PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

Alzheimer Europe

Consultation on Patient Engagement on development of medicines in dementia.

24 October 2018

Contents

1 INTRODUCTION AND OVERVIEW OF PATIENT ENGAGEMENT IN THE DEVELOPMENT OF MEDICINES IN DEMENTIA

PARADIGM WP1 aims to gain a better understanding of the needs, expectations and aspirations of the different stakeholders involved in patient engagement in the development of medicines and research. Specifically, PARADIGM is aiming to understand the role of patient engagement at three time-points during medicines development:

- Setting the research agenda
- Involvement in the design of research and clinical studies
- Early dialogues with regulators and HTA bodies

As part of this work, an online survey was conducted between June and August 2018. In the case of people with dementia and young people, it was decided that in addition to the survey, a face-to-face consultation would be carried out as this was deemed to be a more appropriate method to explore their views. This report presents the methodology used and main findings of the consultation carried out with people with dementia and their carers.

1.1 Overview of Patient Engagement in the process of developing medicines in dementia in Europe.

There is a growing interest and consensus on the relevance of engaging patients throughout the lifecycle of medicines development. Patients' views, expectations and experiences are crucial as they are living with the medical condition, experiencing the symptoms and will be the people taking the medicines as part of their treatment. Furthermore, there is increasing evidence that patients' input and collaboration can bring important benefits for those developing the medicines or involved in this process (Barber et al. 2011, Hoos et al. 2015).

In a few countries, like in the UK, some health research funding schemes require patients and the public to be involved in research design and in the development of grant applications[1]. However, this is not the norm for all European countries. Patients

[1] For example, several research programmes funded through the National Institute for Health Research (NIHR) in the UK require the involvement of patients and the public in the grant application and in the research for which funding will be awarded.

continue to be a largely underutilised resource in medicines development and research.

In the case of dementia, this is an even greater challenge. The importance of engaging and involving people with dementia in research and service development has been recognised in some European countries. However, patient engagement activities linked to the development of medicines in dementia seem to be less common. In a group discussion with sixteen members of Alzheimer Europe (AE) (i.e. national Alzheimer organisations) in a Public Affairs meeting in Brussels, it was highlighted that whilst this is an area of potential interest to associations, people with dementia and carers, patient engagement in the development of medicines is not yet a common practice in dementia. Some Alzheimer organisations have developed good collaboration with pharmaceutical companies, but this is often to raise awareness of existing clinical research in their country and/or to help with recruitment of research participants for a trial. Some of Alzheimer organisations have involved people affected by dementia in research (e.g. in decisions for funding research or about topics of interest) but this is less often in research linked to developing medicines. At European level, members of the European Working Group of People with Dementia (see next section for further information about the EWGPWD) have been involved in different IMI research projects (e.g. providing input about outcomes which are of relevance to dementia and in the area of prevention and disclosure of risk in dementia) and have been invited by the European Medicines Agency (EMA) to take part in evaluations of medicines as patient experts.

2 METHODS

2.1 The European Working Group of People with Dementia

AE set up the European Working Group of People with Dementia (EWGPWD) in 2012. The EWGPWD is comprised entirely of people with different forms of dementia who are nominated by their national Alzheimer associations for terms of two years. In 2018, the EWGPWD had 11 members. Members of the EWGPWD have mild to moderate dementia and every member has the right to be accompanied to the meeting by a person of his/her choice to ensure safe travel and/or provide support during the meeting. The working language of the group is English, some of the members need interpretation and translation support during the meeting. The

EWGPWD works to ensure that the activities, projects and meetings of AE duly reflect the priorities and views of people with dementia. Members of the EWGPWD have been involved in several IMI, FP7 and H2020 research projects through PPI activities.

As part of the Work Package 1 of PARADIGM a consultation with EWGPWD members and their carers[2] was conducted to explore their understandings, expectations, motivations, needs and the expected outcomes of taking part in a patient engagement activity in the development of medicines. The consultation took place during the EWGPWD meeting in Brussels on 27-28 June 2018.

2.2 Preparation of the consultation

A guide for the facilitators was developed with questions about the different topics of interest to PARADIGM. The guide was developed by AE with input from WP1 leaders (Chi Pakarinen from the Synergist and Daphnee Pushparajah from UCB) and from the co-facilitators. The guide included a set of overarching questions that allowed a free-flowing discussion and several prompt questions to be used as needed. In addition, vignettes related to the three decision making-points of interest to PARADIGM (i.e. setting up the research agenda, design of clinical trials and early dialogues with regulators and HTA bodies) were developed. Vignettes can be described as short stories about hypothetical characters in specified circumstances, to whose situation the interviewee is invited to respond. This technique allows actions in context to be explored, encourages all participants to voice opinions and gives them some distance from the topic if needed. A copy of the guide for facilitators is provided in Appendix 1.

Two weeks in advance of the meeting members of the EWGPWD received a document with relevant information about the project and the consultation. Members of the group who are not fluent in English, also received a copy of the vignettes and key questions, which were translated to their mother tongue. This enabled members

[2] This refers to the person who had accompanied the person with dementia to the meeting to provide any necessary support during travel and/or at the meeting. This person was in some cases a family member (e.g. spouse or adult child), a friend or a staff member of the Alzheimer society. The term does not necessarily imply the provision of care per se. Different terms exist (e.g. supporter, caregiver, care partner etc.) but in this report, for the sake of simplicity, the term “carer” will be used.

to discuss in advance their views and opinions with the person accompanying them to the meeting.

2.3 The consultation

The consultation was co-facilitated by AE (Ana Diaz, Dianne Gove), Sebastien Libert (PhD student, AE/INDUCT) and representatives from industry (Sharareh Hosseinzadeh, Novartis), academia (Suzanne Ii, University of Oxford) and HTAs bodies (Neil Bertelsen, HTAi) from the project.

The consultation was held over two days (an afternoon and a morning). Prior to the consultation, an introductory presentation about the PARADIGM and WP1 was provided. Members of the EWGPWD and their carers were given the opportunity to ask questions about the project or the topics of interest before the consultation started. The first afternoon was dedicated to exploring their understandings of patient engagement in general and in dementia, their personal experiences and relevant barriers and facilitators. In the morning of the second day, the group was split into three sub-groups and with the aid of the vignettes, each group discussed about: who should be invited to participate in patient engagement activities, motivation to participate in patient engagement activities and the needs, expectations and outcomes of taking part. Each group addressed one of the three decision-making points relevant to PARADIGM and the discussions were co-facilitated by a member of AE and a member of the consortium with expertise in the decision-making issue.

Although there was a guide, questions were adapted to the needs and dynamics of the group. All people were encouraged to talk. Facilitators promoted a positive and respectful environment which could encourage people to share their perspectives and views. Members of the EWGPWD, their carers and the facilitators had also the opportunity to spend social time together over lunch and dinner.

