project in which he was able to produce evidence of the

---

[41] There are laws in existence in various countries that are actually positively beneficial to telemedicine deployment. Of course, however, legislation undergoes change and modification. For a more in-depth treatment of the legal, regulatory and security issues relating to telemedicine deployment, see the later chapter on these matters. Telemedicine initiatives could suggest possible changes to legislation and also succeed in making that change become real. Because telemedicine is a relatively new area, it would be reasonable to see a first solution being to follow current legislation, and a next step being prepared for a situation that already has suggested the changed legislation in place. This kind of strategic work, in ensuring cultural readiness, could facilitate the development of better and better solutions in the telemedicine sector, always bearing the situation of patients in mind.

quality and efficiency-improving potential of the teleconsultation solution. He then focused his attention on a small group of innovators whom he converted to his cause. Gradually, he increased the number of health workers, health institutions and health insurers involved. He also designed the service by placing the doctors – the primary clients of the service – at the centre, as they could otherwise potentially have been the most resistant partners to this change. Only after he had achieved a significant level of acceptance did the innovator then turn the service into a business. It is significant that, even today, the telemedicine doer in the KSYOS case still markets KSYOS as a healthcare provider and not as a technology service.

- Cardio On Line Europe started small and apparently found a welcome home in Puglia, a region in Italy that was ready to try out its solution. In terms of how cultural readiness can change over time, Cardio On Line Europe is a service that has grown gradually. It proved itself initially at the level of small-scale deployment. Then it generated evidence of success that enabled it to expand to large-scale deployment.

3.1.5 Further useful background information on cultural readiness

Literature about the diffusion of innovation could be pertinent in explaining a number of other factors.[42] The following messages can be identified from the literature:

- In the diffusion of innovation literature, the rate of diffusion of an innovation is significantly determined by the degree of compatibility of the innovation with the values, beliefs, past history and current needs of the individuals involved (Berwick, 2003).

- Another cluster of influences on the rate of diffusion of innovations has to do with the contextual and managerial factors within an organisation or social system that either encourage and support the acceptance of innovation or discourage and impede it. Particular organisations may therefore act as nurturing environments for innovation (Ibid p. 1972).

The importance of this background information is that telemedicine doers need to assess the degree of "openness" and "readiness" in the organisation or system to determine whether it will provide a nurturing and supportive environment as a whole.

3.2 Critical success factor 2: Ensure leadership through a champion

This critical success factor is about the issues surrounding ensuring leadership through a champion.

From the MOMEMTUM case studies, it appears to be crucial to have a champion – or a team of champions – who believes in the importance and viability of the service and is willing to invest considerable effort and energy in pushing the venture forward.

3.2.1 What leadership through a champion means

---

[42] See, for example, Rogers (1962) and Christensen & Grossman (2009).

A champion is a person who is committed to the telemedicine idea or initiative or service. The person may have a considerable range of qualities and competences: the person is willing to put himself/herself "on the line" i.e., to be open to considerable risk to make the service happen; has the ability to enlist others to the cause; can secure the commitment of the leadership of the organisation or the system; and has the ability to mobilise resources to make the initiative happen, including other people who can act as more operational leaders.

Figure 5: A champion.

Characteristics:[43] A champion may be a person who:

- Is either in a position of authority or influence in the organisation or healthcare system.

- Can generate trust at all levels – both on the part of the leadership and at the level of the people who have to implement and use the service.

- Has relevant knowledge, contacts and relationships with like-minded people wherever they are located geographically.

- Has credibility or a "track-record".

- Can create the conditions for continuity and ensure good management at the various critical stages of the initiative.

At the same time, the differences in the various types of champions call into question some of the characteristics or attributes of a champion. In terms of the attributes of champions, therefore:

- Do champions really have to be in a *position of authority*? This characteristic would appear to be more important in services which are public in character than in a commercial service.

---

[43] See also, on characteristics in general, the contents provided in ANNEX of this deliverable.

- Is the ability to *generate trust* really a critical characteristic of a successful champion? Or is it enough that the champion be sufficiently credible so as to offer or promote a service that has fairly easily demonstrable merits?

- Does a *champion work on his or her own*? Clearly, champions do not operate on their own. Hence, considerable emphasis is placed on leadership, team-building, and the involvement of different actors at various stages of the decision-making and deployment processes.

3.2.2 Objectives underlying leadership through a champion

Leadership from a champion is a critical success factor. By taking care of championing the cause, telemedicine doers have a resource in place who will make the service happen; who will deal with relevant obstacles; who will resolve issues emerging from the deployment process; and who will provide stakeholders with a reference point or contact point, hence creating trust in the process that is taking place.

To ensure that a champion is in place, telemedicine doers:

- Need to determine whether they have the necessary characteristics themselves, and can and do want to take on the role themselves of champion.

- If they come to the conclusion that they cannot be the champion themselves, then their objective will be to identify and locate appropriate candidates who can act as champions. Thus, the person concerned will need to enlist other people to the cause.

3.2.3 The context surrounding leadership through a champion

The need for a champion is relevant in any context whether it is at the international, national, regional healthcare system level or organisational level.

The characteristics of a successful champion will be determined by the particular context of telemedicine deployment. For example, if telemedicine doers are to be champions at the systems level, they need to be "known" outside the particular organisation more publicly (i.e., recognised as having a mandate) and accepted. If champions are to work at an organisational level, it is probably sufficient that they are known inside the organisation, or at least known by the leadership/decision-makers in the organisation.

If the telemedicine service to be deployed is a provider-provider system, it might be important that the champion is a doctor or a healthcare professional. If the context is a commercial one, i.e. the telemedicine service is being established as a commercial business, then the champion is likely to be an entrepreneur.

Early studies on factors affecting diffusion of innovation among health professionals suggests that when a group favours an innovation, opinion leaders are likely to be pioneers; whereas, if the group norms and the innovation are in conflict, the pioneer is often an individual who is marginal to the group (Becker, 1970).

3.2.4 Lessons learned from the cases on ensuring leadership through a champion

The five cases cited here illustrate that this critical success factor can be categorised in three ways:

- A champion can be external to the specific organisation that is deploying the service: for example, he or she may be a member of the overall healthcare system of which the organisation is a part (Maccabi).

- Champions can also operate in teams. In a team of champions, the function of championing does not fall on the shoulders of a single individual. Rather, the functions are spread, with the members of the team each bringing a different quality but still being essential to the championing activities of the team (Teledialysis and ITHACA).

- A champion can be an entrepreneur: in which case, in effect, the champion and the telemedicine doer are effectively the same, and may possibly even be just one person (e.g., in RxEye and KSYOS).

In reviewing these five cases, in some experiences there is a tendency to talk about "champion teams". In most organisations, however, as a rule, the process begins with one champion who really wants to push forward an idea or an innovation. In order to succeed, he or she immediately starts recruiting partners and creates a team with which to work. This is an essential step in "socialising" the telemedicine idea within the organisation.

There are also some elements that cut across these three groupings of external individual, team-based champions and entrepreneur:

- In two of the cases (Maccabi and ITHACA), the champion (or a member of the championing team) brought significant financial – and perhaps other important – resources to the deployment of the service. This support continues today.

- In these same two cases (Maccabi and ITHACA), it is significant that the champion who possesses the resources is external to the organisation that is responsible for deploying the service.

- Two of the services (Teledialysis and KSYOS) are teleconsultation services that connect health professionals. In both cases the champion (or the head of the championing team) is a clinician who is a specialist in the particular medical specialty that is at the heart of the new teleconsultation service. While RxEye shows certain other similarities with Teledialysis and KSYOS, it does not fit into quite the same category. This is because, although it facilitates a service between professionals, it is in fact a brokering service between professionals and the institutions that need their services. Thus, in RxEye, the actual profession or specialty of the broker was not really relevant.

- The credibility of the champion appears to be more critical in the three public service cases (Maccabi, Teledialysis, and ITHACA) than in two of the commercial cases (RxEye and KSYOS).

- In two of the commercial services, the utility of the service appears to be more important than the role of the actual champion.

3.2.5 Further useful background information on leadership through a champion

The recognition of the need for a champion to promote the implementation of innovation is not only accepted but is taken for granted in almost every organisation that places a value on innovation.

A quick internet search reveals the existence of many articles, both academic and commercial, along with advertisements on training courses to develop "champions". One such course defines an "Innovation Champion" as a manager or professional who has the expertise, credibility and self-confidence to guide and coach others in helping to build innovation capabilities in the organisation. It is asserted that: "*Champions are critical to the success of innovation inside organizations. Every organization needs individuals who are focused on innovation and the ever-changing environment in which we conduct business.*"[44]

This assertion is supported in academic articles by researchers such as Howell and Boies (2004) in the journal, Leadership Quarterly, on a study that examined the role that champions play in the generation and promotion of ideas in the innovation process. The study found that champions demonstrated more enthusiastic support for new ideas, tied the innovation to a greater variety of positive organisational outcomes, and used informal selling processes more often during the idea promotion (Howell & Boies, 2004).

Another article, by Ted Buswick (1990) in the Training & Development Journal, asserts that: "*The champion is the driving force for getting a technology investigated or implemented. Usually, he or she is either a person with exceptional skills in the technology who also has the zeal and persuasive powers to convince others, or someone near the top of the company who recognizes that new technology is essential to staying competitive, and whose advice will be interpreted as orders.*" Buswick lists ten characteristics of the successful champion: expertise, credibility, planning skills, networking skills, sensitivity, objectivity, tenacity, decisiveness, assertiveness, and confidence (Buswick, 1990).

In terms of current new directions on telemedicine deployment, champions can also be assisted in their activities by pioneer providers and by pioneer stakeholder groups, including patients, their families and their carers. Indeed, there are arguments that patients will become more assertive in this respect than historically.[45] These findings were not, however, particularly evident in the example cases collected by the MOMENTUM thematic network.

Evidence of such pioneering work has been provided by groups like the European Patients Forum http://www.epf.org and, e.g., the Chain of Trust initiative which it led.[46] In terms of examples from individual countries, Sweden's "My healthcare contacts" service provides the means for an individual patient to ask online for renewed prescriptions of drugs and arrange appointment times.[47] Current initiatives that enable greater patient empowerment often relate to the use of electronic health applications ('apps'), in particular (Newbold, 2014).

---

[44] From an Internet advertisement on a customisable Champion Development Programme http://www.desai.com/our-services/INNOVATION-CHAMPION-DEVELOPMENT-outline/tabid/89221/Default.aspx, accessed on 27 October 2014.

[45] See, e.g., the Informed Patient initiative, described by Don Detmer and Peter Singleton, which ended in the early 2000s, http://ec.europa.eu/consumers/archive/cons_org/assembly/8assembly2005/sp8_singleton_en.pdf, accessed on 27 October 2014.

[46] The Chain of Trust project http://www.eu-patient.eu/whatwedo/Projects/EPF-led-EU-Projects/Chain-of-Trust/, accessed on 27 October 2014.

[47] See this explanation of the service (in English) https://minavardkontakter.se/C125755F00329208/p/OSAL-7PBJ24?opendocument, accessed 27 October 2014.

3.3 Critical success factor 3: Come to a consensus on the advantages of telemedicine in meeting compelling need(s)

This critical success factor is about coming to a consensus on the advantages of telemedicine in meeting a compelling need or needs.

Coming to a consensus on what these needs are is obviously a process that involves people: a variety of stakeholders will be involved in deciding on and determining what the particular compelling needs for telemedicine deployment are in any particular case.

Clearly, not all of the current problems inherent in the delivery of healthcare services can be solved by telemedicine. There are still many healthcare services that require face-to-face encounters and/or procedures that have to be performed physically.

However, there is one clear conclusion from the seven cases explored in depth in MOMENTUM: it is that either the needs that telemedicine can meet, or the problems that it faces, are needs or problems that telemedicine **can** solve, and is able to solve with **better outcomes** than any other option (e.g., in terms of quality, cost effectiveness, and patient and clinician satisfaction).

Figure 6: Meeting a compelling need.

3.3.1 What coming to a consensus on telemedicine meeting a compelling need means

This success factor is comprised of two major components about which it is necessary to come to a general consensus:

- Identification of a compelling need (or needs) that must be addressed. A compelling need is a sufficiently high level "problem" – such as a shortage of healthcare professionals, a limitation in other important resources or a high level of preventable morbidity or mortality – for which a telemedicine service can supply a solution.[48]

- Recognition and agreement that the telemedicine solution has clear and demonstrable advantages over all the other possible solutions to the compelling needs/problems.

Issues, needs or problems are compelling when the solutions to them are:

- Essential to the values and underlying raison d'être of the healthcare system or organisation.

- Essential to the accomplishment of the organisation or system's mission.

- Essential to the management of the organisation or the system.

---

[48] Other examples are described in greater detail below.

- Able to successfully assist in cost-control or cost-reduction.

- Necessary to ensure the maintenance of basic principles and values.

- Mandated under law or another outside authority.

Examples of compelling needs that telemedicine services are able to address:

- Demographic and epidemiological characteristics of the population that increase demands for service support.

- Limited resources, either financial and/or human, to meet the demand created by the target population.

- Limitations or constraints in access to the kind of care that meets people's needs.

- The need for care that is appropriate and at the requisite level of quality.

- The need for services that provide care at a sufficient level of efficiency and effectiveness so that it is economically viable, sustainable and affordable.[49]

3.3.2 Objectives underlying coming to a consensus on telemedicine meeting a compelling need

Creating a consensus about the advantages of telemedicine in meeting a compelling need or needs is a critical success factor because, by taking care of this matter, telemedicine doers will:

- Formulate what the compelling need or needs are that can be effectively addressed by telemedicine in all their aspects and implications.

- Take steps to assure that the critical stakeholders are aware of and perceive the compelling need(s).

- Highlight those problems or situations in the system or the organisation (or that are external to the system or organisation) that constitute a compelling need (or needs). As a result, stating these problems or situations can be used as part of the rationale and justification for developing and/or implementing the service.

- Identify and delineate the unique advantages of the telemedicine service over all other potential alternative services/solutions that can/may address the compelling need(s) and determine the main characteristics of the telemedicine service as well as the orientation for any patient inclusion and exclusion criteria.

- Use the "compelling need(s)" that have been identified and the advantages of telemedicine to demonstrate benefit in order to enlist a champion, persuade leadership about the need for support through telemedicine, and mobilise resources.

3.3.3 The context surrounding coming to a consensus on telemedicine meeting a compelling need

The advantages of a telemedicine solution over alternative solutions can be relevant either at an organisational level or at a health system level.

---

[49] This latter factor is being explored by a number of contemporary European Commission co-financed projects that focus on impact assessment and evidence-gathering. One example is the United4Health large-scale pilot: http://www.United4Health.eu, accessed 27 October 2014.

From a contextual point of view, while the type of health system (i.e., whether Bismarckian or Beveridgean) is probably not significant in dealing with this success factor, the level of centralisation or decentralisation of the system may be.

Geographical distances may be an important contextual factor. Such distances contribute to the level and acuity of the compelling need.

The exact nature of the advantages of telemedicine and its benefits will be different for services that are provider-provider or provider-patient oriented. For example, one compelling need that lies behind the provider-provider service in the radiological field may be an acute shortage of radiologists. [50] The advantages of a telemedicine solution in this case are that it (i) not only resolves the radiologist shortage problem but it also, due to digitalisation of the radiological image, (ii) improves the quality of the diagnosis, (iii) saves money by eliminating the need for film, and (iv) improves the timeliness of the transmission of the interpretation to the referring doctor and the patient.

Compelling needs that encourage telemedicine provider-patient services are often long patient queues or acute access challenges in certain geographic settings. These problems can be rectified through the provision of teleconferencing or other telemedicine solutions that enable patients to receive care in a more timely fashion and reduce the need for travel without increasing the number of clinicians/human resources.

With this critical success factor, the prerequisites are:

- The visibility of the compelling need or the ability to make it visible, i.e., identifying it and making other relevant people aware of it. There needs to be a requisite level of awareness and consensus among critical stakeholders and decision-makers that the need(s) are actual, and that they are sufficiently acute and compelling so as to require a solution.
- The visibility of the benefits of the solutions to the various stakeholders or the ability to make them visible, and the ability of the critical stakeholders to understand the advantages of the telemedicine solution relative to the alternatives.

3.3.4 Lessons learned from the cases on coming to a consensus on the advantages in telemedicine in meeting a critical need(s)

In all seven of the cases there was a clearly defined problem or need that had attributes that were specifically amenable to telemedicine. Examples include a shortage of resources, timeliness, and distance from the provision of the services, or some combination of these factors.

- In Maccabi, the problems were a growing shortage of clinical personnel, tight budgets and the burden that having many chronically ill patients placed on these resources.
- In RxEye there was a shortage of radiologists which created a problem of timeliness in terms of obtaining professional interpretations of radiological images.

---

[50] Three further influences on the automation of radiological work have been (i) the degree of subspecialisation in the field; (ii) the need for second opinions to be obtained from other trusted subexperts, and (iii) increased mobility among patients due to "treatment guarantees", in certain countries, that can enable a quicker treatment to be obtained in another location.

- In Teledialysis there was also a shortage of experts, coupled with geographic distances between the patients' place of residence, the community hospitals that were to provide them with dialysis services locally, and the "expert" centres.
- In ITHACA, there was a need to reduce costs and to improve quality by providing a timely service. The first issue placed a limit on resources, whereas the second prevented any additional burden on those limited resources.
- In the Patientenhilfe service, there was a perceived need to reduce avoidable expenditures (i.e., hospitalisation of patients) by creating a more efficient and timely process of care. It was this perception that enabled the service to win contracts with clients.
- In KSYOS, the timeliness of expert consultation was the primary driver.
- In Cardio On Line Europe, the immediate problem was a combination of timeliness and distance which needed to result in preventable mortality.

The core problems of timeliness and distance could conceivably have been resolved in each of these cases by significantly increasing the resources and, along with them, expenditures. The distinct advantage of telemedicine is that it uses technology to overcome time and distance challenges without placing significant strain on already limited human resources.

3.3.5 Further useful information on coming to a consensus on telemedicine meeting a compelling need

The perception of compelling need and the unique advantages of the solution over other alternatives is an important element in the process of adoption and diffusion of innovation, as evidenced by the relevant literature. For example, in his article on disseminating innovations in healthcare, Don Berwick points out that the "*first and most powerful [factor] is the perceived benefit of the change. Individuals are most likely to adopt an innovation if they think it can help.*" (Berwick, 2003, p. 1969). The clear assumption here is that there is an underlying problem or need that the innovation purports to address.

This is closely aligned with the concept of "relative advantage". Meeting a perceived need is a necessary, but not sufficient, factor for the innovation – in this case, a telemedicine service – to succeed. Rather, a telemedicine service must have a distinct advantage over other alternative solutions that address the same need.

3.4 Critical success factor 4: Pull together the resources needed for deployment

This critical success factor describes the issues surrounding pulling together the resources needed for telemedicine deployment. That the ability to pull together the resources needed for on-going large-scale deployment is a critical success factor is well demonstrated by all seven of the MOMENTUM in-depth case studies.

A service cannot be deployed in a sustainable way without resources. Yet resources are generally only forthcoming after a viable solution to a compelling need has clearly demonstrated its benefits and advantages over other solutions. Once the evidence is available, there is a high likelihood of the solution being accepted and implemented in the specific environment/culture for which it is intended.

The core of the shamrock (see Figure 2) shows that resources are a result, consequence, or an otherwise dependent variable[51] of the evidence base on which the decision to scale up is eventually made. That stage involves designing the intervention and its supporting IT system, and assessing its potential impact. These critical success factors (i.e., design; the supporting IT system; and impact assessment) are all prerequisites for scale-up. Nevertheless, they lie outside the scope of the MOMENTUM project.

