Review Article

AUTONOMY VS BENEFICENCE: SHARED DECISION-MAKING IN ALLERGY

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ABSTRACT

Understanding the principles of ethical clinical practice is fundamental to making appropriate decisions. While ethical practice is a regulatory and legal obligation, it more importantly improves clinical judgement and the delivery of effective care. Traditionally, there are four principles: autonomy (giving choice to the patient); beneficence (paternalism); non-maleficence (do no harm); and justice (confidentiality and equality). However, a fifth principle, fidelity, which constitutes fairness, truthfulness and advocacy, must be included.

Balancing between autonomy and beneficence is like walking on a tight-rope, particularly when dealing with children and young people. However, competence to make sensible autonomous decisions is not linearly related to age. Adults sometimes make bad decisions and do not necessarily understand the long-term consequences of their actions. Nevertheless, whereas children are not, adults are legally considered to have autonomous rights. Irrespective of age, generating an accord between clinician and patient through empathetic consultation has the best chance of achieving favourable patient experience and consequent optimal clinical outcomes. In most situations honesty and full disclosure should be the rule; but, very occasionally, it may be necessary to modify approaches to avoid adverse consequences. The five principles are discussed and illustrated with case scenarios. It is not always possible to achieve consensus and sometimes there are no correct answers to ethical dilemmas. But discussion with colleagues, ethicists, patients and their representatives will improve ethical clinical practice.

Keywords: autonomy, beneficence, ethical clinical practice

INTRODUCTION

The principles of medical ethics define the moral code by which doctors are expected to conduct themselves. Ethicists have formulated four pillars which are fundamental to clinical practice. The balance between autonomy and beneficence encompasses two of the principles which are pivotal to making ethical decisions in clinical practice:

- *Autonomy* is giving patients the freedom to choose for themselves when they are considered to be capable of understanding and acting appropriately if given full information on the pros and cons of the range of options in a clinical situation.
- *Beneficence* is effectively paternalism, where doctors decide what is good for patients as they have the knowledge and skills to represent their patients' best interests.

The other two pillars are non-maleficence (based on the Hippocratic oath 'First do not harm') and justice (confidentiality, equal and fair distribution of resources).

A clinician's maintenance of confidentiality in relation to information revealed by their patients is viewed as a legal requirement. However, in some countries legal precedent requires clinicians to provide information that might have an adverse impact on public safety – for instance, a patient who is medically unfit to drive a vehicle or who has expressed criminal intent. For this reason, I think that confidentiality fits better with justice than, as sometimes suggested, into autonomy. An additional principle, fidelity, should also be considered. It constitutes fairness, truthfulness and advocacy.[1]

As litigation for medical negligence has become more common, many have perceived that ethics is the guide to defensive medicine in order to avoid being sued and also a regulatory requirement. These concepts should be relegated to a second tier of importance below the aim of improving medical decision-making and so as to achieve improved concordance, patient experience and outcomes. Clinical judgement is a crucial and defining skill that enables the practitioner to make better decisions in any situation. It involves integrating medical knowledge and reasoning with psychological and social factors, ethical reflection, professional and legal obligations.

In this article I discuss all the principles with a focus on autonomy and beneficence in allergy practice, non-therapeutic intervention, and research, and illustrate the concepts with actual case scenarios.

AUTONOMY VERSUS BENEFICENCE

Autonomy assumes that patients are able to understand information and appreciate the impact of current decisions on the future and to make decisions independently of external influences, values, aspirations, priorities and beliefs. It requires the clinician to provide all the information needed to facilitate sensible decision-making. Hopefully, this will take the form of a process to achieve an accord between clinician and patient which is then more likely to result in subsequent concordance with the management plan. It therefore avoids the paternalistic approach and eliminates the concept of compliance or adherence which implies that patients must follow their clinician's dictates. Whereas autonomy for adults is legally enforced, the assumptions on which it is based are not linear in relation to age. Adults frequently make bad decisions. Their values, aspirations, priorities and beliefs change over time and adults often do not appreciate the implications of decisions on their future lives. Adopting a liberationist approach suggests that children have the same autonomous rights as adults.

A child's ability to understand information and to appreciate the impact of current decisions on the future, independently of parental and social influences, increases with age. Just as in adulthood, a child's values, aspirations, priorities, beliefs and views of their best interests change in a non-linear fashion over time. Nevertheless, paediatricians are expected to make decisions in their patients' best interests. It is therefore considered ethically and legally appropriate to override a child's autonomous decision if that decision is considered not to be in the child's best interests. Accordingly, balancing autonomy with beneficence requires finding a balance between respecting autonomy and the need to protect children from 'bad decisions' to ensure that they reach autonomous adulthood. Respecting autonomy while advocating best interests requires a balanced approach towards patients of all ages.

