

ETHICS MAN Daniel K Sokol

Update on the UK law on consent

Last week's Supreme Court decision has important implications for doctors

All doctors should be aware of the landmark decision in *Montgomery v Lanarkshire Health Board*, given by the Supreme Court on 11 March.^{1,2} Nadine Montgomery was a woman with diabetes who gave birth by vaginal delivery. Her baby, Sam, was born with serious disabilities after shoulder dystocia during delivery. The doctor, Dina McLellan, did not tell Montgomery of the 9-10% risk of shoulder dystocia. McLellan said that she did not routinely discuss the risk of shoulder dystocia with women with diabetes for fear that, if told, such women would opt for a caesarean section. The court held that McLellan should have informed Montgomery of the risk and discussed with her the option of a caesarean section.

After *Montgomery*, the Bolam test, which asks whether a doctor's conduct would be supported by a responsible body of medical opinion, no longer applies to the issue of consent. The law now requires a doctor to take "reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments."

So doctors must now ask themselves three questions. Does the patient know about the material risks of the treatment I am proposing? Does the patient know about reasonable alternatives to this treatment? Have I taken reasonable care to ensure that the patient actually knows this?

To answer the first question doctors must form a view of what counts as a "material risk." The law defines it as either a risk to which a reasonable person in the patient's position would be likely to attach significance or a risk that a doctor knows (or should reasonably know) would probably be deemed of significance by this particular patient.

The focus on "this particular patient" is key. A material risk to one patient may not be to another. A surgeon last week told me that he discloses risks of 1% and more. This

is a perilous habit. In an Australian case there was a one in 14 000 chance of blindness in one eye.³ Although the risk was remote, the claimant was already blind in the other eye, making the risk significant to the claimant. The court found the doctor's failure to disclose this risk to be negligent.

A pro forma approach to consent is common but is ethically and legally dubious. The Supreme Court talks of a "dialogue" between doctor and patient and emphasises the need to give information in clear terms and to avoid "bombarding the patient with technical information which she cannot reasonably be expected to grasp."⁴

If information is material, doctors should generally disclose it. They should not wait for the patient to ask for it. In the *Montgomery* case the court noted that "there is something unreal about placing the onus of asking upon a patient who may not know that there is anything to ask about."

So, when obtaining consent, law abiding doctors will ask themselves these questions:

- Does the patient know about the material risks of the treatment I am proposing?
 - What sort of risks would a reasonable person in the patient's circumstances want to know?
 - What sorts of risks would this particular patient want to know?
 - Does the patient know about reasonable alternatives?
 - Have I taken reasonable care to ensure that the patient actually knows all this?
 - Do any of the exceptions to my duty to disclose apply here?
- To these six questions I would add a seventh: Have I properly documented my consent process?

Exceptional cases

There are three exceptions to the duty to disclose. Firstly, the patient might tell the doctor that he or she would prefer not to know the risks.



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Secondly, the doctor might reasonably consider that telling the patient something would harm the patient's health. Consider this scenario: "Mr Smith is recovering in intensive care after a heart attack. His chances of a full recovery are good. The doctors discover that he has a form of cancer that is quite successfully treatable. His father died from this type of cancer years before, and it is known that Smith has a great fear of the disease. His blood pressure is in poor control, and minimising stress is medically desirable to lower the risks of another heart attack. Should the doctor, at this time, tell Smith that he has a form of cancer?" As long as the doctor's belief that disclosure would cause severe harm is reasonable, withholding the information will not be unlawful. The Supreme Court warns, however, that this "therapeutic exception" should not be abused.

Thirdly, no consent is required in circumstances of necessity, such as when a patient needing urgent treatment is unconscious or lacks capacity.

Ethically astute readers will note that the law now demands a standard of consent broadly similar to that required by the professional guidance of the GMC. Doctors who follow that guidance will not fall foul of the law.

Other readers will hold the view that consent is a myth invented by lawyers and ethicists and may ask, "How do we find the time to get such consent?" The court's answer is that the law must impose some obligations "so that even those doctors who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires."

The law is set. Some doctors will need to adapt. As Porgy sings, "No use complainin'."

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NO HOLDS BARRED Margaret McCartney

Is all knowledge power?

