Competitiveness and Innovation Framework Programme (CIP)

INDEPENDENT

ICT Enabled Service Integration for Independent Living

Deliverable 5.1

INDEPENDENT Pilot Operation

WP5: Pilot Site Preparation

February 2012

Project co-funded by the European Commission within the ICT Policy Support Programme
Grant agreement no.: 250521

Document information

Organisation responsible for the deliverable: empirica

Authors: Pablo Delgado Quinones (ASSDA)
Kalli Liatou (eTrikala)
Delaney Sarah (WRC)
Mark Gretton (UniHull)
Gordon Davies (Adepteq)
Herjan van den Heuvel (SMH)
Lutz Kubitschke (empirica)

Contributing partners: All pilot site teams

Delivery date: 15/03/2012

Dissemination level

P	Public	✔
C	Confidential, only for members of the consortium and the Commission Services	

Version history

Version	Date	Changes made	By	Sent to
0.1	07/03/2012	Draft final	empirica	pilot site managers
0.2	09/03/2012	Final for peer reviews	empirica	City Hull, ASI
1.0	15/03/2012	Final	empirica	CEC

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This deliverable contains original unpublished work except where clearly indicated otherwise.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.

Project co-funded by the European Commission within the ICT Policy Support Programme
Grant agreement no.: 250521

Contents

1 Introduction

The INDEPENDENT project focuses on enabling, with the help of technology, a better joining-up of social and health care services as they currently exist. There is also an emphasis on strengthening the participation of the so called "third sector", family carers and voluntary community workers who would otherwise not be in the usual information sharing loop. Operational work is organised within six interrelated work packages as follows:

- Requirements and use case definition (WP1)
- Service definition (WP2)
- Services specification (WP3)
- System implementation and test (WP4)
- Pilot site preparation (WP5)
- Pilot operation (WP6)
- Evaluation (WP7)
- Dissemination and exploitation (WP8)

Overall, INDEPENDENT brings together six pilot sites across five European countries, each aiming at better capitalising on information and communications technology (ICT) when it comes to supporting older people in their communities: Geldrop (NL), Trikala (EL), Malaga (ES), Dublin (IE), Hull (UK) and Milton Keynes (UK). This report summarises the work that has been pursued in relation to pilot site preparation (WP5) at each pilot site. In particular, this strand of work has focused on setting up the service to be piloted and ensuring staff are empowered to carry out service provision operation.

The following Chapter 2 presents the overall service approach adopted for the purposes of INDEPENDENT. This is followed by a more detailed description how this approach has been implemented at each pilot site (Chapters 3 to 8).

2 The INDEPENDENT pilot service approach

The starting point for INDEPENDENT lies in the fact that ICT-enabled forms of support to older people such as Telecare and Telehealth could be exploited in a more effective way if they were not, as today, embedded in and designed for healthcare and social care organisational "silos". For many years, national welfare and health systems and regional/local support practices were developing more and more specialisation and clear boundaries closed them to cooperation. Only recently, the dangers of closed silo service provision have started to be recognised at the policy level and steps considered to spread responsibility more widely and introduce cooperative structures, including third sector and citizens groups. In practice, however, truly joined-up service provision processes and pathways spanning across established health and social care domain boundaries have remained an exception as of today.

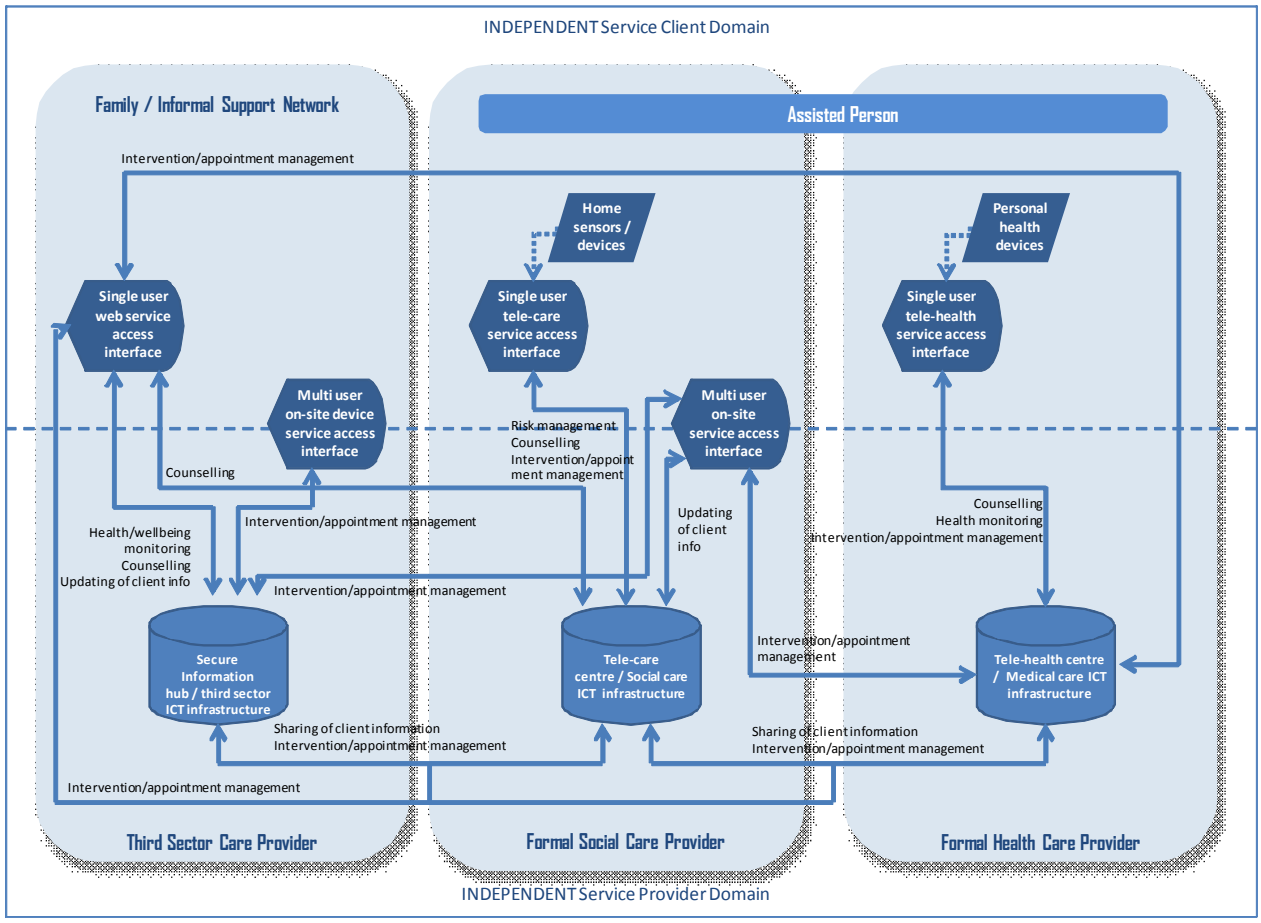
The INDEPENDENT pilot sites do not represent an exception from the general state of affairs in Europe and elsewhere. Organisational and other circumstances under which support is currently provided to older people varies quite a lot, and existing ICT-infrastructures need building on in order to also provide joined up service delivery. Individual forms of support (and stakeholder roles respectively) which are for instance available at one pilot site may not possible at another site, or they may be delivered in different ways and/or different parties. Similarly, given organisational boundaries between social and health care, funding/reimbursement practices and the legislative/regulative environment vary considerably.

Against this background, the INDEPENDENT project approach takes particular account of the current diversity across the pilot sites, as regards the type and nature of support services that are available to older people and ICT-infrastructures to build upon respectively. A controlled migration from existing work practices and technologies was considered and included in the INDEPENDENT approach. Almost by definition, this meant that the project encountered a great deal of legacy technology along the way, which was created in the past to support a range of (dis-jointed) processes and pathways. A generic service process model has been defined in close cooperation with the relevant actors at each site with a view to enable responding to pressing demands. The model spans across established care silos including formal health care, formal social care and the "third sector" as graphically summarised in Exhibit 1 overleaf. It also identifies different actors involved in service delivery as well as different technology and service components utilised.

In response to given demands, each pilot site has developed a clear initial focus on one or more of the relevant issues to be addressed within the project. Ultimately, this demand-driven approach is expected to support the long-term sustainability of the INDEPENDENT services to be piloted, in contrast to mere "technology push". To this end, the project is pursuing a dedicated programme of service process innovation complemented by adapting existing technology, thereby following a number of guiding principles:

- Use appropriate existing technology to provide as many older people as possible with digital access to the support services they need.
- Enable older people to be reached appropriately by means of digital techniques by those who can support them, including so called "third sector" players such as volunteer organisation and family carers.
- Augment and open sectoral Telecare and Telehealth platforms to enable coordinated cross-sector service delivery.
- Develop care coordination applications to run on informal care platforms.
- Adopt a clearly demand-driven, inclusive approach and avoid all 'technology push'.

Exhibit 1 - INDEPENDENT cooperative service process model



In the remainder of this document, it is described in more detail how pilot operation has been prepared in each individual case.

3 Pilot preparation in Hull

3.1 Summary of the local pilot service implementation

The system that is being piloted in Hull is two–pronged, encompassing older people living in shared care facilities, and older people living in private homes. For purposes of clarity, these will be described separately.

Shared-care service enhancement

This service is for elderly people living in one of 3 'sheltered housing' schemes in the City of Hull. These schemes are run by Pickering and Ferens Homes, a locally-based independent housing association for older people operating within Hull and the East Riding of Yorkshire. They offer residents independent living in a choice of properties ranging from one bedroom flats to two bedroom bungalows, with easy access to a range of housing and community services. Each site is supported by a Site Manager who is onsite 9am to 5pm, Monday to Friday and by various paid ancillary staff such as cleaners for the shared areas and gardeners.

The people living in these facilities are overwhelmingly elderly and predominantly single. They live with varying degrees of independence and requiring varying levels of health and social care support depending on their physical capabilities. The service-enhancement is being used particularly by people with little support from relatives, due to them being without a spouse or partner and children and other significant others living some distance away.

As mentioned, these people have varying degrees of support. Some are attended by doctors and community nurses, some have carers that help them with personal cares and shopping, some have support from volunteers; some have support from family members. All of them are supported by paid staff at the schemes themselves. All of these actors are involved in the pilot in some way, depending on the particular needs of any individual involved.

The technical assistive system being utilised is an enhancement of Tunstall's "MyClinic" Multi-user Device (MUD). This is a computer with a touchscreen interface and keyboard that is linked to peripheral monitoring devices such as blood pressure monitors, pulse oximeters and weighing scales using "Bluetooth" short-range open wireless technology. The MUD also has an 'interview' facility whereby users answer a series of questions about their specific health and general well-being. The recordings and interview responses are stored, on the ICP "Triage Manager" (ICPTM) software platform and are transmitted to remote computers via either 3G and GPRS dongles or an ADSL line. This software also allows some limited access to the internet, allowing users to access a directory of services (Looking Local – www.lookinglocal.gov.uk) that they can utilise as they see fit. In addition, it will allow messaging between the MUD and anyone with access to triage manager. This messaging facility has just been developed and a licence acquired and will be available for use by late April 2012.

The benefit of this to the elderly user is various, and depends on their particular needs. Some are concerned about their health and wish to monitor this for their own benefit which they do via the MUD and reassure themselves that their observations are within normal limits. If they have already been diagnosed with a medical condition, such as hypertension, heart failure or chronic obstructive pulmonary disease (COPD) they monitor this condition as directed by their nurse or doctor and track whether they are within the recommended limits. They have the further reassurance that if their observations move outside the pre-set range, there is a monitoring team who contact them and/or pass on this information to the appropriate health care professional. If the user needs some advice, they will use the MUD to contact the monitoring nurses for information. In addition, both formal and informal carers (such as a relative) will be able to access the system via the elderly user's account and use this to message the monitoring team with information about the user's situation, or for any advice that may be needed. Furthermore, the user, again either alone or in conjunction with a formal or informal carer, accesses a directory of services. This provides access to council and other services such as those around health, housing, benefits, transport, and legal advice. Some of these have elements that can be booked online and this can be done via the MUD as needed.

We hope to see various benefits from this. Clinicians who need to monitor their patients health in the community will be able to do this remotely, reducing the need for their patients or themselves to travel. If they do need to see the patient at the patient's home, they can access their record on the MUD and check the trends shown by the monitoring. General Practitioners (GPs) will know that if a patient has chosen to monitor their observations for their own interests and that worrying recordings are produced then the monitoring nurses will contact the patient about this and also inform the GP of the recordings so they can arrange an appointment if they see fit. Formal and informal carers will be able to work with elderly people in their care in sending messages about their health to the monitoring team and in booking and accessing services. If this is family members it will allow them to have a greater input, should they wish it, to the care of their relative. The directors and managers of the scheme are enthusiastic about this as they feel it gives added value to the service that they provide and allows their elderly clients to better manage their own health and allows them as scheme employees to participate more thoroughly in their residents care. All of this helps to improve communication between social carers and health care professionals. This will help break down the 'silo structures' which characterise health and social care in community services in this area.

Private home service enhancement

This service is for people who are currently receiving, or are scheduled to receive, the Hull Telemonitoring Service for heart failure patients. This is a service that is jointly run and administered by the University of Hull and the Hull and East Yorkshire Hospitals Acute Trust, in conjunction with other partners such as NHS Hull (the Hull Primary Care Trust (PCT)) and the local charity Hull Churches Home from Hospital (HCHfH). People diagnosed with heart failure in the Acute Trust, or after a visit to the heart failure clinic, are enrolled onto the monitoring service and monitoring 'goals' are set for them. After they return home, they are visited by a monitoring nurse to explain the system and service to them and then the system will be installed in their home a day or two later. They are then visited by a voluntary worker from HCHfH who checks that the user is managing the technical aspects of the service and answers any questions that they may have. Information from this system is fed through to a team of monitoring nurses in the Acute Trust who monitor trends and alerts and contact the patient, GP or community nurse responsible for the patient's care as appropriate. This service has shown a proven benefit in reducing the need for patients to visit the Acute Trust heart failure clinic and in preventing emergency admissions. It has also been extremely popular with patients and has scored well on patient/user satisfaction surveys.

The current Motiva platform is a television-based service in the patient's home, working from a set-top box. This box uses 'Bluetooth' connectivity to connect with wireless blood pressure cuffs and weighing scales. The patient weighs himself and records his blood pressure, normally once a day and answers a few brief questions. The results of this can be both displayed on the television screen and fed back through wireless broadband to monitoring nurses in the Acute Trust who monitor the patients trends and respond to alerts such as changes in weight or blood pressure, missed logging on times and changes in user status as demonstrated by their answers to questions. Initially this will normally prompt a telephone call to the patient and, depending on the result of this, the monitoring nurse may contact the patient's community nurse or GP to advise them that a visit or similar intervention has been made and to inform them of any changes to the patient's prescription.

The enhancement has broadened the service from being purely a health related one into having a social function. A limited version of Motiva is available to the relatives of participating patients. This enables them to see the answers to questions that have been asked, including whether they would like a visit or telephone call from a relative. This limited Motiva access is also available to the third sector support in the form of the HCHFH employees, so they can respond to requests for visits from patients. The voluntary workers access Motiva via a laptop computer and log into the systems and input the results of the visit so the monitoring nurses are aware what has taken place and whether anything else may be required. For the INDEPENDENT project this opens up the possibility of measuring whether some visits currently made by clinical nursing staff could be done equally effectively – but at a reduced cost – by third sector carers.

Exhibit 2 below shows the INDEPENDENT service model as it is contextualised in Hull (see dark colouring of service model components concerned). Subsequently, Exhibit 3 provides more detail on the types of actors involved in the specific local context and the way these are involved.

