

# MedGUIDE

ICT Integrated System for Coordinated Polypharmacy Management in Elders with Dementia

## D1.1 End-user requirements and specification

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## 1 Executive summary

The MedGUIDE project aims to improve the quality of life of elders, support the network of informal caregivers, and to prevent reduction in the medication self-management capabilities of the elderly patients, all in order to prolong independent living. End-users of the MedGUIDE system are: patients with dementia (PwD) (primary), formal and informal caregivers (secondary) and healthcare and pharmaceutical professionals (tertiary).

These end-users groups have been interviewed in group sessions and face-to-face interviews in Cyprus, Norway and the Netherlands. The central aims of these interviews were to understand the user needs, in order to be able to define the end-user requirements (task 1.1) of the MedGUIDE project.

A research protocol has been developed in order to have uniformity in the exploratory sessions and interviews. The research protocol has been submitted to (national) medical ethical review boards in The Netherlands, Cyprus and Norway to see whether or not approval is needed. In The Netherlands and Norway no approval was needed from the (national) medical ethical review boards. In Cyprus, user research was delayed until approval was granted. In total 23 primary end-users, 24 secondary end-users and 15 tertiary end-users participated in the requirements definition phase.

The findings from the sessions and interviews with PwDs were in line with the results as expressed by secondary end-users and tertiary end-users. In the interviews, PwDs provided a clear overview of their daily lives. In general, medication intake of PwDs is scheduled around their personal activities and usually around their meals. Medication intake is seen as part of having a meal or as something which is provided by their informal carers or care professionals. The PwDs and their informal carers generally try to keep a daily routine. Results retrieved from the interviews with care professionals and tertiary end-users were mostly related to the symptoms caused by dementia syndrome, and how these symptoms limit the functioning of daily life of the PwDs. Also, the occurrence of side-effects and difficulties with the medication-management were mentioned.

Findings regarding the specifications range from; taken into account visual ergonomics, limitations with all senses as to the responsiveness and usability as well as ease of use of the system to develop. According to the end-users, the system should also support PwD independency and feeling of control. The system should help the end-user(s) to get better or easier access to information e.g. medication use and side-effects. The system should not lead to an extra care burden of informal carers but should support the PwDs in their life. The system should enable integration as far as possible by relying on international technology standards or must be embedded in already existing systems used by healthcare professionals.

## 2 Introduction

Dementia is still incurable. Dementia is an umbrella term describing a multifactorial disease which affects the brain. Management of dementia requires both pharmacological as well as non-pharmacological interventions. The treatment of dementia is a huge challenge and only few drugs have been approved for some forms of dementia. Over 21% of the elders suffering from dementia are exposed to polypharmacy. The majority of the older adults with dementia are using over six medications a day such as anti-dementia medication or medications to deal with the symptoms of dementia. On average elders with dementia have two to eight additional chronic diseases. Both medication prescription and medication adherence tend to be a challenge in case of dementia:

- It can be difficult for medical professionals to properly assess the behavioural and psychological symptoms of the patient, since changes are gradual and are likely to be multifunctional;
- Due to cognitive decline, it tends to be challenging for the patient to take the appropriate medication at the right time.

In the MedGUIDE vision, the key to improve the medication process for people with early stage of dementia is to continuously combine automated monitoring with inputs from the elderly patients and their informal network or caregivers. The network of caregivers will be ‘eyes, ears and hands’ of medical professionals. MedGUIDE will build a state-of-the-art tool, which provides:

- Insight in the actual needs of elders with dementia;
- Insight in actual medication use, side effects and adherence;
- Support for improving the care and medication adherence.

The MedGUIDE project aims to improve the quality of life of elders, support the network of informal caregivers, and prevent the reduction in the medication self-management capabilities of the elderly patients, all in order to prolong independent living. End-users of the MedGUIDE system are: patient with dementia (PwD) (primary), formal and informal caregivers (secondary) and medical- and pharmaceutical professionals (tertiary).

Figure 1 shows the high-level planning of user research and user involvement. The end-user requirements analysis is part of phase 1 (understanding). According to the MedGUIDE work plan, this phase should have ended in M4. The consortium did however experience delays in finalizing the research protocol and receiving approval from the review board committees. The document has therefore been finalized in M10.

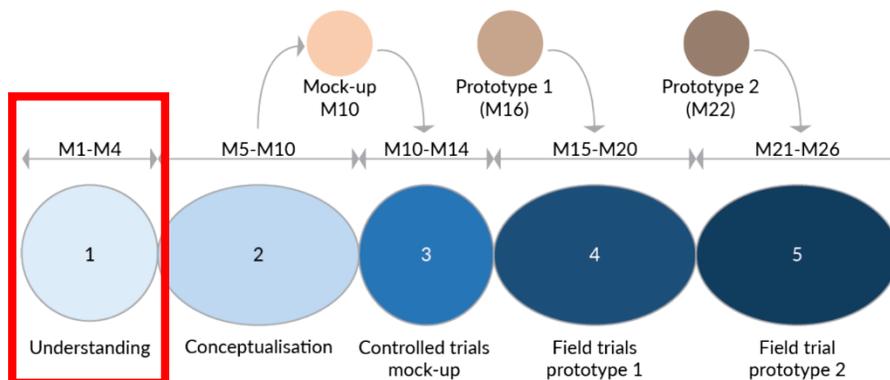


Figure 1: High-level planning of user research and user involvement



This deliverable is the result of task 1.1: “MedGUIDE end-user requirements analysis and technology conceptual model definition”. The end-user requirements are described in D1.1; the conceptual model is described in D1.2 and D1.3. To define the requirements for the MedGUIDE system we used: 1) the findings from our end-user research, 2) findings from literature and 3) the project proposal. The central aim of this task 1.1 is the end-user requirement analysis and technology conceptual model definition.

The report further describes the research protocol, presents the findings from user research, and presents the resulting requirements.

### 3 Research protocol

A research protocol was defined in order to align the exploratory sessions and interviews in Cyprus, Norway and The Netherlands. The full research protocol, defined by the end-user partners and CCARE, can be found in Appendix 1. The research protocol has been submitted to national medical ethical review boards in The Netherlands, Cyprus and Norway to find out if approval by the board is needed. In The Netherlands and Norway no approval was needed from the (national) medical ethical review boards. In Cyprus, however, the protocol had to be approved by the bioethics committee – approval was given in M7.

Group interviews and individual interviews were held to find out the wishes and needs of the PwD through an exploratory session or home visit. The aim of the exploratory session is to get first insights and give directions for possible solutions for MedGUIDE. Also it allowed researchers to get insight into the attitudes of the primary target group and secondary target group (in this case informal caregivers) towards existing technological solutions that support medication adherence in general. The home visits consisted of an in-depth interview with the PwD and their caregiver and an observation of the PwD in their daily routines at home. The interview focused on the following topics:

- Daily activities;
- Use of medication;
- Extra questions for carers, about the relationship with PwD, about the informal care and about the medication of the PwD;
- First feedback on support/tools for medication adherence;
- Use of online tools for medication adherence.

In addition the PwD and the informal caregiver creates a care network map, which provides information to develop a user profile.

Care professionals, pharmacists, family doctors and other care professionals working with persons with dementia are also part of the research. They are interviewed in group sessions or as individual. The topics discussed with them were:

- Adherence monitoring;
- Counselling;
- Communication;
- Technological support;
- Online tools;
- Medication review.

## **Recruitment**

The protocol describes the recruitment process of all the categories of end-users: primary end-users, secondary end-users and tertiary end-users. The protocol includes an Invitation letter; an Information letter; a confirmation letter; and an informed consent form.

*Primary end-users*, being persons with dementia (PwDs)

*Secondary end-users*, being informal caregivers as well as nurses and other care professionals who provide care at home.

*Tertiary end-users* being pharmacist and physicians.

## **Research targeting PwD, informal caregivers and professional caregivers**

The protocol is divided in two parts: (1) research targeting PwD and informal caregivers, and (2) research targeting professionals. The sessions and interviews with PwDs and informal caregivers were combined, since PwD were always accompanied by an informal caregiver.

The protocol describes the procedures for the meetings (exploratory session and home visit) with PwDs and informal caregivers. And the protocol describes the procedures for the meetings (exploratory session) with care professionals. The protocol also contains a planning of the research of task 1.1 and a list of the interview topics.

## 4 Participants

Table 1 below shows the number of end-users participating in the requirements analysis phase.

Table 1: Overview of included end-users										
	Primary**			Secondary			Tertiary			
Understanding (partner, country)	IVM & HU-UAS <u>NL</u>	MAT <u>CYP</u>	KARDE <u>NOR</u>	IVM & HU-UAS <u>NL</u>	MAT <u>CYP</u>	KARDE <u>NOR</u>	IVM <u>NL</u>	HU-UAS <u>NL</u>	MAT <u>CYP</u>	KARDE <u>NOR</u>
Planned	16-24	8-12	18-24	12-16	6-8	8	5	0	0	0
Realized	17*	6	0	7 (3)	9 (6)	8 (3)	5	3	3	4

\*= 13 end-users are included in two group sessions with three interviewers (x)= number of informal caregivers

\*\*= living situation PwDs: 12 PwD lives with partner, 2 PwD lives alone, 9 No Data Available

Due to difficulties with the recruitment of PwDs in Norway (no direct access), it was not possible to include PwDs from Norway in this phase, as can be seen in table 1. In agreement with the end-user partners and CCARE it was decided to use the interviews from Cyprus and The Netherlands as a basis for the PwD user requirements. Norway checked the results and added country-specific requirements based on input of experts. Table 1 also shows more tertiary end-users have been realized than planned. The recruitment call resulted in an unexpected higher number of tertiary end-users – it was decided to make use of this extra number of participants.

### Primary end-users

Table 2 shows the channels that were used by the end-user partners to recruit primary end-users:

Table 2: Channels used to recruit primary end-users (via)			
	IVM-HU-UAS	KARDE	MAT
Care organizations including day care centres and home care	X	X	X
Own organization/ personal network researchers	X	X	X
Patient/elderly associations	X	X	X
Facebook	X	X	
Regional networks/meetings	X		
Web based fora for Alzheimer	X	X	
Associations for professionals			X
Medical doctors		X	X

As can be seen in table 2, PwDs are recruited through direct channels via the organizations' own resources and network as in Cyprus, or through indirect channels as via professionals or via the national Alzheimer association (the Netherlands).

### **Secondary end-users**

The secondary end-users are the informal caregivers of the PwDs and the healthcare professionals. Informal caregivers were recruited together with PwD; the recruitment channels are described in table 2.

In the Netherlands, healthcare professionals were recruited through the existing network of the project partners:

- Pharmacists;
- Family doctors and nursing home physicians;
- Community nurses and case managers dementia (Dutch health care organization professional).

In Norway healthcare professionals were recruited through:

- Pharmacists;
- General practitioners;
- The network of KARDE and persons working in KARDE;
- Geriatric hospital departments in Oslo (Norway);
- Contact with community health care in Oslo (Norway).

In Cyprus, PwDs and their informal caregivers were recruited:

- After identifying the primary end-users, their informal caregivers and healthcare professionals were approached.

### **Tertiary end-users**

The tertiary end-users are the medical professionals and pharmacists. IVM is responsible for this group, they used their network to recruit these end-users.