Figure 7: Pulling together resources.

3.4.1   What pulling together the resources needed for deployment means

Resources refer to the means needed to develop and deploy the telemedicine service and to ensure its sustainability.

There are essentially four major types of resources that need to be made available:

- **Financing** at a sufficient level to develop and support the deployment of the service. Financing may include grants, investments subsidies, or income from the sale of services.

- **People** who have specific attributes and expertise (ideas, concepts and know-how) and are in appropriate positions, and/or people with potential who can achieve the requisite level of know-how after appropriate training.

---

[51] A dependent variable is an item that depends on other factors. For example, for a student to obtain a particular score in a test or an examination could be a dependent variable (i.e., be dependent on other factors). This is because the score could change depending on several factors, such as how much the student studied, how much sleep the student got the night before taking the test, or even how hungry the student was when taking the test. Usually, when a relationship is being sought between any two items, a researcher is trying to find out what makes the dependent variable *change* in the way that it does.

- **Information** on (i) what is going on politically, socially, organisationally, technologically; (ii) in terms of business and, in a more focused way; and (iii) the problems and needs that can be addressed by the telemedicine service.

- **Time** can mean having the time to undertake the initiative needed, at the right time or making time available for the critical people involved, e.g., by establishing priorities, setting deadlines, and applying appropriate phasing and staging.

Items discussed in the general context of this critical success factor on resource aggregation can also be read usefully in conjunction with the description of creating business cases,[52] and also critical success factor 7 on business plans.

3.4.2 Objectives underlying pulling together the resources needed for deployment

Pulling together the resources needed for deployment is a critical success factor because, by taking care of this issue, telemedicine doers will be able to both take into consideration key constraints that can have a major impact on the deployment plan of the services and assess the deployment feasibility.

To pull together the resources needed for deployment, telemedicine doers will have to consider the following elements:

- Identify the necessary resources for the successful deployment and sustainability of the initiative and the development of plans to mobilise these resources.

- Develop schemes which provide the resources that support the long-term sustainability of the service. This may include enabling the service user to access the telemedicine service, by (i) making changes in the care system – including regulatory change where needed, such as inclusion of the service in the public basket of service in the case of users who are patients or (ii) providing reimbursement for providers/clinicians who will be expected to provide the telemedicine service to their patients or to use it in a provider-to-provider context.

- Obtain or aggregate the means and resources to implement the service at each stage of its development into large-scale deployment and integration into routine services. This aggregation includes all of the resources needed: financial, human, technology, know-how and equipment.

3.4.3 The context surrounding pulling together the resources needed for deployment

In terms of this critical success factor, the context can be located either at the system level or organisational level. This is a success factor that is relevant for both provider-provider and provider-patient services. There may be significant differences in the nature and source of resources depending on whether the service is a public or private one or is part of a public-private partnership.

The regulatory context[53] is important for at least three reasons:

---

[52] See sub-section 3.4.5 on the work of the Australian Public Service (APS).

[53] Further discussion on notions relating to the legal context are provided in the chapter in this deliverable on critical success factors for the legal, regulatory and security perspective.

- Regulatory recognition of telemedicine as a legitimate method for delivery of healthcare services supports the decision to dedicate time and people to developing such services.

- Generally, financing schemes for healthcare comply with the relevant legal/regulatory framework. In many countries, telemedicine is not included in these schemes. This is not only a financing issue in its own right, but also a value issue that determines priorities for service development and delivery. In other words, there needs to be recognition at the policy level of the advantages of telemedicine over other alternative solutions as well as an acceptance of the legitimacy of services provided "virtually" as opposed to some other face-to-face physical encounter.

- Reimbursement systems in most countries are subject to regulation steeped in traditional healthcare that is based on face-to-face contact between the provider and the patient. Any change in this situation may have implications for how remuneration and patient fees are organised.

In addition, an up-coming challenge involves regulating devices used by patients either on the move or at home, including technical and quality standards and financing: this is especially so since they involve monitoring and care that does not necessarily occur in a face-to-face context.

Prerequisites: A number of prerequisites underlie this success factor:

- The actual availability of resources.

- Cultural readiness, compelling need, the right organisational setting, and supportive leadership.

- Recognition of the need for the service and perceived benefit of the service over other alternatives.

- The consideration of telemedicine-based healthcare as a legitimate option for healthcare delivery with legal standing.

3.4.4 Lessons learned from the cases on pulling together the resources needed for deployment

Resources needed for deployment can be subdivided into two categories:

- Initial investment for initial deployment of the service.

- Resources for the on-going operation/deployment of the service.

In four of the seven cases – Maccabi, Teledialysis, ITHACA, and KSYOS – there is an explicit reference to "start-up" resources (consisting of either funding and/or people), whereas in RxEye and Cardio On Line Europe these resources are implicit. It would also be safe to assume that there was an initial investment made to start up Patientenhilfe.

Interestingly, on the one hand, in the four cases for which there is explicit information on initial investments, the start-up financial resources were – in some form or another – research or project funding. On the other hand, in RxEye and Patientenhilfe, the resources may very well have been a business investment (perhaps made by the entrepreneur(s) themselves). In Cardio On Line Europe, it is implied that the funding came from the Puglia Region.

The more crucial issues for scale-up, large-scale deployment and integration of the service into routine care are the resources that need to be available to ensure the on-going operation/deployment of the service. In this aspect of resource aggregation, there would seem to be a significant difference between those services that are "public" services and those that are commercial:

- In commercial services, once the clients are convinced that the service is useful and beneficial to them, on-going sustainable financing depends on the entrepreneur's ability to sell the service at a viable fee to a sufficient number of clients. Continuity involves satisfying customers and growing a business.

- In the case of "public services", resources for on-going operation and integration into routine service delivery is more of a challenge. It involves convincing the powers-that-be (which are often external to the deploying organisation or body) that there is a return on investment, cost effectiveness and cost benefit that result from the continuing deployment of the service. In the Maccabi case, the service will continue as long as it is possible to demonstrate that it achieves greater benefit and, at the very least, costs no more than the alternative. The Norwegians, in the Teledialysis case, are apparently satisfied that this benefit has already been demonstrated, as is Cardio On Line Europe. However, the long-range sustainability of ITHACA is far from assured.

3.4.5 Further useful information on pulling together the resources needed for deployment

The Australian Department of Industry is leading work to foster innovation in the Australian Public Service (APS). It has created a website to help public servants develop and apply innovative solutions.[54] This website addresses the issue of resources for innovation, which are of course wider in their remit than the more confined domain of telemedicine deployment.

As the work by the APS shows, the resources needed to develop and implement a new idea are key variables in establishing a business case and gaining approval for the case. A lack of resources may pose a barrier to innovation. However, often existing resources can be applied to a good idea. Thus, this critical success factor – pulling together the resources for deployment – is focused on the gap between the resources that are needed and the resources that already exist.

The APS website describes financial resources as "*the budget allocations to develop and implement [your] idea*". The APS also identifies a number of other resources. One is similar to the people/human resources aspect noted by MOMENTUM. The APS does not mention either information or time as resources. It does, however, focus much more on technical, administrative and operational resources :

- Technical resources consist of functional expertise, system expertise, and domain expertise.

---

[54] http://www.apsc.gov.au, accessed on 27 October 2014.

- Administrative resources are composed of the know-how to manage planning, organisational issues, staff relations and leadership, negotiating, project management and communications.
- Operational resources are investments in space, equipment and systems.
- Human resources consist of the number and types of staff required.

The APS notes that the amount and types of resources depend on the sophistication of the idea and the nature of the problem that the initiative is facing. Having a balance of skills and experience is just as important as the depth of expertise in particular areas. Exactly which skills and experience are important can only be determined on a case-by-case basis. The overriding premise is that the circumstances of the idea dictate the resources needed to implement the initiative. Champions should also make a serious and frank assessment of their own personal skills and experience as compared with what the initiative may require.

As APS says: there is a difference among the criticality of resources, and therefore it is important to distinguish to what extent the resources needed are critical or strategic: "*If you have control over the right mix of resources, then you are in a position to implement your idea. Resources represent the fundamental building blocks of your business case. Not all resources, however, are strategically important. While common resources, such as office space, are necessary to carry out most normal day-to-day activities, it is critical resources, such as key technical expertise, that matter most in evaluating the feasibility of your idea.*"[55]

MOMENTUM stakeholders have commented that formulating a business case for telemedicine deployment stems from the degree of cultural readiness in any context that enables people to ask: "Telemedicine: What's in it for me?" A business case can be used by telemedicine champions as a magnet for discussion among, and involvement of, stakeholders. Discussing the benefits and advantages of telemedicine can act as a mechanism for building consensus. As this specific critical success factor on resource aggregation shows, building a business case can help to address *several* critical success factors and mobilise specific resources. Methodologies such as health economics[56] and health technology assessment[57] can help to facilitate the formulation of such business cases.

---

[55] http://www.apsc.gov.au, accessed on 27 October 2014.

[56] A branch of economics concerned with issues related to efficiency, effectiveness, value and behaviour in the production and consumption of health and healthcare http://en.wikipedia.org/wiki/Health_economics, accessed 27 October 2014.

[57] A multi-disciplinary field of policy analysis that studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology http://en.wikipedia.org/wiki/Health_technology_assessment, accessed 27 October 2014. A type of health technology assessment method, called **M**odel for **AS**essment of **T**elemedicine (MAST), has been used in the Renewing Health large-scale pilot http://tinyurl.com/Renewing-Health-Final-Report and is similarly being used in the United4Health project www.united4health.eu, both accessed 27 October 2014.

4 Critical success factors for managing organisational change

This chapter describes systematically each of the critical success factors relevant to managing organisational change. It covers the five critical success factors relating to:

- Primary clients.
- Stakeholder involvement (i.e., involving health professionals and decision-makers).
- Business plans.
- Change management plans.
- Patient-centeredness.

Each description covers the following five domains: the general background to the critical success factors i.e., what each critical success factor means; its underlying objectives; the surrounding context, and any prerequisites; and lessons learned about that specific critical success factor from the in-depth cases investigated. Fifth, if appropriate, useful further background information is included.

4.1 Critical success factor 5: Address the needs of the primary client(s)

This critical success factor is about the issues surrounding addressing the needs of the primary client. The primary client is the key user that has clear incentives to set up and use the service.

Figure 8: Deciding on the primary client.

4.1.1 What the primary client means

Primary clients are people, specialty groups or organisations that have clear incentives to set up, or contribute to setting up, the service or design the tool and have sufficient resources to do so. Primary clients can differ substantially in their characteristics and their needs can be wide-ranging.[58] The primary client is the initial main partner in implementing the telemedicine service or in designing the telemedicine tool and for whom the telemedicine service provided meets its needs.

According to Ed Schein (1999), the primary client can be seen as the ultimate owner of the problem or issue that is being worked on. If primary clients are aware of a compelling, but

---

[58] See especially the relationship with critical success factor 3 on compelling need(s).

unsatisfied, need, they will often willingly and easily accept the changes proposed or adjustments suggested. This means that they are willing to make the effort to change the work process: for example, to achieve better quality and reduced costs.

While further details on primary clients follow, it is also important to understand what a primary client is *not* and how a primary client differs from other actors.

Primary client(s) may be one or more of the following:

- The main partner who is active during the introduction of the service or the design of the tool. A primary client may or may not be the initiator of the new telemedicine service or tool producer, but will be an important actor in the implementation and scale-up process.[59]

- A direct or indirect payer of the service, through either taxes, insurance or business incentives. A primary client may therefore seek to increase process efficiency and effectiveness through the introduction of telemedicine services.

- People or groups whose requirements should be recognised by the telemedicine doer. This recognition should guarantee the closest possible alignment of the services provided with the client that will benefit most from the new service launched.[60] They can help the provider to focus the service or tool on the precise target market. This may help to avoid sustainability problems involving, for example, the provision of the service to too wide an initial group of users or patients.

Three distinctions should be made between primary clients and other actors:

- The service provider or tool producer should *not* confuse the primary client with the customer that will use the service or tool once it has entered onto the mainstream market.

- The primary client is generally *not* the patient, although it is clear that the patient is a very important participant in the process of telemedicine deployment, and – when the service is a provider-patient service – then the patient needs are extremely important. More details on putting the patient at the centre of the service are handled in critical success factor 9 on putting the patient at the centre of the service.

- A distinction must be made between the primary client and the champion (see the critical success factor on champions). The champion is an advocate of the innovation from the service or tool designers´ perspective, whereas the primary client is the partner of the telemedicine doer(s) from the customer´s point of view.

4.1.2 Objectives underlying addressing the needs of the primary client(s)

There are several objectives which support addressing the needs of the primary client. Among the objectives that the telemedicine doer is attempting to achieve are to:

- Optimise adoption on the part of the client (or business) which will benefit most from the new service and which has the willingness to change the underlying organisational or work process.

---

[59] The primary client may at times be described as a "moving target". See sub-section 6.1.5 on further useful background information where it is explained, in stages, how a primary client may change over time.

[60] See sub-section 4.1.4 for examples of primary clients.

- Have a partner which will help to bring the service or tool onto the market and that has a clear incentive to support its use in daily routine. This partner could provide a good example of the value of the telemedicine service when used.

- Avoid provision of the service to customers who might not benefit from the telemedicine at an initial stage. Identifying the primary client appropriately can help to focus the service/tool ultimately on the right user group or the appropriate patient group.

4.1.3 The context surrounding the primary client(s)

There are usually several actors involved in healthcare service provision. The provider of the new telemedicine service or tool should understand two issues: first, the compelling need of the primary client(s); and second, how the telemedicine service or tool helps primary clients to implement that innovation or change.

Understanding different telemedicine service deployment characteristics will help to identify and locate more precisely the primary client(s) and address their needs.

Characteristics: The characteristics that will help in this task of determining the primary client are as follows:[61]

- The spread of the service
  - o When the telemedicine deployment takes place inside the organisation.
  - o When the telemedicine deployment takes place across organisational borders.

- The service type
  - o Provider-to-patient or provider-to-citizen.
  - o Provider-to-provider.

- The socio-economic rationale underpinning the service
  The business case or socio-economic rationale that motivates the deployment of the service is defined by
  - o A public authority which aims at deploying the service for the benefit of a local, regional or national healthcare system.
  - o A telemedicine provider company or healthcare organisation aiming at deploying the service for its own purpose or commercial use.

- The role of the commercial partner in the service.

Prerequisites: Among the prerequisites relating to primary clients are that telemedicine doers have either (i) to be aware of the needs that the clients have[62] or (ii) to validate the assumptions about these needs with the provider of the telemedicine service or tool.

Primary clients should be recognised as a representative case[63] by the other stakeholders in

---

[61] See also in ANNEX, an overview of telemedicine systems' characteristics.

[62] See therefore critical success factor 3 on compelling need(s).

[63] By representative case, it is meant a "trial case" or a "pilot case". The primary client will be the first group of clients on whom the service is tested or tried out. The service is likely to be expanded to other clients at a later stage of expansion or deployment. The more clearly the roles of the various stakeholders in the system are clarified at an early stage of development, the more effectively the actors involves are likely to interact and understand each others' roles.

the process of telemedicine deployment.

Primary clients have to have sufficiently clear characteristics that they can be differentiated from – and not mixed up with – other possible actors. Primary clients have to have a clear role in the specific telemedicine service that will offer them significant benefits.

4.1.4 Lessons learned from the cases on primary clients

All the in-depth MOMENTUM cases explored show that the successful implementation of a telemedicine service requires finding a partner (i.e., a "primary client") who has the incentive to have the service implemented and who also has sufficient resources to contribute to it.

In the Maccabi and Patientenhilfe cases, the primary client was an insurance company. In the RxEye, Teledialysis and KSYOS cases, the telemedicine service providers worked with healthcare organisations that needed specialist consultants as their primary clients. KYSOS decided to focus on dermatologists, first, as the primary client(s) before the company spread its approach to general practitioners. KYSOS also mentioned that expansion abroad would demand a (re)definition of the primary client(s) according to the local circumstances in the case of each country involved. In the ITHACA and Puglia telecardiology cases, the primary clients were a public healthcare service provider whose incentives were to improve service quality and effectiveness. In the ITHACA case, in addition, a pharmacy company and the technology partner were interested to see how the service fitted their particular market.

In none of the cases analysed did a provider market the service directly to the final beneficiary, i.e., the citizen or the patient.[64] Rather, the provider went to market by finding a partner that had a clear incentive to act, had sufficient resources to implement the service, and had an in-depth knowledge of the potential end-user group.

From the analysis of the MOMENTUM cases, when telemedicine service providers or tool designers scale up the production of their tool or service, finding the right primary client appears to be an underemphasised, although very important, factor. It shows that, for the telemedicine service provider, it can be a complex task to locate *the* appropriate primary client from among the large number of actors involved in the care process.

4.1.5 Further useful background information on primary clients

As discussed in Deliverable 5.1, there are three types of stakeholders in healthcare: the patient/citizen, the healthcare provider,[65] and society.

The telemedicine service can do two things. It can:

- Address and benefit all three stakeholder groups.[66]
- Concentrate on the benefits to one of the stakeholders.

Several issues are of importance: diversity, stages of the telemedicine process, first users,

---

[64] It has been suggested that this could be one of the reasons why so many telemedicine initiatives never "fly" or advance to scale. Particularly in terms of provider-patient services, it could be worthwhile spending more effort on finding directly what added value patients or citizens gain from the use of a new telemedicine service.

[65] The role of the payer needs also to be distinguished.

[66] This would, however, be a very unusual situation because of the complexity of telemedicine services.

and the difference between primary clients and patients.

Diversity: The diversity in circumstances surrounding telemedicine makes it complicated to understand precisely who or what is the party that will benefit the most from the proposed telemedicine service.

Stakeholder recognition: This issue of stakeholder identification emphasises the importance of differentiating between a telemedicine service's primary client or *other* clients, and beneficiaries, and recognising correctly which among them are most critical at the service's implementation stage.

Stages: A primary client should be understood as *the* most important partner for the telemedicine provider during the implementation stage of the tool or service. The primary client may perhaps differ at the piloting phase, and may also change by the time the large-scale implementation phase is reached. For example, as described in the KSYOS implementation case, the primary client was initially a set of dermatologists. Once the service had been accepted by the dermatologists, general practitioners were then included in the service provision. In the scaling-up phase, general practitioners became the primary clients: this was because they were the partners who were able to expand the use of the service.

First users: The role of the primary client is to be the first user and advocate of the telemedicine service or tool outside of the telemedicine provider organisation. The person or organisation which is the primary client will be *the* party which is first motivated to accept provision of the service or the introduction of the tool. The primary client offers initial objective feedback to the provider on the use of the service/tool and how to improve it.

Patients: The concept of the primary client should not be confused with that of the patient. The ultimate goal of any medical service, including telemedicine, is to improve individuals´ health outcomes directly or indirectly. There might be one, or indeed several, clearly defined beneficiaries of the particular telemedicine service in addition to patients.

4.2 Critical success factor 6: Involve healthcare professionals and decision-makers

This critical success factor describes the issues surrounding involving healthcare professionals and healthcare decision-makers. These two sets of actors play the most important role in terms of the changes to be made to the organisational, workflow and work structure, and economic components of the new telemedicine system or service.[67]

---

[67] It is this type of actor that the TREAT assessment model deals with, and presents a method for enabling them to assess the organisational background to their specific telemedicine setting in a shared, collaborative workshop environment. For how MOMENTUM and TREAT have joined forces, see the deliverables D3.3 and, eventually D3.4, that describes the MOMENTUM test phase and validation of its methods.

