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Population Screening: Some Ethical Issues

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In this Issue

The authors of the two articles in this issue of Bioethics Outlook are both undertaking doctoral studies, through the Plunkett Centre, at Australian Catholic University.

Mary Self, a surgeon, examines the issues we need to consider in deciding whether to devote scarce public funds to screening programmes.

Helen McCabe, an oncology nurse, offers an ethical framework in the light of which changes associated with Managed Care may be assessed.

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A happy Christmas and a prosperous New Year.

"Prevention is better than cure." "Early detection saves lives." "Screening can save your life." These are the popular catchcries which express the ideas on which population screening programmes are based. I would like to present some musings on the topic of population or mass screening, from the perspective of an interested, and concerned, clinician. Screening programmes have become an entrenched feature of modern health care, and we commonly hear pleas for introduction of others. These pleas arise out of the inference that, because some individuals benefit, such programmes are a good thing for us as a society. But is this conclusion really true? How justified are the assumptions that certain screening programmes are worthwhile, and indeed that they are a just use of limited public funds?

It is my proposal that screening programmes raise complex ethical issues, some of which have not been given the attention and scrutiny which they deserve. In this paper I shall reflect on just a few of these issues. The areas of particular concern here are the idea of benefit to the community, the risks and harms of screening programmes, and the question of public information about screening.

What is "Screening"?

It might be useful at the start to define what screening is, and to clarify the sorts of screening programmes under discussion. "Screening" means the performance of some kind of examination or diagnostic test on apparently healthy individuals, those without symptoms, in order to discover an early stage of a disease, or a risk factor for a disease. "Population screening" or "mass screening" refers to the organised screening of a population or a large subgroup of the population. Breast cancer screening by mammography, which has been in place in Australia and many other Western countries for about a decade, provides a typical example of such a programme and will serve to illustrate some points below. Other population screening programmes of the type under consideration include screening for cervical cancer by Papanicolaou smears and the testing of newborns for thyroid disorder and phenylketonuria(PKU). There are currently calls for similar publicly funded programmes for detection of prostate cancer, abdominal aortic aneurysms, colon cancer, and others.

It should be pointed out that there are other types of screening which are not really the subject of this discussion. Screening for disease in those known to be at high risk, for example because of a known or likely inherited disposition for a particular condition, is not at issue here. Neither is the sort of *de facto* screening for conditions such as high blood pressure and for risk factors such as high cholesterol which occurs through general practice. And with the rapid advances we are seeing in genetic technology, there will be increasing possibilities of identifying genetic traits associated with a probability of development of some disease in the future. Genetic screening does share some of the same ethical challenges raised by population screening. However, it does throw up a whole set of particular ethical issues which will not be discussed further here.

Characteristics of a Good Screening Programme

What is the fundamental motivation for screening of populations for early disease or risk factors? Screening is a public health measure, based on the laudable aim of improving the health of the population. The idea is that if a disease or risk factor is detected early, before symptoms occur, then more effective treatment or preventive measures can be instituted, and so the health of the population improved. Thus, for breast cancer, the premise is that by detecting cancer early, when it is visible on Xray but too small to be palpated, it is less likely to have spread, and thus is more likely to be successfully treated, often with less aggressive and less mutilating treatment, and women who would otherwise have died of the disease will survive.

Of course, one would not wish to disagree with this general goal, that of improving health or saving lives. So the next question might be whether screening programmes can in the real world deliver such outcomes. There is in fact a set of well-recognised criteria or principles for thinking about whether a screening programme can improve health, that is, be effective. I shall make mention of the most important of these.

Firstly, there are criteria related to *the disease* itself. The disease must be an important public health issue. The disease must be a serious one, and it would make little sense to screen for a disease that was exceedingly rare. The natural history of the condition must be reasonably well understood, and there must be an early stage which is detectable before symptoms develop. There must be good reason for knowing about the existence of the disease in individuals, which in general means there should be a treatment or intervention which is capable of preventing the development of the condition or changing its course, in order to improve the outcome for those who suffer from it.

Secondly, *the test* chosen for screening must have certain characteristics. The test must be accurate and reliable. (In practice, defining how accurate and reliable a test need be in order to be a candidate for a screeening test is another question.) It is in the nature of human biology and the limitations of our technology that all medical tests are associated with a probability of "false negative" and "false positive" results. In the case of a false

positive result, an individual who does not have the disease shows positive on testing. Conversely, false-negative results occur where the disease which a person actually has is not picked up by the test; that is, the disease is missed by the test. Although no investigation is perfect, nonetheless it should be clear that a good screening test must be characterised by a limited number of false negative and false positive results. A screening test which fails to distinguish significant numbers of people with the disease (that is, the test has many false negatives) will not be effective, and a test which identifies with an abnormality unacceptable numbers of people who in fact don't have the disease (that is, the test has too many false positives) is very problematic. This point will be returned to later. As for the practicalities of the test: it must be acceptable to people with no symptoms, not too painful, or inconvenient, or embarrassing. Obviously a screening programme must have participants, who must not be discouraged from being tested.

Thirdly, there are several features of *the screening programme* itself. There must be means of informing and reaching the target population without discrimination against particular groups. There is a requirement for access to treatment for those diagnosed with a condition by screening, a particular problem in countries without universal health care. The programme must be able to be afforded by the society; in general it must be deemed to be "cost-effective" (however that be measured) and ought to be a just use of resources. How such concepts are translated into practical judgements is, of course, an extremely difficult matter.

Fourthly, there are several criteria which relate to the *screening intervention as a whole*. Overall, there must be good evidence that screening for the condition or risk factor actually does provide a benefit for the community. In addition, screening must not result in significant harm to individuals or the society, a point which often tends to be overlooked, and which will be discussed further.