## 5 Results

The transcribed findings from the interviews of all three countries were analysed by CCARE and HU-UAS and separately they identified relevant themes to address with regard to medication adherence (thematic analysis). Analyses began with open coding, forming categories of information about the phenomenon being studied by segmenting the information. The transcripts were reviewed line-by-line, and codes were placed in the margins. In the next phase axial coding, was performed through which the core themes were related, via a combination of inductive and deductive thinking. Relevant quotes were selected and divided into themes by each of the two coders independently. The two coders met to discuss their findings and resolve any differences, they also compared their findings with the findings of CCARE. After consensus by two researchers, the codes were established for each end-users' target group. Findings were presented structured, aligned with the interview topics and other topics not mentioned in the interview topic list.

### 5.1 Primary end-users

From several sources (websites from Alzheimer associations and literature) can be read on how the diagnosis of dementia affects a person and their informal network. Figure 1 gives an overview of the symptoms among PwD and the percentages of carers for whom these symptoms cause problems.

Current symptoms		Most problematic symptoms for carers to cope with	
<b>Activities of daily living</b> 96%	Finding belongings: 77% Financial activities: 74% Shopping: 73% Showering/bathing: 71% Cooking: 70% Using telephone: 69%	<b>Activities of daily living</b> 68%	Showering/bathing: 25% Being left alone: 20% Incontinence: 19% Finding belongings: 16% Moving in general: 14% Sleeping: 12%
<b>Cognition</b> 93%	Memory/confusion: 87% Concentration/attention: 78% Orientation/getting lost: 63% Recognising people: 54%	<b>Behaviour</b> 50%	Agitation/aggression: 16% Personality changes: 16% Irritability: 11% Wandering/restlessness: 10% Depression: 8%
<b>Behaviour</b> 89%	Social withdrawal: 50% Personality changes: 47% Wandering: 44% Lack of energy: 43% Irritability: 40%	<b>Cognition</b> 45%	Memory/confusion: 32% Concentration/attention: 12% Orientation: 12% Recognising people: 7%
<b>Communication</b> 88%	Following conversation: 74% Writing/reading: 70% Comprehension of language: 49% Speaking: 47%	<b>Communication</b> 36%	Following conversation: 16% Comprehension of language: 14% Speaking: 12% Writing/reading: 3%

Figure 1: Overview of symptoms among people with dementia and the percentages of carers for whom these symptoms cause problems<sup>1</sup>

From the interviews it became clear that persons with early dementia go through a phase of denial. This also has an effect on their medication adherence. Some PwDs do not want to take their medication because the benefit of the medications is not clear to them. Many persons with dementia and their family

<sup>1</sup> Ageing-in-place : the integrated design of housing facilities for people with dementia (<http://repository.tue.nl/685914>)

believe that these dementia medication has little or no effect. One informal carer said in the interview; *by presenting the medication as your vitamin pills, my dad was willing to take the medication*. Or, they simply forget what these medications are for and then they refuse to take it. PwDs have difficulty with swallowing the medications or difficulty taking some medications together at the same time. Furthermore, informal carers feel a huge responsibility for the medication adherence of the PwDs. During the interviews with the PwDs there was always an informal carer present, so information in this section comes from PwD and sometimes from an informal carer.

#### 5.1.1 Role of the care network of the PwD

Figure 1 shows how the diagnosis of dementia affects a person and their informal network. To be able to cope with dementia, it is necessary to have a network of (informal and professional) caregivers in place. A care network can consist of many persons, for example: partner, children, family, neighbours, friends, home care nurses, day care facilities, doctors, pharmacist etc. The network can be helpful for many things, including caregiving activities, but also to spare for example the partner for an evening. When there is no (informal) care network in place, it is almost impossible for PwDs to live safely in their own environment, moving to a healthcare organization is then probably necessary.

#### 5.1.2 Day structure and day care

Related to the topic “day structure and day care”, primary end-users pointed out that the system must be adapted to the daily routines of a person with dementia. The amount of daily activities is limited, compared to other older people. Persons with early dementia tend to stick to a fixed daily routine (waking up, bathing, breakfast, leisure activity or working, lunch, leisure or household activity or napping, dinner, toileting, going to bed). This fixed daily structure helps them to memorize things and to maintain their orientation. Medication in-take is in general also structured around the meals during the day. PwDs generally do not think about medication adherence and medication safety. For them it is part of the daily routine. PwDs are supported in their medication adherence and observation of side effects by both formal and informal caregivers of which the latter has the largest volume in care giving.

- A MedGUIDE platform should be able to trigger reminders in relation to daily routines of PwD.

#### 5.1.3 Routing

PwDs try to stick to a fixed routing around their daily activities. This routing helps them memorize their intention to take their medication or execute any task. A PwD: *“When I pass the refrigerator for my breakfast I see the egg-cups with my medicine.”*

- The location of the interactions of the user with the MedGUIDE platform should be adaptable to the route people have at home.

#### 5.1.4 Information

PwDs no longer understand why they have to take their medications, they do not recall the name of the medication which is prescribed, and they do not know the effects the medication has. People with early dementia have resistance to use medication, especially to Alzheimer medication. They do not believe it has any benefit. Due to changes in the prescribed medication, or changes in the looks of the medication due to pharmaceutical amendments, the senior might be less willing to take the medication. Thus, the informal carers give information about the purpose of the medication and explain over and over again how the medication intake should be. The explanation of the informal and formal caregivers helps to convince the senior to take their medication. An informal carer said: *“We all tried (including his doctor) to*

*explain to him why he needs to take the medication but at the end we decided to name them vitamins for forgetfulness instead of medication”.*

- Information to the user should be provided about aspects on medication effects as well as medication administration. Mentioned was: video’s, photo’s or other communicative materials can be used;
- MedGUIDE should communicate to the PwD and his/her care network when the medication prescribed is changed (for example the type, dose, colour or shape);
- MedGUIDE should provide the PwD and his/her care network with information about side- or adverse effects of the medication the PwD is using;
- Information presented should be accessible for all users with all levels of health literacy.

#### 5.1.5 Tracking and sharing self-reported data

When a PwD receives care from formal caregivers, the well-being of PwD is tracked through observation and conversation by the formal caregiver, as well as by the informal caregiver. Informal carers can enrich this information via self-reported data, which can then be shared with the caregivers of the care network.

- The MedGUIDE platform should facilitate sharing of self-reported information with professionals and informal caregivers;
- The MedGUIDE platform should support users in using the platform, e.g. by providing an introduction video or instruction manual.

#### 5.1.6 Triggers

The results from the interviews suggest that the kitchen and the fridge are important spots in a dwelling for medications reminders. Medication intake is in general around meals. Furthermore, it can be helpful if there is a sound signal to remind the PwDs to take their medicines. Another issue regarding prompts is that some PwDs repeat the same information again and again, this can be used as a trigger to remind them their medication.

- The moments and locations of the triggers should be adaptable to consider the daily (instrumental) activities and routines of the PwD.

#### 5.1.7 Privacy

Privacy was also mentioned as an issue to take into account. The MedGUIDE system should have the standard mode of non-sharing data and information. PwDs and informal carers should be able to change these settings by themselves and in communication with their General Practitioners (GP).

- MedGUIDE should support the PwD and his/her informal caregiver to define who has access to the personal data.

#### 5.1.8 Senses

What also is mentioned and what is known from biological ageing, is that PwDs have difficulties with their senses. Especially motor impairment (e.g. tactile), hearing and visual functioning are declined or impaired.

- The MedGUIDE device should take into account decreased motor impairment, hearing and/or visual impairment.

## 5.2 Secondary end-users

The secondary end-users who participated in the research, both the informal carers as well as healthcare professionals, all provide care at home. This section describes the perspective of the secondary end-users towards the MedGUIDE system.

### 5.2.1 Theme: Characteristics Person with Dementia (PwD)

#### 5.2.1.1 *General aspects of the disease*

The daily structure, routine or time consciousness is lost due to the dementia syndrome. The medication adherence is a peculiar topic both for PwDs as well as for next of kin, because it is a daily recurrent hassle and sometimes it ends with a confrontation. The secondary end-users group believes that ICT-based computer assistance is difficult for PwDs to understand. Any system should take into account the psychological, physical and mental capacities of the PwD as well as the dignity of the PwD (not to treat or address them as a child). Also, it is relevant to mention that the PwDs have low adaptive capabilities. So, changes should be adapted to this, e.g. when the medication package changes to another form or colour. Professional: *One of the accepted reasons for not changing, is that this will make problems for the patient (e.g. by being confused that the package and possibly also the tablets look different after the generic change).*"

- The system should take into account the functional decline and loss of memory function due to the dementia syndrome, PwDs have low adaptive possibilities;
- The MedGUIDE tool should be easy to learn and to use and it should be a fluent process.

#### 5.2.1.2 *Impact dementia has on informal carers*

Furthermore, informal carers wanted to give the message that their care load should be considered as well. Informal carer: *"my life changed dramatically after the diagnosis of dementia"*. In some stadia of dementia informal carers have to help the PwD with a lot of things, for example remind them where to go at which time, but also remind them to have breakfast and take their medication. The safety of the PwD is also important and depends on the informal carers, therefore they have to be alert all the time. Informal carer: *"She doesn't know when and what her husband will forget so she has to be alert all the time"*. At the same time informal carers find the care very important, even if it influence their own occupations. Informal carers: *"I take the PwD with me to every place" and "I do not have any time to visit and contact my own social network, and that is regrettable"*. It would be helpful if MedGUIDE can support the informal carer, by giving reminders for example. But also by giving understandable information related to the syndrome for example medication, medication adherence, medication side-effects, doctors' advice and important contact information.

- The system might help in decreasing the care load of the informal carer;
- The system should give understandable information about medication management;
- The system should remind PwD and informal carer to take medication or to go to an appointment.

#### 5.2.1.3 *Medication adherence of PwD*

Informal carers and care professionals pointed out once again that PwDs do not remember to take their medication and they do not understand the purpose of the medication. They said that repeated automated prescription by the pharmacist does not work that well for PwDs, since they cannot check the PwD's houses to know if the medication is taken or thrown away.

In addition, sometimes PwDs are unwilling to take their medication. They resist or have trouble with swallowing the medication or they will keep pills stored in the cavity of their mouth. The effectiveness of medications for PwDs are according to care professionals still part of scientific debate. The PwDs do not notice or are not aware of adverse effects except that informal carers mention that they noticed that PwDs will fall asleep. Informal carer: *“she sometimes sleeps during lunch time which is something that she didn’t used to do.”*.

- The system should give or generate personal information about safe and secure medication intake; take into account that medication can be taken but not swallowed;
- The MedGUIDE device should explain the PwDs and their carer the effectiveness of the medication that are prescribed to them.

## 5.2.2 Theme: Communication aspect: Medication adherence

### 5.2.2.1 Feedback on medication adherence

Professionals who were interviewed said that they have no "clue of" or routines for how to motivate PwDs to adhere to their medication. This problem should be subject of a literature search on objective proven effective interventions. It is relevant that a developed system has an option to give feedback to PwDs or remind them when relevant medication is missing. This message should stimulate adherence. So, it should not merely be a sound or sign. It should be a motivational message, for example a video of a next of kin is recorded and played by the system to remind the PwD that they have to take medication. Informal carer: *“Or if the reminder is a voice message, can it be recorded by the grand children or something like that?”*. Professional carer suggest it is about positive health. Additionally, it would be helpful if positive feedback on adherence is given to the patient. There should be a reward system of some kind. So, if medication is taken according to the prescription, the system gives a reward or the avatar/widget is positive (e.g. a smiley).

- MedGUIDE should provide positive feedback and motive reminders to promote adherence;
- MedGUIDE should support the care network of the PwD to provide positive feedback and motivate reminders to promote adherence and contribute to a manageable care load;
- MedGUIDE should support the PwD with positive feedback to support their daily routines.

