Research is vital if we are to gain a full understanding of dementia, but ethical issues around consent must be resolved when studies include people with the condition.

Involving people with dementia in research

In this article...

- The concept of “consent as a process”
- Discussion on the issue of accidental disclosure of diagnosis
- Implications for nursing practice

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This article considers some of the ethical issues in conducting research involving people with dementia. The process of gaining consent is explored, along with the issue of accidental disclosure of diagnosis. The importance of including people with dementia in research and the possible benefits to them of taking part are discussed and the issues are linked to practice through examples of my own research with people with dementia.

There are over 700,000 people living with dementia in England and Wales (Department of Health, 2009). At any one time, a quarter of hospital beds are occupied by people with dementia aged over 65 (Alzheimer’s Society, 2009), and two-thirds of residents in care homes have dementia (DH, 2009).

The Alzheimer’s Society (2012) suggests that research into dementia falls broadly into four categories: cause, cure, care and prevention. As well as searching for a cure and effective treatment, research aims to develop interventions that can improve quality of life. The National Institute for Health and Clinical Excellence and Social Care Institute for Excellence recommend research into four areas, one to establish the usefulness of existing treatments and the other three related to drug-free interventions (NICE/SCIE, 2006).

This article considers how people with dementia can be included in research and some of the ethical issues arising from this.

Informed consent

Informed consent – being able to decide whether or not to take part in a research study – is an essential ethical consideration stated in the Declaration of Helsinki (World Medical Association, 1964). To give informed consent, a person must have enough information about the research, be able to understand the information and have the power of free choice, so that they can voluntarily consent or decline (Polit and Hungler, 1995).

For people with dementia, the issues around informed consent relate to mental capacity. The symptoms of dementia, such as short-term memory problems and difficulty with concentration and understanding, raise questions as to whether they can give informed consent. As the disease progresses, these difficulties become more of a problem.

As a result, researchers have tended to seek the consent – or rather the assent – of the relatives of persons with dementia that has progressed beyond the early stages. No one can give consent for another person, and, while it is possible to gain approval on another person’s behalf (Procter, 1995), there are difficulties with this approach.

Although the next of kin is most likely to know what the person’s views would be on participating in the study, Procter (1995) points out that there is a risk of the proxy overruling what would have been the person’s view had they been able to express it.

Another ethical dilemma, raised by Kitwood (1995), is where the relative consents and the person with dementia then objects. This was addressed by the Medical Research Council (MRC), which stated in its ethics guide (2007) that the wishes of the person with dementia should in this

5 key points

1. Informed consent – being able to decide whether to take part in a study – is an essential ethical consideration.
2. The symptoms of dementia raise questions about a person’s ability to give informed consent.
3. The Mental Capacity Act states that a person must be assumed to have the capacity to make a decision unless it is established that they do not.
4. It is down to researchers to do all they can to help people with dementia to understand and take part in studies.
5. Seeing consent as a process can help researchers to include people with dementia in their studies.

People may benefit from taking part.
case be taken in to account, rather than the wishes of the relative. If the person with dementia does not have the capacity to consent to take part in a study, involving their relative would be inappropriate—having dementia does not mean a person automatically lacks the capacity to consent.

Pratt (2002) suggested that we cannot be absolutely sure of informed consent when someone has dementia. This may be true, but it is probably the case that we cannot be completely sure of informed consent from any participant. A researcher can never be certain that any potential participant has fully understood the study as it is unlikely that they have been told every detail, such as a full explanation of the data analysis. People do not normally need this level of detail to be able to consent to take part in research but, if they do not understand every single aspect of the study, it could be argued that they are not fully informed.

The Mental Capacity Act
The Mental Capacity Act 2005 states that a person must be assumed to have the capacity to make a decision unless it is found that they do not (Box 1). Furthermore, a person should not be treated as being unable to make a decision unless all reasonable steps to help them to do so have been taken without success.

The Nursing and Midwifery Council code of conduct, standard 16, states: “You must be aware of the legislation regarding mental capacity, ensuring that people who lack capacity remain at the centre of decision making and are fully safeguarded” (NMC, 2008).

It is important that researchers do all they can to enable people with dementia to understand studies they are involving them in; this includes ensuring that the information is available in a suitable format to help them make informed decisions. Consideration also needs to be given as to how the research will be explained to the person with dementia (Nygard, 2006; Dewing 2002), and researchers should also consider what time of day the person with dementia is approached, given that cognition can fluctuate throughout the day.

