Accountability, trust and informed consent in medical practice and research

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ABSTRACT – During the last 25 years public policy in the UK has aimed to replace 'club' cultures and their supposedly suspect reliance on trust between professionals and public with a new public culture based on accountability and 'transparency'. These transformations have changed both clinical practice and public health policy in deep ways. Are the new conceptions of accountability adequate? Are obligations to be 'transparent' any more than requirements to disclose information which overlook the need for genuine communication? Can demands for ever fuller informed consent improve accountability to individual patients and research subjects? Could we devise more intelligent conceptions of accountability that support more intelligent placing and refusal of trust? What might intelligent conceptions of accountability suggest about proper clinical practice, public health medicine and professional responsibilities?

KEY WORDS: accountability, bioethics, informed consent, medical ethics, patient autonomy, professionalism, public health, research ethics, transparency, trust

Widely held views about trust and accountability play a major role in many current debates on health and ethics. Trust is now often seen as obsolete, even dangerous, in public and professional life and particularly dangerous in medical practice. In a mature society, it is said, we should not take matters on trust, but rather establish robust systems of accountability, so replacing trust with structures that secure proper control and reporting. Supposedly, trust and trusting social relations have demonstrably failed; they masked a 'club' culture in which professional cosiness, producer capture and (at worst) corruption flourished. The only way to deal with these problems effectively, it is said, is to impose stronger and more detailed external legal, regulatory and financial disciplines.

This opposition to trust is fuelled by repeated emphasis on salient cases of untrustworthy action in public and professional life. Many of the most discussed cases have arisen in and around health issues, some of them around matters of public health. Public and journalistic debate points to examples of (supposedly) untrustworthy action (by doctors, scientists, civil servants, politicians and others) as leading contributors to environmental or health incidents and disasters, concluding that trust is obsolete in a modern democracy. We have all heard about the headlined scandals such as those at Alder Hey[1] and the Bristol Royal Infirmary[2] (although surprisingly few people can identify accurately just what was scandalous in each case). The correct belief that there have been scandals, dereliction, cover up and even corruption in medicine and biomedical research is then generalised. Other highly publicised cases are cited as further evidence, including some that arguably involved no misjudgement or malpractice of any sort, let alone scandal or dereliction.[3] Although the cases that have raised public concern are of various sorts, many concern public health issues, ranging from bovine spongiform encephalitis and *Escherichia coli* to mobile phones and the addition of fluoride to water supplies.

Although an accurate diagnosis of what has and has not been amiss would have to distinguish many different cases, a single remedy has been confidently prescribed for all cases in increasing doses. Britain has seen the rise and rise of the regulatory state across 30 years during which detailed, uniform, centralised forms of regulation and accountability have been prescribed for business and the public sector and for those who work in them. As the proponents of change see it, this distinctively modernist project of systematic, objective regulation is wholly justifiable. It has swept away the weak disciplines by which professions and professional bodies claimed – but failed – properly to regulate their members, replacing them with more objective, uniform, rigorous and transparent standards of accountability.[4] In the process, trust between professionals and the public has indeed been sidelined. But to would-be modernisers this is welcome, since they see trust as obsolescent, risky and in need of replacement.

Has this enormous transformation of institutional and professional life brought the promised benefits? Do detailed regulation and the new forms of accountability improve on practices that used to be trusted? Or are we barking up the wrong tree? I shall begin with general comments on trust and accountability, then turn to some problems that arise with trans-

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parency and informed consent procedures, and finally discuss some distinctive ethical problems that arise in public health medicine.

From stupid trust to stupid accountability

Trust has been widely criticised and rejected on the assumption that it is intrinsically immature, if not blind: a form of deference that could make sense only on the simplistic assumption that others have goodwill towards us. It is not, I think, surprising that if we start with an intrinsically unintelligent conception of trust we can find good reasons to reject it.