### 5.2.2.2 Improve knowledge on medication and recent development in online assistance tools

Informal carer: *“A better focus on medication, how drugs work and dialogue with the GP would have been useful.”* For informal carers living with a PwD it is useful to add information in the system about recent developments in medication, ICT (e.g. a new app or a new support tool) and healthcare. In this way they can keep the PwD informed. Counselling to identify individual reasons for why PwD do not adhere to their medication is necessary in the management of dementia. Regular meetings by the professional to talk about medication adherence with the PwD and informal carer should be scheduled and could be online. There should be access to a database<sup>2</sup> about new medicines and about possible side effects of medication.

- Information of/and reports on online counselling could be shared with the care network using MedGUIDE;

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<sup>2</sup> In all countries professionals (e.g. GPs and specialisat) used more then one database on medicine interactions.

- Information to the user should be provided about aspects on medication effects as well as medication administration. Mentioned was: videos, photos or other communicative materials can be used as well.

#### 5.2.2.3 Medication intake skills

Professionals also pointed out to take into account problems that PwDs might have with medication intake, for example swallowing; the size or colour of the ampule and intake restrictions. Are PwDs able to grind medication? The system might give information or support in this and enhance the level of secure and safe medication intake skills and contribute to health literacy level.

- Provide information about medication intake; show instructions of medication intake.

#### 5.2.3 Theme: Medication management

More attention should be given to changes in medication type or prescription and for medication reviews. The end-users group, formal and informal caregivers, also mentioned that medication should be stored at the same place, because in this way medication is easy to find by everyone. Medication intake should be built around daily routines for time of intake. Mentioned by a professional carer: “Also nice to have is a checklist for intake of medication and or provide PwDs with plasters of medication, when possible.”. Sometimes professionals do not know whether a specific medication has been taken or not, then a dose is given twice just to be sure (90 % of the medication is taken once a day). Community nurses could assist with the medication intake.

- MedGUIDE should support the PwD to take the correct medication doses and prevent double doses;
- The system should be linked to a daily routine, such as reading the newspaper;
- The system should provide information about possible side-effects to medication reviewers, home care nurses and informal caregivers.

#### 5.2.4 Theme: Technological preferences and dislikes

This theme was discussed by using “talking sheets”. The talking sheets were examples of applications and/or systems which are already used for supporting the medication adherence. See also the research protocol in Appendix 1.

##### 5.2.4.1 General system-settings

A major finding from the interviews is that the system should be connectable to other professional systems in home care, general practitioners or pharmacy organisation. This to enhance the acceptance of the system because professionals already have to deal with multiple (IT) systems. There will be differences in directed by national privacy and ethically legislations and practical opportunities to do this as professionals systems are often closed and secured.

The system should be based on the comments on the talking sheets as shown in Appendix 1:

- The user interface elements (such as symbols and buttons), should be easily understandable;
- The MedGUIDE platform should provide easy access for users with all level of ICT-skills;
- The MEDGUIDE user interface should be adapted based on the different target groups;
- The system must follow accepted and common guidelines and standards in Europe on accessibility; the user interface contrast and font sizes used must be adapted to a PwD;

- Professionals should be able to access only the needed information, and not to be overloaded with information.

Another major point of attention is that all people (personal contacts and professionals) in the circle of trust of the PwDs must use the same device/or tool. Pill-rolls or agenda apps do not apply very well for the group of PwDs according the secondary target group.

- The MedGUIDE platform should take into account the limitations in (functional) decline due to the dementia syndrome

#### 5.2.4.2 *Specific features/suggestions MedGuide system*

The secondary end-users group (informal caregivers and healthcare professionals) also reflected on opportunities for new functions for the MedGUIDE platform. They mentioned that setting priorities or a hierarchy in the signals/feedback to take medication will be good to have, in order to be able to identify which medication is the most urgent and which of them can be eventually missed. Moreover, the means for adherence monitoring, e.g. scanning- the bar code of a Baxter-roll at moment of intake (medication given by professional), might improve the medication adherence. The options of identifying the patient by the system and arranging telephone calls by family carers to remind the PwD about the medication intake should be provided. This is relevant mainly in the evening.

- The system should adapt to the daily routines of PwDs. Add or integrate personalized storage routine or tricks to the system which are personalized;
- Reminders for medication intake should be visualized as clear as possible. By for example, presenting the time of medication intake in big letters or using a clock visualization, and the day of the week should presented, not the specific date;
- Notifications sent to professionals about missed medication should only be send in cases of crucial medication in order to prevent an overload in their work-tasks;
- Healthcare professionals should be able to exchange and add practical knowledge and skills with each other through the "online tool", which have to be efficiently for them (minimum extra effort and time required);
- The MedGUIDE tool should contribute to support communication between care professionals, PwD and their care network. Have to be simple, quickly done and not invasive in the daily main work;
- An e-learning module for professionals regarding the communicate with PwDs to support the medication adherence is good to have.

From the interviews with the formal carers we found that the system should capture monitoring movement or activity via sensors such as:

- Going out etc.;
- Staying in bed longer than regular;
- Sensor in a chair to monitor sitting;
- Sensor in the door telling you how late it is when leaving the house;
- Sensor in the bathroom door to monitor toilet visits; PwD forget to go to the toilet, or using the toilet very often;
- Sensors in the kitchen and around the refrigerator and water faucet, providing information about the probability of medicine in-take.

Professionals stated that the system should also provide the possibility to monitor (side-)effects of the medication, for example level of pain or changes in mood. It is relevant to receive feedback from the patient about their real-time condition (taking in account the condition of the PwD). The monitoring data collected of the daily activities of the senior must be shared with informal caregiver, so that he/she can add extra information about it (e.g. change of medication). *“For evaluating effect of medication for dementia information from the next of kin is important.”* The system should be aligned with the activities people did before the diagnosis of dementia.

- MedGUIDE should support informal caregivers to enrich the sensor data with self-reported data;
- MedGUIDE should monitor possible (side-)effect of the medication;
- MedGUIDE should be aligned with people’s daily routines and should not give additional or conflicting activities.

The secondary groups, in this case the professionals, had serious doubts or questions about whether the MedGUIDE system will fit to skills and level of adaptability of PwDs. A case study of electronic pill boxes showed that it was too complicated for them to use. Furthermore, their skills for (instrumental) daily activities such as dialling, making an appointment or getting to the grocery will deteriorate. Thus the MedGUIDE system should be as simple as possible to use by the PwD.

### 5.3 Tertiary end-users

Pharmacist and doctors (mainly GPs) have been interviewed in Norway, The Netherlands and Cyprus. National differences occur in the type of professionals involved, the health care system and in the supporting systems used in the treatment of PwDs, which are mentioned in the relevant paragraphs. Main topics in the interviews are monitoring medication adherence, counselling and communication, online tools and medication evaluation.

#### 5.3.1 Monitoring medication adherence

Medication adherence and understanding of side-effects are difficult for PwDs. GPs and pharmacists mentioned two categories of PwDs: those who are willing to take their medication but are not able to, and those who are negative towards taking medication. The main problems for PwDs in the first category are: forgetting dosages, taking double dosages, having trouble following intake instructions and reading the instruction on the label. Especially changes in regime make it more difficult for this category of PwDs to adhere to their medication. Changes in medication or dosage regime then cause noncompliance.

PwDs in the second category do not acknowledge their illness and refuse treatment because of ideological reasons. They do not believe in the effect of the medication, they fear the side effects, or simply do not want to take the medication because they don’t see themselves as 'ill'.

GPs and pharmacists mentioned these as the main causes for not being able to take the medication: cognitive disorder, loss of orientation, not having a good overview of the medication intake schedule. PwDs distrust changes and communicate less because they have less overview of their lives. Therefore, changes in medication - such as another brand of generic medication - are a problem and PwDs will often avoid to communicate their problems with medication or syndrome with their GP. For a PwD it is difficult to indicate problems to the GP that are related to side effects of the medication, or to symptoms caused by lacking of proper medication, such as pain.

It is very rare that patients - even in early stages of dementia - are able to take their medication by themselves; their informal or formal caregivers are usually responsible to give them their medication. The patients cannot understand their situation and why they should take the medication.

- The system should support the PwD and his/her caretakers in taking the right dosage, at the right time, in the right way, since PwDs experience problems in this area;
- The system should address the informal and formal caregiver (as well as the PwD) with regard to medication adherence, since they play an important role in helping the PwD adhere to his medication;
- The system could have an added value when supporting changes in medication regime.

### 5.3.2 Monitoring medication adherence by the GP

When asked about motivating the PwD to medication adherence, most GPs refer to the formal caregiver. When they do contact the PwD themselves, GPs stated that motivating the PwD to medication adherence is difficult. GPs then mainly address the informal or formal caregiver of the PwD, while they still try to establish a good relationship with the PwD and the informal caregiver.

For the GP time is a limiting factor. One of the reasons is because PwDs already consume a lot of time on their other diagnosis. The opinion on whether a feedback system for medication adherence would be helpful varies among the GPs. It should in any way not consume too much time. Some GPs prefer the formal caregiver to receive this feedback.

- The system should aim primarily at supporting the practical problems with medication adherence, since the motivational problems are difficult to solve by an electronic system, but need personal attention from the GP and formal caregiver;
- The system should not cost the GP too much time, since they state that time is very limited;
- It should be clear to the GPs what the advantage of the system is for them, since they tend to refer to the formal caregiver for the mentioned tasks.

### 5.3.3 Monitoring medication adherence by the pharmacy

The pharmacy systems in The Netherlands, Norway and Cyprus are advanced and provide a tool for evaluation of medication adherence. The pharmacy system indicates when the PwD acquires his medication too soon or too late. This is helpful but does not provide enough detailed information, because acquiring medication is not the same as actually taking the medication. In The Netherlands adherence is therefore sometimes evaluated through a home visit by the pharmacist.

When possible, the pharmacy can simplify the medication regime by planning the medication on less administering moments. As all changes are delicate for the PwDs, this is not always advisable.

In the Netherlands, intake regimes are often simplified by introducing medication bags on a roll (such as Baxter). This is only possible for pills and capsules, not for crèmes and potions etc.

- The system should be able to exchange information with - or be fed by - the pharmacy system, with regard to medication adherence information of the PwD;
- The system should be able to provide more detailed information about medication adherence than the pharmacy system. For example by collecting data from the PwD.

### 5.3.4 Current support tools for medication adherence

In Cyprus, GPs and pharmacists do not use tools for medication adherence other than the pharmacy system mentioned above, but are enthusiastic to try such tools when available. In The Netherlands and

Norway, GPs and pharmacists mentioned many support tools for medication adherence. There are electronic medication dispensers, medication alarms and many different apps, used by the informal caregiver.

#### 5.3.4.1 Norway

In Norway the medication dispenser Pilly has been purchased by a number municipalities. It is also a registered product in the national database of assistive technologies<sup>3</sup>. Another product, Evondos<sup>4</sup>, is currently gaining market shares and is part of the portfolio of one of the largest suppliers of health technology solutions to municipalities: Telenor. This dispenser also seems to have a design that is much easier for people with cognitive decline to handle than the pill carousels. The app "My Medicine" is developed for patients with Parkinson disease. In the app, names of medicines or barcodes should be entered, there is a link to the database with information about approved drugs in Norway (FEST), so that e.g. warnings for a specific medicines can be displayed in the app. The app contains a drug list for the patient with correct strengths, doses and ways of administration, information about side-effects, warnings from the Norwegian Drug Authority, and interactions between drugs on the drug list. The most important feature is probably that reminders for medication intake pop up on the device (mobile phone or tablet) even if the app is not open (like calendar reminders). Doses taken should be ticked off. Hence historical data about taken medicine and deviations (at least doses not ticked off) can be easily seen.

