COGKNOW

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Consolidated Field Test Report

Version 1.0

WP 4 Field Testing

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Abbreviations

COGKNOW	Project title COGKNOW; Helping people with mild dementia navigate their day
CDN	COGKNOW Day Navigator
CS	COGKNOW Server
CHH	COGKNOW Home Hub
CCA	COGKNOW Cognitive Assistant
CSH	COGKNOW Sensorized Home
MMSE	Mini Mental State Examination
GDS	Global Deterioration Scale
PwD	Person with Dementia
FT	Field Test

1. Introduction

Within COGKNOW three field tests were carried out in three consecutive years to validate the COGKNOW Day Navigator (CDN) prototype with end users and to provide input for the next development phase. The field tests were each year conducted in the homes of persons with dementia at sites in The Netherlands, Northern Ireland and Sweden.

In this concluding field testing report we present an overview of the three COGKNOW field tests, their characteristics, dimensions and durations, and also the procedures followed.

There were project-internal detailed reports from each field test:

- D4.3.1 Field Test # 1 Report [2]
- D4.4.1 Field Test # 2 Report [3]
- D4.5.1 Field Test # 3 Report [4]

Some aspects not covered in this report are: D5.7.1 Final Evaluation Report, that synthesises the evaluation results from user, technical and business perspectives. D7.2.1 Business Plan (project-internal) that specifies the way ahead towards commercialisation after the project formally ends.

In this report, Chapter 1 introduces the purpose and scope of the report, Chapter 2 describes the features available in each of the three main prototype versions and Chapter 3 shows the diverse characteristics of the users participating in each field test. Chapter 4-6 reflects upon what *should* be done before, during and after actual field testing periods with users, and how this was applied in COGKNOW. Chapter 7 draws conclusions about how COGKNOW performed the field tests, necessary further analysis and testing with users, and also recommendations for how to structure main iterative cycles in future projects.

2. Prototype Versions

The COGKNOW Day Navigator (CDN) prototype consisted of the COGKNOW Home Hub (CHH), the COGKNOW Cognitive Assistant (CCA), the COGKNOW Sensorized Home (CSH), and the COGKNOW Server (CS).

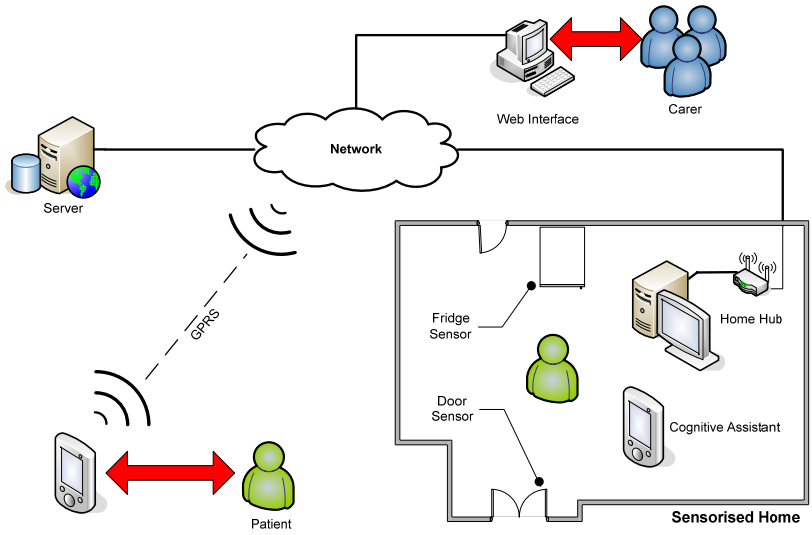

Figure 1. Overall System Architecture of COGKNOW Day Navigator

Figure 2. CHH touch screen with handset, CCA mobile device

During the three years of COGKNOW, the prototype evolved. Between the first and the second field tests, the prototype was completely reworked, while for the remainder of the project the prototype was improved incrementally. In the following table we present an overview of this development by indicating the functionalities verified technically at the sites, per key needs area.

Table 1. Functionalities in main prototype versions[1], per key needs area[2]