Unfortunately, the most widely recommended successor to this unintelligent conception of trust has been an equally unintelligent conception of accountability, usually reinforced with specific requirements for *openness* or *transparency*. The favoured form of accountability for the public sector is broadly *managerial*: it extends the new approaches to public sector management of the last 20 years into a new approach to public sector accountability and regulation. This is a curious conflation. Good management in the public sector, as elsewhere, is evidently desirable, but are there any reasons to think that good forms of accountability, in the public sector or elsewhere, should mirror the structure of good management? Accountability does not have to be managerial. There are evidently many non-managerial forms of accountability, ranging from corporate governance and democratic accountability to professional and bureaucratic accountability. What they have in common is that they provide ways of holding others to account for meeting – or for failing to meet – their primary obligations. Those with primary obligations are accountable when they have additional, second-order obligations to account for their performance to others and to demonstrate that they are discharging their primary obligations to an acceptable standard.

Managerial accountability

Managerial accountability is distinctive because it uses the tools of management to achieve accountability. It seeks to judge performance of primary obligations by setting targets, measuring performance against targets, scoring that performance and sanctioning those who do badly. Managerial accountability is a form of second-order management by which those who are ostensibly *not* managers, but rather regulators, funders or public bodies, set targets and standards from afar for others who manage and work in institutions.

Transparency

Transparency requirements are seen as supplementing managerial accountability by requiring that information about performance be made available not only to government departments and auditors, funders and boards but also to the wider public. Transparency is achieved in part by placing reams of documents on websites, so making them 'available' to the public at large. However, since many members of the public lack capacity, inclination and time to munch their way through a cornucopia of disclosed documents, transparency is usually supplemented by publishing simple numerical tabulations and league tables of indicators. These rankings do not, strictly speaking, enable anyone to tell whether a given institution – say an NHS trust or a primary care trust – is good or bad or well able to meet specific needs. Rather, they allow a wider public to tell whether a particular organisation scores above or below others of the same sort on meeting certain performance targets.

Audit culture

The proponents of managerial accountability and transparency claim that they jointly enable us to base judgement on objective criteria rather than on (suspect) expert judgement, on numbers rather than on narrative, and so dispense with trust. The new forms of accountability have been characterised by Michael Power of the London School of Economics and others as amounting to an *audit culture*.[5,6] He uses the term largely because, like financial audit, accountability takes a second-order view of what has been done. In my view, what is amiss with managerial accountability is not that it is second-order – all systems of accountability are ways of reaching second-order judgements about the adequacy with which primary tasks or duties are performed. What is wrong with managerial accountability is that it is, as Power shows, a *deliberately unintelligent form of accountability*. Rather than relying directly on reports based on knowledgeable inspection of what is actually done, the audit culture looks at simplified, derivative information, such as numerical performance indicators that can be compiled in standardised protocols (often literally by ticking boxes) and aggregated into league tables, thus ostensibly avoiding reliance on experts or professionals. Supposedly, this simplified information is objective, yet the indicators used are often not a particularly accurate representation of the complex performances they (supposedly) indirectly measure or represent.

As the opponents of 'club' cultures see it, managerial accountability and transparency are desirable precisely because they do *not* depend on the judgement of knowledgeable practitioners, whose professionalism may cloak slipshod performance and even corruption. The new accountability culture explicitly seeks to marginalise professionalism and professional standards.

Managerial accountability has, of course, been quite depressing for those subjected to its demands, not least in the NHS. They are told, mostly by pollsters and journalists, sometimes by patient groups and others, that they are not trusted and should not be trusted. They are subjected to criticism and suspicion; all too often they have a sense that the criticism and suspicion are simultaneously misplaced yet hard to rebut. Sometimes they find themselves held to account by performance indicators that they see as destructive of good professional performance. They find they are required to dance to multiple tunes simultaneously, but are judged by how well they move to the tunes that are most discordant. Some openly regret the loss of the old forms of accountability used in public service and professional work; others grit their teeth, remind themselves

that some accusations of professional cosiness were well founded, and soldier on.

Intelligent accountability and intelligent trust

I have come to think that both the diagnosis and the remedy proposed for these problems are unconvincing. The problems we face are not merely a justifiable loss or decline of trust. Managerial accountability and transparency are not obviously better than other forms of accountability or other ways of informing the wider public.[7] If properly structured, professional and public service approaches to accountability need not degenerate into a 'club' culture. Managerial accountability too often leads to an overly formulaic approach to accountability. It holds professionals and institutions to account in unconvincing ways, obstructing the intelligent placing and refusal of trust, whose decline is then cited as reason for introducing yet more intense managerial accountability. In reaching these conclusions I do not claim that accountability is unimportant. I argue for a more intelligent view of accountability that would support rather than supersede the intelligent placing and refusal of trust.