A GP uses a communication tool with the home nurse system, called PLO. It is integrated in the journal system. The home nurses will send him worries for the users by this system. He can read and answer messages in the end of the day, and the home nurses read his messages the next day. Sometimes the GP thinks people are sending him too many messages.

#### 5.3.4.2 The Netherlands

In The Netherlands many systems exist for helping the formal and informal caregiver with medication adherence. For example the Med App<sup>5</sup>, which provides information about the medication - after scanning it - and contains a medication alarm. Med App can be linked to the pharmacy system, which allows the PwD or informal caregiver to order the medication at the pharmacy. The pharmacy can also signal the PwD automatically when the medication should be collected. Med App is usable only for persons in a very early stage of dementia or for the informal caregivers of the PwD.

The medication dispenser Medido<sup>6</sup> can be used for people who have trouble taking the right medication at the right time. The dispenser releases a medication bag with the necessary medication at the indicated moment and gives a signal. It also contains a communication button. The Medido is suitable only for very few PwDs, because it requires already quite some skills.

A GP mentioned eGPO/Congredi<sup>7</sup>, an online system which facilitates making an online care plan and communicate about the goals in this plan with other professionals. The pharmacist is not involved in this system. Signals from the PwD go to a nurse (nurse practitioner, related to the GP), who selects the

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<sup>3</sup> [www.hjelpemiddeldatabasen.no](http://www.hjelpemiddeldatabasen.no)

<sup>4</sup> [www.evondos.com/service/evondos-e300-automatic-medicine-dispenser/](http://www.evondos.com/service/evondos-e300-automatic-medicine-dispenser/)

<sup>5</sup> <https://medapp.nu/en/>

<sup>6</sup> <http://www.medido.philips.nl/>

<sup>7</sup> <http://www.congredi.org/>

information for the GP. This saves the GPs time, which is limited for them. They are motivated to use this system, because it gives them a good view of their patient population.

Other technological supports mentioned are a TomTom on a 'wheeler', door sensors, bed sensors, etc.

- As medication dispensers seem to be of use for only a very small part of the PwD, we should not focus too much on this device.
- Since GPs and pharmacists use huge closed systems with very high security, MedGUIDE must consider possible interoperability by standards usage. MedGUIDE should be able to integrate with solutions from leading existing providers of doctor and pharmacy systems, care apps etc. The GP or pharmacist will not use a separate system voor the PwD.
- The used systems in at least Norway and The Netherlands already contain information on a high level on effects, side effects, interactions and contraindications of medication. It would be efficient if the system could connect to this information.
- All people - personal contacts and professionals - in the circle of trust of the PwDs must use the same device or tool, or use tools that automatically synchronize information.

### 5.3.5 Communication and counselling

In The Netherlands and Norway, the GPs and pharmacists discussed about the different types of professional caregivers who communicate or provide counselling with PwDs. In Cyprus the approach of the GP and pharmacist communicating with the PwD and informal caretaker was discussed.

#### 5.3.5.1 The Netherlands

GPs and pharmacists name the nurse practitioner and the home care nurse as persons that play an important role in providing counselling to the PwD. They often communicate via the informal caregiver. Also there are dementia nurses and dementia case managers who form a special team in the home care organisation. The nurse practitioner role gradually becomes more important in the communication with the PwD. She is a nurse who is connected to the GP practise. The nurse practitioner sometimes visits the PwD at home and advises about medication adherence. The degree of support in medication adherence needed is determined by visiting the PwD and the informal caregiver. A GP states: *"The best way to do this is to let the PwD perform the necessary actions himself and see which support is needed."*

When home care nursing or nurse practitioners are not involved, many signals of adverse drug effects do not reach the GP. It depends on the assertiveness of the informal caregiver and the pharmacist, and the time the GP has and the attention he or she pays to the PwD.

GPs emphasize that the counselling process with PwDs has to be custom-made for every individual. It requires an open mind. Easy access to home care nurses is thereby needed.

- In the system, the home care nurse - or other professional involved in each country - should play an important role in the communication of signals of medication adherence, side effect etc.
- When home care nursing is not available, the role of the informal caregiver in communicating will be more important in the system.

#### 5.3.5.2 Norway

GPs indicate that they do not communicate enough with PwDs about medication adherence. They delegate this communication to the informal caregiver or to the home care nursing system. The home care nurses should follow up medication adherence as GPs have too little time. A GP doubts if every home care nurse is suitably trained for this.

A GP states about medication adherence: *"I usually say to my patients/their carers that when we decide to go a 'medicine-path' we need to stick with it."*

- The home care nurses should filter signals for the GP and pharmacist, to save them time.
- Proper training should be given to the home care nurses about medication adherence, signals of problems with medication such as side effects.

#### 5.3.5.3 Cyprus

The healthcare professionals have regular contact with the patients and their informal caregivers regarding their medication, side effects and any changes that may occur. The professionals receive most information through their discussion with the informal caregivers. However, they highlighted the importance of showing empathy, respect and compassion to PwD so as to develop a good relationship and have good communication with them. This usually helps when the patients are negative towards the prescribed medication.

- Establishing good contact between professionals and PwD remains essential for medication adherence. The system should support this contact.

#### 5.3.6 Talking sheets

In the interviews with the tertiary end-users group several "talking sheets" with existing electronic medication tools are discussed.

GPs and pharmacists stated the following after discussing the talking sheets:

- An electronic device cannot and should not replace personal contact, since PwDs are often lonely and need personal contact;
- Feeding information to an electronic tool can be confronting for a PwD, because he notices what he doesn't know any more;
- The discussed tools are already a bit too complicated for a PwD. Learning new aspects is very difficult for them. Often the informal caregiver will use the tool instead of the PwD;
- Pill reminders will help the PwDs to take their medication by themselves;
- The tool will maybe suit the younger generations better than the current PwDs, because the former will have more experience with smart phones and tablets;
- The electronic medication dispenser does not guarantee that the PwD will actually take its medication after the release of the sachet;
- The electronic medication dispenser Pilly had a too small digital screen and should give a message like "It's time to take your medicine";
- A consequence of using MedGUIDE will probably be that the GP and pharmacist are more involved with the home care nurse. Some consider this as time consuming and a risk, some others consider it as positive since it provides a better view on the PwDs.

The following specifics for an online tool MedGUIDE were suggested by the interviewed pharmacists and GPs:

- The tool has to be larger than a smart phone, like a tablet. Many PwDs have problems using a mobile phone;
- Details on the screen have to be large and straightforward;
- It is important to test if such a tool for improving medication adherence really works for the user.

- The online tool should have a signal function. Signals can indicate to formal caregivers that things go wrong with the PwD. It should also provide information and have an alarm function;
- The tool should give a message like "It's time to take your medicine". This message should repeat itself until the patient physically turns the alarm off;
- It is important that the PwD himself can see the advantage of the online tool. "What's in it for me?";
- The tool should be integrated with other systems and should not cost the GP much time;
- The tool should connect to the activities of the PwD, such as for example the television;
- Mind privacy;
- The tool cannot replace face to face contact, it can select PwDs who need extra care;
- The tool should provide information for the pharmacist about who is involved in the care of the PwD;
- The tool should name the days of the week, not the data. Or use a calendar;
- Use colours and pictures instead of text;
- Insert elements that enable GPs and pharmacists to communicate with other professionals involved in their cases as well as enhance their knowledge and skills through the platform by exchanging knowledge.

### 5.3.7 Medication evaluation

Medication evaluation is an everyday process of signalling the effects of and problems with the medication. In addition the medication is evaluated at fixed moments; the medication review.

#### 5.3.7.1 Medication review in the Netherlands

In The Netherlands, medication reviews are performed once a year by pharmacist and GP in accordance with the 'Multidisciplinary guideline polypharmacy for the elderly'. Inclusion criteria are polypharmacy (five or more medicines), age (65+) and risk factors, such as cardiovascular diseases. Only a small amount of patients is evaluated. The PwD is not often chosen as a group at risk, although 'problems with organizing' is an official criteria for a medication review. The nurse practitioner often has a role in organising the medication reviews.

In The Netherlands, most common changes in a review are discontinuation of medication, adding vitamins, and obtaining kidney and liver functions from the laboratory for adjusting dosage regimes.

The GP will notice interactions and contra indications first, the pharmacist is a 'back up' and has an overview of all prescribed medication, including specialist medication.

In The Netherlands as well as in Norway drug interactions are prevented by a sophisticated automated system for pharmacists and physicians.

- The tool could support the medication review by making the review easier to organise. For example support the planning of the meetings, the exchange of the medication analysis and the suggestions for medication adjustments by the pharmacist, and providing an overview of the state of affairs.
- Information on side effects, drug interactions and contra-indications is not necessary to incorporate in the system for The Netherlands and Norway, since this is already provided for in current systems.
- The tool should be able to connect with the current GP and pharmacist online expert systems.

### 5.3.7.2 Medication review in Norway

In Norway the Norwegian Directorate of Health has made medication review guidelines for health personnel. The regulations for GPs say that GPs should ensure medication reviews are done for their patients using four or more medicines when medically necessary. GPs indicate that they do not perform medication reviews often, since they cost a lot of time. They perform the medication reviews themselves. Most time is used for updating drug lists in their journal system of patients according to hospital discharge summaries. He is also doing drug reviews on inquiries from next of kins or home nurses. There is a tariff for GPs that can be used twice a year for drug reviews of each patient according to the regulations.

- In addition to the bullets above, the tool should support an up-to-date medication overview, since acquiring this costs the GP a lot of time.

### 5.3.7.3 Symptoms

The symptoms of dementia and/or Alzheimer are separated in three categories: mental, physical and psychological.

Mental symptoms: increased aggressiveness due to the fact that they cannot communicate and speak as they used to; their syntax and vocabulary is decreased, subsequently, it makes it difficult for other people to understand them and they get frustrated, disorientation, sometimes they have illusions.

Physical: disorder in bowel movement, urine output, appetite, and sleep.

Psychological: psychosis, schizophrenia symptoms, such as inability to sit still, logorrhea, decrease/loss of feeling of self-preservation – decrease/loss feeling of sense of self care and personal care, and changes of their habits due to loss of independency.

When PwD do not adhere to the medication given (either if they take more or less than the prescribed medication), then they have one or more of the following symptoms: confused, aggression, relapse and changes in their behaviour.

### 5.3.7.4 Side effects

Symptoms like nausea, abdominal pain and diarrhea can be adverse effects of choline esterase inhibitors. This can lead to reduced appetite and reduced food intake. Exelon adhesive plaster can give eczema. The ones who can discover such symptoms are the home nurses. Aricept and Exelon are given in the evening to avoid gastrointestinal adverse effects. Exelon can worsen Parkinson disease.

A GP states: *"When a PwD experiences drowsiness, I always blame the pills first."*

GPs and pharmacists mention the following side effects that are the most important to discover: unsteadiness/falling, side effects on cognitive functions and on mobility. Additionally mentioned side-effects are dry mouth, obstipation, dizziness, nausea, low blood pressure (drop in blood pressure). A lot of PwDs take many different medicaments, so it's difficult to say.

They mention the following side effects that could be monitored and discovered by sensors of the MedGUIDE-system: falling, dizziness, restlessness at night, frequent visits to the toilet during night, and how long the user is staying in his/her bed.

- The tool should be able to discover falling, dizziness, restlessness at night, frequent visits to the toilet during night, and how long the user is staying in his/her bed.