Exhibit 2 - Contextualised INDEPENDENT cooperative service process model

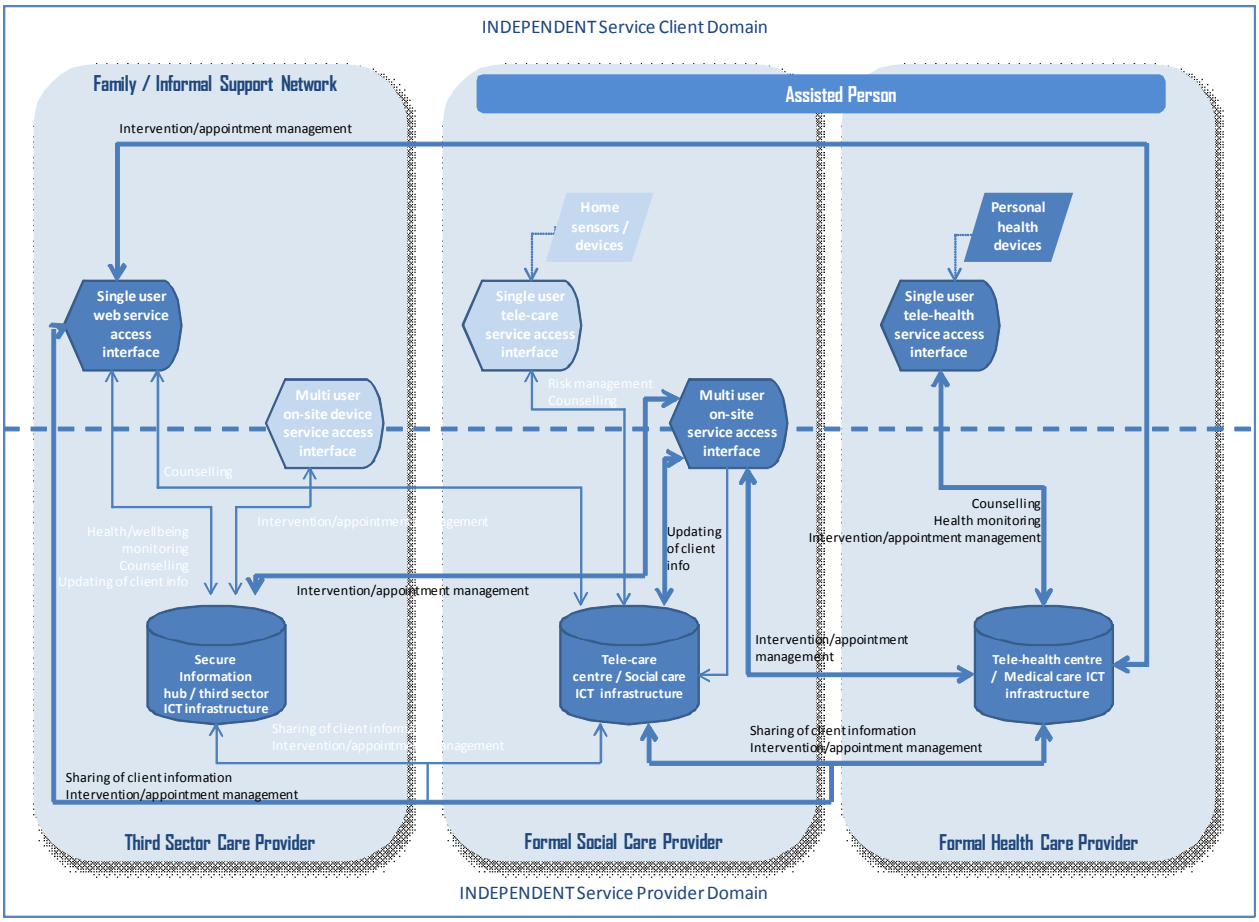


Exhibit 3 - Overview of service components implementation

Generic type of service provider system / interface	Generic type of service client access device /interface	Generic service process component to be piloted	Site-specific implementation of generic service process component
Telecare centre / social care ICT infrastructure	Multi-user onsite service access interface	Intervention/appointment management	Telecare onsite staff alters medical carer re need for unplanned intervention
n.a.	Multi-user onsite service access interface	Intervention/appointment management	Telecare updates relative of client on unplanned intervention
Telecare centre / social care ICT infrastructure & Telehealth centre / health care ICT infrastructure	Multi-user onsite service access interface	Sharing of client information	Onsite social/health care staff document interventions
Information hub / third sector ICT infrastructure	Multi-user onsite service access interface	Intervention/appointment management	Client/family carer books support services
Telehealth centre / health care ICT infrastructure	Single user Telehealth service access interface	Health/ well being monitoring	Client with chronic condition (CHF) regularly measures vital signs and answers survey questions

Generic type of service provider system / interface	Generic type of service client access device /interface	Generic service process component to be piloted	Site-specific implementation of generic service process component
Telehealth centre / health care ICT infrastructure	Single user Telehealth service access interface	Intervention/appointment management	Hospital liaison nurse monitors client information and initiates onsite visit by community nurse
Telehealth centre / health care ICT infrastructure	Single user Telehealth service access interface	Intervention/appointment management	Voluntary carer regularly monitors client information and initiates onsite visit / supportive measures
Telehealth centre / health care ICT infrastructure	Single user Telehealth service access interface	Intervention/appointment management	Family carer monitors client information and sends "ad hoc" medication reminders
Telehealth centre / health care ICT infrastructure	Single user Telehealth service access interface	Counselling	Client accesses video-based information material on various health matters

3.2 Digital service support infrastructure

When it comes to multi-user access, three enhanced Tunstall 'MyClinic' multi-user devices (MUDs) are sited in three Warden-controlled schemes that are part of the Pickering and Ferens Homes social landlord company. Responsibility for installation and maintenance is with the technology provider,Tunstall, for the life of the project, after which they devices will be owned jointly by Hull City Council and the University of Hull.

As regards single-user home access, the hardware installations are already in the patient's homes if they are already on the Hull Telemonitoring programme. In this case, Philips installs the limited version of Motiva on laptops/PCs of any relatives who are involved and onto a laptop for the third sector workers. If the person being enrolled is new to the telemonitoring service, then the hardware and broadband connectivity is installed as it currently is on the Hull telemonitoring service by Philips technical support. Philips maintains and uninstall as appropriate.

ICP Triage Manager is provided by Tunstall for the monitoring nurses, the scheme managers and for the City Council and University pilot site leads. Maintenance stays with Tunstall.

Philips provides the enhanced Motiva platforms to the Hull Telemonitoring nurses and to the pilot site project leads for the University and the City Council.

3.3 Training measures

All scheme managers have had the MUD demonstrated to them on several occasions. They have had further opportunities to familiarise themselves with the device when it was installed and since then.

Monitoring nurses have seen the MUD and had training on ICPTM when it was loaded onto their work computer. They have been included in discussions around the method of informing GPs and community nurses when the trend monitoring merits it.

Paid/Voluntary carers and relatives have been instructed on the use of the MUD if they have a carer who is accessing the device.

Hull Churches Home from Hospital staff have been trained on the use of the enhanced INDEPENDENT Motiva system

No GPs involved have any specific training needs, but all GPs who have patients in the piloted sites have been written to explaining the project and what this will mean for their patients and what it can do for them, as well as providing them with contact information for the pilot site leads and the monitoring nurses.

Also community nurses involved do not have any specific training needs, but will be informed of the device and what it can do on individual basis if they have a patient in one of the sites who is receiving monitoring. Also local community matrons will be invited to the meeting of the residents at their locality so they can see how the MUD and ICPTM will work in the project.

3.4 Pilot users

Residents at each residential site were invited to several meetings at which the MUD was demonstrated and the service explained to them. Some of these were attended by the monitoring nurses and those interested in being enrolled into the programme were. They have been consented into the research and their reasons for wanting to use the MUD ascertained and used to feed into the monitoring parameters, e.g. if they have heart failure or a chronic lung condition. On the second visit they were issued with a barcode to access the system and further instructed in the devices use.

Home based residents identified by the monitoring nurses as suitable candidates for monitoring on the enhanced Motiva system have been approached about taking part in the project. They can now be formally consented into the project and schooled in the difference for them from the current Motiva provision they receive and their relatives, as appropriate, can be trained in the use of the system.

3.5 Help desk

The helpdesk provides ongoing support for end users and their carers. This is predominantly technical, but will also cover other elements of the service delivery process.

Helpdesk support for the Motiva arm of the project has been made available via Philips Healthcare for the INDEPENDENT project. The only addition is that if the problems are beyond the scope of the technical back up or the monitoring nurses either of those contact one of the project officers. Helpdesk support for the MUD service is provided by Tunstall Healthcare for technical matters. For other matters project officers are available.

3.6 Ethics and data privacy

Ethics approval

Formal ethical approval has not been requested for the project as it is best classified as service enhancement rather than research. This view has been arrived at after taking advice from the NHS ethics committee members who confirmed that they would not expect such a project to apply for ethical approval and by comparing it with other service evaluations the University of Hull has been a part of that have not needed formal ethical approval

Compliance with basic ethical principles

The project complies with the "4 principles" approach to ethics. We respect autonomy by providing informed consent (see below). We reduce the risk of harm (malfeasance) by informing users of the risks and by protecting them as described in the 'risk management' section above. Beneficence- doing good towards the project participants will only be proved by successfully carrying out the project and receiving a positive evaluation, but it is reasonable to assume, from the work that has been done with focus groups locally on what the project will achieve for users and from the response from participants so far, that this will be beneficial for project users. The principle of justice is maintained by allowing participation to anyone who fits the project parameters, regardless of other elements of their individual situations.

Informed consent

Signed consent is required from anyone who participates as an end user in the project. All consent is taken by project officers and involves thorough and careful explanation of the project. No one is asked to participate in the project if there is any issue around their capacity, as defined in the Mental Capacity Act (2005)

Data privacy

This is being strenuously monitored within the project between the project officers and the technical providers. No information is viewed by anyone other than usual health/social carers of the individual user and their significant others if agreed, representatives of Philips Health Care and Tunstall Health Care as appropriate and project officers. During the initial test phase post-install it was found that there were some issues surrounding two projects being delivered in Hull utilising the MyClinic systems from Tunstall were not separated when viewed by each project management team. This was rectified prior to any user utilising the project.

3.7 Risks

Risk management overview

Exhibit 4 - Risk management summary table

Risk	Impact	Likelyhood	Remedial action
ICT related	☒ high ☐ medium ☐ low	☒ high ☐ medium ☐ low	Helpdesk protocols initiated
Service process	☒ high ☐ medium ☐ low	☐ high ☐ medium ☒ low	Adequate back up provided to services already in place
User participation	☒ high ☐ medium ☐ low	☐ high ☐ medium ☒ low	INDEPENDENT is providing an enhancement to the current service, not a replacement of elements of it
Information governance	☒ high ☐ medium ☐ low	☐ high ☒ medium ☐ low	Constant monitoring of these issues in conjunction with the technical partners
Sustainability	☐ high ☐ medium ☒ low	☐ high ☒ medium ☐ low	Vigorous promotion of the project is continuing.

ICT related risks

The principle risk here is of technical failure, given that these are technical enhancements to existing technology solutions. These are managed by the helpdesk provision described above and by continued monitoring of the project from regular visits to the pilot sites and by access to ICP Triage manager and Motiva by the project officers.

Service process related risks

The risks in service provision come from deficits within the monitoring team or the voluntary sector. This has been prepared for by ensuring that three monitoring nurses are trained to monitor the systems to cover sickness/absence and to ensure that the voluntary organisation Hull Churches Home from Hospital has back up for their responding staff. All other elements of the project are from a provision that is already required in the current service provision so are covered by protocols already active within the standard service provision.

User participation related risks

There should be no health risks to the end users. Both technical solutions (Motiva and MyClinic MUD) are CE marked systems and we have worked with the manufacturers to ensure that there are no changes to the systems that should imperil this status or cause either system to malfunction. The enhancements to the system are in messaging and access to a directory of services, both elements that are completely new to the end users for whom they are provided, so as additions even if they fail they are taking nothing from the current service.

Data protection related risks

We have worked extensively with the technical providers to minimise this risk. Much of the technical work – including some which has, of necessity, limited the scope of the project – has been around ensuring that information governance is appropriately protected. The project officers are in regular and frequent contact with all of the technical providers to ensure that information of the end users is protected at all times. This has the highest priority within the project.

Other risks

Sustainability beyond the project is a risk here. There are a number of variables that cannot be managed by the project team – e.g. government policy, local government funding – but the project team are working hard to counteract any issues here by vigorously publicising the project locally and nationally (see 'Dissemination' work for more details). Reasons for optimism are in the support we have received from local organisations participant in the project, notably Pickering and Ferens Homes, who are very keen to continue this initiative if it continues to prove popular with their residents and in the interests of other groups, including the fire service and in local groups bidding for re-ablement contracts to be a part of future, INDEPENDENT-type solutions merging health and social services and incorporating third sector carers.

4 Pilot operation in Milton Keynes

4.1 Summary of the local pilot service implementation

The local implementation of the INDEPENDENT service (now called Connecti) in Milton Keynes focuses on helping to delay dependency of older people and maintaining their independence for as long as possible. According to the UK Audit Commission's advice such services should be focused on those older people most at risk. Councils should play a leadership role in delivering targeted services. Many low level interventions can be provided in the community, in partnership with social enterprises and through volunteer schemes.

Against this background, the focus of activity within INDEPENDENT is to focus primarily on the needs of those older citizens that do not (yet) use Telehealth or Telecare services that are gradually becoming available in Milton Keynes, with a view to enabling self-care and preventative intervention and actions through use of web based information and secure messaging including content generation based on affordable/usable delivery platforms.

The actors supported by the introduction of the INDEPENDENT system (now internally called Connecti) are Carers, Assisted Persons and Informal Care Organisations (ICO) such as Carers MK.

Connecti comprises of a number of core components and applications as follows:

- Secure Personalised mini-social web site users within a portal that users subscribe to
- Secure portal to enable sheltered communication between all parties (carer support, carer and AP, with future basic contact data shared with formal social service planned for a later date)
- A repository of useful information, event updates and helpful video's.
- Client views documenting a history of interventions/events attended etc
- Home PC suit including web cam (web browser, email, embedded secure video)

It has widened the ability for information, advice and guidance from ICO to be recorded, updated and tracked and allows the carers to better manage what sometimes is an overwhelming task of caring for a friend or family member. Also, it presents quicker release of links to legislative change, and informative medical or caring research, it also opens up opportunities for them to share and support other carers in their situation. In situations where the assisted person supported by the carer is able to interact with the INDEPENDENT system they learn and share their experiences together to help generated a more supportive environment. It is an essential element in promoting a sense of empowerment to the carer.

The fundamental role that an ICO plays in supporting carers is vital in an economy where formal provision is increasingly struggling to meet the needs and demands of an aging population. In juxtaposition to that, third sector organisations are often less knowledgeable of the benefits that technology can have in supporting their role.

Through prototype testing an increase of provisioning and capacity has now been created, an excellent example would be the need for more counselling contact with carers met by video conferencing facilitated within the new INDEPENDENT system. Less time needs to be spent travelling to visit carers (and vice versa) and the number of carers that the caring support organisation can support with the same resources has already increased. The ability to report quickly and effectively on the needs of carers and assisted people is vital in the future development of the relationships between informal and formal care providers such as Milton Keynes Council.

One of the key next developments of the independent system will be to create the connection between the councils formal assessment platform (Framework) and Connecti so as to enable more effective signposting and tracking between the respective organisations whilst alleviating the need for the carer or the AP to have to repeat much, if not all, of the basic data/information that they have already provided in what might be a pre-assessment of needs. Of course there are data protection concerns

that will have to be directly addressed but these do not look to be a barrier. This approach is also consistent with the UK governments Telesponse initiative.