Consider in the first place some reasons why trust cannot be eliminated from institutional and social life. It is common to hear those who seek to deal with untrustworthy performance claim that we need not *revive* but *eliminate* trust. In its place we should put more oversight, tighter contractual relations, more detailed accountability and more specific and explicit consent procedures. If we were to ask how those who have oversight, set up tighter contracts or devise ever more detailed consent forms are to be held to account, presumably yet further layers of oversight and control would be proposed. Yet any regress of control mechanisms has eventually to end in a decision to place – or refuse – trust. Those who argue in favour of performance indicators, league tables and fuller consent forms would presumably claim that they provide a reliable and objective representation of something of importance, but in doing so they place their trust in those who devise and revise indicators, league tables and consent forms. Pushing trust back a stage, or several stages, does not eliminate the need to place – or refuse – trust. However many layers of control, process, measurement and informed consent we add, we have in the end to decide whether to place – or refuse – trust.

Pushing these thoughts a little further, we can see that trust is not generally a matter of affect or attitude, but of judgement and action in conditions of less than perfect information. To live our lives, we have to make decisions in the absence of full information or guarantees; it is pointless to sulk when the evidence is not perfect. The mirage of a trust-free world is based on the illusion that there can be an infinite regress of accountability, or perhaps on the fantasy that there could be a world in which risk and uncertainty are both wholly eliminated so that all our beliefs and decisions are based on complete evidence or complete control. It is true that in a world that provided complete evidence, or one that we could wholly control, we would not need to judge where to place our trust. Where we have complete proof or complete control, trust is redundant. But, setting fantasy aside, the real question is whether complex systems of managerial accountability, additional transparency and more detailed consent forms help members of the public to place and refuse trust with more discrimination.

Thus the serious question is not whether there is some way of achieving accountability that is miraculously trust-free – there is not and there cannot be. Rather we need to consider *which* forms of accountability best support *which* relations of trust. None of us is much interested in relations of blind trust; none of us would seek to be cavalier about ensuring professional standards. The would-be eliminators of trust are neither accurate nor coherent when they suggest that all trust must be blind trust and so should be eliminated. The serious question is how we can support well-judged trust that enables people to gain enough evidence – never, and necessarily never, total evidence – to judge whether to place or refuse trust. What would it take for us to have forms of accountability that allow people to make *intelligent* and *informed* judgements about where to place their trust? It is not hard to identify some things that would help.

Some things to avoid

Bogus numbers

As a first thought, we could do better if we could bring ourselves not to rely on bogus measurements. Numbers are useful where measurements can be made. The numbers in hospital budgets, employment figures or building plans are useful: here there are units with which to count, add, rank and so on. However, many of the numbers produced in the quest for managerial accountability and transparency introduce numerical performance indicators as surrogates, often rather flaky surrogates, for measurement: bogus numbers can produce spurious precision, but unfortunately lead to bogus accountability. Nobody believes that surgical procedures on differing patients constitute a unit of constant size.

Performance indicators and perverse incentives

Even if we get rid of bogus numbers, performance indicators may provide poor measures of complex activities. Time in hospital for differing patients undergoing a certain procedure provides good information about their average length stay in hospital, but not much basis for judging whether the hospital is performing well or poorly for its particular mix of patients with the relevant condition. Time spent in the waiting room can be accurately measured, but may not provide much of an indicator of quality of medical treatment.

Other performance indicators are worse than irrelevant. They create perverse incentives for institutions and professionals, so risk worsening rather than improving medical practice. Do we really want to measure surgical performance in ways that might deter surgeons from taking on risky cases, whose outcomes could damage their performance indicators? Do we really believe that making waiting time for non-urgent surgery a central performance indicator for hospital trusts is without perverse consequences?

Finally, even performance indicators that use genuine units and create no perverse incentives may have limited use. Position in a league table is a comparative measure, sometimes administratively useful but not a guarantee of quality – or lack of quality. Perhaps even the average surgeon is competent; perhaps even the best is not that good. Yet in medicine, as in the rest of life, we have reason to seek *quality* rather than to settle for *relative success*.