#### 5.3.7.5 *Symptom or side effect?*

All GPs and pharmacists stated that it is very difficult to distinguish between symptoms and side effects. If a PwD sits a lot, is this caused by dizziness? Or uncertainty due to a risk of falling? Subsequent questions are whether are symptoms of the disease or side effects of the medication? If a PwD has swallowing problems, is this due to her antipsychotics or is she in a late stadium of Alzheimers?

Symptoms of which it is difficult to distinguish between adverse effects of drugs or progression of the disease are, according to the interviewed GPs and pharmacists: delirium, anticholinergic side effects, and deterioration of cognition, mood changes, tiredness, aggressiveness, dizziness, abdominal pain or reduced appetite.

The only way to know what the cause of the signal is to stop the medication and see if the side effect stops. A physician states: *"I always blame the pills first. Then I look at the disease."* It is very hard to distinguish between side effect and disease with an online tool. Maybe changes in base line, combined with information of the moment a medication was started can be useful.

- The tool should be able to monitor side effect on a time-line. This way GPs can analyse if a side effect has started at the same time as newly prescribed medication.
- The tool should provide a baseline for activities like sleep, movement, eating pattern and toilet visits, so that a change in baseline can be detected.
- There will always be a need for a GP and/or pharmacist to analyse the signals and changes. Even then it will be difficult to distinguish between side effect and symptoms of the disease.

#### 5.3.7.6 *Discontinuation of medication with PwDs*

"You don't stop medical treatment, you stop giving medication", a GP states. In The Netherlands there are guidelines voor discontinuation of rivastigmine, a medicine for dementia. According to guidelines, rivastigmine should be stopped when no effect is observed any more. Often this is when a PwD is administered in a nursing home. Also, when no improvement is seen, the medication is often stopped. There is more information about discontinuation in Dutch guidelines (Start/Stop criteria, Beers criteria, Verenso-guidelines).

Norwegian guidelines for discontinuation of dementia medication are not known. Sometimes the GP resides the dose.

## 5.4 Technological aspects

Table 3 below shows an overview of the technological aspects suggested in the interviews.

<b>Table 3: Specifications MedGUIDE</b>	
<b>System general</b>	
Get familiar with daily routines to trigger	Only in cases of missing crucial medication should the system send a notification to the professional
Must be incorporate in daily routines of PwD	Able to exchange and add practical knowledge and skills with each other by professionals
Must have a permanent place, just like medication	Support communication between care professionals, PwD and care network
Possibility to add and to share self-reported information	e-Learning module for professionals about how to communicate with PwD about e.g. medication adherence
Define who has access to the personal data	Capture monitoring movement or activity via sensors
Take into account decreased motor impairment, hearing and/or visual impairment	Monitor possible (side-)effects of medication
Take into account functional decline, loss of memory and low adaptive possibilities	Aligned with people's daily routines and should not give additional or conflicting activities
Learning curve should be as low as possible, ease of learn	Able to exchange information by other systems if possible
Lead to a decrease of care load of the informal carer	All people in the care network must be able to use the same system
Reminders for e.g. medication intake and appointments	Should not replace personal contact
Provide positive feedback and motivating reminders to promote adherence	Support the PwD by mention what day it is
Support PwD with positive feedback to support their daily routines	Support the medication review, for example support the planning of meetings and exchange of medication analysis
Possibility to share information and/or reports on online counselling	Monitor side-effect on a time-line
Support the PwD to take the correct medication doses and prevent double doses	Be adapt based on the different target groups
User interface should be easily understandable	High accessibility
Provide easy access for user with al level of ICT-skills	Good to have priorities or a hierarchy in the signals/feedback to take medication
<b>System information</b>	
Provide information about aspects of medication, medication effects and medication administration	Provide information about side-effect to medication reviewers, home care nurses and informal carers
Give information about changes in medication (e.g. type, dose, colour or shape)	Reminders of medication intake should me visualized as clear as possible
Provide information about side- or adverse effects	Information about personal information about safe and secure medication intake
Information should be accessible for all users with all levels of health literacy	Describe the effectiveness of the medication that are prescribed
Introduction and instruction on the interaction with MedGUIDE	Checklist for intake medication or provide e.g. plasters
Information about recent developments in medication, ICT and healthcare	

## 6 Discussion

The report includes the voice of PwDs living alone at home or with a partner. The focus is laid on this group which is trying to age-in-place with dementia. The dementia syndrome has similar symptoms for all and limits a person in the same way. The findings did show that the PwDs have in general a fixed daily structure and that medication intake is around the meals. Findings however did not reveal, all though expected, any cultural or regional (EU) differences. The findings were retrieved in the (group) interviews with PwDs and via the interviews with the informal carers. PwD and informal caregivers stated in the interviews that the PwD themselves do not know which medication they use and have difficulty enhancing the medication regime. They rely mostly on the informal carer for these routines and safety of intake. The informal caregivers do see opportunities for the MedGUIDE system, however they are not all that experienced in using ICT and address the option to make it easily accessible for the PwD and their informal carer and taking notice that the PwD is addressed respectfully and responsive to PwDs needs and values.

Findings retrieved from the interviews with care professionals and tertiary end-users were mostly related to the dementia syndrome symptoms and how these limits the functioning of the PwDs. Also the occurrence of side-effects and difficulties with the medication-management were mentioned. The interviews with the tertiary end-users group provided similar information when compared to the secondary users group.

The requirements are a starting-point for the design phase. The way requirements will be incorporated in the MedGUIDE system is part of the next phases; decisions need to be made about the system, for instance how the suggested e-learning module should look like (booklet or net based information) and the content for the different end-users.

In these interviews, the issues about medication management by the health care professionals and pharmacists were not addressed as expected. Main conclusion is that there is no national evidence based guideline on medication management in PwD and professionals have no idea how to motivate patients to enhance adherence to medication. This could be caused by the fact that the focus in this sub-task was on users-needs. It is expected that more insight about medication management issue in early dementia care will be addressed in tasks 2.3 to 2.5. However, the combination of interviews from three different groups namely, primary, secondary and tertiary end-users give enriched data and are also very much aligned with findings from studies about aging-in-place with dementia<sup>8</sup>. Furthermore, in most publications about persons with dementia, the findings of researchers or others are given about preferences and dislikes of PwDs concerning the use of an electronic or ICT system. One of the exceptions in this study is the development of a web tool for aging-in-place for PwDs<sup>9</sup>.

A practical lesson learned is that recruitment via direct channels was most successful, probably because partners trust one and other.

### 6.1 Limitations

The findings in the report should be read while having in mind that PwDs from different European countries are involved. Not all PwDs in Europe currently have the same access to ICT devices and the internet. Furthermore, the organization of the care provision is not the same while also the acceptance of

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<sup>8</sup> Ageing-in-place : the integrated design of housing facilities for people with dementia (<http://repository.tue.nl/685914>)

<sup>9</sup> Design of a website for home modifications for older persons with dementia (Kort H & van Hoof J, DOI: 10.3233/TAD-140399)

the system needs to be considered. The MedGUIDE system should be such that it can be incorporated within other systems which professionals are using. Another limitation is, in the gathering of the data. In some cases, or countries, group sessions were organized while other interviews were face-to-face. Group sessions have the advantage that participants can be triggered to remember things especially in case of PwDs, while others can be motivated to actively join the session or they just keep quiet without being noticed. The advantage of the face-to-face session is that more in-depth conversations could be held, but when a PwD was tired the session had to end. Interviews in any form have limitations in itself because obvious things might not be mentioned but could be very relevant for the project. Observations were part of the project proposal but due to the complexity of the recruitment of this group not feasible. Observations could have revealed what isn't obvious. The recruitment of the PwDs was complex due to the fact that all had direct access to the PwDs community, although all parties have good relations with Alzheimer organizations in each country.

## 7 Conclusion

Findings regarding the specifications range from visual ergonomics, limitations with all senses as to the responsiveness and usability as well as ease of use of the system to develop. According to the end-users, the system should also support PwD autonomy and feeling of control. The system should help the end-user(s) to get better or easier access to information about e.g. medication use, adverse effects and side-effects. The system should not lead to an extra care or work load for the carers but should support the PwDs and their network. In conclusion, the findings in this deliverable directs to a system which should maintain familiarity for the PwD and which can support them in coping with changes in their medication while professionals are able to communicate with them and give positive feedback.

## 8 References

van Hoof, J. (2010). Ageing-in-place: *The integrated design of housing facilities for people with dementia* (Doctoral dissertation, PhD thesis, Technical University of Eindhoven, Eindhoven).

Kort, H. S., & van Hoof, J. (2014). Design of a website for home modifications for older persons with dementia. *Technology and disability*, 26(1), 1-10.

[www.hjelpemiddeldatabasen.no](http://www.hjelpemiddeldatabasen.no)

[www.evondos.com/service/evondos-e300-automatic-medicine-dispenser](http://www.evondos.com/service/evondos-e300-automatic-medicine-dispenser)

[www.medapp.nu/en](http://www.medapp.nu/en)

[www.medido.philips.nl](http://www.medido.philips.nl)

[www.congredi.org](http://www.congredi.org)



## 9 Appendix 1: Research protocol

Version FINAL 1.2, June 21, 2017

# MedGUIDE

**Research Protocol 21-06-2017**

**Version FINAL 1.2**



HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

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## Introduction

This document describes the protocol for the research study Task 1.1 in Work Package 1 (WP1) of the MedGUIDE Project. The central aim of this Task 1.1 is the end-user requirement analysis and technology conceptual model definition. Within the general group of end-users, three sub-groups can be distinguished: Persons with Dementia (PwD), their informal caregivers, and the health care professionals. In this protocol you can read that each groups has variations in the method used to gather the necessary insights. The protocol is intended for use by the partners HU-UAS (the Netherlands), KARDE (Norway), and MAT (Cyprus). Each of the partners including CCare & IVM were involved with end-user research contributes to the refinement of the protocol, until consensus was achieved.

The following sections are described in this document:

- PwD and informal caregivers
  - a. Selection and recruitment
  - b. Exploratory session
  - c. Home-visits
    - In-depth interviews
    - Observations
- Healthcare professionals
  - a. Selection and recruitment
  - b. Exploratory session
  - c. Home-visits
    - In-depth interviews
    - Observations

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

### 1. PwD and informal caregivers

#### 1a. Selection and recruitment

Recruitment of PwD and their informal caregivers for research into the end-user requirements is done by each of the involved partners, for their own region. A success factor for the recruitment of PwD is having direct access to this group, for example by means of a hospital or day care centre for PwD. Plan enough time for the recruitment. PwD are a vulnerable group, a major barrier to participate is the cognitive and physical constraints caused by dementia.

In the Netherlands, PwDs and their informal caregivers are recruited through:

- The national Alzheimer association;
- Housing associations;
- Elderly associations;
- Regional special meeting groups (e.g. Alzheimer Café);
- Care organizations;
- Regional networks for integrated care of dementia patients;
- Facebookgroups;
- Webbased forums (e.g. [www.dementie.nl](http://www.dementie.nl)).

In Norway, PwD and their informal caregivers are recruited through:

- Facebook – both the Karde-group and the welfare technology group in Norway;
- The Norwegian Health Association (the main organization for persons with dementia and their carers in Norway);
- If accepted by geriatric outpatients clinics in Oslo.

In Cyprus, PwD and their informal caregivers are recruited through:

- Eligible former and current clients of the MATERIA Group that live at home;
- Relevant patients associations;
- Day care centers for the older adults;
- Associations of retired professionals;
- Doctors that specialize in the field;
- Home care services.