From a sociological perspective, the use of telemedicine implies a power shift for many of the actors involved, whether policy-makers/decision-makers, healthcare professionals, and also patients and their families. These shifts need more sophisticated examination than has taken place to date.[68]

Figure 9: Involving decision-makers and healthcare professionals.

4.2.1   What involving healthcare professionals and decision-makers means

This critical success factor includes actions that help healthcare professionals and decision-makers to:

- Collaborate in developing, and accept modifications in the usual way of delivering care as a result of a new service.
- Act as advocates for the innovation.

This critical factor deals with the larger group of healthcare professionals and decision-makers than does critical success factor 5 on meeting the needs of the primary client. This involvement occurs *after* the initial decision to implement the new telemedicine service or

---

[68] Various options and movement are feasible. On the one hand, one could foresee that this shift could create more work for healthcare providers. Thus, it could pose an additional burden on their activities, and could even raise the costs of running healthcare and medical care (for example, through greater demand for second opinions, provision of more explanations to patients about health-related information that patients have uncovered themselves). On the other hand, patients themselves may do part of the work previously undertaken by healthcare professionals (e.g., recording data, keeping records), and thereby either reduce healthcare costs or lead to a slower rise in costs.

tool has been taken.[69]

This process engages both healthcare professionals and decision-makers who are affected by the new telemedicine service.

Depending on the type of telemedicine service to be deployed, the targeted healthcare professionals can vary, i.e., they can be physicians, nurses, or other specific groups of professionals. Decision-maker groups involve various levels of managers: for example, policy-makers or politicians; health plan leaders; or hospital, clinic or organisational department heads. They can include chief medical officers; chief executive officers; chief nurses; or chief information officers.

More precisely, the following healthcare professionals and healthcare decision-maker groups can be highlighted:

- Professionals (such as radiologists, pathologists and dermatologists) employed by the healthcare organisation which <u>buys</u> the telemedicine service.
- Professionals (such as radiologists, pathologists and dermatologists) employed by the healthcare organisation which <u>provides</u> the telemedicine service.
- Decision-makers (such as chief executive officers or chief information officers, and heads of department) in the healthcare organisation which <u>buys</u> the telemedicine service.
- Decision-makers (such as chief executive officers or chief information officers, and heads of department) in the healthcare organisation which <u>provides</u> the telemedicine service.

Healthcare professionals are often neither the decision-makers nor the target group for the telemedicine service implementation. However, healthcare professionals do need to be involved properly in the implementation process since they are often informal organisational leaders and decision-makers.

The involvement of healthcare professionals as telemedicine system users is extremely important: it can be highly beneficial, indeed critical, in gaining their acceptance and feedback in order to make further improvements to the service.

On many occasions, the early involvement of healthcare professionals, including nursing staff, enables adoption barriers to be properly addressed, and helps to avoid or reduce risks.

4.2.2   Objectives underlying healthcare professionals and decision-makers

The objectives behind involving healthcare professionals and decision-makers are to:

- Guarantee that the telemedicine service is properly designed in line with the specific needs of healthcare professionals and provider organisations.
- Engage healthcare professionals in the designing and implementation process in a timely way.
- Satisfy the needs of decision-makers such as the chief medical officer, chief executive officer, chief nurse, or chief information officer.

---

[69] Other commentators believe that the scaling up of a service needs active stakeholder involvement along the path of continuous development of the service, including patient engagement.

- Ensure alignment with the service's IT governance.

4.2.3 The context surrounding healthcare professionals and decision-makers

The context surrounding the Involvement of healthcare professionals includes analysing the potential impact of the new service on daily routines, informing people about the planned intervention and any future potential changes, and specifying professionals´ expectations of the innovation.

There is considerable debate about how the involvement of healthcare professionals should be handled, since – while the professionals may wish to be assured that the planned telemedicine service will not increase their workload or decrease their income – this may ultimately not be the outcome in all cases.

Decision-makers should be assured that investing into the new service will bring clear benefits for them such as increasing efficiency, improving care quality or helping to cope with human resources.

Prerequisites: The main prerequisite in terms of this critical success factor is to understand and be aware of the existence and definition of different healthcare professionals influenced by the new telemedicine service or tool. Different professional groups often have different motivations for being involved in the telemedicine adoption process. Even healthcare professionals who belong to the same profession, such as physicians, could have different incentives and expectations about telemedicine depending on their position or subspecialty: for example, in the case of radiologists as compared to teleradiologists.

As a prerequisite, the organisational structure of the new telemedicine service should be analysed to identify what organisations and actors are involved.

The involvement of professional societies, associations and organisations in this process could improve the involvement and acceptance of healthcare professionals.

4.2.4 Lessons learned from the cases on healthcare professionals and decision-makers

All the MOMENTUM in-depth cases included the activity of addressing healthcare professionals and decision-makers. However, the groups that were involved differed in the various cases.

In the Maccabi, Teledialysis, ITHACA, Patientenhilfe and Cardio On Line Europe cases, the new telemedicine service was implemented inside one organisation:

- In the Maccabi and Patientenhilfe cases, the organisation was a health plan/health insurer.
- In the Teledialysis, ITHACA and Cardio On Line Europe cases, the initiator was the healthcare organisation itself.

In all of these five cases, the service was designed and implemented in close cooperation with different healthcare professional groups and healthcare decision-makers. All parties involved were interested to implement the innovation inside the organisation, and the focus was on the change management process.[70] Accordingly, among the healthcare professionals, the risk of losing their position or job was very low. From the healthcare decision-makers' point of view, the risk of failure was also low because each service was

---

[70] See the later description of critical success factor 8 on change management plans.

developed iteratively hand-in-hand with professionals from their own organisations. The opportunity to return to the former work routines was present, and there were no noteworthy negative consequences.

- In the RxEye and KSYOS cases, the new telemedicine service was designed for service provision between healthcare organisations.

These teleradiological (provider-to-provider) types of service provision included stakeholder groups that were at risk of seeing their working conditions significantly modified, at least potentially.

4.2.5 Further useful background information on involving healthcare professionals and decision-makers

In terms of general background matters at stake when involving healthcare professional and decision-makers, several issues are of importance. They include the following three issues of: who to involve; using what incentives; and at what precise time.

Who to involve: This particular set of activities in terms of who to involve varies from case to case. Three types of service provision and stakeholder group can be mentioned:[71]

- Services provided inside one healthcare organisation and involving professionals and decision-makers only from that organisation, whether it is a hospital, health plan/health insurer or healthcare district.

- Services provided between different organisations and involving professionals and decision-makers from several organisations, each of them with their own agenda.

- Several stakeholder groups (such as clinicians, nurses, general practitioners, and other specialists) that have different incentives and experience different anxieties.

Incentives: Overall, the incentives offered to the various stakeholder groups differed substantially in the in-depth MOMENTUM cases. The involvement of the different professional groups required a good understanding of the needs of each group and thorough planning of the design and implementation techniques.

Timing: Timely involvement of the healthcare professionals and decision-makers speeds up the design and implementation process of a new telemedicine service, even if this seems to absorb or involve additional time at the start of the process. Involvement of different healthcare professionals and decision-maker groups helps them to collaborate in the development process, and to accept modifications to their usual way of delivering care as a result of a new service once it is introduced.

These three issues are related substantially to the processes of organisational change. Hence, it is also worthwhile reading critical success factor 8 on change management in this regard.

4.3 Critical success factor 7: Prepare and implement a business plan

This critical success factor describes the issues surrounding the process of preparing and implementing a business plan.[72] The two critical success factors 7 and 8 relating to business plans and change management plans should be read in close relationship to each other.

Figure 10: Implementing a business plan.

4.3.1 What preparing and implementing a business plan means

A business plan is a written document which results from the careful analysis of available data. It describes the planned telemedicine service, its expected sales and marketing strategy or – if it is not a commercial service – deployment strategy, and financial questions. It takes into account the appropriate reimbursement scheme. It contains a cost and benefit analysis. In the case of large-scale telemedicine deployment for the purpose of a healthcare system, it also includes a socio-economic analysis.[73]

A business plan for the new telemedicine service has to be in place even when the service will be provided by a non-profit or a governmental organisation. The University of Alaska (Foster et al., 2006) has provided arguments that a good business plan encourages a service provider or a tool producer (i.e., a telemedicine doer) to think about who is the potential customer for the telemedicine service, what elements the customer values, what are the underlying economic conditions, and how value can be delivered to customers at an appropriate cost.

A business plan for telemedicine service provision or tool production can include, but is not limited to, a wide range of components (American Telemedicine Association (ATA) (2011)):

- Executive summary.

---

[72] A business plan also include a financial plan, and therefore also incorporate issues related to the reimbursement of telemedicine service.

[73] Socio-economic analysis is much broader than cost-benefit analysis as it aims at quantifying the indirect social and economic impacts of the large-scale service deployment.

- Introduction and background.

- Needs and demands assessment.

- Services plan or tool description document.

- Internal and external assessment (e.g., a strengths, weaknesses, opportunities and threats (SWOT) analysis).

- Marketing plan.

- Technical plan.

- Regulatory environment.[74]

- Management plan.

- Financial plan.

- Presentation(s) to stakeholders.

- Training and testing.

- Operations plan.[75]

- Evaluation feedback and refinement.

- Conclusion and recommendations.

In a business plan, it is particularly important to describe the paying customers, the revenue model, the customer value proposition and service levels, existing solutions, competitive advantage, any hurdles that need to be overcome, and the resources required.

4.3.2   Objectives underlying preparing and implementing a business plan

Having a business plan helps to define clearly the service objectives and its value for each stakeholder. This in turn helps to obtain the necessary support or the resources needed to start to deploy the service or develop the tool. Therefore each stakeholder's requirement needs proper assessment.

The business plan contributes to separate, and integrate, the actual telemedicine service from other similar services provided in the same domain.

A business plan is a critically important tool for ensuring the sustainability of a telemedicine service. All the relevant costs are considered in a business plan, and a cost-benefit analysis is done to check the validity of the investment required. The payer of the service or tool is defined depending on the characteristics and attributes of the reimbursement system, whether it is, for example, a Beveridge-style or a Bismarckian system or the costs are paid out-of-pocket. Additionally, a timetable is defined and validated by all the relevant stakeholders, including the healthcare professionals.

4.3.3   The context surrounding preparing and implementing a business plan

The business plan should consider the applicable business model in its surrounding context, i.e., whether the service is a publicly/privately funded service, for profit or not-for-profit, for

---

[74] The critical success factors relating to the legal, regulatory and security issues are useful in this regard. The legal aspects of data storage and retrieval are important.

[75] Operationally, organisations and businesses need to understand the increase in data, its storage and retrieval, that is being generated by telemedicine services).

the purpose of the organisation or the healthcare system.[76]

It should not matter whether the telemedicine service is provided by a non-profit or a governmental organisation or a commercial/for-profit one: in either case, having a business plan enables thinking about who is the potential customer for the telemedicine service, what elements the customer values, what are the underlying economic conditions, and how value can be delivered to customers at an appropriate cost.

Prerequisites: Preparing a business plan requires knowledge of the existing market of medical services. Opportunities to serve underserved patients, healthcare providers and healthcare managers should be clearly identified.

The telemedicine service provider which is preparing the business plan has either to be a legal entity in its own right or a clearly defined entity within the organisation that takes the responsibility for executing the business plan.

4.3.4   Lessons learned from the cases on preparing and implementing a business plan

Among the MOMENTUM cases, the RxEye company prepared a comprehensive business plan before scaling up its service.

In the ITHACA service, a functional plan was initially drafted to describe the intervention design, set the patient target, inclusion and exclusion criteria and size the service requirements. The joint initiative with Novartis and Indra required a detailed business plan that was built on the original functional plan.

Preparation of a sort of business plan was part of KSYOS service implementation.

All the components of a business plan were prepared in the Maccabi case.

In the three other cases, the implementation plan included parts of a business plan, but a business plan per se was not prepared.

Therefore, it can be concluded that, in all the cases, at least some of the components of a business plan were included in their activities, and were considered as important issues. However, a comprehensive business plan was prepared only in that case – RxEye – where there was a need to bring resources from outside the telemedicine service-providing organisation.

The preparation and implementation of a business plan is not part of the usual tasks or skill sets required in many healthcare organisations (this observation also applies to the telemedicine services designed and implemented as supportive services for traditional diagnostic, treatment and care pathways). However, before designing and implementing a new procedure or process it is of the outmost value to think through the entire concept thoroughly beforehand.[77]

With regard to the MOMENTUM cases, healthcare organisations seemed to prefer to undertake general financial planning for the telemedicine service rather than analysing all

---

[76] See also critical success factor 5 on the primary client and, in ANNEX – An overview of the telemedicine systems' characteristics.

[77] Many stakeholders in the healthcare field are probably not used to talk about business plans or change management plans. Yet, they do understand the need for planning in advance. Intuitively, they probably also see the need to address what change means to people and how to a meet such change.

the components of a business plan.

However, analysing these seven cases reveals that, by looking at the telemedicine service development and implementation process from a wider perspective, customer needs could be understood better and more effective scale-up of the service could be fostered.

Cases that prepare proper business plans may have a better potential to grow outside the organisation and be traded on the healthcare market.

4.3.5   Further useful information on preparing and implementing a business plan

It is argued that creating a business plan – based on a solid business case – can help to facilitate the degree of cultural readiness for stakeholders who might ask "What's in it for me?" Champions can use the business plan or business case as a magnet for increasing the degree of support for telemedicine. Stakeholders may use the case/plan to build a consensus about the meaning of telemedicine, and the mobilisation of resources to support telemedicine in general. See therefore also specifically the arguments presented in critical success factors 2 and 4.

In the face of a lack of evidence in the MOMENTUM in-depth cases for providers to develop specific and comprehensive business plans, there is – as a result – some indication that the need to have a proper business plan could be among *the* most important critical factors in deploying telemedicine further.

For a telemedicine service, writing a business plan is not necessarily easy. However, it provides a worthwhile initiative in terms of involving stakeholders who need to be conscious of the risks that are implied when deploying a service.

Tools and techniques: In addition to writing a business plan, telemedicine doers could benefit from being aware of the existence of different maturity models (van Dyk et al., 2013) and telemedicine assessment tools such as ASSIST[78] and MAST[79].

In the Region of Veneto, Italy, the Business Model Canvas developed by Alexander Osterwalder[80] was recently used to support the decision processes in the deployment of a telemedicine service for patients with chronic heart failure[81].

4.4   Critical success factor 8: Prepare and implement a change management plan

This critical success factor describes the issues surrounding preparing and implementing a change management plan. The two critical success factors 7 and 8 relating to business plans and change management plans should be read in close relationship with each other.

---

[78] ASSIST is an example of a method for assessing cost and benefit analysis and socio-economic impact of telemedicine services. URL: http://www.assist-telemedicine.net/home/ accessed 27 October 2014.

[79] MAST stands **M**odel for **AS**sessment of **T**elemedicine.
URL: http://www.renewinghealth.eu/en/assessment-method, accessed 27 October 2014.

[80] URL: http://en.wikipedia.org/wiki/Business_Model_Canvas for a short presentation of the Business Model Canvas tool, accessed 27 October 2014.

[81] A video of a presentation was made of Claudio Saccavini, from Arsenal IT in the italian Veneto Region, who reported on the use of the Business Model Canvas to support the decision process when deploying a telemedicine service for patients experiencing chronic heart failure.
URL: http://tinyurl.com/YouTube-RH-Claudio-Saccavini, accessed 27 October 2014.

Figure 11: Preparing and implementing a change management plan.

4.4.1   What preparing and implementing a change management plan means

Implementation of new technology into the daily routines of healthcare professionals always affects work habits and the traditional care pathways. A change management plan enables healthcare professionals to understand these changes and accept innovation in their daily work. It also allows non-healthcare professionals, for example, personnel responsible for invoicing processes or data collection or data follow-up, to understand the organisational changes.

This critical success factor is therefore about preparing and implementing a change management plan to simplify and facilitate the adaptation to any new telemedicine service.

A change management action plan may include a range of potential activities, such as:

- The preparation of the change management plan for each department affected by the deployment of telemedicine.

- An explanation of the reasons for the changes.

- The addition of extra resources during the transition phase.

- Support for the telemedicine service to be located in an appropriate position within an existing care pathway.

- Anticipation and counteraction of any challenges that prevent seamless implementation of the telemedicine service into the existing workflow.

- Identification of training and capacity-building needs.

- Development of a communications strategy and communication plan for in-house use as well as for public use, covering different communication channels such as emails, seminars, internal news as well as public news in the wider media.

The new telemedicine service changes' requirements are to be assessed and compared with actual service processes i.e., not telemedicine processes.[82]

There may even be a need for several change management plans, as they may be required to cover various phases of the implementation process.

In a change management plan, the service maturity of the telemedicine service also has to be assessed. This will help to avoid the telemedicine service delivery process or tool production either falling back towards a pilot phase or ceasing real-life production.

As a result, the main modifications to routine care should be addressed by a change management plan that involves all relevant stakeholders, including healthcare professionals.

4.4.2 Objectives underlying a change management plan

A change management plan supports the transformation of the organisation and working processes. Telemedicine introduces changes to the work of healthcare professionals. Yet business operations will also be different from the previous care pathway.

Having such a change management plan ensures that the new telemedicine service can be integrated well into the ordinary routine of the organisation and will not disrupt the care delivered to patients.

By identifying training and capacity-building needs, a change management plan helps to ensure that the new telemedicine service is implemented successfully for healthcare professionals and customers, including patients. The aim is to use a minimal level of resources to guarantee that all stakeholders are aware of these changes and are prepared for them.

A change management plan can make potentially troublesome new interactions and transactions between different stakeholders/parties more acceptable. It encourages the telemedicine service clients to become accustomed to the new type of service or tool and its differences from the medical service or tool that was used previously.

4.4.3 The context surrounding a change management plan

The change management plan itself, and the phasing of the implementation of the service or tool production, can differ depending on whether, for example:

- The service is deployed inside the organisation, between organisations, across the borders, between the organisation or healthcare system and citizen.
- The service is a for-profit or non-for-profit service.
- The new service or tool changes the care pathway, and how.
- The different medical specialties involved.

Prerequisites: A change management plan demands the identification of issues that are

---

[82] The way of undertaking the service, when using more ICT, or more advanced ICT, should be described in comparison to the way it was done previously. This would help to incorporate the need to educate the staff, provide technical service support, allow for "escape routes" if the new service were to break down for a period. Such a process will also make clear the occasions when a fundamental reengineering of a process is needed, and when the telemedicine is just one tool among many. Telemedicine should not support an old-fashioned way of working or undertaking a task that should be removed because it does not add value to either the patient experience or the outcome.

pertinent to the main stakeholders *before* the implementation of the telemedicine service. This includes identification of business processes and the role of telemedicine in them. Understanding what business segment, and to what extent, the new telemedicine service will change current medical service is important.

A change management plan should also include a budget for communication activities: this communication budget could form part of the business plan.[83]

4.4.4 Lessons learned from the cases on preparing and implementing a change management plan

Based on an analysis of the MOMENTUM cases, this critical success factor appears to be an umbrella term for several activities necessary to make change management as acceptable as possible to the different stakeholders in the process.

In none of the seven MOMENTUM in-depth cases was a written change management plan prepared or implemented. Instead, to simplify and facilitate the adaption of new telemedicine service, the telemedicine service providers implemented components of a change management plan incrementally according to the progress of the change and observed findings.

The change management activities differed from case to case depending on the type of the service and stakeholders involved in the service.

