

Is it ethically justifiable to use antipsychotics in long-term care facilities for managing people with behavioral and psychological symptoms of dementia?

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Abstract

The use of antipsychotics (APs) is common practice in long-term care facilities (LTCFs) to manage people with behavioral and psychological symptoms of dementia (BPSD). This practice gives rise to various ethical issues, particularly in light of the fact that the use of APs might have at best modest efficacy in managing people with BPSD and at worst lead to significant adverse effects. This thesis aims to explore and critically examine the ethical justifiability of the use of APs for managing people with BPSD in LTCFs. First, in the empirical part of the thesis, I conduct a scoping review to map out the relevant existing literature. The review identifies rationales given for why, how, when and by whom using APs might or might not be ethically justified. Then, I examine the ethical justifiability of using APs from the standpoint of the well-known four-principles approach to biomedical ethics. Next, I take Tronto's ethics of care approach to offer an ethical examination of using APs as a form of care provided to people with BPSD in LTCFs. Finally, by drawing on the preceding discussions, I identify and suggest potential areas for further ethical investigation.

Statement of Authorship and Originality of the Thesis

Hereby I, Hojjat Soofi, a candidate for the degree of Master of Research (MRes), certify that the work titled '*Is it ethically justifiable to use antipsychotics in long-term care facilities for managing people with behavioral and psychological symptoms of dementia?*' has not been previously submitted in part or as a whole for a degree to any other institution or university other than Macquarie University. The research project for this thesis has been undertaken solely by me during the candidature for the degree of MRes at Macquarie University. The references, the quotes, and other consulted sources are properly cited throughout the text and in the reference list at the end of the thesis.

I also certify that the research project for this thesis did not require an Ethics Committee approval.

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Introduction

Angela's husband, David¹, is diagnosed with Alzheimer's disease and resides in a long-term care facility (LTCF)². He has been recently exhibiting aggressive behavior towards staff in the LTCF. To manage his behavior, the staff consider reinstating the use of an antipsychotic (AP) medication, which David previously used. Nevertheless, Angela is concerned about the aim of using AP and undesirable effects of the medication on her husband:

Over the last weekend he's actually hit one of the nurses again. So now, of course they- they don't know why it's suddenly flared up, ...he might be in pain, and he can't communicate that and so that may- may be what's making him frustrated and therefore he lashes out ... I- I- I will say I don't want him to go back on the antipsychotic because it made him such a zombie ... (Harding & Peel, 2013, pp. 263-264)

Is it ethically justified for the staff in the LTCF to use the medication? If Angela insists on David not taking the medication, what are the ethical grounds for either disregarding or respecting her decision? Do we respect the autonomy of David by obtaining informed consent from Angela as David's surrogate decision-maker?

This thesis revolves around such ethical questions. In this thesis, I explore and critically examine the ethical justifiability of using APs in LTCFs for people with behavioral and psychological symptoms of dementia (BPSD), for instance, aggressive behavior as in the case of David. Though the clinical hallmark of

¹ The case is adapted from Harding and Peel (2013). The resident's name is fictional as no name is mentioned in the original source.

² In this research, I will use the term 'long-term care facilities (LTCFs)' to refer to all long-term care institutions that provide varying degrees of assistance to people with dementia who cannot live independently in the community. LTCFs include, for example, residential aged care facilities and nursing homes.

dementia is a progressive decline in individuals' cognitive abilities such as memory performance, most people with dementia, along with the cognitive decline, also develop BPSD.

BPSD are a heterogeneous set of non-cognitive symptoms such as apathy, depression, aggression, agitation, anxiety, sleep disorders, delusion, and hallucination. These symptoms are very common in individuals with dementia. It has been estimated that almost 90 % of individuals with Alzheimer's-type (the most common variant) of dementia might experience BPSD at one point within the illness trajectory (Harding & Peel, 2013).

BPSD are often described as the most challenging aspect of dementia care (Desai & Desai, 2014) and negatively affect the quality of life in residents with dementia in LTCFs (Samus et al., 2005).

From the 1950s, APs have been the most common pharmacological intervention used to manage people with BPSD (Banerjee, 2009). However, these drugs are associated with various adverse effects. What Angela describes as a 'zombie-like' state is (over)sedation, one of the known adverse effects of APs. Some of the other reported adverse effects of APs include extrapyramidal symptoms (involuntary muscle movements of various sorts) and increased risk of cerebrovascular adverse events (Ballard & Waite, 2006; Lonergan, Luxenberg, Colford, & Birks, 2002).

Further, current evidence suggests that APs might have at best modest efficacy for managing people with BPSD (Schneider, Dagerman, & Insel, 2006; Schneider, Pollock, & Lyness, 1990). Use of APs in managing BPSD either is unapproved or has very limited approval by regulatory bodies. For example, The US Food and Drug Administration (FDA) has not approved any APs for managing BPSD. In Australia, only one AP medication (risperidone) is approved for the short-term

management of specific recurrent and severe types of BPSD (Therapeutic Goods Administration, 2015).

Nonetheless, the use of APs is common practice for managing people with BPSD in LTCFs. Previous research has shown that the prevalence of AP use in individuals with dementia in LTCFs ranges from 20 to 50 % (Snowdon, Galanos, & Vaswani, 2011; Testad et al., 2010). There is some evidence indicating that the use of APs varies between LTCFs independent of residents' clinical characteristics (Chen et al., 2010). This variability has raised concerns about inappropriate or unnecessary use of APs in LTCFs (Kirkham et al., 2017).

Potentially inappropriate use of APs in LTCFs has captured the interest of the media. It has been labeled, for example, as “chemical cosh” (BBC, 2017) or “chemical restraint” (Aljazeera, 2015). Such concerns have also appeared in the political arena. In March 2012, David Cameron, then the UK Prime Minister, launched a national campaign to improve dementia care, including an action plan for an overall two-thirds reduction in the use of APs (The UK Department of Health, 2012).

Further, scholars have taken up issues arising from legal aspects of using APs in an off-label way and as a potential means of chemical restraint (Berns, 2012; Braun & Frolik, 2000; Harding & Peel, 2013; Taylor, 2016). In recent years, there have even been cases of criminal charges against LTCFs staff who allegedly used APs for chemically restraining residents (Taylor, 2016). For instance, in February 2009, three staff in a LTCF in California were charged for using psychotropic medications, including APs, “for their own convenience and for causing the deaths of three residents” (California Advocates for Nursing Home Reform, 2009).

Besides the legal debates and the media coverage, which are undeniably important, it is also necessary to explore and examine the ethical justifiability of using APs for managing people with BPSD in LTCFs. Using APs for managing people with BPSD gives rise to important ethical questions, for example, as to whether using APs in order to enhance the quality of life in people with BPSD might be ethically justifiable (Howe, 2007). This thesis aims to map out and further extend the current debate on the potential ethical justifiability of using APs in LTCFs. The main research question that I explore and examine in this research is *‘in what circumstances, if any, might it be ethically justifiable to use APs for managing people with BPSD in LTCFs?’*

Chapter 1 provides a brief background to the main medical terms such as dementia, BPSD, and APs. I also briefly review the existing evidence for efficacy and adverse effects of APs in managing BPSD. Then, in *Chapter 2*, I conduct a scoping review to explore existing literature on the ethical justifiability of using APs in LTCFs. In *Chapter 3*, in order to extend the existing debate, I provide a detailed examination of the ethical justifiability of using APs by taking the well-known ‘four-principles’ approach to biomedical ethics. I show how obligations based on the four principles might come into conflict when healthcare professionals in LTCFs use APs to manage people with BPSD. Further, I discuss how the use of APs might or might not be ethically justifiable, according to the four-principles approach, in the face of conflicting obligations. In *Chapter 4*, I adopt Tronto’s ethics of care approach to critically examine the ethical justifiability of using APs as a form of care in LTCFs. By doing so, I complement the discussions in the previous chapter by highlighting a number of procedural issues and by capturing ethical considerations related to the wider context within which

care provision for people with BPSD is organized in LTCFs. Finally, in *Chapter 5*, I draw on the discussions in the preceding chapters to call for ethical reflection.

Chapter 1. Background

In this chapter, I first give a brief background to dementia as a syndrome that may be caused by different underlying diseases. Then, I discuss behavioral and psychological symptoms of dementia (BPSD). The subsequent section gives a brief overview of how the use of antipsychotic (AP) medications became common practice for managing people with BPSD. Finally, I briefly review the current evidence for efficacy and adverse effects of using APs for managing BPSD.

1.1. Dementia

Once supposed an inevitable part of normal aging (Ryan, Rossor, & Fox, 2015), dementia is now described as a syndrome caused by a range of underlying pathophysiological conditions, which may affect both elderly and young individuals. The hallmark of dementia³ is a cognitive decline in individuals with previously normal cognitive function in one or more of these cognitive domains: “complex attention, executive function, learning and memory, language, perceptual-motor, or social cognition” (American Psychiatric Association [APA], 2013, Section II, Neurocognitive Disorders). As part of the diagnostic criteria, these cognitive dysfunctions should (1) compromise independence in performing everyday activities; (2) not occur only “in the context of a delirium”; and (3) not be better explained by other mental disorders such as schizophrenia (APA, 2013, Section II, Neurocognitive Disorders).

Many diseases or pathophysiological conditions may cause dementia (*Table 1*). The pattern of symptoms and related brain abnormalities vary according to the different causes of dementia (Alzheimer's Association, 2016). Dementia in some individuals is multifactorial and might be caused by more than one kind of brain

³ In the fifth edition of The Diagnostic and Statistical Manual of Mental Disorders (DSM), dementia is replaced by neurocognitive disorders (NCDs), which are subcategorized as major or mild NCDs (APA, 2013).

abnormality. These cases are described as mixed dementias. It is estimated that nearly half of the elderly individuals with dementia have mixed dementia (Alzheimer's Association, 2016).

Table 1. Major types of dementia

Dementia causes	Prominent features	Prevalence (of all dementia cases)
Alzheimer's disease	<ul style="list-style-type: none"> - Memory loss early in the disease course ^a - Social cognition and procedural memory may remain relatively intact for long periods ^a 	60 % to over 90 % ^a
Dementia with Lewy bodies	<ul style="list-style-type: none"> - Deficits in complex attention and executive function usually precede memory loss ^a - Recurrent visual hallucinations ^a 	1.7 % to 30.5 % ^a
Vascular dementia	<ul style="list-style-type: none"> - Initial signs include diminished ability to organize, arrange plans or make decisions ^b 	10 % ^b
Frontotemporal lobar degeneration	<ul style="list-style-type: none"> - Progressive behavioral and personality changes and/or language impairment ^a 	5 % ^a
Parkinson's disease dementia	<ul style="list-style-type: none"> - Cognitive deficits occur in the background of Parkinson's disease ^a 	3 to 4 % ^c

^a (APA, 2013), ^b (Alzheimer's Association, 2016), ^c (Aarsland, Zaccai, & Brayne, 2005)

1.2. Behavioral and psychological symptoms of dementia

Along with the cognitive deficits, most people with dementia develop some non-cognitive symptoms that involve a number of behavioral and/or psychological disturbances (*Table 2*). These non-cognitive symptoms have come under focus only in the past few decades (Finkel, E. Silva, Cohen, Miller, & Sartorius, 1997). During a series of consensus conferences convened by the International Psychogeriatric Association (IPA) in 1996 and 1997, the non-cognitive symptoms of dementia were characterized as behavioral and psychological symptoms of dementia or BPSD (Verdelho & Gonçalves-Pereira, 2017). Another designation for BPSD is neuropsychiatric symptoms (NPS) of dementia (Perera, Javeed, Lyketsos, & Leroi, 2017).

Table 2. Prevalent behavioral and psychological symptoms of dementia. Adapted from Fauth and Gibbons (2014).

Symptoms	Prevalence
Apathy/indifference	~ 46 %
Depression	~ 40 %
Appetite and eating changes	~ 36 %
Agitation/aggression	~ 35 %
Irritability	~ 34 %
Anxiety	~ 32 %
Aberrant motor behavior (e.g., repetitive habits or activities)	~ 31 %
Sleep and nighttime behavior disorders (e.g., wandering at night)	~ 26 %
Delusions	~ 25 %
Disinhibition	~ 20 %
Hallucination	~ 15 %
Elation/euphoria	~ 8 %

BPSD may emerge before or after the cognitive decline in individuals with dementia and might be a prognostic marker for accelerated decline of cognitive function (Perera et al., 2017). Research has shown that individuals with mild cognitive impairment and depression are twice as likely to develop dementia of Alzheimer's type than those without depression (Modrego & Ferrández, 2004).

Management of BPSD is a critical component of dementia care (Desai & Desai, 2014). Studies have suggested that the presence of BPSD is a predictor for admission to long-term care facilities (institutionalization) in people with dementia (Gaugler, Yu, Krichbaum, & Wyman, 2009). Further, after admission to long-term care facilities, BPSD may have a detrimental effect on residents' quality of life (QoL) (Samus et al., 2005). Aggression and agitation are two BPSD that have been shown to best predict a decline in QoL, followed by apathy and irritability (Samus et al., 2005).

Management of BPSD might involve using pharmacological or non-pharmacological interventions. The use of APs is common pharmacological intervention for managing community-dwelling and institutionalized people with BPSD (Boucherie et al., 2017; Shin, Gadzhanova, Roughead, Ward, & Pont, 2016).

1.3. Antipsychotic medications

Conventional (or first-generation) AP medications (*Table 3*) emerged in the 1950s as treatments for schizophrenia, bipolar disorder with mania, and other psychotic disorders (Ibrahim, Knight, & Cramer, 2012). Chlorpromazine, or thorazine, the first conventional AP, was introduced in 1952 in France (Ban, 2007). In the following years, more potent conventional APs such as trifluoperazine, haloperidol, and fluphenazine were introduced by pharmaceutical manufacturers

(Ibrahim et al., 2012). The main mechanism of action for conventional APs is through blocking dopamine D₂ neuroreceptors (Meltzer, 2013).

In the early 1990s, atypical, or second-generation, APs were developed (*Table 3*) (Laredo et al., 2011). Atypical APs have less affinity for D₂ neuroreceptors but have more antagonistic effects on other neuroreceptors such as 5-HT_{2A} (Meltzer, 2013).

Table 3. Common conventional and atypical APs

Conventional APs	Atypical APs
Chlorpromazine	Clozapine
Trifluoperazine	Risperidone
Haloperidol	Quetiapine
Fluphenazine	Olanzapine
Thioridazine	Aripiprazole

1.4. Antipsychotics for behavioral and psychological symptoms of dementia

Conventional APs, soon after their emergence in the 1950s, were considered as a potential treatment for BPSD (Ibrahim et al., 2012). *Figure 1*, for example, shows an advertisement, back in in the 1950s, that markets the use of thorazine (chlorpromazine) for managing agitation and aggression in elderly people with (then called senile) dementia.

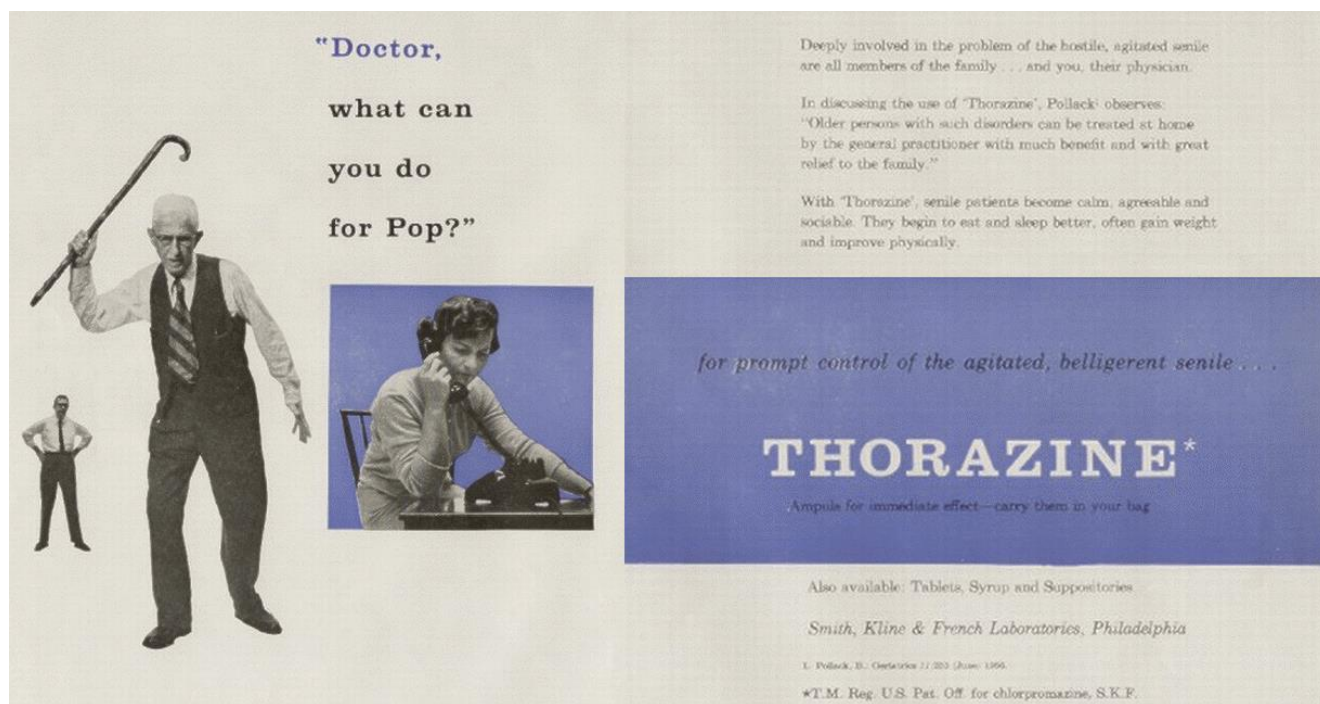


Figure 1. An advertisement marketing thorazine (chlorpromazine) in the late 1950s. From "Thorazine Advertisement, 1957"

(<http://prescriptiondrugs.procon.org/files/1-prescription-drugs-images/thorazine-1957.gif>). In the public domain.

The use of conventional APs, nonetheless, showed a decline following the emergence of atypical APs in the 1990s (Schneider, Dagerman, & Insel, 2005). Over the following years, there was a shift toward atypical APs for reasons such as "perceived relative safety advantages" or "expectations of efficacy" (Schneider et al., 2005, pp. 1934-1935). In the next sections, I briefly review the evidence for efficacy and adverse effects of conventional and atypical APs.

1.5. Evidence of efficacy

Conventional APs

The evidence base for the efficacy of conventional APs in managing BPSD seems unclear and complex to interpret (Sink, Holden, & Yaffe, 2005). Though some studies have shown that conventional APs may be more efficacious than placebo for some types of BPSD, these findings cannot be generalized to all people with BPSD or were not always associated with clinically significant outcomes.