Consent as a process
In research that includes people with dementia, it is useful to consider a process for gaining consent that is used each time the person takes part, rather than just once (Hellstrom et al, 2007; Nygard, 2006; Dewing, 2002; Pratt and Wilkinson, 2001). This provides safeguards for people with dementia in view of their short-term memory problems and variable capacity.

Dewing (2007) developed a process consent method, which she used in a study on wandering in a care home and with people with dementia in a general hospital (Box 2). The procedure devised by Dewing (2007) illustrates how people with dementia, who might not otherwise have been considered able to give consent, were able to take part in research because of this method. The more cognitively impaired the person is, the more in-depth the procedure for gaining and ensuring ongoing consent needs to be.

Allen (2001) also used a process consent method to enable people with dementia to be included in a service evaluation. Both Allen (2001) and Dewing (2007) asked relatives for access to the person with dementia, but a limitation of this is that it enables the relative to potentially override the wishes of the person with dementia. Nevertheless, the relative will have knowledge of the person’s prior wishes and also may know of a reason why the person may be distressed by being invited to take part. In this case, the ethical principle of non-maleficence is being used to avoid harm (Beauchamp and Childress, 1994). If the relative permits the researcher access, it is still the person with dementia’s choice whether to participate in the study or not, so from this respect their autonomy is maintained.

The drawbacks of using Dewing’s (2007) process consent method are the amount of time needed to carry it out and the advanced communication skills and person-centred expertise the researcher needs to have. A further limitation that Dewing pointed out is “an ethical dilemma” in that the researcher engages with the participant and gathers information about them before their consent has been given to take part in the study.

Accidental disclosure of diagnosis
A further issue to consider when trying to obtain the informed consent of people with dementia is that some participants may not know their diagnosis. They may have forgotten or may have never been told. Without disclosure of the diagnosis, there must be a question over the ability of the person to give informed consent. The issue here is how someone with dementia can consent to take part in a study about dementia if they do not realise they have the condition.

BOX 1. MENTAL CAPACITY ACT 2005
A person is deemed able to have capacity to make a decision if they can:
1. Understand the information relevant to the decision, including the likely consequences of making or not making the decision
2. Retain the information
3. Use or weigh the information as part of the process of making the decision
4. Communicate their decision

BOX 2. A PROCESS CONSENT METHOD
1. To gain “permission to access” the person with dementia from staff, a relative or named person is sought. This also involves finding out some biographical information about the person with dementia
2. Establishing the basis for consent. As capacity is situational and variable, the researcher endeavours to find out how the person usually consents to care or other activities in day-to-day life
3. Initial consent for the specific research is sought. Information is provided that is appropriate for that person to help them understand the study. This step includes recording non-verbal communication and facial expressions and referring back to what is already known about how the person usually consents on a daily basis. It is important that the researcher does not rely only on a lack of verbal objection and assumes this to mean consent has been given
4. Ongoing consent monitoring highlights the idea of consent as a process. Dewing (2007) described this stage as “ensuring initial consent is revisited and re-established on every occasion or even within the same occasion”
5. Feedback and support. This includes feeding back to staff any concerns the researcher may have about the participant

Source: Dewing (2007)
The role of Christian religion for people with dementia without accidentally disclosing an unknown (or forgotten) diagnosis. In her study about how people receive their diagnosis, she spoke about the symptoms of dementia, such as forgetfulness and word-finding difficulties, before discussing the diagnosis. She did not mention the word dementia until the interviewee did so.

Similarly, Bartlett and Martin (2002) suggested the word dementia should only be used if participants themselves used it, as they were concerned that it could result in unnecessary harm. They acknowledged that from an ethical point of view this could be considered as a form of deception but noted that this needed to be weighed against the “ethical obligation” of doing no harm and reducing distress (non-maleficence). Although it could be seen as a deception, it is a deception of omission rather than a lie. Andrew (2006) described the approach as “an avoidance of an unnecessary truth”, while Marzanski (2000) described it as “justifiable benevolent deception”. The deception is done in the person’s best interests.

Furthermore, the only way to understand the experiences of people with dementia is through including them in research. Using words such as “memory problems” instead of “dementia” protects participants from the unnecessary distress of accidental diagnosis but also allows for them to use the word “dementia” themselves. This enables them to participate in the study, which may also be a pleasant experience for them. It will also allow us to gain a greater understanding and might benefit others with the same diagnosis in the future.