There are of course already occasions where a carer gives consent for the formal care providers at the council to act on their behalf and pass details to the third sector ICO such as Carers MK. The INDEPENDENT platform (Connecti) is used to record this sign posting in the Carers record reducing some of the repeat information. This only happens with the carers explicit consent.

Exhibit 5 - Contextualised INDEPENDENT cooperative service process model

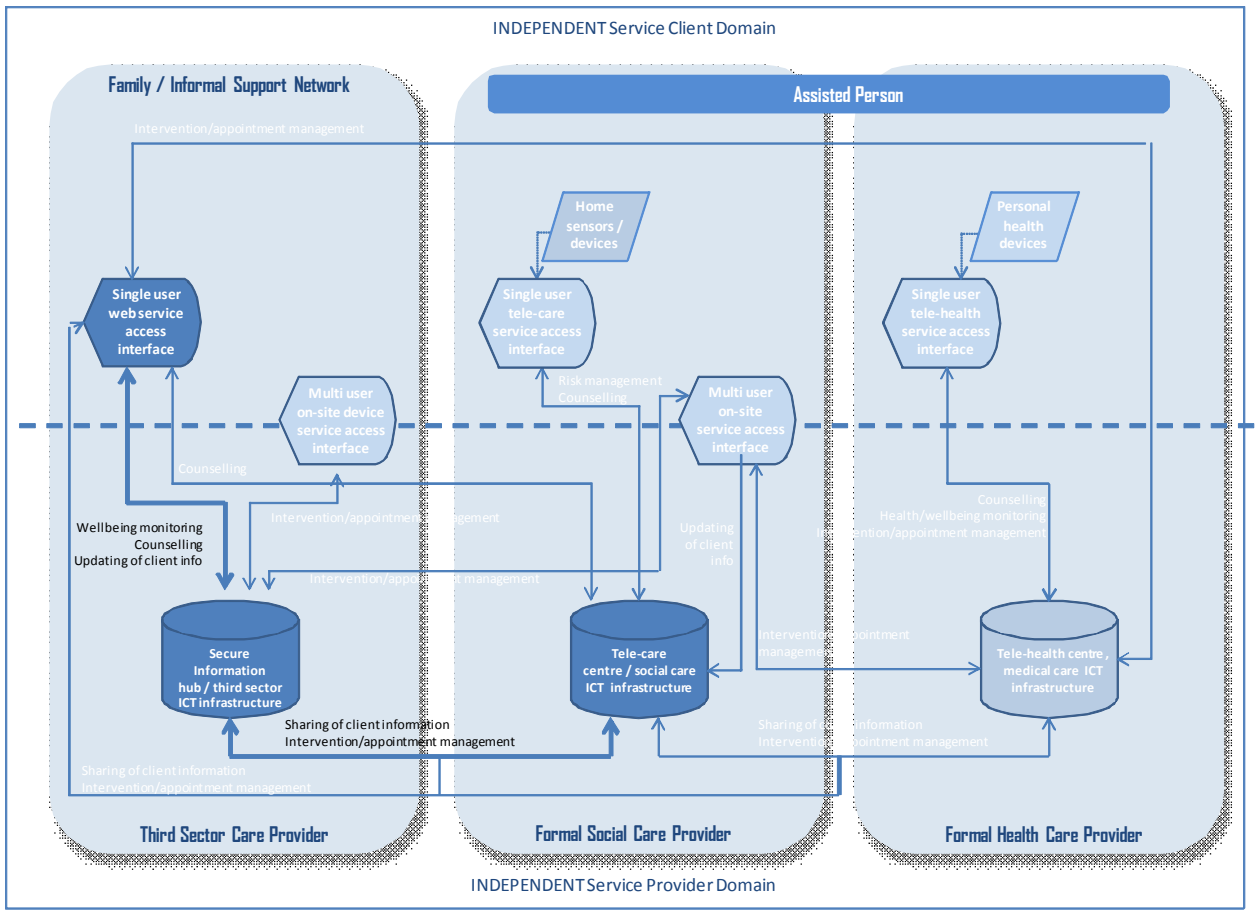


Exhibit 5 above shows the INDEPENDENT service model as it is contextualised in Milton Keynes (see dark coloured service model components concerned). Exhibit 3 below provides more details on the types of actors involved the specific local context and the way these are involved.

Exhibit 6 - Overview of service components implementation

Generic type of service provider system / interface	Generic type of service client access device /interface	Generic service process component to be piloted	Site-specific implementation of generic service process component
Secure information hub / third sector ICT infrastructure	Single user web interface	Counselling	Informal carer poses request to third sector care coordinator
Secure information hub / third sector ICT infrastructure	Single user web interface	Intervention / appointment management	Informal carer enters concerns about client status into shared client record

Secure information hub / hird sector ICT infrastructure	n.a.	Intervention / appointment management	Carer acts with or on behalf of AP using records of Supplier service feedback during reviews with Formal Social Care
Secure information hub / third sector ICT infrastructure & Telecare centre / social care ICT infrastructure	n.a.	Shared client information	Social care provider hosts client data base

4.2 Digital service support infrastructure

The need for the hardware supplied is gauged via an assessment process that takes account of the existing level of access to technology that the carers and the assisted persons have. All equipment including broadband connectivity is supervised by ConnectMK.

Computer hardware includes desk top PC or laptop computers. These are refurbished units supplied through the ConnectMK and Milton Keynes council loan PC scheme, a Microsoft Registered Refurbisher (MRR) programme. Desktop PC's include flat screen monitors, keyboard and mouse. Software packages include Windows XP and Office 2007. Additional hardware includes web cams, speakers and microphone or headset and bespoke equipment. This is equipment required to address dexterity issues highlighted during "needs assessment" and includes tracker ball mice and keyboard with built in mouse pad.

In cases where the client did not have an existing broadband connection and was unable to access one through either a landline telephone, or Satellite Television and fell within the operational coverage area of ConnectMK a service was provided. However ConnectMK has recently had to cease its broadband operation and now offers advice and guidance about the most suitable connectivity options available to them.

The back office equipment is one dedicated share point server installed in a virtual environment combined with a separate SQL database installed at Milton Keynes council's data centre. The maintenance of the environment is the responsibility of Milton Keynes Council.

4.3 Training measures

ConnectMK staff has received training by Adepteq in using the new system according to a well proven 'train the trainer' concept. Following these training sessions Carers MK staff provided training to staff of CarersMK, an Informal Care Organisation, on operational use of the new system. Also, carers and care recipients received such training by CareresMK. However, it has been ascertained that PC literacy skills and learning preference varied dramatically among end-users. In order to deal with this ConnectMK used its knowledge of additional training providers who offer training at no cost to aid the carers and assisted persons to obtain PC literacy training.

4.4 Pilot users

There are distinct types of end-users:

- Informal Carers who are usually, but not exclusively related to the Assisted Person, e.g. family member.
- Assisted Persons, those who are being cared for by an informal carer as described above.

Informal carers are persons who have identified themselves (for legally or obligatory reasons), as caring for a person or persons diagnosed with a condition or illness. For the purpose of this project a person who has "identified themselves" as an the informal carer does not have to be a person who is

legally bound; that is to say that a formal social care arrangement, or financial recompense is not required in order to recognise them as a carer. Informal carers meeting the criteria are on majority over 65 years of age or are caring for someone who is. Carers are caring for an assisted person or persons with a variety of conditions and in some cases also have health or medical issues of their own, although the latter is not being considered as a contributory factor in relation to this project. Assisted persons are persons who are being cared for by an informal carer and as described above may suffer from a variety of health or medical conditions.

The identification of suitable pilot candidates was initially largely identified by the third sector informal care provider; CarersMK, with a smaller number identified from ConnectMK's loan PC client base.

CarersMK staff identified candidates firstly by date of birth of either the carer or their assisted person followed by raising the potential for pilot sites within their newsletter which gave a wider explanation of the INDEPENDENT system (Connecti) and then with follow up explanatory phone calls by CarersMK and ConnectMK support staff, for those that could make it in to CarersMK informal coffee mornings time was also spent giving an overview of what we were doing and brief demonstrations of the platform. From both these approaches a short list of potential candidates was constantly being identified and updated.

ConnectMK would answer any questions a potential user had about a lack of home equipment or more technical questions about existing home equipment and also ascertain the users' competency by way of some fairly basic questions during the telephone call or the informal coffee morning get together. This action would be taken in response to a request made by the staff at Carers Milton Keynes. The response is either passed back to the staff member to relay to the carer or direct to the carer if deemed suitable.

A number of potential pilot users withdrew when it came to the point in the process where they were shown the list of base-line questions they were being asked to answer, although every effort was made to explain why they were necessary and how their identity would be protected, they preferred not to continue any further, but almost all expressed a desire to make use of the platform 'post-trial' if it was fully adopted.

4.5 Help desk

A frontline helpdesk is built into the new system for both the use of the end-user to report and be responded to, although it is expected that at the early stages of the project issues will more likely be reported in person or on the phone, so far that seems to have been borne out in reality.

When a call is routed to the helpdesk a hierarchy has been implemented as follows:

- First Level Support (Front Line): Carers MK and ConnectMK
- Second Level Support (Technical): ConnectMK
- Third Level Support: Adepteq

Specific roles have been assigned to the parties involved as follows.

Carers MK

Answering and resolving issues in the context of operational use of the new system

- Booking events and video conferencing appointments
- Accessing information relevant to their needs
- Log-in issues

In any event where Carers MK are unable to resolve it is escalated to ConnectMK

ConnectMK

Answering and resolving issues in the context operation use of the new system including hardware

- Escalations from Carers MK
- Supporting end-users

- Hardware
- Supporting end-users

In the event where an issue either reported by an end-user or escalated from Carers MK is unable to be resolved it is escalated to Adepteq

Adepteq

Answering any queries determined as technical issues with the INDEPENDENT platform (Connecti) or its hosted environment which might be escalated by ConnectMK

4.6 Ethics and data privacy

Ethics approval

No formal ethics submission has been made to a local NHS body or to any NHS body. This is not deemed to be a clinical trial and as such does not formally require 'standard' NHS ethics approval.

The project has been reviewed and agreed (permitted) to proceed by the Director responsible for MKC Adult Social Care and is sponsored by an MKC Assistant Director responsible for Commissioning Adult Social Care Services.

Compliance with basic ethical principles

The project is subject to local MKC governance processes. A project board has been established to oversee the project and all MKC staff are duty bound to comply with best practice as required by the Council's staff handbook (and Council policies).

The Council arrangements require that such projects are properly commissioned. A statement of principles is documented to clearly establish what those requirements are.

All the staff involved have been briefed and understand the need for best practice in dealing with the participants in the pilot. Respect for the participants is a core (founding) principle.

As the Data Controller the Council takes its data protection responsibilities very seriously. These are very clearly documented in the Council's IT Telecommunications and User Security Policy and in other supporting policies relating to the Data Protection Act (1989). The overall project manager (the AD IT and e-Government and his immediate deputy 'The Senior IT and e-Government Manager) bear the management responsibility for Data Protection within the Council – so are intimately aware of all of the procedures and requirements within this area.

Informed consent

All of the carer participants are at the time of joining of sound mind and able to give informed consent to participate in the pilot trial. Any Assisted Person included in the pilot trial has been assessed to determine their capability to give informed consent to participate and if there is any doubt on this – participation will only proceed with the approval and informed consent of a responsible family member having such authority. Care has been taken to ensure this approach is always adopted. This process is subject to review and scrutiny by members of the project team who are not directly involved in the deployment process.

Data privacy

All data is held on server computers within an MKC data centre. They are protected and backed up with the same rigour as all Council data.

Carers MK staff are trained to ensure they understand and respect the privacy of the client data they are given access to. This is consistent with the normal operations of the Carers MK staff.

Adepteq and Connect MK staff do not ordinarily have access to client data. MKC staff will only have access to such data consistent with their normal professional privilege and 'need to know' such data.

Data is protected within the system by the same operational controls as operates for all MKC IT systems. User ID's and passwords will be required as a minimum.

A formal data protection and data privacy statement has been agreed between MKC and Carers MK pertaining to this pilot project.

Liability

There are no issues around liability in this context – this is not a clinical trial. The systems in use are standard PC system technologies. A review of the project has taken place and no new liabilities have been identified

Licensing & quality control

There are no new issues in relation to this. The caring relationships are already established and are informal – and being supported via a 3rd sector charity – Carers MK.

Formal health care work is not being undertaken by anyone not legally mandated to do this.

Patient Rights

All people recruited into the project have provided a formal consent. No new medical or healthcare delivery activity is involved and it is has not been necessary to obtain ethical approval via an NHS Regional Research ethics committee.

No one has been denied access to services, whether they choose to participate in the project or not.

There has been no recruitment of people (informal carers) who are not competent as defined within the parameters of the Mental Capacity Act 2005.

When the system is made available to an Assisted Person who does come under the requirements of the Mental Capacity Act – appropriate MKC/NHS procedures are followed.

4.7 Risks

Risk management overview

Exhibit 7 - Risk management summary table

Risk	Impact	Likelihood	Remedial action
Incorrect system functioning	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Adepteq use experienced development staff and deliver an application system according to a defined and documented requirement specification The application system is extensively tested with Carers MK staff and with Connect MK staff – it is adjusted in line with user feedback The application system is also tested with end user Carers and adjusted in line with their comments The system hardware is tested and checked by experienced Connect MK technical staff prior to installation Standard equipment is supplied together with standard operating system (Windows) components
delay in system delivery	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Adepteq were paid to deliver the system and initially paid in arrears – there was financial pressure to deliver in good time Adepteq are a committed partner in the project and will apply extra resources to secure the success of the project Adepteq, Connect MK and Carers MK staff resources are all encouraged to meet in the Carers MK offices and to work as a team towards the project goals

Risk	Impact	Likelihood	Remedial action
			MKC are notified by Adepteq/Connect MK of any system delivery barriers – and triggered to take action to clear those barriers Connect MK resources are applied to deliver the hardware implementations; progress is monitored by the MKC AD IT and e-Government – and corrective action for delays is applied by delivering extra resources and ensuring this work area is prioritised. A full inventory of equipment is maintained and readily available in the Connect MK Offices (any new equipment (e.g. web cams or other peripherals) is ordered in good time for deployment. Slow recruitment of pilot users (creating overall delay in system delivery) is overcome by ensuring Connect MK and Carers MK staff work together to secure recruits MKC widen the catchment of potential recruits by extended marketing, by publicity and by seeking recruits via other agencies.
non availability of system components	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	A good stock of equipment (more than is required by the project) is maintained by Connect MK Ltd The AD IT and e-Government has taken steps to purchase further equipment supplies The application software availability (including any fixes or changes) is regularly checked and chased both by Connect MK and by MKC Software licensing is controlled by MKC with support from Adepteq
Difficulties in defining clear project roles	☒ low ☐ medium ☐ high	☒ low ☐ medium ☐ high	The roles for Connect MK, Adepteq and MKC are partially defined in the DOW and have been further defined in local project administration. Each participant is a partner in the project and has committed itself to the project. The role of Carers MK has been negotiated with the CE of that organisation and documented. Carers MK are a preferred partner with an established relationship with MKC; a good working understanding pre-existed the project. The overall MKC project manager has maintained a 'light touch' approach enabling each participant to feel valued and able to flex their participation in line with their organisational needs
Failure to conclude agreements between the organisations involved	☒ low ☐ medium ☐ high	☒ low ☐ medium ☐ high	MKC took action to document the requirement and obtain agreement from Adepteq regarding the application system development. This procurement process was competitive and formally concluded (in writing). The arrangements with Carers MK were agreed and documented in the first year of the project and well ahead of the initial pilot trial running. Connect MK has always been committed to the project – executive action/decision making authority enforces this.
Unwillingness of users/staff to participate in the pilot	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Connect MK and Adepteq have adopted a highly consultative approach in dealings with Carers MK staff. All feedback is acted upon. All Carers identified as participants are treated with great respect and helped at all stages in the process. Incentives are offered to encourage recruits – equipment is loaned for free for up to 6 months and assistance is provided to obtain any other services (e.g. broadband if not already in use) Active marketing and publicity is employed to identify recruits Potential recruits are carefully consulted as to their needs. Where needed additional services/system facilities are provided
Loss of	☐ low	☐ low	Ongoing recruitment will be maintained as the pilot progresses