The two most commonly used actions were training and communications.

The training of healthcare professionals was undertaken in six cases. However, the target groups, the training subject, and the extent of the training differed from case to case.

- In provider-to-provider services (such as RxEye and KSYOS), measures to facilitate change management were targeted to avoid reluctance on the part of the healthcare professionals and to communicate about the service to healthcare decision-makers.

- In provider-to-patient services (such as Maccabi, Teledialysis, ITHACA, and Patientenhilfe), a lot of effort was put into the training of healthcare professionals so that they could use telemedicine tools properly and find patients who would really benefit from the new service.

A communication strategy was the second most frequently mentioned activity in the change management domain.

In addition, in the Maccabi case, the importance of taking clear responsibility for the service and the back-up of senior management in managing the change was highlighted.

To summarise, no MOMENTUM cases were found where a written change management plan was actually prepared. Instead, incrementally telemedicine service providers implemented training, capacity-building, a communication strategy, and other measures, according to the progress they made in the development of their service. Sometimes, the element of a change management plan which would generally plot out the management of the transition phase was either not needed or was organised in an ad hoc way.

---

[83] See critical success factor 7 on the business plan.

4.4.5 Further useful information on preparing and implementing a change management plan

Useful materials and documentation are available from associations like the Association of Change Management Professionals and Canada's Infoway.

- Association of Change Management Professionals (ACMP): www.acmpglobal.org
- Managing eHealth Change: A Pan-Canadian Collaborative Approach: https://www.infoway-inforoute.ca/index.php/resources/toolkits/change-management/methodologies-and-approaches/further-reading/cat_view/2-resources/83-toolkits/99-change-management/103-methodologies-and-approaches/129-further-reading?limit=5&limitstart=0&order=date&dir=ASC

4.5 Critical success factor 9: Put the patient at the centre of the service

This critical success factor describes the issues surrounding putting the patient at the centre of the service. It also draws some attention to user-centeredness in the case of provider-to-provider services.

Telemedicine services can benefit patient involvement in their own healthcare, and can also be of benefit to their families, and both informal and formal carers.

Patients and their families are also a great resource in seeking to improve health services further, i.e., in terms of "crowd sourcing" ideas to develop initiatives to bring them to new levels of quality and performance.

Figure 12: Putting the patient at the centre.

4.5.1 What putting the patient at the centre of the service means

Putting the patient at the centre (or patient-centeredness) means developing the service

with the patients' perspective in mind.

Patient-centeredness is a strategy to improve the fit of services to patients´ actual needs. The importance of citizen or patient satisfaction in the design and implementation of the telemedicine service is absolutely within the scope of the work of telemedicine service or tool developers.

This critical success factor is related to the design phase of the telemedicine intervention. It takes into account the values of the culture, the personal and social needs of the users, and the users' comfort level with the different forms of interaction both face-to-face and virtual.

It seeks to strengthen the human relationship and not to depersonalise it.

Many telemedicine initiatives are starting to address this issue.

4.5.2   Objectives underlying putting the patient at the centre of the service

The objective of this critical success factor is to address a common anxiety on the part of systems' future users: that the technology may replace a human being.

The objective of telemedicine doers is to ensure that user needs and preferences are identified and are taken into account in the design phase of the service.

In conceptualising the service and enlisting support for it, telemedicine doers need to emphasise that the objective of the service is to enable, improve and support human interaction and not replace it.

4.5.3   The context surrounding putting the patient at the centre of the service

Patient-centeredness is much more of an issue in patient-oriented telemedicine services than in provider-to-provider services, although it is also not negligible in the latter.

This critical success factor is relevant to services at both the healthcare system level and the organisational level.

Patient-centeredness is relevant in both public and private settings.

Characteristics: The characteristics of patient-centeredness may differ according to whether the service is a provider-patient or a provider-provider one. For example, in a provider-patient service, a patient-centeredness approach implies that the technology is intended as an enhancement of the personal relationship between the caregiver and patient,[84] not a substitute for it.

- A patient-centred service can be multi-channel, and can include face-to-face physical visits as well as the use of multiple technologies, such as telephones, videoconferences, emails, communications via a web portal or even letters. The technology is perceived as an enabler that facilitates efficiency benefits, but also

---

[84] In reality, processes are likely to change. A comparable service would be that of self-banking or home-banking. For patients or people in general, appreciated services would probably include being able to check the details in their own medical data or personal health records. Patients would not be likely to consider that they necessarily need do this together with (i.e., in interaction with) a nurse or a doctor. Instead, they would do so from a comfortable location at a convenient and appropriate time, such as in their own home. Similarly, undertaking financial transactions – such as paying bills or checking the balance on a savings account – can be undertaken at times of comfort and convenience without bank customers having the sense that this activity has "separated" them from the individual(s) at the bank whom they consult when they have more complex financial items to discuss.

strengthens the therapeutic relationship between the patient and the healthcare team.

- In the case of provider-provider telemedicine, the technology enhances the collaboration between the people involved in the system and also allows for multi-channel communication including face-to-face team meetings when necessary.

Overall, patient-centeredness may be seen as a consequence of the new service being introduced, i.e., patients benefit either from better or more accessible care.

Prerequisites: The prerequisite for this success factor to function is that its context involves human interaction as an integral and essential element. Human needs should be identified in the particular situation, and insights into how these needs may evolve over time.

4.5.4 Lessons learned from the cases on putting the patient at the centre of the service

Putting the patient at the centre of the service was directly or directly evident in all seven MOMENTUM cases.

The issues surrounding putting the patient at the centre of the service depend on the service type, such as:

- Telemedicine service provided from the healthcare provider to the patient.
- Telemedicine service provided from the healthcare provider to another healthcare provider.

In the case of a provider-to-patient service, the patient is directly influenced by the telemedicine service components. In that case, the emphasis of the service is more on assuring that the technology would not replace human interaction. For example:

- In the Maccabi case, each nurse in the telemedicine centre has her own group of assigned patients for whom she is responsible. In this way, the service enhances and strengthens the therapeutic relationship with the healthcare team and does not replace it.

- In the ITHACA case, patient-centeredness was addressed using communication channels via web, phone, and paper complementary to telemedicine that supported the inclusion of all groups of patients regardless of their level of computer skills.

- The Patientenhilfe service provided a complementary service to face-to-face meetings with doctors. Patients were stratified according to their health status so as to ensure that individualised care is provided.

In all provider-to-patient service MOMENTUM cases, important features included the design of the user interface and easy-to-use technology.[85]

In the case of a provider-to-provider service, patient-centeredness was achieved indirectly by improving the care quality to patients or by providing patients with quicker access to the care.

---

[85] In terms of easy-to-use technologies, initiatives such as that of PatientView (Newbold, 2014) are increasingly focusing on the kinds of guidelines to present direct to patients on the use of e.g., mobile applications (apps).

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

This chapter describes the critical success factors relevant to the legal, regulatory and security perspective. It covers the four critical success factors relating to:

- Legal and security conditions.
- Legal and security guidelines.
- Legal and security experts.
- Privacy awareness.

Each description covers the following five domains: the general background to the critical success factors i.e., what each critical success factor means; its underlying objectives; the surrounding context, and any prerequisites; and lessons learned about that specific critical success factor from the in-depth cases investigated. Fifth, if appropriate, useful further background information is included.

5.1 Critical success factor 10: Assess the conditions under which the service is legal

This critical success factor describes the issues surrounding assessment of the conditions under which a particular telemedicine service is legal.

5.1.1 What assessing the conditions under which the service is legal means

This critical success factor gives telemedicine doers an understanding of the degree of latitude they have to take action when developing a new telemedicine service.[86]

Assessing the conditions under which the specific telemedicine service is legal is about finding out:

- Whether the telemedicine service is regarded by the authorities[87] as an appropriate way to offer healthcare services.
- The circumstances under which the telemedicine service is regarded as legal by carrying out a "legal risk assessment".[88]

---

[86] The issues of concern here were first raised in the section of the deliverable on strategy and management e.g., first, the relative newness of telemedicine services and the implications this has for the need for the gradual, on-going, revision of legislation, whether at European or a national levels; second, the reality that, in many cases, there is currently in some jurisdictions no specific legislation that would impede, prevent, or act as a really significant barrier to telemedicine deployment; and, third, overall, a significant learning process is currently underway in terms of deploying telemedicine.

[87] The authorities involved can be of different sorts and levels. They can be located in the European Union and countries geographically close to the Union, and/or countries that are in the European Economic Area. Example authorities include both healthcare authorities and social care authorities.

[88] A legal risk assessment is a process that runs parallel to an information security risk assessment. Possible legal hindrances ("risks") are identified, and measures are planned and then carried out so as to avoid risks and/or mitigate them, cf. the section on the critical success factor related to the involvement of legal and security experts.

- Whether the telemedicine service is covered by law, and if it is not inhibited by law or by bodies with competence in the telemedicine field.
- Whether the telemedicine service is in accordance with general requirements for best practice in medicine.

It is also important to understand the objectives that underpin this critical success factor.

5.1.2 Objectives underlying the conditions under which the service is legal

There are two main objectives supporting this critical success factor:

- The first is to ensure that any personnel involved in the telemedicine development process can be assured that they are providing a legal telemedicine solution.[89]
- The second is to avoid any waste of resources (and any risk of decreased enthusiasm among the telemedicine doers and users), if it were to turn out that the proposed telemedicine service is likely to be illegal.

Both are important objectives.

5.1.3 The context surrounding the conditions under which the service is legal

Depending on the surrounding context of the planned service, various assessments of the conditions under which a telemedicine service is legal must be undertaken. There are two main contextual elements to be explored. The first is whether the telemedicine service is a medical act or not. The second relates to the sharing of patient information. Both are explained below.

Is the telemedicine service a medical act?

It is of great relevance whether the telemedicine service is regarded as a medical act[90] (eHSG, 2014[91]) or not. Current considerations differ from country to country depending on how a medical act is defined in the various national health legislations. If the telemedicine service is recognised as a medical act, legislation applicable to medical acts apply to the service in addition to other relevant legislation.

This non-exhaustive list of questions is of relevance for this legal assessment:

- What is the purpose of the service (i.e., how does it fit with the definition of a medical act)?
- What kind of health profession delivers the service?
- Who are the participants/parties involved in the service (e.g., is it a doctor-to-doctor (D2D) service or is it a doctor-to-patient (D2P) service)?

---

[89] This would include those who are legally liable for providing health or care services.

[90] "*The medical act encompasses all the professional actions, e.g. scientific, teaching, training and educational, organisational, clinical and medico-technical steps, performed to promote health and functioning, prevent diseases, provide diagnostic or therapeutic and rehabilitative care to patients, individuals, groups or communities in the framework of the respect of ethical and deontological values. It is the responsibility of, and must always be performed by a registered medical doctor/ physician or under his or her direct supervision and/or prescription*." (UEMS, 2009)

[91] Note that all abbreviations used in reference to the supporting literature are made clear in the bibliography. All acronyms and abbreviations are also detailed in the deliverable's glossary.

Is there relevant legislation related to the sharing of patient information?

There may be legislation in the country that covers the sharing of patient information. It could relate to geographical or organisational levels across borders that are national, regional or organisational.

Prerequisites: It is a prerequisite that the telemedicine service is legally authorised. The notion of legal authorisation has three aspects:

- Legislation and regulations in the field must make it clear that telemedicine is a legitimate way to deliver healthcare.[92]

- Legislation and regulations in the service provision field must avoid provisions that prohibit or inhibit the delivery of healthcare via telemedicine generally, either directly or indirectly.

- The attitude of the relevant authorities must state or imply that telemedicine is accepted and wanted.

These prerequisites can be either or both country- and system-dependent.

5.1.4   Lessons learned from the cases on whether the telemedicine service is legal

Legal and security issues were not reported to cause problems in any of the seven MOMENTUM cases, although all the case study representatives agreed that these issues had had to be discussed. There was agreement that it is important to handle these issues, but that the right time at which they need to be addressed varies from case to case.[93]

Three of the cases help with the notion of lessons learned, in terms of timing and phasing:

- In the Maccabi case, this investigation had already been done by the time the service was set up (i.e., the investigation had been undertaken for an earlier Maccabi service).

- In the KSYOS case, legal issues were taken care of relatively late in the development process, in what the company calls its scale-up phase. In the other cases in which legal issues were described, these aspects were investigated at the outset.

- In the Teledialysis case, legal and security matters were handled from the start: at later stages, they were dealt with whenever they were needed during the development and implementation phases.

MOMENTUM has not investigated in-depth the notion of timing in either its case study work or its investigation of each critical success factor. The timing issue is, however, raised briefly in the sub-section that follows on further useful background information.

---

[92] The service should be organised in a way that is in accord with requirements for responsible conduct and/or best practice.

[93] In the seven in-depth MOMENTUM cases described in detail (see in the associated attachment to this report), the timing of the investigation of the circumstances under which the service is legal has differed. It has varied from being clarified *before* the implementation of the service (e.g., Maccabi) to taking place relatively *late* in the process (e.g., the KSYOS case). In the other cases, legal and security clarifications took place at an early stage of telemedicine deployment and were then repeated later, when needed.

5.1.5 Further useful background information on whether the service is legal

Three further issues have emerged as a result of MOMENTUM's literature search as well as through observations provided by the consortium members. They are:

- Whether legislation constrains the implementation and use of telemedicine.
- How public authorities can be influenced positively so that they can eliminate any legal constraints.
- The precise timing at which a legal risk assessment should take place.

These three matters are described here.

Does the relevant legislation imply in practice constraints for the implementation and use of telemedicine?

The legal situation in certain countries implies that there are restrictions in the use of certain tele-services in the healthcare sector. Among the example countries are France, Germany, Poland, and Malta. For example,

> "*In Germany, a professional code of conduct – enforced by court rulings – exists that does not allow [one] to [undertake] a standard patient encounter in ambulatory care over distance – thus preventing certain types of tele-services to operate within Germany.*"[94]

Poland and Malta also experience extensive constraints when it comes to the use of tele-services in healthcare. In other countries, such as France and Norway, previous face-to-face contact between physician and patient is recommended in telemedicine use cases (e.g., eHSG, 2014): that is, the first contact between a doctor and a patient should not take place via telemedicine.

How to influence public authorities positively so that they eliminate any legal barriers or constraints?

Possible ways to influence the public authorities, so that legal barriers or constraints are removed, include:

- Providing documentation about the sustainability of running telemedicine services.[95]
- Communicating research results that address the advantages of using telemedicine for different health professional groups.
- Lobbying potential telemedicine doers.
- Focusing on on-going work within the European Union, including e.g., the eHealth Action Plan (EC, 2012), and the green paper on mobile health (EC, 2014).
- Supplementing, in due time, the available policy literature either by policy guidance and/or appropriate green papers for European Union Member States.

---

[94] Information provided by Dr Stephan Schug, EHTEL in an e-mail dated 22 July 2014 to Ellen K. Christiansen.

[95] There is, however, some debate and disagreement whether this approach would result in the removal of legal or regulatory barriers.

What about the "timing" of legal assessments of telemedicine services?

Although the timing issue of when legislation should be introduced was out of the scope of the MOMENTUM thematic project, four interesting issues for further inquiry emerged:

- Investigating further whether handling legal conditions either early or late in the telemedicine deployment process has any particular consequences.
- Formulating any such consequences in a generic way for the benefit of telemedicine doers.
- Relating the assessment of "legal investigation timing" to the particular type of telemedicine service under development.[96]
- Investigating whether the timing of the legal investigation is associated with the characteristics of the service[97] or if there are other circumstances of significance.

5.2 Critical success factor 11: Identify and apply relevant legal and security guidelines

This critical success factor describes the issues surrounding the identification and application of relevant legal and security guidelines to telemedicine service deployment.

Since doers' experience with telemedicine is relatively limited when compared with their in-depth experience with more traditional health services, the need for guidelines in the telemedicine field is critical.

Guidelines that take into account legal, security and clinical[98] aspects could guide doers in the appropriate direction(s), and help to make them feel more confident about developing and implementing new and sustainable services.[99]

5.2.1 What identifying and applying relevant legal and security guidelines means

This critical success factor reminds telemedicine doers to look for useful relevant guidelines on legal and security matters.

Guidelines can be defined in various ways. First, they can be described as "low level legislation", informal rules, or self-regulation mechanisms that can guide telemedicine doers on the process of telemedicine deployment and help them to "*translate their duties into action*" (WHO, 2012). Second, they can be described as "soft law" or social customs and norms of a profession. Typically, guidelines are interpreted as a set of non-binding

---

[96] Cf. the Introduction to this deliverable, where three types of telemedicine services are described – telediagnosis, telemonitoring and teleconsultation.

[97] For example, whether the service is a private or public service, a doctor-to-doctor or a doctor-to-patient service, or a service crossing borders.

[98] The focus of this critical success factor is on guidelines concerning legal and security issues and not on clinical guidelines. While clinical guidelines are related to the other forms of guidelines, MOMENTUM has not elaborated on these.

[99] The American Telemedicine Association (ATA) has produced many different forms of guidelines on how to handle various areas of telemedicine such as teledermatology, telepathology and telerehabilitation. See: http://www.americantelemed.org/resources/standards/ata-standards-guidelines - .VGC1Fd5v3dk, accessed 27 October 2014.

recommendations (EC, 2013). (Guidelines imply compliance with recommended practices, and are therefore to some extent flexible (Loane & Wootton, 2002).)

On this basis, at least three different types of guidelines can be distinguished. They are:

- Non-binding international codes of practice.
- Operational national guidelines related to application of relevant legislation and regulations.
- Codes of conduct (which can also emerge from professional organisations).

Different domains have been covered by them: here a further three are discussed: guidelines that cover particular jurisdictions, guidelines for specific professional groups, and guidelines that cover quality issues.

Guidelines on the legal and security aspects of the use of telemedicine have been published in several countries in Europe and elsewhere, especially in Australia and the United States of America (Loane & Wootton, 2002; Jack & Mars, 2008). A European example is the guidelines concerning telemedicine and responsibility/liability in Norway (HOD, 2001).

There are also guidelines available for professional groups – such as doctors and psychologists – that codify legislative and security measures and ethical and policy considerations. Examples include guidelines for medical doctors' use of telemedicine in Denmark (Sundhedsstyrelsen, 2005) and Finland (Finlands Läkarförbund, 2004) and guidelines for psychologists in Norway (Norsk Psykologforening, 2002).

Another example is the ethical guidelines in telemedicine developed by the Standing Committee of European Doctors (CPME) in 1997 (CPME, 1997).

Even though existing guidelines are aimed directly at a professional group, a specific country, a region, or even a particular service, they might provide useful baselines or examples for other telemedicine doers working to set up telemedicine services. More information, with examples of guidelines, can be found in an article published in South Africa (Jack & Mars, 2008).

There are also quality guidelines for deploying and running ICT systems. Among the International Organization for Standardization's most well-known standards are its quality management family of standards known as ISO 9000[100]. Continual service improvement is one of the many fields covered by the ITIL organisation (formerly known as the Information Technology Infrastructure Library).[101]

5.2.2 Objectives underlying these legal and security guidelines

For telemedicine doers, the objective of this critical success factor is to facilitate the set-up of a telemedicine service in accordance with the basic and accepted principles in the legal and security fields. These principles need to be applied throughout the whole telemedicine development and deployment process.

Use of different guidelines – accommodated to the various groups of telemedicine doers – can help doers sort out the most important legal and security issues to be considered when developing, running, and scaling up a telemedicine service and then making it routine.

---

[100] See http://www.iso.org/iso/iso_9000, accessed 27 October 2014.