For instance, one of the earliest meta-analyses investigating the efficacy of APs for managing agitation in people with dementia found that conventional APs are more efficacious than placebo, albeit with a modest effect size (Schneider et al., 1990). This meta-analysis study, however, included studies that recruited inpatient subjects who might have had severe dementia. The authors, thus, stress that the results might not be generalizable to the outpatient population with milder forms of dementia (Schneider et al., 1990).

In addition, another meta-analysis investigating the efficacy of thioridazine (a conventional AP) in people with dementia showed that thioridazine, compared to placebo, was superior in reducing some anxiety symptoms (Kirchner, Kelly, & Harvey, 2001). However, there was no difference regarding global clinical evaluation scales⁴ (Kirchner et al., 2001).

Atypical APs

Despite the uptake of atypical APs for their perceived greater efficacy than conventional APs, the evidence for the efficacy of atypical APs for managing people with BPSD is modest (*Table 4*) (APA, 2016).

⁴ The study compared the global clinical outcomes based on assessment scales such as Sandoz Clinical Assessment-Geriatric (SCAG). The efficacy of thioridazine on reducing anxiety symptoms was measured by Hamilton Anxiety Scale (Kirchner et al., 2001).

Table 4. The evidence for efficacy of atypical antipsychotics for managing overall BPSD. Adapted from APA (2016) and Maglione et al. (2011)⁵.

Atypical APs	Effect size (Overall BPSD)	Strength of evidence (Confidence)
Aripiprazole	Small	Moderate
Olanzapine	Very small	Low
Quetiapine	Nonsignificant	Low
Risperidone	Very small	Moderate

Further, some evidence indicates that there is no significant difference between the efficacy of atypical APs and that of conventional APs in managing BPSD. For instance, a randomized clinical trial that compared the efficacy of risperidone (an atypical AP) with the efficacy of haloperidol (a conventional AP) in managing overall BPSD found no significant difference between two groups (Chan et al., 2001).

1.6. Evidence for adverse effects

The use of antipsychotics for managing people with BPSD may lead to a range of adverse effects.

Risk of cerebrovascular adverse events

From 2002, emerging evidence pointed to a possible association between the use of APs and risk of cerebrovascular adverse events (CVAEs) in people with dementia (Sacchetti, Turrina, & Valsecchi, 2010). This led to the implementation of various drug safety measures by regulatory agencies. For instance, in October 2002, Health

⁵ There is research evidence for the efficacy of atypical APs for specific symptom domains including psychosis and aggression/agitation (APA, 2016).

Canada warned prescribers about a potential association between the use of risperidone and CVAEs in people with dementia (Health Canada, 2002). Similar safety measures were implemented by Therapeutic Goods Administration, the Australian regulatory agency⁶ (Therapeutic Goods Administration, 2015).

Nonetheless, conflicting findings have emerged from other studies. A retrospective case-control study in people with dementia in LTCFs did not establish an increased risk of CVAEs with the use of either atypical or conventional APs (Liperoti et al., 2005). In contrast, findings of a more recent five-year follow-up study suggest that while dementia might be an independent factor for some CVAEs, the use of APs may further increase the risk of those CVAEs in people with dementia (Liu et al., 2013).

Risk of mortality

The analysis of 17 placebo-controlled clinical trials that enrolled elderly people “with dementia-related behavioral disorders” showed that those treated with atypical APs had a risk of death 1.6 to 1.7 times higher than those in the placebo arms (Food and Drug Administration [FDA], 2008). This finding led to the implementation of a number of drug safety measures. For instance, in 2005, The US Food and Drug Administration (FDA) issued a warning to healthcare professionals that the use of atypical APs for “dementia-related psychosis” is associated with an increased risk of mortality (FDA, 2008).

Further studies indicated that both conventional and atypical APs might be associated with an increased risk of mortality in people with dementia (Gill et al., 2007; Musicco et al., 2011; Schneeweiss, Setoguchi, Brookhart, Dormuth, &

⁶ Along with warning healthcare professionals about the risk of cerebrovascular adverse events associated with the use of risperidone, the Therapeutic Goods Administration has limited the indication of risperidone in dementia (Therapeutic Goods Administration, 2015).

Wang, 2007). Findings from a retrospective cohort study showed that conventional antipsychotics might be associated with a higher risk of mortality than atypical APs in elderly individuals with dementia (Gill et al., 2007). In response to such emerging evidence, the previous warnings about the risk of mortality with the use of APs in people with dementia were updated. In 2008, the FDA extended the previously issued warning by requiring manufacturers of both conventional and atypical APs to add a boxed warning about the risk of increased mortality for dementia-related psychosis (FDA, 2008).

Risk of fall and hip fracture

There is observational evidence that the use of both conventional and atypical APs in the elderly population may be associated with an increased risk of hospitalization for hip fracture (Pratt, Roughead, Ramsay, Salter, & Ryan, 2011).

Sedation

Another reported adverse effect of APs is sedation (Schneider et al., 2006). Sedation may increase the time spent in bed and may lead to an increased risk of other adverse effects such as death caused by CVAEs (Schneider et al., 2006) or fall and hip fracture (Hien et al., 2005).

Increased risk of cognitive decline

The findings of a multiphase randomized study showed that the use of atypical APs may be associated with an increased risk of cognitive decline in people with Alzheimer's disease (Vigen et al., 2011). However, a recent meta-analysis of placebo-controlled randomized clinical trials found that the use of APs in people with dementia did not have a statistically significant effect on cognition in comparison with placebo (Wolf, Leucht, & Pajonk, 2017). Nonetheless, the authors

suggest that duration of treatment with APs may have an effect on cognitive decline (Wolf et al., 2017).

Extrapyramidal symptoms

Another possible complication of APs therapy is extrapyramidal symptoms. These symptoms include various types of involuntary contraction of muscles such as acute dystonic reactions and tardive dyskinesia (Lee et al., 2005). It is estimated that mild types of tardive dyskinesia may happen in 20 % of all individuals treated with conventional APs (Lee et al., 2005). Findings of a retrospective cohort study in people with dementia suggest that the risk of developing medication-induced movement disorders may not be different between the use of conventional APs and the use of atypical APs (Lee et al., 2005).

1.7. Conclusion

The current evidence base for the efficacy and adverse effects of using APs for managing people BPSD is complex to interpret, and at times may seem contradictory. This complicates providing a clear efficacy/safety profile for the use of APs in people with dementia.

Nevertheless, some scholars have offered crude estimations of potential benefits and harms of APs in people with dementia. Banerjee (2009), for instance, has presented a simplified summary of the benefits and adverse effect of short-term use of atypical APs. If 1000 people with BPSD are treated with an atypical AP for almost three months, an additional 91 to 200 individuals with behavioral complications are likely to show clinically significant improvements (Banerjee, 2009). This, however, might lead to 10 additional death, 18 additional CVAEs and no additional falls or fractures (Banerjee, 2009). Longer duration of treatment with APs may increase the risk of some adverse events such as mortality because

adverse events of APs might accumulate over time (Ballard et al., 2009; Banerjee, 2009). This implies that, particularly with respect to the longer-term use of APs, there might be a considerable risk of adverse events associated with the use of APs.

Is it, then, ethically justifiable to use APs with potentially considerable adverse effects that at best might have modest efficacy in managing people with BPSD? In the next section, I explore how scholars have addressed this question.

Chapter 2. Scoping review

In this chapter, my aim is to explore the existing literature on the ethical justifiability of the use of antipsychotics (APs) for managing people with behavioral and psychological symptoms of dementia (BPSD) in long-term care facilities (LTFCs). This is, to my knowledge, the first review conducted on the topic. The chapter is divided into three main sections. First, I discuss the methodology of the review and describe the steps taken to conduct the review. Then, I present the findings of the review. In the following sections, I discuss the findings and conclude by explaining how I draw on the results of the review through the subsequent chapters.

2.1. Methodology

Depending on the aim and approach to engaging with the literature, different types of literature reviews have been identified in the field of biomedical ethics (McDougall, 2013, 2015; Sofaer & Strech, 2012). In general, such reviews may fall into one of two main categories: systematic reviews, and non-systematic reviews. Systematic reviews in biomedical ethics aim “for a comprehensive review of the literature with minimal bias”, entailing “a formal method” and assessment of the quality of included studies (McDougall, 2013, p. 89). Non-systematic reviews in bioethics, however, do not aim for a comprehensive coverage of existing literature, and may or may not entail detailed assessment of the quality of included studies (McDougall, 2015).

Scoping reviews are a type of non-systematic reviews. The objective of scoping reviews is to map out “the key concepts underpinning a research area and the main sources and types of evidence available” (Arksey & O'Malley, 2005, p. 21). Scoping reviews, in general, do not include an assessment of the quality of

included studies, and their guiding research questions are not as specific as those of systematic reviews (Arksey & O'Malley, 2005). This approach to literature reviewing has been taken to explore various topics in biomedical ethics (Koskenvuori, Numminen, & Suhonen, 2017; MacDonald & Shemie, 2017; Wilson, Kenny, & Dickson-Swift, 2017).

In this study, I conducted a scoping review using the method developed by Arksey and O'Malley (2005), for two main reasons. First, I aim to examine “the extent, range and nature of” existing research about the ethical justifiability of using APs for managing people with BPSD (Arksey & O'Malley, 2005, p. 21). Second, by conducting a scoping review, I will be able to identify gaps in existing literature and possible directions for further research. This will allow me to provide a more robust contribution to the existing debate.

Developing a guiding review question is the starting point for conducting scoping reviews. Arksey and O'Malley (2005) recommend that scoping reviews “maintain a wide approach in order to generate breadth of coverage” (p. 23). Consistent with this, in developing the review question in this study, my primary objective was to gain a broad picture of the current state of debate. The guiding review question for this study was:

What is the current state of debate on the ethical (un)justifiability of using APs for managing people with BPSD in LTCFs?

Search strategy

An electronic search was conducted in the following databases: Google Scholar, Web of Science, PubMed, Embase, PsychInfo, and CINAHL. The general search string was: (“dementia” or “BPSD” or “behavioral and psychological symptoms of dementia” or “neuropsychiatric symptoms of dementia” or “NPS”) AND (“ethics”

or “biomedical ethics” or “medical ethics”) AND (“antipsychotics” or “neuroleptics”). In conducting the electronic search, I adopted database-specific strategies. For example, regarding the Embase and PsychInfo databases, the general search terms included both subject headings and keywords. Likewise, both MeSH terms and keywords were searched for the PubMed database. Due to the difficulty of translating from other languages, I only searched for studies published in English. I searched various forms of academic literature including correspondence, book chapters, commentaries, editorials and peer-reviewed articles published prior to July 2017. I searched multiple types of publications to increase coverage of potentially relevant literature. Non-peer reviewed publications (such as correspondence or editorials) were searched based on the hypothesis that they might include relevant discussions. The results of the electronic search in each database were collated, and duplicates were removed.

Identification of relevant studies

The next step in conducting the scoping review was to identify relevant literature. The methodology involved two levels of identifying and selecting publications: an initial screening based on titles, abstracts, and keywords, and a subsequent full-text review of the screened publications based on specific exclusion and inclusion criteria (Arksey & O'Malley, 2005).

In this review, my initial step to identify relevant studies was a pilot process to improve my decision-making in identifying relevant publications based on titles, abstracts, and keywords. I first read the abstracts, titles, and keywords of a set of publications selected randomly from the search results (n=10). I marked them as being likely or not likely to have relevant content in their full texts. I then read full-

texts of that set of publications selected randomly to identify those that met the following inclusion criteria for being included in the review:

- publications that discussed *why* or *how* or *when* or *by whom*, the use of APs might be ethically (un)justified for managing people with BPSD, in general, or with regard to a specific issue (e.g., informed consent), or in a specific case;

I excluded publications that:

- discussed the ethical (un)justifiability of using APs exclusively in settings other than LTCFs; or
- discussed the use of APs for residents in LTCFs for indications other than BPSD (e.g., psychosis in Parkinson's disease)

By using these inclusion/exclusion criteria, I identified a number of relevant publications to be included in the final review. I, then, compared this list of relevant publications with the list of potentially relevant papers generated by the review of titles, abstracts, and keywords. I repeated this process twice, each time with 10 other publications selected randomly from the initial search result. This pilot process was used to increase my accuracy to estimate the relevance of publications based on the titles, abstracts, and keywords.

Then, I screened the rest of publications (with the exception of those already screened in the pilot process) based on their titles, abstracts, and keywords to identify those eligible for full-text review. At this stage, I further strengthened the identification process by searching for ethics-related terms such as “ethics,” “informed consent,” “dignity” and “autonomy” in the titles, abstracts, and keywords to find publications that might be eligible for full-text review.

After this initial screening, I read full-texts of publications identified as eligible for full-text review. Then, I applied the aforementioned inclusion/exclusion criteria. By doing so, I identified and compiled the list of publications to be included in the final review.

Next, I used Google Scholars' citation tracking in a process described as 'reverse snowballing,' which aims to identify recent studies that cite a particular publication (Sayers, 2007). The complete list of publications to be included in the review (either identified through the pilot and the main screening process) was examined for potentially relevant citations using Google Scholars' citation tracking. I read the full-text of the publications identified as potentially relevant and added any further publication(s) that met the inclusion criteria for being included in the review.

Charting and summarizing the key items

The final set of publications was iteratively examined to form a general understanding of the content. Specific passages discussing the ethical justifiability or unjustifiability of the use of APs for managing people with BPSD were identified. Next step involved what Arksey and O'Malley (2005) describe as "charting the key items of information", that is, identifying and sorting the data to form a summarizing outline (p. 26). As Arksey and O'Malley (2005) note, this process of charting and summarizing primarily aims "to present an overview of all material reviewed" (p. 27).

The publications included in the final review were examined to extract these items of information:

- Type of publications
- Setting under focus

- Characteristics of the population/disease under focus
- Which questions regarding the justifiability of the use of APs for managing people with BPSD are addressed by specific passages
- Rationales given for the ethical justifiability or unjustifiability of the use of APs for managing people with BPSD

These items of information were, then, charted and compared with each other to provide an informative, concise outline of the data.

2.2. Results

The initial search retrieved 562 publications from all the six databases. Of these, 65 duplicate publications were removed. Three other records were excluded because they were published in languages other than English. Overall, 464 publications were screened based on their titles, keywords, and abstracts. Of these, 85 publications were selected for full-text review, out of which, 17 publications met the inclusion criteria. Through the reverse snowballing process, I identified one further publication that met the inclusion criteria. Altogether, 18 publications met the inclusion criteria and were included in the final review (*Figure 1*).

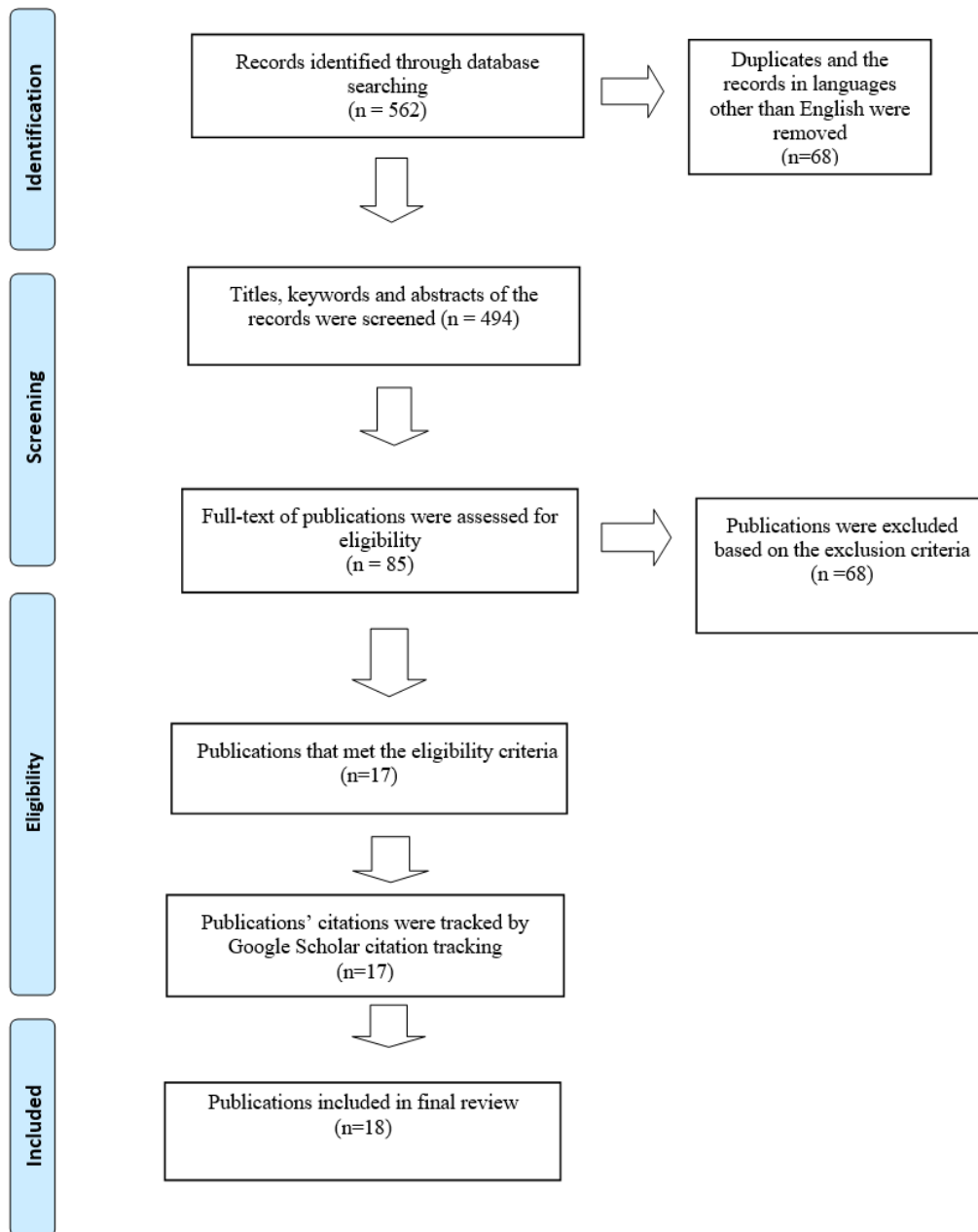


Figure 1. Flow diagram of searches in electronic databases. Adapted from “Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement” by Moher et al., 2009, *PLoS Medicine*, 6(7): e1000097.

