Evidence-based medical practice: ethical considerations

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The practice of medicine according to ethical principles requires that decisions regarding treatment, preventive or interventional strategies, or quality of life of patients in relation to life-support treatment should be based on evidence as far as possible. Available evidence for Hong Kong is reviewed under the following categories: use of drugs, management strategies, service provision, and interventions to prevent disease and/or disability. These examples highlight the need for studies to obtain evidence in the local population, as findings from studies in other countries may not be applicable. Although evidence exists in many areas to guide practice, the biggest challenge is how to implement such practice to ensure equitable access to prevention and treatment, particularly in the presence of health care resource limitations.

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Introduction

Ethical principles in the practice of medicine require that we consider the following: autonomy, beneficence, non-maleficence, equity, life-supporting treatment, and assisted death.[1] Doctors should inform patients so that they can make an independent choice within the bounds of the law and ethical considerations (if they are competent to make decisions). The principle of beneficence requires that we should prevent and reduce suffering, maintain or improve the quality of life (from the patient's point of view); one should also 'avoid doing harm'. The principle of equity requires that all are given the same consideration and chance to benefit. In reality, advocacy is often needed to achieve this for certain groups as a result of prejudice or because of limited resources. It follows that with limited resources, the most cost-effective treatment should be used. Decisions regarding life-support treatment usually requires some judgement about quality of life issues by doctors, together with discussion with relatives.

To enable these decisions to be made, it is better to have evidence that a certain action will lead to a desired result, rather than rely on an assumption. To enable patients to make decisions about treatment options, they should be informed of the available evidence (or lack of it) regarding the efficacy of available options. To prevent or reduce suffering, evidence regarding preventive or interventional strategies that would result in the reduction of disease or disability is needed. Likewise, evidence is needed to define what constitutes a good quality of life from the patient's point of view. For service provision to be equitable, given resource limitations, it is particularly important to have evidence that treatments, whether therapeutic or non-therapeutic, are in fact effective, and to choose those with the lowest cost. Regarding decisions on life-support or resuscitation, it is important to have evidence that the judgement made by doctors on a patient's quality of life is correct—the opinion should correlate closely with that of patients. Studies are needed to obtain evidence in these areas to enable doctors to follow ethical principles in their practice. In carrying out research to address these questions, clinical research ethical committee approval based on the considerations listed in the Box should be obtained.[2]

In the following paper, the available evidence is discussed using examples for Hong Kong. Examples

Ethical considerations in clinical research

Is the question asked worth asking?
Is the study designed to answer it?
Is the study humane?
Informed consent — explanation of risk, benefit, use of placebo, freedom to withdraw, future care not compromised
Cost of research — if routine health services resources are used, prior agreement with service providers should be obtained

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of the lack of evidence are also described, followed by an examination of whether the provision of evidence is followed by evidence-based practice.

Available evidence

This will be discussed in four categories: use of drugs, management strategies, service provision, and interventions that may prevent disease and/or disability.

Use of drugs

Currently, the dosage of many drugs is determined following trials in non-Chinese populations. It is possible that potential pharmacokinetic and pharmacodynamic differences exist between Chinese and Caucasian populations, since there are differences in body weight, diet, lifestyle, and genetic factors. Ideally, evidence is required before the dosage recommendations can be extrapolated to Chinese populations. Studies so far have shown that the local Chinese population has a lower dosage requirement for warfarin[3] and propranolol.[4] Other inter-ethnic variations in drug response have been extensively reviewed.[5] Two studies of Chinese diabetic hypertensive subjects suggest that the efficacy of angiotensin converting enzyme (ACE) inhibitors in lowering blood pressure is reduced.[6,7] In a double-blind, randomised study of the antihypertensive efficacy of perindopril and ketanserin in 44 elderly non–insulin-dependent diabetes mellitus (NIDDM) patients aged 60 years and older, neither drug produced a significant blood pressure–lowering effect.[6] In a study comparing enalapril and nifedipine in diabetic hypertensive patients younger than 60 years, enalapril monotherapy controlled blood pressure in only 20% of patients, despite adequate dosages being given.[7]