[101] See http://www.itil.org/en/vomkennen/itil/index.php, accessed 27 October 2014.

5.2.3 The context surrounding the legal and security guidelines

If a service is defined as a medical act (see sub-section 5.1.3 on the context in which a service is legal), the relevant general legislation in the field has to be applied when the telemedicine service is established.

In general, rules and laws about healthcare come from a time when traditional, face-to-face, delivery of healthcare was the norm, before telemedicine was developed. Today, this original health legislation also governs telemedicine, a fact that is not always easy to handle in practice.

Bearing this historical background in mind,[102] relevant legal and security guidelines might represent a useful support, interpretation, and supplement to the available national legislation or regulations for telemedicine doers. In many cases, of course, such guidelines are defined ahead of legislation being in place, since legislation may take a substantial length of time to be brought into existence. Once the legislation is in place, guidelines may need to be revised appropriately so as to fit well with the law.

The use of guidelines is particularly important for telemedicine doers who have little experience of telemedicine and limited resources: this can be the case when initiatives emerge in either small institutions, municipalities or when a service is useful for only small groups of patients, or all of these conditions.

Guidelines must be issued by trusted bodies, such as public authorities, telemedicine advisory groups, telemedicine provider business services, or combinations of telemedicine providers represented throughout Europe.[103] These guidelines must be known to, and considered important and useful by, the relevant target groups and be adapted to their needs. Target groups include, among others, medical staff, technologists and vendors, as well as small- and medium-sized enterprises (SMEs) and innovators. In particular, rules and guidelines may be particularly useful for independent innovators and SMEs – that may not have easy access to legal counsel – to understand the surrounding legal, regulatory and security contexts. In this sense, they are able both to progress their own business aims and goals and, at the same time, advance the European digital agenda.

Since laws change, and people gather new knowledge throughout the telemedicine deployment process, continuous annotations to the guidelines from telemedicine doers in general, and legal experts in particular, should be welcomed. Guidelines need to be up-to-date for them to be trusted and used.

Prerequisites: As a prerequisite, legal and security rules must not restrict the use of telemedicine or state directly or indirectly that delivery of healthcare via telemedicine is inadvisable, not recommended, or illegal.

---

[102] A notion that already has to be borne in mind under cultural readiness (see the chapter on cultural readiness in this deliverable).

[103] Examples of guidelines that are worth further reading, include those emerging from, e.g., the European co-financed project, TELEscope (http://www.telehealthcode.eu) as well as national telemedicine advisory service/ competence centres such as the Telecare Service Association in the United Kingdom (http://www.telecare.org.uk), both accessed 27 October 2014.

5.2.4 Lessons learned from the cases on identifying and applying relevant legal and security guidelines

Six of the cases that reported their experiences on legal and security guidelines did indeed use some sort of guideline. Clinical, and legal and security, guidelines related to both telemedicine services and health services generally were used.

In the cases where information is available, either guideline(s) had been taken into account or else the organisations and companies ensured that the telemedicine service that was adopted was approved by relevant bodies. In other cases, both legal and security guidelines (e.g. in Maccabi, Teledialysis, and KSYOS) and clinical guidelines (e.g. in RxEye and ITHACA) were applied.

In the cases described, some particular important topics were mentioned in addition to legal and security guidelines. These were, in general: reliability, good practice (RxEye); and codes of conduct for information security in the healthcare sector, and responsibility and liability matters (in the Norwegian Teledialysis case).

5.2.5 Further useful background information on legal and security guidelines

Ideally, each country should work out guidelines for telemedicine doers, based on European regulations and relevant national legislation.

Creating incentives for the production of such telemedicine guidelines could also be discussed. Suggestions include:

- In order to support each country in working out telemedicine guidelines in the legal and security fields, fundamental ethical, legal, and security principles for telemedicine services should be further elaborated and outlined at the level of the European Union.

- Already existing guidelines in the legal and security fields should be mapped, systematically collected, translated, and made available, i.e., on the internet.

- An overview of the crucial topics that need to be addressed in legal and security guidelines for telemedicine should be worked out.

- A simple template for such guidelines should be suggested and recommended.

By working on these activities, the various guidelines that already exist would become better known, understood, available, and applied appropriately throughout the European Union.

Guidance on relevant topics, and a template, could make this work easier overall, and facilitate the writing of similar guidelines in all 28 countries in the Union, even though healthcare is a national responsibility and is therefore governed by each country's national legislation.

It is particularly important that the type of language and the approach used in the guidelines are carefully accommodated to the various stakeholder target groups.

Because certain guidelines are available in only particular countries or regions, their translation into other European languages might also offer useful background information to doers in other nations that use other languages.

General guidelines cannot substitute for advice that is specifically adapted to the legal and security issues that may emerge in the telemedicine deployment process. That challenge is the topic of the next critical success factor on involving legal and security experts.

5.3 Critical success factor 12: Involve legal and security experts

This critical success factor describes the issues surrounding involving and asking advice from legal and security experts in the telemedicine service development and implementation process. These points are addressed below.

Figure 13: Involving legal and security experts.

5.3.1 What involving legal and security experts means

This critical success factor incorporates involving and asking advice from legal and security experts when needed, to minimise the risk of experiencing legal and security problems when deploying a telemedicine service. Legal and security assessments include covering pertinent ethical and privacy considerations, among the telemedicine experts, the telemedicine doers and the healthcare personnel involved. Usually, telemedicine doers are indeed not experts in these matters.

It is important to be aware of the skills and expertise that legal and security experts must have, and the tasks that they will undertake. Legal and security experts must be knowledgeable about regulations relevant to telemedicine at all levels, internationally, nationally, and locally, and must be aware that different queries may emerge at different stages of a development and implementation process. These experts are not necessarily experts on medicine. However, they do need to know the healthcare system intimately and be aware that telemedicine can provide healthcare in new and innovative ways. They must be informed that, as a rule, the general legislation in this field constitutes the basis for traditional health services being delivered in new ways (see also sub-section 5.2.3 on the context surrounding legal and security guidelines).

The experts must be able to handle legal and security subjects as they arise during the whole process of planning, developing, and implementing a telemedicine service. Their tasks may comprise:

- Identifying, exploring and applying current legislation and regulations that are relevant to the telemedicine service under development.

- Undertaking "legal risk assessments" throughout the whole process, as indicated in sub-section 5.1.1 of this deliverable.[104]
- Undertaking information security risk assessments, where risks to confidentiality, privacy, integrity, and availability are identified, and security measures are planned. By running such assessments at an early stage of the service development, "privacy by design"[105] can be achieved for the service. Risk assessments should be repeated whenever changes are made which could influence the information security of the service.

It is also important to understand the objectives underlying this critical success factor, which are described below.

5.3.2 Objectives underlying legal and security experts

The main objective is to make sure that the telemedicine service under development is ultimately legally and securely implemented. This implies that any legal and security issues, including any ethical and privacy matters, must be scrutinised and taken care of when they are relevant.

Involving legal and security experts throughout the whole telemedicine deployment process will facilitate as smooth a process as possible, and ensure that any legal and security obstacles are identified and handled at an early stage.

As a result, legal and security challenges should not emerge unexpectedly. The handling of legal and security issues will be tackled as an integral part of the development process. Therefore, they will not postpone or obstruct any on-going telemedicine development or deployment. If unexpected legal and security uncertainties were to emerge in relation to a telemedicine service in operation, this could influence – in a negative way – employees' and users' willingness to use and expand the service, both among health professionals and patients.

5.3.3 The context surrounding legal and security experts

For a start, the legal and security experts should consider the following issues:

- The initial activity should be to determine whether the service is a medical act or whether it is not.
- If the telemedicine service crosses any borders – national, regional, or organisational – there will be more complex legal matters to solve than if the service takes place within one organisation. It will also entail taking more complex technical security measures. One type of "cross-border" service is the cooperative delivery of health services to patients among healthcare institutions located either in the same region/country or in different regions/countries. In such situations, the roles and

---

[104] A legal risk assessment can be described as a process that runs parallel to an information security risk assessment. In it, possible legal hindrances ("risks") are identified and measures are planned and carried out to avoid risks and/or mitigate them.

[105] Privacy by design originated in the mid-1990s, and has been much promoted particularly by the Canadian authorities ever since. See especially (Cavoukian et al., 2009).

responsibility/liability of the health personnel involved should be described and the need for legal agreements and/or contracts determined.

- The socio-political or economic system in which the telemedicine service operates will influence the legal requirements (i.e. laws) that the service has to comply with. The legality of the service, the underpinning legislation and reimbursement rules, all have to be investigated when a service is shifted to another region or country, i.e., it expands from one socio-political/-economic system to another.

The need for experts in the legal and security field is especially connected with the fact that the roles and the organisational tasks of healthcare personnel alter once telemedicine is used.[106] The role of the patient also changes as a result of telemedicine services being introduced and used. This issue also requires scrutiny by legal and security experts.

Prerequisites: As a prerequisite, one has to consider that adequate resources must be allocated for the involvement of legal and security expertise. This success factor is thus connected to the aggregation of resources (i.e., the pulling together of the resources needed for telemedicine deployment), see critical success factor 4 (see section 3.4).

5.3.4 Lessons learned from the cases on legal and security experts

Four of the MOMENTUM cases explicitly reported that legal and security experts were consulted at some stage during the development and deployment process:

- Maccabi – did not use legal experts at the time of establishing the service, because they were used to help develop the underlying services from which this particular Maccabi service emerged.

- RxEye – used legal experts to make sure that this new type of telemedicine service would fit into the relevant legal framework.

- Teledialysis – used legal and security experts to conduct risk assessments in both the security and legal fields, and for clarifications, whenever they were needed.

- ITHACA – used legal experts for its collaboration agreements (contracts and service level agreements). As was the case in ITHACA, legal agreement is even more demanding when there are several partners taking part in the development of a new service. One of the partners (BSA) had the responsibility to ensure privacy and security was compliant with Spanish law.

The three other case respondents did not state that legal and security experts were *not* used. They simply did not comment on the matter since other aspects of telemedicine deployment were in focus when the specific services were presented and discussed.

The fact that this critical success factor was not commented on by three of the services might illustrate that, to a certain extent, the factor overlaps with and elaborates on the other two previous factors about whether (or not) the service is legal and appropriate guidelines are available. It seems, however, that these two factors might be important at different stages of the development and implementation process.

---

[106] In particular, there are four critical success factors (6-9) that cover a number of issues that relate to managing organisational change.

It could be debated whether the two critical success factors concerning the use of legal and security guidelines and experts should be integrated in or presented as sub-sections of the "Assess the conditions under which the service is legal" critical success factor. However, it may be important to draw attention to these two subjects in particular since they could help telemedicine doers to focus on legal and security issues throughout the whole development and implementation process.

5.4   Critical success factor 13: Ensure that telemedicine doers and users are "privacy aware"

This critical success factor describes the issues surrounding ensuring that telemedicine doers and users are "privacy aware". Privacy awareness training is an essential part of the development of a privacy aware organisational or company culture.

Depending of the type of service, privacy awareness training should be given to a wide range of end-users.

Healthcare workers should certainly be expected to have the necessary knowledge in the privacy field. Training in privacy awareness should be offered to new doers and users when new services are adopted, and repeat or "refresher" training should be offered whenever health information systems are updated or maintained.

For telemedicine services where patients are directly involved (i.e., in doctor-to-patient services), privacy awareness training that is specially accommodated to the patients' needs should be offered to patients. This approach fits particularly well with the notion of patients becoming more informed and more digitally literate.

Figure 14: Ensuring privacy awareness.

Therefore:

- Patients should be made privacy aware in any accompanying patient consent information, as a basis for their giving informed consent to the processing of their personal health information.

- Privacy awareness training/education to health personnel (i.e. telemedicine doers) should include information on the legal requirements on how to obtain patient consent properly.

As has been mentioned earlier, several respondents to the MOMENTUM 2012 survey commented on issues relating to privacy awareness and patient consent.[107] While, these two matters are not identical, there is nevertheless a relationship between them.

5.4.1 What ensuring telemedicine doers and users are "privacy aware" means

Knowledge about appropriate practice when it comes to privacy and security behaviours can be termed "privacy awareness". Such knowledge is based on ethical and legal principles and applies to developers during system design and implementation, as well as end-users during operational use.

It is related to "privacy by design".[108] It is therefore important to make sure that everyone who is involved maintains a high degree of privacy awareness, knows the regulations in the field and acts in accordance with them whether they are: involved in the deployment of a telemedicine service; using a service; or handling health information.

Promoting "Privacy awareness" can be achieved in at least four ways, through

- Strategic attitudes that are transferred to appropriate behaviours *throughout* the organisation.
- Developing a privacy aware company culture or organisational culture.
- Educating people and personnel.
- Training.

"Culture building" is intended to make telemedicine doers, the relevant stakeholders, and end-users – including patients – aware of good practice. Security measures to ensure privacy must be prioritised even if their inclusion might occasionally be experienced as bothersome and time-consuming. Privacy awareness and a good security culture can also be achieved and maintained through repeated training measures and steady educational reminders about these topics.

Training must introduce norms and basic principles for secure and privacy aware behaviour, illustrated by local guidelines, policies, and examples. Appropriate training and education could comprise the following themes:

- What is privacy and Personally Identifiable Information (PII).
- Privacy laws, policies, and principles.
- Roles and responsibilities in protecting privacy.
- Potential threats to privacy.
- Consequences of privacy violations.
- Protection of PII in different contexts and formats.

---

[107] See details on consent, ethical approvals, and concerns analysed in MOMENTUM deliverable D.6.1 in response to question 26 in the MOMENTUM 2012 survey, see http://telemedicine-momentum.eu/deliverables/.

[108] Privacy by design (Cavoukian et al., 2009) requires privacy awareness among developers and can help to avoid many security challenges.

Further useful background information is continued later in sub-section 5.4.5 on practicalities on training.

5.4.2   Objectives underlying privacy awareness

There are three main objectives supporting this critical success factor:

- The first objective is based on the assumption that privacy awareness can contribute to strengthening peoples' confidence in and, hence, their willingness to use telemedicine, whether they are healthcare professionals or patients. By focusing on privacy awareness, two achievements are accomplished:
  - It contributes to the development of routine use of telemedicine services in accordance with best practice in the field.
  - The focus on patient confidence should not be neglected. For example, in the Chain of Trust project[109] it was concluded, among other items, that "mutual confidence between users is considered crucial and should not be underestimated" (eHSG, 2014, p.10).
- The second objective involves taking care of a patient's privacy in general in accordance with the regulations in the field.
- Third, privacy awareness must enable organisations to make sure that:
  - They are not handling patient data illegally.
  - Their employees are acting legally with regard to patient privacy.
  - Their patients are handling their data appropriately in terms of privacy legislation.

The overall objective is to avoid breaches of privacy that can lead to the erosion or loss of trust.

5.4.3   The context surrounding privacy awareness

All over Europe there is an increasing focus on the privacy of personal data, with a growing number of reports on the occurrence of privacy violations such as identity theft (Eurobarometer, 2010).

At the same time, the European Union is strengthening online privacy rights with the adoption of a new General Data Protection Regulation (EurActiv, 2013). Technological progress and globalisation have profoundly changed the way in which data is collected, accessed, and used. Thus, the rules in Directive 95/46/EC (EC, 1995) need to be modernised, since they were introduced when the internet was still in its infancy and they fail to consider recent technological developments such as social networks and cloud computing (EC Directorate-General for Justice, 2012).

The context in relation to both health professionals and patients has to be borne in mind:

- First, when telemedicine services involve personnel from various organisations in the same or in more than one country, the organisations' policies concerning privacy and information security need either to be the same or are at least to be compatible.

---

[109] Chain of Trust http://www.eu-patient.eu/whatwedo/Projects/EPF-led-EU-Projects/Chain-of-Trust/, accessed on 27 October 2014.

- Second, when patients are directly involved in the telemedicine service (i.e., in the case of doctor-to-patient services), they too should also be made "privacy aware".

Prerequisites: As a prerequisite, resources for privacy awareness training must be allocated and routines for such training must be established and made systematic, both for the developers of the new service and for the healthcare workers.

In deploying a new service, privacy awareness training should be part of the change management plan (see critical success factor 8 in the chapter 4.4 on change management for relevant details). It should therefore be part of the job description of the employees in the healthcare institutions involved in providing or using the telemedicine service.

Such training should be considered as a benefit by the healthcare workers and as relevant for the individual's professional development. Receiving the training should be documented in the resumé or work record, and become a part of the career path of each individual.

The institution's management must also recognise the importance of privacy awareness culture building.

5.4.4 Lessons learned from the cases on ensuring that telemedicine doers and users are privacy aware

Privacy awareness is essential for those telemedicine doers who are aware of privacy issues in their daily work (e.g., in ITHACA and Teledialysis). The Norwegian Teledialysis case developed brief guidelines for secure conduct, based on the risk assessment that its staff had undertaken. It is of importance in cases where patients should know who precisely can access their data (e.g., in Maccabi and RxEye).

Patient consent arose as an important matter in four of the MOMENTUM telemedicine services that have been analysed more thoroughly:

- Maccabi – bases its telemedicine service on the patients' consent to access to their medical records being given to relevant Maccabi personnel.
- RxEye – indicates that institutions that are using teleradiologists from outside the organisation acquire informed consent from the patient.
- ITHACA – reports that patients signed an informed consent document before starting to use the service.
- KSYOS – states that there has to be informed consent on the part of the patient.

5.4.5 Further useful information on privacy awareness

With regard to privacy awareness there are, first, some more practical issues and, second, some issues related to both the practicalities and the concepts around patient consent that need to be considered.

Practicalities about training: When privacy awareness training is undertaken, particular circumstances have to be taken into account. These circumstances include the size of the service, both in terms of number of persons to be made "privacy aware" and the geographical dispersion of the population. These will influence the resources needed in terms of both time and financing. Distance learning and e-learning courses are obvious options as potential training methods that can be used in the context of larger telemedicine services.

There might be other relevant aspects in terms of adapting the available training to:

i) Various target groups.

ii) Specific topics related either to the actual service or the particular context.

A presentation from the United States Department of Health and Human Services offers some ideas on what can be included in privacy awareness training (HHS, 2014). Other books on training programmes are available (Herold, 2010), as well as e-learning courses on privacy awareness (NIH, 2014) and video courses (STH, 2014).

Privacy, personal data and patient consent: Often, patient consent is mentioned as an example of privacy awareness. Two discussion items emerge:

- The first issue is about "signing away" privacy rights when personal information is passed on to the third parties, which is not in accordance with the European Data Protection Directive 95/46/EC (EC, 1995). As has been noted, however, this 1995 legislation is currently under revision. It cannot yet be determined how the revised European law (which it is reputed will take the form of a Regulation rather than a Directive) will affect the future handling of personal data.

- The second issue is that consent emerges as an important topic when telemedicine in used. In some MOMENTUM cases, it has been stated that use of telemedicine presupposes consent on the part of the patient. When a telemedicine service has become routine, in terms of the way in which a healthcare service is delivered, how should this be handled? Should the "old-fashioned" (i.e., face-to-face) way of doing things be maintained, in parallel, just in case an individual patient does not give his or her consent to the new telemedicine service being used?

6 Critical success factors from an ICT perspective

This chapter describes systematically each of the critical success factors relevant to the ICT perspective. It covers the five critical success factors relating to:

- IT and eHealth infrastructure.
- User-friendliness.
- Service monitoring.
- Market procurement.
- Potential to scale up.

Each description covers the following five domains: the general background to the critical success factors i.e., what each critical success factor means; its underlying objectives; the surrounding context, and any prerequisites; and lessons learned about that specific critical success factor from the in-depth cases investigated. Fifth, if appropriate, useful further background information is included.

