

(Grant Agreement No 297320)

Knowledge gathering Questionnaire

Version 2

[Summary, not to be used for answering – more by contacting info@telemedicine-momentum.eu]

Work Package: WP3 "Knowledge gathering & consolidation"

Version & Date: V2. / 2nd October 2012 – Summary prepared on 22 October 2012

Deliverable type: Questionnaire

Distribution Status: External

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Filename: MOMENTUM WP3 Questionnaire 2 v2 - Headings

Remark

This questionnaire is to be completed for a telemedicine service in daily operation, defined as a service that

- a. is part of the regular way of providing care or treatment to a significant number of patients/citizens, <u>and</u>
- b. is funded or reimbursed as part of the normal funding or reimbursement system in your healthcare system.

It is also for <u>a terminated service</u>, in other words a failed attempt to deploy a telemedicine service in daily operation: Momentum considers it equally important to learn from the lack of success.



Introduction and background

The overall aim of the MOMENTUM thematic network is to create a blueprint for European deployment of telemedicine services. The work towards the aim is divided between four special interest groups (SIGs) that will each focus on a specific area. These areas are:

- 1. Telemedicine strategy and management
- 2. Organisational implementation and change management
- 3. Legal, regulatory and security issues
- 4. Technical infrastructure and market relations

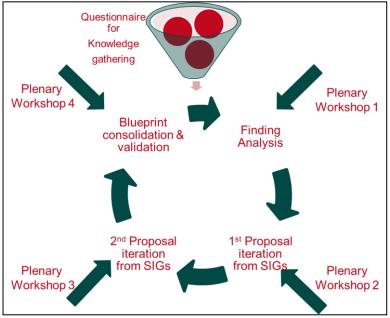
First, it is necessary to have a basis of knowledge on which to build the work of each SIG. This is the purpose of this questionnaire. It is structured in 2 parts:

- An introductory part that is only to be completed once per healthcare authority regardless of the number of services included in the questionnaire.
- The main part consists of 5 sections (service specific introduction, Strategy and management;
 Organisational implementation and change management; Legal, regulatory and security issues; and
 Technical infrastructure and market relations), of which four are directly associated with the SIGs.
 Each section contains a number of sub-topics.

This questionnaire is a mixture of open and closed questions in order to balance the content received and to allow for individual views and assessments.

Please be aware that the questionnaire may take you around 3-4 hours in total per telemedicine service to complete depending on the complexity of the service.

Work within the consortium will start from the data collected with this questionnaire and will develop a set of best practices and guidelines by passing through different stages as described below:



From "knowledge gathering" to outcome via 4 consultation workshops



Contents

Introductory questions – general	7
A. Organisation and affiliation	7
B. Health and care system	7
C. Overall strategy and legislation relating to telemedicine	7
Introductory questions – service specific	8
1. Respondent	8
2. Title of service	8
3. Description of service and main beneficiary	8
4. Current status of telemedicine service	8
5. Targeted population and condition	9
6. Characteristics of the service	9
7. Conventional treatment	
8. Expected outcomes and results	9
Strategy and Management	
9. Policy context and support and role of political environment	10
10. Decision-makers and stakeholders	10
11. Financing	10
12. Assessment of outcomes	11
Organisational Implementation and Change Management	12
13. Involvement in process	12
14. Patient flow and work processes	12
15. Collaboration with external institutions/organisations	12
16. Training and education of professionals	12
17. Professional's experience with research, development and telemedicine in general	13
18. Healthcare professionals' satisfaction	13
19. Training and education of patients	13
20. Patient satisfaction	13
21. Patient empowerment	
22. Ethical issues relating to patients	
Legal, regulatory and security issues	
23. Telemedicine legislation	
24. Legal issues, including accreditation, liability, conflicts of law	
25. National guidelines for clinical responsibility and liability	
26. Consent, ethical approval and concerns	
27. Data management procedures	
28. Information security risk assessment	
29. Security issues	17
30. Privacy training for personnel	
31. Mapping of legal, regulatory and security stakeholders	
Technical Infrastructure and Market Relations	
32. Infrastructure	
33. Connections and networks	
34. Integration, standards and interoperability	
35. Risk management	
36. Purchase and procurement strategy	
37. Alternative equipment	
38. Integration and documentation of the telemedicine treatment	20