Table 1. Characteristics of the studies included in the final review

Author(s)	Title	Type of the publication	Setting under focus	Population/disease characteristics
(Levenson, 2002)	<i>Comments on the case of Esther M</i>	Case commentary	LTCFs	Psychosis with underlying dementia
(Mitchell, 2014)	<i>Therapeutic lying to assist people with dementia in maintaining medication adherence</i>	Case commentary	LTCFs	Advanced Alzheimer's disease
(Treloar, Philpot, & Beats, 2001)	<i>Concealing medication in patients' food</i>	Viewpoint	Unspecified	People with dementia
(Jones, 2001)	<i>Commentary.</i>	Commentary	Unspecified	People with dementia
(Treloar et al., 2010)	<i>Ethical dilemmas: Should antipsychotics ever be prescribed for people with dementia?</i>	Editorial	Unspecified	People with BPSD
(Howe, 2007)	<i>Five ethical questions involving Alzheimer's disease</i>	Article	Unspecified	People with Alzheimer's disease
(Passmore, Ho, & Gallagher, 2012)	<i>Behavioral and psychological symptoms in moderate to severe Alzheimer's disease: A palliative care approach emphasizing recognition of personhood and preservation of dignity</i>	Review	Unspecified	BPSD in moderate to severe Alzheimer's disease
(Pulsford & Duxbury, 2006)	<i>Aggressive behaviour by people with dementia in residential care settings: A review</i>	Review	LTCFs	People with dementia and aggressive behavior
(Edvardsson, Winblad, & Sandman, 2008)	<i>Person-centred care of people with severe Alzheimer's disease: Current status and ways forward</i>	Review	Unspecified	Severe Alzheimer's disease
(Bishara, 2009)	<i>Using antipsychotics in dementia patients creates a clinical and ethical dilemma</i>	Article	LTCFs	People with BPSD
(Toiviainen, 2014)	<i>Case commentary 1</i>	Case commentary	LTCFs	Person with Alzheimer's disease
(Brannelly &	<i>Case commentary 2</i>	Case	LTCFs	Person with

Whitewood, 2014)		commentary		dementia
(Ihara & Arai, 2008)	<i>Ethical dilemma associated with the off-label use of antipsychotic drugs for the treatment of behavioral and psychological symptoms of dementia</i>	Review article	Unspecified	People with BPSD
(Kuepper & Hughes, 2011)	<i>The challenges of providing palliative care for older people with dementia</i>	Article	Unspecified	People with BPSD and in need of palliative care
(Naarding, van Grevenstein, & Beekman, 2010)	<i>Benefit-risk analysis for the clinician: 'primum non nocere' revisited--the case for antipsychotics in the treatment of behavioural disturbances in dementia</i>	Editorial	Unspecified	People with dementia and behavioral disturbances
(Passmore, 2013)	<i>Neuropsychiatric symptoms of dementia: Consent, quality of life, and dignity</i>	Review	Unspecified	People with BPSD (neuropsychiatric symptoms)
(Maria-Roxana & Vasile, 2010)	<i>Ethical implications of the institutionalising patients with dementia</i>	Article	LTCFs	Institutionalized people with dementia
(Hilmer & Gnjdic, 2013)	<i>Rethinking psychotropics in nursing home</i>	Perspective article	LTCFs	Residents with BPSD

Four main questions (*why, how, when and by whom*) regarding the ethical justifiability of using APs for managing BPSD were addressed by the publications included in the final review (*Table 2*). Some publications discussed more than one question. In addition, in addressing the question of *how* and *by whom*, a number of publications discussed both the ethical justifiability and unjustifiability of using APs (*Table 2*). With respect to each main question (*why, how, when and by whom*), several rationales were identified (*Table 2*).

Table 2. The list of the main questions and identified rationales

The four main questions		Identified rationales	References
<i>Why ...</i>	might the use of APs might be justified?	Because of increased quality of life, and/or reducing distress or suffering	(Howe, 2007) (Treloar et al., 2010) (Passmore, 2013) (Kuepper & Hughes, 2011)
		Because APs may enhance care-givers' interactions with people with BPSD	(Howe, 2007)
		Because of consequences of undertreatment or nontreatment of BPSD	(Passmore et al., 2012) (Naarding et al., 2010)
	might not the use of APs be justified?	Because of challenges of relying on pharmacological interventions to address the people's needs	(Pulsford & Duxbury, 2006) (Edvardsson et al., 2008)
		Because APs may not assist people with BPSD to interact with others	(Pulsford & Duxbury, 2006)
<i>How ...</i>	might the use of APs be justified?	In an off-label way	(Ihara & Arai, 2008)
		With extensive safety measures	(Passmore et al., 2012) (Bishara, 2009) (Treloar et al., 2010)
		By considering people's prior wishes and/or with informed consent	(Howe, 2007) (Passmore et al., 2012) (Bishara, 2009) (Hilmer & Gnjidic, 2013)
		With a palliative purpose	(Passmore et al., 2012) (Treloar et al., 2010) (Passmore, 2013) (Kuepper & Hughes, 2011)
		In a covert way and/or with therapeutic lying	(Treloar et al., 2001) (Jones, 2001) (Brannelly & Whitewood, 2014) (Mitchell, 2014)

			(Toiviainen, 2014)
	might not the use of APs be justified?	In a covert way and/or with therapeutic lying	(Treloar et al., 2001) (Brannelly & Whitewood, 2014) (Mitchell, 2014)
		In an “unthinking” manner	(Pulsford & Duxbury, 2006)
		As chemical restraint	(Passmore et al., 2012)
When ...	might the use of APs be justified?	When there is danger to self or fellow residents	(Maria-Roxana & Vasile, 2010)
		When surrogate decision-maker disagrees with healthcare professionals	(Levenson, 2002)
	might not the use of APs be justified?	When other treatable causes are identified and/or there is no distress	(Treloar et al., 2010) (Passmore et al., 2012)
		When more appropriate and rewarding treatments are available	(O'Sullivan, 2013)
By whom ...	might the use of APs be justified?	By experts	(Bishara, 2009)
	might not the use of APs be justified?	By general practitioners	(Bishara, 2009)

2.2.1. Why might the use of APs be justified?

Three reasons were identified in the existing literature as to why the use of APs might be ethically justified for managing people with BPSD (*Table 2*).

First, some scholars hold that the use of APs may increase individuals’ quality of life and/or reduce their suffering or distress. Howe (2007) states that in spite of the risk of adverse effects associated with the use of APs, the increased quality of life “may be worth the increased risks” (Howe, 2007, p. 31). Similarly, Kuepper and Hughes (2011) and Treloar et al. (2010) discuss the justifiability of judicious use of APs for severe distress.

Second, Howe (2007) considers the ethical justifiability of using APs in relation to individuals' interaction with others. Howe (2007) claims that managing agitation or aggression by using APs may allow care-givers in LTCFs to construct a more "caring and patient" relationship with residents (p. 31).

Thirdly, some authors maintain that undertreatment or nontreatment of BPSD might lead to compromising people's dignity or personhood (Passmore et al., 2012), and that there are harms arising from leaving BPSD untreated (Naarding et al., 2010).

2.2.2. Why might NOT the use of APs be justified?

The review identified two reasons as to why the use of APs might not be ethically justified (*Table 2*).

First, BPSD may be "ways to communicate unmet basic needs" (Edvardsson et al., 2008, p. 363). Using APs may decrease the occurrence of BPSD. However, since BPSD might be a means by which people with dementia communicate their needs, decreasing the occurrence of BPSD may not address underlying causes of BPSD, that is, individuals' unmet needs (Edvardsson et al., 2008; Pulsford & Duxbury, 2006).

Second, using APs may affect the relationship between people with dementia and others. In particular, the sedative effect of APs, which is argued to be the main aim for using APs by healthcare professionals in LTCFs, does not help people with dementia to interact with others (Pulsford & Duxbury, 2006).

2.2.3. How might the use of APs be justified?

Five rationales were identified as to how the use of APs might be ethically justified for managing people with BPSD (*Table 2*).

In an off-label way

Ihara and Arai (2008) discuss in detail the ethical justifiability of using APs in an off-label way. They note that sometimes there might be a gap between what might benefit patients in practice and “what the health service authority approves” (Ihara & Arai, 2008, p. 32). The authors refer to a gap between what the regulatory bodies in Japan approve for managing some BPSD and what practitioners tend to prescribe. In Japan, a conventional AP (thioridazine) is approved for the use in elderly patients for managing specific BPSD (delusions or hallucinations), but practitioners tend to use atypical APs because of favorable safety profile. Although prescribing atypical APs stands in contrast to the guidelines, Ihara and Arai (2008) imply, it might be ethically justified as “clinicians’ preference of atypical agents to conventional neuroleptics is based on ethical motivation regarding the safe use of the drug” (Ihara & Arai, 2008, p. 36).

With extensive safety measure

Three publications emphasized that extensive safety measures must be implemented for an ethically justified use of APs. Bishara (2009) maintains that APs should be used in “the lowest dose possible” and “for the shortest period necessary” with detailed documentation of reasons for which a specific AP is being used (Bishara, 2009, p. 57). Likewise, Passmore et al. (2012) and Treloar et al. (2010) discuss the need for regularly reviewing the use of APs in people with BPSD in order to rule out the unnecessary continuation of APs.

By considering people’s prior wishes and/or with informed consent

Four publications pointed to the importance of considering people’s prior wishes and/or integrating informed consent into treatment with APs in individuals with dementia. Hilmer and Gnjidic (2013) emphasize the importance of respecting the

autonomy of people with BPSD. They note that people with BPSD (or their surrogate decision-makers) need to make “informed, free” decisions with regard to the use of APs (Hilmer & Gnjdjic, 2013, p. 77). Similarly, Bishara (2009) points to the necessity of a clear discussion with people with BPSD or their surrogate decision-makers about the risks associated with the use of APs. Howe (2007) suggests that discussions about possible treatments of agitation or aggression in people with Alzheimer’s disease should begin early in the disease trajectory. Such discussions demonstrate “respect for them as persons” (Howe, 2007, p. 32). Further, Passmore et al. (2012) discuss the necessity of prioritizing people’s prior wishes or preferences with regard to treatment with APs.

With a palliative purpose

In four publications, scholars investigate the ethical justifiability of using APs for managing BPSD with a palliative purpose (Kuepper & Hughes, 2011; Passmore, 2013; Passmore et al., 2012; Treloar et al., 2010). Treloar et al. (2010) draw an analogy between the use of palliative radiotherapy or chemotherapy in patients with terminal cancer and the use of APs in patients with advanced dementia. They imply that severe distress can be seen as a target for palliative care in advanced dementia. They hold that with the development of palliative models for patients with advanced dementia, the prescribers might be more able to justify the use of APs for severe distress (Treloar et al., 2010). Passmore et al. (2012) and Passmore (2013) share the same view about the importance of palliative models in justifying the use of APs, although they base their discussions on concepts such as dignity and personhood.

In a covert way and/or with therapeutic lying

In five publications, scholars discuss how the use of APs in a covert way and/or with therapeutic lying⁷ might be ethically justified. Treloar et al. (2001) claim that in exceptional cases, it is justified for healthcare professionals to administer medications covertly to “mentally incapable patients” in order to carry out the duty of care (Treloar et al., 2001, p. 63). In response to Treloar et al. (2001), Jones (2001) emphasizes the necessity of benefiting people with dementia by providing potentially useful medications (APs) despite the challenges of cooperating with patients with resisting behaviors.

Mitchell (2014) presents a case in which healthcare professionals in a LTCF face a dilemma as to how it might be justified to (dis)continue administering AP medication in a patient (Sam) who has been lied to about the medication for years by his wife. Mitchell (2014) claims that some might justify continuing what he terms therapeutic lying in the case based on the principles of beneficence and non-maleficence.

Toiviainen (2014), and Brannelly and Whitewood (2014) comment on the case discussed by Mitchell (2014). Toiviainen (2014) points to the trust between Sam and his wife. Toiviainen (2014) implicitly suggests that continuing the use of APs with therapeutic lying might be justified given the potentially harmful consequences of revealing the lie on the relation between Sam and his wife. Sam’s case is discussed by Brannelly and Whitewood (2014) through the lens of Tronto’s ethics of care. They argue that covert administration of APs might be justified if a “therapeutic alliance” is established with people with dementia and their families (Brannelly & Whitewood, 2014, p. 849).

⁷ Though no clear definition of therapeutic lying is provided in the sources cited here, therapeutic lying can be broadly defined as deliberately deceiving patients in order to provide medical benefits to them.

2.2.4. How might NOT the use of APs be justified?

In contrast, three rationales were identified as to how the use of APs for managing people with BPSD might not be justified (*Table 2*).

In a covert way and/or with therapeutic lying

Three publications that discussed how using APs in a covert way might be ethically justified also discussed how covert use of APs might *not* be ethically justified. Treloar et al. (2001) raise the issue that the secrecy associated with the covert administration of APs leads to “professional-care staff failing to discuss the issue with others, and is a potential form of patient abuse” (Treloar et al., 2001, p. 64). Mitchell discusses how therapeutic lying stands in contrast with “the principles of veracity, dignity, and autonomy” (Mitchell, 2014, p. 845).

Therapeutic lying may lead to not disclosing information about APs, and thus, the patient would not be able to decide between taking or not taking the medications (Mitchell, 2014). Brannelly and Whitewood (2014) adopt Tronto’s ethics of care approach to examine the case presented by Mitchell (2014). They discuss how therapeutic lying may fail to enact ethical elements of care in LTCFs. In particular, they raise the issue that therapeutic lying might not allow people’s “voice to be present to guide care” (Brannelly & Whitewood, 2014, p. 848). They also raise the concern that long-term therapeutic lying might make it difficult to “build trust and solidarity” with residents in LTCFs (Brannelly & Whitewood, 2014, p. 849).

In an “unthinking” manner

In one publication, the authors mention that the use of APs “in an unthinking way” might compromise residents’ personhood (Pulsford & Duxbury, 2006, p. 616). The authors characterize this “unthinking” way of using APs as relying on pharmacological/physical approaches as the only way to manage challenging

behaviors in LTCFs, “which views challenging behaviour as the more or less random consequence of neurological damage” (Pulsford & Duxbury, 2006, p. 613).

As chemical restraint

Passmore et al. (2012) argue that although people with BPSD may need “external control measures” such as the use of APs to compensate “for the loss of their internal control mechanisms” to preserve their dignity and comfort, the use of APs should not be pursued as chemical restraint (Passmore et al., 2012, p. 9).

2.2.5. When might the use of APs be justified?

Two rationales were identified as to when the use of APs might be ethically justified (*Table 2*).

When there is danger to self or fellow residents

Maria-Roxana and Vasile (2010) discuss ethical implications associated with institutionalizing people with dementia. They assert that if a person with BPSD acts in such a way that puts in danger her life or the life of her fellow residents in LTCFs, the use of APs in small doses is justified (Maria-Roxana & Vasile, 2010).

When surrogate decision-maker disagrees with healthcare professionals

Levenson (2002) comments on a case in which a surrogate decision-maker refuses AP treatment. Healthcare professionals, nonetheless, believe that the surrogate decision-maker's choice does not align with the needs of the resident. The author claims that in some cases, surrogate decision-makers might misunderstand the aims of using psychotropic medications such as APs, partly due to the rather long history of ineffective use of the medications in LTCFs (Levenson, 2002). Despite any surrogate decision-makers' disapproval, Levenson (2002) implies that the use

of APs may be justified if there is a medical necessity, and after a clear, extensive discussion with surrogate decision-makers.

2.2.6. When might NOT the use of APs be justified?

Two rationales were given as to when the use of APs for managing people with BPSD might not be justified.

When other treatable causes are identified and/or there is no distress

Treloar et al. (2011) point out that the use of APs is not ethically justified when BPSD do not cause distress to people with dementia. Furthermore, they mention that the use of APs is unjustified when “no treatable cause is identified”, for example, using APs for making people with dementia “more manageable” (Treloar et al., 2010, p. 89). This view, in general, is endorsed by Passmore et al. (2012), although they mention that persistent, unmanaged BPSD may compromise individuals’ dignity even if there is no apparent distress.

When more appropriate and rewarding treatments are available

Drawing on feedback from a change process implemented in a LTCF, O’Sullivan (2013) states that the use of APs is unjustified “when alternative ways of treating the cause of behaviours are more appropriate and rewarding for all concerned” (O’Sullivan, 2013, p. 119).

2.2.7. By whom might the use of APs be justified?

Bishara (2009) holds that the use of APs in elderly individuals with dementia is justified when prescribed by “experts in the field”, implying that geriatric psychiatrists might be more able than general practitioners (GPs) to provide a thorough risk/benefit assessments (Bishara, 2009, p. 57).

2.2.8. By whom might NOT the use of APs be justified?

Bishara (2009) suggests that it might not be justified to allow GPs to prescribe APs in elderly people with dementia. The author assumes that not allowing GPs to prescribe APs might be a move towards more judicious use of APs.

2.3. Discussion

In this scoping review, I provided a broad picture of the current debate about the ethical justifiability of using APs in residents with BPSD in LTCFs. Nineteen rationales were identified in the current literature for *why*, *when*, *how* and *by whom* the use of APs might be ethically (un)justified for managing people with BPSD.

Most of the rationales, nonetheless, are not framed in explicit ethical terms. For instance, Treloar et al. (2010) and Passmore et al. (2012) discuss the unjustifiability of using APs for people with BPSD when other treatable causes are identified and/or there is no distress. This rationale for when the use of APs might not be ethically justified is based upon concrete, practical considerations rather than framed in explicit ethical notions or principles. Another example is the discussions about the justifiability of using APs because of the increased quality of life, and/or reducing distress or suffering in people with BPSD. Likewise, this rationale is not framed in explicit ethical term.

Regarding some of the other identified rationales, scholars refer to ethical concepts or principles without detailed clarifications about how those abstract concepts or principles might be applied to the issues arising from the use of APs for managing people with BPSD.

For example, Passmore et al. (2012) refer to ‘autonomy’ as an important ethical consideration with respect to the use of APs for managing people with BPSD. They hold the view that to address the autonomy of people with dementia who are

not capable of making informed decisions about the treatments, the main focus needs to be on the individuals' prior wishes. This implies that the individuals' current interests either are not morally relevant or have less moral relevance than their precedent wishes. Passmore et al. (2012), nevertheless, do not elucidate the relationship between current and prior wishes or interests in the context of diminished autonomy associated with dementia.

Another example is the reference to Tronto's ethics of care by Brannelly and Whitewood (2014). Their discussion is based upon Tronto's account of five ethical elements of care. Brannelly and Whitewood (2014), however, do not go into a detailed discussion about the meaning of those five elements of care or how they relate to the use of APs.

An interesting finding of this scoping review is discussion about the ethical justifiability of using APs in a covert way and/or with therapeutic lying. Some scholars discuss both the ethical justifiability and unjustifiability of covert administration of APs, without explicitly favoring one side. This indicates a level of implicit agreement in the existing debate about the complexities of assessing the ethical justifiability of covert administration of APs. In this study, nonetheless, a number of more explicit agreements between scholars were identified. For instance, Passmore et al. (2012) quote, and are in general agreement with, Naarding et al. (2010) and Treloar et al. (2010).

2.4. Limitations

Although I aimed for comprehensiveness, some relevant publications may not have been covered in this scoping review. Moreover, I did not include publications in languages other than English. In this review, I included relevant publications that discussed the use of APs in (either implicit or explicit) ethical terms. There might

be, nonetheless, medical literature that discusses the justifiability of using APs without drawing on ethical notions or principles.

