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## Ethical and Practical Dimensions of Prescribing for Older People as Quality of Life Decreases

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### ABSTRACT

Prescribing medicines for older people always presents difficulties, never more so than when quality of life decreases or the process of dying begins. The problem confronting doctors, and others caring for older patients, is the option of intervening or not intervening. The principles of bioethics can be used to assist those making decisions regarding the medical management of older people. Decisions that are made must consider the likely benefit and associated harms that may accrue from continuing or commencing treatment. Respect for individuals and their wishes must be maintained even when the patient's decision-making capacity is impaired and others need to make decisions for them. Management dilemmas include when to stop or reduce prescribing as the end-of-life approaches, the use of medication to manage behavioural disturbance, multiple medication use increasing the risk for harm and the use of drugs for which the evidence of benefit is not available for older patients or for which there is evidence of increased adverse effects that may impair quality of life. Those caring for older people must consider a wide range of options and can be assisted by asking key questions to help guide appropriate decision making.

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### INTRODUCTION

Bioethics is about questions, not about answers. An appreciation of this can help clinicians approach the ethical conundrums that characterise care of older people, especially as their quality of life markedly decreases or the dying process starts. The bioethics principles regarding prescribing for older people are no different to those that are relevant for people of all ages, and as always, their application needs to be adapted to each clinical situation. Clinicians need to consider what ethics-related questions need to be addressed to arrive at wise treatment choices.

The dictum *primum non nocere* (first do no harm) is taught to all medical students, but possibly is not always considered by doctors on a day-to-day basis. This dictum reflects the ethical principal of non-maleficence and guides the approach to medicine and to prescribing in particular. It proposes that doctors should approach their patients in ways that have the least risk of causing harm. In situations where there are risks of harm, both from not intervening and from intervening, then any harms resulting from not intervening are considered preferable

to any harms caused by intervening. This key principle is especially salient as clinical practice is characterised by uncertainty, with both action and inaction carrying risks.

When there are obvious best options, then all reasonable clinicians and patients choose them, however, the best course of action is not always obvious. The option of intervening or not intervening is always present. Further, if interventions are to be made, what exactly should they be? How can possible harms and benefits be judged, and then benefits balanced against harms to reach decisions regarding what are the best management options? In addition to patient-specific considerations, bioethics principles also consider broader societal issues. Applying the principles of bioethics can help reach decisions about treatment. This is achieved by asking questions that lead to the proper consideration of all the relevant issues. Table 1 provides some key questions that may help to address the ethical and practical dimensions of prescribing for older people as their quality of life decreases.

### PRINCIPLES OF BIOETHICS

#### Respect for Individuals

Possibly the most important bioethics principle is that of respect for individuals. Out of respect for individuals, the opinions and desires of the people for whom treatment decisions are to be made are sought, and these opinions and desires determine the ultimate decision. Thus the individual patient's autonomy is protected. Getting a patient's opinion requires communication about the health conditions for which treatments may be indicated and discussion of the possible benefits and harms of treatment approaches. The aim is to achieve 'adequate disclosure' about the health conditions, and the possible treatments. Adequate disclosure has both legal and ethical dimensions. The latter entails giving enough information to patients, in genuinely accessible ways, to enable them to provide informed consent to proposed therapy. Conceptually, adequate disclosure is simple for people who have the capacity to make decisions for themselves about their health care and about the treatments that have been proposed for them. Capable individuals are dealt with as the autonomous agents they are, and able to request more information as they need it.

It is not ethical to treat people with reduced autonomy as though they are autonomous agents. People with reduced capacity need to be provided with protection (to protect their dignity and their rights). Where treatments appear indicated for people who clearly lack decision-making capacity a process must be put in place whereby substitute decision makers can be briefed and appropriate decisions made.

Achieving adequate disclosure and obtaining informed consent to (or rejection of) proposed therapy is much less simple for people who have borderline decision-making capacity, for example due to delirium or dementia. For legal and practical purposes these patients' decision-making capacity must be

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**Table 1. Questions that may help to address the ethical and practical dimensions of prescribing for older people as quality of life decreases**