“Knowledge is power,” says the personal genomics company 23andMe.¹ For £125 it offers genetic testing to the public and a report on “over 100 health conditions and traits.” Its website predicts that you will be “excited about providing your sample” of saliva. The company’s founder has stated that “everyone has the right to access and understand their genetic information . . . imagine if someone told you that you couldn’t look in a mirror.”²

Healthcare data are measured in mountains, however, and can lead to inaccurate³ or unsafe⁴ conclusions. The information offered by this direct to consumer testing is advertised as a way to “better manage your health and wellness.” In reality it’s a massive data dump of genetic variants for traits, minimal risk factors, and conditions, from familial Mediterranean fever to “norovirus resistance.”

We know that patients overestimate the benefits of medical interventions and underestimate their harms.⁵ We should expect an explanation of false positives, false negatives, and limitations of usefulness, because real power is not simply about information but about

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understanding caveats, reliability, and hazards of results, and understanding not only statistical but also clinical significance.

If you test positive for the genotype associated with norovirus resistance, 23andMe says, “It is important to note that not having this variant does not make someone completely resistant.” So what use is it? Should this test change how we manage it? Can it ever be good advice to wash our hands less? What should we do with the knowledge that we have factor V Leiden deficiency, given that no treatment is required? Even when prescribing oral contraceptives it is likely to create many unforeseen dilemmas.⁶

A video on 23andMe’s website describes a patient with symptoms having genetic screening for predisposition to coeliac disease before it was finally diagnosed. This is back to front medicine: diagnostic tests would have been better first.

In 2013 the US Food and Drug Administration



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stopped 23andMe offering health reports as it was “concerned about the public health consequences of inaccurate results,” particularly regarding the BRCA gene.⁷ Indeed; and the advice about how to lower your risk (exercise and diet) still stands, whatever the results.

The claim that this is all about democratised information holds only if the information does more good than harm. When companies offer screening without evidence of benefit and without individual shared decision making, insurance should be built in to protect the NHS from having to deal with the fallout. 23andMe’s funders have included Google, the Roche Venture Fund, and Johnson and Johnson Innovation.^{8,9} 23andMe says it “may share anonymised and aggregate information with third parties.” Do we really know what we are buying into?

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IF I RULED THE NHS Bob Morley

Only the mother of all reorganisations can save the NHS

“No more top-down reorganisations” is a familiar mantra. Sorry, folks, but the NHS has been reduced to such a state that only the mother of all reorganisations can now save it.

After three decades of wanton destruction, from Margaret Thatcher’s Griffiths report on NHS management in 1983 and her internal market measures, then New Labour’s initiation of the competition and privatisation agenda, and finally Andrew Lansley’s cataclysmic Health and Social Care Act 2012 and its fallout, only radical measures can now restore the modern wonder of the world to its rightful place.

If I ruled the NHS I would seek to abolish the 2012 act, competition, Monitor, and clinical commissioning groups. The NHS must always be the default provider of first choice. For the rare



A return to true medical leadership in the NHS is essential

occasions when NHS provision isn’t possible, I would outsource only on the basis of partnering and quality, not competition and price. Governments and politicians must have the courage to realise that the NHS and its patients are best served by their having no role in running it or determining policy beyond the broad areas of funding and accountability. Administration will be through properly independent national, regional, and local health authorities.

Provision of health, social care, and public health must be integrated within the NHS, not local

authorities. The commissioner-provider split must be abolished, so that commissioning and provision, in effect, become the planning and operational arms of the same organisation, rather than commissioning being a mechanism for promoting competition and fragmentation.

A return to true medical leadership in the NHS is essential. The inexorable rise of managerialism since Griffiths has been disastrous. Abolish trusts and foundation trusts and demote their organisational status; we will simply have “NHS hospitals”—bricks, mortar, and facilities but, more importantly, the clinical teams and support staff who work in them and reach out to the local communities. No more empire building chief executives. Medical directors, leading through professionalism and clinical expertise, will be in

charge, operating through their clinical teams, with all managers in purely supporting roles.

GPs will form large super-partnerships, with care still GP led, locally focused, and based on registered patient lists. I would radically expand primary care budgets, with GP partnerships employing most community staff and providing most care outside hospitals, as well as hospital in-reach. There will be increased partnering with community based specialists, evolving to integrated medical partnerships that provide holistic general practice, community, social, and hospital care, incorporating public health and commissioning and planning functions.