	1st prototype (FT1)	2nd prototype (FT2)	3rd prototype (FT3)
General	CHH & CCA languages: English, Dutch, Swedish	CHH & CCA languages: English, Dutch, Swedish *CHH selectable services* *selectable icons* *selectable text captions and font sizes*	CHH & CCA & *CS* languages: English, Dutch, Swedish CHH & *CCA* selectable services selectable icons selectable text captions & sizes *selectable voice prompts*
Support in Reminding	Date & time & *part-time indication* configurable pop-up reminders in CHH & CCA (text only, audible signal, one-time) find mobile device	Date & *weekday* & time indication *analogue or digital* *24-hour or am/pm* *suppress seconds hand* *agenda & quarter hour clock* pop-up reminders in CHH *remotely configurable* one-time *user-defined text* *user-defined image* audible signal *extended repetition* *appointment mode* find mobile device (unstable) item locator	Date & weekday & time indication analogue or digital 24-hour or am/pm suppress seconds hand agenda & quarter hour clock pop-up reminders in CHH&*CCA* remotely configurable one-time or *daily* user-defined text user-defined image *user-defined audio* extended repetition find mobile device. item locator
Support social contact	picture dialling priority photos of relatives (CHH only) *using existing phone*	picture dialling priority photos of relatives (CCH&*CCA*) *using simple handset*	picture dialling priority photos of relatives *landline prefix* *using better-quality handset* *SIP calling (abandoned)*
Support daily activities	radio control using X.10 (unreliable) music player	radio/lamp control using X.10 (unreliable) music player *selectable music* *activity assistant* (stepwise video+voice instructions) for daily activities *automatic music during lunch*, (MotivateToEat)	radio/lamp control using Tynetec music/*story* player selectable music activity assistant (stepwise video or *image*+voice instructions) for daily activities automatic music during lunch, (MotivateToEat)
Enhance feelings of safety	*emergency contact* *primary carer photo* pop-up safety warnings *doors*	*help* *life-saver ring icon* pop-up safety warnings doors *household appliances* *navigation when outdoors* (TakeMeHome) *sensorised night light*	*help/emergency* *personalised contact/help icon* pop-up safety warnings doors household appliances navigation when outdoors (TakeMeHome) sensorised night light

[1] *Italic text* indicates functionality that differs significantly from preceding or next main prototype versions.
[2] Note: not all main prototype functionalities were tested in each field test, depending on stability and evaluation goals.

3. User Characteristics

People with mild dementia of the Alzheimer type and their carers were recruited from memory clinics and/or the meeting centres support programme for people with dementia and their carers in Amsterdam (VUmc), Belfast (BCH) and Luleå (NLL). At every test site, five to six patient-carer dyads were recruited for each test.

Inclusion criteria that were applied were:

- People with a diagnosis Dementia of the Alzheimer type (possible/probable) as described in the DSM-IV-TR.
- Severity of dementia: Global Deterioration Stage 3,4: mild cognitive decline (early confusional; GDS 3) and moderate cognitive decline (late confusional; GDS 4) (assessed by using the standardized Brief Cognitive Rating Scale [1]) and/or MMSE (30 item version) 25-17.
- People are willing and able to participate actively (interviews, focus group and test sessions) in a research project developing an ICT device that aims to support memory, daily activities, communication with family and friends, and feelings of safety.
- The informal carer is regularly in contact with /cares for the PwD.

The following number of persons participated in the field tests: in FT1 16 PwD and their carers, in FT2 14 PwD and 13 carers, and in FT3 12 PwD and their carers. Some PwD and carers participated in more than one field test. Reasons for couples to discontinue participation in next field tests were: PwD were too much deteriorated in cognitive functioning, nursing home admission of PwD, not being interested in the project anymore.

The participating persons with dementia varied in age from 56 to 90 years and most of them were cared for by their spouses (31 out of 42). The carers varied in age from 23 to 79 years.

Details about participating PwDs and their carers can be found in the following tables.

Table 2. FT1 characteristics of participants

Characteristic/Site	**Amsterdam (n=5)**	**Belfast (n=5)**	**Luleå (n=6)**
Age	Mean 64,7 (range 56-78)	Mean 70,8 (range 66- 78)	Mean 69,5 (range 60-77)
Gender	3 female 2 male	4 female 1 male	4 female 2 male
Civil status	4 married 1 divorced	3 married 1 widowed 1 single	5 married 1 single
Carers			
Age	Mean 59,2 (range 49-78)	Mean 64.2 (range 45-72)	Mean 58,5 (range 23 – 78)
Gender	3 female 2 male	2 female 3 male	2 female 4 male
Relation to patient	4 spouses 1 daughter	3 spouses 1 children 1 cousin	4 spouses 2 son

Table 3. FT2 characteristics of participants

Characteristic/Site	**Amsterdam (n=5)**	**Belfast (n=5[3])**	**Luleå (n=4)**
Age	Mean 78 (range 57-90)	Mean 75 (range 66-80)	Mean 69 (range 61-77)
Gender	2 female 3 male	5 female 0 male	3 female 1 male
Civil status	2 married 1 divorced 2 widowed	3 married 2 widowed 0 single	3 married 1 single (without informal carer)
Carers			
Age	Mean 66 (range 52-79)	Mean 62 (range 40-78)	Mean 72 .(range 62–77)
Gender	3 female 3 male	0 female 5 male	1 female 2 male
Relation to patient	3 spouses 1 son 1 friend	3 spouses 2 children	3 spouses