This observation may not be related to ethnicity, since low-dose captopril has been shown to be effective in Chinese elderly hypertensive patients.[8] The likely explanation is that hypertension in NIDDM is characterised by sodium retention due to hyperinsulinaemia, increased sympathetic nervous system activity, and reduced natriuretic capacity. As a result, plasma renin activity is often suppressed and the antihypertensive effect of ACE inhibition may be attenuated in these patients.[9] On the other hand, a trial examining the lipid-lowering effect of fluvastatin in Chinese patients has shown that maximal reduction is obtained at a daily dosage of 20 mg and that 40 mg may not be necessary.[10] The side effects of drugs may differ in different populations. Consequently, the Chinese population has a higher incidence of cough associated with the use of ACE inhibitors than do Caucasians.[11]

The efficacy of drug treatment of two common conditions in Hong Kong has been demonstrated by two randomised trials: eradication of *Helicobacter pylori* using triple therapy has been shown to prevent ulcer recurrence and non-steroidal anti-inflammatory drug (NSAID)–induced peptic ulceration,[12,13] while treatment of acute ischaemic stroke using low molecular weight heparin has been proven to reduce patient dependency and mortality 6 months after the event.[14]

Some examples of drug use for which there is no evidence of efficacy, include the use of antacids to prevent NSAID-induced gastrointestinal bleeding and vitamin B_{12} to treat limb numbness.

Management strategies

The importance of adequate nutrition to maintain immunocompetence has been documented[15] and nutritional supplementation can be used to aid recovery from acute illness. Evidence is available from a randomised trial that this may be beneficial in elderly patients who have a chest infection after their discharge from hospital. Eighty-one subjects aged 65 years and older who were admitted to an acute medical ward were randomised to received 500 mL of the supplement Ensure (Abbott Laboratories; Columbus, Ohio, USA) for 1 month or no supplement on discharge, and followed up for a 3-month period. The group receiving supplement showed improvement in more anthropometric measurements, riboflavin and pyridoxine status, had a higher level of functional ability, and some measures of well-being compared with the group who were not given supplement.[16]

Decisions regarding resuscitation or life-support treatment are based on doctors' assumptions about patients' quality of life, in the absence of a living will. A local study examining the perceived severity and disadvantage of selected real life handicap scenarios in subjects with a wide age range, education, and socio-economic background showed that doctors and medical students rated scenarios as worse than did the elderly and those with poor subjective health status (Lo SK et al, unpublished observations). It seems doctors' assumptions may be different from a patient's and may not be justified. A local study queried 543 subjects on their preference for resuscitation and life-support treatment, and was assessed giving consideration to their socio-economic background, functional ability, and self-perceived health.[17] Most subjects wished to be resuscitated; however, age, not having a spouse, and female sex were factors associated with the tendency to decline resuscitation. About 20% changed their wish after they were told of the poor outcome of the procedure they were to undergo. A considerable pro-

portion of older people wished to be involved in decision making regarding life-sustaining treatment. This study emphasises the need to give patients more information about life-sustaining therapy and the need for their involvement in treatment plans.

No study has been carried out in those with diminished mental capacity. Such people tend to have a lower priority in areas such as health care provision, resuscitation, or life support; decisions regarding the quality of life being based on the health care provider's or carer's assumptions. The practice of living wills in America, where one can state clearly that life-support treatment is unwanted, will go some way to solving this ethical dilemma.

Service provision

In recent years, studies have been carried out in Hong Kong to examine the effectiveness of one method of service provision compared with another. One study compared structured care in a diabetic centre with usual clinic care (4-monthly follow-up by a doctor) using a retrospective cohort analysis over a 5-year period.[18] Structured care consisted of 2-monthly follow-up by a nurse, who checked blood pressure, body weight, and drug compliance. Patients were seen every 4 months by a doctor when their glycaemic index (HbA_{1c}) was checked. Eye and feet function, lipid profile, renal function, HbA_{1c}, and urinary albumin excretion were checked annually. Outcomes at 5 years included body weight, mean arterial blood pressure, fasting blood glucose, renal function, use of ACE inhibitors, and mortality. Those receiving structured care had lower body weight, mean arterial blood pressure, fasting plasma glucose, better renal function and greater use of ACE inhibitors. The 5-year mortality rate was 6% in this cohort compared with 24% in patients who received usual clinic care. Overall, users of ACE inhibitors had better survival rates and slower deterioration of renal function.[18]

