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## **Hook line and sinker: Legal and ethical issues in diabetes care**

### **Abstract**

The rise in diagnosed cases of type 2 diabetes is well documented with the World Health Organisation (WHO 2013) stating that 347 million people world-wide have diabetes: they predict that by 2030 it will be the 7th most prevalent cause of death. Within England the Health Survey (HSCIC 2012) showed the prevalence of diabetes was 9.1% in men and 6.8% in women, up from 6.8% and 5.5% respectively in 2003. Quite apart from the human cost of mortality and morbidity, the cost of prescriptions for diabetes accounted for 9.3% of the total spend on drugs in England 2012-13 (HICSC 2013) representing and year on year rise.

In response practitioners across the board in primary and secondary care are charged with working together to manage patient care effectively. By uniting to address a common problem the potential for innovation in professional practice is opened and boundaries between professions are blurred. In addition, the diagnosis and treatment of type 2 diabetes and its related complications is a competitive multi-million pound international business, for which practitioners are often the decision makers when choosing and deploying resources. Against such a backdrop, this paper aims to explore the legal and ethical challenges faced and where the limits or 'edges' of responsibility and scope of practice lie.

## **Introduction: a diabetic practitioner; philosophy, ethics and law**

In order to start to explore this subject the first question addressed is what it is to be a 'diabetic' practitioner. The human inclination to define and categorise things has its roots in philosophy with Aristotle for example, exploring the definitions of an oak tree as deriving from an acorn: it has some properties which are shared with other trees (and indeed plants) but some that are uniquely essential to be categorised as 'oak tree' thus shape, leaf, seed all indicate oak, rather than ash or sycamore. A 'good' or successful acorn will flourish, growing into a healthy oak tree, with strong branches, a long life and – eventually –acorns of its own (The Stanford Encyclopedia of Philosophy 2010).

Categorising a diabetic practitioner is much less straightforward. It is likely that someone who is successful and flourishes in this discipline will have experience in the field, and specialist knowledge, but there is no definitive professional qualification and no single measure of what it is to be 'good' or to offer the 'best' service. Diabetes practice will include for example medical doctors, nurses, nutritionists and pharmacists who may have specialist knowledge in a number of related fields.

A second question asks what it means to practice ethically. Beauchamp and Childress (2013) offer four 'rules' for professional engagement:

- *Can you be truthful, giving an honest appraisal of the person's condition, options and prognosis:*

Truthfulness seems like a straightforward rule; indeed, most practitioners would feel uncomfortable at admitting to having deliberately lied to a patient in order to knowingly deceive them, but truths in health care are rarely absolute. A decision about treatment options may be a matter of balancing the odds, or offering the best evidence based opinion at a given time. In reality options may also be mediated by cost. Thus truthfulness may be a matter of judgement, no deceit intended but a decision to explain a situation in one way, rather than another.

- *Can you be confidential, sharing what you know only with others who need the information:*

Traditionally within healthcare confidentiality is associated with implied consent, for example to the sharing of medical records and information with others in the team caring for someone; however digitalisation of records adds to the issues faced. Lesk (2013), discussing the unification of patient

records in the US, notes that in some European countries such as Denmark electronic patient records have been in place for 10 years or more, and are reported to be effective. However Lesk goes on to explore the practical and legal issues in the US, not least tensions between research and patient care and security of systems. At the time of writing the NHS 'care.data programme' which aims to share large quantities of patient data for research has been delayed following public outcry and a campaigning by Health Watch England (Healthwatch England 2014) who state that adequate information, confidentiality and informed consent have not been achieved. In researching confidentiality of patient records in HIV cases, Williams (2011), highlights the difficulties faced. Thus confidentiality is no longer, if it ever was, simply a matter for the immediate health care team.

- *Can you be discreet, absorbing the extra things that health professionals inevitably know about their patients without this affecting care or relationships:* Often, without even realising it we 'know' things about our patients such as their disposition, personal circumstances and preferences. Separating this from the care that we give and the way we talk about and report on them to others is a hallmark of the professional relationship and leads to the final rule:

- *Can you be trusted:* Some patients may defer to rank and expertise, expecting health professionals to make decisions for them, or may be young or vulnerable and thus unable to exercise full capacity. In contrast other patients may be educated, articulate and internet informed, requiring a different approach to communication and decision making. In all cases professionals need to be confident that their behaviour and decision can be trusted.