It would be possible to summarise these criteria by saying that they offer a guide as to whether a screening programme may provide a benefit to a population. Some concrete examples may illustrate. Prostate cancer screening provides an example of a questionable screening intervention, given the current state of knowledge. Why so? There are several reasons. With respect to the disease itself, there is some uncertainty as to whether, and in which patients, early treatment actually alters the outcome. In addition, it is arguable whether the screening test, in this case a blood test (PSA), discriminates adequately between those who have cancer and those who do not. On the other hand, screening of babies for PKU is very effective; the disease, though rare, is serious, but early intervention by means of a diet clearly prevents the manifestations of neurological damage. The test is a simple blood test, which is accurate, and the programme is able to reach its target: newborn babies. Thus, screening for PKU fulfils virtually all of the criteria for an effective programme.

Having discussed in general terms the most important characteristics which allow a screening intervention to achieve its aim, I would like to ponder further some of the concepts raised. Clearly "benefit" and "effectiveness" are key notions in thinking about screening programmes. Yet surely we need to ask questions about *what* constitutes a benefit, and what *sorts* of benefits and what *magnitude* of benefit ethically justify screening. Another important concept is that of harm. Questions must be asked about the harms and risks of screening. Yet effectiveness is all too often put forward as implicit justification for a screening programme; it is assumed that benefits themselves justify screening. Costs, other than financial ones, if they actually are considered in the debate at all, tend to be minimised and traded against the benefit. It is my view that these harms demand attention and debate in their own right.

Benefit

It is fair to say, I think, that enthusiasm for the goals of screening tends to result in somewhat exaggerated claims about the benefits achieved. Of course, we would like to think that firm evidence, even "proof", of the benefits of particular screening interventions (in terms of specific outcomes

and the number of people benefiting) could be obtained. Unfortunately, such evidence is often very difficult to obtain. The best scientific evidence for benefit is that provided by randomised controlled trials, and evaluation of some screening programmes has been performed by such trials. Yet interpretation of even this evidence is fraught with difficulties.

Breast cancer screening provides an excellent example of such problems. Publicly funded mammographic screening programmes have been in place in much of the Western world for some years, and are enthusiastically promoted to the target age group, women aged 50-70 years. Institution of the programmes was based on the results of several large well-organised trials involving hundreds of thousands of women in several countries, followed up for upward of fifteen years. Overall, these studies were interpreted as showing a 30% decrease in breast cancer mortality in those screened in the 50-70 year age group. This figure, 30%, is widely accepted as the truth of the matter. When one considers the incidence of breast cancer in that age group, it comes as no surprise that screening was greeted so warmly. There is no doubt that breast cancer is a terrible disease, and it is obvious that we should be putting our best efforts into finding means of decreasing its burden. Yet subsequent screening trials have not duplicated the findings of the original trials, and there are increasing numbers of eminent people in the field expressing scepticism about the interpretation of the original studies. Some now suggest that the observed fall in the death rate may not have been due to screening at all, but could be explained by the introduction of adjuvant chemotherapy in treatment regimes. Others are questioning the magnitude of the observed benefit, and suggest that inadvertent methodological flaws in the studies compromise their validity. Thus, despite extensive study of breast screening, the benefit in terms of lives saved remains unclear. Furthermore, results of screening for younger women, those aged 40-50 years, are more questionable. Yet despite this, there are increasing demands for screening programmes to be extended to include younger women, even those under 40 years.

There is a good argument for saying that it is unethical to recommend mass screening in the absence of good evidence of benefit. Yet, even if a benefit is shown, it needs to be asked what magnitude of benefit is significant enough to consider screening for the disease. Let me quote the figures for breast cancer. In the target age group, 50-69 years, an optimistic estimate in terms of lives saved is 18 per 10,000 women screened for 10 years; in the younger age group, 40-49 years, it is considerably less, perhaps 7 per 10,000 screened for 10 years. Do these figures really provide an unambiguous argument for recommendation of screening?

Harms

Let us concede that there are significant benefits of a particular screening programme. (With respect to breast cancer screening, it would seem reasonable to conclude that the balance of evidence is in favour of there being a significant benefit in terms of mortality reduction in the 50-70 year age group.) But this cannot be the end of the matter. Benefits of screening are achieved at the cost of some harm. However, in the literature and in public discourse about screening, there is an obvious tendency to concentrate on the benefits for those whose lives are saved or improved, without scrutiny of the other side of the coin, the harms to the vast majority who do not benefit. If harms are acknowledged at all (and often they are not), there appears to be a common unstated assumption that the benefits of screening are such as to outweigh these harms. This, I think, is a serious omission. It is of course a fundamental ethical principle of health care that we attempt to minimise the risks and harms inevitably associated with medical interventions. Harms associated with public health measures, such as screening, are difficult problems with which to grapple. Here, unlike in individual doctor-patient interactions, large numbers of people are affected relative to the numbers that ultimately benefit. The individuals who suffer the harms are not the ones who derive the benefit, and there may be many harmed for each one benefited. In addition, there may be more intangible harms to the population at large. It is imperative that we give due consideration to these harms. In assessing

screening interventions, attention is owed to the overall effects on the population at large, not just on those relative few who derive a benefit.