Open call to the public for recruitment, the following documents are available:

- Invitation letter (appendix A);
- Information leaflet (appendix B), to be received together with the invitation letter;
- Confirmation letter (appendix C), to be received by the participants 3 days prior to the exploratory session and/or interview.

HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

1b. In- and exclusion criteria for PwD and informal caregivers (final version accepted March 2017).

Inclusion criteria for Person with Dementia (PwD).

- Formal self-reported diagnosis of dementia of any type. Ask PwD and carer for status of diagnosis.
- Polypharmacy: Using 5 or more prescribed medications (EU policy; Dutch rule) or what is considered polypharmacy in each of the three participating countries.
- Living independently, not in nursing or elderly home setting.
- Dementia is in an early phase. PwD still has consent competence and is willing and able to participate for the end-users requirement interview.
- Male or female of 40 years of age or over. PwD older than 85 need to be in a clinically stable state. (Informal caregiver or investigator's judgement).
- Informal caregiver who is willing and able to support the PwD during the research (See inclusion criteria for informal caregivers).
- Ability to complete the project activities: to hear, speak, read and write in a basic way (Dutch, Greek or Norwegian).

Additional criteria:

- It is preferable that the PwD has a basic level of experience with a computer or computer skills or is motivated to learn to do so. The level of experience may vary between the PwDs included. Some PwD may be more experienced, others not. However, to speak about (e-)health and technology and ICT-solutions, it is recommendable that PwD with experience are included in the study population for the needs assessment.

Exclusion criteria

- Currently under treatment for major depression.

Inclusion criteria for informal caregivers are as follows:

- Next of kin, spouse, relative or informal caregiver of person with dementia.
- Actively involved in the care of the PwD.
- Knowledge on the management of the PwD medications.
- Basic level of experience with a computer or computer skills or willing to learn.
- Ability to read and write at a basic level Dutch, Greek or Norwegian.

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

### 1c. Exploratory session: Aim

The aim of the exploratory session is to give a first introduction of the project to the participants of the user research. The exploratory session are optional and can be used if the partner deems it necessary. The focus group session can be used to provide extra information about the project, sign informed consent forms and get a first experience in interacting with the selected participants. When the partner already has contact with the PwD and/or informal caregiver during the selection procedure, and sufficient experience in communicating with persons in early stages of dementia the session the partner can directly proceed to in-depth interviews.

In each session 3 to 4 PwD will be invited as well as their informal caregivers. The exploratory session is to explore the research topic with PwD, their informal caregivers and health care professionals (see section 2B). This session will give a first insights and give possible solutions for the Medguide. It will allow the researchers to get insight into the attitudes of PwD and informal caregivers toward existing technological solutions that can help correctly administer medication and what they would wished to have in jet to develop technological solutions.

The following preparations for the exploratory session have to be done by the project-team:

- Wheelchair-accessible location with food and drinks as appropriate for the time of day and country of the organizing partner (consider lighting, noise and other disturbing factors for this target group);
- Printed program and list of participants (not to share with the participants);
- PowerPoint presentation to support the introductory speech (appendix D);
- Printed examples of applications and/or webpages (talking sheets), which can be used to support the conversation (appendix E);
- Printed information leaflets about the study and informed-consent forms (appendix F);
- Travel expense forms, if appropriate.

The exploratory session could have the following setup and time-schedule. It is an illustration of the exploratory session, there is some room for your own adaptations, required is the group discussion about medication adherence. Considering the low burden this session should place on the PwD we advise to keep track of time and stop the session after an hour. Stop earlier when PwD is getting tired.

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

*Box 1. Example setup and timeschedule of exploratory session.*

Duration In minutes	Activity	Content	Responsible
60	Coffee & Lunch  Project members welcome the participants	Make the participants feel at home. Have informal conversations with them from the start. This lunch is optional and adopt the time schedule of this lunch to your local situation or possibilities.	Project members
15	Plenary introduction	<ol style="list-style-type: none"> <li>1. Plenary welcome and introduction;</li> <li>2. Presentation about the project and study outline;</li> <li>3. Room for questions;</li> <li>4. Informed consent procedure.</li> </ol>	Project members
	<p>Warming-up activity "Raise your hands if..." (Optional exercise. Not necessary in small groups or individual interviews).</p> <p>In case of a group smaller than 3-4 PwD start a conversation about their use of cellphones, pill boxes or tablets.</p>	<p>Ask the group to raise their hands if they:</p> <ol style="list-style-type: none"> <li>1. Measure their own blood pressure;</li> <li>2. Use Skype or WhatsApp to contact friends and family;</li> <li>3. Have a digital agenda they can share with other people;</li> <li>4. Can use a digital camera on whatever device and know how to share the pictures;</li> <li>5. Send e-mail to friends and family;</li> <li>6. Receive digital outcomes of medical examinations;</li> <li>7. Use an GPS-tracer when going outside.</li> </ol> <p>Ask people how they experience these technological devices. Let this be a "warming up" experience. Keep it briefly.</p>	Project members

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HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

45	<p>Group discussion on "medication adherence"</p> <p>Divide in groups of 4 participants. Keep couples of PwD and informal caregiver in one subgroup.</p>	<p><u>Impression of daily routines</u></p> <p>Ask how the PwD starts the day. Just let them talk for a while about subjects they address. If you wish you can use questions from the document (<a href="https://ln.sync.com/dl/409266820/e6duek7h-9y5x85fv-4cdgemmb-jeiw79dk">https://ln.sync.com/dl/409266820/e6duek7h-9y5x85fv-4cdgemmb-jeiw79dk</a>). (on Sync)</p> <p>This is for an <u>introduction and to start the session</u>. It is important for the development of MedGuide that we collect data about daily life and daily routines.</p> <p>Keep track of time and take care that the questions about medication adherence (see below) get enough time and energy from the PwD and informal carers.</p> <p>-----</p> <p><u>Technology and Medication Adherence</u></p> <p>Place the "talking sheets" (printed websites and apps) on the table to get focus on daily routines and medication adherence. Or if possible show them on a screen/tablet.</p> <p>Ask questions such as:</p> <ol style="list-style-type: none"> <li>1. How do you get your prescriptions from the pharmacy?</li> <li>2. Where do you store your medication?</li> <li>3. How does your caregiver/partner assist you with taking the medication?</li> <li>4. When do you take your medicines?</li> <li>5. Which cues do you use to remember the moment of the day when you have to take your medicine?</li> <li>6. Tell me about the system or routines you use to manage your medications?</li> <li>7. How are your medications helping you?</li> </ol>	<p>Project members</p> <p>(time management, guiding conversations, taking notes)</p>
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## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

		8. What could be improved in the way you are treated with medication?  Let the conversation take its course and use the printed images once in a while to redirect them back on topic.	
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A first exploratory session by HU-UAS in the Netherlands has revealed the following, which is taken into account in designing the interview and observation setup, and has resulted in the revised setup above:

- Visual support in the form of images is very useful to help PwD return to the initial subject of a conversation;
- Half an hour to forty-five minutes is the maximum amount of time that PwD can stay focused, after which they become too tired;
- Interviewers need to be trained in guiding a conversation with PwD who have early-stage dementia, to get the required insights.
- Record the session after permission of the contestants OR project members take notes during the session.

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

#### 1d. Home visit

The home visit contains of an in-depth interview with the PwD and their caregiver and an observation of the PwD in their daily routines at home. The home-visit can be stopped at any moment if the interview is too intense for the PwD. The home visit is additional to the exploratory session for those PwD who have participated in this. Keep track of time during the home visit. We advise to keep the interview shorter than 1.5 hours ( 90 minutes).

The purpose of the home-visit is to get answers into the following subjects:

- What medication regime do users need to adhere to, and what problems do they experience?
- Which cues and support systems do PwD already use to help them to adhere to their medication regime more successfully?
- Do PwD fail to adhere to their medication regime on purpose, and why?
- In what contexts do the users mainly take their medication and what effect does that have on their adherence?
- How is the informal caregiver involved in the medication regime? How do they monitor the adherence of the PwD?
- How would the informal caregiver like to be involved in the medication of the PwD, and why?
- What is the attitude towards the use of online tools for medication support? What problems do PwD and their caregivers anticipate.
- What are the attitudes and beliefs towards medication in general? (for more information on this topic see: <https://www.ncbi.nlm.nih.gov/pubmed/24312488>)

The following steps are taken for the home-visit:

- Each partner (HU-UAS, KARDE and MAT) selects the PwD and informal caregivers, according to the inclusion criteria in section 1b.
- For HU-UAS/IVM 16-24 primary users in the Understanding Phase have to be interviewed, for MAT (Cyprus) it is 8 -12 primary users and for KARDE (Norway) it is 18-24. See page 11 of the MedGuide Application. Primary users are PwD.
- PwD and their informal caregivers are asked to receive the interviewer in the home-setting of the PwD. An appointment is set one and a half hour (max 10 minutes for a short introduction, 60 minutes for the interview of the PwD and the carer, and 15 minutes for additional questions for the carer separate of the PwD). If the participants haven't been involved in an exploratory session already, they are given the invitation letter, information leaflet, and confirmation letter (see section 1a)
- At the date and time of the appointment, the interviewer/observer visits the participants. They have prepared:
  - A printed informed consent form (if not signed at the exploratory session, see appendix F);
  - An audio recording device and photo camera (for observations, see section 1d);
  - A list of questions with room for notes and pens;
  - A small token of gratitude, such as cookies, chocolate, or flowers (optional).

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

- The interview for WP1, task 1.1 is done after a short introduction, with PwD and informal caregiver at the same time. If PwD and caregiver did not attend the exploratory session, start the home visit with getting acquainted and a short introduction on the project. Audio is recorded if consented to, and notes are taken. There is sufficient room for questions from the participants' side.
- At the end of the conversation, the interviewer thanks the participants for their hospitality
- Explain them about the MedGuide project and ask them if they can be contacted for a next phase of the project.

### **In-depth Interview questions:**

Choose themes of questions that fit to the situation. Focus on medication and related activities. When possible or relevant explore in more detail on the topic. The interviews are semi-structured. Not all questions have to be mentioned. Guard time and energy level of PwD.

#### **Introduction exercise about Daily life/Routines (for getting acquainted):**

Start with the trigger images (for explanation see below) if reaction of PwD on this questions is little to none. Total amount of time spend on the questions about daily activities is 10 to 15 minutes.

Ask the seniors together with the informal caregiver to create a daily live timeline using trigger images.

Trigger images are images that can be interpreted in multiple ways based on the participants own imagination. During this exercise, you ask the participant to explain why they select which image and what that activity in their lives means to them.

Trigger images choose your own (it is about images on daily life, such as drinking coffee, marriage, school, work, eating).

#### **Topic: Daily activities**

*These questions are for getting started or getting acquainted with the PwD.*

1. Could you please describe your typical day to me ?
2. What do you do for fun?
3. Do you have any hobbies or special interests?

#### **Topic: Use of medication**

*Ask PwD to name one medication they daily use and focus on this medication in the next questions. Carer may help answering.*

1. Can you tell me how you use your medication?
2. Where are you when you take your medication?
3. When do you take your medicines? And how often?
4. Where do you store your medication?
5. How are your medications helping you?
6. Can you tell me how important your medication is to you?
7. What do you do if you maybe sometimes forget taking your medication?