CASE I

A 13-year-old boy with moderately severe asthma who is on inhaled corticosteroids (ICS) presents in the allergy clinic with his mother. There is a disagreement between mother and son about his symptoms and treatment. He reports that the problem is exercise-induced cough and wheeze compromising sport activities. His mother says it is the nocturnal cough and wheeze disturbing his parents' sleep that requires attention. She also says that he is resistant to taking ICS regularly and instead uses bronchodilator dosing increasingly frequently. Clearly both perspectives indicate poor asthma control and changing the treatment plan is mandated. The primary clinical concern is that an increasing use of bronchodilators instead of regular ICS is a recipe for severe exacerbation and increases the risk of a fatal outcome.[2] In addition, poor control compromises sporting prowess, which impairs self-esteem and concordance with treatment, whereas sleep disturbance impairs day-time and intellectual performance.

There are three overlapping principles to apply to achieve the desired health outcomes that balance the boy's and the family's values and expectations:

- Basic interests, which include the clinical risks, the family concerns and expectations, and their perception of the burden of the disease and its treatment.
- Autonomy, which takes account of the boy's wishes and assumes he is mature enough to understand and has the capacity to act on an agreed programme.
- Developmental interests, which take into account the adverse impact on education and exercise, which in turn affects relationships with peers and self-esteem.

Aiming for an accord with the boy by focusing his attention on the effects of regular ICS treatment to improve exercise tolerance and performance is more likely to achieve concordance than by responding to the mother's concern about sleep. This approach has moved the consultation from a paternalistic approach where the doctor and mother dictate the treatment plan through to an informative model requiring patient education and training. This model requires the combination of a deliberative approach, where clinicians give their view of the best strategy, and an interpretive model, where the clinician, having provided all the facts, allows the boy to decide on the treatment plan (ie reaching an accord).[3] This will require sensitivity and empathy, particularly if it is considered appropriate to ask the mother to stand back and allow her son to have more independence in managing his asthma.

There are strategies which may improve outcomes: shared medical appointments for peer groups and the use of apps delivered through electronic media, which are much favoured by children. A meta-analysis of the use of electronic health interventions revealed small but significant improvements.[4] However, more collaborative working with children and young people to co-design interventions is required. My experience from focus group qualitative research sessions is that children and young people are very enthusiastic about co-designing asthma and allergy care apps. They would like to include peer e-discussion groups and were happy with the concept of monitoring being transmitted to their doctor. However, their parents were unhappy and preferred traditional hard-copy action plans. With electronic media, there are certainly issues relating to confidentiality and the transmission of false information to resolve.

FIDELITY AND JUSTICE

In my clinical practice in the United Kingdom, the issues of fidelity and justice are rather different from those in South Africa because the National Health Service (NHS) is expected to offer access to any treatment considered clinically indicated to all patients irrespective of their socio-economic status. However, the resources to fund the NHS are limited. Consequently, if I insist that a small number of my patients with very severe, poorly controlled eczema or asthma should have extremely expensive biological therapies, I may be depriving much larger numbers of individuals from having timely hip replacements. So while my responsibility is to my patients and I must be their advocate, my experience in such situations is that the clinicians who 'shout loudest and most vociferously' are more likely to be successful. This does not sit comfortably with the concepts of fidelity and justice.

CASE II

You have two patients with severe allergic asthma poorly

controlled on the Global Initiative for Asthma (GINA) Level 5 therapy. One is a private patient with the resources to pay for omalizumab (Anti-IgE monoclonal antibody). The other is unemployed and the local health services will not provide the required financial support. Will you explain that international guidelines recommend omalizumab and other new biologicals in severe poorly controlled asthma[5] to both, to neither, or only your private patient?

Deontology is also known as 'duty-based ethics'.[1] The derivation of the word is from the Greek for duty, *deon*. It states that the correct course of action is dependent on rules in relation to duty and obligation. Therefore, the ten commandments are a classical set of deontological rules. As such they do not sanction action which is modified because of concerns about potential adverse consequences. Do not kill is a perfect duty but may be imperfect in a situation when high-dose morphine is knowingly administered to relieve intolerable pre-terminal pain but predictably increases the risk of an earlier demise. While deontology provides consistency and emphasises total honesty in all situations, it misses the consideration of consequences, which must be a component of ethical decision-making.