Issue	Question to ask/approach to take
Does the person have capacity to make decisions?	Use the Six Step Capacity Assessment Process. <sup>1</sup>
In a person who lacks capacity, to guide the substitute decision-maker into using substituted judgement, if possible, rather than a 'best interests' standard of judgement.	What would the person have wanted done? Did they ever talk about this situation and make their wishes known? What general values did the incapable person hold that are relevant to the situation?
Balance autonomy and beneficence	Is the evidence for a particular course of action strong given the circumstances? If yes, then strongly recommend this, but accept the patient's right to decline (provided adequate disclosure has occurred and the patient has decision-making capacity). Otherwise, avoid making a recommendation unless the patient appears to want to have this.
Allocative justice	Is it fair to prescribe medications for my patient knowing that the funds used will not be available for other purposes in society?
Equality of outcome versus equality of opportunity	Can the cost of the (expensive) medications for my patient be justified?
Righting of past wrongs	Does the righting of past wrongs justify increased prescribing/resource allocation now?
End of life decision-making. We can never know the truth, the right thing to do, but it is our task to seek this. With deconstruction it is possible that one set of endpoints is just as true as another set.	Has the dying process started? Are life-prolonging medications appropriate at this time? What is the right thing to do? Could another option be equally right?
Availability of evidence in the older patient	Is there evidence of benefit for use of the medicine in older patients (with multiple comorbidities)? Is there evidence for harm in the older patients (with multiple comorbidities)?
Time for treatment effect	Is the timeframe for the benefit of the medication within the predicted life expectancy of the patient?
Quality of life or quantity of life	What are the patient's preferences? Has this been discussed?

assessed to dichotomise them into those who retain decision-making capacity and those who have lost decision-making capacity. This categorisation is critical because capable people can make decisions for themselves whereas people who have lost decision-making capacity must have others make decisions for them. Valid ways of determining capacity underpin the clinical ability to show respect for persons when dealing with people who have borderline decision-making capacity.<sup>1,2</sup> It would be disrespectful (and indeed against statute law and common law) to ignore the wishes of capable persons. Similarly, it is also disrespectful to ignore the fact that some people lack the capacity to make appropriate decisions concerning their own medical management. Decisions regarding the management of such people should be sought from substitute decision-makers, such as those with an Enduring Power of Attorney, rather than relying on the decisions made by those without appropriate decision-making capacity.

When decisions are made for incapable people by substitute decision-makers it is important that clinicians ensure the substitute decision makers understand their role. They are to make decisions for the persons as though they 'stood in the shoes' of the incapable persons for whom they are making the management decisions. In coming to their decisions, the substitute decision makers must use the previously expressed wishes (if any) or relevant values (if known) of the persons for whom they are substituting. Using the previously expressed wishes or values to make decisions for incapable people is termed 'substituted judgement'. Only if the substitute decision makers do not know the incapable person's wishes or values and, hence, are unable to make decisions based on substituted judgement may the substitute decision maker use a lower standard, the 'best interests' standard, to make decisions. This seemingly trivial point is actually quite important as it is possible that the decisions reached by substituted judgement may differ from those reached by 'best interests' decision making.

### **Beneficence**

Beneficence is the obligation to maximise possible benefits and to minimise possible harms (non-maleficence). The possible harm is not just physical harm, but also psychological or emotional distress, discomfort and social or economic disadvantage.

Society has an interest in the wellbeing of its members. In Western societies 'wellbeing' is substantially defined as being what people would have wanted for themselves, with the liberal philosopher John Stuart Mill being a strong proponent of this notion.<sup>3</sup> Being able to make choices for oneself is an expression of autonomy. There is a tension between autonomy, the freedom to make choices, and beneficence, which is when society makes decisions based on a 'best-interests' standard for its members. The tension arises because the choices people make for themselves may not always be the best choices for them from the point of view of society. For example, people may choose to exercise their autonomy to smoke cigarettes or to engage in unsafe sex. These behaviours carry risks, and society, through an interest in beneficence, may attempt to curtail these harmful practices. When prescribing, doctors need to balance beneficence, their beliefs regarding what would be best for their patients, with autonomy and their patients' wishes. For example, doctors may strongly recommend that older people who have lone atrial fibrillation, where there is a risk of systemic embolisation, take antiplatelet drugs or anticoagulants as the risk of embolisation is reduced by around one-third with regular aspirin and by two-thirds with full anticoagulation. Both of these treatment options may be unattractive to patients who may choose to ignore the proffered advice. The beneficent advice that patients be anticoagulated to minimise the risk of major systemic embolisation may seem quite inappropriate for people at the end of their lives with multiple irreversible medical problems some of which could cause their death.

In considering whether a treatment may be worthwhile doctors and patients may not value the same factors. Doctors may value endpoints to which they have been acculturated through their training or by deft marketing by the pharmaceutical industry. Patients may not value the same endpoints, for example, in atrial fibrillation doctors may place great positive value on the reduction of systemic embolisation with anticoagulation whereas patients may place great negative value on having to take anticoagulants which carry significant risks of adverse events and which also serve as a daily reminder that they have a serious condition. Patients may wish to trade off quantity of life for better quality of life.