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

8. Which cues do you use to remember the moment(s) of the day when you have to take your medicine?
9. Are you aware what the aimed effect is of your medication?
10. Do you feel that you need the medication to function? (Do you feel you that you are dependent on the medication? Explain that is different from addicted to the medication. It is about dependent to function or dependent to release the pain).
11. Does your caregiver/partner assist/home nurse you with taking the medication?
12. What system or routines do you use to manage your medications? Do you e.g. use a medicine dispenser? If so, what kind of dispenser? Who inserts your medicine into the dispenser?
13. Are you worried about possible side effects the medication have? If yes, do these worries influence on your medication adherence? And how do they influence your adherence?

**Topic: Extra questions for carer. In case of questions related to privacy or the relationship between carer and PwD, please ask them to carer alone.**

1. What is your relationship with the PwD?
2. How long ago did you start helping the PwD?
3. How important is helping the PwD for you?
4. How do you experience helping the PwD?
5. What do you find the most positive aspects of caring for the PwD?
6. What do you find the most difficult aspects in caring for the PwD?
7. How involved are you in the medication intake of the PwD?
8. How would you like to be supported in improving the medication adherence of the PwD?
9. What kind of information you would like to have in relation to the medication the PwD is taken?
10. What kind of electronic tool for correct medication adherence would you prefer the PwD to have/use?

**Topic: Support/Tools for medication adherence****Support tools can be pill boxes, Baxter rolls, individually developed techniques or routines to keep up with adherence.**

1. Which support tools for medication adherence do you use now? Do you use any digital/online/ technological tools?
  - What is useful for you?
  - What is not useful?
  - Why or from where were the support tools provided?
  - To the caregiver: How did you become aware of the tools? When would you recommended a tool to others?
2. What are your wishes for newly to develop support tools for medication?

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

**Topic: Use of online tools for medication adherence**

**Online tools can be for instance digital agenda, electrical medications dispensers. To use online tools you need access to internet.**

1. Do you have access to the internet at home? Or elsewhere? If not, why not?  
If elsewhere access to the internet, do you need extra support via the internet at home?
2. What is the role of internet in your daily life?
3. What kind of medical information would you like to get via the online tool(s)?
4. Do you know any technological solutions or online tools? If yes, name them.
5. Do you need support via the internet for the use of your medication?
  - If yes, why?
  - If not, why not?
6. What kind of online support for medication adherence can be useful for you? (application, website, forum, agenda)

**Exercise Care network**

***This exercise gives us information about the care network which is important for developing a user-profile.***

At the end of the interview draw a care network map with the PwD and carer. If the PwD is tired make the map with the carer. A care network map (see example below) is an overview on all people or reminder products involved in the medication use of the PwD. During the exercise ask the participants to explain how these people are involved, and how they help in their medication adherence. Make a list of who is doing what in taking care for the PwD.

Questions you can ask during the exercise:

1. Can you tell me who is involved in your medication adherence?
2. Can you tell me what his/her role is?
3. Can you place the persons in the network map based on how important they are to you concerning your medication adherence?
4. Can you place also any tools you use to improve your medication adherence. Even a pillbox can be added to the network map.

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

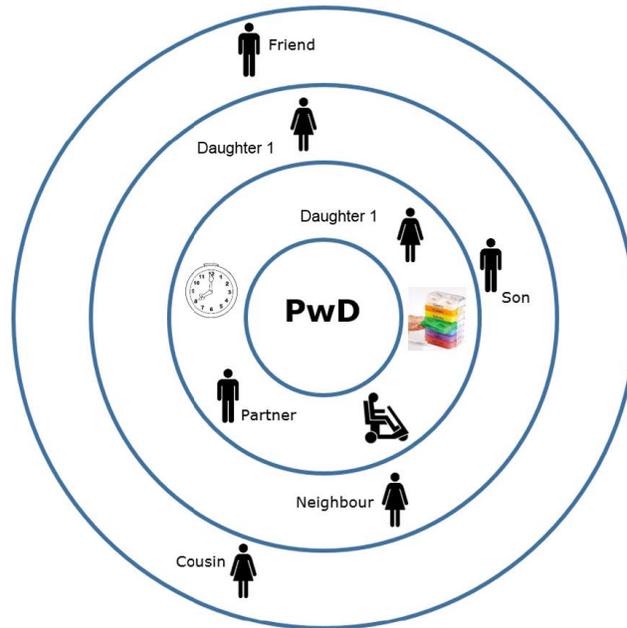


Figure 1: Example of a care network figure

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

### Observations

The purpose of the observation during the home-visit is to gain rich information about the context in which the PwD and informal caregiver cope with medication regimes and the problems they encounter. Rather than focusing on what people say, this helps to analyze what people actually do.

During the interviews, when a PwD or informal caregiver is explaining their tricks and support systems used in medication adherence, the interviewer should ask whether they can show what they are talking about. With permission, the interviewer (observer) takes a picture of the situation, taking care that participants aren't included in the image in a recognizable way. Examples can be an electronic pillbox in the windowsill, a post-it note on the refrigerator door, or an extra alarm clock in the bathroom.

## 2. Healthcare professionals

### 2a. Selection and recruitment

Recruitment of healthcare professionals for research into the end-user requirements is done by each of the involved partners, for their own region.

In the Netherlands, healthcare professionals are recruited through the existing network of the project partner:

- Pharmacists;
- Family doctors and nursing home physicians;
- Community nurses and case managers dementia (Dutch health care organization professional).

In Norway healthcare professionals are recruited through:

- The network of Karde and persons working in Karde;
- Geriatric hospital departments in Oslo;
- Contact with community health care in Oslo .

In Cyprus, PwD and their informal caregivers are recruited through:

- After identifying the potential participants their informal caregivers and healthcare professionals will be approached.

For recruitment, the following documents are available and can be adapted and used according to local needs in each country:

- Invitation letter (appendix G);
- Information leaflet (appendix H), to be received together with the invitation letter;
- Confirmation letter (appendix I), to be received by the participants 3 days prior to the exploratory session and/or interview.

Inclusion criteria for healthcare professionals are as follows:

Inclusion criteria pharmacist

- Occupation as a community (common) or hospital pharmacist;
- Experienced with medication review in persons with mild dementia;
- Experienced in medication administration at client level.

Inclusion criteria family doctors, nursing home physicians, home nurses or case managers (Dutch health care professional managing the health care process around the PwD).

- Participates in the management of the PwD medication;
- Basic level of experience with a computer or willingness to learn;

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

## 2b. Exploratory session

For the healthcare professionals, we advise to organize a group meeting for the exploratory session, because professionals are limited in time. And next to this, the group effect and interactions deepens the reactions on the topic of polypharmacy management within the group of PwD in the early phase. If you decide to do individual interviews, maybe at the workplace of the professional, make an appointment of one hour.

For the exploratory session, you can use the time scheme below.

Duration In minutes	Activity	Content	Responsible
60	Coffee & Lunch Project members welcome the participants	Make the participants feel at home. Have informal conversations with them from the start.	Project members
15	Plenary introduction	<ul style="list-style-type: none"> <li>• Plenary welcome and introduction;</li> <li>• Presentation about the project and study outline;</li> <li>• Room for questions;</li> <li>• Informed consent procedure.</li> </ul>	Project members



HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

	<p>Communication (All professionals)</p> <p>Technological support (All professionals)</p> <p>Online tools/"talking sheets" (All professionals)</p>	<p>promote adherence. Which support tools do they use for improving adherence in PwD? For example electronic pill boxes? How do they simplify the regimen of daily adherence? Is adherence discussed in regular medication reviews?</p> <p>How do they support the PwD to get the medication regime in their daily routines? Which tips and tricks do they have?</p> <p>How do they improve the health behavior and knowledge/education about the medication and skills for adherence within this group? How is the counselling-process with PwD and their caregivers?</p> <p>How do they communicate to patients about their problems within medication adherence and their concerns and fears?</p> <p>How do they evaluate adherence within PwD?</p> <p>What technological support do you use to monitor/evaluate/improve medication adherence?</p> <p>What other technological support do you know?</p> <p>Do you think an online tool aimed at improving/supporting adherence in PwD is useful?</p> <p>What do they think of the online tools presented in the "talking sheets" do they have comments or suggestions? ("talking sheets" see appendix E; Presented on a screen or in print).</p> <p>Which functions should an online tool to support adherence in PwD have according to the professionals? Do they have suggestions?</p>	
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HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

	<p>Medication Review  (questions for pharmacist or professionals managing/reviewing medication).</p>	<p>How can this online tool be incorporated in their daily work-routines?</p> <p>Do they see opportunities for an online tool for interprofessional cooperation? Which suggestions do they have?</p> <p>How would you like to be supported in the care process? What would you like to know about the senior's wellbeing?</p> <p>How often is review of drugs done for PwDs?</p> <p>Who is doing this drug review?</p> <p>How often is medication changed after drug review?</p> <p>Is there any trend in such changes? If so, what?</p> <p>What is used to prevent drug interactions (e.g. which online tools should be used when prescribing)?</p> <p>Who usually suspects drug interaction in a PwD?</p> <p>Which adverse effects of medication used by PwD (both for dementia and other diseases) do you consider most important to discover?</p> <p>How are these adverse effects discovered?</p> <p>Which adverse effects do you think could be monitored and discovered by sensors now or in the future?</p> <p>Which symptoms are difficult to know if they are adverse effects of drugs or progression of the dementia disease?</p> <p>How could such adverse effects and progression of disease be differentiated?</p> <p>How could sensors and an ICT system help differentiate between adverse effects and progression of the dementia disease?</p> <p>When should medical treatment for the</p>	
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## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

		<p><u>dementia disease</u> in PwD be discontinued? (for example when PwD notice no effects of dementia medication).</p> <p>Are there guidelines in your country for such discontinuation of treatment? if so, where can they be found?</p>	
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### Numbers to be included

The following numbers of secondary end-users (formal and informal caregivers) have to be included in the Understanding phase (see page 11 of the application form of MedGuide):

KARDE (Norway): 8

MAT (Cyprus): 6 – 8

IVM & HU-UAS (the Netherlands): 12 – 16.

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

## 3. Planning

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
<i>Selection/ Recruitment</i>									
<i>Organization session</i>									
<i>Interviews at home</i>									
<i>Local analysis</i>					Local results to HU-UAS no later then 31 may 2017				
<i>Project analysis</i>									
<i>Meeting Oslo</i>									

In this table the planning is given to gather the input for the requirements of the PwD, their carers and the professionals.

Make sure that the input from Norway and Cyprus is send to HU-UAS at the beginning of week 22.



HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

## Appendix

### Appendix A: invitation



Dear Sir / Madam,

MONTH 2017

MedGUIDE is a project that provides an innovative approach to support people with dementia with their medication adherence. MedGUIDE is a digital platform that will bring together informal caregivers, medical professionals, pharmacists and the patient themselves.

MedGUIDE supports patient, the informal caregivers and the professionals. The patient and informal caregivers will be able to prolong independent living by improving medication adherence, by learning about the disease, and by creating a personalized roadmap. The pharmacist will be able to monitor medication adherence, identify potential harmful side effects of medication, and to provide guidance in dementia polypharmacy management.

We kindly ask you to join the MedGUIDE project. You are approached for this project because you or your partner has early dementia. You decide whether you want to join the project.

In the information letter, you will find more information about the project and what you can expect. Read this letter therefore carefully before making a decision. The project is implemented by NAME OF YOUR ORGANIZATION and partners in this project and is funded by the European Active and Assisted Living Program (AAL).

To develop MedGUIDE we want to know what your wishes and needs are, therefore we would like to talk with you. If you want to participate in this project we invite you to the meeting of DATE, TIME AND LOCATION. Travel costs can of course be declared. You can register yourself by contacting NAME, EMAILADRES AND PHONE NUMBER. Please mention in your notification the following information:

- Name;
- Telephone;
- Alternatively, e-mail address.