The ethical response to case two should be based on whether you followed the rules or adjusted the action based on your assumption of the consequence of following the rules. In this case you have the choice of being open and honest with both patients, which will allow the private patient to pay for the treatment but cause disaffection in, with possible adverse consequences for, the second patient. You could be economical with the truth for the second patient by omitting to say that there is any better treatment available on the grounds that being open would lead to a loss of trust, future non-attendance and a potentially serious adverse clinical outcome. This is an insoluble dilemma unless you can persuade the private patient to pay for both to have omalizumab or find the finances from other sources.

Full disclosure is considered the norm in the United States but is variably applied world-wide.[1] This case scenario requires time, diplomacy, tact and sensitivity. You may choose to prescribe oral steroids with attendant side-effects and explain that omalizumab is too expensive and its benefits are uncertain. But uncertainty about outcomes might cause confusion and the patient may not understand complex information or may not want to know. Under such circumstances, patients should have the option to be accompanied by their representatives and could opt out of having full disclosure. However, in most situations, honesty and complete explanation should be the rule. Indeed, it should be possible to adhere to the principles of deontology; but to sustain hope you will need to demonstrate that you are the advocate for your patient and pursue all avenues to acquire the best treatment irrespective of financial considerations.

CONFIDENTIALITY

Clinicians should not disclose confidential information about a patient to any another party without the patient's authorisation. However, it is often in the interests of patients to ensure that medical information is shared with other medical and social agencies with whom the patient comes into contact. For instance, educational institutions should have information about their learners who have acute food allergy or asthma and they should have action plans in place to deal with emergencies. Children may not be comfortable with the transmission of information because of possible stigmatisation and the potential for bullying. These issues must be dealt with in advance so that agreement can be reached on the strategy.

Maintaining confidentiality becomes a problem if your patient has a medical disorder which, for instance, compromises driving, such as very limited vision. Ideally, the consultation should involve a discussion about the impact of the medical problem on public and personal safety – which will mean that there is no need to breach the principle. However, in the absence of agreement, some countries by legal precedent will expect the information to be transmitted to the relevant authorities.

Data-protection legislation has created problems for public health and research. Pooling information on prevalence, geographical distribution and demographics is needed to advance our understanding of the long-term outcomes of specific disorders or for disease control, as amply illustrated by the COVID-19 pandemic. Identifying whether those admitted to hospital or who had fatal outcomes were or were not vaccinated required the linking of individual data, but legislation in some counties blocks this approach. It is possible to overcome this impasse by pseudo-anonymising the data, but linking must be performed by third-party teams independent of the original clinical source and the researchers, which is expensive and time-consuming.[6] This is a situation where health professionals should strongly advocate appropriate changes to the data-protection laws. There are many past examples where health professionals challenged the law directly – which has been considered ethically appropriate – and their action ultimately resulted in changes to legislation. This is illustrated, for example, by the evolution of laws governing medical terminations of pregnancy.

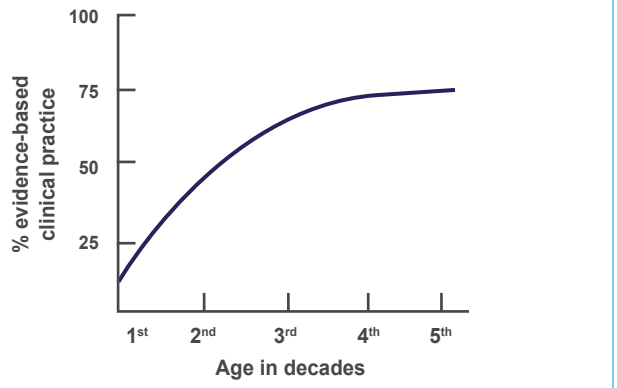
NON-THERAPEUTIC INTERVENTIONS

Non-therapeutic interventions pose considerable ethical dilemmas, which are increasing as new technologies become available. An example of this is screening for future risks of allergy, which includes cord blood immune endotyping and genotyping.

CASE III

A mother with asthma, eczema and fish allergy requests allergy testing for her healthy nine-month-old son. He has no signs of eczema and has thrived. He has already tolerated most common allergenic foods during weaning, but has not been given fish or peanut. Should you agree to see the family and conduct allergy tests? This is at the margins of established evidence. He is highly unlikely to be fish-allergic as he has never been exposed by any route pre- or postnatally. Being given fish now may induce tolerance, but cooking it could compromise his mother's health. What about other potential allergens? His mother eats peanuts and they are in the house and therefore the dust is also present. Is it ethical to do skin-prick or blood tests, and for what?