Some things to aim for

Intelligent accountability

Some criticisms of older ways of holding to account are serious. It is surely important to combat the old culture of smoke-filled rooms – not merely by shifting to smoke-free rooms – by combating professional cosiness and habits of closing rank in the face of failure or malpractice. How can we have serious and intelligent accountability that addresses the traditional problems of 'club' cultures? Can it be done without measuring performance by illusory units of account?

The answer is hardly startling. Professional and institutional performance can be assessed by those who are both sufficiently *informed* to judge what they assess and sufficiently *independent* to judge it objectively. Those assessments can be communicated to the wider community by those sufficiently literate to communicate *intelligibly* with the relevant audiences. It is only where these standards are met that we have an intelligent form of accountability that supports trustworthy performance and an intelligent substitute for transparency that supports the placing and refusal of trust.

In saying that accountability depends on *informed* judgement we accept that those lacking the relevant competence cannot judge complex matters adequately. Expertise is not dispensable. It is generally a matter of judging how well a *task* was performed; where tasks are complex, this cannot usually be reduced to judging whether some *target* was met. Complex tasks do not usually have a single or intrinsic target. Accountability for complex matters is therefore likely to be better if geared to judging the performance of tasks rather than to mechanical registering of scores on targets since the latter often do not correlate well with performance of the relevant tasks.

In saying that accountability requires *independent* judgement we claim that serious accountability cannot rely on insiders to judge quality of performance. Yet can judgement be both informed and independent? If we insist on extreme conceptions of what is needed for informed and intelligent judgement they will not be compatible. For example, if we deem anybody who has trained as a pathologist, a psychiatrist or a pharmacist *ipso facto* incapable of independent judgement of performance in these fields, we will have boxed ourselves into a position in which we have to choose between ignorant judgement or insider judgement. Equally, if we regard all outsiders as *ipso facto* incompetent to make an informed judgement of performance, we box ourselves into a position in which we have to accept ignorant judgement as the price of independent judgement.

We are generally not so stupid. It is not usually impossible to find outsiders with the necessary competence or expertise. Independence can be achieved by school examiners who are not teachers of the candidates, by university examiners who are employees of other universities, by health and safety inspectors who are not employees of the companies inspected and by auditors who are barred from selling further services to those whom they audit. Medical practice can achieve similar – or better – standards. Methods for securing the independence of those who hold to account may need improving, but improvement is neither impossible nor obscure. A large range of measures, including those set out in successive reports of the Committee on Conduct in Public Life (originally the Nolan Committee) are relevant.[8]

If we drop the artificial pretence that expertise and independence are intrinsically incompatible, we can set about securing intelligent forms of accountability by making sure that those who hold to account are appointed for their expertise and are strengthened by measures to secure their independence. We can look for robust ways of marginalising professional cosiness, laxness and impropriety, and establish ways to prevent and remedy poor practice. Professional judgement and the institutions and disciplines within which it is exercised need to be properly structured if they are to secure adequate independence. The Enron scandal illustrates the dangers of allowing auditors to enter profitable relationships with companies whose accounts they audit, so undermining independence by incentivising a 'soft' audit. Similar approaches can be used to bear down on lack of independence and impartiality in certification, appointing to posts, daily professional practice and investigating failure. In each activity, accountability for good practice must combine *informed* with *independent* judgement.

If we want serious and intelligent accountability, we cannot turn our backs on professionalism and expertise and settle for simplified 'box-ticking'. Equally, we cannot settle for cosy, unmonitored professionalism in which conflicts of interest persist unchallenged and professional solidarities swamp the needs of public service and patient care. We need do neither: we can support and maintain robust ways of monitoring standards, investigating failure, disciplining the slipshod and removing the incompetent.

To achieve these standards some professions and organisations may need to change a good deal and demonstrate that they have effective procedures in place for securing independent judgement. There may be good reasons to have 'lay' voices in processes by which poor performance is judged, to limit periods of accreditation, to require and make public declarations of interest and require those with conflicts of interest to stand down. In my view, better attention to securing the institutional conditions for independent judgement would do more to support the intelligent placing and refusal of trust than any amount of trying to replace expert with mechanical assessment of performance.

Transparency and communication

Securing intelligent accountability by institutionalising informed and independent judgement may not be enough for

accountability to wider audiences. Informed and independent judgements can of course be disclosed by making the relevant documents available, but many members of the public will lack competence, inclination and time to read or assess complex judgements. Transparency, it may seem, requires the simplified information provided by performance indicators, since they allow anyone to tell at a glance who comes first – or last – or in between.