2.5. Conclusion

Findings of this scoping review showed that majority of the rationales provided in the existing debate for the (un)justifiability of using APs for managing people with BPSD are not framed in explicit ethical terms. Further, where scholars appeal to abstract ethical concepts or principles, they do not provide detailed clarification about the meaning or implications of those concepts or principles. In the next chapter, I map some of the concrete, practical rationales identified in this review onto more explicit ethical concepts. Along with that, I provide detailed clarifications about what the abstract concepts such as autonomy, beneficence or non-maleficence might indicate with regard to the use of APs for managing people with BPSD.

Chapter 3. The four-principles approach

In this chapter, I examine the ethical justifiability of using antipsychotics (APs) for managing people with behavioral and psychological symptoms of dementia (BPSD) in long-term care facilities (LTCFs) through the lens of the four-principles approach to biomedical ethics.

I start with giving a brief background to the four-principles approach. Then, I discuss what the principles might indicate with regard to the use of APs for managing people with BPSD. The next section deals with how the four principles might come into conflict when healthcare professionals use APs for managing people with BPSD. I explain how justifying the use of APs in cases of conflict between the principles requires ‘weighing and balancing’ the principles. Then, I discuss the conditions for a justified weighing/balancing process. Finally, I conclude with discussing how concrete rationales identified in the previous chapter for the (un)justifiability of using APs can be reframed in more explicit ethical terms using the four-principles approach.

3.1. Background

From the emergence of bioethics as a distinct field of inquiry in the 1960s and 1970s, the principle-based approach (or Principlism) has been one of the most dominant frameworks to analyze bioethical issues. Through seven successive editions of *Principles of Biomedical Ethics* (first published in 1979), Beauchamp and Childress (2013) developed an account of four principles of biomedical ethics, which has been hailed for offering “a basic moral language and a basic moral analytic framework” (Gillon, 2015, p. 115).

The four-principles approach starts with the notion of *common morality*; a shared set of core beliefs, which Beauchamp and Childress claim, “are not relative to

cultures, groups, or individuals” (2013, p. 3). Basic rules of obligation such as ‘do not steal’ or ‘do not kill’ represent some of the general moral norms found within the common morality, from which four clusters of principles are derived to “form a suitable starting point for biomedical ethics” (p. 13). These clusters of principles are (1) *respect for autonomy*, (2) *non-maleficence*, (3) *beneficence*, and (4) *justice*. The four clusters of principles function as general guidance in specific circumstances. More detailed and “specific in content” norms of obligation are *rules*, though the authors make only a “loose” distinction between rules and principles⁸ (p. 14).

Principles and rules create obligations. In some circumstances, one may be faced with conflicting obligations. To allow compromise, Beauchamp and Childress (2013) rely on a distinction between *prima facie* obligations and *actual* obligations⁹. A *prima facie* obligation “must be fulfilled unless it conflicts with an equal or stronger obligation” (p. 15). The actual obligation is determined by “examining the respective weights of competing *prima facie* obligations” (p. 15).

The scope and content of the four clusters of principles (and paralleling rules) need to be defined in specific circumstances. The principles (and paralleling rules) also need to be weighted to define “which moral norms should prevail” (Beauchamp & Childress, 2013, p. 20). These levels of analysis are described, in the four-principles approach, as *specification* and *balancing*, respectively.

An example of specification is interpreting the principle of respect for autonomy in the case of an incompetent patient through the following rule: “respect the autonomy of competent patients by following their advance directives when they

⁸ Beauchamp and Childress (2013, p. 14) also refer to other types of norms such as rights and virtues. Here, I only discuss principles and rules.

⁹ This distinction has been originally developed by Ross (1930).

become incompetent” (p. 17). Here, specification adds content and scope to the abstract principle of respect for autonomy.

An example of balancing is the case of forced confinement of individuals when there is an epidemic of a highly contagious and deadly infectious disease. In such a case, infringing the autonomy of individuals by isolating them from the rest of population may seem to have less weight than benefiting and protecting the general population (beneficence and non-maleficence considerations)¹⁰.

3.2. Specification of the four clusters of principles

In what follows, I explain what the four clusters of principles may indicate when APs are being used to manage people with BPSD.

Respect for autonomy

Broadly speaking, autonomy denotes personal self-rule, which is conceptualized as the absence of “controlling interference” and “limitations that prevent meaningful choices” (Beauchamp & Childress, 2013, p. 103). Respect for autonomy has roots in the liberal notion of personal “freedom and choice” (Beauchamp, 2007, p. 4). On this account, an autonomous agent is the one who “acts freely in accordance with a self-chosen plan” (Beauchamp, 2007, p. 4).

Respect for autonomy in the biomedical context is safeguarded through the practice of informed consent. According to Beauchamp and Childress, informed consent entails that a patient *intentionally* with sufficient *understanding* and *voluntarily* (free from either external or internal¹¹ sources of control) authorizes

¹⁰ Though the specification and balancing may lay the groundwork for an initial moral judgment about a specific case, Beauchamp and Childress (2013) discuss how judgments about different cases need to cohere with each other as much as possible. They refer to *reflective equilibrium* as a reflective process to test and make different moral judgments more coherent. See Beauchamp and Childress (2013, pp. 404-410).

¹¹ External sources of control refer to controlling influences exerted by one person on someone else. Internal sources of control, on the other hand, refer to influences that limit voluntariness such as mental illness.

healthcare professionals to proceed with a specific course of action (2013, p. 122). If these conditions are met, informed consent is considered to be an “autonomous authorization of a medical intervention” (Beauchamp & Childress, 2013, p. 122).

The criteria of understanding and freedom from control, Beauchamp and Childress claim, are matters of degree. A patient’s understanding can be on a continuum from complete understanding to the total absence of understanding (2013, p. 105). Likewise, there might be a range of freedom from being under no control to being completely constrained (p. 105). By contrast, Beauchamp and Childress hold that the criterion of intentionality cannot be a matter of degree: “acts are either intentional or nonintentional” (2013, p. 105).

Due to the gradual decline in cognitive abilities, people with dementia may have varying levels of understanding during the illness trajectory. The decline in cognitive abilities may also limit voluntariness in individuals with dementia due to internal controlling influences. As mentioned above, understanding and voluntariness, according to Beauchamp and Childress, are matters of degree. Thus, one might reasonably expect that at least some residents with dementia in LTCFs at some points in time meet the thresholds of understanding and voluntariness regarding the use of APs. The criterion of intentionality, however, poses a significant challenge for specifying the principle of respect for autonomy in people with dementia.

Beauchamp and Childress state that intentional actions entail plans “in the form of representation of the series of events proposed for the execution of an action” (2013, p. 104). This account of intentionality regarding planned actions seems incongruous with the everyday experience of many people with dementia who have lost some of the cognitive resources necessary to form or adhere to plans

(Jacques, 1997). Unlike the other criteria of understanding and voluntariness, the criterion of intentionality is an ‘all or nothing’ condition: intentionality is either present or absent. A person with dementia may have some understanding of the medical intervention (here the use of APs) and may be largely free of (internal or external) controlling influences. If, however, she does not have the cognitive abilities to form a plan of action or communicate it effectively, her decisions, according to Beauchamp and Childress may not be considered as *autonomous*. On this account, giving a valid consent (or a valid refusal) requires the capacity to make *autonomous* decisions.

So far, I have discussed general outline of a valid informed consent (or otherwise informed refusal) according to Beauchamp and Childress. But then, how can we proceed with specifying the principle of respect for autonomy when individuals are unable to give a valid informed consent? In what follows, I discuss two possibilities: advance directives and surrogate decision-making.

Advance directives are formal documents stating individuals’ wishes about medical decision-making “during periods of incompetence” (Beauchamp & Childress, 2013, p. 189). Advance directives might be a possible way of extending individuals’ *precedent* autonomy.

However, a number of theoretical objections have been leveled against relying on advance directives in people with dementia (Vollmann, 2001). For example, it has been suggested that the identity of people varies with the stage of dementia, being different at the early stages of dementia compared with during advanced stages (Vollmann, 2001). Some individuals with dementia develop major personality changes. It might, then, be argued that advance directives “can claim moral validity

only if they concern an identical person and not a second, “new” person” (Vollmann, 2001, p. 165).

Additionally, there are some practical complexities in relying on advance directives, particularly in individuals with dementia. First, not all people compose advance directive. Second, even if advance directives are present, these might not contain “sufficiently explicit instructions” (Beauchamp & Childress, 2013, p. 189) as noted somewhat exaggeratedly by a healthcare professional:

it was so non-specific or it wasn't legally binding in any stretch of the imagination ... it wasn't worth the paper it was written on.
(Robinson et al., 2013, p. 404)

Even if advance directives are considered a desirable way of specifying the principle of respect for autonomy, many individuals do not compose advance directives. In such cases, an alternative way of specifying the principle of respect for autonomy is the use of surrogate decision-makers, in many cases, one of the individuals' family members. Family members are considered to be appropriate surrogates on the premise that they are in a unique position to identify with the interests and wishes of their relatives with dementia.

There are two main approaches to surrogate decision-making: substituted judgment and best interests.

Using substituted judgment implies that a surrogate decision-maker tries to make the same decision that the now incompetent person “would have made if competent” (Beauchamp & Childress, 2013, p. 227). By applying this standard, a surrogate decision-maker, basically answers the question of “what would the

patient want in this circumstance?” (p. 227). Relying on substituted judgment requires sufficient familiarity with individuals’ prior values and wishes (p. 227).

According to best interests, on the other hand, a surrogate decision-maker determines “the highest probable net benefit among the available options” (Beauchamp & Childress, 2013, p. 228). The use of this approach entails evaluating risks and likely benefits of different available treatments. According to Beauchamp and Childress, surrogate decision-makers, in general, should use the best interest standard only if there are no reliable indicators of the preferences of a formerly competent, and “now nonautonomous”, individual¹² (2013, p. 229).

Overall, specifying the principle of respect for autonomy poses a number of difficulties in people with BPSD. Such difficulties, however, in the four-principles approach, do not lead to discounting *prima facie* obligations based on the principle of respect for autonomy. Even if an individual with dementia cannot give a valid informed consent, the principle of respect for autonomy still needs to be specified in one way or another, for instance, by relying on the individual’s advance directive or her surrogate decision-maker.

Non-maleficence

The principle of non-maleficence refers to obligations of not causing harm to others. The well-known medical saying of ‘first do not harm,’ or its Latin equivalence ‘*primum non nocere*’, demonstrates the long-held importance that has been placed on physicians’ obligation to “avoid doing harm to their patients” (Beauchamp, 2007, p. 4).

¹² Beauchamp and Childress (2013), however, acknowledge that there might be cases in which it might be unjustified to bind some “now nonautonomous” individuals by some prior decision (p. 229). See the discussion about the case of Margo, a patient with Alzheimer’s disease (p. 229).

The notions of harm and harmful actions lie at the heart of the principle of non-maleficence. There are different ways of construing harm and, accordingly, harmful actions. Broad definitions of harm, according to Beauchamp and Childress, may include setbacks to others' interests in privacy, liberty or reputation (2013, p. 153). Narrower construal of harm, by contrast, includes only setbacks to others' "physical or psychological interests" (p. 154). In their discussion about the principle of non-maleficence, Beauchamp and Childress, focus on physical harms such as suffering, disability or death (2013, p. 154).

The principle of non-maleficence gives rise to two types of obligation. First, there are "obligations not to inflict harms"; and second, there are "obligations not to impose *risks* of harm" (Beauchamp & Childress, 2013, p. 154). The use of APs for managing people with BPSD, as discussed in *Chapter 1*, might be associated with an increased risk of some adverse effects such as the risk of fall or hip fracture. Thus, one might frame an obligation based on the principle of non-maleficence as follows: 'do not put residents in LTCFs at the risk of physical harms such as the risk of fall and hip fracture by using APs'. Nevertheless, as I mentioned earlier, in the four-principles approach, this obligation is considered only as a *prima facie* obligation. Using APs might still be ethically justified by showing that other obligations based on other principles override the *prima facie* obligation based on the principle of non-maleficence.

Beneficence

Healthcare professions are characterized by the goal of contributing to and "attending to the welfare of patients" (Beauchamp & Childress, 2013, p. 202). Such beneficial actions are captured by the notion of *beneficence*. The principle of

beneficence obligates healthcare professionals to take active steps to promote the welfare of patients.

Obligations of beneficence differ from obligations of non-maleficence in a number of ways. Most notably, while the obligations of non-maleficence entail a “negative prohibition of action”, the obligations of beneficence involve a “positive requirement of action” (Beauchamp & Childress, 2013, p. 204).

Beauchamp and Childress differentiate between two senses of beneficence. While *positive beneficence* obligates moral agents to benefit others directly, *utility* refers to moral agents’ obligation to “balance benefits, risks, and costs” and provide “the best overall results” (2013, p. 202). With regard to the use of APs, acting on the obligation of positive beneficence means estimating the degree to which APs provide direct benefits to individual residents in LTCF by managing their BPSD. Utility, on the other hand, entails considering those positive outcomes vis-à-vis the overall risk of harms and costs associated with the use of APs.

Discussing how the principle of beneficence might apply regarding the use of APs requires information about the benefits and the harms of APs for managing people with BPSD. As noted in *Chapter 1*, there are considerable complexities in assessing the evidence base for the efficacy and the risk of adverse effects of APs in managing people with BPSD.

There are similar complexities with respect to assessing other indicators of benefit or harm such as the impact of APs on individuals’ quality of life (QoL). In *Chapter 2*, I referred to the claim that it might be justified to use APs because of the improvements in QoL (Howe, 2007; Treloar et al., 2010). There are, however, gaps and contradictions in the existing body of knowledge as to whether the use of APs increases QoL in people with BPSD.

First, the placebo-controlled trials designed to investigate the efficacy of APs for managing people with BPSD have not utilized formal QoL measurements¹³ (Ballard & Margallo-Lana, 2004). Second, data from other sources such as observational studies seem contradictory. Some observational studies suggest that the use of APs is negatively related to QoL in people with dementia. In a cross-sectional study, use of psychotropic medications (including antipsychotics) was independently associated with poor QoL in both moderate and advanced stages of dementia (Wetzels, Zuidema, de Jonghe, Verhey, & Koopmans, 2010). Similarly, another study across a number of LTCFs showed a negative association between the use of APs and resident-reported QoL (Zimmerman et al., 2005). In contrast, a more recent longitudinal study suggests that using APs, by itself, does not negatively affect QoL in people with dementia in LTCFs (Ven-Vakhteeva, Bor, Wetzels, Koopmans, & Zuidema, 2013). The gaps and contradiction in the current evidence may, therefore, make it difficult to justify using APs based on their impact on people's QoL as a beneficence considerations.

To conclude, the complexities of the current evidence base for the benefits of APs in managing people with BPSD imply that healthcare professionals might not be at all times under *prima facie* obligation based on the principle of beneficence to *use* APs. In some circumstances, however, there might be *prima facie* obligations based on beneficence considerations to use APs. For instance, healthcare professionals in LTCFs might feel obligated to use APs as the only possible way to contribute to the welfare of people with severe dementia and with persistent, aggressive behavior unresponsive to non-pharmacological alternatives

¹³ Measures for evaluating QoL can be, in general, categorized into generic and disease-specific measures. Generic measures such as The Duke Health Profile and the Schedule for the Evaluation of Individual Quality of Life (SEIQOL) have some limitations to evaluate QoL in people with dementia. For instance, SEIQOL is shown to be too cognitively complex for people with dementia (Smith et al., 2005). In recent years, disease-specific measures such as DEMQOL have been developed to evaluate QoL in people with dementia (Smith et al., 2005).

(Therapeutic Goods Administration, 2015). In this example, from the standpoint of the four-principles approach, the healthcare professionals might be under *prima facie* obligations based on the principle of beneficence to use APs.

Justice

Broadly construed, the concept of *justice* refers to treating others “according to what is fair, due or owed” (Beauchamp, 2007, p. 6). A relevant and more specific term is *distributive justice*, which refers to a “fair, equitable, and appropriate distribution of benefits and burdens” within societies (Beauchamp & Childress, 2013, p. 250). The principle of justice¹⁴ gives rise to “obligations of fairness in the distribution of benefits and risks” (Beauchamp, 2003, p. 269). These obligations arise in recognition that available resources in most societies are limited.

In the healthcare context, obligations based on the principle of justice are primarily concerned with setting priorities and allocating resources within different sectors of the healthcare system. Beauchamp and Childress discuss a number of different, though related, types of resource allocation decisions in healthcare systems. First¹⁵, policymakers must make decisions within an overall budget that is allocated to healthcare provision in a given society (2013, p. 280). This means, for instance, determining how many overall resources, if any, need to be allocated to healthcare provision in LTCFs. Then, policymakers must allocate resources within each targeted budget, for example, deciding how many resources (out of the overall budget for healthcare provision in LTCFs) need to be allocated to managing people with BPSD in LTCFs.

¹⁴ Beauchamp and Childress (2013), though, emphasize that no single principle of justice can address “all problems of justice” (p. 250).

¹⁵ Here, I discount the discussion at the highest macro-level or “partitioning the comprehensive social budget” (Beauchamp & Childress, 2013, p. 250).

Use of APs in LTCFs is a type of healthcare provision. It requires resources both in terms of direct cost of the medications, and indirect costs such as staff allocation or costs arising from any adverse effects. Some types of formal analysis such as cost-benefit analysis (CBA) are used to consider, in monetary terms, “the value for outcomes” of available treatment options (Beauchamp & Childress, 2013, p. 231). Particularly in the second level of resource allocation decision-making, formal analyses such as CBA may be the basis on which policymakers decide how to weight different therapeutic options in light of the monetary constraints. By relying on CBA, policymakers might be able to compare the benefits and costs of the use of APs with the use of other (pharmacological or non-pharmacological) alternatives for managing people with BPSD in LTCFs.

Formal analyses such as CBA, which may seem to be a set of objective and unbiased considerations, nonetheless, “do not dictate a conclusion” (Beauchamp & Childress, 2013, p. 231). Such analyses provide useful data “for a society needing to allocate resources” (p. 232). This implies that in resource allocation decision-making, societies might also take into account other considerations.

An example of other such considerations is ‘age-based rationing’ policies. These policies may give a higher or a lower priority in allocating resources to people in a specific age group (Beauchamp & Childress, 2013, p. 285). Such policies consider age as a relevant consideration in making resource allocation decisions. One, somewhat controversial, argument for justifying the use of age in resource allocation policies has been offered by Daniels (1983). He holds that as a society we should allocate fewer resources to the elderly in exchange for more resources

earlier in life¹⁶ (Daniels, 1983). Since the majority of people with BPSD in LTCFs are elderly, Daniels' argument could be held as a justification of reducing resources available for elderly residents in LTCFs.

To sum up, the principle of justice (specified either by relying on CBA or other considerations) might obligate healthcare professionals, in some circumstances, to use APs¹⁷. Even so, this *prima facie* obligation based on the principle of justice to use APs might be overridden by other *prima facie* obligations *not* to use APs.