2.4 Who participated in the consultation?

All members of the EWGPWD and their carers took part in the consultation. Whilst, usually in the meetings of the EWGPWD, the carer is only expected to facilitate communication and not to speak on his/her own behalf, this consultation also sought the views of any carers in attendance.

In total, 11 people with dementia and 10 carers from the following countries, participated in the consultation:

- Belgium
- Bosnia & Herzegovina
- Czech Republic
- Finland
- Germany
- Ireland
- Portugal
- Slovenia
- Switzerland
- UK: England, NI and Wales
- UK: Scotland

Photos of members of the group, carers and facilitators in Brussels.

2.5 Approach to analysis and presentation of the input provided in the consultation

With permission from people with dementia and their carers all the discussions were audio recorded. In addition, during the meeting, summaries of the discussions were written in a flipchart to help people with dementia keep track of the discussions and issues raised. A rapporteur from each of the three sub-groups working on the vignettes, presented a summary of the discussions and conclusions to the whole group. Two people with dementia and a carer acted as rapporteurs.

After the meeting, members of staff of AE listened to the audio recordings (including the summaries provided by the three rapporteurs) and looked at the notes in the flipcharts. A thematic approach to analysis was used to organize the input provided during the discussions and to write the feedback for PARADIGM.

A draft of the report was shared with the co-facilitators of the consultation and their feedback was taken into account. In order to achieve a Patient and Public Involvement (PPI)-informed perspective on the data, two members of the EWGPWD and one carer were also invited to review the way the input was presented and their feedback was included in the report.

The vignettes looked at the perspectives of people with dementia and their carers at each of the three PARADIGM decision-making points separately. However, the majority of the issues and concerns raised were quite similar across the three points. Thus, in the presentations of the findings, differentiation between the three points is only made when necessary, otherwise the suggestions and concerns are applicable to the three points. Direct quotes from the discussions and from the rapporteurs's summaries are used in the presentation of results.

3 RESULTS

3.1 Patient engagement in the process of developing medicines in dementia

3.1.1 Understandings and definition of patient engagement

All members of the group and carers agreed on the importance of patient engagement in the process of developing medicines. When asked about the first word that came to mind when they heard the word patient engagement, the most frequent words mentioned were "hope" and "future". Other words that were mentioned included: "trust", "commitment", "quality", "transparency", "benefit for patients", "involvement", "support and patience" and "awareness".

The group had the opportunity to look at the definition of PARADIGM of patient engagement in medicines development and to provide some feedback in the context of dementia. PARADIGM's definition is as follows: *"The effective and active collaboration of patients, patient advocates, patient representatives and/or carers in the processes and decisions within the medicines lifecycle, along with all other relevant stakeholders when appropriate. Meaningful patient engagement brings mutual benefit to the community of medicine developers (meaning all stakeholders involved from patients, industry, regulators, HTA bodies to payers) and ultimately better patient outcomes. It requires inputs into decision-making, co-production and dissemination of knowledge".*

In general terms, it was welcomed that different people could provide patient input (e.g. patients, carers, patient advocates and patient representatives) but this was also a concern in terms of potential lack of transparency about which kind of stakeholder had been involved in any particular involvement process. This was perceived as particularly relevant in the case of dementia, where involving a proxy (e.g. a family carer or a patient representative) may be less challenging than involving the person with the condition him/herself. It was also highlighted that some of the words used in the definition were a bit vague. For example, in relation to the word “collaboration”, it was felt that it could be more clearly spelt out that collaboration should include the implementation of input into a project or activity and feedback to patients after the engagement on what had been implemented. The patient’s experiences and input should not just be heard but also acknowledged, appreciated and used. Patient engagement activities should be carried out in a systematic way and it should be acknowledged that different levels of involvement are possible. It was suggested that the definition should include that collaborations should start as early as possible in the process and also that it should contain some reference to ethical principles. Another issue of concern was the term “when appropriate” as it was not clear why and by whom it would be decided when it was or not appropriate to involve patients. In the case of dementia, it was highlighted that patient engagement needs to be accessible and inclusive of the whole patient community. This is something that could be included in the definition. Patient engagement should take into consideration the values, needs and preferences of all patients including those who, for different reasons, may be more vulnerable.

3.1.2 Diversity of experiences across Europe

Overall, it was felt that this type of involvement was not as frequent in their country as they would have liked it to be. Some participants said that, in their country, there was a lack of interest in dementia and in dementia research, and thus very little or nothing had been done in patient engagement in this area. Stigma and late diagnosis of dementia were also considered as playing a role in the lack of patient engagement activities in some countries.

In some countries, it was felt that progress had been made and that although still not to an ideal standard, there was an improvement on the way patients were engaged by different stakeholders.

> *In [name of country] there has been a certain change in the pharmaceutical industry. I think mainly [name of company]changed a lot because they realized that they could get some benefit out of a better cooperation with patients and now they are really collaborating and I think it is for the best (Person with dementia 1).*
>
> *Having that commitment in the [name of agency] is a massive step for us, for people with dementia and carers to be able to say why are we not involved from the beginning? why are you only talking to a carer when is coming to an end? It is an important step. It is moving in the right direction (Person with dementia 2).*

There was a concern in relation to tokenism, and it was felt that sometimes the involvement of patients came too late and it was just to "tick a box".

> *Everything has changed and nothing has changed in [name of country]. There is a lot of tokenistic involvement, we have been led to believe that we are involved but we are not actually involved from the beginning to the end (Person with dementia 3)*
>
> *I sit in a panel in the (name of state agency that supports research) in (name of country). They were funding projects so we had to evaluate them, the PPI involvement, and one thing that came out was that absolutely none of them had engaged with PPI at the start and that was the discussion. They couldn't see why. A number of organisations and research bodies, they couldn't see what the benefit was of bringing the patients in early (Carer 1)*

3.2 Who should be engaged?

3.2.1 The voice of the person with dementia

There was a strong agreement among members of the EWGPWD and their carers that the voice of the person with dementia is critical and should, in all cases, be

prioritized over the voice of others such as patient representatives or carers. They are the people living everyday with the condition and their involvement can help to ensure that any developed medicines are responsive to the needs, preferences and values of people living with dementia. They are the "experts by experience" and their input is unique as the people living with the condition can bring to the table knowledge and experience that other experts, such as clinicians or researchers, may not always have.

> *Nothing should be done without an "expert by experience" around the table, nothing about us should be done without all of us. We are experts in our dementia. I am living with my illness daily, I experience and feel things that can't always be learnt by the professionals in my care or who sat around a committee table. We see things that perhaps the professional will never learn, and we don't know things that the professionals have learnt (Person with dementia 3).*

> *It is important to involve the person with the diagnosis, with the lived experience. How can others speak on their behalf? They do not have the "lived" experience. (Carer 2).*

The perspectives of other people affected by the condition such as carers, family members and friends were considered as important and it was felt that their input should also be taken into account, however their voice should not replace or take over the "true" voice of people living with the condition.