What might these harms be? The problem here is not that of the test itself, but the consequences of those test results, particularly to those who test false-positive. Consider the problem for those who test false-positive, again using mammographic screening to illustrate. Women whose mammograms demonstrate an abnormality are recalled for further investigation. This is likely to involve further special mammographic views, ultrasound, various types of needle biopsy, and, for some, admission to hospital for open surgery in order to obtain a diagnosis: invasive investigations, not without some potential complications, for what in the end turns out to be a benign condition. In addition, there is a psychological burden accompanying this traumatic process of further investigation, the practicalities of which may take some weeks. These adverse psychosocial effects are increasingly being recognised, and persist in some women, even after they obtain an eventual "all-clear" result. It is true that attempts are made to minimise these burdens, but the harm is indeed real for women who in fact were well, without significant breast disease, before they attended screening. Some figures may help put this in perspective. In Australia, about 30 to 50 women of every thousand screened are recalled for further tests. Three to five of those recalled are diagnosed with cancer, the remainder are subjected to series of further investigations, of whom perhaps 1 or 2 will require an open biopsy. Thus for each person diagnosed with cancer, about 10 others undergo the consequences of testing false-positive.

What of those who actually are diagnosed with cancer, those with a true-positive test? There are problems here also. Firstly, there is a group who undergo what is in effect unnecessary treatment. This is the group for whom treatment is overtreatment. This is particularly an issue for breast cancer screening, but also for other screening interventions. There is an early form of cancer, ductal-carcinoma-in-situ, which now accounts for over 20% of screen-detected breast cancers. At this stage the cancer does not have the potential to spread, and so is curable by surgery and radiotherapy. However, what is only poorly understood is the natural history of this condition. Certainly it is known that some cases progress. But some do not, and unfortunately, we do not as yet know which do and which do not progress. (It is hoped that current research will elucidate these questions.) It follows that some women are undergoing treatment, which may involve mastectomy, for a condition which would never have caused a problem. Clearly this is a matter of concern.

Secondly, there is another important point regarding those diagnosed correctly with the disease. Only a proportion of these, perhaps as few as 1 in 10 women who are diagnosed with breast cancer by screening, actually benefit *as a result of* having had the screening test. The remainder would have had the same outcome if diagnosis had been delayed until a lump or other symptoms occurred. It could be said of these people that the only effect of having been screened is that they had to live with the diagnosis of cancer for a longer time.

Population screening may have further, less obvious, but broader negative effects, and many have been suggested. In those screening positive for treatable conditions such as high blood pressure, there is increasing evidence of other psychological morbidity including decreased perceived health status and absence from work. Even the large group of those with a true-negative result are not immune to effects of screening. There may be an inadvertent effect on the health related behaviour of this group, the so-called "certificate of health" effect. Being told that the test shows no disease or risk factor may result in a person's indulging in increased risk-taking behaviour, related to a kind of subconscious belief that the disease is not going to occur. Such effects have been seen in, for example, men with high cholesterol. With respect to breast cancer, the fact of a recent negative mammogram may cause a woman to consider it not necessary to present for investigation of subsequent breast symptoms. There are other behavioural effects worthy of mention. For example, an unpleasant experience of a screening test, particularly being recalled for further tests,

may cause a person to discontinue screening in the future, or to avoid investigation of symptoms.

In addition to these potential adverse effects for those whose test result correctly reflects the presence or absence of the condition, there are clearly implications for those whose disease is missed by the test. Breast cancer screening misses 10% of cancers in the target age group; mammography will detect only 75% of cancers in women aged 45 years. (This relates to the "density" of normal breast tissue in younger women, which makes cancers less able to be distinguished on Xray.) Those with a cancer not detected by screening suffer psychological effects, which may bear on future treatment. There may be the further harm of delay in diagnosis, because subsequent symptoms may be ignored in the belief a normal test has excluded the possibility of disease. In addition, there are the legal implications of a missed diagnosis.

Finally, one might wonder whether the effects of screening may extend beyond those directly affected. The thinking and perceptions of the general public are subtly shifted by screening programmes, the associated publicity, and so on. For good, there may be raising of public awareness, and spin-offs such as improvements in diagnosis and treatment of symptomatic disease as a result of expertise gained through screening programmes. (This has been very apparent in the case of breast cancer.) On the other hand, disproportionate anxiety may be engendered, or false hopes and expectations of cure raised. In general, public health programmes will have an impact on the community's perception of health and disease. These sorts of effects are by no means specific to screening; we see them too with new medical technologies. I do not pose these observations as arguments for or against screening, but simply to point out that these broader considerations should be recognised in public debate.

What does acknowledgement of this litany of harms mean? Are they just unfortunate side-effects, to be minimised of course, but accepted as the price paid in order to obtain the benefits? Or should they present a challenge to the widespread assumption that screening is a good thing for society to engage in, because of the benefits to some? Many would argue, on utilitarian grounds, that the harms and risks are justified if they are outweighed by the benefits. This may well be the case where the benefits are significant and the harms trivial. However, even if one accepts such a consequentialist justification, balancing benefits and harms is not a simple matter. How does one measure anxiety and intangible social costs? It is easy to ignore what is not measurable. What sort of adverse effects, to how many, outweigh benefits, even life saved, to a few? More fundamentally, how do we conceptualise the relationship between the individual and the common good? Are there, indeed, some harms to individuals and communities that are not justified, regardless of the benefit? I raise these genuine questions as deserving of being asked about public health interventions in general, including screening programmes.