Glossary

Word	Description / meaning in questionnaire
Assessment / evaluation	How the elements of a service (such as its technology, clinical effect,
	economy and user satisfaction) are measured and appraised. In the
	questionnaire, assessment and evaluation are treated as synonyms.
Bespoke	The technical solutions (devices, systems, platform, interface) and
	services that are specially made or customised for a given service or
	organisation.
Conventional treatment	How the medical treatment or task was performed prior to the
	implementation of the telemedicine service. The telemedicine service
	then either replaces the conventional treatment method or provides an
	alternative or supplement to it.
Data controller	'Controller' shall mean the natural or legal person, public authority,
	agency or any other body which alone or jointly with others determines
	the purpose and means of the processing of personal data; where the
	purposes and means of processing are determined by national or
	Community laws or regulations, the controller or the specific criteria for
	his nomination may be designated by national or Community law.
Deployment / implementation	How a telemedicine service is rolled out at local level in an institution or
. ,	organisation or, more broadly, across multiple organisations, e.g. at the
	regional or national level. Implementation covers technical,
	organisational, or economic aspects. In the questionnaire, deployment
	and implementation are treated as synonyms.
Direct user fee	A direct user fee is the principle of users paying directly for a service, i.e.
	if a patient herself or himself pays from her/his own pocket the full
	amount for receiving a service or part of it. Indirect payment through e.g.
	tax, insurance etc. is not covered by this term.
Empowerment	Improved independence and self-management of the patients in relation
	to their condition.
Mainstream service delivery /	The service is an integrated part of an organisation's service delivery.
Running operations	Services still under development or are part of a study/project are not
	considered mainstream, as they are offered under special conditions.
	Other terms are daily or running operations as well as routine care.
Patients	The full range of citizens/people that, in relation to a condition or health
	or social care problem, is a recipient of a service.
Payment structure	The flow of money in the health and care system of a given country,
	region or institution.
Set-up	The overall structure of the telemedicine service solution, including
·	organisations, personnel groups, communication flow and technologies.
Special Interest Group (SIG)	In MOMENTUM there are four SIGs which, throughout the project, will
,	each focus on their particular topic related to telemedicine.
Telemedicine	The type of health and care services that are delivered through the use of
	technology. Telemedicine includes services that are also are known as
	telehealth, telecare or welfare technologies. It does not , for the purposes
	of this questionnaire, include well-being services.
VPN	A virtual private network (VPN) is a technology for using the Internet or



	another intermediate network to connect computers to isolated remote
	computer networks that would otherwise be inaccessible in a secure
	manner.



Acceptance of publication rights
By clicking the button marked 'I accept', please agree that MOMENTUM has the right to share and publish the information and data you provide in the questionnaire. Personal information will not be made public, but information that you provide on the telemedicine services themselves will be published as a part of MOMENTUM's products and services, such as articles and reports.
☐ I accept ☐ I do not accept.



Introductory questions – general

To be answered only once for the overall national healthcare system that relates to your telemedicine initiative.

A. Organisation and affiliation

B. Health and care system

C. Overall strategy and legislation relating to telemedicine

- C.1.) Do you have a strategy for telemedicine?
- C.2.) Do you have a strategy in other health-related or IT domains that includes telemedicine in some way?
- C.3.) Does the regional authority have a strategy in other health-related or IT domains that includes telemedicine in some way?
- C.4.) Does a national authority have a strategy in other health-related or IT domains that includes telemedicine in some way?
- C.5.) Does your country have legislation that deals with telemedicine specifically?

Is the issue of liability clarified in your country's legislation?

C.6.) Does your country have legislation that in any way hinders or obstructs the implementation of telemedicine services?