Table 4. FT3 characteristics of participants

Characteristic/Site	**Amsterdam (n=4)**	**Belfast (n=4)**	**Luleå (n=4)**	**Total (n=12)**
Age PwD, mean ± sd Range	70.8 ± 11.33 57-81	73.5 ± 5.00 68-80	78.5 ± 4.04 75-84	74.3 ± 7.58 57-84
Sex, n male female	 2 2	 1 3	 2 2	 5 7
MMSE, mean ± sd score 0-30	22.0 ± 2.58	21.0 ± 1.41	22.0 ± 1.63	21.7 ± 1.84
Living situation, n together alone	 4	 4	 3 1	 11 1
Type of housing, n house apartment	 3 1	 4	 3 1	 10 2
Living area, n town/city village/countryside	 3 1	 4	 1 3	 8 4
Computer facilities with internet/email, n yes weekly used seldom/never	 4 1 3	 2 (of 4) n/a n/a	 1 (of 4) 0 1	 7 (of 12)
Mobile phone, n yes weekly used seldom/never	 2 2 0	 0	 2 1 1	 4 (of 12)
Carers				
Age Carer, mean ± sd Range	67 ± 12.46 53-78	74.3 ± 1.89 73-77	70.8 ± 10.60 55-77	70.7 ± 9.14 53-78
Sex, n male female	 2 2	 3 1	 2 2	 7 5
Relation PwD/Carer, n Partner Other (son of sister and home help)	 4	 4	 3 1	 11 1

[3] From one couple the field test findings could not be analysed due to postponed testing and delivery of data.

4. Pre-test Procedures

Prior to a field test several preparatory activities have to be conducted, to ensure a successful field test. For this reason preparation has to start early enough to ensure that there is time to carry out all of these activities. Continuous dialogue and cooperation between clinicians, researchers, technical developers and the participants (people with dementia and their relatives) is necessary in order to reach a consensus of what functions to test and what to achieve during the test [1].

All persons involved in the field test should be committed to an agreed Master Plan [1], with

- The overall aim with the field test;
- Which functions to be tested during the field test;
- Starting date of the test period;
- Duration of the test period;
- Number of participants and inclusion criteria;
- Milestones - release dates of functions, purchase and delivery of equipment etc;
- Deadline of when pre-test interviews and other pre-test info are needed; and
- Named responsible persons for each task necessary for the field test.

In COGKNOW, a comprehensive Master Plan with templates was created before FT1 [D4.1.1,project-internal], which was later adapted into detailed planning for FT2 and FT3.

4.1. Site Organisation

At each test site, an overall responsible *site leader*, ensured that there was a structure and planning for all the actions needed in order to set up and conduct each field test.

Each site had *technical staff* responsible for system setup, site testing, on-site installation and de-installation. During the field tests a helpdesk was organised, consisting of first line contacts (human factors researchers and local technical staff) and second line contacts (technical specialists on the different CDN functions from technical project partners). A helpdesk manual described procedures to be followed in case of problems during the field test and when remotely configuring and adjusting the system. All telephone numbers, e-mail and skype addresses of the first and second line contacts were listed in the helpdesk manual.

Human Factors researchers were responsible for carrying out the user tests and collecting data for the evaluation by means of semi-structured interviews with the PwD and the carer; through observations of the PwD's behaviour when using the system; by logging data and by bottle-neck lists and diaries. This data collection took place during the first field test, and in field tests 2 and 3 the data were collected in the beginning of the field tests when the system was installed and also just before de-installation. During the final field tests also in-between interviews were conducted and impact questionnaires were administered before and after the field test period.

4.2. User Recruitment

The recruitment of users should be done early, generally a couple of months before the planned starting date of each field test [1]. In the COGKNOW project, persons with dementia were recruited from memory clinics, meeting centers, via networks for the target group and clinical departments. Some persons with dementia and carers participated in more than one field test (only when they still met the inclusion criteria) and for each field test also new participants were recruited.

The aims, goals and procedures in the field tests were carefully explained to the prospective participating users, and their carers. They were also provided with written information about

the project. Informed consent was obtained from all participants. It was reassured that the participants would remain anonymous in all data analyses and reporting, by the use of subject numbers. For the publication of photos and video material of the participants written consent was obtained from the persons with dementia and carers.

4.3. Pre-Trial Visit

Approximately one month before the test period, a pre-trial interview / pre-trial visit was conducted, where information regarding personalisation of the system was gathered using a standardized checklist. Information regarding service preferences, pictures, phone-numbers, preferred pieces of music, type of reminders, layout of the screen and CHH placement was collected. It was also checked that the users still fulfilled the inclusion criteria. Appointments were made with each user for their individual starting date and length of the test period.

4.4. Equipment Setup

During the preparatory phase it is important that the equipment needed in the field test is delivered from the technical partners to the test sites well in advance of the test period [1]. This makes it possible for the site technician to get familiar with the hardware, and verify that it is working properly. It is also a pre-requisite for setting up the necessary number of equipment kits for the actual testing, including installing latest software versions.

In COGKNOW, delivery of the equipment to the sites was completed fairly close to the intended start of each field test (days), due to uncertainty of which stable prototype configuration would be available. However, this did not in itself cause delays, since software problems anyway meant that the start of each field test had to be postponed.

Setting up the stationary CHH and CSH equipment was complex and time-consuming, since they consisted of many hardware components that had to be connected and most of their addresses had to be manually configured. Different ways of packaging the system for easy transport and neat installations in homes were tried.