Public Perception

There is another ethical issue I wish to touch upon. This is the matter of the information provided to the public about screening programmes. Are the target population being adequately informed of the harms as well as the benefits? How much information should be given? How aggressive should promotion of a screening programme be? Clearly in order to market a screening programme to the community, the positive aspects need to be emphasised, but one might wonder whether the population are being informed in a balanced fashion about screening. In the process of increasing participation of the population in screening, in trying to reach the targets and to keep the message simple, has there perhaps crept in a kind of deception? For example, it could be said to be a stretching of the truth to suggest that screening can pick up cancers the size of a grain of rice, and that the chance of dying from breast cancer may be decreased by 50% by screening. Yet both these statements are used in marketing of breast screening in Australia. Little information is given about the possibility of

missed cancers; often the information is only that mammograms are not 100% accurate. It is known that women overestimate the accuracy of mammograms. (This lack of understanding of the limitations of tests and treatment is a pervasive problem in medicine generally.) Limited or no information is given about the implication of false positive tests. We would not think that such a degree of misunderstanding and limitation of the information provided is acceptable in ordinary medical practice. Should public health medicine be any different? It has been said that screening for various conditions has been portrayed as simple, effective and inexpensive. This representation is at best a distortion of the truth. Education of the public about health care is, to be sure, extremely difficult, but surely we should be delivering a more balanced message, and attempting to correct rather than reinforce the misconceptions which are known to exist in the community.

Cost

Finally, mention must be made of an issue of major ethical import, and that is the matter of financial cost. Even if particular programmes have worthwhile benefit and acceptable risks, it does not necessarily follow that screening programmes deserve public money over other legitimate healthcare needs. Is screening an appropriate allocation of public resources? Is it justified to spend $80 million per year in Australia on breast screening, which optimistically may expect to save 18 lives per 10,000 screened in 10 years, or perhaps 200 per year, when there are other pressing demands such as care for the aged or disabled or dying? Perhaps it is. Should we offer screening to all women aged 40-49 years, of whom 2500 would need to be screened for 13 years to save one life, rather than spend the money on, say, prevention of smoking or drug abuse, and perhaps limiting screening to those at higher risk? Perhaps that is what the community judge as worthwhile. How and by whom should these decisions be made? The point is that these questions must be asked more often, and reflected upon more carefully than is the case at present. When decisions are made about use of public funds for new public health interventions and many kinds of new medical treatments, we cannot assume that the answer to these questions is already known.

Conclusion

In conclusion, then, my aim has not been to suggest that we should not be engaging in screening programmes, or that we should disband some of those in existence. However, I do wish to challenge the seductive assumption, so often heard, that certain screening programmes are such a good that our society is wrong to do without them. I want to argue against the idea that the only thing that matters in screening is the benefit. I propose that introduction of screening programmes, or proposals to expand those in existence, should be considered very carefully, with due attention to the risks and harms and costs to individuals and to the community. Evidence of benefit alone is not a sufficient justification for screening. To be able ethically to recommend a screening intervention demands looking beyond the notion of benefit, with a deeper and broader perspective.

Notes

1. For a more detailed and critical discussion of screening, see H.M. Malm "Medical screening and the value of early detection: When unwarranted faith leads to unethical recommendations", *Hastings Center Report* (1999) 29(1): 26-37.

2. For an example of a recent critique of the interpretation and statistical analysis of the original breast screening trials, see P. C. Gotzsche, O. Olsen "Is screening for breast cancer with mammography justifiable?", *Lancet* (2000) 355: 129-134.

3. Australian figures have been obtained from publications of the National Breast Cancer Centre, and from conference presentations.

Principles for assessing the ethics of "Managed Care" arrangements

Helen McCabe

In thinking about a system of organising and financing health care services, the need to locate a starting point from which to deliberate the ethical issues is desirable. In order to locate such a starting point, we need to discern the meanings and values which inform a system of health care, and to answer the prior questions concerning the roles, purposes and goals of such a system. Against such an understanding we can formulate the necessary principles to test the ethical status of features, processes and outcomes of any system of health care administration. Advancing such meanings, values and principles will form the first part of this paper.

The second part of this discussion will proceed to draw on the proposed understanding of health and health care so as to derive a framework of basic principles for guiding decision-making and activity within Australia's health care system. In the third part, I will examine some particular features of Managed Care in order better to understand them, and to see how well they cohere, ethically, with the proposed principles.

Meanings and Values of Health

An understanding of health as a basic human good offers a substantial foundation upon which to reason about the role of a health care system. This way of thinking about health derives from natural law theory, in which health is valued as a basic good, its value being self-evident: health is valued in itself, for its own sake[1]. The claim that health is a basic human good is supported by the reasons for which we seek it: we pursue health, most simply, for the vitality and the integrity of mind and body which its presence reveals. This understanding of health differs from one in which health is viewed as an instrumental good: while it is, indeed, valued for the desirable consequences its presence brings, an understanding of its intrinsic worth reveals a *kind* of value which is far deeper. And it is this deeper, richer understanding which underlies the special nature of health, as it does all other basic goods.

As a basic good, health forms a practical principle or basis upon which to explain actions, commitments, and projects participated in for its promotion. Together with other basic goods, such as knowledge, friendship and aesthetic experience, health contributes to human flourishing and self-determination[2]. In this sense, health is rightfully constitutive of the human person: to lack health is to be harmed in some way. While not being the only good to be concerned with in the living of our individual and communal lives, health is important enough to inspire social organisation, frequently on a grand scale, around its preservation and promotion, including the institutionalisation of a system of health care.