> *The person with dementia is an expert in their own experience, but also the person with them, the carer is also an expert in dementia as well, because they know the person, sometimes better than themselves. (Person with dementia 3).*

> *It should not just be the carer taking along the person, you want to also listen to the voice of the person with dementia. It is not just the carer having the voice. (Person with dementia 3).*

Organisers of patient engagement activities in the development of medicines should be clear and transparent about who was engaged in the activity (e.g. the person with the condition or another person on their behalf).

> *A patient by experience is the person who lives with the condition. Some companies may invite a patient representative or a carer, if this is the case, this has to be clear, whether it is the person with the condition him/herself or a person on his/her behalf. It is not the same, the perspectives may not be the same (Person with dementia 1).*

3.2.2 Diversity and representation

Relevant discussions were held around the issue of the diversity of patients' voices (e.g. age group, sex, country, type and stage of dementia etc.) and fairness. Participants felt that several different voices should be heard and considered and that as many people as possible should "*be given the opportunity*" to take part in PE. In relation to fairness, some concern was raised in relation to people who may experience more difficulties for taking part in PE activities such as for example, people living in rural or remote areas and unaffiliated people with dementia and their carers.

> *Where we live there is barely any information about possibilities to take part in this kind of activities, in patient engagement. I look for information in Internet, in google, but other people don't. More information about this should be available. (Carer 3).*

The topic of representation was also raised in the discussions, and in particular, the caveat of whether and to what extent a person can "represent" a whole group or community. The idea of diversity of opinions and of various lived experiences was perceived as more important than that of representation. Each person can bring the richness of their own experience of receiving a diagnosis and living with the condition. A diversity of experiences are needed to input into patient engagement process.

> *Dementia affects people in different ways, so how can one single person say? We are only experts in our own dementia for the period of time that we have had the diagnosis. So it is very difficult for any of us to go and give advice and generalize it. We can base it in our own experience entirely, we are all different. (Person with dementia 3).*

3.2.3 Profile of the person involved

Different views were expressed in relation to the skills and experience that may be required for a person with dementia to be engaged in the process of developing medicines. On the one hand, for some "living with the condition" was the only factor that should be considered. This would allow for more people to be able to participate and it was perceived as more democratic way of organising engagement activities.

> *You are an expert because you are the one living everyday with the condition, that's it. It is the lived experience that matters. (Person with dementia 4).*
>
> *It should not be all the time the same people, it is not fair. (Carer 1).*

Other people felt that well-defined and clear criteria should be developed when considering the kind of person who should be invited to participate in the patient engagement activity. In the case of dementia, there are a range of criteria that can define a person's experience with the condition such as: the symptoms they experience, the progression of the condition and their own life experiences, situation and background. The person with dementia should be open and willing to share and communicate his/her lived experience.

> *You can't be tokenistic about this, you can't just plug someone off the street with the diagnosis, you need to spend a bit more of time and get to know the person and try to find someone a bit relevant, so he can give you the advice that you are asking. (…) You should not just look at their dementia. The person might have been a researcher or a doctor so her skills, you should not forget that. (Person with dementia 3).*

It was highlighted that engaging people at advanced stages of dementia could be more challenging, particularly when this involves highly technical and complex discussions. Also, it should be taken into consideration that receiving a diagnosis of dementia is life changing. When the diagnosis of dementia is disclosed, people may experience a range of different emotions (shock, fear, anxiety, sadness etc.) and some people may need some time to adjust and come to terms with the diagnosis. Finding the right time to engage people after diagnosis is important and may differ from person to person.

3.2.4 Finding people to be engaged

Members of the group and their carers recognised the value and importance of developers of medicines contacting and working together with Alzheimer associations. Some members felt that the associations know well the people with dementia and this could help them to decide whom to invite and also to the type of support this person may need. Some felt this could also reassure the patient about the trustworthiness of the company/organisation.

> *It is good that the pharmaceutical companies are working with the Alzheimer Societies, because they know me (name), so therefore they may have some ideas of … like the stage of my illness, my personality, and how to involve me (Person with dementia 2.*

> *It is a matter of trust. There are so many companies now out there announcing they have a cure for dementia, they have something … whatever and you don't know who they are, what their motives are. So if the invitation comes through the association then you feel you can trust them. (Person with dementia 5).*

On the other hand, there was a concern that only a proportion of the people affected by dementia are members of an Alzheimer association.

> *Because it may be for example a Society, but in our country that's only meeting a 5% of the people with dementia. You got to find ways to engaging the other 95%. There are people out there who want to be involved but don't know how. (Carer 4).*

Raising awareness of the relevance of patient engagement and research and of the opportunities that exist, was perceived as an important step to reach out to these communities. This was for many an important task where Alzheimer Societies could play a significant role.

3.3 Enabling meaningful engagement

It was highlighted that a rights-based approach should be used when thinking about patient engagement. A person with dementia should have the same opportunities to participate in patient engagement activities than any other patient. The topic of

enabling engagement, and in particular how to best address their specific needs and preferences and make engagement meaningful was a very salient topic in all the discussions.

Six main broad themes were identified as particularly relevant in enabling meaningful engagement in dementia:

1. Myths and misconceptions about dementia,
2. Issues related to accessibility and reasonable accommodation,
3. Personal support,
4. Information,
5. Training and induction,
6. Guiding principles (autonomy, respect and equality).

3.3.1 Addressing the myths and misconceptions about dementia

An issue of concern raised in several different contexts during the discussions was that of the existing stereotypes about, misconceptions of and stigma surrounding dementia. Members and carers explained that once the person is diagnosed, there is often an assumption about what the person can and can no longer do, and a tendency to focus on images which are more representative of fairly advanced dementia. As one of the members of the group eloquently said, "*The diagnosis doesn't make us stupid, we just need the support*".

There was a reference to a double jeopardy, as they are described as "patients", a term which has negative connotations and carries implications of passivity, and also as having dementia which is often linked to diminished or impaired capacity and decline of abilities. It was felt that in order to promote and respect the autonomy of people with dementia these misconceptions and stereotypes need to be overcome.

3.3.2 Issues related to accessibility and reasonable accommodation

The meaningful engagement of people with dementia is dependent on measures having been taken to ensure accessibility. The group emphasised the importance of reasonable accommodation or adjustment which was described as any change or action that had to be implemented in the activity, or in the way things were customarily done, that would provide an equal opportunity to participate to a person

living with dementia. These measures or actions would enable the person with dementia to participate in the patient engagement activity in the development of medicines on the same basis as patients without dementia. Discussions on this topic focused on two aspects: (i) the structure and format of the patient engagement activity/meeting and (ii) its contents.