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“Doctor: I’m going on holiday after my next chemo”

Exotic life affirming trips abroad are becoming common for today’s patients with cancer, reflects **Richard J Epstein**

Half a century ago Bob Dylan’s protest anthem *The Times They Are a-Changin’* proclaimed that people could survive only if willing to adapt. Flash forward to now, and this same sentiment of self efficacy has morphed into a medical mantra for balding baby boomers. For this is a generation that is pursuing its bucket list ambitions to an extent never seen before.

We might not be able to cheat death, goes the thinking, but we can at least squeeze the last drop of blood out of life. Healthcare has now become a means to this end, as reflected in the boomers’ booming consumption of medical services.¹

This should be no surprise; having enjoyed unprecedented access to labour saving devices and fast food, the emerging cohort of senior citizens now finds itself cursed by a glut of lifestyle associated cancers, diabetes, and cardiovascular disease.² Although also blessed with better healthcare information and self assertion than their forebears,³ these combined trends have led to an exponential escalation of demand on health services.⁴

One expression of this generational change is the rising popularity of patients with cancer taking holidays abroad while receiving treatment, a phenomenon that may be ahead of the curve in isolated countries such as Australia. In many oncology practices here it has become common for patients to schedule a life affirming trip abroad every few months. These patients tend not to be the younger and fitter patients receiving adjuvant therapies, whose priority seems to be to finish the treatment and get back to normal, but rather those with incurable metastatic disease, particularly men, who see no end of palliative treatment short of death.

Return of the pilgrimage

The benefits for patients taking such trips are clear enough: they are a way to transcend illness, whether by providing a break from poisonous drugs, by facilitating self renewal in a healthy environment away from the psychosocial stigma of illness, or by offering the experience of something beautiful (or at least unrelated to disease).⁵ Above all, the “metastatic cancer holiday” provides a goal for patients with terminal illness who otherwise feel cast adrift. And it may be the planning for the journey, rather than either the travelling or arrival, that matters most.

Patients with cancer may react to disempowerment in part by supporting their



GREENVILLE COLLINS COLL/MEPFL

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health outside the conventional system: vitamins, homeopathy, exercise, meditation, thermal treatments, diets, herbs, and prayer are some strategies they use.⁶ But “wellness travel” has also always been popular⁷; the idea that to get better one must first escape the environment where the malady began is not unreasonable, and has forebears in sanatoriums in airy alpine locations or in spa towns used to “take the waters.”

Health tourism includes many variations on this theme: the idea of combining self care, leisure, pleasure, or counselling is attractive to people whose medical management has hitherto been restricted to a litany of toxic treatments with valid but underwhelming statistical benefits. Although there is a danger of such patients being fleeced by unproved claims from entrepreneurs, it is also plausible that some patients may be happy enough to invest in a temporary period of optimism and positivity for its own sake.⁸

When patients with metastatic disease tell their oncologist that they are planning a foreign trip, the inference may vary with the intended location, distance, duration, companion, and activities. A journey to see loved ones may imply acceptance of terminal prognosis, and hence a wish for a final visit. A trip to an international medical centre flags a hope for a fresh opinion. A sojourn in an alternative medicine centre implies needs unmet by conventional support.

Between a rock and a hard place

Still subtler nuances may be implicit in a holiday request. Perhaps the commonest involves a patient testing the oncologist’s reaction to the proposed timing or duration of the trip: for example, a request to book a three month break in the Greek islands in three months’ time may

be a way of stating, “By the way, I hope to be alive and mobile in six months.”

Faced with such cues, how should oncologists navigate their responses between scaremongering at the one extreme and complacency at the other? No journey is guaranteed to be smooth, and long haul travel for ill patients⁹ such as those with cancer¹⁰ ranks among the most hazardous.

But perhaps the main concern for doctors is that the extra work involved in preparing such patients for travel can be substantial. Each holidaying patient may require special letters, forms, contacts, prescriptions, and treatment rescheduling, and it is fast becoming the norm here for entire clinics to be full of such patients. As such, the end of a clinic can all too often merely signal the start of many more piles of paperwork.

Compromises may be forged through honest doctor-patient communication. Help from organisations with expertise in patient travel¹¹ may become a growth area. Public sector doctors may elect to move into private practice, charge fees, and have shorter clinic lists so that extra time can be given for each client. But the ultimate solution may prove to be cultural rather than medical or economic. Grey nomads with metastatic cancer may have to come to accept—as the Rolling Stones sang at the end of the 1960s in *You Can’t Always Get What You Want*—that the needful rather than the wishful must sometimes be good enough.

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