Figure 3. Cabinet packaging (Amsterdam and Belfast)

Figure 4. Boxed CHH packaging (Luleå and Amsterdam)

The cabinet type installation looked neater in homes, while the boxed approach was easier to transport, even by a single person. The packaging used was suitable for field testing, even though any viable commercial product will need to be smaller and much more integrated.

4.5. Lab Testing

Before the field test starts, it is essential that the different functionalities to be used during the field test are tested in a laboratory environment by the partners responsible for the technology. This is done to confirm that the hardware and software components of the devices and their services is stable, and that the functionalities requested are working in a satisfactory way – in other words to check that the technical equipment is operational and stable. It also gives the people involved a chance to learn how the system works [1].

In COGKNOW, this was done first as integration testing by University of Ulster according to normal software engineering principles, then site testing in Luleå and Amsterdam to ensure that all site technicians were familiar with the system and that all equipment and software was operational. Some bugs were discovered, and some suggestions for improvements were made. However, in all three field tests, the time for testing the system became quite short, due to delays in developing the software components, and difficulties at the sites in setting up systems for testing.

4.6. Configuration and Personalisation

Configuration and user-specific personalisation was done before each test period, by the site technicians or researchers, by editing CHH and CCA configuration files and screens. The user accounts and the reminders were configured remotely, using web interfaces to CS.

Connecting devices to the right users was error-prone, because settings had to be made in different systems: user accounts were created in CS generating a carer password and a long "PwDID" machine credential; the PwDID had to be manually installed in CHH; a common IMEI code had to be set in CCA and CHH.

CHH needed a static IP address so that CCA could get service selection settings, reminder data and synchronisation of reminder confirmations. Multiple CHH and CCA could be used in the same home, with some limitations. The CS address was hardcoded in the CHH software.

The configuration settings were distributed across multiple configuration files and forms in CHH, CCA and CS, making switching to other devices and users time-consuming.

Detailed suggestions for simplified configuration and personalisation were given in Annex G of D4.4.1 Field Test #2 Report (project-internal).

4.7. Preparing Manuals

Different kinds of manuals are needed both prior to and during field tests. For the technical partners an installation manual is necessary for set up and configuration. The clinical staff need a use manual to guide in using the system. The participating users need a simple user's guide which describes the functions of the system and helps them in their daily use [1].

4.8. User Training

Before the test period the users should be offered pre-test training. In the training sessions the functionality to be tested should be explained. The format and procedures of the field test is explained in detail [1].

In COGKNOW, the pre-training sessions were given on an individual basis in the users homes, and involved hands-on operation of the system assisted by clinical and technical staff in order to get familiar with the system. The users were also reassured that they would have access to a help desk throughout the test period.

5. Test Procedures

For ethical reasons, field tests in the homes of persons with dementia must be conducted on the terms of the users, respecting their homes and avoiding making the homes test laboratories [1].

The duration of the COGKNOW test periods was increasing from FT1 to FT3.

Table 5. Durations of test periods (with users)

Site / test	**FT1**	**FT2**	**FT3**
Amsterdam	4-5 hours	7 days	6-7 weeks (one user only 26 days)
Belfast	2-4 hours	7-10 days	about 8 weeks (one user only 9 days)
Luleå	about 4 hours	6-10 days	3-4 weeks (one user only 5 days)

5.1. Installation Day

At the beginning of the test period the equipment must be installed in the user's home, facilitated by information collected during the preparatory phase. Then a full demonstration should be carried out by the clinical staff or researcher with support from the site technician. The user's guide should be left with the users so that they have access to support [1].

In COGKNOW; the installation times varied between 30 and 195 minutes.

Table 6. FT1 installation and de-installation times

Site	**Installation times**	**Deinstallation times**
Amsterdam	80, 120, 30, 60, 40 minutes	approx. 15 minutes
Belfast	on average 30-40 minutes	n/a
Luleå	120, 120, 120, 80, 70, 60 minutes	approx. 20 minutes

Table 7. FT2 installation and de-installation times

Site	**Installation times**	**Deinstallation times**
Amsterdam	180, 195, 120, 110,120 minutes	approx. 15 minutes
Belfast	180,150, 210, 90	approx. 20 minutes
Luleå	Approx 15 minutes+ sensors and rfid	approx. 15 minutes

Table 8. FT3 installation and de-installation times

Site	**Installation times**	**Deinstallation times**
Amsterdam	Approx 2 hours + sensors (20 min., more with Activity Assistance)	approx. 15 minutes
Belfast	180,150, 210, 90 minutes	approx. 20 minutes
Luleå	Approx 30 minutes + sensors, personalization and test	approx. 15 minutes

After installation, the system was explained to the PwD and carers. The COGKNOW researchers made observations while the PwD performed prescribed tasks, in order to obtain first data for evaluating the operability, the user-friendliness and usefulness of the system. Also, semi-structured interviews with PwD and carers were conducted.

5.2. Helpdesk

During the field test period it is crucial to set up a well-organised helpdesk. At each site the site technician should be responsible for solving technical problems, and be the first-line contact point for the users and the clinicians/researchers. It is essential to solve all problems promptly to facilitate the smooth running of the trial. This means that the technical partners need to be available at all times (within reason!) [1].