Risk	Impact	Likelihood	Remedial action
participants during the pilot	☒ medium ☐ high	☒ medium ☐ high	The intention is to secure extra recruits so as to achieve suitable take up and use (to mitigate losses during the pilot) Participants will be asked to sign a commitment to follow through on the pilot trial Participants will be actively supported throughout the trial
Uncertainties on Data Protection Compliance – compliance with local arrangements and National legislation	☒ low ☐ medium ☐ high	☒ low ☐ medium ☐ high	The MKC Data Protection Officer is a member of the project team and brings substantive expertise directly to bear on the project The project is subjected to period review to ensure compliance with Data Protection requirements Local literature is reviewed to ensure relevant Disclaimer Statements are in use and Participants are asked to sign authorisation forms Data is held securely by MKC on MKC servers
Lack of management and political buy in creating sustainability issues	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	The project is briefed to the MKC CE and a local sponsor is obtained within the MKC Social Services Group The project is briefed to the Member ICT Portfolio holder (who is also the deputy Leader of the Council) The project evaluation results are carefully documented and reported to all senior stakeholders

ICT related risks

An assessment of ICT technology related risks affecting the pilot project has focussed onto improper functioning and/or delayed/non-availability of required ICT components:

- Incorrect system functioning would have medium to high impacts, whereby the likelihood of occurrence is low due to foreseen mitigation actions.
- Delay in system delivery would again have medium to high impacts, whereby the lis a medium likelihood of occurrence due to foreseen mitigation actions
- Non availability of system components would again have medium to high impacts, whereby there is a low likelihood of occurrence due to foreseen mitigation actions;

Service process related risks

An assessment of the service related risks affecting the pilot project in relation to the the service delivery process has focussed onto difficulties to define clear roles and responsibilities and/or conclude required agreements between parties/organisations involved:

- Difficulties in defining clear project roles would have a medium impact, whereby the likelihood of occurrence is rather low due to mitigating actions foreseen.
- Failure to conclude agreements between the organisations involved would have a high impact. Again mitigating actions lead to a low likelihood of occurrence

User participation related risks

An assessment of the User Participation risks affecting the pilot project has focussed onto the following risk issues unwillingness of targeted end users/staff to participate in the pilot, drop out of participants during the pilot and doing harm to users:

- Unwillingness of users/staff to participate in the pilot would have medium impacts, with a medium likelihood of occurrence
- Loss of participants during the pilot would have high impacts, whereby mitigating actions contribute to a low to medium likelihood of occurrence.

Data protection related risks

Uncertainties on data protection compliance, i.e. compliance with local arrangements and national legislation, would have high impacts, whereby there is a low likelihood of occurrence due to mitigation actions foreseen.

Other risks

Lack of management and political buy in creating sustainability issues would have high impacts with a medium likelihood of occurrence due to mitigating actions foreseen

5 Pilot operation in Trikala

5.1 Summary of the local pilot service implementation

The INDEPENDENT pilot in Trikala responds to the need for closer collaboration of the municipality's care delivery organisations DEKA and ASKLIPIOS (formerly KAPI); in supporting informal carers and those they are caring for. In particular, the digital infrastructure is utilised for supporting formalised cooperation of community services and family carers of older people with mild cognitive impairment or mild depression. Joint access to extended electronic care records supports easier coordination of service delivery, hence rendering them more integrated, productive and cost-effective.

Also, the digital infrastructure enables specialist psychological counselling to be remotely delivered to informal carers, helping them to better care for their relatives and cope with any problems that may occur in this context. Prior to INDEPENDENT no formal interfacing existed between community care services and informal carers.

Exhibit 8 below shows the technology and service process components of the generic INDEPENDENT overall service model which are piloted in Trikala (see dark coloured service components concerned). Subsequently, Exhibit 9 provides more detail on the types of actors involved the specific local context and the way these are involved.

Exhibit 8 - Contextualised INDEPENDENT service process model

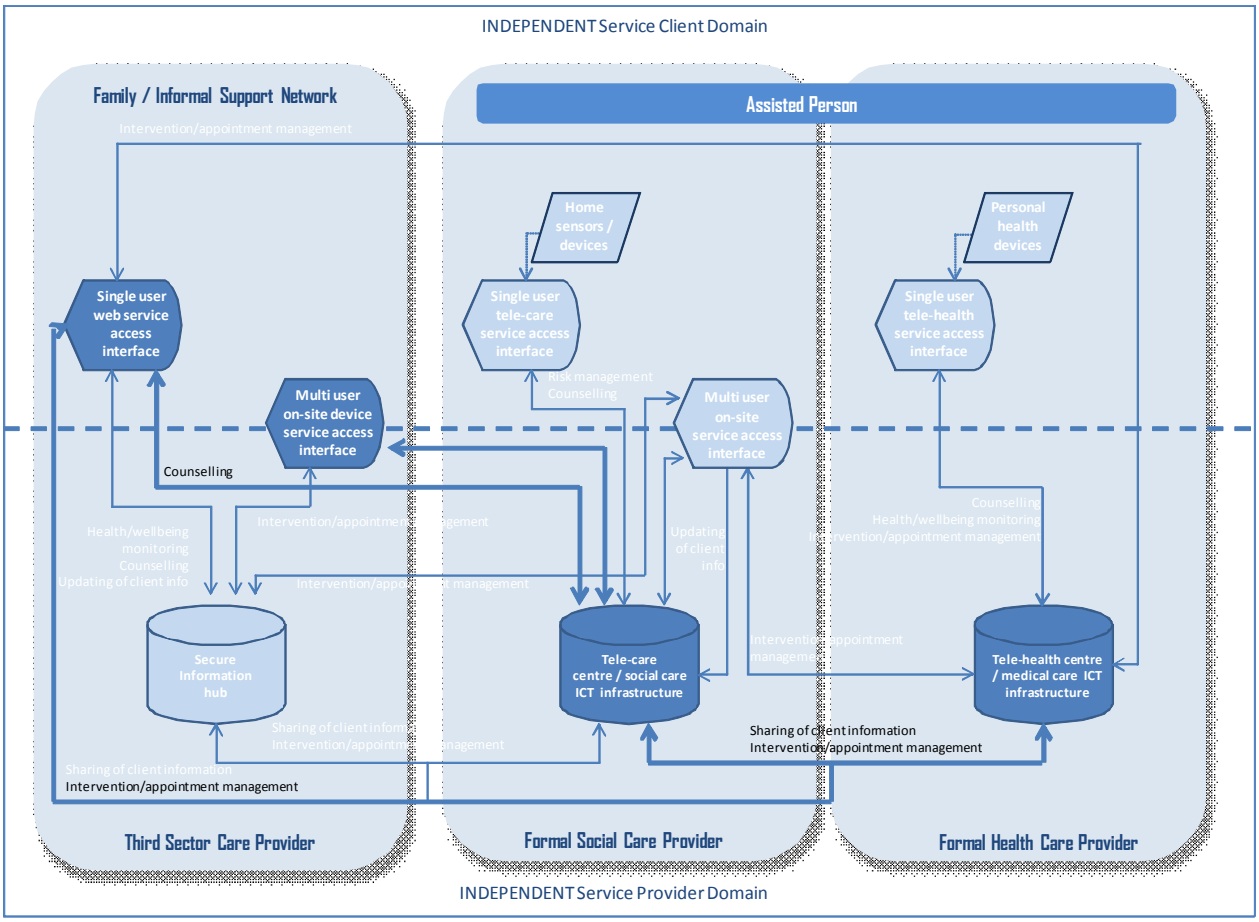


Exhibit 9: Overview of service components implementation

Generic type of service provider system / interface	Generic type of service client access device /interface	Generic service process component to be piloted	Site-specific implementation of generic service process component
Telecare centre / social care ICT infrastructure	Single user Telehealth service access interface	Counselling	Psychologist provides video-based counselling to family carer of client with dementia at home
Telecare centre / social care ICT infrastructure	Multi-user Telecare service access interface	Counselling	Psychologist provides video-based counselling to family carer of client with dementia at local KAPI centre
Telecare centre / social care ICT infrastructure & Telehealth centre / health care ICT infrastructure	n.a.	Sharing of client information	Psychologist and Physician populate and lookup joint client folder
Telecare centre infrastructure	n.a.	Intervention/appointment management	Psychologist alerts physician re need for looking-up information newly added into client folder
Telehealth centre / health care ICT infrastructure	n.a.	Intervention/appointment management	Informal caregiver accesses client record though the web interface. Restricted access is provided (e.g. medication). No data alteration can be performed

5.2 Digital service support infrastructure

With a view to reflecting prevailing frame c onditions for the further mainstreaming of the INDEPENDENT service different access scenarios are piloted. To begin with, the service is accessed by family carers through a multi-user access device installed at a so called Open Care Community Centre (KAPI). In Greece, these centres offer not only a range of social facilities and events in what are usually purposes built centres, but also some primary health care facilities (doctor, physiotherapy, occupational therapy etc). These are financed by the state and implemented by the Local Authorities, aiming at the provision of preventive health services and psycho-social support to older persons in order to enable them to keep on living in their own home environment. More than 600 KAPI's do currently exists across the country. They tend to be staffed with multi-disciplinary teams comprising social workers, medical staff, visiting nurses, occupational and physical therapists and family assistants. At the KAPI centre IP video phones (GRANDSTREAM, GXV3140) based on the SIP protocol are utilised as multi-user access devices.

Moreover, the service is accessed by family carers from their own homes by means of single-user access devices. Here again a confined number of IP video phones are used. Where applicable, the IP phone devices are connected to a TV set, in order to have a bigger screen of the interlocutor. The telecommunications links at every point required an ADSL line (up to 24Mbps download and 1Mbps

upload). The SIP server on which the IP video phones are registered is CendOS – Linux with Asterisk application loaded on the server.

Alternative home access devices are used in other cases. More specifically, laptops and/or PCs with screens are provided by e-Trikala. There are also cases where pilot users rely on their own PCs/laptops. These devices are equipped with Skype software which is considered as the most efficient application for video calls. Another important feature is the fact that it is based on the TCP protocol. Except from these software characteristics only a camera and a microphone are necessary. For technical installations, adjustments and maintenance, e-Trikala technicians are responsible. Furthermore, any connection to the internet with any accompanying devices is installed by the technicians of e-Trikala, with no cost for the users.

Regarding the back office level, the core equipment component is the dedicated server which supports the IP phone devices. The SIP server on which the IP video phones are registered is CendOS – Linux with Asterisk application loaded on the server. The server which consists of both hardware and software components lies on the premises of e-Trikala. Furthermore, the platform which hosts the EHR is generally treated as an integrated web site. It is developed and maintained by the technical partner, Vidavo SA. Vidavo S.A.

5.3 Training measures

The technicians at e-Trikala SA have trained the psychologists and the social care givers to use the INDEPENDENT system. The latter have been shown the functionality of the IP video phone devices and part of the Telehealth EHR platform. Furthermore, they provide instant instructions to end users immediately after they have installed any equipment at the users' premises. Furthermore, eTrikala technicians and psychologists of DEKA together train the pilot users if possible in group sessions whereby the number of 10 participants is not exceeded. Both technology related issues and service process related aspects regarding the tele-counselling are addressed. Also, technicians at Vidavo SA have trained e-Trikala staff in the use of the EHR platform, in dedicated face-to-face sessions according to a "train the trainer" approach.

5.4 Pilot users

Pilot users can be distinguished in the following categories;

- Older people with mild cognitive problems or mild depression who may quality for the pilot are mainly identified by KAPI staff, with the support of psychologists of DEKA. If they qualify according to specified criteria (mild cognitive impairment or mild depression patients that are not institutionalized), they join the project. Although they are not the main service beneficiaries they are allowed to have limited access (counselling information is not included) to the EHR concerning their medical status. Their main benefit is the opportunity to have a better family care through the psychological support of their care giver.
- Family carers, mostly relatives, potentially qualifying for the pilot are identified by KAPI staff as well, assisted by social workers involved in a dedicated programme entitled "Help at Home".
- Professional users consist of staff (psychologists, social care workers, KAPI's doctor) employed by ASKLEPIOS. The KAPI centres apart from all the social services mentioned above also have a medical professional that visits the centres on a weekly basis conducting basic medical procedures such as prescriptions etc. This doctor also has limited access to the EHR which enables them to be informed for any major change on the elderly as well as the care giver's status and vice versa.

5.5 Help desk

A help desk operated by e-Trikala serves a dual purpose. To begin with, it provides support of the end-users in case of questions concerning the service delivery process. Users who are enrolled to the pilot service can call or even physically visit the helpdesk. Contact details are provided in the framework of

the recruitment process. Furthermore, the help desk provides technology related support, which initially may include remote instructions (by phone) and if required a home visit by a technician. Staff at e-Trikala's regularly operated Telecare call centre has received special training by DEKA's psychologists and the e-Trikala technical personnel in interfacing with the pilot users.

5.6 Ethics and data privacy

Ethics approval

According to Greek regulation, no ethical approval is necessary apart from the notification to data protection authority.

The Ethical Committees in Greece exists in Universities for approval of the research protocols eg http://www.uth.gr/ethics for the University of Thessaly in our region. As Trikala acts as a pilot site and has not conducted any research of such type, the pilot has proceeded without any such committee. The National Bioethics Commission has similar responsibilities (http://www.bioethics.gr/). In addition, when conducting a clinical trial the National Organization for Medicines and Health Technologies (www.eof.gr) has to be informed or provide approval, depending on the type of the trial.

The legal department of the Municipality has taken the required steps for the above approvals, when required in the past eg in PSP-ICT Pilot A www.renewinghealth.eu, where the Municipality of Trikala and eTrikala SA are partners. The above institution authorities do not apply in the services of INDEPENDENT in Greece.

We have submitted however an update of the 'acknowledgement' to the Data Protection Authority www.dpa.gr for the use of the EHR in INDEPENDENT project, since the present 'acknowledgement' to the Data Protection Authority of the Telehealth and Telecare services of the Municipality do not include the INDEPENDENT services.

Compliance with basic ethical principles

During the pilot Trikala region has shown compliance with the basic ethical principles, which protect a person's right for respect and his/hers principle of autonomy. The following steps have been established.

- All potential users of the pilot have been informed on every aspect of the project in written and oral form.They will also be informed on every stage of their participation. There is planned to be constant information to anyone willing to participate or even if they already are participants. In addition, they have been informed that they have the right to break their participation on the project and leave it, at whichever stage they wish to, without any penal or financial consequences.
- All data used is available only on the professional participants of the pilot.

We have made it clear to the participants that only the involved professionals have access to their personal data and only when they are needed. These professionals include doctors, psychologists, technicians and operators. This means that there are involved health professionals who already are compliant with bio-ethical rules and the rest of the professionals are employees of the enterprises running the pilot.

No third parties have access to personal data, as declared in the Hellenic Data Protection Authority (HDPA, www.dpa.gr). The processing of the data complies with "Law 2472/1997", regarding the protection of individuals with regard to the processing of their personal data. As far as the use of the Electronic Health Record is concerned, it also complies with "Law 3471/2006", regarding protection of personal data and privacy in the electronic telecommunications sector, as amendment of Law 2472/1997.