Introductory questions – service specific

Questions #1-8

1. Respondent

- 1.1.) Are you answering the specific telemedicine service part of the questionnaire on behalf of the same organisation and country as you did the general introduction part?
- 1.2.) What is the name of the organisation on behalf of which you are responding?
- 1.3.) Which country is your organisation based in?
- 1.4.) What level of experience does your organisation and yourself have with telemedicine?
- 1.5.) to 1.8.) [contact details for survey follow-up not to be published]

2. Title of service

2.1.) What is the title of the telemedicine service you are describing in the questionnaire?

3. Description of service and main beneficiary

- 3.1.) Please describe the overall aim of the service and the outcomes/results that you expected as a result of the introduction of the intervention (e.g. cost-savings; clinical effectiveness; quality of life)
- 3.2.) Who are the main beneficiaries of the (new) telemedicine service?

4. Current status of telemedicine service

4.1.) Is the telemedicine service that you describe in operation and running as part of mainstream service delivery?

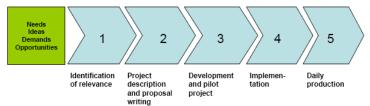
(1)

The service is not in operation because it has been:

- Discontinued before the service was implemented
- Discontinued after the service began to be implemented
- Never launched
- Other reasons that explain the current and past status of the service.

(2)

Identify at which phase or at which time in the procedure the decision to discontinue the telemedicine service was made.





5. Targeted population and condition

- 5.1.) Overall, which category fits your targeted population best?
- 5.2.) Please describe in your own words and in more detail the targeted population of the service (e.g., who is the telemedicine service intended for?; what is their condition or problem?; etc
- 5.3.) Overall, what is the estimated size of your targeted population?
- 5.4.) Please indicate the number of patients who receive it on a monthly basis.

6. Characteristics of the service

- 6.1.) Overall, how would you categorise the telemedicine service?
- 6.2.) Overall, what is the relationship between the key actors in your telemedicine service? There is no need to distinguish between public and private providers of care.
- 6.3.) Please describe the telemedicine service in terms of e.g., its type of treatment, technology (telecommunications, service platform), set-up and parties involved.

7. Conventional treatment

7.1.) Please describe the set-up of the conventional treatment for which you were looking to replace/change/provide an alternative to (e.g. in what way and to which extent was the telemedicine service expected to be superior to any former treatment?; are there other alternatives to the conventional treatment than the telemedicine service?)

8. Expected outcomes and results

8.1.) Please describe the outcomes/results that you expected as a result of the introduction of the telemedicine service (e.g. cost-savings; clinical effectiveness; quality of life.



Strategy and Management

Questions # 9 - 12

9. Policy context and support and role of political environment

- 9.1.) Has the decision to implement the telemedicine service been influenced by particular policy or the entry into force of some new legislation?
- (1)

If Yes, please state which policy or which legislation.

(2)

To which domain is the policy or legislation relevant?

(3)

Did the policy or legislation have an influence on the design of the telemedicine service and its implementation strategy?

(4)

Has the policy or legislation contributed to transform the telemedicine service into a sustainable service that is used in routine care (i.e., it is part of mainstream service delivery)?

10. Decision-makers and stakeholders

- 10.1.) At which institutional level has it been generally decided which telemedicine services are to be implemented?
- 10.2.) At which institutional level was it decided to implement/not to implement this specific telemedicine service?
- 10.3.) For the institution that you think was the most influential in the decision to implement the service, who generally makes the final decision on whether to implement/not to implement telemedicine services?
- 10.4.) Please identify if there were external stakeholders with a particular interest in implementation (or non-implementation) of the telemedicine service.

11. Financing

- 11.1) Is the financing of the telemedicine service different from the financing of the health or care sector in your country that is not using telemedicine services?
- 11.2.) Was a formal business case prepared for your telemedicine service?
- (1)

If No, how was the funding obtained?

(2)

If Yes, who prepared the business case?

(3)



Were all the relevant parties identified and were they engaged with preparing the business plan?

(4)

Was appropriate ownership assigned to all the key elements of the business plan?

(5)

Were the relationships between the telemedicine intervention and existing care provision services identified in the business plan? Were the collaboration models in place and appropriate for this?