**Including people with dementia in research**

In the past, people with dementia were not included in research about issues directly affecting them, such as service evaluation, as it was thought they would not be able to contribute due to cognitive impairments; the views of their relatives or carers were used instead. This paternalistic approach shows a lack of respect for the dignity of people with dementia who have their own opinions, which may or may not be the same as those of their carer.

The challenge for researchers is to find ways to involve people with dementia so that we can learn more about their experience of living with the condition and their views on the services they receive. As Hellstrom et al (2007) stated, “the issue is not should we include the person with dementia but how can we best do it”. Similarly, Dewing (2007) suggested that researchers should not assume a person lacks the capacity to consent to take part in a study because of poor scoring on cognitive testing. This should instead be seen as a challenge for the researcher to find ways to include the person in the study.

People with dementia are one of the most excluded groups in society (Dewing, 2002; Bamford and Bruce, 2000). The MRC (2007) noted that people who do not have the capacity to consent should not be discriminated against by being excluded from research as this would be stopping them from participating fully in society. Any such research would, however, require appropriate safeguards due to the vulnerability of the group.

**Benefits for people with dementia**

Berghmans and Ter Muehlen (1995) pointed out that research can have a social benefit for people with dementia – such as someone spending time with them. For those living in care homes, the opportunity to have someone spend time listening to them and taking an interest in them is likely to have a positive effect on their wellbeing.

Being interviewed has been reported as enjoyable for people with dementia and a positive experience (Clark and Keady, 2002; Dewing, 2002; Barnett, 2000). Barnett (2000) reported that people with dementia who took part in research felt valued and that their self-esteem was boosted. Furthermore, they enjoyed the opportunity to speak about their feelings and experiences (Clark and Keady, 2002; Barnett, 2000).

Kapp (1998) reported that asking someone with dementia to take part in a research study can make them feel recognised as someone who is capable, in contrast to stereotypical images of dementia that show them to be inferior and incompetent. In addition, Hellstrom et al (2007) proposed that while excluding people with dementia from taking part in research could be seen as reducing their dignity, including them could enhance it.

**Implications for nursing practice**

Nurses working in all settings provide care to people with dementia. In order to effectively meet their care needs, we as nurses must understand what those needs are. It is clear that this information is best obtained from people with dementia themselves.

Nursing research that aims to understand the experience of living with dementia will help to improve the services provided to people with this diagnosis and is therefore essential. Having a better understanding of their care needs and their experiences can allow us to re-think our practice and provide better care.

An example of this is my own study, currently under way, the aims of which are set out in Box 3. I used a process method of consent based on Dewing (2007) and interviewed 10 people with dementia living in care homes to understand more about their religious needs and how these needs might be met in the care-home setting. My reflections on using a process method of consent are described in Box 4. Spirituality is an area of holistic care that is often overlooked and, although this is a small study, it illustrates how nurses are in a position to help improve the care of people with dementia by including them in research.

**Conclusion**

People with dementia should be supported to take part in research if they wish to do so. Hopefully the use of a process method
of consent can be taken up more widely which would allow more people who would otherwise be excluded, or included via assent from relatives, to decide for themselves about participating. The challenge is for researchers to find the best ways to do this; it undoubtedly requires a flexible and sensitive approach that may take longer and be emotionally demanding but, nevertheless, is worth the effort. NT

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References


BOX 4. USING A PROCESS METHOD OF CONSENT

Using a process method of consent provides a framework for ensuring the consent of the participants. Contacting the relatives first was invaluable. They were able to provide background biographical information as well as advise on any subjects that I should steer clear of in the interview to avoid causing any unnecessary distress. I also established the best time of the day for the person with dementia to meet me.

I provided an information leaflet designed specially for people with dementia, which used a large font and was clearly worded. To avoid distress I used the words “memory problems” instead of dementia on this leaflet.

I decided to combine points 3 (initial consent) and 4 (ongoing consent monitoring) of the consent procedure for my study. I had originally planned to visit and gain initial consent then return another day for the interview. On further consideration, I felt it was possible that, after giving their initial consent, the person may have no recollection of me or my study when I visited again to interview them. I decided, therefore, that if they were able to consent to take part and wanted to participate, I would ask if they would like to go ahead with the interview that day. If they preferred not to, I would return on another day but in practice that did not happen.

I made sure throughout the interviews that participants were not in any distress and appeared to be willing to continue, through what they were saying, the way they said it and through their non-verbal communication.

I provided feedback to the relatives to let them know the interview had proceeded as planned. This was appreciated by them.


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