3.3. Balancing and weighing principles

There is still much to be explored in specifying the four principles with regard to the use of APs in people with BPSD. I now focus on how we can evaluate “relative weights and strengths of different moral norms” (Beauchamp & Childress, 2013, p. 20). This process is *balancing and weighing* and requires a detailed consideration of different, relevant moral norms to reach a judgment about a particular moral dilemma (p. 20)

The process of balancing and weighing entails recognition of, what Beauchamp and Childress call, a genuine *moral dilemma*: a state of conflict between two (or more) sets of moral considerations (2013, p. 11)¹⁸.

¹⁶ Daniels' argument has provoked sharp criticisms. For instance, it has been criticized for its 'ageist' repercussions (Evans, 1997) or its incongruence with “ethical frameworks and universal principles expressed in the most prominent documents on human rights” (Giordano, 2005, p. 90).

¹⁷ Here, I discuss potential obligations based on the principle of justice to *use* APs. There might be, however, justice considerations *not* to use APs. For instance, when the use of APs has less desirable cost/benefit ratio than non-pharmacological alternatives for people with BPSD, there might be a *prima facie* obligation based on the principle of justice *not* to use APs.

¹⁸ Note that not all dilemmas that entail some moral considerations, in the four-principles approach, are moral dilemmas. Some of them are perceived as *practical dilemmas* involving some moral considerations (Beauchamp & Childress, 2013, p. 12).

Four types of moral dilemmas arising from the use of APs

The use of APs for managing people with BPSD gives rise to four types of moral dilemmas (*Table 1*). These dilemmas entail conflicts between different clusters of principles.

Table 1. Four types of moral dilemmas arising from the use of APs

Principles involved in moral dilemmas	Examples
Beneficence vs. non-maleficence	Potential benefits of APs vs. the risk of adverse effects
Respect for autonomy vs. beneficence	Covert administration of APs vs. potential benefits of using APs
Justice vs. beneficence	The use of APs may have the best overall cost/benefit ratio but provides less benefits to the individual than a non-pharmacological intervention
Respect for autonomy vs. justice	The use of APs might have the best overall cost/benefit ratio but contravenes an individual's prior wishes as stated in his or her advance directive

Beneficence vs. non-maleficence

Based on the obligations of beneficence, healthcare professionals in LTCFs might consider that the benefits of APs in a particular case justify their use, given the nature of the patient's symptoms. On the other hand, the principle of non-maleficence obligates healthcare professionals not to put residents in LTCFs at the risk of harms arising from the adverse effects of APs. A moral dilemma, then, emerges from the conflict between obligations based on the principle of

beneficence and those based on the principle of non-maleficence. Acting beneficently may require overriding the obligations of non-maleficence.

Respect for autonomy vs. beneficence

Depending on how the principle of respect for autonomy is specified, moral dilemmas may arise from a conflict between obligations based on the principle of respect for autonomy and those arising from the principle of beneficence. One example is the covert administration of APs through therapeutic lying. This practice, according to Mitchell (2014) might be justified based on beneficence considerations. Nonetheless, Mitchell (2014) also points to how covert administration of APs might violate obligations of respect for autonomy. Covert administration of APs might undermine autonomous decision-making because it deprives individuals who are capable of so doing of the opportunity to make an autonomous decision about whether or not to take the medications. Covert administration of APs, therefore, brings into conflict obligations of respect for autonomy and beneficence considerations.

Furthermore, specifying the principle of respect for autonomy, in some cases, may require relying on a surrogate decision maker. In *Chapter 2*, I referred to how Levenson (2002) presents a case of disagreement between a surrogate decision maker and healthcare professionals in a LTCF. That case, however, does not point to a clear moral dilemma in that the healthcare professionals seemed to question the very competence of the surrogate decision maker. A genuine moral dilemma would have arisen if the surrogate decision maker was considered competent, but her decision was felt by the healthcare professionals to conflict with the obligations of beneficence.

In more hypothetical¹⁹ situations, advance directives (as a mechanism to preserve autonomous decision-making) might conflict with beneficence considerations. For example, a person might specify an overall general preference for not being treated with APs in her advance directive. However, in cases of severe behavioral or psychotic complications, healthcare professionals might think that the use of APs is the only option with a reasonable prospect of benefit. In such circumstances, there is a genuine moral dilemma between obligations of respect for the individual's autonomy (as expressed through her advance directive) and present obligations of beneficence.

Justice vs. beneficence

I discussed earlier how we could specify the principle of justice by relying on formal analyses such as CBAs. Such forms of analysis may suggest limiting provision of, for example, a costly non-pharmacological alternative for some residents with BPSD in LTCFs. Those residents might benefit more from that costly non-pharmacological alternative, but instead, APs are used as the less expensive intervention. This brings into conflict obligations of justice with obligations of beneficence. Simply put, justice considerations, in those cases, may require healthcare professionals to provide less beneficial therapeutic intervention²⁰.

Respect for autonomy vs. justice

Another moral dilemma may arise from a conflict between the obligations of respect for autonomy and the obligations of justice. Consider again the case of an

¹⁹ Hypothetical in the sense that I did not find any (implicit or explicit) mention of this dilemma in the existing empirical literature about the use of APs in LTCFs.

²⁰ A similar moral dilemma might arise if we rely on age-based rationing policies as articulated by Daniels (1983), which might suggest limiting the provision of a costly non-pharmacological alternative to manage BPSD in the elderly population in LTCFs.

individual with an advance directive indicating an overall general preference for not being treated with APs. Justice considerations, nevertheless, might lead us to conclude that other alternative options are too costly to be provided for that person. In that case, healthcare professionals are facing a moral dilemma: acting upon obligations of justice (using APs) is incompatible with acting upon obligations of autonomy (not using APs).

Conditions of a justified weighing/balancing

In the aforementioned moral dilemmas, healthcare professionals might think that, based on *prima facie* obligations, it is justified to use APs. Another set of *prima facie* obligations, nevertheless, leads to the opposite conclusion. In such circumstances, according to the four-principles approach, healthcare professionals need to weigh and balance different obligations. In order to decide whether or not it is justified to use APs, one needs to “justify infringing one *prima facie* norm in order to adhere to another” (Beauchamp & Childress, 2013, p. 20).

Beauchamp and Childress discuss a number of conditions²¹ to be met for a justified weighing/balancing process (2013, p. 23). On their account, first, good reasons should be provided for infringing one norm and acting upon another. This requires healthcare professionals to be clear about *why* some obligations should override other obligations.

Three other conditions for a justified weighing/balancing process refer to *how* healthcare professionals should proceed with putting into practice a moral conclusion.

First, there needs to be a “realistic prospect of achievement” (Beauchamp & Childress, 2013, p. 23). For instance, if a healthcare professional overrides

²¹ To simplify, I discuss only four of six conditions proposed by Beauchamp and Childress (2013, p. 23).

obligations of non-maleficence in favor of obligations of beneficence, there should be a sufficiently clear prospect of benefiting people with BPSD in LTCFs.

The second condition requires that healthcare professional select “the lowest level of infringement” proportionate to the main aim of the proposed intervention (Beauchamp & Childress, 2013, p. 23). In the aforementioned example, this implies that healthcare professionals use the lowest dose of APs commensurate with the potential benefits.

Third condition requires minimizing negative effects of overriding one obligation in favor of another obligation (Beauchamp & Childress, 2013, p. 23). This implies that, for instance, the adverse effects of APs need to be closely monitored or APs need to be used for minimal length of time consistent with therapeutic objectives if healthcare professionals decide to give more weight to obligations of beneficence than obligations of non-maleficence.

3.4. Reframing rationales in the existing literature

The four-principles approach, then, provides a framework to reframe concrete, practical rationales identified in the previous chapter in more explicit ethical terms (*Table 2*). For instance, the rationales identified in *Chapter 2* as to why the use of APs might be justified can be reframed in terms of reasons for overriding the obligations of non-maleficence and acting upon the obligations of beneficence in the weighing/balancing process. Likewise, requiring extensive safety measure, in justifying how APs might be used, can be reframed in terms of a justified infringement of obligation of non-maleficence while acting upon obligations of beneficence.

Table 2. Reframing rationales identified in Chapter 2

The questions	The rationales 	Reframing the rationales according to the four-principles approach
Why might the use of APs be justified?	Because of increased quality of life, and/or reducing distress or suffering	Increasing quality of life and/or reducing distress might be good reasons for overriding the obligations of non-maleficence and acting upon the obligations of beneficence in the weighing/balancing process
	Because of consequences of undertreatment or nontreatment of BPSD	Negative consequences of undertreatment or nontreatment of BPSD might be reasons for overriding the obligations of non-maleficence and acting upon the obligations of beneficence in the weighing/balancing process
How might the use of APs be justified?	With extensive safety measures	This minimizes the negative effects of infringing the obligations of non-maleficence while acting upon obligations of beneficence
	By considering people's prior wishes	In using APs, healthcare professionals need to consider <i>prima facie</i> obligations of respect for autonomy of people with BPSD
	With a palliative purpose	The benefits of using APs in a palliative way might be a reason for overriding the obligations of non-maleficence and acting upon the obligations of beneficence in the weighing/balancing process
	In a covert way and/or with therapeutic lying	The use of APs in a covert way brings into conflict obligations of respect for autonomy and beneficence; in the weighing/balancing process, the obligations of beneficence override the obligations of respect for autonomy
How might not the use of APs be justified?	In a covert way and/or with therapeutic lying	The use of APs in a covert way brings into conflict obligations of respect for autonomy and beneficence; in the weighing/balancing process, the obligations of respect for autonomy override the obligations of beneficence
When might the use of APs be justified?	When surrogate decision-maker disagrees with healthcare professionals	In some cases, the use of APs brings into conflict obligations of respect for autonomy (specified as relying on a surrogate decision-maker) and obligations of beneficence; in the weighing/balancing process, the obligations of beneficence override the obligations of respect for autonomy
When might not the use of APs be justified?	When other treatable causes are identified and/or there is no distress	Giving less weight to obligations of non-maleficence and acting upon obligations of beneficence is unjustified if there is no reasonable prospect of benefiting people with BPSD by using APs

3.5. Conclusion

To sum up, the use of APs brings into conflict *prima facie* obligations based on the different principles. To resolve the moral dilemmas, according to the four-principles approach, healthcare professionals need to weigh and balance different obligations. This requires offering good reasons for overriding one obligation and acting upon another obligation. A number of other conditions also need to be met for a justified infringement of an obligation: being realistic about the aim of infringement, selecting the lowest level of infringement, and minimizing the negative effects of infringement. With regard to the use of APs, these conditions, respectively, imply a sufficiently clear prospect of benefiting people with BPSD by the use of APs, using the lowest dose of APs commensurate with the potential benefits, and close monitoring of the adverse effects of APs.

Though the four-principles approach provides a useful and structured framework for examining the ethical justifiability of the use of APs, there are other relevant moral considerations beyond those captured by the four-principles approach. Some rationales that I identified in *Chapter 2*, such as the use of APs for enhancing caregivers' interactions with people with BPSD, are based on a wider consideration of the care provision to people with BPSD in LTCFs.

We might then ask, what moral norms should govern the use of APs within the context of care for people with BPSD in LTCFs. To answer this question involves moral considerations “not in the form of principles, rules, obligations, and rights” (Beauchamp & Childress, 2013, p. 30), such as how we can enact ‘caring virtues’ or ‘caring attitudes’ with regard to the use of APs. As Beauchamp and Childress (2013, pp. 30-62) acknowledge, these types of considerations go beyond the scope of the four-principles approach. Exploring such moral considerations, in my

opinion, are necessary to enrich and deepen what I have discussed in this chapter. In the next chapter, I take up this task by adopting Tronto's ethics of care to examine the justifiability of using APs for managing people with BPSD in LTCFs.

Chapter 4. The ethics of care

In this chapter, I complement my discussion in the previous chapter by examining the ethical justifiability of the use of antipsychotics (APs) understood as a form of care in long-term care facilities (LTCFs) provided to people with behavioral and psychological symptoms of dementia (BPSD). In doing so, I draw upon the ethics of care as proposed by Joan Tronto for two main reasons. First, Tronto's ethics of care provides a framework to systematically identify and examine procedural and contextual issues arising from using APs as a potential form of care for people with BPSD in LTCFs. Secondly, Tronto's account of ethics of care broadens the scope of ethical examination by allowing us to discuss ethical ramifications of the use of APs beyond the interaction between individual healthcare professionals and residents in LTCFs.

The chapter is structured as follows. First, I provide a brief background to the origins and characteristics of Tronto's ethics of care. Next, I introduce the general outline of Tronto's ethical framework. Then I examine how using APs might or might not be ethically justified according to Tronto's framework. In the final part of the chapter, I discuss how Tronto's ethics of care captures ethical considerations beyond those identified using the four-principles approach.

4.1. Tronto's ethics of care: the origins and the main characteristics

The notion of 'the ethics of care' or 'care ethics' developed in the second half of the 20th century based on the works of feminist thinkers such as Carol Gilligan. On the basis of her empirical observations, Gilligan suggests that in addition to the dominant account of morality based on rights and duties, there might be an alternative, different conception of morality (Gilligan, 1982).

In that alternative conception of morality, “the moral problem arises from conflicting responsibilities rather than from competing rights” (Gilligan, 1982, p. 19). Broadly construed, the ethics of care centers on this different conception of morality, which emphasizes “responsibility and relationships” and resolves moral conflicts through “contextual and narrative” approaches (Gilligan, 1982, p. 19).

Based on Gilligan’s insights, many scholars have offered different accounts of the ethics of care. One of such accounts has been developed by Joan Tronto, and differs from other accounts in at least two main ways.

First, Tronto conceptualizes care both as a practice and as a set of dispositions or attitudes. In this respect, she differs from scholars such as Blustein (1991) who conceptualize caring and the ethics of care based mainly on dispositions or attitudes²². According to Tronto, defining care merely in dispositional terms runs the risk of “sentimentalizing” and “containing the scope of care in our thinking” (Tronto, 1993, p. 119). Tronto, however, emphasizes that her interpretation of care is not devoid of caring dispositions or attitudes. Instead, what she maintains “is that these dimensions are only a part of care” (Tronto, 1993, p. 119). Tronto describes the dispositional dimensions of care as “habit of mind”, which along with “particular acts of care” amount to “the practice of an ethic of care” (Tronto, 1993, p. 127).

Second, Tronto frames the practice of care beyond a *dyadic*²³ interaction between a care-giver and a care-receiver. On this point, Tronto disagrees with scholars such as Nel Noddings (1984) who theorize care as a *dyad* between a care-giver (e.g.,

²² Beauchamp and Childress also refer to the ethics of care as a virtue ethics in that “the ethics of care emphasizes traits valued in intimate personal relationships such as sympathy, compassion, fidelity, and love” (Beauchamp & Childress, 2013, p. 35). Tronto, however, criticizes “theories of care-as-virtue” for overlooking the importance of relationships and revolving around “the perfection of the virtuous individual” (Tronto, 2013, p. 36).

²³ Dyadic interactions connote interactions that occur between two individuals.

mother) and a care-receiver (e.g., baby). By presuming that care is a dyadic activity, Tronto (1993) argues, we fail to account for “the ways in which care can function socially and politically in a culture” (p. 103). Simply put, she aims to broaden the scope of the ethics of care by exploring practices of care within the wider socio-political context.

Provision of health care in long-term care facilities is an example of how ‘practices of care’ are situated within the broader socio-political context. By its nature, care provision in LTCFs is an institutional form of care-giving (Tronto, 2013, p. 2). Healthcare professionals, as care-givers, rely on the healthcare contexts in LTCFs to provide care to residents. The healthcare context of LTCFs may govern, for example, how many resources can be allocated to meeting the needs of a resident (or a group of residents). In addition, the healthcare context in LTCFs is shaped by the wider socio-political context. In one context, LTCFs might function as corporate, for-profit facilities. In other contexts, LTCFs may function with government funding or as charitable not-for-profit institutions. Hence, the interaction between a care-giver and a care-receiver in LTCFs is situated within a wider socio-political context and cannot be framed merely as a dyadic interaction.

4.2. Five phases of care and five moral qualities

Tronto brings *care*, conceptualized as a practice and within the wider socio-political context, to the forefront of ethical reflection. She notes, however, that we should not consider “all care as good care” (Tronto, 2013, p. 24). Rather, it is necessary to analyze caring processes across the different phases of care (*Table 1*). Caring processes at each of the various phases of care need to realize specific moral qualities (*Table 1*). These moral qualities lay down the “criteria by which we can judge care itself” (Tronto, 2013, p. 161).

Table 1. The five moral qualities aligned with the five phases of care

Five phases of care	Five moral qualities
Caring about	Attentiveness
Taking care of (caring for)	Responsibility
Care-giving	Competence
Care-receiving	Responsiveness
Caring with	Plurality, trust, and solidarity

The use of APs may be a form of care provided to people with BPSD in LTCFs. To morally judge the use of APs as a form of care, according to Tronto, we need to analyze the caring processes across different phases of care. In addition, we need to clarify what the moral qualities of care indicate with respect to the use of APs, and how those moral qualities can be realized across the different phases of care. This is a different approach to ethical analysis compared to the four-principles approach adopted in the previous chapter.

Before examining the ethical justifiability of the use of APs from the standpoint of Tronto's ethics of care, I need to clarify two important points.

First, Tronto, herself, to my knowledge, has not referred to 'justified' or 'unjustified' care. Rather, she refers to 'good' or 'bad' care (Tronto, 2010). What I refer to in the next sections as potentially 'justified' and 'unjustified' use of APs are approximate equivalents to 'good' and 'bad' care, respectively. In other words, to the extent to which the moral qualities are realized across different phases of care, we would be more able to justify the use of APs for managing people with BPSD. Conversely, failure to realize the moral qualities makes it more difficult to ethically justify the use of APs from the standpoint of Tronto's ethics of care.

Second, by adopting Tronto's ethics of care approach, one might arrive at moral judgments that are concerned more with the *process* of care-giving rather than justifying the care itself. This indicates, with respect to the use of APs, that we will be more concerned with the question of '*how* might or might not the use of APs be ethically justified' instead of '*why* might or might not the use of APs be ethically justified?'²⁴

4.3. How might the use of APs be ethically justified?

To recap, the use of APs (as a form of care) may be ethically justified, from the perspective of Tronto's ethics of care, if a number of moral qualities are realized. In what follows, I elucidate what those moral qualities at each phase of care indicate with respect to the use of APs.

Caring about

The first phase of care, according to Tronto, is *caring about*. In this phase, someone (or a group of people) notices the existence of unmet need for an individual or a group of people and makes "an assessment that this need should be met" (Tronto, 1993, p. 106). With respect to the use of APs in LTCFs, *caring about* implies identifying unmet needs of residents reflected in symptoms such as anxiety or agitation, which might potentially be met by using APs.