The COGKNOW users and carers were given a direct telephone number and an e-mail address to the helpdesk in order to report problems as they occurred. The COGKNOW technical partners supported the help desks at the three test sites, whenever this was necessary. Each COGKNOW system component had a technical partner to support it.

In FT2 and FT3, the help desk had to solve a wide variety of problems. There were problems with batteries running out, cables coming loose, computers running hot and prepaid SIM cards with no credit left, as well as needs to restart CCA and sometimes CHH. Software bugs had to be addressed by installing newer versions of the software. The helpdesk also made most necessary changes to configuration and personalisation on behalf of the users.

In FT3, many problems could be solved by remotely accessing CHH, or by a brief visit to the home of the user. Some problems could not be solved during the test period, as reported in D4.4.1 and D4.5.1.

5.3. Usage Monitoring

Automatic logging of usage of the system during the field test gives an overview of how the system is used. Regular telephone calls or follow-up visits during the field test are essential to monitor the participants' use of the system, and helps identify any difficulties not reported to the help desk. Also, some users may require more support in using the system [1].

In FT2 and FT3, weekly phone calls and bi-weekly visits ensured that information was received directly from the users of their usage of the prototype. The SeniorXensor research data logging system (see D5.2.1) was consulted early in FT2 and FT3 to get objective data on the level of use of the system. The users were also asked to fill in a bottle neck list and diary, to help collect information about actual problems, potential improvement issues or positive experiences from a direct user perspective.

5.4. Final Day

At the end of the test period the initial prescribed tasks were performed again by the PwD, researchers made observations and interviewed the PwD and carers to obtain a second measurement of the operability of the system, and to evaluate the user-friendliness, usefulness and impact of the COGKNOW Day Navigator.

6. Post-test Procedures

A formal end point should be agreed between all persons involved. After the field test has ended the site technician must uninstall the system. It is essential for all staff, to respect the participant's home and ensure that it is left as it was prior to installation. It is also important to maintain contact after the field test ends so that any remaining issues can be addressed [1].

In COGKNOW, the equipment was closed down and taken away from each user's home. After ensuring that all in-situ measurement data (SeniorXensor) had been properly transferred, all personally identifiable data were cleaned out of each equipment kit.

After each field test, the participants at each site were thanked with a small gift and given feedback about the results of the field test.

7. Conclusions

To have a successful outcome of any field test it is important *that agreements about deadlines* and appointments are respected, since changes in planning affect all persons involved including potentially vulnerable test subjects. It is also essential that all persons involved, technical, clinical and test subjects, have the same perspective and understanding about the overall goal of the project and what is expected in every field test.

Due to existing experience within the COGKNOW consortium, the test sites were well organised for performing the field tests, already in the first year. After FT1, formal ethical guidelines were added to the Project Management Handbook [D0.1], with checklists for developers, researchers and site technicians. See Annex A. We believe *COGKNOW has performed all field tests in an ethical manner*, respecting in particular the privacy rights of our test subjects, and any personal limitations in their involvement in the field tests.

COGKNOW progressed from performing user testing hours (FT1) to days (FT2) to weeks (FT3), with a similar number of users (12-18). However, *wider (>30 users) and longer (months) testing with a stable prototype is required* to validate impact on daily life and to assess for how much longer PwD can remain autonomous in their own homes by using the COGKNOW system.

The COGKNOW prototype versions progressed towards more functionality and stability. In the first field test there were many problems with the technology, as might be expected. However, there were many system stability problems also in FT2 and FT3. During FT2 and FT3, the prototype was significantly changed, resulting in various versions being used for different users. *The procedures for ensuring timely and stable prototypes for field testing should be improved*.

Iterative field tests should be a learning process, bringing from each field test the best knowledge and experiences into the following development and testing cycle. In COGKNOW, not all results could be brought into the next field test, due to time constraints. It should be considered in future three-cycle projects, to have a *longer project duration*, or to *make the first prototype a less heavy implementation*, possibly being just a simple mock-up for eliciting feedback about usefulness and critical user-friendliness factors.

8. References

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[3] Dröes, R.M., Meiland, F. (Eds.), *D4.4.1 Field Test # 2 Report* COGKNOW-consortium, 2008

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Annex A. Ethical Guidelines

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A.1. Introduction

In the COGKNOW project, persons with dementia are the primary target group and they are seen as active collaborators in the process to develop a system that aims to support them in different aspects of their daily life. Particular ethical concerns is that PwD may or may not be able to give informed consent as the disease progresses; that the research concerns health matters; and also that the system deals with highly personal data for reminders and daily activity support [DoW].

In this annex, it is described overall recommendations and checklists for research, development and use of the COGKNOW Day Navigator, based on [A1] and [A2][4]. This material is copied from the project-internal D0.1 Project Management Handbook.