The care of elderly stroke patients was investigated in a prospective randomised study that compared the outcome of 120 patients managed by a geriatric team using a geriatric day hospital facility versus conventional medical management.[19] Functional improvement was greater in the group managed by the geriatricians and the number of out-patient visits were also fewer, while costs for the two types of service were similar.

There is a widely held belief that institutional care is less desirable and more expensive than home care, and that elderly people prefer to be cared for at home. Therefore many health authorities put greater emphasis on the development of home support services than in the building of nursing homes. This view is based on health care providers' assumptions taking into account demographic and clinical variables. In fact, studies have shown that patient attitudes about living permanently in a nursing home cannot be reliably predicted from these factors and are frequently misunderstood by surrogates and physicians.[20] Elicitation of patient preferences regarding permanent nursing home placement should be explored before patients become unable to participate in the decision making. In Hong Kong, a cross-sectional survey of a stratified random sample of 2032 subjects aged 70 years and older showed that age and marital status were the main factors associated with institutionalisation (odds ratios of 13.6 and 7.1, respectively).[21] It follows that requirements for nursing home places are unlikely to be lessened to a great extent by preventive measures. The attitude of older people towards old-age homes was examined in 197 non-institutionalised subjects. Factors influencing their decision to live in a nursing home included living alone, presence of disability, and previous experience of nursing homes. Only a minority of subjects opted to remain at home with social service support (Kwok CY et al, unpublished observations). Currently, available evidence suggests that resources should go towards the provision of more nursing homes rather than predominantly to the provision of community support.

For the care of terminally ill patients, palliative care units have been formed in recent years. It is encouraging that such units are able to provide significant symptom improvement and thus improve the quality of dying. In a local study, quality of symptom control was evaluated in 133 patients, which documented the presence and severity of 13 physical symptoms and seven core items of anxiety, insight, and communication.[22] The greatest improvements were noted in the symptoms of pain, fatigue, and anorexia, and in patient insight, and communication between patients, their families, and the professionals, showing that palliative units are effective in influencing the quality of dying.

There are many examples of areas in service provision where evidence is needed. The assumption that community care is cheaper than institutional care needs to be examined.

Interventions to prevent disease and/or disability

Osteoporosis and cardiovascular diseases are diseases where risk factors have been documented in the Hong Kong Chinese population, and therefore are amenable to intervention. A study of elderly residents living in

an old-age hostel examined the effect of calcium supplementation and physical activity on bone mineral density (BMD) and showed that both interventions have an additive effect in increasing BMD.[23] However, it may not be appropriate to adopt the recommended daily intake of calcium of 800 to 1000 mg promoted in western countries to prevent osteoporosis, since the incidence of osteoporotic fractures in Hong Kong is not greater than those in Europe or the United States despite a very low calcium intake.[24] It is possible that a genetic difference in vitamin D receptors may result in more efficient absorption of dietary calcium in the Chinese population. It has been documented that there is a lower prevalence of the vitamin D receptor BB genotype (associated with increased fracture risk in Caucasians) in Chinese compared with Caucasian populations.[25] Consequently, the optimum calcium intake for Hong Kong Chinese people in relation to bone health remains to be defined. Similarly, the cost-effectiveness of screening methods (eg bone densitometry, biochemical measurement of markers of bone turnover)[26] is uncertain, and needs to be assessed in the context of long-term clinical trials in which patients are randomised to different methods of screening or no screening. Such evidence is required before recommendations can be made regarding whether screening should be performed or which method of screening should be used.