Meanings and Values of Health Care

Health *care* has been described as a 'polyvalent good'[3]. Firstly, it is a public good in that it is designed to improve the health status of whole populations. In this sense, health care is a shared or common good,

providing opportunities for all to flourish as individuals and as a community: the whole community is affected by the loss of health

and well-being of any of its members[4]. In Australia, equity of access to the shared good of health care has been formally recognised as a right for all citizens through the adoption of Medicare which has ensured, to a considerable degree, access to health care for the whole population. It is important to remember that immediately prior to Medicare's introduction in 1984, 35% of Australians had no health insurance at all[5]. The uninsured were largely from the ranks of the low income earners, a situation which obtains in the United States today, where 40 million people are uninsured, and even more are dangerously under-insured.[6] And so, if we are to uphold the common good of health care, justice requires that it must be accessible to everyone, regardless of an individual's ability to pay. At this point it is worth noting that a focus on equity in access to health care is limited to a notion of fair distribution of benefits and burdens among individuals, and, in this sense, represents a limited and narrow conception of justice.[7]

Research into the causes and treatment of illness, and into the care of the chronically ill and the dying, is an important feature of health care at the population level, as is the education and training of health care professionals. These aspects of health care are necessarily provided through the pooled means of a society's resources. It is a good and just society, then, which provides for the health needs of its members. When a society does so, it stands in solidarity with those who suffer illness and injury, and those who fear its menace. Justice, in this sense, is demonstrated in good relations between people: it becomes an expression of friendship and an acknowledgment of the interdependent reality of our communal life[8].

Secondly, health care is an individual good in that it is designed to improve the health status of individuals through its rescue, curative and palliative measures. It is at this particular point of concern that the effects of health care are most obviously discerned, and at which the moral test of the whole system of health care can be assessed[9]. It is also at this level that conditions for the expression of relational values, such as compassion, concern, and care are created and sustained, these relational values being necessary for the sustenance of individuals through illness, whether they recover or not[10]. And, again, justice becomes important at the level of individual health care, where impartiality in health care provision is required: discrimination between individuals in need of care is morally out of order here, as it is at all other levels of the system. That is, respect and concern for the dignity of individuals is paramount within the individual context. To date, this particular context has been ethically informed by the tenets of various professional moral codes such as those derived from the Hippocratic tradition and from the philosophy of Hume.

Thirdly, health care is a reciprocal good: the health of individuals depends on a good and well-functioning society and vice-versa[11]. The provision and appreciation of other basic goods depend on there being high levels of population health: likewise, people need such basic goods as education, aesthetic experience, and sociability in order to maintain and nurture their health.[12] At some point, a balance must be struck between providing the means to health care and providing the means of other necessary basic goods.

In a similar vein, health care can serve as a "good of restoration" in the sense that health care is provided in greater abundance to those who suffer a greater degree of ill health. Notably, those same people frequently experience greater socioeconomic disadvantage. Brocks reports on the studies of this phenomena, concluding that health differentials within societies are marked by *relative* differences in income levels between social groups, differences in class, and in education.[13] In his important article, Brocks also demonstrates that the effects of lifestyle factors, such as high fat diets, smoking, substance abuse, and lack of exercise, account for only 25% of the differences in the incidence of illness between socioeconomic groups. In this sense, justice would require that the factors contributing to this situation be understood more clearly and addressed. Justice would also require that, in the meantime, a preferential option for the poor be upheld in the provision of health care services.

Having reviewed, albeit briefly, the values and meanings of health, and the goods of health care, I will attempt to derive some principles from these understandings in order to offer an ethical context in which to evaluate our system of health care organisation and provision.

Some Ethical Principles for Australia's Health Care System

- **Principle 1:** Care for the vitality of the human person and for the integrity of mind and body of all individuals is the proper goal of health care. The activities of the health care system, including organisation, research efforts, curative approaches, and rehabilitative and palliative measures, ought to be directed towards the realisation of this goal.

- **Principle 2:** The distribution of health care resources should be determined by health care need. Equity in access to the good of health care must be maintained in accordance with a needs-based criteria.

- **Principle 3:** The role of health care administrators is one of service to the common good. Careful stewardship of resources held in common ought to be of primary concern at this level.

- **Principle 4:** Actions related to the rescue, cure and care of those who suffer illness, disability and injury are more soundly guided by the principles and virtues of health care professional norms. The contexts of professional health care provision ought to be guided and sustained by these same influences.

- **Principle 5:** In the provision of health care, both patients and health care professionals ought properly to be united in the common endeavour of improving health and well-being. Relationships of earned trust ought to be promoted for this purpose.

- **Principle 6:** There are limits to what can be achieved through health care, as well as limits to what can be afforded in the way of more expensive approaches to medical treatment. Acceptance of these limitations necessarily requires a temperate approach to resource utilisation, while maintaining the caring and supportive approaches of health care for patients and their carers.

- **Principle 7:** While health care is a highly valued good, other basic goods contribute to the flourishing of individuals and communities. Resources allocated to health care are to be constrained by this fact.

Having formulated this basic ethical structure in which to consider the obligations of the health care system, it is now possible to test the features of the system of Managed Care for ethical soundness and coherence. Presently, elements of this system are being adapted to the administrative structures of Australian health services as a means of containing the high cost of health care. This strategy calls for careful consideration.

Managed Care in Australia

Managed Care is malleable to the broader societal and particular institutional contexts in which it is situated. In the United States, the birthplace of Managed Care, this system is entrenched within the market, where health has become a commodity and health care a commercial transaction. Accordingly, this context imbues the concept of Managed Care with particular meanings and values, and gives rise to foreseeable consequences. So, I will begin this examination of the ethical acceptability of Managed Care by considering the contemporary commercialist context in which it resides.

The Commodification of Health and the Commercialisation of Health Service Provision

In making the distinction between the American and Australian systems of Managed Care, closer inspection reveals merging similarities between the two nations: Australia has been incorporating market strategies into our health care system for some time. Now this may be well and good, given the need for careful stewardship of our limited resources: accounting procedures and processes are a necessary means of controlling costs and conserving resources. What is at issue here, however, are two concerns: the first

is that of determining the proper limits or scope of the market in health care, and the second concern is that of the use of market-oriented language which normally accompanies such strategies. If we think about our language, we will notice a new development whereby people accessing health services are now called 'customers', health care professionals are 'providers' and health care is a 'product'. These developments must give us pause.