This thought has two limitations: first, simplified information may mislead – which performance indicators often do. Thus disclosing these numbers and tables can hardly count as a way of supporting accountability to the wider public. Secondly, there is little reason to think that numerical rankings and tabulations are the only forms of simple information. For example, most parents would be able to read the narratives provided by OFSTED reports on schools and learn more from them than they can learn from school league tables – if not, perhaps, enough. Intelligible narrative can convey more than a league table. Still better, intelligible narrative combined with genuine two-way communication can provide opportunities to check and to challenge, and so to place, modify or refuse trust intelligently. Openness or transparency is an inadequate substitute for communication to the wider public because it is *only a matter of disclosure* of (selected) information; it neglects the needs of genuine two-way communication with actual audiences. It is hardly surprising if the public, the supposed beneficiaries of transparency, do not find that mere disclosure of information provides a basis for the intelligent placing or refusal of trust.

Individualism, autonomy and informed consent

As medical practice and biomedical research have developed over the last 25 years they have also tried to improve accountability to individual patients and research subjects by seeking ever fuller informed consent. Informed consent is seen as a natural companion to managerial accountability. Requirements to obtain informed consent secure accountability for procedures affecting individuals; managerial accountability and transparency secure accountability for medical practice in general.

Informed consent is usually said to be important because it operationalises so-called *patient autonomy*. It also has another, less lofty purpose in that it transfers (a measure of) responsibility from professionals to the supposedly autonomous patient, so providing (a measure of) protection for professionals and institutions if anything later goes wrong. Respect for 'patient autonomy', like managerial accountability, is typically seen as a welcome successor to reliance on patient trust. The story that we tell ourselves is that traditional doctor-patient and researcher-subject relationships were based on trust, that trust was often abused, and that we have dealt with the problem by ensuring that medical treatment and biomedical research do not take place without the informed consent of autonomous individuals which provides an ethically superior basis for medical practice and biomedical research.

However, the appeals to patient autonomy commonly used to justify informed consent requirements are usually obscure, if only because numerous conceptions of autonomy are in play and rarely distinguished. Contemporary conceptions of autonomy are much weaker than the classical Kantian conception of autonomy often invoked as reason for insisting on patient autonomy. Kant indeed linked autonomy closely to morality, even claiming that:

> Morality *is thus the relation of actions to the autonomy of the will, that is, to a possible giving of universal law through its maxims.*[9]

Although contemporary work in ethics and bioethics relies on much weaker conceptions of autonomy, many writers help themselves to versions of Kant's conclusion, then embrace the thought that respect for autonomy is the key to acceptable medical practice.

We can distinguish at least three ranges of ideas that might be thought to lie behind the claims that informed consent is needed to secure respect for autonomy.

Individual autonomy

On the simplest and weakest view, *individual autonomy* is only a matter of individual choice, and respect for autonomy only a matter of respecting individual choice. Respect for individual choice is likely to be morally important, but it is not (*pace* libertarians) likely to be the only thing that is morally important. For example, many choices harm self or others, are short-sighted, regrettable or irrational, unfair or unjust. An unconditional respect for *individual autonomy* is a highly selective and incomplete basis for ethics or for medical ethics.

Rational autonomy

In a second range of views, it is *rational autonomy* rather than mere individual choice that should be respected. Rational autonomy has been characterised in many ways. In general, action is said to be rationally autonomous if it reflects the deeper and more systematic aspects of an individual's life, identity, plans, character or even desires. These ways of characterising rational autonomy differ, but (stretching a point quite hard) all might be thought of as going some way towards the Kantian conception of autonomy in that all of them conceive of autonomous action not merely as spontaneous choice but as systematic or 'law-like' choice.

Rational autonomy therefore looks as if it might be morally more important than radically individualistic conceptions of autonomy, but it too is not likely to be the only thing that is morally important. Moreover, there are internal difficulties with many conceptions of rational autonomy and the underlying conceptions of rationality on which they are based. Therefore, we might reasonably be unsure whether morality can be equated with respect for each individual's deeper and more rational choices since these too can be morally inadequate.