- 11.3.) Please describe where the financing of the telemedicine service came from during the project phase (i.e. the phase prior to implementation as a routine care service before the service became part of mainstream service delivery) or in development, testing and/or validation.
- 11.4.) Please describe the payment structure of the service; i.e. who pays and how. Please tick all the relevant answers.
- 11.5.) Was any direct investment required to implement the telemedicine service?
- 11.6.) Is there a direct relation between those financing the service and those who receive the main benefits?
- 11.7.) Does the principle of a direct user fee apply to the delivery of the telemedicine service?

12. Assessment of outcomes

- 12.1.) How were the effects and consequences of the implementation of the telemedicine service measured / evaluated? Please tick all relevant answers.
- 12.2.) What methods were used to collect evidence / documentation of the effects of the telemedicine service?
- 12.3.) Please indicate the number of patients with which the telemedicine service was tested/piloted (do not include the control group if one was used).
- 12.4.) Which topics were included in the evaluation / assessment you performed?
- 12.5.) Please name the overall outcomes / results of the evaluation?



Organisational Implementation and Change Management

Questions # 13 - 22

13. Involvement in process

- 13.1.) On a scale from 1-5, how involved was the **department management team** in the **development and planning** of the telemedicine service (5 being the highest score)?
- 13.2.) On a scale from 1-5 how involved was the **department management team** in the **actual carrying out of the telemedicine service**?
- 13.3.) On a scale from 1-5 how involved was the **top-level organisational management team** in the **development and planning** of the telemedicine service?
- 13.4.) On a scale from 1-5 how involved was the **top-level organisational management team** in the **actual carrying out** of the telemedicine service?

14. Patient flow and work processes

- 14.1.) Was the patient flow directly affected by the telemedicine service, e.g. physical vs. virtual consultations, passive measurement vs. own measurement and/or entry of health data?
- 14.2.) How did the service affect the work processes?
- 14.3.) Which personnel groups were affected by these shifts in tasks? Please tick all the relevant answers.
- 14.4.) How did the service affect the resource distribution of personnel?

15. Collaboration with external institutions/organisations

15.1.) Was delivery of the telemedicine service dependent on collaboration with healthcare and/or care institutions and organisations outside your own?

16. Training and education of professionals

- 16.1.) Did the solution require any specific training or education of the professionals involved?
- 16.2.) Which type of training or education was required for the healthcare professionals involved?
- 16.3.) Was more training or education than expected or planned needed at any point?



17. Professional's experience with research, development and telemedicine in general

- 17.1.) On a scale from 1-5, how would you rate the experience of the primary healthcare professionals involved in the telemedicine service **with medical research in general**?
- 17.2.) On a scale from 1-5, how would you rate the experience of the primary healthcare professionals involved in the telemedicine service with **development projects and innovation in general**?
- 17.3.) On a scale from 1-5, how would you rate the experience of the primary healthcare professionals involved in the telemedicine service with telemedicine services (both projects and in operation) in general?

18. Healthcare professionals' satisfaction

18.1.) On a scale from 1-5 how would you rate the healthcare professionals' satisfaction with using the telemedicine service? Please tick the box above the number.

Please describe how the healthcare professionals' satisfaction was measured.

On what approximate number of personnel is your last answer based?

18.2.) Did the degree of satisfaction vary greatly among the personnel involved?

If Yes, please indicate if there were any patterns in the differences e.g., in relation to different personnel groups, ages, or level of involvement in decisions about the telemedicine service.

19. Training and education of patients

19.1.) Did the patients receive any training or education prior to the use of the telemedicine service?

20. Patient satisfaction

20.1.) On a scale from 1-5 how do you rate the overall satisfaction of the patients with the telemedicine service?

On what approximate number of patients is your last answer based?

20.2.) Was patient satisfaction measured systematically?

(1)

If Yes, please describe how patient satisfaction was measured:

(2)

If No, was it not measured at all or not officially measured – but informal feedback from patients and relatives was obtained



20.3.) Please describe if there were any issues of special concern or interest to the patients?