6.1 Critical success factor 14: Ensure that the appropriate information technology infrastructure and eHealth infrastructure are in place

This critical success factor describes the issues which ensure that the appropriate information technology (IT) and eHealth infrastructures are available at the time of deployment and scale-up. The availability of these two infrastructures implies that the parties involved will be able to embrace the particular telemedicine service.

Figure 15: Putting appropriate infrastructures in place.

6.1.1 What the ensuring that the appropriate IT and eHealth infrastructures are in place means

This critical success factor means ensuring that the appropriate IT infrastructures and

eHealth infrastructures are available so that the telemedicine implementation can rely on these infrastructures from the initial deployment to the last stage of the scale-up phase.

The distinction between IT infrastructure, eHealth infrastructure and eHealth services such as telemedicine is represented in the model, called a Common Working Model, developed by the CALLIOPE project in 2011 (see Figure 16, below).[110]
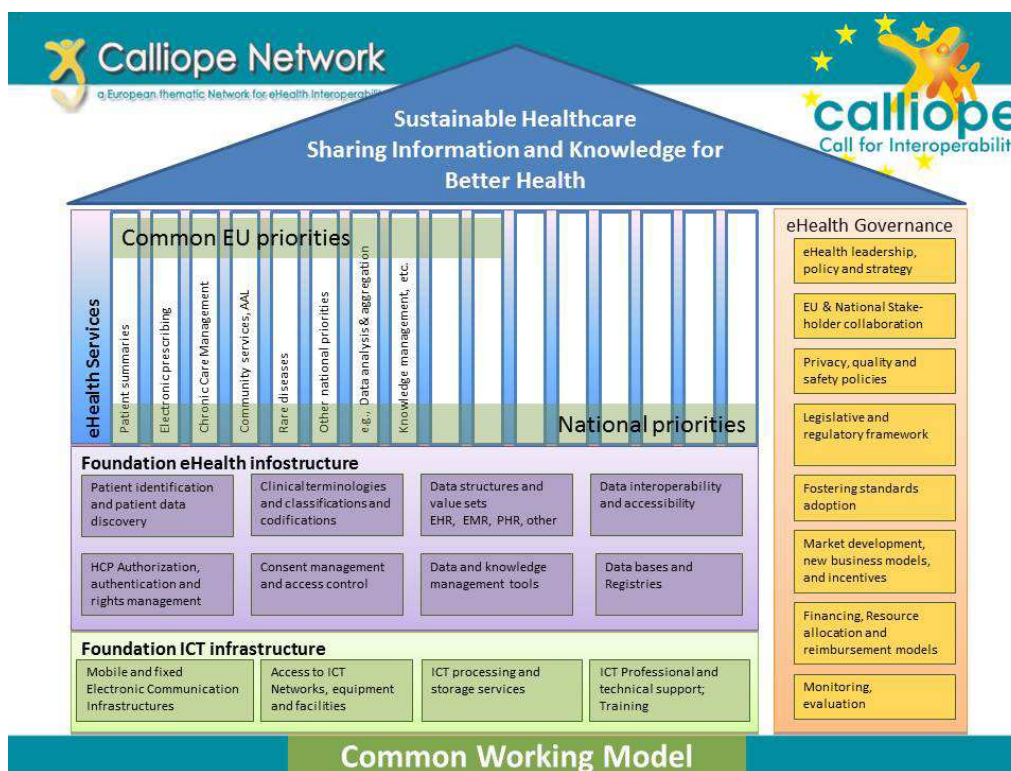

Figure 16: Calliope Common Working Model

IT infrastructure consists of all active elements in an IT operation. A typical IT infrastructure includes the following components: hardware, software, networks (including internet connection and security systems), and the IT staff responsible for network, hardware and software development and maintenance. Together, they all have the mission to supply access, storage and processing capacity to the telemedicine service users.

In the context of telemedicine, IT infrastructure is the set of industry-neutral infrastructure elements – available for all sectors – that supports the successful deployment and good functioning of new healthcare services.

eHealth infrastructure is a sector-specific subset of the IT infrastructure. It includes hardware, software or networks designed specifically for healthcare provision. For instance,

---

[110] The diagram is available at: http://www.calliope-network.eu, accessed 27 October 2014. Particularly with regard to the various pillars and layers implicit in the structure of the CALLIOPE model, the MOMENTUM project has made further progress on the pillar entitled "eHealth Governance": this is related to the critical success factors addressed by the two MOMENTUM deliverables, D4.2 "Strategy and Management" and D6.2 on "Legal, regulatory and security issues" and further explored in two chapters of this deliverable on the deployment strategy and the legal, regulatory and security perspective.

health information systems incorporate elements such as electronic health records or patient health records able to capture, store and distribute clinical data across different levels of care and among different health providers and patients.

The communication of health data may require interoperable health information systems that use clinical terminologies, codifications and data exchange standards such as DICOM, HL7 or SNOMED.[111]

6.1.2 Objectives underlying these two infrastructures

The main objectives of this critical success factor are related to the efficiency and the interoperability of the telemedicine service with their focus on time, costs and the embedding of the service in the information systems currently available.

First, ensuring that these infrastructures are available is crucial to reduce the development and implementation time and costs of the telemedicine services. The overall aim is to rely on and use existing IT and eHealth infrastructures without either risking the quality of the new telemedicine service or its obsolescence over time.

Second, using available IT and eHealth infrastructures means that the new telemedicine service is embedded in *current* information systems. It guarantees the service's interoperability over time with other healthcare services or healthcare providers. This is because there would otherwise be a risk that stand-alone solutions could be refused by end-users.

6.1.3 The context surrounding these two infrastructures

There are several important contextual factors that include the following critical elements:

- **Scale**: How critical an eHealth infrastructure is varies dependent on the type of telemedicine service initiative being introduced. In the case of public or private provider initiatives, the critical point is the *scale* of the implementation plan as measured by the number of organisations or centres that will be involved, and the diversity of health information systems that they operate. In the case of private vendor initiatives that aim to sell telemedicine services in a healthcare market, the *design* of interoperable solutions to their potential customers is fundamental.

- **Interoperability**: Complex eHealth infrastructure situations need health data integration, which implies interoperability: a key example is when there are at least two health information systems operating together within the same healthcare organisation.

- **Service type**: Another critical element is the type of telemedicine service involved. In doctor-to-patient initiatives, the availability of appropriate IT infrastructure is more influential with regard to the implementation than the eHealth infrastructure. In doctor-to-doctor initiatives, [112] health professionals expect health information systems integration to support more effectively the care that is offered.

- **System configuration**: In the telemedicine field, access to electronic health records and clinical data provided by other health providers may be needed for data to be

---

[111] See MOMENTUM's list of abbreviations and terminology.

[112] Here, the notion of a doctor includes all kinds of other health professionals.

shared and to avoid data silos. The health system configuration is important, as better data integration in health systems and a strong form of IT stewardship is expected.

Prerequisites: In terms of prerequisites, public or private telecommunication operators will have had to invest in a network IT infrastructure (i.e., broadband) that is mature at the time of implementation. The health information system that will capture telemedicine data must be ready to accept data from third-party sources through intercommunication systems (such as web services) or evolve in parallel with the telemedicine implementation to accommodate data interoperability needs.

6.1.4 Lessons learned from the cases on the two infrastructures

The appropriateness and availability of information technology infrastructure and eHealth infrastructure was illustrated by all MOMENTUM cases explored in-depth. Without doubt, the maturity of communication systems developed in the last decade has contributed to easing development and acceptance of telemedicine services. It has enabled the application of telemedicine solutions in a safe and reliable way to all types of users.

However, the level of interoperability supported by an appropriate eHealth infrastructure differed among the cases. On the one hand, eHealth infrastructure was fundamental to enabling scaling-up in the Maccabi case, and the potential to scale up in ITHACA and Teledialysis. On the other hand, in the private initiatives oriented to the market – such as KSYOS, RxEye and Cardio On Line Europe – integration of the service with customer health information systems was critical to success.

Having an eHealth infrastructure has brought quality of care and efficiency to these telemedicine services. In the Maccabi case, system integration was a guarantee of high quality care, while in all other cases it helped to avoid duplications and errors in data entry.

The use of technology standards is a guarantee of both success and efficiency, as was illustrated in various cases: videoconference in Teledialysis, web development standards in Maccabi, ITHACA and KSYOS, and communication standards in six of the seven cases.

6.1.5 Further useful background information on infrastructure

Often, IT or eHealth infrastructures are not yet fully in place and health and clinical information systems are only partially deployed.

Interoperating with them can be difficult and costly. Paradoxically, due to economies of scale, the smaller the size of the telemedicine initiative, the greater is the relative size of budget for systems integration in the overall IT infrastructure.

Both the time and the space dimensions of technology solutions are important. Some telemedicine solutions are so advanced in character that they encounter adoption difficulties due to a lack of technological skills or technological awareness on the part of members of institutions, health professionals and even patients.

It is therefore important to ensure that technology is in the right place at the right time.

6.2 Critical success factor 15: Ensure that technology is user-friendly

This critical success factor is about ensuring that the technology used in the telemedicine deployment is user-friendly.

Figure 17: Ensuring that technology is user-friendly.

6.2.1 What ensuring that technology is user-friendly means

User-friendliness is a combination of attributes from both the technical and human dimensions. It helps users to learn about and adapt easily to a new technological environment (Lehoux, 2004). These attributes include simplicity, responsive design, and usability. Users adopt innovation easily when they perceive it as simple and easy-to-use. Responsive design is a method to achieve simplicity and usability through user-centred design. User-centred design is mainly achieved through user involvement in the design process. Simplicity and usability in technology is also related to the use of standards that reduce unnecessary technological dependencies.

From a technological perspective, all these features should ensure fitness for purpose, cost efficiency, ease of understanding, ease of use, and reliability to all telemedicine service users. Thus, user-friendliness in a telemedicine service is critical to increase the speed of user adoption and avoid rejection by end-users.

The technology described here relates not only to end-user devices and their displays, but also the whole system configuration. Hence, ultimately, the notion of user-friendly technology is not limited to the case of web services, as was largely the example used in this report. Ultimately, it is anticipated that user-friendliness would also imply the design and creation of technologies that can be used easily and flexibly with people who are experiencing multiple chronic conditions.

6.2.2 Objectives underlying user-friendly technology

User-friendliness has two objectives. On the one hand, it aims to make the technology easy to use by average users – whether they are health professionals or patients – without the need for a long learning curve or an extended training period. On the other hand, the

technology has to be reliable both at the device and system levels.

6.2.3 The context surrounding user-friendly technology

The technological and organisational context where the new solution is introduced determines the level of technological complexity. For example, the co-existence of multiple health information systems or a heterogeneous user base – which involves a mix of different types of users with a range of different skills – may require additional efforts being made towards user-friendly design.

Awareness of this background context helps users to avoid experiencing feelings of complexity, particularly when health professionals have to work with different information systems.

When the telemedicine service end-users are patients, the human dimension of user-friendliness is even more important so that the system is accepted by a diverse user base. Ultimately, the telemedicine service should be user-friendly for all concerned.

Prerequisites: Three prerequisites are particularly important when developing user-friendly technology:

- **Simplicity** is a subjective experiential factor that is measured by end-users. It may determine the degree and speed of adoption.

- The **level of eHealth literacy** (that is, e-skills applied to healthcare) (Chan et al, 2009) of both health providers and patients will ultimately be a prerequisite for the success of this critical success factor. Having had some form of earlier exposure to IT-based healthcare can help end-users to adopt new telemedicine services more easily.

- Efforts on **change management** can improve the "point of departure" in terms of people's eHealth capacities.[113]

6.2.4 Lessons learned from the cases on user-friendly technology

User-friendliness was fundamental in the design and implementation phase in all cases to guarantee and support an easier user adoption.

Different approaches to usability were identified among the cases, depending on the types of end-users they involved. Usability can provide support for different user groups. Doctor-to-patient cases – such as Maccabi and ITHACA – focused on usability in terms of accessibility for patients. Cases typified as doctor-to-doctor telemedicine services focused on usability to avoid additional data-entry and reduce clinicians' workload.

The Maccabi and ITHACA cases involved patients as telemedicine service end-users. Their solutions offered a wider range of accessibility that covered the diversity of chronic care patients and emphasised the importance of simple user interfaces so as to compensate for the risk of complexity implicit in a multi-channel approach.

The remaining cases reviewed – RxEye, Teledialysis, KSYOS and Cardio On Line Europe – were doctor-to-doctor telemedicine services. In them, healthcare quality, safety, and user comfort were all crucial to the acceptance by the health professionals involved.

In conclusion, user-friendliness is mission critical in accelerating user adoption of

---

[113] See also critical success factor 8 on change management.

telemedicine services and reducing the risk of rejection due to a lack of usability.

6.2.5   Further useful background information on user-friendly technology

User-friendliness is often enhanced when end-users are involved in the design process. As the Christie Commission of the Scottish Government on the future delivery of public services proposed, effectiveness can be further increased through bottom-up design approaches and particularly throughout the involvement of people and communities. Usability should be included in the design and deployment processes (Christie et al, 2011).

6.3   Critical success factor 16: Put into place the technology and processes needed to monitor the service

This critical success factor describes the issues surrounding putting in place the necessary technology and processes to monitor the telemedicine service. The form of service monitoring explored here is technological in character. It does not refer to the evaluation of the quality of the service.[114] Nor should it be confused with the term telemonitoring that is often used in the field of telemedicine.[115] The quality of service monitoring should be distinguished from service quality in general.

6.3.1   What service monitoring means

Service monitoring guarantees that telemedicine functions without excessive delay in routine use or technical interruption – with the exception of those interruptions scheduled for system maintenance. Service monitoring includes all activities needed to govern IT, such as maintenance plans, security issues, service continuity, a help desk and access management.

Service monitoring may be provided either internally by the healthcare service provider or externally through a contractor.

Successfully introducing technology in healthcare practice should avoid that clinicians lose time: time loss is a big source of frustration for doctors as it may prevent them from caring for patients. A good quality technology monitoring service is therefore important to guarantee continuity of care.

It is also important to consider the needs of end-users through service monitoring as this will identify possible refinements to services that improve adoption and use.

Staff members who are involved in service monitoring are in a privileged situation in terms of capturing end-users' needs as their main activity is trouble-shooting. Personnel responsible for maintenance and service monitoring have the opportunity to deal with, and eventually register, the technical problems that users may face when using telemedicine

---

[114] With the exception of some findings explored in D4.1 of MOMENTUM on the strategic elements of MOMENTUM's 2012 survey, evaluation mechanisms were not in the scope of the MOMENTUM project. Telemedicine service monitoring and measurement can form part of a larger user satisfaction questionnaire: for an example of this, see the Cardio On Line Europe case (described in the attachment to this document). Quality assessment, in general, is covered in this deliverable in terms of the four critical success factors 6-9 on managing organisational change.

[115] Telemonitoring involves the remote monitoring of patients who are not at the same location as the healthcare provider.

services.

6.3.2 Objectives underlying service monitoring

Service monitoring is intended to:

- Guarantee a continuous level of service.
- Solve any incident that may occur during the service.
- Support end-users in resolving any doubts that they might experience.

Besides these three objectives, it is also important to understand the context surrounding this critical success factor.

6.3.3 The context surrounding service monitoring

The service monitoring depends on the type of service developed or contracted out, and how long the service has been running.

It is important to define who provides the service, particularly in the case of a joint venture: the service monitoring may be provided by the same company that developed the service or by a third party that is responsible for maintenance and service contracts.

Other contextual factors are the synchronicity involved – i.e., whether the service is online as compared to offline – and the scale of the telemedicine service, in terms of its size and the number of organisations involved. The larger the scale or the customer base, the more critical this success factor becomes.

Prerequisites: As an after-sale type of services, service monitoring may or may not be included in the contracted or developed service. Telemedicine doers need to verify the specificity of a service level agreement in the signed final contract to avoid any lack of compliance with the objectives described for service monitoring.

6.3.4 Lessons learned from the cases on service monitoring

The technology and processes needed to provide continuous and reliable maintenance and telemedicine service monitoring was evident in all seven MOMENTUM cases. In all cases, good collaboration among service monitoring teams and technology providers was seen as crucial to guarantee the quality of the service. Various elements of service monitoring were illustrated.

Vendor initiatives included service monitoring as a key value proposition, an element that is not unexpected.

With the exception of ITHACA – due to its partnership with an IT company – the healthcare providers opted to internalise the service monitoring.

Two of the cases– Maccabi and Teledialysis – had internal service monitoring. In the case of Maccabi, it was the quality assurance needed by a big scale-up in a large healthcare organisation that motivated this decision; in Teledialysis, the decision was supported by the diverse maintenance requirements. In four of the other cases – RxEye, ITHACA, KSYOS and Cardio On Line Europe – service monitoring was provided by external suppliers (for example, in the case of ITHACA) or by their own telemedicine companies (in the remaining cases).

What can be learned from these cases is the importance of a good form of collaboration organised in conjunction with customers' IT governance teams that then guarantees a high

level of service and integration.

Two other significant lessons learned are the importance that service monitoring has in relation to the *scale* of the telemedicine service (Maccabi), and the *criticality* of the healthcare service provided (Cardio On Line Europe).[116]

6.3.5 Further useful information on service monitoring

Service monitoring needs to be tackled from a dynamic perspective. It has both a present aspect and a future aspect. It is not enough simply to guarantee a well-functioning system at the present time. It is also necessary to explore how maintenance will adapt to future changes in the technological and administrative environments, and how these changes will be supported financially.

Often, it is the service monitoring team that is in charge of further developments of the technological – mainly software – infrastructure to support the telemedicine service.

Other forms of monitoring are generally wider than simply service monitoring, for example, quality assurance and monitoring, and the monitoring of patient satisfaction.

6.4 Critical success factor 17: Establish and maintain good procurement processes

This critical success factor describes the issues surrounding ensuring good procurement processes.

6.4.1 What establishing and maintaining good procurement processes means

Good procurement processes involve two main focus areas: *content* and *method*.

As for content, any service that is contracted out may be delivered with a wide range of quality variability. Unless these aspects are specified in the contract signed with telemedicine providers, the risk lies fully with the procurer. A good practice in procurement terms is to specify these aspects in a transparent, straightforward service level agreement to be signed by the contracting parties.

In referring to *method*, the implication is to have a formal process of procurement for the purchase that acts as a guarantee of the quality of the final output of the service. This method encompasses issues of transparency and competition present in procurement legislation derived from the 2014 European directive on public procurement (EU, 2014).

6.4.2 Objectives underlying maintaining good procurement processes

Good procurement processes aim to ensure the fairness of the relationship between the procurer and the provider, the quality of the service during the terms of the contract and, in the case of public procurement, to guarantee competition among different providers.

Quality is ensured by preparing service level agreements and contracts that define clearly what is expected from both parties and what the specific rights and liabilities are of engaging in the particular telemedicine project or initiative.

---

[116] These issues also emerged in terms of the context surrounding critical success factor 14 on infrastructures.

6.4.3   The context surrounding maintaining good procurement processes

Sound procurement mechanisms are needed both from the perspective of buying and selling. Healthcare organisations also have to be accountable for their operations to different stakeholders.

In the case of public institutions, this accountability is legally reinforced by the obligation to be compliant with the relevant public sector public procurement laws derived from the 2014 European Union directive (EU, 2014). This type of legislation regulates how the procurement process has to be undertaken in terms of competition, publicity given to any call, and duration of calls for tender.