The Kantian origins of these thoughts about autonomy do not set undue weight either on mere, sheer choice or on choice that reflects deeper and more systematic aspects of individual agents. It singles out the more complex and less individualistic notion

of choice on principle on which anyone could have reason to act. Kant's conception of autonomy as acting on principles that can be principles for all has some claim to provide a negative criterion of morality.[10]

However, in medical practice informed consent procedures are usually connected only to the weakest conception of individual autonomy, so offer only limited justification for medical interventions or for research. Also, where (as usually the case) the informing required for informed consent requires is equated with mere transparency (ie with the mere disclosure of information to patients or volunteers) even this limited justification begins to wobble. Disclosure does not guarantee comprehension, uptake or assimilation: what is disclosed may be not be understood and may be disregarded.[11] Informed consent is surely important, but its purposes are both exaggerated and obscured by attempts to justify it as the key to respecting patient autonomy.

An alternative and more robust way of thinking about informed consent procedures might build on the other morally significant purposes that they serve. For example, informed consent procedures allow patients and research subjects:

> *… to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress… or other ulterior form of constraint or coercion …*[12]

We may grasp more about the importance of informed consent procedures if we can link them to these morally solid requirements than by trying to link them to notions of 'patient autonomy' that are poorly explicated and themselves need justification.

How informed is informed enough?

Justifying informed consent requirements has also become more problematic in recent years as one influential and well-meaning public body[13] after another has tried to reformulate informed consent requirements with (supposedly) greater vigour and rigour. Two additional claims about informed consent are now widely made. The first is about the process of securing consent, the second about the content of the consent that should be secured. In current jargon, the first claim is that consenting should be *explicit*, rather than *implied* or *tacit*, the second that consent should be *specific* rather than *general* or *generic*. I shall consider the two supposed ways of improving consent in turn.

Explicit versus implied or tacit consent

The distinction between explicit and implied consent contrasts ways of consenting. Explicit consent typically relies on documents, signatures and formal statements; it may require witnesses who confirm that proper procedures for consenting have been followed. The formal procedures are typically designed to create enduring records, thereby reducing later uncertainty about the consent given and perhaps forestalling dissatisfaction, complaint or litigation. Patients and research subjects who consent explicitly to proposed interventions thereby accept that they cannot later claim they were injured or wronged and will not, if what is done accords with their consent, have grounds for complaint or litigation.

By contrast, implied consent is inferred from a patient's action. For example, agreement to blood being taken or having an injection is standardly signified by extending one's arm for the doctor to take the blood or give the injection. No documentation of the consent is required, although it would be possible (if strenuous) to introduce explicit consent procedures for minor and routine medical interventions.

However much we introduce additional explicit procedures and consent forms for interventions now performed on the basis of implied consent, explicit consent always relies on background understandings that remain implicit. The longest and most complex consent form cannot include a complete description of everything that will be done. Much is taken as understood, and consent based on those understandings can only be implied. No programme for replacing implied with explicit consent can be complete. All this is true for research subjects as well as patients: not everything can be made explicit.

Specific versus general or generic consent

The proposal that all consent should be specific rather than generic also has limitations. The distinction between specific and generic consent applies to the propositions to which consent is given rather than to the processes of consenting. For example, consent may be given to the removal of tissues or, alternatively, to the removal of a specific tissue – or even to the removal of specific tissue for a specific use such as diagnosis, cancer treatment or to determine the cause of death.

Unavoidably, the descriptions to which consent is given are always incomplete; it would always be possible to add more detail. Those who believe that informed consent should be highly specific need to explain *how* specific it has to be in order to constitute ethically adequate informed consent. Answering this question may be no easier than answering the pseudo-question 'How long is a piece of string?'. The difficulties created by these over-zealous attempts to 'perfect' informed consent are not merely theoretical. They lead to practical problems for all medical treatment, all research and many public health measures.

Informed consent, biomedical research and public health

These problems are most acute for retrospective biomedical research and public health. If consent has to be specific, it will constantly turn out that consent sufficiently specific to permit one piece of research will also be sufficiently specific to preclude other research. This is perhaps a coherent (although not necessarily sensible) requirement in the case of prospective research, but an absurd demand in the case of retrospective research.