(i) Issues related to the structure and format

It was felt that often the patient engagement activity or meeting is organised in a way that does not respect the specific needs of the person with dementia. For example, meetings may be planned very early in the morning after travelling, may be too long, may not have regular breaks planned, or the pace of the discussions may be too fast and technical. In addition to this, in some cases, insufficient consideration has been given to ways in which to involve them in a meaningful way. This could be particularly relevant in meetings with regulators and HTA bodies where highly technical discussions may take place.

> *Sometimes you get invited to a meeting, this is great, but then they just bring you there and they carry on as if you weren't there. They haven't thought about you being there and how to make it a bit easier for you. (Person with dementia 6)*

Appropriate adjustments to the structure and format of the patient engagement activity / meeting could encourage a person with dementia to confidently contribute during the engagement, while making sure that the time and energy commitment was appropriately matched to their particular needs.

The need for a flexible approach was widely discussed. Examples included flexibility in the methods of communication which may be more suitable to the person with dementia and consideration about the time of the day when people with dementia may be more alert and when it may be easier for them to contribute. Also, if travelling is too challenging or not possible for the person alternative ways of participation should be considered (e.g. by video conference or in writing).

> *If possible meetings should be in the morning, never in late afternoons, because then we are too tired and it is more difficult to contribute. (Excerpt from rapporteur's summary).*

The presence of the carer in the meeting when required was also perceived as very important. If the person with dementia requires support during the meeting, the carer, should receive any relevant documentation and be allowed to sit in the meeting to provide any necessary support to the person with dementia. This may be a challenge when information discussed is confidential and also, in some cases, when only one person is expected to attend the meeting.

> *Some people with dementia need support during the meeting. There should be a place at the table in the meeting for the person supporting the person with dementia. (Person with dementia 3).*

Some other suggestions to facilitate meaningful participation included the person with dementia receiving a few questions or topics from which his/her feedback would be particularly relevant in advance of the meeting, allocating specific time during the meeting for the person to speak and offering the person breaks during the meeting if necessary. It was highlighted that some people find an "I want to speak" card/symbol helpful in meetings.

> *You receive a lot of information but it is not clear what is expected from you, where … in all of this your views are relevant. If there is anything specific that they want from the person with dementia, then they should be explicit before the person gets there, of course there may be also other questions or issues that may crop up during the meeting but at least to know what they think would be valuable to know or discuss from the perspective of the patient. This can gives us some food for thought, a bit of structure. (Excerpt from rapporteur's summary).*

ii) Contents

The contents of the patient engagement activity /meeting should be adjusted and suitable to the needs of the person. Some of the issues highlighted included: the accessibility of the materials received, the use of plain language during the meeting and in particular and avoiding the use of jargon, acronyms and highly technical terms. Efforts should also be made to ensure that the questions asked and the way in which the questions are presented, are appropriate for a lay person/patient. For example, the input from a person with dementia about clinical trial endpoints could be very relevant for a regulator or a company, however the question should be

phrased in a way which is understandable for the person and which make his/her contribution possible. Some of these issues are discussed in more detail in the section 3.3.4 information.

> *Don't ask me questions that I don't know how to answer. Don't make it terribly complicated. Ask me about my quality of life, what this means to me, what I like to do or what I need to carry on with my life … not about outcomes or endpoints or whatever words you use. (Person with dementia 2).*

Other relevant practicalities that could enable their participation included:

(i) if the meeting is held early in the morning, the person with dementia and the carer should be offered the possibility to arrive the day before the meeting, so that they could have sufficient rest and make a good contribution to the meeting,
(ii) organising the travel and accommodation of the person in advance so that the person does not incur any costs and reimbursing any costs as soon as possible,
(iii) accessible parking at the venue if necessary,
(iv) clear signposting and information about relevant places in the building (e.g. toilets, exits etc.),
(v) offering drinks or a meal particularly during long meetings.

3.3.3 Personal support

Many people with dementia may need to be supported to be able to take part in a patient engagement activity. The group emphasised that the type of support the person may need, when the support is required (e.g. for travelling, preparation of the activity, during the activity) and the person providing such support may be different for each person. This has to be taken into consideration when organising the patient engagement activity and discussions should be held, early on in the process, with the person with dementia to address this. Costs incurred during the travel and accommodation should be covered for both, the person with dementia and carer.

> *Ask the person if he/she needs support, who will be accompanying him/her… what does the person need? All the arrangements for travel need to be done well beforehand, this needs to be discussed with the*

person and carer, ask them about the best way they want to travel. (Excerpt from rapporteur's summary).

Personal support was also discussed in relation to the organisation, company or agency organising the patient engagement activity. Often, these organisations are very large and complex and it can be difficult for the person with dementia to know whom to contact and where to ask questions. This should happen in a context of trust. More specifically, this was described as a trusted named person or a single point of contact, a person with whom they could speak freely if any problem arose and who could provide support to the person with dementia and carer throughout the process.

A named person … or a single point of contact. A point of contact is very important from the beginning to the very end, if you get lost or you don't understand something, that you can ring someone up and you get the support. (Excerpt from rapporteur's summary).

The support should be provided by a "trusted" person, someone who knows you, who can provide information and support to the person. (Person with dementia 6)

3.3.4 Information

Information was perceived as a key aspect for enabling and empowering any patient, with or without dementia, to participle. The person should have enough information and understanding of the meeting, so that he/she can make an informed decision about whether he/she wants or not to take part.

Information should be detailed, and conversations should be hold about all different aspects, including travel and financial issues (e.g. reimbursements and compensation).

The more clear and detailed information is given, the better it is going to be for everyone. Transportation, expenses, keeping receipts ... you don't know what you don't know. All needs to be explained beforehand. Don't make assumptions in both parts. (Excerpt from rapporteur's summary).

Any relevant information and reading material should be provided in writing and should be sent well in advance of the meeting, particularly, if it is not in the person's mother tongue.

> *I translate all information to my mother. I need more time to translate. I need to spend time with her and explain it to her. If it is a complex topic, it is important to have enough time so we can look at it together, we can discuss about it before the meeting. (Carer 3)*

The information should be clear and in an accessible format and language which is free of jargon, plain and respectful to the person. The use of a clear layout, contrast, short sentences and bullet points whenever possible, can also greatly improve the accessibility of the documents.

> *We need to be able to understand all information that we receive. Don't ask me questions that I cannot or I don't know how to answer. Make sure that it is adapted. Use language which is respectful to us. Don't refer to us as "demented", we are people living with dementia. (Person with dementia 2)*

> *The information has to be clear and in plain English, so that any person, no matter the level of education can understand it. Also the way it is presented … clear headings, not in a ridiculously small print and bullet points whenever possible and ideas which are presented in a logical way, in a clear manner. (Person with dementia 6).*

Summaries of the materials in plain language, a list of the acronyms that will be used during the meeting in alphabetical order, and the use of reminders could be very helpful for people with dementia. If jargon or technical terms cannot be avoided, these terms should be explained in a glossary.