Rogers & Ballantyne's (2010) research, extrapolating the professional values of medical doctors from professional conduct investigations, highlight four characteristics which reinforce and develop the notion of trustworthiness:

- responsibility;
- relationships with and respect for patients;
- probity and honesty;
- self awareness and capacity for reflection.

The inclusion of 'self awareness and capacity for reflection' offers a richer less procedural view allowing for growth and development rather than simple rule following.

Beauchamp and Childress (2013) argue that the four rules can be derived from the core ethical principles of respect for autonomy, beneficence, non-maleficence and distributive justice. Respect for autonomy is often described as the 'prima facie' principle, meaning it is the one that should be considered first, and if achievable, should override all other considerations. How far a practitioner can go in instructing, or persuading a patient to behave in a certain way, or to change their behaviour is an area that all will have faced at some stage. J S Mill's notion of free will, and his description of autonomy may be of use in exploring this. A 19th century philosopher, JS Mill, wrote about free will in 'on liberty ' (JH Mill, 1859), where he describes a situation where you see a person considering crossing a bridge that you know to be dangerous. He says that you have moral obligation to stop the person and inform them of the danger. However, he states that once you have given the warning, you can do no more to prevent the person's actions, or to influence their behaviour. Respect for their autonomy means that they are free to take their own risks, and you have no right, let alone obligation to interfere.

However health professionals are bound by their Codes of Practice to act in the best interests of their patients [beneficence] and to do no harm [non maleficence]. This creates dilemmas for the diabetic practitioner faced with a patient who knowingly risks their health by not following the advice given. Such a practitioner may sympathise with Mill's character, watching with anxiety as the person crossing the bridge risks their lives, but may also wonder where the point at which stepping forward to prevent the person's fated path is the right thing to do.

The final principle, distributive Justice, asks that resources are shared fairly amongst all people. As gatekeepers to specialist services, and pharmaceutical prescribers, diabetic practitioners have access to and control over significant resources of time and money. Faced with finite resources and infinite demand utilitarian principles of 'the greatest good to the greatest number' (Bentham, 1907) may help

to direct resources to those who can gain most, but will not be a fairly distributed or even allocation. Conversely sharing resources equally may appear fair, but not clinically effective.

The third and final question is where and how are diabetic practitioners accountable. Dimond's (2008) description of the 4 arenas of accountability may be helpful in addressing this:

- Accountability to criminal law will apply to all practitioners as citizens and includes serious crimes such as assault, manslaughter or murder.
- Accountability to civil law again applies to all practitioners as citizens and covers areas where a member of the public, perhaps a patient, makes an accusation of negligence or breaches of privacy and confidentiality.
- Accountability to an employer is derived from employment legislation, so may not apply to all diabetic practitioners, as some will be self-employed. It will include general rights and obligations to an employer but also specific elements such as 'gagging' clauses relating to whistle blowing.
- Finally, accountability to one's profession derives from professional regulator's codes of practice. Whilst each regulators code may be slightly different, they all include elements that relate to standards of competency and behaviour, public protection and maintaining public confidence.

As can be seen regulated professions will always have significant additional burdens of accountability above those expected of the average citizen, or even the average employee.

## The limits of practice

Having set out some philosophical, ethical and legal concepts two case studies explore the areas where professional practice may be stretched to its limits and where the tensions between competing priorities may exist.