### Justice

Justice, or fairness, has several different aspects. One concerns the fair distribution of benefits and burdens in society. Substantially, this relates to the allocation of resources. Since there is a greater demand for health care than the resources available to satisfy it, healthcare funding must be considered to be a scarce resource. If the scarce resource is allocated to one intervention it is not available for another. Hence, prescribing for individual patients cannot be done without considering the effect of using the expended resources in a different way to provide benefits to other patients. Clinicians must deal with the tension that may arise from balancing the needs of their individual patients with the needs of other patients and the wider society. Where the costs of the prescribed treatments are small and the benefits are large the decisions to prescribe are not difficult, but where the costs of the prescribed treatment are large, and/or the benefits are small, then any decision to prescribe become complex. Some clinicians shirk from this responsibility by saying that their concerns are solely for their immediate patients without reference to others' needs, and that should society be genuinely concerned it should limit their ability to prescribe medications. For example, the cholinesterase inhibitor cognitive enhancers are available in Australia and New Zealand but may not be publicly funded as funding agencies have determined, on behalf of the people they serve, that the high cost of these medications are not justified by the limited benefits they provide.

Procedural justice is another dimension of the broad notion of justice. Procedural justice relates to the use of fair methods to make decisions. If some patients are to be given treatments and others denied treatments, then following the rules of procedural justice will ensure that all patients' circumstances are properly considered before decisions are made. Usually the notion of procedural justice relates to institutional approaches to issues.

Other perspectives on justice are also possible. These relate to equity of opportunity and equity of outcome. The former is non-contentious as much as possible all people should have the opportunity to live well. It is up to individual effort, personal lifestyle decisions and the play of chance to determine what actually happens to individuals. Given that the occurrence of much illness and disease is beyond human control when disease occurs, those who strive for equity of opportunity, provided resources to prevent disease have been allocated equally, must simply accept there has been bad luck and accept the situation. Those who seek equity of outcome adopt a different approach in the face of disease and illness. They seek to use health resources to redress the inequality that the occurrence of the disease and illness has caused and devote all available resources to ameliorate the situation. Such disease focused spending depletes resources available to others, hence funding that aims to ensure equality of health outcomes diminishes the funding available for ensuring equality of opportunities to have good

health. Extensive spending on patients with disease, for example by prescribing medications, will diminish the funds available for improving people's lives in other ways.

The notion of justice can also be applied to the righting of past wrongs, i.e. corrective justice. The clock cannot be turned back and past wrongs prevented, however, it is possible to attempt restitution. For example, through a combination of ignorance, mismanagement, neglect and disenfranchisement many indigenous peoples have come to have poorer health than that of the dominant, colonising societies. This could be considered a wrong that requires correction, which would justify increased health expenditure (including through prescribing) directed at improving the health of the indigenous peoples.

Application of the three cardinal ethical principles of respect for persons, beneficence and justice, guides decision-making regarding treatment. Ethical dilemmas occur when values, loyalties, principles or duties are in conflict. The answers are seldom absolutely clear and unquestionable. It is important to note that solutions may change as circumstances change or as more information becomes available.

### Philosophical View Points

The values that individuals harbour affect their world view and the treatment decisions they make. Nowhere is this more true than when dealing with end-of-life decision-making. The two main opposing value sets are the Consequentialist and the Deontological. The Consequentialist framework values the benefits, the utility, that something brings. Its central tenet is to make decisions in such a way as to maximise utility to maximise benefits and to minimise harms. A state of being is valued by the benefits that state offers. For example, good health that enables people to contribute to society is valued, whereas chronic illness that precludes people from contributing to society is not valued. By contrast, the Deontological approach values states of being for their intrinsic value, not for any benefit the states may bring. Actions are right or wrong not because of their consequences but because of their right making characteristics such as fidelity to promises, truthfulness and justice. When end-of-life decision-making, such as may concern people with late Alzheimer's dementia who are requiring extensive nursing care, is addressed with a Consequentialist utilitarian approach this is likely to result in a completely different evaluation than would a Deontological approach. Consequentialists would judge that people with dementia provide no benefit, indeed they provide negative benefit, hence existence in that state has no, or even negative, value. By contrast the Deontological approach would value the lives of the people with dementia for their own intrinsic value. Hence, if there were to be life-threatening conditions, such as aspiration pneumonia, Consequentialists might judge the people with dementia as not warranting life-saving treatment, whereas Deontologists would likely strive to provide therapy that would maintain life.