Their consent is also asked for the use of the EHR (Electronic Health Record) and they were reassured that no third party outside the pilot will have access to any of their personal data

Informed consent

Any participant in the INDEPEDENT pilot has the right to know the purpose of the activity he or she is involved in, the expected duration, procedures, use of information collected, the participant's right as a part of the study and any risks, discomfort, or adverse effects. This information has been conveyed during the recruitment process and then reiterated at the beginning of the activity when an informed consent form was distributed and signed by the participant. Participants also have to feel free to withdraw from any activity without penalty. All participants have signed the consent form to acknowledge being informed of these things and agreeing to participate. This consent form is accompanied with a doctor's formal and signed statement that the participant is physically or legally capable of giving consent.

All the participants have being asked to sign this consent form at the beginning of the pilot.

Data privacy

The collection, processing and management of sensitive personal data hold threats to the patients who have the legal right to be protected according to the 9th Article of the Greek Constitution. In Greece, these people's rights are safeguarded by the Independent Authority of Personal Data Protection.

Before recording of the voice or image of any individual permission will be obtained. This will be accomplished with a dedicated consent form.

Participants have a right to anonymity. Their information will be kept confidential and participants name will never associate with his/her data or other personally identifiable information. Instead a participants ID will always be used.

In every activity, we ensure that the data we collect are free from bias, accurate, valid and reliable. We will inform stakeholders about the limitations of the collected data.

Collected original data will be retained only for as long as it is relevant for the project.

The extent to which health information can be stored with access limited to those who are authorized is called "security." Security involves protecting data at rest and data in motion. At rest, personally identifiable health data exist in clinicians' offices, hospitals, other health care facilities, health plans and other third-party payers' offices. Data in motion include personally identifiable health data that are transmitted from one location to another over local area networks, telephone lines, the Internet, or other means. Data in motion needs to be protected like data at rest, but doing so presents a different set of challenges and requires sophisticated technologies.

5.7 Risks

Risk management overview

Exhibit 10 - Risk management summary table

Risk	Impact	Likelihood	Remedial action
Unavailability of ICT equipment offered to the end users	☐ low ☐ medium ☒ high	☐ low ☒ medium ☐ high	In case that the equipment of a user is damaged or sfails to operate, e-Trikala's personnel will be in place in order to replace the impaired device. To explain the procedure of the device replacement, there are two probable situations. If the device belongs to the user, it is examined whether there is a guarantee for the device, and if there is, it is repaired by the vender. The second case is that the device belongs to e-Trikala. Under the circumstances, the appliance is repaired or replaced with the cost being borne by e-Trikala.

Risk	Impact	Likelihood	Remedial action
Low Internet connectivity caused by the service provider. This would cause interpolations during the video counselling sessions.	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Specifically, at first the technical personnel of e-Trikala are going to be in touch with the technical department of the ISP on behalf of the end user in order to set up the adequate configuration and fix the problem. The concept is to check whether the problem concerns only the Internet Service Provider infrastructures or the internet hardware devices (modem/router) of the user.
Low Internet connectivity caused by the municipal wireless internet	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	The remedial action for the occasion of prolonged disconnections, the user is going to be equipped with an adequate antenna in order for the signal to be amplified.
Improper functioning of peripheral devices	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	It will be examined whether the personal computer is a laptop or desktop. In case it is a laptop, it is likely to have an inbuilt camera on the top of the screen. e-Trikala's personnel check whether the integrated camera is no longer usable or it has compatibility or webcam driver's issues or maybe it is locked by another program. When all these assumptions are considered, the remedial actions are going to take place. In case there are compatibility issues, the appropriate applications are installed and the corresponding drivers will be updated. If the webcam is no longer usable, e-Trikala will offer to the user a separate camera.
Malfunction of the SIP (Session Initiation Protocol) server which is used for controlling communication sessions and serves for the video conferencing	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	The computer engineers and the technicians of eTrikala would be in place to reconfigure the primary settings. This scenario is not of great probability to take place. The SIP server is based on an operating system which is very stable and is called CendOS where minimum instabilities can be caused. Additionally, it is stored in the safe data room of the Operational Control Centre of e-Trikala.
Forgetting appointments or rescheduling them too often.	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	The above risk will be addressed with a thorough recruitment during which the two psychologists will be able to exclude those who are at risk. What is more during the counselling process they will "train" their users to be consistent with the time schedule.
User recruitment would be at risk in case that there is not sufficient number of end users in order to meet the goals.	☐ low ☐ medium ☒ high	☐ low ☒ medium ☐ high	During the preparation process scheduled visits to the KAPI centres are going to be deducted on a weekly basis in order for extra users need to be recruited.
Very often people tend to have unrealistic high expectations concerning psychotherapy and therefore drop out feeling disappointed if the counselling session doesn't fix everything in the lives.	☐ low ☒ medium ☐ high	☐ low ☒ medium ☐ high	The risk will be addressed with a thorough recruitment during which the two psychologists will be able to exclude those who are at risk. What is more during the counselling process they will "train" their users to be consistent with the time schedule.

Risk	Impact	Likelihood	Remedial action
Users' personal data protection	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	These forms are kept in a room located in the Business Control Centre of e-Trikala. Data handling and circulation is of great importance, so the emphasis on security both on a digital and real level is crucial. The building is equipped with a modern alarm system that detects movement and works by security code (password). The windows of the building are protected with metal bars prohibiting the entrance and the doors to the main workplace operate with an electronic lock system, where each entry is to be granted by a special access card. Thus, the data of the access card that opens the door is recorded on a database.
Financial recession crisis – Subscription costs for the services	☐ low ☒ medium ☐ high	☐ low ☐ medium ☒ high	Find balanced subscription amount or even adjust to the needs of each user wherever applicable.
Financial recession crisis – Political decision to pause the free functioning of the Municipal wireless network - Subscription costs for the ADSL connectivity	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Find private (mostly) or public (unlikely) funds.
Availability of TechnicalPartner	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Regular maintenance of the service (server hosting the EMR)
More external expertise – conduction of new contracts – increase in the sustaining costs	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	Technicians of e-Trikala SA to troubleshoot any issues by own means, and proceed to new contracts only in severe occasions.

ICT related risks

When it comes to users accessing the service from home by means of their own ICT equipment unavailability of suitable access equipment represents a moderate risk to the local implementation of the pilot service in Trikala. Specifically, in such cases an inclusion criterion is that the end user owns a device that operates properly. In case that the equipment of a user is damaged or stops to operate, e-Trikala's personnel are in place in order to replace the impaired device. To explain the procedure of the device replacement, there are two probable situations. If the device belongs to the user, it is examined whether there is a guarantee for the device, and if there is, it is repaired by the vender. If no guarantee exists, then the users will have to replace their own equipment as they would prior to their participation in the pilot or they will be given the alternative to be equipped free of charge with other devices owned by e-Trikala. The second case is that the device belongs to e-Trikala, from the beginning of the pilot. Under the circumstances, the appliance is repaired or replaced with the cost being borne by e-Trikala. This risk scenario is addressed by upfront examination of all technical equipment (hardware/software) by the technicians to identify potential malfunctions or any other potential problem.

Low Internet connectivity that is caused by service provider problems represents another risk when it comes to accessing the service from home. This would cause interpolations during the video counselling sessions. Foreseen remedial action includes connecting the user through the municipal wireless network. Specifically, at first the technical personnel of e-Trikala will be in touch with the technical department of the ISP on behalf of the end user in order to set up the adequate configuration and fix the problem. The concept is to check whether the problem concerns only the Internet Service Provider infrastructures or the internet hardware devices (modem/ router) of the user. In case the problem which starts from the ISP persists and cannot be solved in a concrete amount of

time, the user is going to be connected to the Internet through the municipal free wi-fi. On the other hand, if the problem concerns the internet devices (modem/routers) it should be replaced by the ISP in due time.

Low internet connectivity for those who are connected through the municipal wireless internet and live in the border or in the suburbs of the city is considered a moderate risk as well. Again, this would cause unexpected interpolations during the counselling sessions in case of increased traffic in the network. The remedial action for the occasion of prolonged disconnections, the user is going to be equipped with adequate antenna in order for the signal to be amplified.

Malfunction of the SIP (Session Initiation Protocol) server which is used for controlling communication sessions, and serves for the video conferencing, represents a minor risk, e.g. in case of blackout or sudden reset of the initial configuration. Remedial action includes intervention by computer engineers and technicians of e-Trikala, e.g. by reconfiguring the primary settings. This scenario is not of great probability to take place. The SIP server is based on an operating system which is very stable and is called CendOS where minimum instabilities can be caused. Additionally, it is stored in the safe data room of the Operational Control Centre of e-Trikala.

Service process related risks

Forgetting appointments or rescheduling them too often represents a moderate risk for the smooth operation of the pilot service. Experiences from current practice suggest that people - deliberately or not - tend to forget their appointment with their psychologists, especially when in denial. Denial is a clinical symptom often found in people who are experiencing burnout due to long-term stress and burden. In this case although they may show high scores on the burden scale they tend to deny feeling tired or stressed when asked. These are the users who are most likely to hide important information during counseling or even reschedule it. The psychologist will be able to detect users with denial by comparing their burden scale scores with the profile that will shape from the very first.

User participation related risks

Drop out of pilot users represents a certain risk for completing the pilot within the time frame set out in the work plan. Experiences from current practice suggest that often people tend to have unrealistically high expectations concerning the effects psychotherapy may have on their lives and may feel disappointed if the counseling session doesn't fix everything in their lives. In such a case we risk spending a lot of time (for evaluation, training and counseling) as well as budget (for enabling an ADSL line) for a participant who will use the service for a very short period. To avoid such a risk psychologists have made it clear to the users from the very beginning that the Independent services will not eliminate all problems they potentially may have. Rather, the Telecare centre as well as the psychologists, is there to offer a helping hand in coping with their everyday burden. On the other hand, experiences from current practice show that sometimes clients get too attached to their therapist and therefore tend to phone almost every day for no serious reason. This kind of emotional attachment can be surpassed from the psychologists by setting boundaries to their client's requests. This is an integral part for any counselling procedure in psychotherapy.

Data protection related risks

Each end user participating in the project has to provide a signed form accompanied with a doctor's formal and signed statement that the participant is physically or legally capable of giving consent. Also, demographic information for the EHR needs to be provided. The above forms are kept hidden in order to preserve user's anonymity. These forms are kept in a room located in the Business Control Centre of e-Trikala. Data handling and circulation is of great importance, so the emphasis on security both on a digital and paper-based level is crucial. The building is equipped with a modern alarm system that detects movement and works by security code (password). The windows of the building are protected with metal bars prohibiting the entrance and the doors to the main workplace operate with an electronic lock system, where each entry is to be granted by a special access card. Thus, the data of the access card that opens the door is recorded on a database. The space of the server (data room) is protected by special security door that operates with the same electronic card lock system. The space is cooled so that the temperature is kept stable, because the servers produce heat that can possibly create small malfunctions to the system. The servers' Operating System is constantly updated to be at

a high level of security and access is granted only by username and password. The interconnection within the internal and external network is handled through network equipment (firewall hardware) that detects and prevents external attempts to "attack".

Personal or health-related information is not disclosed to people or institutions that the users do not want to be able to see their data. From their point of view, it is important to have easy and secure access to the system. However, from security and privacy point of view this is a matter of authorisation and one way to achieve controlled access to different pieces of data is to apply profile-based or role-based access control.

Another important aspect to consider is the intellectual property of software used to manage and elaborate the data of the end-users. Confidentiality, in this case, means protecting executable software from unauthorized parties gaining access.

Integrity will be safeguarded by means of preventing unauthorized modification of the information. In relation to the subsequent authentication, it will be proved through electronic protocols for authentication which preserve that digital information has not been changed or lost.

For those utilising a multi-user access device located at a KAPI centre, a separate room is available from which the end users can have their tele-counselling sessions privately. At the part of the psychologists privacy is ensured as well by using are placed in isolated offices, in which no other employee or visitor may have access unless permitted by the psychologists. Furthermore, any communication with involved doctors is considered to be totally compliant to their medical oath and their professional confidentiality they have to follow.

Other risks

Taking into account not only the Greek but also the global financial recession crisis, there is a possibility for e-Trikala SA not to be able to provide equipment and sustain the services after the end of the pilot phase of the project to all users who would like to continue using the service. This means that it may not be possible to sustain them for free but only with a subscription paid from the interested users, with an amount to be decided in time. In order to succeed in sustaining the services, the amount should satisfy both the end-users and the Municipality as well. A good metric to approach the desired balance could be the conduction of a survey amongst the users, or even – if possible – to adjust it on the financial convenience of each willing user to continue their services.

For the time being, the Municipal free wireless network continues to function with no problems. Despite the fact that there is (still) no need for alterations, for sustaining reasons, there might be taken a political decision from the Municipal Board to add to the free Municipal Wireless network a subscription. This decision could lead even to problems in the pilot phase, as many people would be reluctant to continue in case they had to pay any amount for internet connectivity, instead of using the free wireless network for their services as they used to do so being in the pilot phase. The only solution could be to find funds either from public or private sector, which entails objective difficulties, especially nowadays.

6 Pilot preparation in Dublin

6.1 Summary of the local pilot service implementation

The INDEPENDENT project in Dublin is built around the collaboration of two separate entities, Emergency Response LTD (ERL), and the Alzheimer Society of Ireland (ASI). The latter is a voluntary (non-profit) organisation providing frontline services as well as information, support and advice services to people with dementia and their carers. Emergency Response is a private company providing Telecare services to older people with dementia and their carers.

The INDEPENDENT service supports collaboration between both parties by providing a case management tool that enables ERL operators to collate all the information and actions related to an incoming call. Care coordinators at ASI will benefit from close-to-real time information about the condition of users and an improved reporting tool to support the reassessment process. Care teams in ASI can see exactly where and when the client is using the Telecare, allowing advanced care planning as changing care needs are evident, safety issues are highlighted and therefore care planning is adapted accordingly.

Exhibit 11 below shows the INDEPENDENT service model as it is contextualised in Dublin (see dark coloured service components concerned). Exhibit 12 further below provides more details on the types of actors involved the specific local context and the way these are involved.