### Professional judgement v patient wishes

*Annie is a woman in her late 40s who is diagnosed with type 2 diabetes. She is a little overweight but not morbidly obese. She has a full time job and is married with two teenage children who live at home. Annie is fully informed about her diabetes and understands the effects this will have on her body over time. As an autonomous informed adult, she makes a number of decisions and compromises in her life:*

- She is reasonably compliant with her medication but struggles to maintain a regular healthy diabetic diet whilst also catering for her family. In order to share the household chores she, her husband and the older child take it in turns to cook. They do not always understand or follow her dietary needs, and she does not like to refuse so takes 'little holidays' from her diabetes every so often.
- She made a big effort to give up smoking two years ago, on the advice of her practitioner, but has put on several kilograms since then which she just cannot seem to shift.
- Her busy job leaves little time for leisure, and is difficult to reach by public transport so she gets little exercise in the day. When she does have 'me time' she is tired, and feels justified in putting her feet up.

Annie, just like JS Mill's man on the dangerous bridge, is making her own choices in life. No matter how much her practitioners may wish her to take greater care of her own health they have limited powers to control her behaviour and no rights to restrict her freedoms. Changing patient behaviour is very difficult. In addition to the usual information giving, counselling skills and persuasive techniques such as motivational interviewing (Hunt 2011) may be evidence based resources that practitioners can develop to try to help patients make choices that are most beneficial to their health. Despite the clear

imperative to respect Annie's autonomy, professional regulators expect practitioners to do the best for their patients, for example the Nursing and Midwifery Council opens their code of practice with the statement that: 'The people in your care must be able to trust you with their health and wellbeing' (NMC 2008). This puts practitioners in an impossible position if they are obliged to observe or actively support patients choosing sub optimal levels of health. Beauchamp and Childress (2013) argue that all such professional codes obligate practitioners to behave beneficently if they have the ability to do so, and if their knowledge and understanding of the patient's condition leads them to believe that a particular course of action is more likely to be helpful than another.

The feelings evoked by such dilemmas are sometimes referred to as 'moral distress' which may be defined as:

'... the cognitive-emotional dissonance that arises when one feels compelled to act against one's moral requirements.' (Berger, 2014:395)

Whilst this concept is one that is still being developed and critiqued (Deady & McCarthy, 2008), it captures the stress that respect for autonomy inevitably brings.

*Years have rolled by and Annie is now approaching 70. She retired early as her visual acuity is poor and her weight has gradually crept up since she had to give up driving. Her diabetic team are concerned that circulation in her right foot is deteriorating and that surgery may be a necessary intervention.*

Annie remains fully aware of her situation but does not want to face up to the possibility of an amputation, and refuses to consider this or to consent to any surgical intervention. The diabetes team supporting her know that her freedom to choose is narrowing and need to consider the point at which her capacity to make an informed decision may be compromised. From a legal perspective the Mental Capacity Act (Ministry of Justice 2005) Code of Practice is helpful in identifying 5 key principles (see Figure One). They remind the practitioners to respect patient choices, even when they may be considered unwise; to only act against these if they can be sure that capacity is not present, and even then to only act in the least invasive or restrictive way possible.



From an ethical point of view Beauchamp and Childress' (2013) justification for paternalistic action (see Figure Two) takes the practitioner through a stepped decision process where action against the patients wishes is only justified when the six features are in place. Taken together, the guidance offers a strong framework that might be helpful in reducing anxiety and strengthening decision making in difficult cases.

**Figure one: Mental Capacity Act (Ministry of Justice 2005) code of practice: 5 key principles**

- Every adult has the right to make his or her own decisions and must be assumed to have capacity to make them unless it is proved otherwise.
- A person must be given all practicable help before anyone treats them as not being able to make their own decisions.
- Just because an individual makes what might be seen as an unwise decision, they should not be treated as lacking capacity to make that decision.
- Anything done or any decision made on behalf of a person who lacks capacity must be done in their best interests.
- Anything done for or on behalf of a person who lacks capacity should be the least restrictive of their basic rights and freedoms.

**Figure Two ( Beauchamp & Childress 2013, chapter 5) justification for paternalistic action**

- If - - The person is at risk of illness or injury
- And - The risks associated with the intervention you envisage are low
- And - You judge that the benefit of the action you wish to take outweighs any risks
- And - There is no feasible / acceptable alternative
- And - The extent to which you have denied their autonomy is minimal
- And - The action is the least that can possible be done
- Then - - a paternalistic act may be justified.