The final outcomes when contemplating end-of-life decision-making can be very different depending upon the dominant values of those making the decisions. There is no clearly superior set of values, and decisions that flow from application of either Consequentialist or Deontological frameworks can potentially both be quite appropriate. This is extremely troubling for some as the decisions made following either value set may be profoundly different. For example, it is hard to contemplate that decisions that result in withholding of life prolonging therapy and early death can be no 'better' nor 'worse' than decisions to provide whatever life prolonging therapy is reasonably available to stave off death a little bit longer.

The National Institute for Health and Clinical Excellence in the UK, an independent organisation responsible for providing guidance on the promotion of good health and the prevention and treatment of ill health, has set up an explicit process for gaining input from the public about values. Using an arm's length process the National Institute for Health and Clinical Excellence has established a Citizens Council, through which people broadly representative of the population, can consider and report on the social values that influence treatment. For example, the Citizens Council has deliberated on whether there are circumstances in which age should be taken into account when making decisions and whether public funds should be allocated to pay for medications to treat very rare diseases.<sup>4</sup>

A further set of values that deserves examination is that which concerns fidelity. Fidelity or faithfulness can be applied to professional roles and institutional roles. The public expects that doctors, without special knowledge of the individual doctor's personal values, will act in ways that are consistent with their professional roles and are consistent with the ethos of their employing institutions. For example, doctors are expected to be objective, to apply the best available evidence to carefully evaluate the various possible alternatives and then to recommend treatments that optimise the balance of likely benefits and possible harms, and when in doubt preserve life.<sup>5,6</sup> Despite this belief and expectation on behalf of the public that doctors will pursue evidence-based practice there is compelling evidence that pharmaceutical industry representatives, through giving gifts to prescribers, powerfully influence their prescribing patterns, and that prescribers' integrity has been comprehensively compromised by this systematic gifting.<sup>7-9</sup>

## MANAGEMENT DILEMMAS

### End-of-Life Prescribing

At the end-of-life when the process of dying has started, which can be thought of as the process that progresses relentlessly to death, there is no argument that life-prolonging medication is not just futile, but may in fact be inappropriate as it may prolong the dying process. At this stage, medications that ensure comfort should be continued and other medications that aim to prolong life or minimise long-term risk of disease may be discontinued. For example, anti-hyperlipidaemic drugs, anti-osteoporosis drugs, and antihypertensives prescribed for blood pressure control or for renal protection in diabetes, could all be stopped. Ethically, out of respect for persons, decisions about stopping treatments need to be made together with the capable patients themselves or together with the substitute decision-makers of incapable patients.

Cessation of treatment is primarily based on judgement that the potential benefit of treatment is reduced, such that the overall benefit to risk ratio is less favourable.

There is no ethical or legal need to continue futile treatment. The dilemma for clinicians is to recognise when dying has started. Is it when the terminal illness is fully declared and well advanced, or is it possible to identify the dying process at an earlier stage? May admission to residential aged care per se, especially to high-level care, be a suitable marker that dying has commenced (as death accounts for 87% of separations from residential care with more than a third of people dying within 12 months of admission) and that life-prolonging therapy is no longer appropriate?<sup>10</sup> If not, then how do we identify an appropriate marker at which point we reconsider what medication should be continued and what should be ceased?

Recently there appears to be a push to not discontinue cognitive enhancing medication for people with dementia admitted to residential aged care facilities.<sup>11</sup> It might be hard to reconcile such prescribing with the principle of allocative justice,

especially if a Consequentialist set of values is applied. In a recent editorial the author asks 'Is paying for cholinesterase inhibitors, even if deemed worthwhile for severe Alzheimer's disease, the best use of scarce resources?'<sup>12</sup>

### Behavioural Disturbance

The behavioural and psychological symptoms of dementia are common in advanced dementia. Behavioural management remains the mainstay of the management of behavioural and psychological symptoms of dementia. Antipsychotic drugs are often prescribed to people with behavioural and psychological symptoms of dementia. This is potentially troubling as antipsychotic drugs are not particularly effective for this indication and they can cause death and discomfort to patients. For whose benefit are the antipsychotic drugs prescribed? Often it appears the medications are prescribed not to settle any genuine agitation or inner turmoil, but rather antipsychotic drugs are given to people with behavioural and psychological symptoms of dementia for the convenience of carers. This leaves the 'costs' of the treatment to the patients while providing benefit to the carers. This may be reasonable in situations where the care-giving is provided by families to enable care to continue at home, which may be an important benefit. Antipsychotic therapy for behavioural and psychological symptoms of dementia may be less reasonable in institutional settings, where staff are paid to provide care, and will continue to provide care even if calming of the patients is not effected by blunting of their thought. The concept of beneficence would suggest that these treatment decisions are not in the best interest of patients and should be reconsidered. Residential care legislation in the US, restricting use of antipsychotic drugs, resulted in a reduction of antipsychotic drug use by 30%, but there was no concomitant rise in the occurrence of severe troubling behaviours.<sup>13</sup> This could be interpreted as demonstrating that many people were receiving the medications without substantial benefit.