This family were referred to me and my secretary booked the appointment without any opportunity to consider whether a consultation was appropriate. During the consultation, the



mother was very agitated and persuaded me to test, though I informed her of the lack of sensitivity and almost inevitable negative test for fish. Skin-prick tests (SPTs) to fish were negative, with a 4 mm response to histamine; but the peanut test was positive, with a 4 mm weal. In retrospect, would it have been better to refuse to see the family, which might have pushed them towards alternative and unvalidated allergy diagnoses which are widely available on-line? I was now required to consider whether to organise a day-case peanut challenge and whether peanut oral tolerance induction should be employed. The latter now has evidence for efficacy and safety beyond 12 months of age.[7] The easier option was to recommend avoidance of peanut and ask his grandparents to feed him with fish and review in one year to repeat SPTs. Should the decision be influenced by the family's psycho-social and financial status? There are no easy answers, but the application of deontology, total honesty and openness is the best approach.

Allergy primary prevention strategies have been suggested pre-conception, during pregnancy and in the first years of life.

An increasing number of studies suggest that weaning onto common allergenic foods should commence from four months so as to achieve tolerance.[8] The World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) insist that exclusive breastfeeding should continue to six months. The early weaning recommendations arise from research in developed world settings, whereas the WHO and UNICEF are focused primarily on the developing world, where failure to maintain breastfeeding can have serious adverse consequences.[9] How should this information be publicised in South Africa, where both very different socio-economic settings exist? The answer may come from further research because it is possible that the key is not the timing of weaning but the maintenance of breastfeeding during weaning in order to achieve the best outcomes.[8]

MEDICAL RESEARCH

Medical research is necessary for medical progress and today's children benefit from previous research involving children. Is there a duty for paediatricians to encourage children to participate in medical research? We do not consider that adults have a duty to participate in medical research and their participation is voluntary because we assume that they understand the purpose and risks of participation. However, as indicated above, competence to understand and make sensible decisions about involvement in research is not exclusive to adults, and many older children are keen to be consulted about clinical research. Furthermore, evidence-based clinical practice becomes progressively less secure the younger the patient (see Figure 1). In other words, much paediatric practice is based on extrapolation from adult medicine and is therefore 'experimental', and theoretically mandates a call for research.

There is a very confusing real-world situation. Risky medicine, such as giving treatment without evidence, is accepted as ethical and does not require ethics committee approval. On the other hand, cautious, thoughtful medicine – such as establishing a research project around a treatment without evidence – is considered potentially unethical and requires research ethics committee clearance.[10]

There are rules and published guidance on conducting of research applicable to all ages but issues specific to children include these:

- It is not relevant to carry out the research in adults.
- The condition being studied is specific to young children.
- Parental consent and child assent are obtained.
- It carries no or minimal risk.

However, the second and third items will be mutually untenable in the cases of severe acute disease in premature infants, where immediate intervention is required before consent can be obtained. Furthermore, the advent of paediatric implementation plans to extend the patent times on new medicines has imposed additional dilemmas on pharmaceutical companies and paediatricians. A new medicine will require phase 1 and 2 dose-ranging studies of safety, pharmaco-kinetics and pharmaco-dynamics on children of different ages before therapeutic trials can be commenced. In such situations, ethics committees are left with the responsibility to work with researchers to devise ethical solutions.

CASE IV

A physician from Czechia offered a series of bronchial biopsies taken from infants with wheezing illnesses which had the potential to aid the understanding of the early pathological changes in asthma. However, the practice of taking such biopsies in the United Kingdom would not have been considered clinically appropriate. Should I accept the biopsies for more detailed immuno-histological studies?

The ethical considerations were these:

- Who owns the biopsies? It depends on the original consent form.
- Did the consent form include retention for research purposes? If not, the parents are the custodians.
- Given the potential clinical value of the research, would it be unethical to not proceed?
- My institution's research ethics committee concluded that it could not approve a proposal because it was the responsibility of the Czech host institution.

The solution:

- Co-production of the study design with patients, parents and health professionals.
- Trace the families to request a return visit for research to establish current respiratory status, including soliciting signed permission to resurrect the biopsies.
- Apply for ethics committee approval.

The outcome:
A publication with 156 citations on Web-of Science.[11]

FINAL THOUGHTS

I do not have all the answers. The best outcomes are achieved by sensitive balancing of autonomy and beneficence, always addressing non-maleficence and with consideration of fidelity and justice. Honesty and full disclosure should in virtually all circumstances be the rule. If there is time, discussing the dilemmas with colleagues, ethicists and patient representatives will aid better decision-making. Indeed, in my hospital there are separate clinical and research ethics committees. Consulting the former has been particularly helpful in resolving conflicting issues of morality in clinical practice.

CONFLICT OF INTEREST
The author declares no conflict of interest.
This article has been peer-reviewed.

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