> *Summaries can be very useful to many of us. For some people it is difficult to read hundreds of pages! (Person with dementia 3).*

> *If I don't reply to an email or I haven't sent a document within the deadline, this may be due to dementia and not just lack of interest, contact the person again or give the person a call, send her/him a*

reminder the day before of the meeting. (Excerpt from rapporteur's summary).

Examples of the type of information that people with dementia should received included information about:

- The organisation, company or agency organising the patient engagement activity.
- What is expected from the person with dementia and carer and what they can expect from the company/agency.
- Organizational aspects and contents (e.g. who will be attending the meeting, format of the meeting, what issues will be discussed etc.)
- Travel arrangements and forms of compensation and reimbursement of costs.
- Goals of the patient engagement activity, roles, what it will involve, agenda and timeframes. In the case of clinical trials, information should also be given about the trial itself for which the person is providing input.
- How the input provided will be used.
- Benefits/gains for the person and any potential risks
- Venue, including maps and photos of the building and the room where the meeting will be held.

3.3.5 Training and induction

The topic of training, education and induction was also a very salient topic. This was addressed in two different ways. On the one hand, this related to the induction or training that people with dementia participating in patient engagement activities in the process of developing medicines should be offered. This was particularly important due to the nature and complexity of topics discussed in these meetings. People with dementia and carers felt that, in many cases, discussions could involve quite technical and complex information, and this could be intimidating and daunting for some people. The complexity of the meetings was linked to the biomedical nature of the topics addressed but also to the format, high-level discussions and the composition of the panels of experts involved in the process of developing medicines. Some people with dementia, because of their professional background

or their personal experience may already have enough knowledge to feel confident and be able to participate in these meetings.

> *You need to look at the background as well. You should not just look at their dementia. The person with dementia might have been a researcher or a doctor so her skills, her background should also be considered. (Excerpt from* rapporteur's summary).

Other people may need some training or to undergo some form of brief induction. This could assist them to offer their views and expectations

> *Just some kind of preparation, a morning … an induction session for example, a few hours to take you through some of the main concepts … this can help, it gives you the knowledge and the confidence to participate. (Person with dementia 2)*

> *If the person has not enough information or experience, he may not have the confidence, he may feel bad. We don't want to do that. It may be difficult for the person just to cope with the diagnosis as it is, and then you put the person into a place where they don't feel suitable. (Person with dementia 3).*

More specifically, this was perceived as particularly important in the case of patient engagement in the design of clinical trials. In that case, education on basic understanding of clinical trials should be provided if required.

In the case of patient engagement in setting the research agenda, a carer who had been involved in evaluating research applications for funding, also referred to challenges related to the application form itself.

> *(…) the funding agency should have gone through a research application form with us rather than giving us three samples and telling us "go home and look at that", because they are so daunting. So if they have gone through one research application with us … It is just telling us, explaining it to us …. Take the fear so that people understand no matter what level of education they have. (Carer 1).*

On the other hand, this education referred also to the people organising the patient engagement activity. People involved in the organisation and on the patient engagement activity itself should have some basic understanding of dementia and sufficient skills to support the person to contribute in a meaningful way. The education about dementia should not just relate to medical aspects. The topic of stereotypes and misconceptions of dementia were also raised in these discussions. This education could help the professionals involved in the patient engagement activity to understand better how the person could contribute and what to expect from the participation of a person with dementia.

3.3.6 Guiding principles

A key discussion revolved around the need to build a good relationship with the person with dementia and carer throughout the process of engagement. An open, clear and transparent communication between all involved was essential for this. Key principles that should guide this relationship included autonomy, respect and equality. The issue of protecting the interests and wellbeing of people with dementia in engagement activities was also discussed.

(i) Promoting autonomy

The topic of promoting and respecting the autonomy of the person with dementia was of great importance to the members of the group and their carer. There were many examples in the conversation of the relevance of asking the person with dementia him/herself about what he/she may need, his/her preferences and the type of support that may need to be in place. This also related to respecting the decisions of the person, for example in relation to the decision of taking part (or not) in the patient engagement activity.

(ii) Respect

A crosscutting topic, which was raised in several different contexts, was that of respect. This was, for example, discussed in relation to autonomy, equality, accessibility and human rights. There were also several references to showing respect for the contribution of the person by listening, valuing and taking into account what they say.

Respect was also linked to receiving feedback about how their contribution had been used and about the progress of the activity for which they had provided input. The feedback and outcomes of the patient engagement activity should be transparent, clear and accessible in terms of content and format. The group identified different types of feedback which would be relevant to the person taking part in a patient engagement activity:

- Feedback about the patient engagement activity itself, so all people involved could learn and think how the patient engagement process could be improved. The person with dementia and carer might like to know if they did what was expected of them, what they could do to make their contribution more useful. The patient organisation and the company or agency could receive feedback about what went well and what didn't work.
- The person with dementia should receive feedback about the results of the patient engagement activity: what input was used, how it was used, if not used why it was not used, and what impact is expected. Even in the cases where the person has to sign a confidentiality agreement, some feedback should be provided about this.
- In addition, in the case of clinical trials, the person with dementia should receive feedback about the results of the research or activity for which he/she provided feedback (i.e. outcomes of the study – even if not successful).

There was also an emphasis on showing appreciation to the person who was involved. The group felt that this appreciation could in some cases be just a token of gratitude.

> *A lot of time we have been to meetings and we all have given advice and we don't even get a thank you, just goodbye. It is about appreciating. (Excerpt from rapporteur's summary).*

(iii) Equality

The relationship with the person with dementia should be built on the recognition that everyone has something to gain from this collaboration and capitalize on this.

> *But something positive is that we joined the campaign called "Join Dementia Research" which advertises for university, researchers,*

anybody who is conducting research, and you advertise on their website. It is much more accessible, more available, it is much easier than these websites which are doing research. They make people with dementia champions for it so we go out and tell other people how important this is and not just disease brains but also healthy brains to use as a comparator, by making a campaign and making people with dementia champions, we are helping each other, and that's collaboration. (Person with dementia 3).

The process was described as one of mutual learning, a process where every one could learn from each other.

It is cross learning. They learn from us and we learn from them. (Carer 4)

It was described as a relationship between equals where all different parties involved (e.g. professionals and patients) should work in partnerships as equals.

We [professionals and patients] make a whole team, we need to be treated as equals, we need to be sat around the table as equals and we need to be involved from the very beginning to the end. (Excerpt from rapporteur's summary).

Don't have us there just to tick a box, have us there as equal partners and listen to us, and if we are wrong, tell us, we are all human beings. And when we are right value that. (Excerpt from rapporteur's summary).

The members of the EWGPWD also highlighted that this relationship also involved responsibilities from the person with dementia, as for example:

- the person should read all information provided and ask any questions they have (about contents, process, expectations, how long it will take, "etiquette" (rules) of the meeting etc.) beforehand so that he/she is well prepared for the meeting. The person should not make assumptions or be shy about asking questions.