A.1.1. Charter of Fundamental Rights of the European Union

From this Charter, we have

> **Article 8 - Protection of personal data**
>
> 1. Everyone has the right to the protection of personal data concerning him or her.
>
> 2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
>
> 3. Compliance with these rules shall be subject to control by an independent authority.
>
> **Article 25 - The rights of the elderly**
>
> The Union recognizes and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.
>
> **Article 26 - Integration of persons with disabilities**
>
> The Union recognizes and respects the right of persons with disabilities to benefit from measures designed to ensure their independence,

With respect to Chapter 1, Article 3 of the Charter we wish to abide by the requirements with regard to “respect for the free and informed consent of the person concerned, according to the procedures laid down by law” aware, as we are, of the potentially vulnerable individuals we are attempting to help. Chapter 2, Article 6 “Protection of Personal Data” represents an area of the utmost importance to the consortium. [DoW]

A.1.2. European Standards on Confidentiality and Privacy in Healthcare

COGKNOW project participants are expected to use the "guidance for healthcare professionals" in [A1], assisted by the checklists in chapter 4. Since the COGKNOW Day Navigator in part performs functions similar to what healthcare professionals do, the

[4] Note that references in this annex are listed in section A.4.

guidance points in [A1] are applied also to the COGKNOW Day Navigator system. The information stored and processed by the COGKNOW Day Navigator is considered to be "health information", except when noted otherwise.

Healthcare professionals should respect key principles of healthcare confidentiality [GP1]:

- Individuals have a fundamental right to the **privacy** and **confidentiality** of their health information.
- Individuals have a right to **control access** to and disclosure of their own health information by **giving, withholding or withdrawing consent**.
- For any **non-consensual disclosure** of confidential information, healthcare professionals must have regard to its **necessity, proportionality** and attendant **risks**.

A.1.3. COGKNOW Ethical Approval

National ethical approval has been obtained in the three main test sites, Amsterdam, Belfast, Luleå. Main considerations from these approvals are:

Sensitive personal data are collected by clinicians and trained researchers, using standard questionnaires and scales, logging and user experience measurement, as described in section A.5. These data shall be anonymized by trained researchers before being reported on, and it is carefully seen to it that they are deleted and made non-recoverable on test equipment as part of uninstallation.

The person with dementia must give an informed consent to storage, use and sharing of personal data. Agreement (assent) is also obtained from the legal representative or informal carer. They can withdraw the consent at any time and are not obliged to give a reason. Procedures follow normal principles for obtaining informed consent from vulnerable persons.

The COGNOW system must guarantee full confidentiality for personal information.

A.1.4. Assumptions

- The *only* purpose of the COGKNOW system is to help the PwD to navigate the day.
- A person with dementia must be regarded as v*ulnerable* [GP2][GP3], having reduced cognitive ability to understand all consequences of the usage of the COGKNOW services and the participation in the project.
- PwD that are not capable to give *informed consent* for using their personal data in COGKNOW are considered out-of-scope for introduction to COGKNOW services.
- Each informed consent lasts for the duration of one test phase, and can be withdrawn by the PwD, a legal representative or the informal carer. It is implicitly withdrawn if the cognitive abilities of the PwD falls below the COGKNOW threshold.
- There will be necessary personal data in each COGKNOW system, that identifies the user (for example photos of relatives, phone numbers etc.).
- User experience logs are encrypted so that they can only be decrypted offline by authorized researchers.

A.2. Recommendations

In this chapter we adapt the recommendations given in [A1] to the use of the COGKNOW Day Navigator. General recommendations for healthcare processes and organisation are omitted, except when applicable to the COGKNOW field tests. The recommendation references ([REFx]) in section A.4 are from [A1].

A.2.1. Addressing Vulnerability

Policies and procedures should be in place within the project to ensure that PwDs who may lack the capacity to decide about the protection, use and disclosure of their confidential healthcare information are correctly **identified**. [REC2]

A PwD who has the capacity to decide about the protection, use and disclosure of their COGKNOW information may nevertheless be vulnerable to undue influence. Patients should have access to **independent confidential support** to make such decisions. [REC3]

Patients should be involved to the greatest extent possible in decisions about the protection, use and disclosure of their confidential information. All reasonable measures should be taken to ensure **maximum participation** in spite of any vulnerability. [REC4]

A.2.2. Use for Healthcare Purposes

All people working with the PwD should be under a **legal obligation to protect PwD confidentiality**. [REC7]

The sites must establish and ensure the adoption of clear publicly accessible protocols for **information sharing** within teams, beyond teams and with outside organisations. [REC8]

A.2.3. Use for Indirect Healthcare Purposes

The recommendations below addresses secondary uses of information in healthcare organisations. The same principles should apply to the use of information for research purposes in COGKNOW.