Exhibit 11 - Contextualised INDEPENDENT cooperative service process model

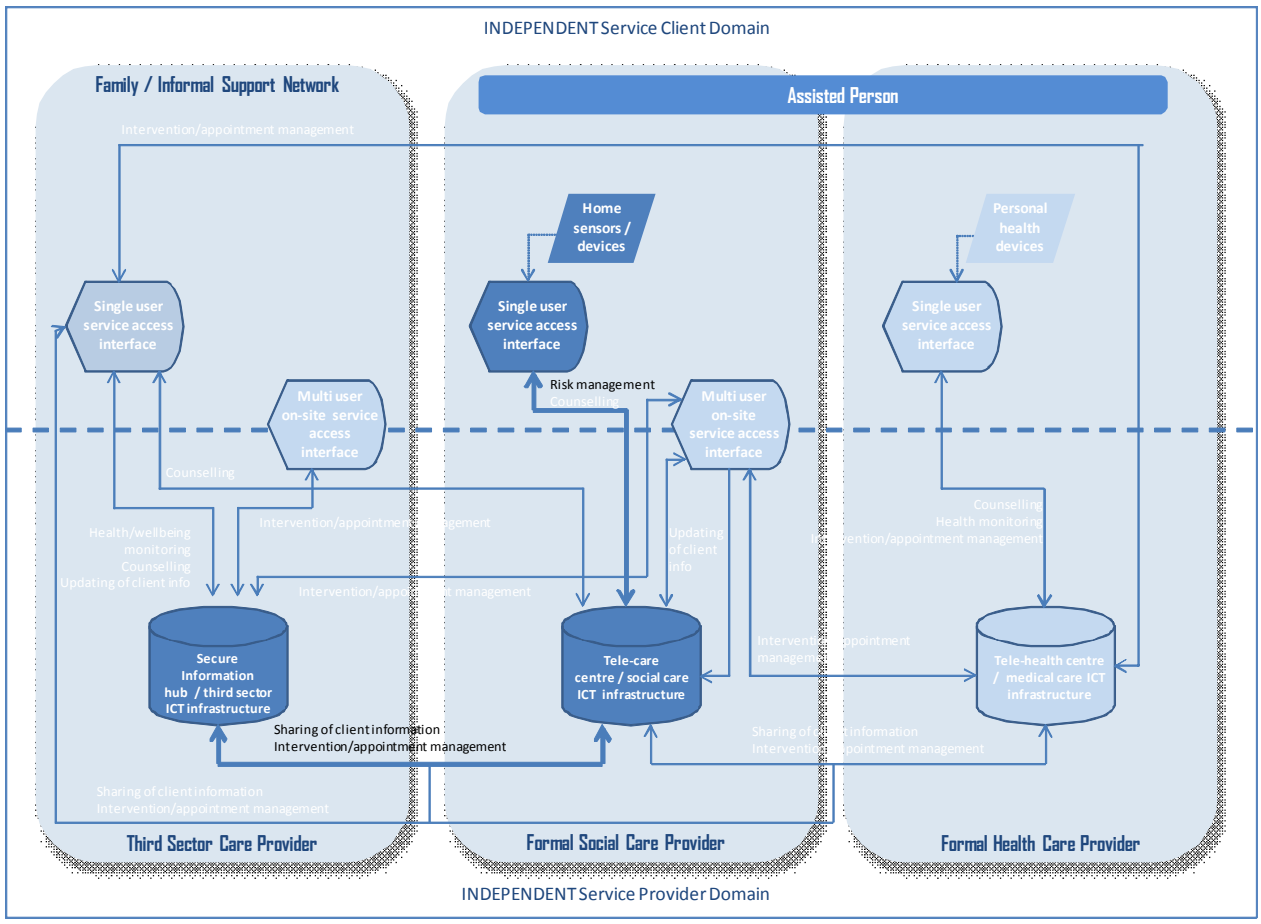


Exhibit 12 - Overview of service components implementation

Generic type of service provider system / interface	Generic type of service client access device /interface	Generic service process component to be piloted	Site-specific implementation of generic service process component
Telecare centre / social care ICT infrastructure	Single user web interface	Risk management	Telecare operator responds to alerts received by client's home unit
Secure information hub / third sector ICT infrastructure & Telecare centre / social care ICT infrastructure	n.a.	Shared client information	Telecare provider shares data on alarm history of client with dementia with third sector carer
Secure information hub / third sector ICT infrastructure & Telecare centre / social care ICT infrastructure	n.a.	Intervention/appointment management	Telecare provider updates third sector carer on red flag events concerning client with dementia to support on-site care planning.

6.2 Digital service support infrastructure

Home equipment utilised for the purpose of INDEPENDENT includes Telecare devices (base Telecare unit), and including devices such as a smoke detector, flood detector, extreme heat detector, bed sensor, property exit sensor, and bogus caller button. All of the above pieces of equipment are the responsibility of ERL to install, commission and maintain.

It is ERL's responsibility to install and commission the web portal which will provide the platform for the ASI co-ordinators to observe the behavioural patterns of their clients.

6.3 Training measures

ERL will provided training to ASI care – coordination staff on the web portal, their access to it and their use of it in terms of client monitoring and package recycling.

This training was done in 2 phases; the first phase was with larger groups of care-coordinators at both sites. The second phase involved ERL doing onsite training with care-co-ordinators and their staff on the web-portal. Phase one was completed by end of December 2011 with all care coordinators being proficient in their use of the web portal and phase 2 took place in January as the portal went live and care co-ordinators begun to use it increasing as more Telecare packages go into clients homes.

Phase 2 involved ERL staff conducting one-to-one visits to ASI staff at their own locations and 'hand holding' them through any issues that may arise.

6.4 Pilot users

All participants are clients of the ASI. Potential participants are identified, recruited and consented, and initially assessed. Baseline assessment of quality of life is being carried out with people with dementia and their informal carers. Clients who drop out of the study due to illness, entry into residential care, or due to death are assessed using a proxy exit assessment with their family carers. New clients will be recruited to the study as the ASI recycles Telecare packages routinely. Currently an average of 25 Telecare packages is recycled every year.

Access to people with dementia and their family carers for both control and intervention groups is negotiated through the ASI. The researcher, in collaboration with ASI Care Co-ordinators, uses a functional approach to assessing capacity, according to the criteria set out by the UK Mental Capacity Act Code of Practice and the Alzheimer's Association. This involves careful explanation of the study, what the interview entails, the rights of the participants, arrangements to protect their confidentiality and to what use the findings will be put.

People with dementia who have been assessed as having capacity to give informed consent are consented by the ASI Care Co-ordinators, and again by the researcher at the time of the interview. Carers of people with dementia who have capacity are also asked to give informed consent for the person with dementia to take part in the interview, and also for informed consent on their own behalf. People with dementia who lack capacity are not going to be interviewed.

Care co-ordinators were invited to participate via an email with a participant information sheet, and two copies of the consent form attached. The consent form was signed and returned to the researcher at the time of the interview. Participants were given pseudonyms for transcription, analysis and reporting.

Recruitment has begun and 12 baseline interviews have been carried out as at 8th March 2012.

6.5 Help desk

There will not be a dedicated help desk as such but a dedicated engineer who combines the web portal with other aspects of his role in ERL. Any program-related issues with the portal case manager will be resolved by Tunstall help desk in the UK or Spain. ERL functions as a contact point for ASI staff, supported by the Tunstall help desk.

6.6 Ethics and data privacy

Ethics approval

Ethical approval has been sought and provided for the study from the Royal College of Surgeons Research Ethics Committee.

Compliance with basic ethical principles

Access to participants is via the ASI care co-ordinators who pass contact details on to the research. The researcher will conduct interviews in the company of the ASI care co-ordinator to ensure participants are adequately supported and feel safe at all times.

People with dementia and their carers who take part in the study are given a screening number at baseline. All information that could identify participants is stored separately from data. All data is stored on the Royal College of Surgeons in Ireland's Secure Server and will only be accessible by the researcher. Participants have the right to withdraw from the study at any time, in which case all data relating to them will be erased. Participants have the right to refuse to answer any question put to them.

Informed consent

The ethical issue of concern is the process of obtaining informed consent from people with dementia. A key factor in this is the assessment of the capacity of participants with dementia to give informed consent. The Scheme of Mental Capacity Bill 2008 upholds the presumption of an individual's capacity unless there is evidence to the contrary, and implies that the functional approach to assessing capacity is the favoured approach.

The functional approach involves an assessment in relation to a specific choice at a specific point in time. There are no formal guidelines in Ireland related to the Mental Capacity legislation; however the UK Mental Capacity Act 2005, covering England and Wales, provides a statutory framework for assessing capacity. The Alzheimer Society of Ireland recommends these guidelines for use in this study. The Mental Capacity Act Code of Practice (ref) sets out a two-stage test of capacity.

Stage 1 requires proof that the person has an impairment of the mind or brain, or some sort of disturbance that affects the way their mind or brain works. If a person does not have such an impairment or disturbance, they will not lack capacity under the Act. Stage 2 requires proof whether the impairment or disturbance does mean that the person is unable to make a specific decision when they need to. For a person to lack capacity to make a decision, the Act says their impairment or disturbance must affect their ability to make the specific decision when they need to. Stage 2 can only apply if all practical and appropriate support to help the person make the decision has failed. A person is unable to make a decision if they cannot:

1. Understand information about the decision to be made
2. Retain the information in their mind
3. Use or weigh that information as part of the decision-making process
4. Communication their decision (by talking, by using sign language, or any other means)

In order to ensure that the correct balance is struck between including people with dementia as far as possible, so that their voices can be heard, and minimising the risk of coercion or lack of informed consent, the following process is being used:

1. Meetings were held with the Alzheimer Society of Ireland's Head of Services, Regional Co-ordinators and Care Co-ordinators to plan recruitment and consenting process.
2. Random sample of people with dementia and their family carers has been generated
3. Potential participants (people with dementia and their carers) are invited for interview
4. Of those who accept the invitation, people with dementia are assessed by the researcher in partnership with the Alzheimer Society of Ireland for their capacity to give informed consent to interview. This involves careful explanation of the study, what the interview entails, the rights of the participants, arrangements to protect their confidentiality and privacy, and to what use the findings will be put.
5. People with dementia who are assessed as having capacity to give informed consent will be consented by the ASI Care Co-ordinators, and again by the researcher at the time of the interview. Carers of people with dementia who have capacity are also asked to give informed consent for the person with dementia to take part in the interview, and also for informed consent on their own behalf.
6. Carers of people with dementia who lack capacity are invited for interview and to give informed consent on their own behalf. People with dementia who lack capacity are not interviewed. If participants become distressed or upset during the interview, they are put in touch with the Alzheimer Society of Ireland who intervenes to assist them.

In the case of people with dementia who have progressed too far in their disease to be able to comprehend a capacity assessment, a waiver form is in place for ASI professionals to sign, indicating that a person should not undergo a capacity assessment. In this case the carers of people with dementia will be consented as proxies.

Data privacy

ASI staff interviewees were given the option of having their interview recorded via audio recording or note-taking. Hard copies of transcripts and notes will be shredded and audio files have been erased. All transcripts have been anonymised.

The audio recordings of the interviews will be transcribed and the transcripts stored as an electronic copy. The audio files on the recording device will be overwritten and erased. Any contemporaneous notes for the interviews and for the observations will be typed up and the transcripts stored as electronic copies; the hard copies will be shredded immediately after transcription. Any identifiable data in the transcripts from the interviews and observation will be removed to ensure confidentiality. The transcripts will first be returned to participants for review and feedback, and after this process is complete, will be anonymised. The electronic data for the study will be stored on the RCSI's secure server and files are encrypted and password-protected. They are stored in a 'Research Management'

sub-folder in the secure Population Health Sciences folder on the RCSI server; this sub-folder is only accessible by Dr Anne Hickey, Professor David Smith, Sarah Delaney, and Laura Phelan (the Divisional Research Manager). A secure subfolder is also in place for email correspondence and consent forms which are encrypted and password-protected and only accessible by the named individuals on the application and Laura Phelan.

Consent forms are scanned and stored electronically and the original copies shredded in accordance with the PHS Data Handling Guidelines. Identifiable data is kept in a separate file to the interview and observation transcripts and is protected with a different password, and encrypted. The data will be stored for 7 years after the submission of the final report or publication (whichever occurs last), and then destroyed. This is in accordance with the RCSI Division of Population Health Sciences Research Data Handling Guidelines. This is the joint responsibility of the three individuals listed above. The IT department will be contacted to ensure any back-up files are also erased.

Any identifying information from the recruitment process and qualitative interviews is only accessible by the named individuals in section 10iv and will not be used in any publications. Pseudonyms will be used in any publications. The RCSI Division of Population Health Sciences Research Data Handling Guidelines are followed as detailed above to ensure best practice. The participants are reminded of the confidentiality information detailed in the participant information sheets, including how the data will be used before and after the interviews and observation and they will be given the opportunity to ask questions at any stage.

6.7 Risks

Risk management overview

Exhibit 13 - Risk management summary table

Risk	Impact	Likelihood	Remedial action
Web portal failure	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Disaster recovery plan with Tunstall in place
User information shared beyond ERL and ASI	☐ low ☒ medium ☐ high	☐ low ☒ medium ☐ high	Briefing of all home care co-ordinators on the use of coding for evaluation participation
Relationship breakdown between ERL and ASI	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	SLA in place so each knows own responsibilities. Continuous site meetings to maintain open communication and problem solving.
Users are not informed fully about participation in project	☐ low ☐ medium ☒ high	☐ low ☒ medium ☐ high	Revised information project leaflets and planned information sessions with home care co-ordinators about recruitment of new users in 2012 to the project.

ICT related risks

There is an anticipatable risk in relation to the technology which we utilise in relation to the availability of the web portal. This risk is managed by the fact that ERL have a service level agreement in place with Tunstall who will manage a disaster recovery facility in the event of the portal going offline.

Service process related risks

A Service Level agreement has been development between the ASI and ERL to govern the partnership between both organisations. This SLA protects both the ASI and ERL and ensures that clarity exists on how the service is delivered and received. It lays down what both organisations can expect from each other and how ultimately the end user, the person with Dementia is best served. It is imperative that

the relationship between ASI and ERL at a national and local level is optimum at all times to address issues as they arise and maintain optimum use of the web portal by both services.

User participation related risk management

The web portal is designed the portal in such manner that it is fully compliant with the current Irish Data Protection legislation and can only be accessed by a unique log on by the ASI co-ordinators and which only allows them access to their own specific client base. ASI must continue to protect the service user's privacy, confidentiality and ability to give informed consent to taking part in the evaluation. ASI staff has been briefed on the use of coded information to describe client who have packages in home for the evaluator. The ability to give informed consent is necessary for people with dementia to be included in the evaluation. A capacity assessment is conducted to ensure people with dementia are able to give fully informed consent. If an individual does not have capacity, their carers are interviewed as proxies.

Careful management of the recruitment process is required to avoid delays. Recruitment progress is monitored on a weekly basis and the pilot preparation template is updated accordingly

This population of people with dementia is subject to attrition due to death, illness or entry into residential care. Clients who drop out of the study will be assessed using a proxy exit assessment with their family carers. New clients will be recruited to the study as the ASI recycles Telecare packages routinely. Currently an average of 25 Telecare packages is recycled every year. Each patient and family carer is followed for twelve months.

Data protection related risks

The web portal has been designed in such manner that it is fully compliant with the current Irish Data Protection legislation. ERL is fully compliant with current legislation and all data is treated in compliance with provisions of such legislation. This applies to all levels of access to the portal also even from an ASI Co-ordinator perspective. ERL are subject to independent audits in relation to all aspects of data compliance from an internal parent company perspective and also ISO level.

Management of other risks

ASI care co-ordinators continue to brief all new clients on the possibility of future payment of monitoring fee on completion of the project. This is vital to ensure that an informed decision can be made about accepting the service in the first instance.

Funding for sustainability and expansion of the service beyond the pilot phase is a risk and in the current economic climate is made more difficult due to the lack of financial certainty in the statutory health service in Ireland. Some discussions have taken place with the "Health Service Executive" (HSE) about Telecare and some interest has been shown however, the wider dissemination process will now have to develop this interaction in a formal way through workshops, information sharing and further meetings.

7 Pilot preparation in Malaga

7.1 Summary of the local pilot service implementation

In Málaga, the INDEPENDENT service revolves around the closer integration of the services provided by ASSDA with those provided by Salud Responde. ASSDA is a public organisation responsible for the provision of social care and independent living services, and operates one of the largest Telecare service centres in Europe. Salud Responde is a public organisation which provides several health services throughout the province of Andalusia.

Current social support services provided by ASSDA are improved through better integration of and coordination with existing services provided by the health authorities (Salud Responde). To this end, the INDEPENDENT digital support infrastructure enables sharing of client data and joint call handling in case of requests by clients and informal carers concerning both social care and healthcare needs.

One use case originally planned to be piloted ('Hospital Discharge') had to be discarded due to orders from the Regional Government, which has decided not to proceed with this use case because of problems in defining the allocation of competences between medical and social services. Therefore, ASSDA won't be able to interact straight away with the medical information from people discharged from hospital, but they can call on their own wish to the Telecare service provided that they are already users of the service.