A notion of health as an intrinsic good must undergo a metamorphosis, it would seem, if it is to be imbued with the language of the market metaphor. In order to see the health care system as a market, for example, we would have to give up the deeper and richer conceptions of health care from the above analysis. For within the market metaphor, health care, like all other commodities, becomes morally neutral. The consumer goods traded in the market are goods of utility, or goods of mere use value; they are "fungible, exclusive, want-regarding, and egoistic"[14]. Goods traded on the market are necessarily rival, whereas the value of shared goods is realised in the shared enjoyment of, and participation in, that good[15]. In fact, the necessary concepts for realising the value of health and its care are absent from the market: within a market metaphor, no distinction can be drawn between needs and preferences, or between reasons and mere tastes[16]. While needs make moral claims upon us, preferences do not. In this sense, situating health care within a market metaphor involves both demeaning the values and meanings of health care, and hiding the obligations which claim us.

The language of markets is limited and shallow: it lacks the language necessary to make sense of words like suffering, caring, compassion, vulnerability, or stewardship. However, its use does form our perceptions and understandings of reality and of what is required of us in action and intention. The market metaphor upholds a highly individualistic conception of the human person, thereby negating the need for sociability, and ignoring the fact of interdependency. It encourages us to see patients as 'savvy consumers', for example, purchasing health care as they would televisions or lipstick. At the same time, it encourages us to see medical knowledge and skill as private property, available at market prices: the notion of professionalism is subordinated, and even jeopardised, within a system concerned with the priorities and concerns of commercialism[17]. And it blithely hides from view the experiences of suffering and of frailty, as well as the value of caring: they are an enigma in the culture of markets. The language of professional health care cannot be adequately translated by the speakers of market language; without speaking the necessary words, however, we may forget that caring is worth valuing in the first place[18].

Advocates of the market approach claim it is a superior means for improving efficiency in providing health care services, notably, the value of efficiency is a tenet of Medicare. While efficiency is a laudable goal, a requirement of stewardship no less, one must reconsider the meaning of this word when it is uttered by the speakers of market language, and ask 'efficient for whom'? If we consider the goals of market transactions, we are struck by the notion of profit as the all-determining reason for action. Efficiency within markets, then, is promoted for the sake of enhancing profit. Now, while even non-profit organisations must procure at least some degree of surplus in order to remain viable, we must, at the same time, ask 'profitable for whom'? When health care is provided within the market, the goal of health care provision becomes profit, rather than health, and those who profit from market transactions include shareholders, insurers, doctors, and suppliers of technology and equipment. For these earners of profit, then, 'efficiency' means being able to provide extra services so as to derive additional profit. And within the individualist culture of the market, the word 'efficiency' becomes entangled with personal profit. This situation becomes clearer when we consider the machinations of our private system of health care.

The fee-for-service model contains incentives which act to encourage over-servicing: the more treatments and procedures offered a patient, the more the treating practitioner or clinic is likely to profit. In fact, the fee-for-service model is Managed Care's 'reason for

being' in the United States: when medicine was practised purely within the fee-for-service model, the costs of health care grew unchecked until purchasing agents installed measures to contain the system. Within the fee-for-service model, the notion of what I will call 'efficiency-for-profit' is not efficiency in meeting overall health care need. 'Efficiency-for-profit' does not concern itself with the requirements of stewardship: ultimately, market notions of efficiency act to increase the overall cost of health service provision[19]. These problems would be even more contentious within the newly-emerging corporate arrangements for general practice, as well as the established corporate pathology and radiology practices[20].

Finally, to situate Manage Care within the commercialist context is to run the risk of violating all seven ethical principles for Australia's health care system. Firstly, profit-seeking threatens to bypass the goal of health in health care activity. Secondly, distribution of health care resources becomes determined by supplier preferences or consumer demand, or in response to want-satisfaction as opposed to health care need. Thirdly, the requirement of stewardship of health care resources, including the tradition of medical knowledge and skill, is violated in a market context. Fourthly, respect for the dignity of patients and professionals is limited, if not unintelligible, within this context. Fifthly, the necessary level of trust within professional-patient relationships is endangered. The last two principles are violated by the incapacity of the market either to uphold the notion of solidarity or to recognise the overall needs of communal life and flourishing.

These, and other problems, are related specifically to the market metaphor which accompanies managed care in its contemporary form. However they are not necessarily related to features of Managed Care in themselves, as the original expression of this system teaches us.[21] The problems I have just raised represent some of the difficulties which arise out of a conception of health care in a commercialist setting. They may, however, be avoidable in different circumstances.

I will now leave this concern to address a second potential objection raised by Managed Care, its influence on the professional-patient relationship.

The Professional-Patient Relationship

The system of Managed Care operates to bring the focus of cost considerations to the forefront of health care concerns by incorporating financial strategies into the clinical encounter. Three objections have been raised in response to this move, and will be considered here.

- There is a perception of interference with clinical decision-making arising, firstly, from the introduction of clinical guidelines, and secondly, from the power of Managed Care Organisations (MCOs) to deny funding for particular treatment options, particularly those deemed experimental. Now, the problem of clinical guidelines, which has raised considerable concern in the United States, may not be insurmountable. Firstly, the use of such guidelines may prove beneficial in some aspects of treatment and care provision, providing that sufficient flexibility is factored into their implementation. Medical and nursing practice ought to comply with best practice standards: it would seem difficult to justify aberrations from the highest standards for the sake of clinical independence. As well, the use of guidelines can serve as educational tools, particularly in remote areas where access to specialist services in unavailable. (This benefit would be negated, however, should clinical guidelines become proprietary, as has sometimes happened in the United States). However, sufficient room to improve these standards, whether clinically or financially, ought not be stifled in the process of standardisation. Nor should they be employed to any concerted degree in more complex and less determinate areas of clinical practice, such as psychiatry and palliative care: clinical guidelines must permit appropriate responses to those patients with atypical presentations and more complex care needs.