#### **Project partners**

MedGUIDE is a joint project with parties from the Netherlands, Switzerland, Romania, Norway and Cyprus. The parties are: Connected Care (project coordinator), University of Applied Sciences Utrecht, Karde AS, Technical University of Cluj-Napoca, Vigisense, Dutch Institute for Rational Use of Medicine

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and Materia Group. The project is part of the AAL Joint Program funded by the European Union and with the cooperation of National Funding Authorities.

You can read more about the project: [URL OF YOUR WEBSITE WITH PROJECT INFORMATION](#)  
We hope to welcome you on [DATE AND LOCATION](#).

## HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

### Appendix B: information letter MedGUIDE



#### **Background**

We are all getting older, more and more people get age-related diseases. Medications are essential for the treatment of various health problems. Usually there is multiple health problems at the same time, bringing the number of prescription drugs is high. If this is the case we speak of polypharmacy. It is important that medications be taken at the right time and in the right dosage. When there is dementia have shown that taking the medication regularly is becoming increasingly difficult. This shows that there is a need for support to increase adherence. To support the therapy we are developing a technological intervention. We feel it is important to take into account the needs of the person with dementia and the caregiver. We hope to support the caregiver so professional care can be reduced, the caregiver can be spared and the security can be increased.

#### **Aim**

At the end of the study we want to know what the needs are for people with PwD living at home with early dementia with polypharmacy and the needs of their caregiver (s) are related to online support adherence. The information will be used to MedGUIDE shape, with the aim to support compliance.

#### **MedGUIDE**

MedGUIDE is a digital platform that caregivers, healthcare professionals, pharmacists and the person with dementia brings together. The platform collects information in several ways, so that a display can be given of how it goes with compliance.

#### **Project partners**

MedGUIDE is a joint project with parties from the Netherlands, Switzerland, Romania and Cyprus. The parties are: Connected Care (project coordinator), Utrecht University of Applied Research (HU-UAS), Karde AS, Technical University of Cluj-Napoca, Vigisense, Dutch Institute for Rational Use of Medicine and Materia Group. The project is part of the AAL Joint Program funded by the European Union and with the cooperation of National Funding Authorities .

#### **First Meeting**

NAME OF YOUR ORGANIZATION is one of the partners in the project and is responsible for exploring the needs and requirements of end users. The end users are people with early dementia, the carers and also healthcare professionals.



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The first meeting of the MedGUIDE project is DATE, TIME AND LOCATION. This meeting will provide more information of the project and there is the possibility to ask questions. For this meeting, people with early dementia, carers and healthcare professionals will be invited. The meeting will contribute to map out the wishes and needs. The meeting will conclude with a lunch.

#### [Appendix C: confirmation letter](#)

Dear Sir/Madame,

Thank you for your commitment and confirmation to participate in the first session.  
The address to be located is as follows:

Address + date and time

**Accessibility**

Parking information (pay and free)

Walking directions

Building information

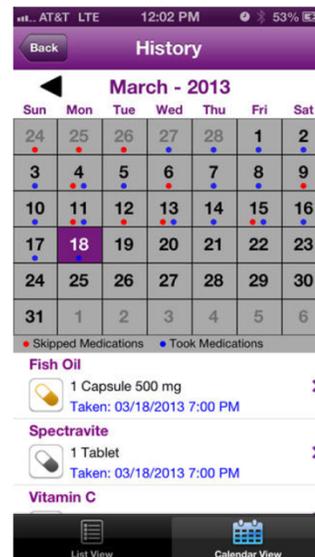
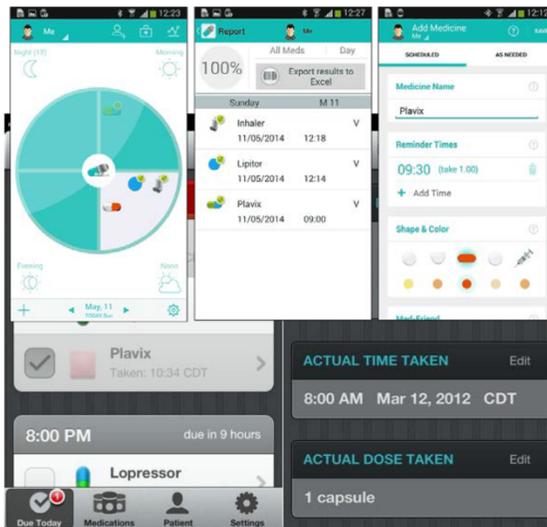
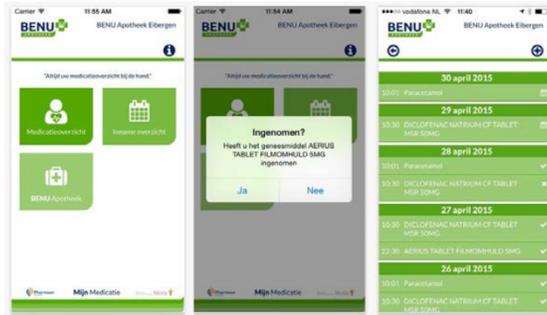
Names and phone numbers

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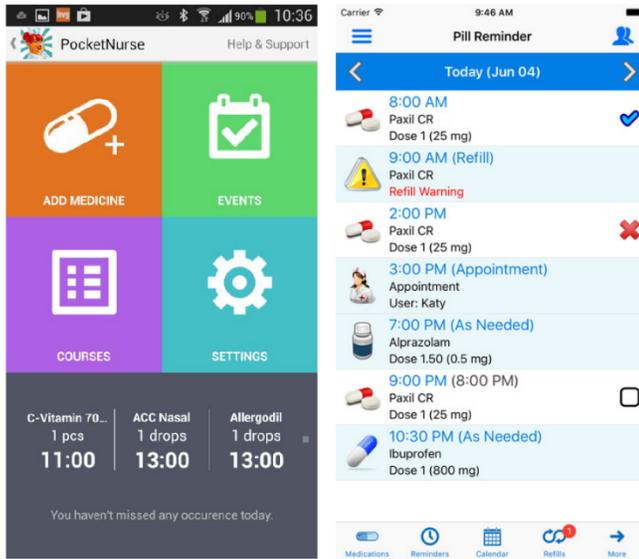
Appendix D: PowerPoint presentation

HU-UAS used the PowerPoint from the kick-off session in Arnhem (only used for professionals)

Appendix E: examples of talking sheets



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Appendix F: informed consent

**Certificate of consent (MedGUIDE)**

*Title research:*

MedGUIDE: technological intervention in support of dementia therapy

*Responsible researcher:*

NAMES

To be completed by the participant

I declare to be informed in a clear manner about the nature, method, purpose and [if present] the risks and taxes of the investigation. I know that the data and results of the research will only be disclosed anonymously and confidentially to third parties. My questions have been answered satisfactorily.

I volunteer to participate in this research. I hereby reserve the right to terminate my participation in this investigation at any time without giving reasons.

Name contestant: .....

Date: ..... Signature of participant: ... ..

To be completed by the executive researcher

I have given an oral and written explanation of the research. I will answer remaining questions about the research into ability. The participant will not suffer from any premature termination of participation in this research.

Researcher's Name: .....

Date: ..... Signature of researcher: ... ..

Source: Baarda & De Goede (2006)



Appendix G: invitation professionals



**Invitation**

Dear Sir / Madam,

MONTH 2017

MedGUIDE is a project that provides an innovative approach to support people with dementia with their medication adherence. MedGUIDE is a digital platform that will bring together informal caregivers, medical professionals, pharmacists and the patient themselves.

MedGUIDE supports patient, the informal caregivers and the professionals. The patient and informal caregivers will be able to prolong independent living by improving medication adherence, by learning about the disease, and by creating a personalized roadmap. The pharmacist will be able to monitor medication adherence, identify potential harmful side effects of medication, and to provide guidance in dementia polypharmacy management.

We kindly ask you to join the MedGUIDE project. You are approached for this project because as a professional since you have experience with the care of people with dementia. You decide whether you want to join the project.

In the information letter you will find more information about the project and what you can expect. Read this letter therefore carefully before making a decision. The project is implemented by NAME OF YOUR ORGANIZATIONxxx and partners in this project and is funded by the European Active and Assisted Living Program (AAL).

To develop MedGUIDE we want to know what your wishes and needs, therefore we would like to talk with you. If you want to invite us to participate in this project you to the meeting DATE, TIME AND LOCATION. Travel costs can of course be declared. You can register yourself by contacting NAME, EMAIL, PHONE NUMBER. Please mention in your notification the following information:

- Name;
- Organization;
- Telephone;
- Alternatively, e-mail address.



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**Project partners**

MedGUIDE is a joint project with parties from the Netherlands, Switzerland, Romania and Cyprus. The parties are: Connected Care (project coordinator), University of Applied Sciences Utrecht, Karde AS, Technical University of Cluj-Napoca, Vigisense, Dutch Institute for Rational Use of Medicine and Materia Group. The project is part of the AAL Joint Program funded by the European Union and with the cooperation of National Funding Authorities.

You can read more about the project: [URL OF YOUR WEBSITE WITH PROJECT INFORMATION](#)  
We hope to welcome you on [DATE AND LOCATION](#).

## Appendix H: information letter professionals

**Information letter MedGUIDE****Background**

We are all getting older, more and more people get age-related diseases. Medications are essential for the treatment of various health problems. Usually there is multiple health problems at the same time, bringing the number of prescription drugs is high. If this is the case we speak of polypharmacy. It is important that medications be taken at the right time and in the right dosage. When there is dementia have shown that taking the medication regularly is becoming increasingly difficult. This shows that there is a need for support to increase adherence.

To support the therapy we are developing a technological intervention. We feel it is important to take into account the needs of the person with dementia and the caregiver. We hope to support the caregiver so professional care can be reduced, the caregiver can be spared and the security can be increased.

**Aim**

At the end of the study we want to know what the needs are for people with PwD living at home with early dementia with polypharmacy and the needs of their caregiver (s) are related to online support adherence. The information will be used to MedGUIDE shape, with the aim to support compliance.

**MedGUIDE**

MedGUIDE is a digital platform that caregivers, healthcare professionals, pharmacists and the person with dementia brings together. The platform collects information in several ways, so that a display can be given of how it goes with compliance.

**Project partners**

MedGUIDE is a joint project with parties from the Netherlands, Switzerland, Romania and Cyprus. The parties are: Connected Care (project coordinator), Utrecht University of Applied Research (HU-UAS), Karde AS, Technical University of Cluj-Napoca, Vigisense, Dutch Institute for Rational Use of Medicine and Materia Group. The project is part of the AAL Joint Program funded by the European Union and with the cooperation of National Funding Authorities.

**First Meeting**

is one of the partners in the project and is responsible for exploring the needs and requirements of end users. The end users are people with early dementia, the carers and also healthcare professionals.



#### HU-UAS Task 1.1 – MedGUIDE: Research Protocol FINAL

The first meeting of the MedGUIDE project is on Tuesday, April 11th, 2017 at 10:00 am at the University, Padualaan 99 in Utrecht (Uithof). This meeting will provide more information of the project and there is the possibility to ask questions. For this meeting, people with early dementia, carers and healthcare professionals will be invited. The meeting will contribute to map out the wishes and needs. The meeting will conclude with a lunch.

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[Appendix I: confirmation letter professionals](#)

**Confirmation letter**

Dear Sir/Madame,

Thank you for your commitment and confirmation to participate in the first session.  
The address to be located is as follows:

Address + date and time

**Accessibility**

Parking information (pay and free)

Walking directions

Building information

Names and phone numbers