Private organisations enjoy a higher degree of freedom in their procurement methods but remain accountable to their boards of trustees. They may regulate internal procedures with warranties similar to those practiced in the public sector. Private organisations, like service sellers, such as one of the cases explored by MOMENTUM – RxEye – will themselves also need to procure various forms of infrastructure for themselves.

Being a public-private initiative introduces additional complexity into the procurement process as the solution found will have a pre-commercial character, i.e., the design of the service will be undertaken by the building of a cooperative relationship between the public sector organisation and the private sector partners or contractors without necessarily a commitment to take-up a particular commercial service (for more detailed descriptions, see Bos (2008)).

Procuring telemedicine services relates to contracting services based on data. Data protection and privacy issues are issues at stake that have to be formally addressed in the contract clauses.[117]

Prerequisites: In the contracting process, a facilitating characteristic can be the availability of guidelines and service level agreement templates used in previously contracted services. This may guide new procurers of services to avoid any past errors.

In classical procurement processes, the market needs to be sufficiently large and competitive to enable delivery of the technology, whereas in pre-commercial procurement the market needs to be ready to step in and to bring a business perspective (Ibid., 2008).

6.4.4   Lessons learned from the cases on maintaining good procurement processes

Particularly when healthcare providers introduce telemedicine for the first time, it is recommended to reduce ambiguities and uncertainties through the signature of clear service level agreements.

Having clarity in the procurement process, and the agreed business plan,[118] may help to define appropriate roles, levels of responsibility, ownership and status with regard to further developments, thus covering the agenda of any venture partner.

Clarity in both the procurement process, and access to expert advice, was considered to be critical in all the MOMENTUM in-depth cases in order for the organisations concerned to face future developments better. Clear specification of the functions and deliverables of the

---

[117] For further useful insights on data protection and privacy, see the three critical success factors (10-12) related to these issues.

[118] For further useful insights on business plans, see critical success factor 6 on this issue.

service is a cornerstone for both its clients and providers.

In order to streamline the procurement process, having access to expertise in the organisations' procurement departments – in the Teledialysis and ITHACA cases – appears to have been indispensable. This factor emerged as extremely important in the case of ITHACA, where a public-private partnership was formed to develop the telemedicine service.

RxEye, KSYOS and Cardio On Line Europe were all providers of telemedicine services to healthcare organisations. Having good procurement processes proved to be relevant, as most of their potential customers have had to comply with public procurement legislation.

Despite the fact that none of the cases explored reported on following a pre-commercial procurement process, the public initiatives, such as Maccabi, Teledialysis and ITHACA, could in fact be considered as pre-commercial developments: all the risk involved was borne by the healthcare provider in Maccabi and Teledialysis, and was partially shared in the case of ITHACA.

6.4.5   Further useful information on maintaining good procurement processes

Telemedicine development and implementation is not a linear process. Uncertainty increases with the presence of multiple partners. Procurement processes can help avoid confusion among the partners involved. Roles and responsibilities, timelines and milestones have to be defined clearly in the various binding documents associated with procurement processes.

Procuring telemedicine services is not an easy task. A high degree of uncertainty is present in the design, development and deployment phases.

Innovative procurement methods have been developed in recent years. Systems such as pre-commercial procurement are now being tested so as to develop services that are at interface of healthcare and technology: see also, in particular, the very recent policy development around these issues (EU, 2014).

Pre-commercial procurement helps the commissioners of services to reduce their level of uncertainty and transfer part of the risks involved to vendors. As a result, the procurement process has become more flexible (Edler & Georghiou, 2007).

6.5   Critical success factor 18: Guarantee the technology has the potential for scale-up

This critical success factor describes the issues to do with the technology's potential to be scaled up.

6.5.1   What putting the potential for scale-up means

From a technological standpoint, this critical success factor means considering that it may be important to extend the telemedicine service to a larger scale. The appropriate vendor(s) and the right technology(ies) therefore need to be chosen.

The potential for scale-up can be achieved by using either standard technologies or technologies that are similar and yet are produced/offered by a range of suppliers.

Failure to do this may work in the short term and on a small scale, but will probably cause bottlenecks at the scale-up stage of deployment.

Figure 18: Scaling up.

6.5.2   Objectives underlying the potential for scale-up

Telemedicine doers have to take into account what actions are needed to make the leap from pilot to large-scale deployment in both technological and commercial terms.

Scalability is directly related to the degree of standardisation of the technical solution either as defined (*de facto*)[119] by market adoption or specified (*de jure*)[120] by a standardisation organisation.

6.5.3   The context surrounding the potential for scale-up

In analysing and considering the relevant dimensions for scale-up, telemedicine doers will need to consider the following contextual elements:

- The potential of the service to be mainstreamed.
- Broadband and mobile network coverage.[121]
- Service level agreements.[122]
- Automated service enrolment.

In particular, technology that has historically been used in-house needs to be scaled-up (outside the organisation), and to take on board various external challenges.

When the telemedicine solution depends on a technology partner or provider, scalability may be related to so-called provider lock-in.[123] Ways to avoid lock-in include the presence of a competitive market to avoid supplier-dependency and the clear specifications in the contracts.

The size of the implementation foreseen also determines the potential for scale-up, taking into account the surrounding level of organisational complexity.

---

[119] A Latin, legal term that implies "in practice".

[120] A Latin, legal term that implies "in law" (or through formal regulation).

[121] See elements of critical success factor 14 on infrastructures.

[122] See elements of critical success factor 17 on good procurement processes.

[123] Lock-in implies that a customer is highly dependent on a specific vendor for the provision of its products and services, and may only be able to change vendor at substantial cost to itself.

Prerequisites: The availability of technical standards, whether *de facto* or *de jure*, is a prerequisite to scaling-up on a large-scale level: for example, when the scaling process involves either different healthcare systems, different countries or different ministries' budgets, or various healthcare organisations.

6.5.4   Lessons learned from the cases on the potential for scale-up

The MOMENTUM cases show how important it is to incorporate scale and scope in the early planning stages of development, and how this influences technology selection, procurement processes and organisational decisions.

All MOMENTUM cases have experienced scale-up in some way. Maccabi, RxEye, KSYOS and Cardio On Line Europe deployed their service to different care teams in the first stage of deployment. This took place either inside the organisation (Maccabi) or with new customers (in other cases). ITHACA and Teledialysis deployed telemedicine first only in a care environment, although both had plans to scale-up from the beginning.

Differences in the upscaling approach were detected between cases based on their (technical) configuration. Private and market-oriented cases – like RxEye, KSYOS and Cardio On Line Europe – followed technology standards closely and were keen to adopt interoperability standards so as to maximise their market opportunities. The public-sector promoted cases – Maccabi, Teledialysis and ITHACA – relied on interoperability standards. They needed to ensure good integration with their own electronic health records and improve their internal scaling capacities.

All cases considered mature and standard technologies and interoperability to be critical for scaling-up their solutions.

In terms of the technologies chosen, innovative technologies may over-promise and may be risky when compared with more established technologies, both in terms of customer acceptability and the capacity of technology providers to deliver their service.

Avoiding provider lock-in and assuring potential interoperability with different health information systems through the use of technology standards are two relevant lessons from the ensemble of telemedicine experiences that have been reviewed.

6.5.5   Further useful information on the potential for scale-up

Scalability is not simply a technological issue. It also encompasses three other perspectives – geographical, functional and target market perspectives. For this reason, scaling-up has to be addressed seriously from the beginning of a telemedicine project or initiative.

Bibliography

This bibliography lists all the references relating to the 18 critical success factors, and the relevant cases, and cited throughout this deliverable and its accompanying attachment.

Amado Guirado, E., C. Brotons Cuixart, A. Dalfó Baqué, E. Gibert Llorach, J. M. Pepió Vilaubi, and N. Salleras Marcó (2003). "Hipertensió Arterial. Guies de pràctica clinica i material docent." [Hypertension. Clinical practice guidelines and educational material], Institut Català de la Salut http://www.gencat.cat/ics/professionals/guies/docs/guia_hipertensio_completa.pdf. Accessed 27 October 2014.

American College of Radiology (ACR) (2013). "ACR White Paper on Teleradiology Practice: A Report from the Task Force on Teleradiology Practice." Journal of the American College of Radiology 10, no. 8 (August 2013): 575–585. http://www.jacr.org/article/S1546-1440%2813%2900185-3/pdf. Accessed 27 October 2014.

American Telemedicine Association (ATA) (2011). "Business Plan Template Summary." American Telemedicine Association Business and Finance Special Interest Group. Southwest Telehealth Resource Center, University of Arizona Health Sciences Center, Tucson, Arizona. http://www.southwesttrc.org/sites/southwesttrc.org/files/files/Business_Plan_Template_Summary.pdf. Accessed 27 October 2014.

Bashshur R.L., Shannon G.W. (2009). "National Telemedicine Initiatives: Essential to Healthcare Reform." Telemedicine and e-Health, Vol. 15 No.6: 600-610.

Becker, M. H. (1970). "Factors Affecting Diffusion of Innovations Among Health Professionals." American Journal of Public Health 60, no. 2 (February 1970): 294-303.

Berwick, Don (2003). "Disseminating Innovations in HealthCare." Journal of the American Medical Association 289, no. 15 (April 16, 2003): 1969.

Bos, L. (2008). Community Research and Development Information Service. "Pre-commercial Procurement: PCP related initiatives in countries around Europe." http://cordis.europa.eu/fp7/ict/pcp/msinitiatives_en.html. Website updated 13 January 2014. Accessed 27 October 2014.

Brownsell, S., T. Ellis (2013). Ready Steady Go. January 2013. Sheffield Teaching Hospital NHS Foundation Trust and the University of Sheffield: Sheffield. ISBN: 978-1-908. http://clahrc-sy.nihr.ac.uk/resources/toolkits/SY CLAHRC Toolkit Exec Summary.pdf. Accessed 27 October 2014.

Brunetti, N. D., G. Di Pietro, A. Aquilino, A. I. Bruno, G. Dellegrottaglie, G. Di Giuseppe, C. Lopriore, L. De Gennaro, S. Lanzone, P. Caldarola, G. Antonelli, and M. Di Biase (2014). "Pre-hospital electrocardiogram triage with tele-cardiology support is associated with shorter time-to-balloon and higher rates of timely reperfusion even in rural areas: data from the Bari-Barletta/Andria/Trani public emergency medical service 118 registry on primary angioplasty in ST-elevation myocardial infarction." European Heart

Journal: Acute Cardiovascular Care 3, no. 3 (September 2014): 204-13. doi:10.1177/2048872614527009.

Buswick, Ted (1990). "Champions of Technology Innovation." Training and Development Journal 44, no. 2 (February 1990): 48-54.

Cavoukian A., D. A. Hoffman, and S. Killen (2009). "Remote Home Healthcare Technologies: How to Ensure Privacy? Build It In: Privacy by Design." Information and Privacy Commissioner of Ontario, Canada. http://www.privacybydesign.ca/index.php/paper/remote-home-health-care-technologies-how-to-ensure-privacy-build-it-in-privacy-by-design/. Accessed 27 October 2014.

Centre for Telemedicine and Telehealthcare (2014). Check! Telehealthcare at Scale. Centre for Telemedicine and Telehealthcare: Aarhus, Denmark. http://www.telemedicin.rm.dk Accessed 27 October 2014. [Available in Danish http://www.rm.dk/sundhed/faginfo/center+for+telemedicin/værktøjskasse/tjek!+telemedicin+i+stor+skala. Accessed 27 October 2014.]

[Chalmers John, et al.] Guidelines Committee (1999). "World Health Organization-International Society of Hypertension Guidelines for the Management of Hypertension", Journal of Hypertension 17, no. 2 (February 1999): 151-183.

Chan, C. V., L. A. Matthews, and D. R. Kaufman (2009). "A taxonomy characterizing complexity of consumer eHealth literacy." In American Medical Informatics Association Annual Symposium Proceedings 2009: 86. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2815448/. Accessed 27 October 2014.

Christensen, C.M., J.H. Grossman, and J. Huang (2009) The Innovator s Prescription - A Disruptive Solution for Healthcare. McGraw-Hill: New York.

[Christie, C., et al.] Commission on the Delivery of Future Public Services (2011). Report on the Future Delivery of Public Services. Commission on the Delivery of Future Public Services. http://www.scotland.gov.uk/Resource/Doc/352649/0118638.pdf. Accessed 27 October 2014.

[Chobanian, Aram V., et al.] Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (2003). "The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The JNC 7 report", Journal of the American Medical Association 289 no. 19 (2003): 2560-2571. doi:10.1001/jama.289.19.2560.

COCIR (2011) COCIR telemedicine toolkit. Supporting effective deployment of telemedicine and mobile health. Brussels: COCIR, May 2011 http://www.cocir.org/uploads/documents/Telemedicine Toolkit LINK2.pdf. Accessed 27 October 2014.

(CPME) Comité Permanent des Médecins Européens (CPME) (1997). "Ethical guidelines in telemedicine", Comité Permanent des Médecins Européens [Standing Committee of European Doctors]. http://www.unav.es/cdb/cpme97a.html. Accessed 27 October 2014.

EC (1995). 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. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML. Accessed 27 October 2014.

EC (2008) Commission of the European Communities, Brussels, 4.11.2008, COM(2008) 689, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society.

EC (2012). Digital Agenda for Europe. "eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century." http://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century. Accessed 27 October 2014.

EC (2013). Guidelines on Minimum/Non-exhaustive Patient Summary Dataset for Electronic Exchange in Accordance with the Cross-border Directive 2011/24/EU., Release 1, Version: 1.0, 19 November 2013. http://ec.europa.eu/health/ehealth/docs/guidelines_patient_summary_en.pdf. Accessed 27 October 2014.

EC (2014). COM(2014) 219 final "Green Paper on mobile health ('mHealth')." 10 April 2014. http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth. Accessed 27 October 2014.

EC Directorate-General for Justice (2012). "Commission proposes a comprehensive reform of the data protection rules", Data Protection news release, 25 January 2012. http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm. Accessed 27 October 2014.

Edler, J. and L. Georghiou (2007). "Public procurement and innovation—Resurrecting the demand side." Research Policy 36, no. 7 (September 2007): 949-963. doi:10.1016/j.respol.2007.03.003. http://www.sciencedirect.com/science/article/pii/S0048733307000741. Accessed 27 October 2014.

EFQM (2012). An overview of the EFQM Excellence Model. Brussels: EFQM.

(eHSG) eHealth Stakeholder Group (2014). "Widespread Deployment of Telemedicine Services in Europe." Report of the eHealth Stakeholder Group on implementing the Digital Agenda for Europe Key Action 13/2 'Telemedicine', Version 1.0 final, 12 March 2014. http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=5167. Accessed 27 October 2014.

EHTEL (2008). Sustainable Telemedicine: paradigm for future-proof healthcare. A Briefing Paper. Version 1.0. Brussels: EHTEL, 20 February 2008 http://www.ehtel.org/activities/references-files/task-force-telemedicine/ehtel-briefing-paper-sustainable-telemedicine.pdf. Accessed 27 October 2014.

EU (2014). Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.094.01.0065.01.ENG. Accessed 27 October 2014.

European Society of Radiology (ESR) (2014). "ESR white paper on teleradiology: an update from the teleradiology subgroup", Insights into Imaging 5, no. 1 (February 2014): 1-8. http://link.springer.com/article/10.1007%2Fs13244-013-0307-z. Accessed 27 October 2014.

EurActiv (2013). "EU lawmakers vote stricter data privacy rules." 22 October 2013. http://www.euractiv.com/infosociety/eu-lawmakers-vote-stricter-data-news-531217. Accessed 27 October 2014.

Eurobarometer (2010). "Attitudes on Data Protection and Electronic Identity in the European Union", Special Eurobarometer 359. Report of survey conducted by TNS Opinion & Social at the request of Directorates-General Justice, Information Society & Media, and Joint Research Centre. http://ec.europa.eu/public_opinion/archives/ebs/ebs_359_en.pdf. Accessed 27 October 2014.

Finlands Läkarförbund (2004), "Medicinsk etik" [Ethics in Medicine], Suomen Lääkäriliiyyo/Finlands Läkarförbund [Finnish Medical Association]. http://www.laakariliitto.fi/site/assets/files/1273/med_etik06.pdf. Accessed 27 October 2014.

FOR-2000-12-15-1265 (2000). "Forskrift om behandling av personopplysninger (Personopplysningsforskriften)." [Regulations on the processing of personal data (Personal Data Regulations)]. http://www.lovdata.no/for/sf/fa/xa-20001215-1265.html. Accessed 27 October 2014. Available in English at http://www.ub.uio.no/ujur/ulovdata/for-20001215-1265-eng.pdf. Accessed 27 October 2014.

Foster, M. (2006). Telehealth business models. An assessment tool for telehealth business opportunities in rural remote communities. Report to the University of Alaska, Anchorage, Institute of Social and Economic Research. http://www.iser.uaa.alaska.edu/Publications/TelehealthReport1b.pdf. Accessed 27 October 2014.

Hardaker, M. and B.K. Ward (1987). How to make a team work. Harvard Business Review, Vol 65, pp112-119 http://www.hull.ac.uk/php/sbsad2/Article_3__How_to_make_a_team_work.pdf, accessed 27 October 2014.

Helsedirektoratet (Hdir) (2014). "Norm for informasjonssikkerhet helse- og omsorgstjenesten (Normen)" [Code of Conduct for information security in the healthcare, care, and social services sector]. http://normen.no. Accessed 05 September 2014. English version available at: http://helsedirektoratet.no/lover-regler/norm-for-informasjonssikkerhet/english/Sider/default.aspx. Accessed 27 October 2014.

Herold, R. (2010). Managing an Information Security and Privacy Awareness and Training Program. 2nd ed. Boca Raton, Florida: CRC Press.

(HOD) Helse- og omsorgsdepartementet (HOD) (2001). "Telemedisin og ansvarsforhold" [Telemedicine and Responsibility]. http://www.regjeringen.no/nb/dep/hod/dok/rundskriv/2001/i-122001.html?id=108946. Accessed 27 October 2014.

Howell, J.M. and K. Boies (2004). "Champions of Technological Innovation: The Influence of Contextual Knowledge, Role Orientation, Idea Generation, and Idea Promotion on Champion Emergence." Leadership Quarterly 15, no. 1 (February 2004): 123-143. doi:10.1016/j.leaqua.2003.12.008

(HHS) Department of Health and Human Services (2014). "Privacy Awareness Training", US Department of Health and Human Services http://www.hhs.gov/ocio/securityprivacy/awarenesstraining/privacyawarenesstraining.pdf. Accessed 27 October 2014.

International Organization for Standardization (ISO) (2008). "ISO 9001:2008, Quality management systems – Requirements." International Organization for Standardization: Geneva. http://www.iso.org/iso/catalogue_detail?csnumber=46486. Accessed 27 October 2014.

International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) (2011). "ISO/IEC 27005:2011, Information technology — Security techniques — Information security risk management." International Organization for Standardization: Geneva. http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=56742. Accessed 27 October 2014.

International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) (2013). "ISO/IEC 27001:2013, Information technology — Security techniques — Information security management systems – Requirements." International Organization for Standardization: Geneva. http://www.iso.org/iso/home/standards/management-standards/iso27001.htm. Accessed 27 October 2014.

Jack, C. and M. Mars (2008). "Telemedicine: a need for ethical and legal guidelines in South Africa." South African Family Practice 50, no. 2 (March/April 2008): 60-60d. http://www.ajol.info/index.php/safp/article/viewFile/13441/64239. Accessed 27 October 2014.