The role of statins in the secondary prevention of myocardial infarction and stroke has been well established in Caucasians.[27-29] Is further evidence required for Chinese populations? Available data for Hong Kong Chinese people suggest that cost-effectiveness studies may be needed locally, since it is possible that cholesterol concentration may not be as important a risk factor compared with Caucasians. The incidence of ischaemic heart disease in Hong Kong is one fourth of that in the United States[30] in spite of similar lipid profiles[31] and other protective factors may be important, such as racial differences in changing endothelial function[32] and clotting profiles—lower fibrinogen levels have been found in the Japanese population.[33] With regard to dietary recommendations for coronary heart disease, a vegetarian diet with low saturated fat and high phyto-oestrogen content should be beneficial, and indeed vegetarians have better lipid profiles compared with omnivores.[34] However, the very low protein intake has been shown to be deleterious to bone health.[35] Studies in Japan suggest that a diet where approximately half the protein is of animal origin is associated with the longest life span.[36]

With the aim of preventing disability, epidemiological studies in Hong Kong have identified certain diseases that should be targeted; stroke, dementia, fractures, Parkinson's disease, diabetes mellitus, and asthma have been identified as major diseases giving rise to functional limitation, stroke being the disease with the highest attributable fraction for severe limitation.[37] Exercise as an intervention to prevent functional decline has been demonstrated to be effective in two studies in Hong Kong. Among elderly patients recovering from acute medical illnesses, progressive high resistance training has been shown to increase parameters of muscle strength and speed of transfer and walking.[38] In a randomised study of a group of elderly people living in a hostel, a balance and exercise intervention programme that lasted for 3 months also showed similar effects, in addition to improving balance.[39]

Efforts to effect changes in the prevalence of a disease or disability usually involve a community-based health promotion. The effectiveness of such programmes has been studied in other countries as well as in Hong Kong. Unfortunately, a Belgian community experiment that attempted to reduce sodium intake in a large population using mass-media techniques over a 5-year period was disappointing.[40] A meta-analysis of randomised controlled trials in workforces and in primary care of multiple risk factor interventions for prevention of coronary heart disease shows that such interventions implemented through standard health education methods have limited use in the general population, and suggests that fiscal and legislative measures may be more effective in bringing about health protection.[41] However, interventions in selected groups may show a benefit. Guldan et al have shown that a community-based nutrition education intervention in Szechuan resulted in better growth at 12 months and lower rates of anaemia.[42] A programme of cardiovascular health education carried out at the worksite for 1050 participants in Hong Kong resulted in improved lipid profiles after 1 year of intervention.[43] For a population-wide programme to be effective, many obstacles need to be overcome,[44] and in the implementation of any programme, these factors need to be dealt with to increase the chance of the programme's success.

In the previous paragraphs, an attempt has been made to gather studies carried out in Hong Kong which attempt to provide evidence to guide clinical practice. As for other populations, such studies may be biased or have weak methodology, and there are many unanswered questions. For example, no control group was used in the study of lipid profiles in Hong Kong.[43] It is also unclear whether high cholesterol levels have

the same clinical significance in all age groups for the Chinese population. Therefore, it is important to assess these studies critically.

Has available evidence influenced clinical practice?

Where evidence is available to guide clinical practice, it would be expected that all patients would receive similar treatment for the same condition. There are many examples, however, where this does not happen. The use of thrombolytic therapy in acute myocardial infarction, ACE inhibitors in diabetic patients with proteinuria (to retard the rate of decline in renal function), and renal replacement therapy for chronic renal failure, are common examples where certain forms of rationing occur as a result of a limitation of resources. There is a bias against disadvantaged groups such as the elderly or mentally infirm, which would be against ethical principles. On the other hand, there is an opposing view that it may not be ethical to 'squander' resources on those with limited life expectancy or a poor quality of life, and various formulae are being used to determine who should benefit.[45] The issue remains controversial, particularly in the application to older people. For example the use of quality-adjusted life years (QALYs) as a basis for resource allocation has been viewed as no better than arbitrary 'shroud waving'.[46] In Hong Kong, this question has not been debated as the official government position is that health care resources are adequate and the need to ration health care has not been formally recognised.

While it is important to emphasise the need to obtain evidence to guide clinical practice, the biggest challenge is how to implement such practice to ensure equitable access to prevention and treatment. Studies on how to achieve this target will be equally important.

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