The second problem - of coverage refusal, (beneficial services being denied by funding bodies) - is more problematic. Though forgoing futile or overly - burdensome makes both good clinical and good economic sense,

coverage refusal goes further than that. It involves treatments which *may* offer some, unpredictable degree of benefit to a particular patient. Determining the degree of benefit for individual patients in offering, for example, a CAT scan as opposed to an x-ray, is sometimes difficult to predict, and can only be determined with hindsight, and after the money is spent. Or deciding to hospitalise a patient for observation when clinical signs are inconclusive may ultimately benefit the patient, or it may prove a waste of the patient's time and the community's resources. These clinical decisions are often difficult to make, and will presently be ruled on the basis of degrees of risk in doing one thing or another[22]. In Managed Care arrangements, however, these decisions may also be made by funding bodies through limitations on coverage. Whenever this is the case, the issues of accountability and professional autonomy emerge.

In relation to the first issue of accountability, it would seem only just that, whenever treatment is withheld by funding bodies, legal protection for clinicians ought to be assured. Alternatively, Managed Care entities, in their capacity to direct actual content and quality of care, must be held liable for any harm consequently encountered[23]. The second issue of professional autonomy is related to the problem of resource limitation: given that resources are, indeed, finite, it may be morally acceptable to withhold funding in certain circumstances, after careful consideration of medical opinion. The degree to which health care funds may be withheld will depend, ultimately, on the availability of the community's resources for health care, the limits of which may quite legitimately demarcate the limits of professional autonomy in health care provision. That is to say, decisions regarding spending priorities may have to be decided by particular communities at various times.

In Managed Care the loyalties of health care professionals are thought to be divided, given both the changing role of health care professionals and the terms of employment conditions to which professionals become subject in this system. This two-pronged problem receives considerable attention in the literature, but it may hold different meanings for Australians. Firstly, Managed Care highlights the role of doctors in making resource allocation decisions, a role which requires choosing between the well-being of the individual patient that of a larger group of patients, and even that of a society as a whole[24]. However, our own Medicare system is based on the notion that health care is a shared good, and a certain level of rationing is tolerated for the sake of the common good. The need for rationing in a finite world is not at issue so much as is the question who, indeed, makes those decisions and with what form of legitimacy. To date, the role of doctors in making allocation decisions has been limited, being more a matter of complying with limits set by the system of Medicare funding. In this sense, and given the limited availability of resources, doctors are ethically obliged to comply with those limits. However, the role of administrators in rationing decisions is, at present, somewhat problematic, given the lack of explicitness in the process. It would seem morally necessary that a broader debate be pursued, along the lines of international experience[25], and that a better informed public be included in the process. This requirement will necessarily call for a more reasoned response from the national media.

The second prong of the problem concerns the conflict of interest which arises when the interests of professionals are pitted against those of their patients. This dilemma occurs in relation to particular financial incentives which have been built into Managed Care systems in the United States, whereby professional salaries are affected by the costs or savings incurred in actual practice. That is, treatment decisions are required to take costs into account, and spending must remain within the limits of capitated funds: when treatment costs exceed those limits, doctors' salaries may be penalised, or MCOs may terminate their employment contracts. Conversely, when savings are made, and there is a surplus at the end of the financial term, doctors themselves stand to gain financially[26]. This problem is related to perverse incentives within the commercialist system of Managed Care, and can only threaten the level of patient trust upon which the clinical encounter is made possible[27].

The Problem of Informed Consent

The ubiquitous problem of informed consent raises additional concerns within the Managed Care model. Instances of withholding information from patients, with regard to a full range of treatment options, have been reported at length in the bioethical literature to date. The so-called 'gag clauses' have raised great concern abroad where MCOs have been accused of instructing contracted medical practitioners to withhold more expensive forms of treatment and diagnostic services. However, a U.S. General Accounting Office inquiry conducted in 1997 was unable to find any actual gag clauses in the 1150 contracts from 529 MCOs that it examined. Nevertheless, the inquiry did report the existence of clauses pertaining to anti-disparagement agreements which limit open discussion between doctor and patient[28]. Importantly, these agreements are accepted norms in business practice, representing yet another example of difficulties of the commercialist mindset in health care services.

Another matter concerning informed consent has to do with the use of patient information for the purposes of utilisation review. This process of accounting involves access to essentially private information for an array of purposes unrelated to patient care and, importantly, without patients having consented to the fact[29]. This is a matter which needs to be guarded against in our own system of health care, particularly with regard to the introduction of such mechanisms as case-mix funding in the public sector.

While other problems emerge within the professional-patient relationship, and in relation to the notion of informed consent, these matters I have just raised form representative elements upon which to gauge the moral tenor of a system of Managed Care. From the above discussion, then, we can now test the professional-patient relationship in Managed Care against the principles of the health care system. Firstly, only those arrangements whereby health remains the goal of health care activity are ethically salient: profit-seeking for its own sake would be unacceptable in Australia, therefore, casting a cloud on loosely regulated corporate arrangements for general practice, pathology and radiology services, as well as "for-profit" hospitals and nursing homes. Secondly, these arrangements *are* able to meet the requirement that resources be allocated to those in health care need, and, in avoiding commercialist arrangements, are capable of enabling responsible stewardship of resources. The fourth and fifth principles could be upheld providing that honesty within the therapeutic relationship is maintained, and that troubling financial incentives within the system be removed. With regard to the sixth principle, ensuring a preferential option for the sickest members of society can be achieved provided that resource allocation is based on health care need. And finally, the constraints on health care spending imposed by Managed Care could liberate funds for use in other valued aspects of communal life.