Attentiveness is the moral quality tied with *caring about*, and connotes "a capacity genuinely to look from the perspective of the one in need" (Tronto, 2013, p. 34). In this sense, *attentiveness* echoes what has been recommended as a 'person-centred' approach to managing people with BPSD (NSW Ministry of Health, 2013). This person-centred approach implies the provision of care to people with BPSD with

²⁴ I do not claim here that one cannot discuss *why* the use of APs might or might not be justified by adopting the ethics of care approach. For instance, one might contend that the use of APs meets no need in people with BPSD; and hence, it is unjustified, according to the ethics of care, to use APs for people in BPSD. I presume, however, that the use of APs might meet some needs in some people with BPSD in LTCFs.

the aim “to meet their needs” on the basis of “the person’s values and experiences” (NSW Ministry of Health, 2013, p. 2). This orientation towards assessing and managing BPSD from the individual residents’ perspective lies at the heart of *attentiveness* as a moral quality of care. The following set of questions points more explicitly to what *attentiveness* might require with respect to the use of APs in LTCFs:

- Has a resident moved recently from another care environment (such as hospital) to LTCF?
- What do we know about the resident’s past behaviors and response to care environment(s)?
- What might have been the trigger or precipitant for BPSD, and if it is a recurrent trigger, how have BPSD been managed in the past?
- What do we know about the resident’s personal history and the socio-cultural background?²⁵

Taking care of (caring for)

The second phase of care is *taking care of* (or *caring for*). After identifying a need, someone (or a group of people) takes on the responsibility and the burden of meeting that need. *Responsibility* is the moral quality aligned with the second phase of care. Tronto differentiates between *responsibility* as obligations and as a moral quality of care.

Obligations can be framed as answers to ‘self-oriented’ questions such as “what, if anything, do I (we) owe to others?” (Tronto, 1993, p. 136). The questions related to *responsibility* to care, however, are more relational in that they are raised and

²⁵ For instance, elderly residents in LTCFs from some socio-cultural backgrounds might exhibit behaviors that result from losing the active role that they have had in their communities (NSW Ministry of Health, 2013).

answered within a web of relationships (Tronto, 2013, p. 50). In other words, the questions related to *responsibility* are other-oriented and can be framed as “how can I (we) best meet my (our) caring responsibilities?” (Tronto, 1993, p. 136).

Realizing *responsibility* as a moral quality of care with respect to using APs echoes recent calls for establishing personal bond with people with BPSD, which require “effective verbal and non-verbal communication tailored to the needs of the person with dementia” (NSW Ministry of Health, 2013, p. 11).

Care-giving

Care-giving is the third phase of care, which entails “doing the actual work of care” (Tronto, 2013, p. 35). The moral quality associated with caregiving is *competence*. From a care perspective, *competence* ensures that the needs of care-receivers are effectively met (Tronto, 1993, p. 133).

With respect to the use of APs, *competence* may require the care-giver to have a clear and predefined treatment plan. In addition to ensuring that using APs meets the needs of people with BPSD, the probability of adverse effects should be minimized. In this respect, what I referred to in *Chapter 3* as the justifiability of using APs with extensive safety measures can be reframed as requirements for *competent* use of APs. Considerations relevant to *competent* use of APs might include:

- Clarifying which type of BPSD are being targeted by the use of APs
- Ruling out other causes of the behavior or psychological symptoms such as physical pain, thirst or the need to urinate
- Checking the resident’s past response to the use of APs
- Finding an optimum dose of APs that provides the desirable outcomes while minimizing the probability of the adverse effects


- Considering comorbid conditions such as hypertension or diabetes in dose adjustments
- Establishing a timeframe for the use of APs
- Clarifying how the treatment plan should be adjusted if the clinical profile of the resident changes due to, for example, adverse effects of APs or other comorbid conditions

Care-receiving

When care work is performed to meet a need, from the perspective of Tronto's ethics of care, it is necessary to observe the response from care-receivers to the provided care. This phase of care is described as *care-receiving*. *Responsiveness* is the moral quality aligned with the fourth phase of care. This moral quality of care refers to the capacity to make a judgment about “for example, whether the care given was sufficient, successful, or complete” (Tronto, 2013, p. 35).

Responsive care should take into account “the other's position as that other expresses it” (Tronto, 1993, p. 136). This implies that the response of residents in LTCFs to the use of APs needs to be monitored and evaluated from the perspective of care-receivers, namely, the residents. Nevertheless, residents with dementia might face difficulties in communicating with their care-givers in LTCFs. When the response to the use of APs cannot be assessed entirely based on residents' communication with healthcare professionals in LTCFs, healthcare professionals can rely on behavioral assessment tools such as Dementia Observational System (DOS) (British Columbia Interior Health, n.d.) (*Figure 1*). Such assessment tools establish a baseline behavioral profile, making it possible to detect and evaluate the changes in behavioral profile through the timeframe of the use of APs. Assessment

tools such as DOS might provide objective, detailed and thorough evaluation of the use of APs.

 **Interior Health**

Name: _____ Dates: From _____ to _____

Use corresponding numbers to record behaviours in ½ hour intervals:

1. Sleeping in Bed	3. Awake/Calm	5. Restless/Pacing	7. Aggressive – verbal	9. Other: _____
2. Sleeping in Chair	4. Noisy	6. Exit Seeking	8. Aggressive – Physical	10. Other: _____

Dates:							
Time							
0730							
0800							
0830							
0900							
0930							
1000							
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Figure 1. Example of behavioral charting used in Dementia Observational System (DOS). From “Dementia Observation System (DOS) Tool” by British Columbia Interior Health, n.d.
<https://www.interiorhealth.ca/sites/Partners/SeniorsCare/DementiaPathway/MiddleDementiaPhase/Documents/DementiaObservntlSysmDOSTool.pdf>. In the public domain.

Caring with

The fifth phase of care is *caring with*. It entails “thinking about the effects of multiple care processes on trust and respect” (Tronto, 2013, p. 148). A number of moral qualities are associated with the fifth phase of care, namely, *plurality*, *trust*, and *solidarity*.²⁶

Generally speaking, *plurality* refers to forms of care-giving that are “flexible enough to have several ways to meet people’s needs” (Tronto, 2013, p. 164). *Trust* implies provision of care in a way that creates and maintains trust between care-givers and care-receivers. The third moral quality linked to *caring with*, *solidarity*, signifies forms of care-giving that represent “a sense of common purpose” with care-receives (Tronto, 2013, p. 157).

With respect to the use of APs, *plurality* might be understood in terms of flexibility in offering forms of care other than the use of APs. This is on the premise that the care-receives (here, people with BPSD) might have different preferences or concerns about the use of APs. *Plurality*, then, may make care more “democratic” through bringing care “closer to the concerns of the people” (Tronto, 2013, p. 44).

Other moral qualities, *trust* and *solidarity* refer to the overarching ramifications of the use of APs as a form of care. *Trust* requires that caring processes related to the use of APs create and maintain a level of confidence between care-givers and residents in LTCFs. Realizing *solidarity* might refer to the notion that the interactions between care-givers in LTCFs and people with dementia need to rests upon “the idea that we are all ‘fellow-travellers’ and that we have duties to support

²⁶ Tronto (2013) also refers to ‘communication’ and ‘respect’ as other moral qualities aligned with *caring with*. To simplify, I do not discuss communication and respect here.

and help each other and in particular those who cannot readily support themselves” (Nuffield Council on Bioethics, 2009, p. 29).

The covert use of APs highlights what *trust* and *solidarity* require with respect to the use of APs. As Brannelly and Whitewood (2014) briefly mention, therapeutic lying might stand in the way of establishing a sense of trust and solidarity with residents in LTCFs. This is because, according to Tronto’s ethics of care, establishing *trust* and *solidarity* require a level of transparency in caring processes and treating “others with respect in their choices as people” (Tronto, 2013, p. 164).

4.4. How might *not* the use of APs be ethically justified?

Thus far, I have discussed how realizing the five moral qualities of care are requirements for a justified use of APs for managing people with BPSD. Failure to realize the moral qualities of care, on the other hand, might lead to an ethically unjustified use of APs. In what follows, I give a more explicit account of how, based on Tronto’s ethics of care, the use of APs might not be ethically justified.

Lack of sufficient attentiveness

First, it might be unjustified to use APs without sufficient *attentiveness* to the needs of people with BPSD. Insufficient *attentiveness* might involve the use of APs without gathering relevant information about the resident’s past and current clinical profile. Another example might be continuing the use of APs in newly admitted residents to LTCFs without a new assessment of the residents’ needs.

Insufficient *attentiveness* to a primary need in people with BPSD might lead to negative outcomes, which then may result in a secondary need. This is described as ‘cascading effects’ of unmet needs in people with dementia (Kovach, Noonan, Schlidt, & Wells, 2005). For example, a thirsty resident needs to drink water. She might express her need to drink water through repetitive behavior. Lack of

attentiveness to the repetitive behavior (a type of BPSD) due to the use of APs, could result in the resident's primary need (fluids) not being met. This might in turn lead to negative outcomes such as constipation, creating further needs such as the need for increased fiber or laxative agents (Kovach et al., 2005).

Lack of adequate *responsibility*

The use of APs may not be ethically justified, according to Tronto's ethics of care, if healthcare professionals fail to assume adequate *responsibility* for using the medications. *Responsibility* signifies a commitment to residents' welfare beyond formal obligations. This requirement is not met when, for instance, residents' physicians do not spend time to "conduct interviews" or "establish relationships" with residents (Cody, Beck, & Svarstad, 2002, p. 1403). Therapeutic decisions to prescribe APs may be based on reports from staff, often via telephone (Cody et al., 2002), rather than direct contact with the residents or first-hand evaluation of their clinical profile. While this might not necessarily lead to a violation of formal obligations, failure to engage directly with residents when prescribing APs may amount to assuming inadequate *responsibility*.

Use of APs as *incompetent* care

Failure to provide *competent* care is another way in which the use of APs might be considered unjustified. The use of APs, in an *incompetent* way, might involve, for instance, not establishing a clear indication, not considering residents' comorbid conditions in dose adjustment, absence of a clear timeframe for the treatment plan or lack of adequate skills in alternative ways of managing people with BPSD.

Insufficient *responsiveness*

The use of APs might be unjustified in the absence of sufficient *responsiveness*, that is, failure to observe and evaluate the response of people with BPSD to the use

of APs. A number of undesirable consequences may result from insufficient *responsiveness*. First, by not observing the response, it cannot be ensured that the use of APs provides actual benefits to people with BPSD. Second, there would be no possibility of changing the treatment plan in case of, for instance, severe adverse effects. Third, in the absence of ongoing assessment, the use of APs might unnecessarily continue in people with BPSD.

Insufficient *responsiveness*, then, may lead to ineffective use or overuse of APs in LTCFs. The excessive use of APs indicates that people with BPSD in LTCFs might receive the medications when they do not need them. This might harm the residents in LTCFs by unnecessarily putting them at the risk of the adverse effects of APs. Being vigilant to such potential for harm in caring processes is, according to Tronto, one of the main reasons that *responsiveness* needs to be considered as a moral quality of care (Tronto, 1993, p. 135).

Failure to realize *plurality, trust, and solidarity*

Finally, at the fifth phase of care, *caring with*, the use of APs might fail to result in moral qualities of *plurality, trust, and solidarity*. From Tronto's standpoint, such failures in the use of APs in LTCFs may not be ethically justified.

Lack of *plurality*, in its most extreme form, signifies relying on the use of APs as a 'one-size-fits-all' solution for managing people with BPSD in LTCFs: "If all you have is a hammer, everything looks like a nail" (Evans, 2011, p. 27). In the complete absence of *plurality*, APs in LTCFs might be used as the 'only' solution for managing all forms of behavioral or psychological problems in people with dementia, with no flexibility for offering other alternative interventions for managing BPSD.

Failure to realize *trust* and *solidarity* with respect to the use of APs as a form of care in LTCFs might reflect a general lack of transparency about the aim of the treatment plans, not spending time “building up trust” (Barnes & Brannelly, 2008, p. 386) or not recognizing residents with dementia as fellow citizens. These are issues that go beyond the dyad of care-givers (healthcare professionals)/care-receivers (residents with BPSD) in LTCFs. For example, establishing a sense of solidarity with residents in LTCFs connotes a collective, societal task beyond ‘personal’ solidarity of an individual care-giver. Furthermore, the collective, societal task of solidarity is not directed solely at residents with BPSD but also needs to “show solidarity towards care workers, in the form of appropriate support and recognition” (Nuffield Council on Bioethics, 2009, p. 30). In the next section, I investigate how, based on Tronto’s ethics of care, discussions about the ethical justifiability of the use of APs should extend beyond the dyad of care-giver/care-receiver.

4.5. The use of antipsychotics beyond the dyad of care-giver/care-receiver

There are two major reasons as to why, based on Tronto’s ethics of care, we need to go beyond the dyad of care-giver/care-receiver for examining the justifiability of using APs in LTCFs.

First, people with BPSD cannot be considered as ‘solitary’ care-receivers in LTCFs. Based on what is conceptualized as a “relational ontology”²⁷ (Tronto, 2013, p. 89), people with dementia need to be considered as individuals situated in a web of relationship with their families, relatives or other beloved ones. One implication of this view is that realizing the moral qualities of care requires focusing on both the care-receivers and their web of relationships. For example,

²⁷ Broadly speaking, relational ontology signifies a conceptualization of “selves as fully relational – existing in and through complex, constitutive webs or relations with others” (Robinson, 2011, p.131).

realizing *trust* as a moral quality of care in LTCFs requires that, in addition to building up trust with residents, the care-givers need to develop a level of trust with relatives or other people with whom individuals with BPSD are in an intimate or caring relationship. This is of particular relevance to the use of APs since, as I referred to the case of David at the outset of the thesis, relatives of people with BPSD might have concerns or reservations about the aims of using APs in LTCFs.

Second, care-givers provide care to people with BPSD within the specific healthcare contexts of LTCFs. Realizing the moral qualities of care with respect to the use of APs requires, at the very least, allocation of sufficient resources, and sufficient professional training and support. Realizing *responsiveness*, for instance, needs a robust system for checking the past and current clinical profile of residents with BPSD. Likewise, the use of APs in a *competent* way necessitates sufficient time and skills for checking the residents' comorbid conditions and dose adjustments. From the perspective of Tronto's ethics of care, we need to explore the interaction between the care-givers and the healthcare context in LTCFs for a more 'contextual' ethical understanding. In some cases, the use of APs might be unjustified because of unjust policies or care arrangements within the healthcare contexts of LTCFs.

For example, in some LTCFs, APs may be used to solve problems caused by staff shortages (Sawan, Jeon, Fois, & Chen, 2016), which in turn may be due to insufficient allocation of resources (Sawan, Jeon, Fois, & Chen, 2017). Such care arrangements are ethically problematic as they impede realizing the moral qualities of care. Using APs for reasons other than residents' clinical needs signifies shortcomings including a lack of *attentiveness* to the needs of people with BPSD in LTCFs, and untrustworthy behavior.

In this example, not only is the use of APs for solving the problem of staff shortage ethically unjustified, the underlying caring arrangement that *normalizes* the use of APs in those ways is also ethically unjustified. This shows how, by relying on Tronto's ethics of care, we can account for ethical considerations related to using beyond the dyad of care-giver/care-receiver and consider the broader context within which care provision for people with BPSD is predicated in LTCFs²⁸.

4.6. Conclusion

In this chapter, to complement the ethical examination in the previous chapter, I examined the justifiability of using APs from the standpoint of Tronto's ethics of care. The main question that I dealt with in this chapter was 'how might or might not the use of APs be ethically justified for managing people with BPSD in LTCFs?' In addressing this question, I highlighted a number of procedural and contextual issues. These issues ranged from the ethical significance of assessing the needs of people with BPSD prior to the use of APs to considering the impact of the use of APs as a form of care in LTCFs on overarching values such as trust and solidarity. Further, I showed how through the lens of Tronto's ethics of care, we could go beyond the dyad of care-givers (healthcare professionals)/care-receivers (people with BPSD) in examining the ethical justifiability of the use of APs. In the next chapter, I draw on what I discussed in this chapter and the preceding chapters to call for further ethical reflection.

²⁸ Tronto (2013), in particular, criticizes what she describes as "the commodification of care", that is to say, to consider care as a commodity, which leads to considering "any increase in caring time as a cut in time for another activity" (p. 164).

Chapter 5. The way forward

In this chapter, in order to move forward the existing debate, I call for further ethical reflection on the justifiability of using APs for managing people with BPSD by identifying two main areas for future research. These include attending to a number of practical considerations and discussing theoretical issues that may be fruitful areas for further research.

5.1. Practical considerations

A number of practical considerations are relevant to the debate on the ethical justification for using APs in the management of people with BPSD.

Beyond BPSD as a ‘unitary’ designation

Differences in the evidence base for the efficacy of APs for individual behavioral or psychological symptoms that are broadly labeled as BPSD may have ethical significance. For instance, wandering and psychotic symptoms such as delusion are both categorized as BPSD. However, the evidence for the efficacy of APs for managing wandering in people with dementia is less clear compared with that for managing psychotic symptoms such as delusion (Royal Australian and New Zealand College of Psychiatrists, 2016). Such differences indicate that compared with the use of APs for managing delusion, there might be, in general, less scope for justifying the use of APs for management of wandering in people with dementia on the ground of beneficence considerations. That is to say, deliberations about the ethical justification for using APs should take account of very specific symptoms.

Different stages of the use of antipsychotics

Different ethical issues arise from different stages of antipsychotics treatment for people with BPSD, namely, *initiation*, *continuation* of AP medications,

deprescribing APs, and *escalation* in terms of increasing dose or increasing frequency of use. These different stages of the use of APs might give rise to specific ethical issues. For instance, deprescribing can be considered an action or omission (i.e., not continuing a previous action). Some scholars argue that “deprescribing as an act creates stronger moral duties than if viewed as an omission” (Reeve, Denig, Hilmer, & Ter Meulen, 2016, p. 581). Further research is warranted to investigate these issues and implications.

Undertreatment of pain a risk of harm associated with the use of antipsychotics

There is a close relationship between pain and BPSD. It is estimated that between 45% to 80% of residents in LTCFs experience varying degrees of pain that may have a negative effect on their functional ability and quality of life (Ferrell, 2004). Despite this potential negative impact, pain is often unrecognized and undertreated in LTCFs (Ferrell, 2004; Lukas et al., 2013).

Existing tools for pain assessment in patients with dementia extensively overlap with BPSD diagnostic inventories (Flo, Gulla, & Husebo, 2014). Many symptoms, such as agitation/aggression and night-time behavior disorders that are categorized as BPSD are also included in pain assessment tools for individuals with dementia (Flo et al., 2014).

When the primary cause of BPSD is pain, the use of APs might be ineffective and even harmful. In those cases, the use of APs may lead to masking symptoms that precipitate or exacerbate BPSD (Gerlach & Kales, 2016). It is estimated that almost one-quarter of patients with dementia receive restraints and APs instead of pain treatments (Flo et al., 2014). This indicates that besides the risk of adverse effects, there is also a risk of physical harm arising from undertreatment of pain by using APs. Though in *Chapter 3* and *Chapter 4* I focused on the risk of adverse

effects with respect to non-maleficence and *responsiveness* considerations, there is scope to further investigate other physical harms arising from the use of APs.