21. Patient empowerment

- 21.1.) Was patient empowerment part of the service as an intended goal?
- 21.2.) Please describe if patient empowerment was achieved (deliberately or unintentionally) and to what extent.

22. Ethical issues relating to patients

- 22.1.) Are there or were there any aspects or consequences of the service that led to any particular ethical considerations?
- 22.2.) Is an alternative service available for patients who refuse or are not able to manage the telemedicine treatment?



Legal, regulatory and security issues

Questions # 23 - 31

23. Telemedicine legislation

23.1.) Were changes to healthcare legislation a prerequisite for the implementation of telemedicine services in your country?

If there is specific telemedicine legislation in your country, please outline its core elements and provide a reference to it.

23.2.) Have any changes to legislation or other legal rules been made as a result of your particular telemedicine service?

If there is specific telemedicine legislation as a result of your telemedicine initiative, please outline its core elements and provide a reference to it.

23.3.) Is it your opinion that further changes in legislation in your country are necessary for wider and easier implementation of sustainable telemedicine services?

If yes, please describe in what way.

24. Legal issues, including accreditation, liability, conflicts of law

- 24.1.) Was specific accreditation of health care personnel legally required to implement your service?
- 24.2.) Is there a clear distribution of responsibility for legal liability among the healthcare providers that participate in the delivery of your telemedicine service?
- (1)

If there is any specific telemedicine liability legislation, please outline its core elements and provide a reference to it.

(2)

If distribution of liability is only partly clear, or not clear, please describe your concerns about the lack of clarity.

24.3.) Are liability and/or responsibility issues barriers to the large-scale implementation of your telemedicine service?

If Yes, please describe how.

24.4.) Does your service cross any borders relating to any legal authorities? Please tick all the relevant options.

If Yes, were any conflicts of law identified as a result of this crossing of borders?



If Yes, please describe the conflict(s) and how they were managed.

25. National guidelines for clinical responsibility and liability

25.1.) Is it within the framework or standards of professional responsibility for a doctor to treat patients via telemedicine (without face-to-face contact) in your country?

Are there any national guidelines or recommendations regarding distribution of clinical responsibility between the health care professionals when they use telemedicine services?

If yes, which institution is responsible for the guidelines?

25.2.) Are there any national guidelines or recommendations regarding distribution of legal liability between institutions involved in telemedicine services?

If Yes, which institution is responsible for the guidelines?

26. Consent, ethical approval and concerns

- 26.1.) Do patients need to give their explicit and informed consent in order to receive the telemedicine service?
- (1)
- In the event that patients have to give their informed consent, how do they do it? (2)

How is information about the telemedicine service provided to the patients?

26.2.) Has the telemedicine service been assessed by an ethical committee at any time?

If Yes, did the ethical committee have any comments or reservations related to legal, regulatory or security issues?

If Yes, please give a brief description.

If any ethical issues have been raised in relation to the telemedicine service by anybody, please describe which they were and by whom they were raised.

27. Data management procedures

- 27.1.) Is it obvious to you which organisation or individual is responsible for the security and legal standards of your telemedicine service?
- 27.2.) Has a data controller been identified?
- 27.3.) Did you have to make any changes to your normal data management procedures to implement your telemedicine service?

If you had to change a data management procedure, please describe the changes.



28. Information security risk assessment

28.1.) Has an assessment of risks to the information security been performed, i.e. risks to confidentiality, information integrity or availability?

29. Security issues

29.1.) Does the telemedicine service give a healthcare professional or other health service employees access to patients' health information?

If Yes, which methods of authentication are used to obtain access to the telemedicine service, including the patients' health information?

- 29.2.) Is the user automatically logged out from the system/service after a certain idle time (i.e., does the application timeout)?
- 29.3.) Is the data transfer (i.e., communication) encrypted?
- 29.4.) Is the communication performed via a VPN connection?
- 29.5.) Is all access to the system/service logged?

If yes, does anyone inspect the logs?

30. Privacy training for personnel

30.1.) Have all personnel had privacy training?

If Yes, how often is this training repeated.

30.2.) Are staff contracts and insurance in your organisation adequate for covering their use of your telemedicine system(s)?