Exhibit 14 - Contextualised INDEPENDENT cooperative service process model

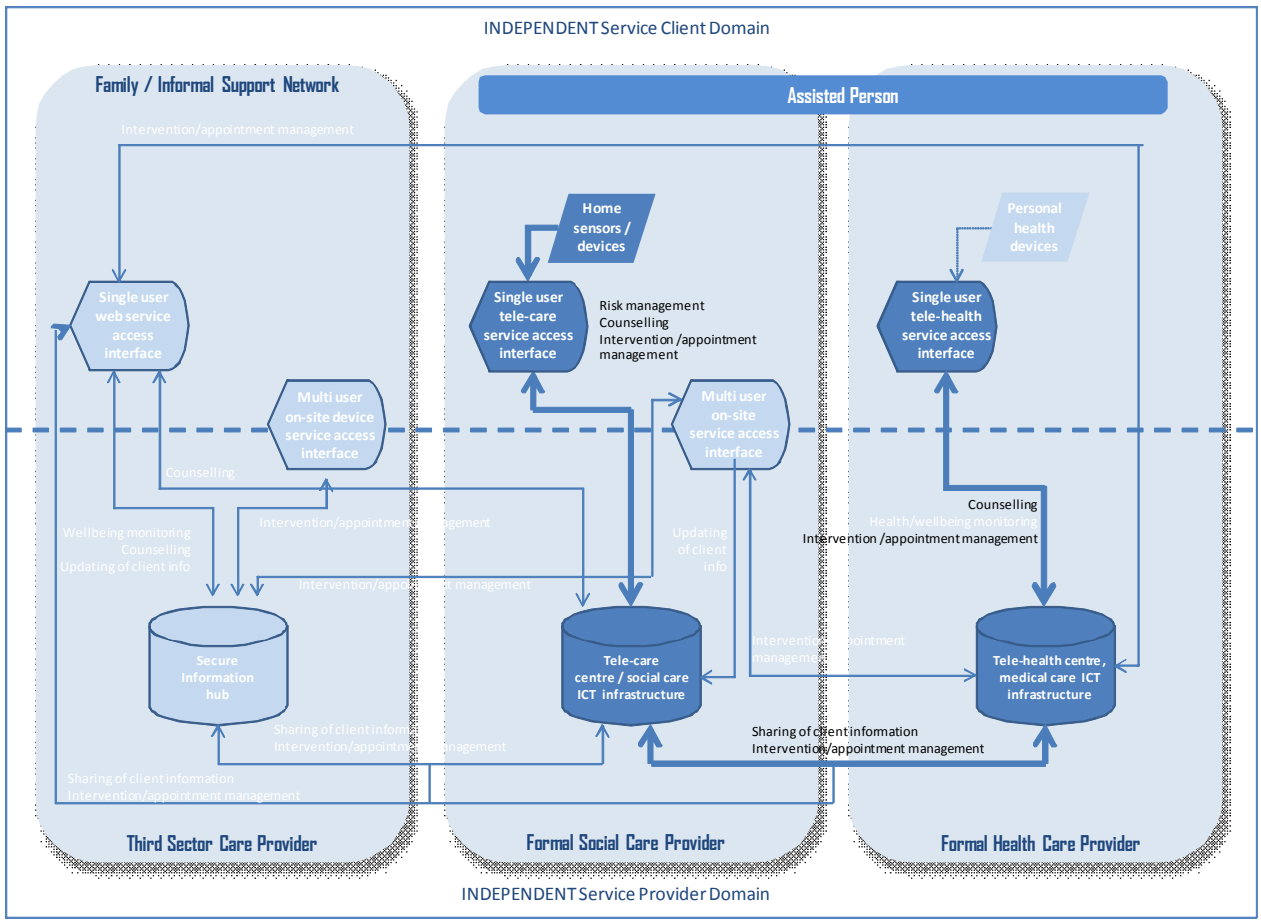


Exhibit 14 above shows how the generic INDEPENDENT overall service model has been contextualised in Malaga (see dark coloured service components concerned). Overlaf, Exhibit 15 provides more details what actors are involved and in what way these are involved.

Exhibit 15 - Overview of service components implementation

Generic type of service provider system / interface	Generic type of service client access device /interface	Generic service process component to be piloted	Site-specific implementation of generic service process component
Telecare centre / social care ICT infrastructure	Single user Telecare service access interface	Risk management	Telecare operator responds to alerts received by client
Telehealth centre / health care ICT infrastructure & Telecare centre /social care ICT infrastructure	n.a.	Sharing of client information	Telecare operator and Telehelath operator have share information on joint clients through dedicated platform
Telecare centre / social care ICT infrastructure & Telehealth centre / health care ICT infrastructure	Single user Telehealth service access interface	Intervention/appointment management	Telecare operator provides counselling to client and/or informal carer and routs call concerning medical appointment/advise to Telehealth operator
Telehealth centre / health care ICT infrastructure & Telecare centre / social care ICT infrastructure	Single user Telehealth service access interface	Intervention/appointment management	Telehealth operator provides counselling to client and/or informal carer and routs call concerning social advise to Telecare operator

7.2 Digital service support infrastructure

At the part of the assisted person, the installation requisites are the following for the new users:

- A Connect+ device
- A telephone line
- A main socket

This is the standard Telecare package that is installed for all the new users of the ASSDA Telecare service. Existing users do not need new equipment or upgrades to the one they already have installed at home. Tunstall as ASSDA service provider is responsible for the installation and maintenance of equipment.

At the part of the ASSDA call centre, the installation requisites are the following:

- PNC version 6 installed
- Web service to transfer calls and data to Salud Responde

Third generation application than handles the data gathering for the transfer via the web service

Tunstall as ASSDA service provider is responsible for the installation and maintenance of any equipment.

At the part of Salud Responde, the installation requisites are the following:

- Deploy new configuration (DTMF tones decode) at Siemens Interactive Voice Response
- Deploy new call routing logic at the PPABX
- Implement changes at Data Base

- Deploy web services and new business logic at Siebel CRM
- Indra as Salud Responde service provider is responsible for the installation and maintenance of develops and equipment. At both sides appropriate communications channels have been enabled.

7.3 Training measures

Training sessions were organised to train staff involved in service delivery. The training was provided in stages, the managers and the supervisors were the first ones to be trained in the new INDEPENDENT tool. The training was then provided to the teleassistants and teleoperators in specific workshops of around 10 people organised by the protocol specialists and quality department. Each teleassistant received an average training of two hours.

The overall length of the whole training was three weeks, prior to the pilot start date.

The formative sessions were developed with the aim of knowing the new procedure among ASSDA and Salud Responde, as well as managing the new implemented functionality.

This involved:

- The use of the new Software and interface
- Answering and reverting calls asking for medical appointment or health advice following specific protocols
- New protocols for identification of users discharged from hospital during weekends and provision of social monitoring to them
- To provide specific new follow up procedures
- Understand the new protocols and the mitigation measures during the piloting

7.4 Pilot users

End users include all ASSDA clients (people living in Andalusia, aged over 65, disabled or people in a dependant situation) and formal/informal carers. The service was tested with end users and formal/informal carers who call to ASSDA teleassistance service asking for medical appointment or health advice. These calls are transferred directly to Salud Responde so that they can speak with both the social and health services in the same call.

During the trial any incoming calls at ASSDA that meet the necessary criteria (ask for medical appointment or for health advice) are transferred to Salud Responde through the new system, becoming part of the trial.

The number of users is based on the number of requests derived to the health centre via the Telecare service during the field trial period.

7.5 Help desk

Both, Salud Responde and ASSDA are running their own helps desks. For the service delivery the help desk supports operators as well as users in case of problem with the Telecare units at their home.

The existing help desk lines were updated with the INDEPENDENT information, providing technical support and advice when experiencing technical difficulties or when having questions related to the Independent system. Support is provided during the whole pilot. The help desk provides contact information of the technical providers (Tunstall and Indra for ASSDA and Salud Responde respectively) in case the problem is related to the tools provided by them.

7.6 Ethics and data privacy

Ethics approval

According to the nature of the pilot services no formal ethics approval is required according to national regulation (Real Decreto 223/2004)

Compliance with basic ethical principles

In Andalucia the pilot preparation has been set up in a way to comply with the ethical principles and requirements that relates to this type of pilot, by providing informed consent where confidentiality of the data is guaranteed, non disclosure of their personal data, information about the project, the implication and any risk associated with the pilot and the withdrawal option at any time. The treatment to the user will be respectful at any time by the service staff. The commitment from both ASSDA and Salud Responde also includes information on any modification of the service provided and the acknowledgement by the users. Also we will comply by collecting and assessing any suggestion, complaints and claims by the users at anytime of the procedure, ensure that the adaptation of the pilot and the protection of their rights are covered at all times. All this will set an ethically sensitive work environment throughout the pilot phase to prove and collect the necessary feedback from the users and proven finally by the results of the evaluation phase at the end of the project which will be communicated to any of the participants who wish to get access to the information before during or after the pilot operation.

Informed consent

Users of the Andalusian Teleassistance Service sign a contract agreement when they register to the service, in which the rights and obligations when using the service are listed (according to the Regulation of the Teleassistance Service)

In this consent form they authorize the Regional Ministry of Equality and Social Welfare (from which ASSDA is dependent on), under the protection of the Organic Law 15/1999 for the Protection of Personal Data, to use and communicate the personal data entered in the system for the attributions of the Ministry and services addressed to the users.

This authorization includes the transfer of personal data to collaborative public or private entities responsible to deliver the service or complementary services through agreements signed between these organizations provided that under any conditions the user has the right of access, rectification, cancellation and opposition to the transfer of personal data.

Data privacy

The data of the users of the service is protected according to the national regulation regarding this issue (Law 15/99 of 13 December for the personal data protection). Based on the INDEPENDENT services, a pre-agreement has been put in place in order to manage this range of services, going from what the existing agreement covered (emergency situations) to services transfers or alignments with the health sector such as emergency calls and or medical advice. In the case of Salud Responde they belong to the public health regional minister, and as such, the hold already the medical information from the users.

The data shared between both organisations respect the current legislation in data protection and it is stated in the contract agreement with the users.

In the contract agreement users also authorize the Ministry to record and use the telephone conversations held with the teleassistance unit with the purpose of optimizing the service from which the user can claim withdrawal of the agreement at any time.

In the case of the Independent use cases, a previous assessment pointed out the need for further research in relation to the hospital discharge use case and the transfer of medical information from Salud Responde to ASSDA.

The other two use cases were considered within the normal functioning of the service agreement where ASSDA is allowed to transfer the data from the user to Salud Responde but no medical information as such is to be exchanged by the service providers.

Use case no. 3 ('hospital discharges') has been finally discarded by the regional government after consultation and assessment due to incompatibility of the service, resources and current agreement.

7.7 Risks

Risk management overview

Exhibit 16 - Risk management summary table

Risk	Impact	Likelihood	Remedial action
Malaga unit is not operative	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Calls will be attended from Seville • Taking incidences manually • The call will be transferred from Seville to Salud Responde along with the required data • Once the central unit is re-established the procedure will be as usual
Calls cannot be transferred but the data can be transferred	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	Medical appointment and health advice will be handled: • ASSDA will call Salud Responde manually to communicate the user request, retaining the user call. Salud Responde will have access to the data previously sent • Once the request is reported, ASSDA will communicate the user that Salud Responde is going to call • Salud Responde call the user in order to get information and solve the request • ASSDA will call the user to know what Salud Responde has communicate him
Data cannot be transferred but the call transfer succeeds	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	The data transfer must be handled manually: • The call will be transferred from ASSDA to Salud Responde • ASSDA teleassistants will tell Salud Responde operators the user request • The rest of the call workflow proceeds as usual

Risk	Impact	Likelihood	Remedial action
Neither data nor the call can be transferred	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	The procedure must be handled manually: • ASSDA teleassistants will keep the user on hold while they call Salud Responde • ASSDA teleassistance tells the operator the user request • ASSDA teleassistant communicates the user that he will be called by Salud Responde • Salud Responde calls the operator in order to get information and solve the request • ASSDA calls the user to know what Salud Responde has communicated
Mix up of call handling protocols	☒ low ☐ medium ☐ high	☐ low ☒ medium ☐ high	• Staff will be accordingly trained in the new procedures • Handling protocols will be continuously supervised
Identification of calls as emergencies or not emergencies	☒ low ☐ medium ☐ high	☐ low ☒ medium ☐ high	• If the teleassistance thinks the request for health advice is not an emergency the call will be transferred to Salud Responde • Nurses at Salud Responde will attend the call and evaluate the situation • If the call is assessed as an emergency it will be transferred from Salud Responde to the emergency services (061) • The required data will be sent from ASSDA to 061
Drop out of users	☒ low ☐ medium ☐ high	☒ low ☐ medium ☐ high	• More users that the target will be contacted in order to ensure enough number of users in case of hospital discharge
Transfer of personal data not allowed to be shared	☐ low ☐ medium ☒ high	☐ low ☒ medium ☐ high	• The agreement between ASSDA and Salud Responde will be reviewed to check if they are allowed to transfer all data or some data have to be quit

ICT related risks

In case Malaga central unit is not operational the calls will be received at the Seville unit, and will be transferred along with the required data following the same procedures as if it would be attended at Malaga

In case data can be transferred but calls cannot be, ASSDA will call Salud Responde manually to communicate the user requests, retaining the user call. Salud Responde will have access to the data previously sent. Once the request is reported ASSDA will communicate the user that Salud Responde is going to call. Salud Responde calls the user in order to get information and solve the request. ASSDA calls the user to know what Salud Responde has communicate to them and to check if the request has been solved

In case calls can be transferred but data cannot, Salud Responde Teleoperator asks the user for their personal data. There will be no automatic confirmation of appointment or advice.

Service process related risks

To minimise the risk of mixing-up call handling protocols all staff has been train accordingly in the new procedures and the handling protocols will be continuously supervised

Difficulties in evaluating a user request for health advice as an emergency call or not may occur. In case the teleassistant does not identify a health advice request as an emergency call, the call will be transferred to Salud Responde along with the required data, and the nurses will evaluate if the call is an emergency call or not. In case of emergency, the call will be re-transferred from Salud Responde to the emergency services (061) along with the required data that will be sent from ASSDA to 061.

User participation related risks

No risks can be anticipated here.

Data protection related risks

Transfer of data in the existing cooperation agreement between ASSDA and EPES has only covered the emergency cases situations. The actual agreement will be reviewed to ensure that all data to be transferred, are allowed to be shared between both organizations ASSDA and Salud Responde, ensuring the protection of personal data in accordance to law and the users acknowledges the procedure in case of medical advice and medical appointment use cases.

Other risks

In the event that a service call originally classified as "medical advice" turns out as an emergency situation after being assessed by Salud Responde, this call will automatically be transferred to the 061 Emergency Services from EPES which will handle the call as required. Additionally, a notification will be sent straight away to ASSDA so they can transfer the data from the users directly to EPES assigning the ID of the user and the call. The emergency services will access to the users information in real time. This will allow for a direct interaction with the CommonWell service which has been piloted in the region of Andalucia between ASSDA and the emergency health services from EPES.