Legido-Quigley, H., N. Doering, and M. McKee (2014). "Challenges facing teleradiology services across borders in the European union: A qualitative study." Health Policy and Technology 3, no. 3 (September 2014): 160-166. doi:10.1016/j.hlpt.2014.04.001. http://www.healthpolicyandtechnology.org/article/S2211-8837(14)00029-X/abstract. Accessed 27 October 2014.

Lehoux, P. (2004). Patients' perspectives on high-tech home care: a qualitative inquiry into the user-friendliness of four technologies. BMC Health Services Research 4, no. 28 (5

October 2004). doi:10.1186/1472-6963-4-28. http://www.biomedcentral.com/1472-6963/4/28. Accessed 27 October 2014.

Ley Orgánica 15/1999 (1999). Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal [ORGANIC LAW 15/1999 of 13 December on the Protection of Personal Data]. BOE-A-1999-23750. Agencia Estatal, Boletín Oficial del Estado: Madrid. https://www.boe.es/buscar/doc.php?id=BOE-A-1999-23750. Accessed 27 October 2014. Unofficial English translation (maintained by the Spanish Data Protection Agency, AGPD) available at: https://www.agpd.es/portalwebAGPD/english_resources/regulations/common/pdfs/Ley_Orgaica_15-99_ingles.pdf. Accessed 27 October 2014.

Loane, M. and R. Wootton (2002). "A review of guidelines and standards for telemedicine." Journal of Telemedicine and Telecare 8, no. 2 (01 April 2002): 63-71. doi:10.1258/1357633021937479. http://jtt.sagepub.com/content/8/2/63.full.pdf or http://jtt.sagepub.com/content/8/2/63.full.html. Accessed 27 October 2014.

Merck, Sharp & Dohme Ltd. (2014). Things to consider when designing your telehealth service. Closer Care™. Hoddlesdon, Herts: Merck, Sharp & Dohme Ltd.

Newbold (2014) Launch of the first-ever toolkit to help people understand and use health apps. http://www.scribd.com/doc/241465352/Health-apps-a-toolkit. (1 October 2014.) Accessed 27 October 2014.

(NIH) National Institutes for Health (2014). "NIH Information Security and Privacy Awareness Training." National Institutes of Health. http://irtsectraining.nih.gov/. Accessed 27 October 2014.

Norsk Psykologforening (2002). "Veileder for psykologers faglige virksomhet på Internett" [Guidance on psychologists' professional activities on the Internet]. Tidsskrift for Norsk Psykologforening 39 (2002): 528-530. http://www.psykol.no/content/download/34530/345933/version/1/file/veilederTNPF2002.pdf. Accessed 27 October 2014.

Rogers, E.M. (1962) Diffusion of Innovations. Glencoe: Free Press.

(STH) SANS Securing the Human (2014). "STH.Healthcare Training Video Courseware." http://www.securingthehuman.org/healthcare/demo-training-lab. Accessed 27 October 2014.

Schein, Edgar H. (1999). Process consultation revisited: Building the helping relationship. Reading, MA: Addison-Wesley.

Sundhedsstyrelsen (2005). "Vejledning om ansvarsforholdene mv. ved lægers brug af telemedicine" [Guidance on Responsibilities etc. by Doctors' use of Telemedicine]. http://sundhedsstyrelsen.dk/da/udgivelser/2005/vejledning-om-ansvarsforholdene-mv-ved-laegers-brug-af-telemedicin.aspx. Accessed 27 October 2014.

(UEMS) Union Européenne des Médecins Spécialistes (2009). "European definition of the Medical Act." UEMS 2009/14, 25 April 2009. Brussels: Union Européenne des Médecins Spécialistes. http://www.uems-

ophtalmologie.org/uems_documentation_doc_9i_definition_medical_act.php. Accessed 27 October 2014.

van der Heijden, J., N.F. de Keizer, J.D. Bos, P.I. Spils, and L. Witkamp (2011) "Teledermatology applied following patient selection by general practitioners in daily practice improves efficiency and quality of care at lower cost." Br J Dermatol. Nov; 165(5):1058-65. doi: 10.1111/j.1365-2133.2011.10509.x. http://www.ncbi.nlm.nih.gov/pubmed/21729026. Accessed 27 October 2014.

van Dyk, L. and C. S. L. Schutte (2013). "The Telemedicine Service Maturity Model: A Framework for the Measurement and Improvement of Telemedicine Services." In Telemedicine, edited by Ramesh Madhavan and Shahram Khalid. doi:10.5772/56116. http://www.intechopen.com/books/telemedicine/the-telemedicine-service-maturity-model-a-framework-for-the-measurement-and-improvement-of-telemedic. Accessed 27 October 2014.

(WHO) World Health Organization (2012). Legal frameworks for eHealth. Global Observatory for eHealth series, vol. 5. Geneva: World Health Organization. http://www.who.int/goe/publications/ehealth_series_vol5/en/. Accessed 27 October 2014.

Yorkshire and Humberside HIEC (Health Innovation and Education Cluster) (n/d). Introducing Telehealth at Scale and Pace. A Development Resource for Telehealth Pioneers. http://yhhiec.org.uk/telehealttoolkit/ Accessed 27 October 2014.

ANNEX 1: Indicators for the critical success factors

This annex contains the originals of all the possible statements to be used in the test phase of MOMENTUM, an exercise that was run in Kristiansand, Norway on 27 October 2014.[124]

How these statements (posed as questions) were updated and used is explained in detail in the MOMENTUM deliverable, D3.3 action plan. A further set of explanations will be provided in deliverable D3.4.

It has been observed by the MOMENTUM community that these 18 example questions could be criticised constructively and then further refined before they are used again.

Critical success factors relating to strategy and management

1. Ensure that there is cultural readiness for the telemedicine service

- In my organisation/region doctors and other healthcare professionals are ready to share clinical information with each other and with the patient i.e. there is a level of trust among all the stakeholders.[125]
- In my organisation/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).
- In my organisation/region financial and other incentives are aligned with the service to be deployed.
- In my organisation/region an underpinning culture embraces technology.
- In my organisation/region an underpinning culture welcomes and even promotes change, innovation and shows openness to new ideas.

2. Ensure leadership through a champion

- In my region/organisation there is one or several influential person(s) who take(s) on a leading role and leads the way towards deployment of the telemedicine solution tested in our project.

3. Come to a consensus on the advantages of telemedicine in meeting compelling need(s)

- In my region/organisation there is general consensus on the current telemedicine solution being the best available solution for meeting a compelling need.
- I believe that the current telemedicine solution is the best available solution for meeting a compelling need.

4. Pull together the resources needed for deployment

- In my region/organisation the financial resources needed for deployment of the telemedicine solution are available.

---

[124] The wording of the four categories of critical success factors was correct as of 15 September 2014. The wording of each individual critical success factor is still correct as of 14 November 2014.

[125] This success factor is relevant in both provider-provider services and provider-patient services. However, in a provider-provider service, the willingness to share information with the patient is less important.

- In my region/organisation the IT competences needed for deployment of the telemedicine solution are available.
- In my region/organisation enough time for the training needed in order to implement the telemedicine solution is available.

Critical success factors relating to organisation and management

5. Address the needs of the primary client(s)

- The telemedicine solution addresses the needs of the primary clients.
- The telemedicine solution is sufficiently adapted to the needs of the primary users.

6. Involve healthcare professionals and decision-makers

- Healthcare professionals have been involved in the development of the content of this project.
- Healthcare professionals have been involved in the development of the process and time schedule for this project.
- Decision-makers have been involved in the development of the content of this project.
- Decision-makers have been involved in the development of the process and time schedule for this project.

7. Prepare and implement a business plan.

- A business plan for the project has been developed.
- A business plan for the project has been implemented.
- The business plan has been approved by the relevant management level.

8. Prepare and implement a change management plan

- A change management plan for the project has been developed.
- A change management plan for the project has been implemented.
- A change management plan has been approved by the relevant management level.

9. Put the patient at the centre of the service

- In this project the patients have been sufficiently involved in the development of the telemedicine solution.
- In this project telemedicine service is based on the patient´s needs.
- In this project we are able to provide enough information and training for the patients in order for them to obtain the best results possible from using the telemedicine solution.

Critical success factors relating to legal, regulatory and safety issues

10. Assess the conditions under which the service is legal

- Prior to the project we assessed the conditions under which the service is legal.

11. Involve legal and security experts

- We have received advice on the project from legal experts.
- We have received advice on the project from experts on legal matters.
- In this project we are not experiencing any data security problems.
- I have confidence in the legality of this project.
- I have confidence in the security of this project.

12. Identify and apply relevant legal and security guidelines

- The project is carried out in accordance with the relevant guidelines on legal matters.
- The project is carried out in accordance with the relevant guidelines on security matters.

13. Ensure that telemedicine doers and users are "privacy aware"

- In this project the telemedicine doers are aware of protecting the patients´ privacy in terms of health information and other information collected during the course of the project.

Critical success factors relating to technical and infrastructural issues

14. Ensure that the information technology infrastructure and eHealth infrastructure are available

- We have ensured that the IT and eHealth infrastructures needed are in place for deployment and large-scale implementation.

15. Ensure that the technology is user-friendly

- The telemedicine technology used in our project is user-friendly for both patients and for health professionals.
- The telemedicine technology used in our project does not need an extended training process prior to using it.

16. Put in place the technology and processes needed to monitor the service

- We have set up a system to monitor our telemedicine service ensure that it is running smoothly at all times.
- We have set up a system to solve any incident that may occur during the service.
- We have a system which supports the end-users in resolving any doubts that they might experience with the telemedicine solution.

17. Establish and maintain good procurement processes

- We have clear agreements regarding the quality of the deliveries provided by our vendors.
- We have clear agreements regarding the service level provided by our vendors.

18. Guarantee that the technology has the potential for scale-up.

- We are fully aware of what it takes for the technology to be deployed on a large scale.
- In our region/organisation we are ready for large-scale deployment of the technology.
- The project will supply the documentation needed to ensure that there is a basis for large-scale deployment of the project.

ANNEX 2: An overview of telemedicine systems' characteristics

This short annex aims at providing MOMENTUM blueprint readers with a list of the possible characteristics of telemedicine systems. Telemedicine doers can compare this list of characteristics with the terms and conditions under which they intend personally to deploy their own system or service. They may also use the list as a form of preparation for undertaking the MOMENTUM-TREAT assessment phase: hence, it is useful to examine the table below in conjunction with the indicators described in ANNEX 1.

Some observations on the potential characteristics of telemedicine systems follow as does a table containing the characteristics.

Potential characteristics of telemedicine systems

From the work undertaken by the MOMENTUM community, several distinctive characteristics have been developed which typify the telemedicine systems developed by telemedicine doers. These characteristics are not definitive or absolute; rather, they form a kind of "typology", which needs further, future, elaboration.

The first set of characteristics describes the organisation, its patients, the relevant technology infrastructure(s), and the deployment characteristics.

The table that follows contains a set of five general characteristics or attributes to the background to the health system that is being described. The five elements are:

- Socio-political characteristics, including the legal system.
- Organisational characteristics.
- Technology infrastructure characteristics.
- Deployment characteristics.[126]
- Patients' characteristics.

The table can be used to examine telemedicine deployment cases. Examples include the seven specific cases that the MOMENTUM community has already explored, i.e., chronic disease management (Maccabi), RXeye, Norwegian Teledialysis, ITHACA, Patientenhilfe, KSYOS and Cardio On Line Europe. Each case can be described by the way in which it is typified by these various characteristics. As a result, it may be possible to assess the way(s) in which these background attributes have an effect on the 18 critical success factors.

---

[126] These issues might include: the spread of the service, the socio-economic rationale, the role of the commercial partner, the type of primary client, the ultimate purpose of the service, and the potential for scale-up.

Table 2: General characteristics or attributes of the background to the system

1. Socio-political characteristics, including the legal system
[ ] Country's healthcare system is a Beveridge-style system
[ ] Country's healthcare system is a Bismarckian (insurance-based) system
[ ] Country's healthcare systems is a semi-privatised or privatised system
[ ] Country has a law relating to integrated care (i.e., social care and healthcare brought together)
[ ] Country has a law relating to telemedicine services
[ ] Other (specify)
2. Organisational characteristics
[ ] The organisation is a publicly-financed organisation.
[ ] The organisation is a privately-financed organisation.
[ ] An organisation is based on a public-private partnership.
[ ] Several independent organisations are contributing to the system or service.
3. Technology infrastructure characteristics
[...] High-speed broadband architecture in the country or region.
[...] High-quality digital television.
[...] Available health information systems.
[...] Available electronic health records.
[...] Available electronic health data.
4. Deployment characteristics   **(including e.g., the spread of the service, the socio-economic rationale, the role of the commercial partner, the type of primary client, the ultimate purpose of the service, and the potential for scale-up)**
4.1 Spread of the service
[ ] The telemedicine deployment takes place inside the organisation.
[ ] The telemedicine deployment takes place across organisational boundaries.

[ ] The telemedicine service takes place provider[127] to patient.
[ ] The telemedicine service takes place provider[128] to healthcare professional (e.g., doctor to doctor).
4.2 Socio-economic rationale underpinning the service
[ ] The business case (or socio-economic rationale) motivating the deployment of the service is defined by a public authority which is aiming at deploying the service for the benefit of a national or a regional healthcare system.
[ ] The business or socio-economic rationale motivating the deployment of the service is defined by a healthcare organisation aiming at deploying the service for its own purpose.
Role of the commercial partner in the service
[ ] The associated commercial organisation is: an active partner, alongside one of the above entities (e.g., a public authority, a national healthcare system, a regional healthcare system), that is seeking to deploy the telemedicine service(s).
[ ] The associated commercial organisation is: an active partner, alongside one of the above entities (e.g., a public authority, a national healthcare system, a regional healthcare system), that is seeking to replicate a similar deployed service elsewhere.
[ ] The associated commercial organisation is: not actively involved in such a partnership.
Type of primary client(s) of the service
The primary client may be a person, specialty group or organisation that uses the telemedicine service and is interested to maintain and improve it.
The primary client may be a direct or indirect payer of the service (through taxes or insurance, or business incentives).
Ultimate purpose of the service.
The service is intended to provide a better service and increase professional or service quality.
The service is intended to get quicker, and cheaper access to the healthcare services at the place he/she wants to use them.
The service is intended to Increase process efficiency and effectiveness.
Potential for scale-up of the service
[ ] The wider deployment of the currently deployed telemedicine service is replicable in other organisations or another geographic area with minimum

---

127 In other parts of the MOMENTUM study, e.g., those on the subject of organisation and management, the expressions "doctor-to-patient" (D2P) or "healthcare professional-to-patient" have also been used.

128 In other parts of the MOMENTUM study, e.g., those on the subject of organisation and management, the expressions "doctor-to-patient" (D2P) or "healthcare professional-to-patient" have also been used.

adjustments.
[ ] The wider deployment of the currently deployed telemedicine service needs major adaptation before its deployment either in other organisations or other geographic areas.
5. Patients' characteristics **If the service is intended for patients, the patients' offered the service have these particular characteristics (i.e., they experience these particular health problem(s))**
[ ] Cardiovascular disease.
[ ] Chronic pulmonary disease.
[ ] Diabetes (type II).
[ ] Other co-morbidities.
[ ] Other (specify).

ANNEX 3: Outline of the MOMENTUM project methodology

This annex outlines the general way in which MOMENTUM has operated, and the means by which the seven in-depth case studies illustrating the 18 critical success factors were chosen.[129]

General approach

To arrive at the (personalised) blueprint guidelines, MOMENTUM has worked with a wide range of stakeholders involved in telemedicine deployment. The MOMENTUM network includes many kinds of doers: both those who are currently involved in the day-to-day provision of telemedicine services such as health managers, clinicians, and public administrators, and those stakeholders who define and drive the policy framework for telemedicine but who are not necessarily quite so "hands-on".

The concrete work of MOMENTUM has consisted of an exchange of experiences, the documenting of the lessons learned through those experiences, and their distillation into a practical blueprint for implementation. These responsibilities have been carried by telemedicine doers: people who are working daily to deploy telemedicine services into routine care. They have identified what strategic, organisational, technical and market-related issues needed to be addressed, the stakeholders to engage, and the practical measures to be adopted. Organised into four special interest groups (SIGs), the groups worked on four specific themes in an in-depth way so as to advance this (blueprint) set of guidelines. The groups liaised with one another and with associated stakeholders in workshops, conference calls, and online. Their leaders and key representatives consulted with each another regularly. They also met in the context of MOMENTUM's executive committee (EXCO) to identify any common or overlapping issues.

Selection of the seven in-depth cases

The methodology employed by MOMENTUM was an inductive one. It proved to be a practical and easy-to-apply approach. A sampling methodology was not used.[130] .

The consortium gathered information on some 30 telemedicine services. Most of these services have progressed from a pilot phase to either small-scale or large scale deployment. Others have been integrated into the routine delivery of health services.

These services were analysed from four perspectives:

- The strategic elements necessary for the initiation of the services.
- The management challenges for successful implementation of the services.
- Important legal and security issues.
- Technical infrastructure and market relations.

Critical success factors were identified in each of these four domains. This identification process was based on a two-stage approach to the analysis, one initial analysis exercise and

---

[129] An earlier version of this explanation of the methodology is available in the MOMENTUM deliverable D3.1b.

[130] http://tinyurl.com/Renewing-Health-Final-Report, accessed in 27 October 2014

a second, subsequent in-depth analysis of a limited number of cases. Four cases were first explored: they were the four MOMENTUM cases that had achieved a level of large-scale deployment, and had been successfully integrated into the routine delivery of services. The resulting critical success factors were then applied to three additional cases which were not part originally of the MOMENTUM database. This wider investigation was undertaken in order to determine whether the 18 observed critical success factors continued to be valid in other settings.

Details

The MOMENTUM consortium used the materials it had collected in the project in the following ways:

- An In-depth exploration of four cases collated between September 2013-May 2014: Maccabi, RXeye, Norwegian Teledialysis, and ITHACA. These four cases were selected carefully from a body of example success factors first observed in 17 successfully-deployed cases. (These 17 were originally gathered by Momentum in spring/summer 2012 using a detailed questionnaire.[131]) The cases selected were intended to reflect different types of telemedicine in a variety of countries/systems, and over a range of time-periods. For example, they showed how deployment into routine care could be done in both provider-to-provider and provider-to-patient systems and under different reimbursement mechanisms.

- Further in-depth exploration also took place of three cases (two of which were presented to the consortium and a wider community of attendees, in Athens, Greece on 14/15 May 2014): Patientenhilfe in Germany[132], KSYOS in the Netherlands, and Cardio On Line Europe in Italy.

Benefits of the method

This approach was intended to exploit thoroughly the complete body of evidence collected by MOMENTUM over the project's duration. It has had several benefits:

- Overall, the approach shows that the seven cases represent several configurations of classes of telemedicine services, involving both public and also private ownership, and types of end-users – either health professionals or patients. This makes them applicable to multiple other telemedicine scenarios.

- The results offer a lively illustration of a range of 18 key critical success factors (e.g., champions, and business cases) from throughout the EU, and wider.

- The cases have been gathered as a result of cooperation developed among the members of the MOMENTUM expert network.

- The method illustrates that the experiences of others can be used as concrete, productive learning exercises.

---

[131] This has, however, been the method used in some recently run European Commission co-financed projects, such as the Renewing Health large-scale pilot: see http://telemedicine-momentum.eu/europe/, accessed in 27 October 2014.

[132] This case was also presented at a MOMENTUM project steering committee in spring 2012 in Berlin, Germany.

- The method shows that good practice examples can be used productively by other people on different sites to assess the terms and conditions operating in their own setting.