31. Mapping of legal, regulatory and security stakeholders

31.1.) Do you know of authorities, organisations, or others working to clarify security, regulation, and/or legal aspects of telemedicine in your country?

If Yes, please specify and offer URLs or documentation where feasible.



Technical Infrastructure and Market Relations

Questions # 32 - 38

32. Infrastructure

- 32.1.) Please indicate which overall infrastructure (regional, national or organisational) is available to run the telemedicine services.
- 32.2.) Please indicate the specific infrastructure used to run the telemedicine service

33. Connections and networks

33.1.) Please describe the connections and networks and the locations on which your service is dependent. i.e. what you need for the devices and systems to function and where (e.g. wireless network for mobile devices; telephone line, broadband, ADSL, Videoconferencing or satellite in the home).

34. Integration, standards and interoperability

- 34.1.) Please indicate if the technology used to run the telemedicine service (devices and/or systems) and basic IT-system are integrated.
- 34.2.) Is the integration of your telemedicine system achieved using standards?
- 34.3.) Were relevant identity (ID) verifications technically and legally interoperable (i.e., were the IDs valid across organisations borders)?
- 34.4.) Did you use only certified systems (e.g. ISO 13473, EU 93/42/EEC) in your telemedicine service?
- 34.5.) Did all the necessary sensor devices used in the telemedicine service automatically interact with the controlling devices?
- 34.6.) Could the data be seamlessly transferred between home or other location for monitoring and the receiving part, e.g. telemedicine service centre, hospital, etc.?
- 34.7.) Could the data be seamlessly transferred between the receiving part (e.g. the telemedicine service centre) and other actors in health and social care?
- 34.8.) Are any of the devices you use as part of the technical set-up of the telemedicine service certified with regard to their interoperability with other devices, using e.g. Continua Health Alliance?
- 34.9.) Please name the family of standards used for interoperability in the context of the plugand-play interoperability of your telemedicine system: _____
- 34.10.) Does your public authority have any instrument or procedure for the accreditation



/certification of providers that comply with the interoperability requirements that your administration requires for its telemedicine system?

Which institution is responsible for this?

35. Risk management

35.1.) Do you have methods in place for the risk management of the devices and/or systems of the telemedicine service (e.g. to ensure effectiveness, security and safety)?

If yes, which one(s)?

36. Purchase and procurement strategy

- 36.1.) The telemedicine service you purchased/procured was it.
- 36.2.) Please indicate how the service was purchased/procured. Please tick all the relevant answers.
- 36.3.) Were appropriate service agreements established in connection with the purchase/procurement?

Please specify if you have anything to add.

36.4.) Did you co-operate with another telemedicine service provider in relation to the purchase/procurement?

Did this allow for a better deal with a vendor?

36.5.) Does your telemedicine infrastructure include devices or systems from different vendors?

If Yes, how did you integrate them?

36.6.) Are you using a bespoke platform to run the telemedicine service?

(1)

What is the name of the bespoke solution?

(2)

In the event of a bespoke solution, please name the main reasons why this solution was chosen?

What were the financial conditions of the development process of the bespoke solution? Please tick all relevant answers.



(4)

If you are not using a bespoke platform, please name all the proprietary products (systems/platforms) that you are using to run the telemedicine service.

36.7.) In both cases of a bespoke solution or a vendor product, please indicate who was directly involved in the development. Please tick all the relevant answers.

37. Alternative equipment

37.1.) At the time you purchased, was there alternative equipment, systems or services to your telemedicine service available on the market?

If alternatives were available at the time of selection of your telemedicine service, please describe what were the main reasons for choosing the technology used in your service.

37.2.) Do you know of similar alternative telemedicine systems/solutions now running in other territories in your country or in other countries?

If yes, please describe where.

38. Integration and documentation of the telemedicine treatment

38.1.) Are the telemedicine service events integrated with an Electronic Health Record?

If No, is there a separate documentation system for medical treatment including clinical data delivered and collected via the telemedicine solution?

Thank you for your help!

If you are interesting in following the MOMENTUM project, please sign up for MOMENTUM news and visit us at





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