In Conclusion

Managed Care is a morally-neutral concept in itself. However, the contexts in which it is conceived imbue this system of health care administration with orientations and mechanisms which stand either to uphold or to demean the richer, deeper understanding of health and health care which I have advanced. Adapting the system of Managed Care to the Australian health care system, then, calls for a principled approach to the choices we make in directing its implementation.

REFERENCES

1 Finnis, J. 1980 *Natural Law and Natural Rights* Oxford University Press, Oxford.

2 Finnis, J. op.cit.

3 Kaveny, M.C. "Commodifying the Polyvalent Good of Health Care", *The Journal of Medicine and Philosophy* 1999, 24 (3), pp. 207-223.

4 Fisher, A. (OP) 1994 "The Principles of Distributive Justice considered with reference to the Allocation of Healthcare" Unpublished doctoral thesis p.132.

5 Leeder, S. 1999 *Healthy Medicine,* Allen & Unwin, Sydney p.27.

6 By 1995, 59.7% of American children lacked any form of health insurance at al. Levey, S. & Anderson, L. "Painful Medicine: Managed Care and the Fate of America's Major Teaching Hospitals", *Journal of Healthcare Management* 1999 44 (4), pp. 231-249.

7 See, for example, Sherwin, S. in Sumner, L.W. & Boyle, J. [eds.] 1996 *Philosophical Perspectives on Bioethics,* University of Toronto Press, Toronto, London.

8 Fisher, A. op. cit. p.133.

9 Pellegrino, E. "Managed Care at the Bedside: How Do We Look in the Moral Mirror?", *Kennedy Institute of Ethics Journal* 7 (4), pp. 321-330,

10 Kaveny, M. C. op. cit.

11 Pellegrino, E. "The Commodification of Medical and Health Care: The Moral Consequences of a Paradigm Shift from a Professional to a Market Ethic", *The Journal of Medicine and Philosophy,* 1994, 24 (3), pp. 207-223.

12 See Finnis' list of basic goods in Finnis, J. op. cit. Chapters 3 & 4.

13 Brocks, D. "Broadening the Bioethics Agenda", *Kennedy Institute of Ethics Journal,* 10 (1) 2000 pp. 21-38.

14 Anderson, E. 1993 *Value in Ethics and Economics* Harvard University Press, Cambridge, London, pp. 144-145.

15 Anderson, E. ibid.

16 Anderson, E. op. cit. p. 146.

17 Churchill, L. "Similarly-Situated Patients with Different Benefits Packages", in Priester, R. et al [eds.] 1999 *Ethical Challenges in Managed Care* Georgetown University Press, Washington D.C. pp.233-248.

18 Kaveny, M. C. op. cit.

19 See, for example, a study revealing increased rates of procedures performed in private hospitals compared with those performed in the public system in Robertson, I. & Richardson, J. "Coronary angiography and coronary artery revascularisation rates in public and private hospital patients after acute myocardial infarction", *Medical Journal of Australia,* 173, 18 September, 2000. Also, see a study of comparative costs between the private and public sector, indicating expenses of twice the rate in private hospitals as compared with public, in Harper, R. et al "Costs, charges and revenues of elective coronary angioplasty and stenting: the public versus the private system", *Medical Journal of Australia,* 173, 18 September, 2000.

20 Gray, B. discusses the problem of increased administrative costs in for-profit entities in the United States, noting especially the salaries of administrators. He reports the earnings of the CEO of Oxford Health Plan to have been $112 million in 1996 in *"CEO salaries in for-profit and non-profit health plans"* in Priester, R. et al [eds.] op. cit. pp.168-180.

21 McCabe H, "The ethical implications of Managed Care: a matter of context in *Bioethics Outlook*, 11, No.3 pp.1-6

22 Morreim, E. H. "Medicine Meets Resource Limits: Restructuring the Legal Standards of Care", *University of Pittsburgh Law Review,* 59 (1), pp. 1-95.

23 Noone Parsons, G. & Ubel, P. *"Advocating for Patients in Managed Care"* in Priester, R. et al [eds.] op. cit. pp.217-232.

24 Pellegrino, E. "Ethics", *Journal of American Medical Association* 7 (4), 1997, pp.1668-1669.

25 See, for example, Coulter, A. & Ham, C. [eds.] 2000 *The Global Challenge of Health Care Rationing* Open University Press, Buckinham, Philadelphia.

26 Sawyer, R. "General Surgeons in the World of Gatekeepers", *American Journal of Surgery* Vol. 170, December, 1995, pp. 528-531.

27 Churchill, L. "Damaged Humanity: the call for a Patient-Centred Ethic in the Managed Care Era" in Thomasma, D. [ed.] *The Influence of Edmund D. Pellegrino's Philosophy of Medicine,* Kluwer Academic Publishers, Dordrecht, London.

28 Stoltzfus Jost, T. "Regulation of Managed Care in the United States" A paper presented at the 1999 Health law Seminar Series, University of Sydney, Sydney.

29 Gostin, L. "Personal Privacy in the Health Care System: Employer-Sponsored Insurance, Managed Care, and the Integrated Delivery Systems", *Kennedy Institute of Ethics Journal* 7 (4), pp. 361-375.

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