5.2. Theoretical issues

In addition to the practical considerations discussed above, I suggest attending to a number of theoretical issues in further ethical reflection.

Harms resulting from ‘medicalizing’ BPSD by the use of antipsychotics

The potential for undertreatment of pain might not be the only other risk of harm resulting from the use of APs. In *Chapter 2*, I referred to suggestions that using APs may be unjustified because people with dementia might express their unmet need through BPSD (Edvardsson et al., 2008; Pulsford & Duxbury, 2006). This concern may be understood as a ‘medicalization²⁹ critique’: pharmacologic interventions such as the use of APs may medicalize BPSD as *symptoms* of dementia instead of considering BPSD as *expressions of needs*. Based on this medicalization critique, one might argue that the use of APs in people with dementia can be associated with a risk of harm resulting from medicalizing BPSD (i.e., not attending to the underlying needs of people with BPSD).

Harm to others as the ground for the ethical justifiability of using antipsychotics

Further ethical reflection is necessary to investigate the justifiability of using APs for people with BPSD who pose a danger to other residents or their care-givers. Some scholars hold that it might be ethically justified to use APs when people with BPSD pose a danger to self or fellow resident (Maria-Roxana & Vasile, 2010). Within the four-principles approach, however, the view held by Maria-Roxana and Vasile (2010) would require extending the scope of non-maleficence with respect

²⁹ Medicalization is a term originated from sociological studies of health and illness that, in the context of people with dementia, indicates “the process whereby behaviour is defined as a medical problem” (Bond, Corner, Lilley, & Ellwood, 2002, p. 315).

to the use of APs beyond the individual with BPSD to others in the vicinity. Beauchamp and Childress (2013), however, do not explicitly argue for the justifiability of extending the obligations of non-maleficence to third parties. Further research might elucidate whether (and to what extent) harm to others may or may not be the ground for the ethical justifiability of using APs in people with BPSD.

Alternative conceptualization of autonomy in people with BPSD

As discussed in *Chapter 3*, according to the four-principles approach, healthcare professionals in LTCFs need to consider the *prima facie* obligation of respect for autonomy in using APs to manage people with BPSD. As I noted, there are challenges in specifying the principle of respect for autonomy in people with dementia. These challenges, in part, arise from the ‘all or nothing’ criterion of intentionality as discussed by Beauchamp and Childress (2013). Relying on such ‘all or nothing’ conditions in conceptualizing the autonomy of people with dementia has drawn some criticism. For example, Holm argues that decisional competence in individuals with dementia “is spread out along a wide continuum” (Holm, 2001, p. 157). Moreover, some scholars discuss the promise of ‘relational autonomy’ as an alternative conceptualization of autonomy for people in LTCFs (Sherwin & Winsby, 2011). Clarifying the promise and challenges of these alternative ways of conceptualizing the autonomy of people with dementia with regard to, for instance, consent to treatment with APs would be a fruitful area for future studies.

General and particular levels of discussing the justifiability of using antipsychotics

Apart from some case studies, most publications identified in the scoping review discussed the ethical justifiability of the use of APs at a rather general level. It

should be, however, noted that there are different levels of examining the ethical justifiability of using APs.

First, At the level of general rules, we might consider the use of APs in some circumstances either morally justified or unjustified. However, the use of APs as a particular act may have a different moral standing.

The debate at the first level is useful for developing some general rules or guidance as to when the use of APs might be or might not be morally justified. Nonetheless, the general rules or the outline may not guide us adequately in examining all particular cases of using APs in people with BPSD. Considering the general rules or the outline as ‘guideline’ or ‘logical precedence’ runs the risk of discounting particularities of each case of using APs. Further studies, thus, need to attend explicitly to the different levels of examining the ethical justifiability of using APs in people with BPSD.

Morally justifiable (permissible) and morally required use of antipsychotics

In this research, my focus was on the ethical justifiability (or permissibility) of the use of APs for people with BPSD. However, not all ethically justifiable or permissible uses of APs are ethically required. The ethical justifiability for using APs is a necessary but not sufficient condition for their ethically required use. In other words, the ethically required uses of APs can be considered as a subset of ethically justified or permissible uses of APs (*Figure 1*).

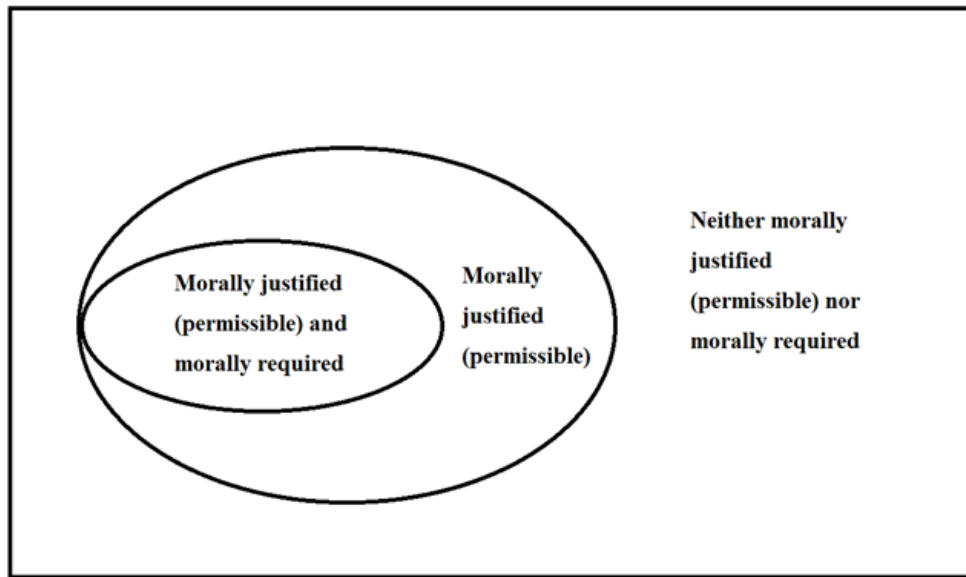


Figure 1. The schematic difference between morally (un)justified or (im)permissible and morally (un)required acts.

There might be different ways of conceptualizing the difference between the morally required and the morally justified use of APs. For instance, one can argue that for the use of APs to be morally required, first, we need to be convinced that the use of APs is the *only* possible option to prevent some potential harms, and second, it should be sufficiently clear that the benefits outweigh the risk of adverse effects of APs. One possible example of a morally justified and morally required use of APs in LTCFs may be cases in which residents with severe auditory hallucination have responded favorably to APs, and previous attempts to taper the dose or discontinue the use of APs have resulted in relapse of hallucination, and accordingly, serious deterioration in the residents' well-being (Patel et al., 2017).

A morally justified use of APs may entail a risk/benefit assessment in favor of the use of APs. Nevertheless, this advantageous risk/benefit assessment may not be sufficiently rigorous to morally require the use of APs. In some circumstances, the

use of APs or the use of a non-pharmacological alternative might both be morally justified for managing BPSD, yet neither might be regarded as morally required.

In some cases, however, the use of APs might be neither morally justified nor morally required. One possible example of morally unjustified and unrequired use of APs may be the use of conventional APs in people with Lewy-Body type of dementia as a first-line treatment of psychotic symptoms such as delusion. People with Lewy-Body type of dementia have a higher risk of developing adverse effects of conventional APs such as extrapyramidal symptoms (Boot, 2015). The risk of the adverse effects, in those individuals, might far outweigh any potential benefit from the use of conventional APs as first-line treatment of the psychotic symptoms (National Health and Medical Research Council, 2016).

Further ethical investigations can sharpen the distinction between the morally required and the morally justified (permissible) use of APs in people with BPSD. This would lay the groundwork for further ethical deliberation that specifically focuses on the circumstances in which it might be morally required (and not only justified) to use APs.

5.3. Conclusion

I have identified a number of practical and theoretical issues in need of further attention and investigations. These include differences in the current evidence base for the efficacy of the use of APs for different BPSD, the relevance of different stages of the use of APs, and undertreatment of pain as a risk of physical harm associated with the use of APs. In addition, I aimed to show how further research is warranted to examine potential harms of medicalizing BPSD by the use of APs and whether harm to others can be the ground for the ethical justifiability of using APs. Finally, I discussed alternative ways of conceptualizing the autonomy of people

with dementia, different levels of determining the justifiability of the use of APs, and the distinction between morally justified and morally required use of APs.

These new paths of research have the potential to further extend the existing debate on the ethical justifiability of the use of APs for managing people with BPSD in LTCFs.

Concluding remarks

This thesis explored and examined the ethical justifiability of using antipsychotics (APs) for managing people with behavioral and psychological symptoms of dementia (BPSD) in long-term care facilities (LTCFs).

In the empirical part of the thesis, I conducted an original literature review on the topic. The review found a number of rationales provided for *why*, *how*, *when* and, *by whom* the use of APs might be or might not be ethically justified. I indicated that further ethical examinations were warranted to spell out the ethical underpinnings of those rationales and associated discussions.

To extend the existing literature, in *Chapter 3*, I examined the ethical justifiability of using APs from the standpoint of the four-principles approach. I showed how the use of APs creates conflict between obligations based on different principles. To justify the use of APs, in the face of conflicting obligations, first and foremost, healthcare professionals in LTCFs need good reasons to infringe one obligation and act upon the other. Along with that, healthcare professionals also need to ensure that (1) people with BPSD are likely to benefit from the use of APs, (2) the lowest possible dose of APs is used, and (3) APs are used for the minimal length of time with close monitoring of the adverse effects. Further, I showed how through the lens of the four-principles approach we could map rationales identified in the literature review onto more explicit ethical justifications.

In *Chapter 4*, I adopted Tronto's ethics of care approach to complement the ethical analysis in the previous chapter. I examined the ethical justifiability of the use of APs as a form of care provided to people with BPSD in LTCFs. To justify the use of APs from the standpoint of Tronto's ethics of care, we need to consider a more extensive set of contextual and procedural considerations than those captured by

the four-principles approach. In particular, I showed how Tronto's ethics of care invoke considerations that call us to account for the broader context within which the care provision for people with BPSD is predicated in LTCFs.

In *Chapter 5*, by drawing on the discussions in the preceding chapters, I identified and discussed further paths of research. There are many fruitful areas for future ethical reflection on the ethical justifiability of the use of APs for managing people with BPSD.

Overall, this research contributes to a clearer, more detailed, and nuanced ethical reflection on the justifiability of using APs for managing people with BPSD in LTCFs. In particular, this research indicates the value of drawing on different perspectives and ethical frameworks in capturing the relevant ethical considerations and issues.

References

- Aarsland, D., Zaccai, J., & Brayne, C. (2005). A systematic review of prevalence studies of dementia in Parkinson's disease. *Movement Disorders*, 20(10), 1255-1263.
- Aljazeera. (2015). Can nursing homes get 300,000 dementia patients off deadly antipsychotics? Retrieved from <http://america.aljazeera.com/watch/shows/america-tonight/articles/2015/10/5/nursing-homes-drugging-dementia-antipsychotics.html>
- Alzheimer's Association. (2016). 2016 Alzheimer's disease facts and figures. *Alzheimer's & Dementia*, 12(4), 459-509.
- American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders (DSM-5®)* [Electronic Version]. Retrieved from <http://dsm.psychiatryonline.org.simsrad.net.ocs.mq.edu.au/doi/full/10.1176/appi.books.9780890425596.dsm17>
- American Psychiatric Association. (2016). The American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia. Retrieved from <http://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426807>
- Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology*, 8(1), 19-32.
- Ballard, C., Hanney, M. L., Theodoulou, M., Douglas, S., McShane, R., Kossakowski, K., . . . Jacoby, R. (2009). The dementia antipsychotic withdrawal trial (DART-AD): Long-term follow-up of a randomised placebo-controlled trial. *The Lancet Neurology*, 8(2), 151-157.
- Ballard C., & Waite, J. (2006). The effectiveness of atypical antipsychotics for the treatment of aggression and psychosis in Alzheimer's disease. *Cochrane Database of Systematic Reviews*, CD003476.
- Ballard, C. G., & Margallo-Lana, M. L. (2004). The relationship between antipsychotic treatment and quality of life for patients with dementia living in residential and nursing home care facilities. *Journal of Clinical Psychiatry*, 65, 23-28.
- Ban, T. A. (2007). Fifty years chlorpromazine: A historical perspective. *Neuropsychiatric Disease and Treatment*, 3(4), 495.
- Banerjee, S. (2009). The use of antipsychotic medication for people with dementia: Time for action. London: Department of Health. Retrieved from <https://www.rcpsych.ac.uk/pdf/Antipsychotic%20Bannerjee%20Report.pdf>

- Barnes, M., & Brannelly, T. (2008). Achieving care and social justice for people with dementia. *Nursing Ethics*, 15(3), 384-395.
- BBC. (2017). Call for proof of 'chemical cosh' cuts in care homes. Retrieved from <http://www.bbc.com/news/uk-wales-39006759>
- Beauchamp, T. L. (2003). Methods and principles in biomedical ethics. *Journal of Medical Ethics*, 29(5), 269-274.
- Beauchamp, T. L. (2007). The 'four principles' approach to health care ethics. In R. E. Ashcroft, A. Dawson, H. Draper, & J. McMillan (Eds.), *Principles of health care ethics* (2nd ed., pp. 3-10). West Sussex, England: John Wiley & Sons Ltd.
- Beauchamp, T. L., & Childress, J. F. (2013). *Principles of biomedical ethics* (7th ed.). New York, NY: Oxford University Press.
- Berns, A. (2012). Dementia and antipsychotics: A prescription for problems. *The Journal of Legal Medicine*, 33(4), 553-569.
- Bishara, D. (2009). Using antipsychotics in dementia patients creates a clinical and ethical dilemma. *Pharmacy in Practice*, 19(2), 55-58.
- Blustein, J. (1991). *Care and commitment: Taking the personal point of view*. Oxford: Oxford University Press.
- Bond, J., Corner, L., Lilley, A., & Ellwood, C. (2002). Medicalization of insight and caregivers' responses to risk in dementia. *Dementia*, 1(3), 313-328.
- Boot, B. P. (2015). Comprehensive treatment of dementia with Lewy bodies. *Alzheimer's research & therapy*, 7(1), 45.
- Boucherie, Q., Gentile, G., Chalançon, C., Sciortino, V., Blin, O., Micallef, J., & Bonin-Guillaume, S. (2017). Long-term use of antipsychotics in community-dwelling dementia patients: Prevalence and profile accounting for unobservable time bias because of hospitalization. *International Clinical Psychopharmacology*, 32(1), 13-19.
- Brannelly, T., & Whitewood, J. (2014). Case commentary 2. *Nursing Ethics*, 21(7), 848-849. doi:10.1177/0969733014543886b
- Braun, J. A., & Frolik, L. A. (2000). The Legal aspects of chemical restraint use in nursing homes. *Elder's Advisor*, 2, 21.
- British Columbia Interior Health. (n.d.). Dementia Observational System (DOS) Tool. Retrieved from <https://www.interiorhealth.ca/sites/Partners/SeniorsCare/DementiaPathway/MiddleDementiaPhase/Documents/DementiaObservntlSysmDOSTool.pdf>
- California Advocates for Nursing Home Reform. (2009). Attorney general charges nursing home drugging. Retrieved from http://www.canhr.org/newsroom/newdev_archive/2009/AG-Charges-NH20090220.html

- Chan, W. c., Lam, L. C. w., Choy, C. N. p., Leung, V. P. y., Li, S. w., & Chiu, H. F. k. (2001). A double-blind randomised comparison of risperidone and haloperidol in the treatment of behavioural and psychological symptoms in Chinese dementia patients. *International Journal of Geriatric Psychiatry*, 16(12), 1156-1162.
- Chen, Y., Briesacher, B. A., Field, T. S., Tjia, J., Lau, D. T., & Gurwitz, J. H. (2010). Unexplained variation across US nursing homes in antipsychotic prescribing rates. *Archives of Internal Medicine*, 170(1), 89-95.
- Cody, M., Beck, C., & Svarstad, B. L. (2002). Mental health services in nursing homes: Challenges to the use of nonpharmacologic interventions in nursing homes. *Psychiatric Services*, 53(11), 1402-1406.
- Daniels, N. (1983). Justice between age groups: am I my parents' keeper?. *The Milbank Memorial Fund Quarterly. Health and Society*, 61(3), 489-522.
- Desai, A. K., & Desai, F. G. (2014). Management of behavioral and psychological symptoms of dementia. *Current Geriatrics Reports*, 3(4), 259-272.
- Edvardsson, D., Winblad, B., & Sandman, P. O. (2008). Person-centred care of people with severe Alzheimer's disease: Current status and ways forward. *The Lancet Neurology*, 7(4), 362-367.
- Evans, J. (2011). The Ethics of antipsychotics in Alzheimer's. *Caring for the Ages*, 12(5), 27.
- Evans, J. G. (1997). The rationing debate: Rationing health care by age: The case against. *BMJ*, 314(7083), 822. doi:10.1136/bmj.314.7083.822
- Fauth, E. B., & Gibbons, A. (2014). Which behavioral and psychological symptoms of dementia are the most problematic? Variability by prevalence, intensity, distress ratings, and associations with caregiver depressive symptoms. *International Journal of Geriatric Psychiatry*, 29(3), 263-271.
- Food and Drug Administration. (2008). Information for healthcare professionals: Conventional antipsychotics. Retrieved from <https://www.fda.gov/Drugs/DrugSafety/ucm124830.htm>
- Ferrell, B. A. (2004). The management of pain in long-term care. *The Clinical Journal of Pain*, 20(4), 240-243.
- Finkel, S. I., E. Silva, J. C., Cohen, G., Miller, S., & Sartorius, N. (1997). Behavioral and psychological signs and symptoms of dementia: A consensus statement on current knowledge and implications for research and treatment. *International Psychogeriatrics*, 8(S3), 497-500.
- Flo, E., Gulla, C., & Husebo, B. S. (2014). Effective pain management in patients with dementia: Benefits beyond pain? *Drugs & Aging*, 31(12), 863-871.