- The person should be willing and open to speak and share his/her experience of living with the condition. During the meeting it could be useful to write down what he/she wants to say in case he/she needs to wait to speak.
- The person should ask about the outcome of the meeting and provide feedback to the patient organisation and company / HTA on their experience (what worked, what could be improved etc.).

(iv) Protecting the interest and wellbeing of people taking part in patient engagement

In many cases, when a patient is involved in a patient engagement activity in the process of developing medicines, he/she may be asked to sign an agreement of confidentiality or a declaration of interest. Two issues can be raised in this context. On the one hand, concerns regarding the legal capacity of the person to sign this type of document may be a barrier for some companies or organisations and may deter them from engaging people with dementia in the process. In the majority of the cases, people involved in these activities are at the early stages of the disease and thus, often their capacity to sign these documents may not have been affected by dementia.

Concerns can be also raised in relation to the wellbeing of the person, for example, if the person does not fully understand the consequences of the confidentiality agreement. Efforts should be made to explain this in clear terms to the person with dementia so that he/she can understand the implications of any documents he/she has to sign.

3.4 Why not? Barriers for engagement

Some of the most important factors that could preclude people with dementia from participating in patient engagement activities in the development of medicines included:

- Late diagnosis and stigma of dementia. Whilst, nowadays, in some countries in Europe diagnosis tends to happen in a more timely manner, in many countries people still receive the diagnosis at advanced stages of dementia or

are never diagnosed. In addition, in some countries the stigma of dementia prevails and people do not come forward for diagnosis.

- Stage of dementia: people may experience more difficulties participating in patient engagement activities in the advance stages of the disease. This can involve challenges related to travel, reading materials and keep track of discussions during long meetings.
- Lack of awareness among patients and carers about possibilities to take part in PE activities.

  There are maybe people who want to take part and they just don't know about it. (Excerpt from rapporteur's summary).

- Lack of awareness from the organisation and the researchers about how and why to involve patients

  It is out of ignorance that they [researchers, companies, etc.] don't ask us, that they don't involve us, but once you professionally and politely inform people that there are other ways, they do listen. They value what we can bring as experts on our own right. (Excerpt from rapporteur's summary).

- Fear of taking part in PE. Patient engagement can be intimidating and even daunting to some people with dementia and carers. Some people may lack confidence to participate in these activities. They may feel they do not have enough or appropriate knowledge to take part. Also, in some cases, some people may not understand the difference between participating in research and participating in a PE activity.

  Some people are afraid of research and of being involved in these kind of activities so it would be nice to explain to them, something like what we are having here today, so that people are not afraid of saying what they think. (Person with dementia 7)

- Lack of connection between people with dementia in the country. For example lack of working or peer support groups for people with dementia.

  Also unfortunately in my country there are no groups of people with dementia, people with dementia have no connection, I don't know about other people. So it is difficult. (Person with dementia 7).

- Stereotypes. Often, prevailing stereotypes of dementia with a focus on late stages may prevent companies / organisations from considering inviting a person with dementia to a patient engagement activity.
- Role of gatekeepers: in some cases, the carer or the patient organisation may act as a gatekeeper and decide on behalf of the person
- Reaching unaffiliated people affected by dementia and other difficult-to-reach communities (e.g. people with dementia from ethnic minority groups, etc.) may involve greater challenges.

3.5 What is in it for patients? Outcomes

An important area of discussion was around possible outcomes for the patient involved in a patient engagement activity. The potential outcomes of the PE activity could be group in four themes: (i) direct gain or benefits; (ii) altruism; (iii) getting across the lived experience and (iv) changes.

(i) Direct benefit

Participants felt that a main expected outcome of taking part in a patient engagement activity was a direct benefit for the person. The most immediate perceived benefit was related to having a "positive experience" and more generally for all people involved in the patient engagement activity. Another important outcome was feeling valued, empowered, or gaining purpose or hope. This was particular relevant in dementia as often after the diagnosis the person may no longer feel that they have a purpose in life or hope.

> *When you take part in something, you feel valued, you have a purpose which you lose when you get dementia, you lose that purpose or that value. And everyone needs to be valued in the community. (Excerpt from rapporteur's summary).*
>
> *For me is most important that I can still think and participate and do my best. (Person with dementia 1).*

Also in some cases, the benefit was linked to gaining knowledge about the disease and new treatments or personal connections with professionals and researchers considered as experts in this area.

> *What is in it for me? Well it's just been incredible the whole experience. I got the opportunity to meet so many more people, to see what's going on, to learn, and we are learning and we are going back sharing, so we are broadening the whole spectrum of knowledge. (Carer 1)*

> *For me, personally is the possibility of gaining more information and knowledge about the condition and the illness, new treatments … so that I would get a lot of knowledge and benefit from being there. (Person with dementia 8).*

Finally, some hoped that their engagement could bring better treatments for them in the future.

(ii) Altruism

The outcome which most people with dementia and carers felt was important was developing better medicines for the generations to come. It was highlighted that in dementia, most of the medicines currently being tested are for people in very early stages or even before the dementia stage, so in many cases, they felt any new medicine would, likely not be suitable to them. Many mentioned better medicines could be of benefit to their own children, if they developed dementia in the future, or could prevent it.

> *But the outcome is that you would help not just yourself but you would help others. That would be my value. It may be helping my children. I am helping the professionals. I am helping the world. (Person with dementia 2)*

In the case of patient engagement in the design of clinical trials, another important outcome was for the participants in the clinical trial to have a better experience during the trial. Patient engagement could also help in the recruitment of participants.

(iii) Lived experience and greater involvement of patients

Another important outcome was to get across the lived experience and make sure that the perspective of people with dementia is considered. There was a sense that if patient engagement was satisfactory and positive for all involved, this might promote more awareness and more patient engagement in other areas.

I would hope the major outcome would be that everybody has a positive experience and it would engage the team to be more proactive and engage more people in other different areas. (Carer 4)

(iv) Change

Finally, there was a general hope that their involvement would help to "change" the attitudes of professionals, policy makers and researchers, their perception of patients and the way patients are involved, and ultimately, help to make a "better world" for all.

From myself I would hope to bring a human-rights approach and change the view and how we can participate, how we us people with dementia can participate and convey our knowledge. And for the future I just hope that my contribution has changed the world. It is about us going changing the world, changing views. And I think from me personally, I hope there will be a better world for the next persons diagnosed. (Person with dementia 2).

4 CONCLUSIONS

The consultation with the members of the EWGPWD and their carers highlights the importance of and need to engage people with dementia themselves in the process of developing medicines. They can bring an "expert voice" to the process of developing medicines. Their expertise lies in their lived experience, which may offer unique insight into living with the condition and using the medicines which will be (or have been) developed.