8 Pilot preparation in Geldrop

8.1 Summary of the local pilot service implementation

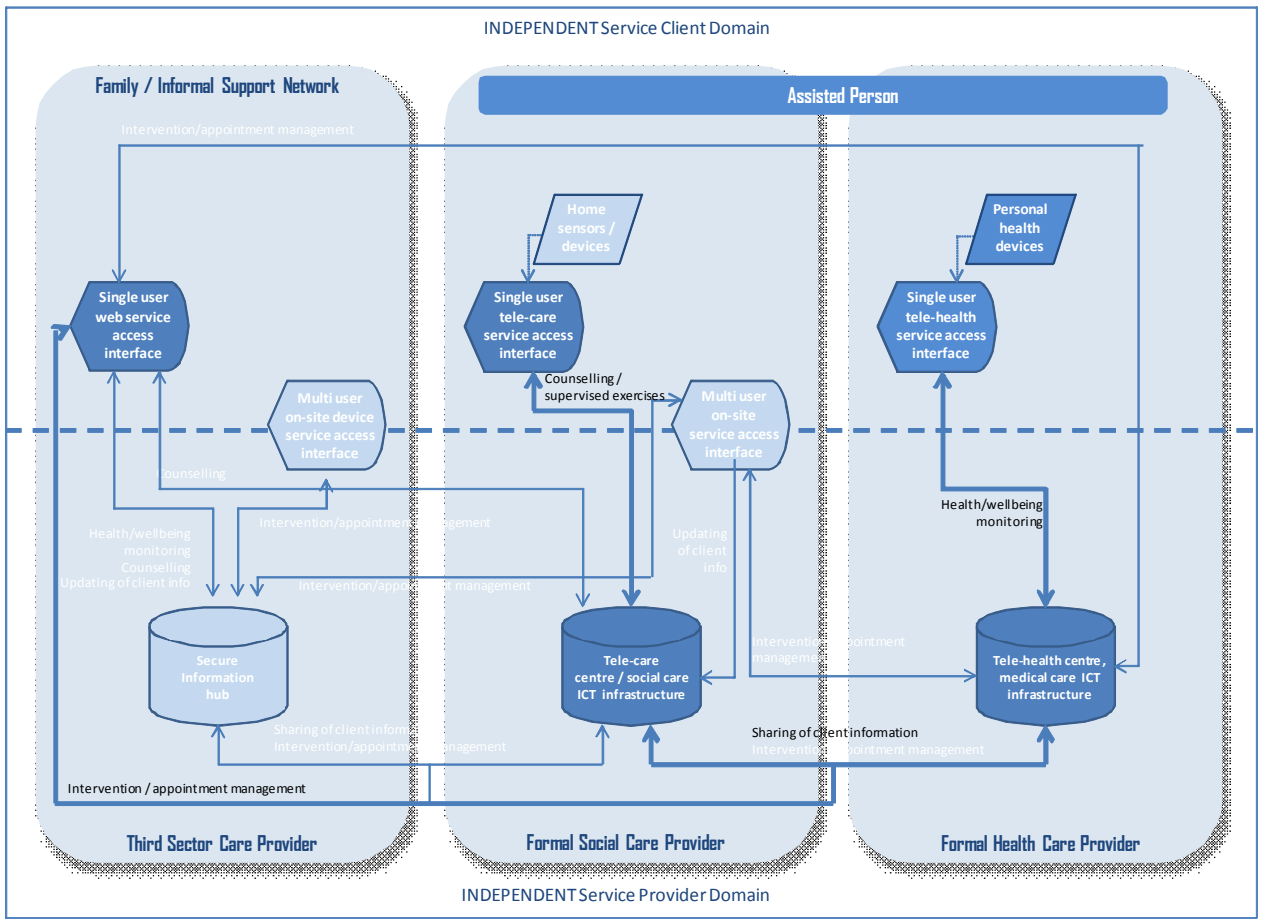
The INDEPENDENT project in Geldrop is built around the collaboration of several separate care facilitators; physiotherapists and sport coaches from TopSupport, pulmonologists and pulmonary nurses from the St. Anna Hospital, and informal caretakers (family). The concept is aimed at supporting Chronic Obstructive Pulmonary Disease (COPD) patients at home, through the use of smart technology and by enhancing communication between the various caretakers.

The concrete parts of the system are:

- An online audio/video environment to do physical exercises at home, coached by the physiotherapist through live audio and video, including hardware at the client side, and at the physiotherapist's side.
- An online electronic health record (EHR) with an overview of the patient's health status, treatments, progress, exercise program, vital sign measurements for the patient and all caretakers involved (medical professionals, physiotherapists, informal carers).

A wearable hardware device measuring physical activity in a very precise way, especially developed for COPD patients, including an online environment to upload and analyse the collected data.

Exhibit 17 - Contextualised INDEPENDENT cooperative service process model



Concrete aims of the pilot are to increase patients' motivation towards daily physical activities, and integrate care from different organisations. It is important for patients to explore the positive health

effects by following an exercise program and monitoring their daily activities. This monitoring also creates a better context for the whole group of caregivers that are involved. Through activity monitoring and an online health record, there is a better sharing of important health information between the various caregivers, and better management of care in a more organized way. Desired outcome of the pilot is a reduction of the amount of exacerbations and a more active lifestyle, resulting in a higher quality of life for patients and a cost reduction for society.

Exhibit 17 shows how the generic INDEPENDENT overall service model has been contextualised in Malaga (see dark colouring of the service components concerned). Subsequently, Exhibit 18 provides more details what actors are involved and in what way these are involved.

Exhibit 18 - Overview of service components implementation

Generic type of service provider system / interface	Generic type of service client access device /interface	Generic service process component to be piloted	Site-specific implementation of generic service process component
Telecare centre / social care ICT infrastructure	Single user Telecare service access interface	Remote exercises	Clients with chronic condition (COPD) dial into group exercise sessions that are remotely provided by a physiotherapist
Telehealth centre / health care ICT infrastructure	Single user Telehealth service access interface	Intervention / appointment management	Informal carer updates/looks-up his/her client with chronic condition (COPD)
Telehealth centre infrastructure / health care ICT infrastructure & Telecare centre / social care ICT infrastructure	n.a.	Sharing of client information	Pulmonologist and physiotherapist populate/look-up joint folder for clients with chronic condition (COPD)
Telehealth centre infrastructure / health care ICT infrastructure	Single user Telehealth service access interface	Health / wellbeing monitoring	Client with chronic condition (COPD) regularly measures vital signs

8.2 Digital service support infrastructure

Home equipment utilised for the purpose of the pilot include a computer, webcam and internet connection (for live training, accessing the online EHR, and uploading activity data). These components, devices and services are only provided when people do not already own the right components. Installation and de-installation of the hardware devices and services has been provided by OnsNet Eindhoven.

Physical activity monitors are provided to all users. Maintenance of the device and service is provided by the manufacturers McRoberts and Philips (both subsidised). TopSupport holds responsibility for installation and training.

Pulse oximeters, measuring oxygen saturation in blood, are provided to all users. Installation and training is provided by TopSupport. TopSupport and Smart Homes hold responsibility for maintenance..

The one and only central contact point for all technologies is TopSupport. They manage contacts between all other parties and the end users.

Furthermore, when procuring the hardware/software technologies from the manufacturers, it is negotiated and contractually agreed that installing (if applicable) and maintenance is included.

After the pilot, all hardware equipment will be de-installed. The software equipment (EHR, and online live audio/video tool) will remain available to those users that would like to continue the programme, if it will be continued in this form.

No hardware needed to be installed at the "back offices" of the various service providers, as they all have the necessary components and devices, being a computer, internet connection, and for the physiotherapists a webcam, except for one big screen for seeing multiple patients at once, while doing the remote exercises. Installation and maintenance of this device has been provided by TopSupport.

The following software is installed at the back offices:

- The EHR (online) at the physiotherapists and hospital.
- Software for monitoring and/or analysing incoming vital signs (McRoberts and Philips, both online) at the physiotherapists.
- Live audio/video home exercises (online) at the physiotherapists.

8.3 Training measures

End-users receive four 1-session training modules: (by TopSupport and Smart Homes)

- How to use the activity monitor. Sports coach shows participants (individual or as group) how to wear the device, upload data, and charge batteries during the exercise program. Also the way of measuring physical activities by the activity monitor is explained.
- How to use the pulse oximeter. The working of the pulse oximeter is demonstrated. Patients ask anything if things were unclear.
- How to use the live video communication tool. The company who has developed the live video communication tool has installed software individually, and has presented an information evening about how to use the live video communication tool.
- How to use the EHR

Health care service providers are trained in using the online EHR for COPD. People from TopSupport (physiotherapist, sports coaches and pilot coordinator) are educated by Fastguide through an online training session.

The pulmonary nurse is trained in a one-to-one training by one of the sports coaches from TopSupport.

Informal/family carers receive a 1-1 training session on how to use the EHR. (By TopSupport and Smart Homes)

8.4 Pilot users

End users are COPD patients, mostly of GOLD class II or III. Next to this, inclusion criteria are not having dementia, and not being bed-bound.

Recruitment mainly takes place in the St. Anna Hospital. Three pulmonologists and a pulmonary nurse redirect their patients to the Independent programme. A second channel is the existing COPD support group "Luchtgenoten". A third channel is an existing network of Brainport/OnsNet in Eindhoven, used in several other e-health pilots. Representatives of either TopSupport or Smart Homes have visited info days of these networks, and the two networks have circulating information about the Independent pilot internally, to inform and recruit patients. A last channel is word of mouth by other participants.

After recruitment, all patients have been assessed medically and technology-wise. Medical assessment exists of an extensive intake with the physiotherapist, including several questionnaires. Then the COPD patient has to do the 6-minute walking test, hand grip strength and strength of shoulder abduction and knee extension. Those are the T0 measurement.

Their home situation has been assessed in terms of available ICT devices and infrastructure. These are not inclusion criteria, but necessary information to provide patients with the right devices and/or infrastructure if needed.

8.5 Help desk

The live video communication tool is installed by OnsNet Eindhoven, the suppliers of the tool. They go to people's homes for a personal installation. After all installations, they organise an information meeting to give instructions and demonstrate how the live video communication tool should work.

The pilot's helpdesk offers telephone support to the end users for technical and all other problems related to the Independent service. The Independent service does not contain any alarm functionality, e.g. thresholds to vital sign measurements, that would require a dedicated 24/7 emergency response being provided by Independent. In case of an emergency situation, e.g. concerning a patient's lung function, he/she will call the usual emergency service. Other non-urgent medical problems are assessed by TopSupport and if needed they will be redirected to the hospital in cooperation with the pulmonologists.

TopSupport and Smart Homes provide the first point of contact helpdesk service. They are available from 8 a.m. to 5 p.m. on workdays. In case of medical related problems, TopSupport handles this. In case of technical problems, they will either be solved by Smart Homes or redirected to OnsNet.

No helpdesk is foreseen outside office hours. Patients are expected to use the service mostly during the day. If problems occur outside these hours, they can contact the helpdesk on the next day, as no high priority problems are expected.

8.6 Ethics and data privacy

Ethics approval

As there is no significant change in the care and management of any individual end user, for which the project partners have already received ethical approval in the past (WMO), and because no demented people will be approached to take part in the pilot, there is no need to gain the approval of the relevant medical ethics committees.

The Geldrop pilot is a large-scale pilot of new technology and services, but does not include a clinical trial. Therefore, no ethics approval is required according to current regulation/legislation.

Compliance with basic ethical principles

It will be ensured that the autonomy of all potential participants will be respected and any risks will be minimized, as end users will at no time receive care inferior than would normally be provided to them outside the pilot project.

Informed consent

A full participant's consent to take part in the project will be recorded in writing, in line with standard principles of informed consent, explaining in detail what the pilot will include, what patients may expect and what their rights are.

Only BIG-registered health care professionals will be involved in the service delivery and are allowed access to the patient's data.

As the service providers involved in the pilot are official regular health care providers, they all adhere to the "Kwalitetswet Zorginstellingen" law and "Wet Geneeskundige Behandelovereenkomst" law.

Data privacy

The new EHR especially designed and developed for COPD patients, has been verified and is found to adhere to all national and European laws and legal constraints concerning data protection.

No data will be made available to outside agents about any patient other than those who already have a duty of care and, as stated above, are BIG-registered professionals, with the exception of the patients themselves.

Only when an individual patient him/herself gives a separate full consent, his/her informal and/or social carer will be granted access to a small summarizing part of the online EHR, to allow this carer to update other carers about the patient's status when needed.

8.7 Risks

Risk management overview table

Exhibit 19 - Risk management summary table

Risk	Impact	Likelihood	Remedial action
Improper functioning of ICT components	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	a 3-round test phase
Delayed/non-availability of ICT hardware components	☐ low ☐ medium ☒ high	☐ low ☒ medium ☐ high	using only simple and standardized components
Delayed/non-availability of ICT software components	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	software has been installed and made available
Limited availability of informal carers as test users	☒ low ☐ medium ☐ high	☐ low ☒ medium ☐ high	Through a recruitment monitoring chart, we check the numbers of carers early on in recruitment process
Unwillingness to participate in the service by informal carers	☒ low ☐ medium ☐ high	☐ low ☒ medium ☐ high	clearly showing the added value of their cooperation, informal carers are asked to join the pilot
Unwillingness to participate in the service by professional health carers	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	professional health care organisations are all partners in the project consortium
Unwillingness to use the service by COPD patients	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	involving COPD patients from the beginning of the project on, acceptability has been assessed as best as possible
Limited availability of COPD patients as test users	☐ low ☐ medium ☒ high	☐ low ☐ medium ☒ high	hospital in the consortium as a full partner, a constant flow of COPD patients is guaranteed.
Drop out of participants during the pilot	☐ low ☒ medium ☐ high	☐ low ☐ medium ☒ high	user recruitment continues after the target number of patients is reached
Doing harm to users	☐ low ☐ medium ☒ high	☒ low ☐ medium ☐ high	having well-educated, well-trained and well-experienced professionals
Improper use of patients' private and medical data	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	data is safely stored at the TopSupport and only the minimally required data is stored in the EHR

Risk	Impact	Likelihood	Remedial action
Improper use of users' pilot evaluation data	☐ low ☒ medium ☐ high	☒ low ☐ medium ☐ high	data is gathered and stored by Smart Homes on a secured system

ICT related risks

The following measures have been taken addressing potential risk for the start and operation of the pilot:

- Delayed/non-availability of ICT hardware components: by using only simple and standardized hardware components, in-time availability is guaranteed.
- Delayed/non-availability of ICT software components: during the 2nd prototype tests and pre-pilot tests, all software has been installed and made available, so no extra software is needed than the ones now in place.
- Improper functioning of ICT components: a 3-round test phase (1st prototypes, 2nd prototypes, and pre-pilot phase) has guaranteed availability and proper functioning of the required components.

Service process related risks

There are a few points of service process related risk management. One of those is the limited availability of informal carers as test users. Once COPD patients are included, we contact their informal carers as soon as possible. Through a recruitment monitoring chart, we continuously check the numbers of carers during the recruitment process.

Another risk item can be the unwillingness to participate in the service by informal carers. These groups have been involved in the concept and process definition phases of the project, to bring this risk down to a minimum. By clearly showing the added value of their cooperation, informal carers are asked to join the pilot. It seems that most patients live independently.

Also professional health carers like the pulmonologists, pulmonary nurses and physiotherapists should participate. Their unwillingness could be a risk, however as the professional health care organisations are all partners in the project consortium, and individuals have been involved in the project from the start, this risk is very small.

User participation related risks

Limited availability of COPD patients as test users is mitigated by having the St.-Anna hospital in the consortium as a full partner, a constant flow of COPD patients is guaranteed.

Potential unwillingness of COPD patients to start using the service represents another risk. By involving COPD patients from the beginning of the project, acceptability has been assessed as best as possible. Furthermore, by involving the pulmonologist and pulmonary nurse, they see the benefit of the pilot and strongly advise all their patients to join the programme.

Another issue receiving attention here is the drop out of participants during the pilot. COPD patients have a weakened health compared to other people. In any long-term pilot project, drop outs occur, especially with these kinds of patients. Therefore, user recruitment continues after starting the pilot, to compensate for these drop outs. So far (February 2012) dropout rates are very low.

Doing no harm to users is highly important, for all sorts of reasons. By having the service thoroughly tested before the pilot, but especially by having only well-educated, well-trained and well-experienced professional health carers involved in the service delivery, this risk is brought to a minimum.

Data protection related risks

Improper use of patients' private and medical data has to be prevented. Therefore all data is safely stored at the TopSupport office, only accessible by specific TopSupport staff and hospital specialists.

Only the minimally required data is stored in the online EHR. Most data in here is only accessible by the professional carers. Only summaries and overviews are accessible by the patient and his/her informal carers. The EHR adheres to all national and international safety and data protection standards. National standards include facilitating work processes from physiotherapists, following KNGF standards of reporting, kind of data saving, and safe transferability of data between different care givers, only if the patient allows this.

The same holds true for the use of users' pilot evaluation data. These data is gathered by and stored by Smart Homes on a secured system. Only aggregated and summarised data will be shared with the rest of the consortium and the outside world.