### Multiple Medical Conditions

Old age is characterised by the presence of multiple medical problems. Some may be aetiologically linked, such as hypercholesterolaemia-induced heart and cerebrovascular disease, others may occur together simply due to the co-occurrence of diseases such as cancer, asthma and dementia without an apparent link between the conditions. In prescribing for older people with multiple medical problems doctors must consider whether the medical problems warrant treatment to the same extent that they would were they to occur alone rather than together with other conditions, and recommendations discussed with patients and/or carers. It is also important to consider whether using medication to treat adverse effects of medications is warranted or rather whether this should be an indication that the original medication could be ceased or its dosage decreased.<sup>14</sup>

### Absence of Evidence

Medicines should only be used where there is evidence for their benefit. Much of the research that provides evidence of benefit is not conducted in older patients.<sup>15</sup> This means that there is little or no evidence of benefit for many medications routinely used in older people. Consideration must also be given to the time required to achieve a benefit and whether this is within the life expectancy of the patient. Medications prescribed for primary or secondary prevention, such as aspirin or statins, need a longer time for an observable benefit than those used to treat acute conditions, such as pain or infection.<sup>16</sup> How then can ethical and appropriate decisions be made concerning the management of older people in the absence of evidence of benefit, especially where there may be evidence of harm?

## Improve Quality of Life and Risk Quantity of Life

Some older people may wish to accept the risk of side effects of treatment to gain improved quality of life. For example, they may choose to take non-steroidal anti-inflammatory drugs for degenerative knee pain despite the risk of peptic ulceration. This requires adequate assessment of the clinical problem, followed by adequate disclosure to the patients.<sup>17</sup>

### SUMMARY

The fundamental principles of prescribing for older people as quality of life decreases are the same as those that apply to prescribing for all adults. Their application is modified by the possible presence of incapacity to make treatment decisions, when valid assessments of decision-making capacity are required, and if indicated, consent for treatment must be sought from substitute decision makers. Their application is also modified by the recognition that some treatment is futile such as when the dying process is present. At the end-of-life, when quality of life decreases, patients' may prefer to attempt to improve quality of life and accept the risk this may shorten life. Equity, and the concepts of allocative justice, may influence decision making as it may not seem reasonable to spend scarce resources on futile treatments for people at the end of their lives. Decisions in this context must also consider the lack of evidence of benefit for treatments in older people, especially if they might not live long enough to obtain a benefit. Inspection of patients' circumstances through the 'lens' of the major principles of bioethics can provide insights that guide treatment decisions. The proximate mechanism for doing this is by asking questions about the situation that can reveal the relevant issues.

**Competing interests:** None declared

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The material in this article has been accredited by SHPA as suitable for inclusion in an individual pharmacist's CPD plan as outlined in the **shpacpd** program <[www.shpa.org.au/docs/cpd.html](http://www.shpa.org.au/docs/cpd.html)>. A series of questions that can assist you to evaluate your learning outcomes can be found on the SHPA web site. Answers to these questions can be lodged until March 2009 <[www.shpa.org.au/docs/cpd.html](http://www.shpa.org.au/docs/cpd.html)>.

In **shpacpd** this is considered an Activity Group 2 activity: Improving Knowledge and Skills with assessment; the number of hours will be dependent on the time you have taken to read the article and complete the multiple choice questions and submit the answers.

The learning objectives are as follows:

1. To list questions that may be asked to help address the ethical and practical dimensions of prescribing for older people as quality of life decreases.
2. To describe examples of situations in which ethical considerations come into play for older people as quality of life decreases.
3. To apply the principles of bioethics to prescribing decisions in older people nearing the end of life.

Pharmacist competency units addressed include:

Competency Unit 1.2.2: Behave in a professional and ethical manner.

Competency Unit 3.1: Participate in therapeutic decision making.

Competency Unit 3.2: Provide ongoing pharmaceutical management.

Competency Unit 3.3: Promote rational drug use.

Competency Unit 4.2: Evaluate prescribed medicines.