Care providers must ensure that patients and/or their legal representative are **informed of all proposed secondary uses** of their information and that they are aware of their choice on such issues. [REC10]

Independent data protection officers or Ethics Committees should be involved whenever judgments of **impracticability or impossibility** are given as grounds for secondary uses of confidential information without receiving consent. [REC11]

Personal information should wherever possible be maintained in **a form that protects the identity** of the patient from disclosure to unauthorised persons. [REC12]

In addition to meeting the general requirements for secondary uses of patient information, training providers must ensure that **students** are aware of their **obligations of confidentiality** and the consequences of any breaches. [REC14]

It is essential that the initial consent to including participants' data include **consent to limited conditions for research use of the collected data**, specifically healthcare purposes and named diseases. [REC15]

All research using **databases of personal identifiable information** should be **independently ethically reviewed**. In particular, the independent ethical reviewers should decide on the permissibility of new research uses and the necessity for recontacting research subjects. [REC16]

A.3. Checklists

In this chapter we present top-priority issues that should not be overlooked.

A.3.1. For professionals and field test personnel

- Professional carers and system administrators must have knowledge of key principles of healthcare confidentiality that follow from ethical considerations: **privacy, explicit or implicit consent, and conditions for non-consensual disclosure** [GP1].

- Since PwD are *vulnerable*, they shall be given **all necessary support to understand the confidentiality issues and express their wishes** [GP2]. The individual's capacity to understand the implications of their inclusion in the project should be assessed by experienced clinical personnel at study entry. The individual's ability to understand, retain and weigh up information as well as communicate their decision should be examined. Those not fully able to appreciate the implications of allowing project-related access to personal health and care details will not be included.
- The **consent** should be given **until *end-of-service***, i.e. until end of user test, death or explicit withdrawal of consent, so that the consent also covers later stages in the disease when the PwD might be incapable of giving consent [GP4].
- **Remote access to equipment in homes of PwD** (for example using www.LogMeIn.com) should be allowed only in the following contexts:

  - For supporting system setup and site testing: Initial approval by a site technician is required. Remote access can be very helpful at this stage.

  - For correcting problems when system is present in home of PwD (if found acceptable at the site): The site researcher to be informed before each access. Each time approval by the user (possibly represented by the carer) to be required when the Home Hub is accessed remotely.

  - For remote observation (only if found ethically acceptable and valuable as an evaluation method): This must be clearly mentioned in the consent form signed by the user prior to the field test. Only site researchers to be allowed to do remote observation.
- Personally identifiable data shall be **deleted and made non-recoverable** on the test equipment as part of uninstallation.
- Using **staff from other agencies** requires explicit consent and possibly formal information protection agreements. [REC13]
- Necessary **secondary uses of information** (for example for payments or management) requires explicit consent.
- The basis for the **configuration** of the device should at all times be the subjective needs and wants of the person with mild dementia. [DoW]
- The benefits of **information sharing with the informal carer** should be discussed with the PwD [GP13].
- **In emergency situations *minimum necessary* confidential user information** may be used or disclosed. [GP5]
- Confidential data relating to PwD shall be stored on **secure computers**, with up-to-date protections against unauthorized access and malware.

A.3.2. For researchers

- Researchers that execute the evaluation of the prototype with user dyads shall have **no business dependencies** themselves with commercial organizations within or outside the project consortium. [DoW]
- Personally identifiable data must be stored in **encoded form** [DoW].
- Mapping collected data to individuals must use **keys stored separately** in locked closets [DoW].
- Only encoded data will be transmitted **between COGKNOW sites** [DoW].
- Be sensitive to the changing clinical **phases of dementia** that may influence the subjects' autonomy and capacity
- Under no circumstances permit reporting of **details during dissemination** that would allow the identification of any subject involved. [DoW]
- Study **Annex 1 in D4.1.1**, table over the data collected and methods for ensuring data protection and privacy [DoW]

A.3.3. For developers

- **Security analyses** should be performed at unit and system levels. It should be performed at the specification stage, and as part of evaluation. The security analysis should address requirements for confidentiality, data integrity, availability and accountability. It should analyse malware threats and the potential for system abuse by users.
- An **authorization model** should be defined so that any access to identifiable personal data is strictly controlled. PwD access should be made by means of implicit or automatic authentication at the CHH and CCA devices. Accesses by all other users (eg. carers, researchers and administrators) should require user-level authentication. [GP14][GP15]
- A **service model** should be defined so that PwDs and their carers can be informed of what kinds of information is being recorded, and for what purposes [GP10][GP11].
- Build the system so that it **minimizes the potential to stigmatise the user** [DoW]. This means that devices should preferably be perceived and used as normal technology artefacts, also by people that do not suffer from dementia.
- There must be a **generic way to access stored data**, for system administrators (for research, emergency or legal purposes), and for PwD's access to their own stored data (as guaranteed by Data Protection laws) [GP5][GP9][GP20-24].
- Data should be **stored with as little identifying information as possible** [GP18][GP19]. If possible, the system should be partitioned into one part where identifiable personal data exists (for example the CHH and CCA), and other parts where it is impossible to trace to which physical person some data belongs (CSH, possibly CS).
- The **personal codes** that are used in data collection **for research purposes, must NOT be reused** in the normal operation of the COGKNOW system.
- Only **near-future data should be cached** in other nodes than where the original data resides.
- **Data that is not needed anymore** for the operation of the system should immediately be made **inaccessible**[5].
- All **communication links should be secure**.
- **Encrypted files and databases** must be used for storing identifiable personal data.