This should involve a meaningful and active collaboration and not just a "ticking the box" exercise. Meaningful patient engagement requires sufficient resources and careful planning and thinking about whom to involve and how to involve them. It also requires certain openness to consider and value what the person has to say, implementing it and providing feedback to the person. The engagement should start as soon as possible.

Several barriers exist for involving people with dementia in the process of developing medicines, such as prevailing misconceptions about dementia, the stigma surrounding the condition and diagnosis often happening at late stages of the disease.

People with dementia should have the same opportunities to participate in a patient engagement activity as any other patient with any other condition. They can meaningfully contribute if the appropriate support is provided. The engagement of people with dementia is dependent on measures having been taken to ensure accessibility. Their specific needs should be respected and addressed. Reasonable accommodation should cover not only the contents but also the format and structure of the meeting/patient engagement activity.

Communication should be open and transparent and the information provided should always be clear, respectful and accessible. People who are invited to take part in a patient engagement activity should feel that they can confidently participate. Enough information, and when necessary some training or induction, can help people to feel more comfortable when participating. During the meeting, enough consideration should be given to ways of making their engagement possible and meaningful. Their input should be valued and appropriate feedback about how it has been used should be always provided. Important principles guiding patient engagement should include promoting and respecting autonomy, respecting people’s needs and contributions and working in equal partnerships.

People with dementia often perceive patient engagement in terms of hope for a better future. It can also empower them and help them feel valued and respected. They expect their involvement will contribute towards changing attitudes of professionals involved in developing medicines and ultimately, and most importantly developing better treatments and a better world for people with dementia in generations to come.

5 REFERENCES

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6 ANNEX : Guide for facilitators

PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

Alzheimer Europe

Schedule for PARADIGM consultation with EWGPWD

27-28 June 2018, Brussels

Day 1: 27 June 2018 (14.00 to 17.30)	**Real time**	**Time**
Arrival, brief welcome and introduction of PARADIGM colleagues (Dianne)	10	2.00-2.10
Presentation of PARADIGM • Overview of the project and WP1 (Suzanne) • Why is paradigm relevant to industry, academia and HTA/regulators (Suzanne, Sharareh and Neil) • AE's role in PARADIGM (Ana) • Q&A	45	2.10-2.55
Explanation about how the consultation will be done (Dianne)	10	2.55-3.05
Round the table of introductions: each person from the EWGPWD and carers to: • Introduce him/herself briefly (e.g. name, country, a few words about him/herself) • Say one word which comes to mind when he/she hears the word "patient engagement " This session will be moderated by Dianne with support from Sebastien	25	3.05-3.30

TOPIC 1: Brainstorming activity about what is meant by patient engagement in PARADIGM (moderated by Dianne) In PARADIGM, PE is defined as "the effective and active collaboration of patients, patient advocates, patient representatives and/or carers in the processes and decisions within the medicines lifecycle, along with all other relevant stakeholders when appropriate. Meaningful patient engagement brings mutual benefit to the community of medicine developers (meaning all stakeholders involved from patients, industry, regulators, HTA bodies to payers) and ultimately better patient outcomes. It requires inputs into decision-making, co-production and dissemination of knowledge". • How do you feel this definition fits for people with dementia? • Is it there anything that needs to be added? We are interested in hearing about your understanding of what the drug development process involves. (Let people with dementia and carers talk about their understandings of the drug development process, the meaning that this has to them and after this, Sharare and Neil, could provide / expand on the necessary information so that participants have a clear and broad understanding of the process and where the 3 paradigm points fit) Coffee break	15 15	3.30-3.45 3.45-4.00

TOPIC 2: Personal experience and PE in drug development (Ana to moderate)
We would like to know more about your personal experience of taking part in PE activities in the context of medicines development:
 	
• Generally speaking, do you think people with dementia have been involved in medicines development in the last few years?
  ○ What is your impression of how current PE in dementia compares to ideal PE in medicines development? (from 0 to 10)
  ▪ Moderators: In flipchart have the 3 points and ask participants to put a red dot for the ideal situation and green dot for current situation in their country (with initials of the country in the dot).
  ○ Why do you think this is the case?
  ○ Are there any issues which may make PE more challenging in some areas than in others?
 	
TOPIC 3: PARADIGM SURVEY - Complete the survey with all members (paper version)
• Introduce the survey (Ana and Suzanne)
• Members and carers to complete the survey
(AE to transfer the surveys to the system later on)
	10
	
	30
		4.00-4.30
		
		4.30-5.00

Day 2: 28 June 2018 (9.00-12.30) **TOPIC 4: Motivation, needs and expectations, outcomes, impact and sustainability of PE at the three points of drug development** Welcome and introduction (Ana) As it was mentioned yesterday, in this project we are interested in PE activities at three specific points in the drug development lifecycle, these are: 1. research priority setting 2. design of clinical trials 3. early dialogues with regulators and HTA bodies We would like to work now in small groups, and each group will focus on one of these points. We have prepared some vignettes and questions to facilitate the discussions. At the end of the activity, we will ask each group to present their ideas and we will try to put this all together on the flipchart so we can all contribute to the three points. (Each group will be composed of 5-6 participants (people with dementia and carers and will be jointly moderated by a representative of the project and a member of AE staff). • Vignette 1. Research priority setting (moderated by Suzanne and Sebastien) • Vignette 2. Design of clinical trials (moderated by Shara and Ana) – Shara see vignette attached in a different document. • Vignette 3. Early dialogues with regulators and HTAs (moderated by Neil and Dianne) **Coffee break**	15 90 15	9.00-9.15 9.15-10.45 10.45-11.00
A rapporteur from each group to explain what was discussed in their group After all these discussions we would like to end this session by identifying together as a group 5-6 relevant aspects for each of topics addressed in the vignettes (Dianne and Ana) • Who should take part • Motivations / challenges • Needs / expectations • Outcomes / impact Invite Suzanne, Sharareh and Neil to say from their point of view what were the most relevant aspects of the discussions over the 2 days. Also give them the opportunity to ask any further question if they want Close of the session (Ana and Helen)	60 30	11.00-12.00 12.00-12.30 12.30-12.45

Vignette 1: Research priority setting (Suzanne and Sebastien)

Edo is 59 years old and was diagnosed with dementia two years ago. He lives and works in Amsterdam, the Netherlands. He and his daughter joined the local Alzheimer Society after he was diagnosed and attend a peer support group. Edo works in a waste disposal recycling centre and his daughter has a part-time job and is caring for two young children at home.

They have just heard that in Amsterdam the funding agency for neurodegenerative research has contacted the Alzheimer Society to discuss ways of involving patients in setting research priorities for the next 5 years. After this discussion, the Alzheimer Society is considering whether the best approach would be to set up an advisory panel or to seek advice on an individual basis.

The Society has asked their members about their opinions for each of the options and who would be interested in participating. Edo and his daughter are in the process of weighing up the pros and cons of being involved, either in the panel or an individual advisor.

Warm-up question: What do you think of this way of involving people with dementia?