## Whose decision is it?

*The multidisciplinary team supporting diabetic patients are having their regular meeting. One colleague has just returned from a professional development seminar where a pharmaceutical company, who were funding the event, promoted a new medication. All the evidence available is that this may have the edge on current treatment regimens and several patients, like Annie, might benefit. It is, inevitably, more expensive.*

The team engage in a debate about the relative benefits of different treatments. With 42.5 million items prescribed for diabetes, costing £764.1 million (net ingredients) in the financial year 2012-13 (HSCIC 2013), they know the costs can only increase as more cases are diagnosed and treatment costs rise. They are also aware that the evidence base they have to rely may be flawed, or at least incomplete. Jones et al (2013) illustrated this by an analysis of drug trials registered with trails.gov, this being the definitive database. They chose only trials that were completed by 2009, thus allowing a reasonable amount of post-trial time for dissemination, and where there were at least 500 participants, thus ensuring that the trial was large enough to warrant publication.

Of the 585 trials that fulfilled these two criteria, 29% (171) were still unpublished at the time of analysis and of these 133 (78%) no data had even been submitted to the trails.gov database. The reasons for the missing data are not clear, perhaps some of these trials found no evidence that support a particular treatment, and some found a treatment was harmful. Even if this is the case the absence of the data means the evidence base is incomplete. By excluding more than a quarter of trial results from practitioners, decisions must inevitably be biased towards those published and marketed most aggressively.

The team is of course aware of this, but it does not really help. Furthermore they are cognisant of the World Health Organisation's assertion that 'Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use can prevent or delay the onset of type 2 diabetes' (WHO 2013). These effective actions are potentially the cheapest and least controversial, but are also those most difficult to achieve, despite some government-led progress in addressing advertising, obesity and promotion of health lifestyle (Houses of Parliament 2012). The debate that the team

engage in, regarding treatment choices, finite resources and patient care revolve around four core questions:

What *can* they do: this relates to competence, the skills, expertise and personal resources they all bring to their roles. In Annie's case this might be about setting out the options and using the relationship they have established with her to help her reach a decision. More generally it might involve deciding on a team-wide philosophy of promoting a particular ethos. It might also involve choosing which groups of patients to target with limited resources.

What *should* they do: what are they accountable for within the law, their contract with their employers and their code of practice. The team need to be aware of what they must provide for Annie, or any patient within their caseload. This might include accurate information, choices of treatment options and the consequences of different decisions.

What *ought* they to do: not just the 'bottom line' in terms of legislation or rights, but what is the right thing to do, the known good, or best practice. Here tensions begin to appear as the most desirable practice may not be possible due to time or funding constraints, as well as patient compliance.

What *may* they do: in the case of Annie they may have all the competency and skill they need, clear lines of accountability and a moral imperative but without her permission they may be unable to offer the optimal help. This final choice or lack of choice is arguably the most stressful faced by health professionals. Unless capacity has reached a stage outlined in figures one and two above, practitioners may not impose their view of a desirable outcome, no matter how strong the evidence base, against a patient's wishes.

### **In summary**

No one said ethics was easy: trying to do the right thing, and do it correctly, have been the hallmarks of evidence based practice expectations for some time (Gray 2009) but navigating these principles with the messy world of diabetic practice is not straightforward. Beauchamp and Childress (2013), and

(Dimond 2008), offer rules and principles plus a model of accountability that practitioners can use: Rogers and Ballantyne (2010) add richness to this by acknowledging the importance of self awareness and reflection.

A final conceptualisation, is the modern day interpretation of Aristotelian virtue theory developed by Banks & Gallagher (2009). The 'virtues ' they espouse for professionals are:

- Care
- Respectfulness
- Trustworthiness
- Justice
- Courage
- Integrity

Virtue theory holds that by cultivating the virtues and avoiding their related vices good citizens may be come wise, flourish, achieve practical wisdom and govern well.

By including 'care' as a virtue Banks and Gallagher celebrate the importance of compassion and humanity, and by highlighting 'courage' they acknowledge the challenges practitioners face in everyday practice.

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