A.4. Annex References

[A1] European Standards on Confidentiality and Privacy in Healthcare, EuroSOCAP project, 2003-2006.

European-Standards
-on-Confidentiality-ar

[GP1] - Guidance Point 1 in [A1], pp29-31
[GP2] - Guidance Point 2 in [A1], pp29-31
...
[REC1] - Recommendation 1 in [A1]
[REC2] - Recommendation 2 in [A1]
...

[A2] Review of the regulatory framework for electronic communications, http://europa.eu/scadplus/leg/en/lvb/l24216c.htm

[5] By deleting the data, or by one-way encryption where decryption keys are stored in external protected systems.

A.5. Overview of data collected in COGKNOW

(copied from D4.1.1)

Update overview of data collected in COGKNOW, their use, storage and dissemination - part 1 –October 2006						
Type of data	**WP**	**Method**	**By whom**	**Use**	**Storage**	**Dissemination**
Informed consent	1,4	Information booklet and consent form	Clinicians/coordinators of meeting centres for people with dementia and carers	Informed consent procedure	Signed consent forms are archived in locked closet	Informed consent procedure will be reported on in publications
General personal characteristics	1,4	Standard questionnaire	Trained researchers	Description of patient groups in project and test sites	All data are anonimized and key of the codes will be stored in locked closet Anonymized paper data are stored in locked closet Anonymized data are stored in computerized databases (e.g. Excel) Between test sites only exchange of anonymized data will take place	Anonimized report in internal reports and scientific, professional and popular publications
Diagnosis	1,4	Criteria described in DSM IV-TR	Clinician	Selection criterion Alzheimer's disease		
Severity of dementia	1,4	Global Deterioration Scale (GDS)	Clinician/ coordinator of meeting centre	Selection criterion Mild dementia		
Individual cognitive disabilities	1,4	CAMDEX Cognitive test (CAMCOG)	Trained researchers	a) Description of features of persons with dementia as the usergroup on which the COGKNOW device is tested b) International comparison of the user groups at the three test sites c) Qualitative solution analysis d) Storyboards with all types of users e) specification of the requirements of the device		
Daily activities of person with dementia	1,4	Interview Deterioration in Daily Living in Dementia (IDDD) Interview with carer				
Quality of Life	1,4	Ouality of Life in Alzheimer's Disease (QOL-ad; patient and family version)				
Experienced autono-my	1,4	Standardized interview with patient (to search in literature)				
Ways of coping	1,4	Jalowiec Coping Scale (JCS) for general coping styles to describe types of participants and Dementia Coping Scale (DCS) for assessment of changes in coping behavior and to get ideas for the development of ICT devices				
Contextual information	1,4	Observation (with list of themes); semistructured interview with carer and patient (background characteristics) and Network Assesment (PANT Questionnaire)				
Information on received care	1,4	Interview with carer (List Use of Services)				

Update overview of data collected in COGKNOW, their use, storage and dissemination - part 2–october 2006						
Type of data	**WP**	**Method**	**By whom**	**Use**	**Storage**	**Dissemination**
Needs and wants of potential users	1,4	Literature study, see "Living with early-stage dementia: a review of qualitative studies", Steeman et al. Journal of Advanced Nursing 54(6), 722-738, and " Needs in people with dementia. A review of the literature", Van der Roest et al. (2007, sent under embargo); an article on problems in using ICT by Nygard & Starkhammer, 2007 (sent under embargo); Workshops & individual interviews (patients & carers); needs questionnaire (CANE)				
Information on user friendliness and usability	4	Semi-structured interview with checklist composed for the COGKNOW project; Diary to inventory user problems	Trained researchers	Human Factors analysis test 1 and 2 to fine tune the prototype device	This data should be anonymized by trained researchers before being reported in WP1 and WP5 deliverables, and it should be ensured that these data are deleted and made non-recoverable on the test equipment as part of uninstallation.	
Information on usability and efficacy in daily life	4	Measurement of impact of device on actual an perceived autonomy and QoL in the selected domains of daily life of the person with dementia by semi-structured interviews	Information from patients and carers	Human Factor Analysis test 3; Impact of device on aspects of daily life (usability and efficacy)		
Activities of person with dementia and localisation	2	Limited monitoring of the persons activities e.g. by sensors in the home and GPS outside home	Monitoring centre placed e.g.. at non-cohabiting informal carers and/or research centre	Develop functionality to monitor activities and support spatial orientation as well as contextual reasoning capability for the mobile device		
Data about application usage, behaviour, context and user experience	3,5	User experience toolkit based on SocioXensor; Participatory observation; focusgroups	Trained researchers and engineers	Detailed, dynamic insight into phenomena related to dementia to design a successful context-sensitive application for target group		
Data on different alternative buisiness models	5,7	Business assessment workshops with relevant stakeholders (e.g. policy makers, health insurance, executives in health care,industry)	Researchers	Business assessment of COGKNOW service	Archived workshop reports	Scientific & professional publications
Data on available technologies	7	Literature study on available hardware and software	Researchers	Technological exploitation	Literature archive, reports	