1. Who to involve

- How do you think the Alzheimer society should decide whom to ask for this?

Neither Edo nor his daughter have been involved in research or any similar activity before.

- Is this something that the Alzheimer society should take into account when deciding who should take part in this activity?

2. Motivations and challenges

- Why do you think Edo and his daughter might like to participate in this activity?
- Why might they decide not to take part?
- What do you think the main challenges would be of being involved in this way (i.e. if the society decides to set up an advisory panel or if the involvement is on individual basis)?

3. Needs and expectations

- What would Edo and his daughter need to be successfully involved?

One possible way of approaching this task would be to take one sheet from the flip chart and put in on the table, make three columns with the three heading below (Alzheimer's Society, Funding agency and Edo's entourage) and keep in mind the before, during and after as prompts to make sure the three steps are considered. When finished, get the group to mark each need as minimum (M) or ideal (I) and use a red dot to mark which three of all needs mentioned are the most important.

Alzheimer Society	**Funding Agency**	**Edo's entourage**
– Before the PE activity – During PE activity – After the PE activity	– Before the PE activity – During PE activity – After the PE activity	– Before the PE activity – During PE activity – After the PE activity
– Minimum – Ideal	– Minimum – Ideal	– Minimum – Ideal

- What could the funding agency expect from Edo and his daughter in order to consider their input as meaningful? What would make their input less meaningful?

4. Outcomes and impact

- What do you think Edo would hope to get out of being involved?
- What would be the likely impact of Edo and his daughter's involvement?
- How could this impact be measured?

- What might be the benefits and challenges of paying Edo and his daughter for their involvement (not just covering their cost)?
    - What type(s) of compensation / honoraria would be more important for them? (E.g. care or time missed for the person with dementia or the carer, transport, family support etc.)

5. Sustainability (this section will be addressed only of there is enough time)

The Society would like to continue this kind of involvement in the long term with the funding agency.

- Why do you think people with dementia might like this to continue?
- What should they do to make this work in the long term?
    - How should these activities be financed?

Vignette 2: Design of clinical trials (Sharareh and Ana)

Tom was diagnosed with Alzheimer's a year ago. Together with his wife he has recently been involved in the local Alzheimer society. They just heard that the Society is looking for a person with dementia or a carer to collaborate with a pharmaceutical company which is planning a big trial in their country, for a new drug for people with mild dementia.

The pharmaceutical company would like the person to review the protocol, the materials they plan to give to participants (e.g. information sheet and consent procedures) and to comment on their recruitment outreach.

Tom and his wife are in the process of weighing up the pros and cons of such involvement.

Warm-up question: What do you think of this way of involving people with dementia?

1. Who to involve

- How do you think the Alzheimer society should decide whom to ask for this?

Tom and his wife have been already involved in 2 similar activities with other companies lately.

- As the Alzheimer society is thinking about whom to ask, should the society bear this in mind? And is this an advantage or should they consider giving someone else the chance?

2. Motivations and challenges

- Why do you think Tom (or his wife) might accept?
- Why might they decline the invitation?
- What do you think the main challenges would be of being involved in this way?

3. Needs and expectations

- What would Tom and his wife need to be successfully involved?

Alzheimer Society	Pharma company	Tom's entourage
– Before the PE activity – During PE activity – After the PE activity	– Before the PE activity – During PE activity – After the PE activity	– Before the PE activity – During PE activity – After the PE activity
– Minimum – Ideal	– Minimum – Ideal	– Minimum – Ideal

- What could the pharmaceutical company expect from Tom and his wife in order to consider their input as meaningful? What would make Tom and his wife's input less meaningful?

4. Outcomes and impact

- What do you think Tom would hope to get out of being involved?
- What would be the likely impact of Tom and his wife's involvement?
- How could this impact be measured?

- What might be the benefits and challenges of paying Tom and his wife for their involvement (not just covering their cost)?
    - What type(s) of compensation / honoraria would be more important for Tom and his wife? (E.g. care or time missed for the person with dementia or the carer, transport, family support etc.)

5. Sustainability (this section will be addressed only of there is enough time)

The Society would like to continue this kind of involvement in the long term with this and other pharmaceutical companies.

- Why do you think people with dementia might like this to continue?
- What should they do to make this work in the long term?
    - How should these activities be financed?
- Do you think the pharmaceutical company should have gone through the Society to find the person with dementia and carer?

Vignette 3: Early discussions with regulators and HTAs (Neil and Dianne)

Mary was diagnosed with Alzheimer's two years ago. Together with her daughter she has recently been involved in the local Alzheimer society. They just heard that the Society is looking for a person with dementia and/or a carer to attend a meeting at the national HTA agency (the body which decides if new treatments offer value to the healthcare system and should be reimbursed for patients in the country).

A company developing a new drug for people with dementia has asked the HTA agency for advice on the evidence they would need to generate in their clinical trials to show value to the healthcare system. This advice will be used to shape the clinical trials that the company will undertake as they develop the medicine.

The HTA agency would like a patient or carer to attend this advice meeting so that all participants at the meeting can gain a better understanding of the experiences, preferences and needs of people with dementia.

Mary and her daughter are in the process of weighing up the pros and cons of such involvement.

Warm-up question: What do you think of this way of involving people with dementia?

Who to involve

- How do you think the Alzheimer society should decide whom to ask for this?

Mary and her daughter have never been involved in similar activities before**.**

As the Alzheimer society is thinking about whom to ask, should the society bear this in mind? Is the fact that Mary and her daughter have never done this before a problem or an advantage?

2. Motivations and challenges

- Why do you think Mary (and/or her daughter) might accept?
- Why might they decline the invitation?
- What do you think the main challenges would be of being involved in this way?

3. Needs and expectations

- What would Mary and her daughter need to be successfully involved?

Alzheimer Society	HTA agency	Mary's entourage
– Before the PE activity – During PE activity – After the PE activity	– Before the PE activity – During PE activity – After the PE activity	– Before the PE activity – During PE activity – After the PE activity
– Minimum – Ideal	– Minimum – Ideal	– Minimum – Ideal

- What could the HTA agency expect from Mary and her daughter in order to consider their input as meaningful? What would make Mary and her daughter input less meaningful?

4. Outcomes and impact

- What do you think Mary would hope to get out of being involved?
- What would be the likely impact of Mary and her daughter's involvement?
- How could this impact be measured?

- What might be the benefits and challenges of paying Mary and her daughter for their involvement (not just covering their cost)?
    - What type(s) of compensation / honoraria would be more important for them? (E.g. care or time missed for the person with dementia or the carer, transport, family support etc.)

5. Sustainability (this section will be addressed only of there is enough time)

The Society would like to continue this kind of involvement in the long term with this and other HTA and regulatory agencies.

- Why do you think people with dementia might like this to continue?
- What should they do to make this work in the long term?
- Do you think the agencies should go through the Society to find the person with dementia and carer?