- Gaugler, J. E., Yu, F., Krichbaum, K., & Wyman, J. F. (2009). Predictors of nursing home admission for persons with dementia. *Medical Care*, 47(2), 191-198.
- Gerlach, L. B., & Kales, H. C. (2016). Learning their language: The importance of detecting and managing pain in dementia. *American Journal of Geriatric Psychiatry*, 25(2), 155-157.
- Gill, S. S., Bronskill, S. E., Normand, S.-L. T., Anderson, G. M., Sykora, K., Lam, K., . . . Herrmann, N. (2007). Antipsychotic drug use and mortality in older adults with dementia. *Annals of Internal Medicine*, 146(11), 775-786.
- Gilligan, C. (1982). *In a different voice*. Cambridge, Massachusetts: Harvard University Press.
- Gillon, R. (2015). Defending the four principles approach as a good basis for good medical practice and therefore for good medical ethics. *Journal of Medical Ethics*, 41(1), 111-116.
- Giordano, S. (2005). Respect for equality and the treatment of the elderly: Declarations of human rights and age-based rationing. *Cambridge Quarterly of Healthcare Ethics*, 14(1), 83-92.
- Harding, R., & Peel, E. (2013). 'He was like a Zombie': Off-label prescription of antipsychotic drugs in dementia. *Medical Law Review*, 21(2), 243-277.
- Health Canada. (2002). Important Drug Safety Information: RISPERDAL (Risperidone) and Cerebrovascular Adverse Events in Placebo-Controlled Dementia Trials – Janssen-Ortho Inc. Retrieved from <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2002/14720a-eng.php>
- Hien, L. T., Cumming, R. G., Cameron, I. D., Chen, J. S., Lord, S. R., March, L. M., . . . Sambrook, P. N. (2005). Atypical antipsychotic medications and risk of falls in residents of aged care facilities. *Journal of the American Geriatrics Society*, 53(8), 1290-1295.
- Hilmer, S. N., & Gnjidic, D. (2013). Rethinking psychotropics in nursing homes: While evidence supports psychotropic use in nursing homes in some scenarios, we use them too often, for too long, at doses too high and in dangerous combinations with other medications. *Medical Journal of Australia*, 198(2), 77.
- Holm, S. (2001). Autonomy, authenticity, or best interest: Everyday decision-making and persons with dementia. *Medicine, Health Care and Philosophy*, 4(2), 153-159.
- Howe, E. (2007). Five ethical questions involving Alzheimer's disease. *Psychiatry (Edgmont)*, 4(8), 31.

- Ibrahim, F., Knight, S. R., & Cramer, R. L. (2012). Addressing the controversial use of antipsychotic drugs for behavioral and psychological symptoms of dementia. *Journal of Pharmacy Technology*, 28(1), 3-9.
- Ihara, H., & Arai, H. (2008). Ethical dilemma associated with the off-label use of antipsychotic drugs for the treatment of behavioral and psychological symptoms of dementia. *Psychogeriatrics*, 8(1), 32-37.
- Jacques, A. (1997). Ethical dilemmas in care and research for people with dementia. In S. Hunter (Ed.), *Dementia : Challenges and new directions* (pp. 24-27). London: Jessica Kingsley.
- Jones, R. (2001). Commentary. *Advances in Psychiatric Treatment*, 7(6), 450-452.
- Kirchner, V., Kelly, C. A., & Harvey, R. J. (2001). Thioridazine for dementia. *Cochrane Database of Systematic Reviews*(4). doi:10.1002/14651858.CD000464
- Kirkham, J., Sherman, C., Velkers, C., Maxwell, C., Gill, S., Rochon, P., & Seitz, D. (2017). Antipsychotic use in dementia: Is there a problem and are there solutions? *The Canadian Journal of Psychiatry*, 62(3), 170-181.
- Koskenvuo, J., Numminen, O., & Suhonen, R. (2017). Ethical climate in nursing environment: A scoping review. *Nursing Ethics*. Advance online publication. doi: 10.1177/0969733017712081
- Kovach, C. R., Noonan, P. E., Schlidt, A. M., & Wells, T. (2005). A model of consequences of need-driven, dementia-compromised behavior. *Journal of Nursing Scholarship*, 37(2), 134-140.
- Kuepper, A. L., & Hughes, J. C. (2011). The challenges of providing palliative care for older people with dementia. *Current Oncology Reports*, 13(4), 295-301.
- Laredo, L., Vargas, E., Blasco, A. J., Aguilar, M. D., Moreno, A., & Portolés, A. (2011). Risk of cerebrovascular accident associated with use of antipsychotics: Population-based case-control study. *Journal of the American Geriatrics Society*, 59(7), 1182-1187.
- Lee, P. E., Sykora, K., Gill, S. S., Mamdani, M., Marras, C., Anderson, G., . . . Rochon, P. A. (2005). Antipsychotic medications and drug-induced movement disorders other than parkinsonism: A population-based cohort study in older adults. *Journal of the American Geriatrics Society*, 53(8), 1374-1379.
- Levenson, S. (2002). Comments on the case of Esther M. *Journal of the American Medical Directors Association*, 3(4), 264-265.
- Liperoti, R., Gambassi, G., Lapane, K. L., Chiang, C., Pedone, C., Mor, V., & Bernabei, R. (2005). Cerebrovascular events among elderly nursing home

- patients treated with conventional or atypical antipsychotics. *Journal of Clinical Psychiatry*, 66(9), 1090-1096.
- Liu, M. E., Tsai, S. J., Chang, W. C., Hsu, C. H., Lu, T., Hung, K. S., . . . Chang, W. P. (2013). Population-based 5-year follow-up study in Taiwan of dementia and risk of stroke. *PLoS One*, 8(4), e61771.
- Lonergan, E., Luxenberg, J., Colford, J. M. & Birks J. (2002). Haloperidol for agitation in dementia. *Cochrane Database of Systematic Reviews*, CD002852.
- Lukas, A., Mayer, B., Fialová, D., Topinkova, E., Gindin, J., Onder, G., . . . Denking, M. D. (2013). Treatment of pain in European nursing homes: results from the Services and Health for Elderly in Long TERM Care (SHELTER) study. *Journal of the American Medical Directors Association*, 14(11), 821-831.
- MacDonald, S. I., & Shemie, S. D. (2017). Ethical challenges and the donation physician specialist: A scoping review. *Transplantation*, 101(5S), S27-S40.
- Maglione, M., Maher, A. R., Hu, J., Wang, Z., Shanman, R., Shekelle, P. G., . . . Ewing, B. A. (2011). Off-label use of atypical antipsychotics: An update. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK66081/pdf/Bookshelf_NBK66081.pdf
- Maria-Roxana, M., & Vasile, C. (2010). Ethical implications of the institutionalising patients with dementia. *Revista Romana De Bioetica*, 8(2), 141-145.
- McDougall, R. (2013). Systematic reviews in bioethics: Types, challenges, and value. *Journal of Medicine and Philosophy*, 39(1), 89-97.
- McDougall, R. (2015). Reviewing literature in bioethics research: Increasing rigour in non-systematic reviews. *Bioethics*, 29(7), 523-528.
- Mead, N., & Bower, P. (2000). Patient-centredness: A conceptual framework and review of the empirical literature. *Social Science & Medicine*, 51(7), 1087-1110.
- Meltzer, H. Y. (2013). Update on typical and atypical antipsychotic drugs. *Annual Review of Medicine*, 64, 393-406.
- Mitchell, G. (2014). Therapeutic lying to assist people with dementia in maintaining medication adherence. *Nursing Ethics*, 21(7), 844-845. doi:10.1177/0969733014543886
- Modrego, P. J., & Ferrández, J. (2004). Depression in patients with mild cognitive impairment increases the risk of developing dementia of Alzheimer type: A prospective cohort study. *Archives of Neurology*, 61(8), 1290-1293.

- Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & Prisma Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*, 6(7), e1000097.
- Musicco, M., Palmer, K., Russo, A., Caltagirone, C., Adorni, F., Pettenati, C., & Bisanti, L. (2011). Association between prescription of conventional or atypical antipsychotic drugs and mortality in older persons with Alzheimer's disease. *Dementia and Geriatric Cognitive Disorders*, 31(3), 218-224.
- Naarding, P., van Grevenstein, M., & Beekman, A. T. (2010). Benefit-risk analysis for the clinician: 'Primum non nocere' revisited--the case for antipsychotics in the treatment of behavioural disturbances in dementia. *International Journal of Geriatric Psychiatry*, 25(5), 437-440. doi:10.1002/gps.2357
- National Health and Medical Research Council. (2016). Clinical practice guidelines and principles of care for people with dementia. Retrieved from http://sydney.edu.au/medicine/cdpc/documents/resources/LAVER_Dementia_Guidelines_recommendations_PRVW5.pdf
- Noddings, N. (1984). *Caring: A feminist approach to ethics*. Berkeley: University of California Press.
- NSW Ministry of Health. (2013). Assessment and management of people with behavioural and psychological symptoms of dementia (BPSD). Retrieved from https://www.ranzcp.org/Files/Publications/A-Handbook-for-NSW-Health-Clinicians-BPSD_June13_W.aspx
- Nuffield Council on Bioethics. (2009). Dementia: Ethical issues. Retrieved from <https://nuffieldbioethics.org/wp-content/uploads/2014/07/Dementia-report-Oct-09.pdf>
- O'Sullivan, G. (2013). Ethical and effective: Approaches to residential care for people with dementia. *Dementia*, 12(1), 111-121.
- Passmore, M. J. (2013). Neuropsychiatric symptoms of dementia: Consent, quality of life, and dignity. *BioMed Research International*, 2013. doi:10.1155/2013/230134
- Passmore, M. J., Ho, A., & Gallagher, R. (2012). Behavioral and psychological symptoms in moderate to severe Alzheimer's disease: A palliative care approach emphasizing recognition of personhood and preservation of dignity. *Journal of Alzheimer's Disease*, 29(1), 1-13.
- Patel, A. N., Lee, S., Andrews, H. F., Pelton, G. H., Schultz, S. K., Sultzer, D. L., . . . Colon, S. (2017). Prediction of relapse after discontinuation of antipsychotic treatment in Alzheimer's disease: The role of hallucinations. *American Journal of Psychiatry*, 174(4), 362-369. doi:10.1176/appi.ajp.2016.16020226

- Perera, N., Javeed, M., Lyketsos, G. C., & Leroi, I. (2017). Neuropsychiatric aspects of dementia. In D. Ames, J. O'Brien, & A. Burns (Eds.), *Dementia* (5th ed., pp. 59-66). Boca Raton, Florida: CRC Press.
- Pratt, N., Roughead, E. E., Ramsay, E., Salter, A., & Ryan, P. (2011). Risk of hospitalization for hip fracture and pneumonia associated with antipsychotic prescribing in the elderly. *Drug Safety*, 34(7), 567-575.
- Pulsford, D., & Duxbury, J. (2006). Aggressive behaviour by people with dementia in residential care settings: A review. *Journal of Psychiatric and Mental Health Nursing*, 13(5), 611-618.
- Royal Australian and New Zealand College of Psychiatrists. (2016). Professional Practice Guideline 10: Antipsychotic medications as a treatment of behavioural and psychological symptoms of dementia. Retrieved from https://www.ranzcp.org/Files/Resources/College_Statements/Practice_Guide_lines/pg10-pdf.aspx
- Reeve, E., Denig, P., Hilmer, S. N., & Ter Meulen, R. (2016). The ethics of deprescribing in older adults. *Journal of Bioethical Inquiry*, 13(4), 581-590.
- Robinson, F. (2011). Care ethics and the transnationalization of care: Reflections on autonomy, hegemonic masculinities, and globalization. In M. Rianne & F. Robinson (Eds.), *Feminist ethics and social policy: Towards a new global political economy of care* (pp. 127-144). Vancouver: UBC Press.
- Robinson, L., Dickinson, C., Bamford, C., Clark, A., Hughes, J., & Exley, C. (2013). A qualitative study: Professionals' experiences of advance care planning in dementia and palliative care, 'a good idea in theory but...'. *Palliative Medicine*, 27(5), 401-408.
- Ross, W. D. (1930). *The right and the good*. Oxford, England: The Clarendon Press.
- Ryan, N. S., Rossor, M. N., & Fox, N. C. (2015). Alzheimer's disease in the 100 years since Alzheimer's death. *Brain*, 138(12), 3816-3821.
- Sacchetti, E., Turrina, C., & Valsecchi, P. (2010). Cerebrovascular accidents in elderly people treated with antipsychotic drugs. *Drug Safety*, 33(4), 273-288.
- Samus, Q. M., Rosenblatt, A., Steele, C., Baker, A., Harper, M., Brandt, J., . . . Lyketsos, C. G. (2005). The association of neuropsychiatric symptoms and environment with quality of life in assisted living residents with dementia. *The Gerontologist*, 45(suppl_1), 19-26.
- Sawan, M., Jeon, Y.-H., Fois, R. A., & Chen, T. F. (2017). Exploring the link between organizational climate and the use of psychotropic medicines in nursing homes: A qualitative study. *Research in Social and Administrative Pharmacy*, 13(3), 513-523.

- Sawan, M. J., Jeon, Y.-H., Fois, R. J., & Chen, T. F. (2016). A qualitative study exploring visible components of organizational culture: What influences the use of psychotropic medicines in nursing homes? *International Psychogeriatrics*, 28(10), 1725-1735.
- Sayers, A. (2007). Tips and tricks in performing a systematic review. *British Journal of General Practice*, 57(542), 759-759.
- Schneeweiss, S., Setoguchi, S., Brookhart, A., Dormuth, C., & Wang, P. S. (2007). Risk of death associated with the use of conventional versus atypical antipsychotic drugs among elderly patients. *Canadian Medical Association Journal*, 176(5), 627-632.
- Schneider, L. S., Dagerman, K., & Insel, P. S. (2006). Efficacy and adverse effects of atypical antipsychotics for dementia: Meta-analysis of randomized, placebo-controlled trials. *The American Journal of Geriatric Psychiatry*, 14(3), 191-210.
- Schneider, L. S., Dagerman, K. S., & Insel, P. (2005). Risk of death with atypical antipsychotic drug treatment for dementia: Meta-analysis of randomized placebo-controlled trials. *The Journal of the American Medical Association*, 294(15), 1934-1943.
- Schneider, L. S., Pollock, V. E., & Lyness, S. A. (1990). A metaanalysis of controlled trials of neuroleptic treatment in dementia. *Journal of the American Geriatrics Society*, 38(5), 553-563.
- Sherwin, S., & Winsby, M. (2011). A relational perspective on autonomy for older adults residing in nursing homes. *Health Expectations*, 14(2), 182-190.
- Shin, H. Y., Gadzhanova, S., Roughead, E. E., Ward, M. B., & Pont, L. G. (2016). The use of antipsychotics among people treated with medications for dementia in residential aged care facilities. *International Psychogeriatrics*, 28(06), 977-982.
- Sink, K. M., Holden, K. F., & Yaffe, K. (2005). Pharmacological treatment of neuropsychiatric symptoms of dementia: a review of the evidence. *The Journal of the American Medical Association*, 293(5), 596-608.
- Smith, S., Lamping, D., Banerjee, S., Harwood, R., Foley, B., Smith, P., . . . Levin, E. (2005). Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology. *Health Technology Assessment (Winchester, England)*, 9(10), 1-93.
- Snowdon, J., Galanos, D., & Vaswani, D. (2011). Patterns of psychotropic medication use in nursing homes: surveys in Sydney, allowing comparisons over time and between countries. *International Psychogeriatrics*, 23(9), 1520-1525.

- Sofaer, N., & Strech, D. (2012). The need for systematic reviews of reasons. *Bioethics*, 26(6), 315-328.
- Taylor, B. M. (2016). Drugging grandma: The severe dangers of chemically restraining nursing home residents with potent antipsychotic and psychotropic pharmaceuticals. *Elder Law Journal*, 24, 213.
- Testad, I., Auer, S., Mittelman, M., Ballard, C., Fossey, J., Donabauer, Y., & Aarsland, D. (2010). Nursing home structure and association with agitation and use of psychotropic drugs in nursing home residents in three countries: Norway, Austria and England. *International Journal of Geriatric Psychiatry*, 25(7), 725-731.
- Therapeutic Goods Administration. (2015). Risperidone and risk of cerebrovascular adverse events in dementia patients. Retrieved from <https://www.tga.gov.au/sites/default/files/medicines-safety-update-volume-6-number-4-august-2015.pdf>
- The UK Department of Health. (2012). Prime Minister's challenge on dementia. Delivering major improvements in dementia care and research by 2015. . Retrieved from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215101/dh_133176.pdf
- Toiviainen, L. (2014). Case commentary 1. *Nursing Ethics*, 21(7), 846-847. doi:10.1177/0969733014543886a
- Treloar, A., Crugel, M., Prasanna, A., Solomons, L., Fox, C., Paton, C., & Katona, C. (2010). Ethical dilemmas: Should antipsychotics ever be prescribed for people with dementia? *British Journal of Psychiatry*, 197(2), 88-90.
- Treloar, A., Philpot, M., & Beats, B. (2001). Concealing medication in patients' food. *Lancet*, 357(9249), 62-64.
- Tronto, J. C. (1993). *Moral boundaries: A political argument for an ethic of care*. New York, NY: Routledge.
- Tronto, J. C. (2010). Creating caring institutions: Politics, plurality, and purpose. *Ethics and Social Welfare*, 4(2), 158-171.
- Tronto, J. C. (2013). *Caring democracy: Markets, equality, and justice*. New York, NY: New York University Press.
- Ven-Vakhteva, J., Bor, H., Wetzels, R. B., Koopmans, R. T., & Zuidema, S. U. (2013). The impact of antipsychotics and neuropsychiatric symptoms on the quality of life of people with dementia living in nursing homes. *International Journal of Geriatric Psychiatry*, 28(5), 530-538.
- Verdelho, A., & Gonçalves-Pereira, M. (2017). Neuropsychiatric symptoms in cognitive impairment and dementia: A brief introductory overview. In A.

- Verdelho & M. Gonçalves-Pereira (Eds.), *Neuropsychiatric symptoms of cognitive impairment and dementia* (pp. 1-7). Cham: Springer.
- Vigen, C. L., Mack, W. J., Keefe, R. S., Sano, M., Sultzer, D. L., Stroup, T. S., . . . Lyketsos, C. G. (2011). Cognitive effects of atypical antipsychotic medications in patients with Alzheimer's disease: outcomes from CATIE-AD. *American Journal of Psychiatry*, 168(8), 831-839.
- Vollmann, J. (2001). Advance directives in patients with Alzheimer's disease; Ethical and clinical considerations. *Medicine, Health Care and Philosophy*, 4(2), 161-167.
- Wetzels, R., Zuidema, S. U., de Jonghe, J. F., Verhey, F., & Koopmans, R. (2010). Determinants of quality of life in nursing home residents with dementia. *Dementia and Geriatric Cognitive Disorders*, 29(3), 189-197.
- Wilson, E., Kenny, A., & Dickson-Swift, V. (2017). Ethical challenges in community-based participatory research: A scoping review. *Qualitative Health Research*. Advance online publication. doi: 10.1177/1049732317690721
- Wolf, A., Leucht, S., & Pajonk, F.-G. (2017). Do antipsychotics lead to cognitive impairment in dementia? A meta-analysis of randomised placebo-controlled trials. *European Archives of Psychiatry and Clinical Neuroscience*, 267(3), 187-198.
- Zimmerman, S., Sloane, P. D., Williams, C. S., Reed, P. S., Preisser, J. S., Eckert, J. K., ... & Dobbs, D. (2005). Dementia care and quality of life in assisted living and nursing homes. *The Gerontologist*, 45(suppl_1), 133-146.