Indeed, the only case where specific and explicit consent would be even approximately achievable in a research context would be for a single, well-defined prospective research for which volunteers are recruited *de novo* (eg a clinical trial).

Demands for specific consent *cannot* be met for research that uses past medical data or archived tissues for unforeseen or unforeseeable purposes. For example, the research that established that variant Creutzfeldt-Jakob disease (CJD) was a new disease could not have been done without studying tissue samples and clinical information from those who had previously died of other forms of CJD and who could hardly have been asked for specific consent to this project. For the same reason, specific consent cannot be achieved for research projects that analyse existing clinical data (eg secondary data analysis and epidemiology) or that draw on databases with multiple uses (eg BioBank UK).

Informed consent faces even greater problems in the area of public health: neither specific nor generic informed consent can be required in reaching decisions about public health provision. Public health provisions are public goods, in the economist's sense of the term. Consumer goods – for this purpose we may look on clinical care as a quasi-consumer good, since it is provided to individuals – can be provided on the basis of individual consent. The difficulties that informed consent requirements raise may prove irresolvable in some cases and resolvable in others. By contrast, where public goods are provided for *any*, they have to be provided for *many*. Some types of public good must be provided (or not provided) for whole populations; others may be provided (or not provided) for more restricted groups. Public goods such as road, food and water safety, safe medicines and measures that protect against infection *cannot* be tailored to individual choice, so informed consent *cannot* be ethically required for their provision.

The implications of these thoughts about public goods are wider than may at first appear. For example, clinical care itself has to be provided to standards and formats that are also largely fixed and uniform which *cannot* be varied on the basis of individual choice. The scaffolding of professional training, institutional structures, public funding, physical facilities and a blood transfusion service are all public goods. Another example is that security against infection might in some circumstances require universal monitoring of those who may have been exposed, mandatory vaccination (where a vaccine is developed) and restrictions on free movement or quarantine. Making public health measures such as these compulsory would hardly have seemed controversial a century ago. It has come to seem controversial on the basis of an illusory assumption that all medical provision, and with it public health provision, can be organised on the basis of informed consent of individuals. This is not possible.

Public health provisions can reflect democratic process, and thereby certain forms of collective or democratic choice, but they *cannot* be geared to individual choice. Informed consent can play no part or, at most, only a minor part in large areas of medical practice. Equally, biomedical research presupposes a background scientific culture, laboratory provision and professional skill which *cannot* be varied with individual choice. If we insist that all medical practice requires informed consent, the entire field of public health provision and all retrospective research would have to close down.

Conclusions

In this paper I have not argued against accountability, communicating information to patients and research subjects or informed consent, but against unintelligent views of accountability, attempts to reduce communication to mere disclosure and views of informed consent that lack justification or coherence. If we want accountability that achieves its aims, we must look for intelligent and independent ways of holding professionals and institutions to account. If we want to extend accountability to the wider public, information must be communicated in ways that allow for check and challenge. If we want a sound ethical framework for public health medicine and biomedical research, we will not make much headway by trying to extend informed consent requirements to areas where they cannot be deployed. Neither accountability nor informed consent is improved by aiming for high detail and specificity. More is not always better, and demanding the impossible is always worse.

Notes and references

1 The Report of the Royal Liverpool Children's Inquiry. http://www.rlcinquiry.org.uk/

2 The Bristol Royal Infirmary Inquiry. http://www.bristol-inquiry.org.uk/

3 For example (a) the refusal of a health authority to give 'child B' an experimental cancer treatment, (b) the demand that a set of single vaccine inoculations replace MMR.

4 Moran M. *The British Regulatory State: High Modernism and Hyper-innovation*. Oxford: Oxford University Press, 2003. I am deeply indebted to this work which offers a detailed and dispassionate account of those enormous transformations.

5 Power M. *The Audit Explosion*. London: Demos, 1994. See also http://www.demos.co.uk/catalogue/auditexplosion–page115.aspx

6 Power M. *The Audit Society: Rituals of Verification*. Oxford: Oxford University Press, 1997.

7 They may even be worse. Michael Power writes in *The Audit Explosion*: 'Audits do not contribute automatically to organisational transparency. Despite the fact that audit talk is driven by demands for greater transparency of organisational and individual action, the capacity of audit to deliver this is problematic. Often the extension of audits can make organisations more obscure, and the audit process itself remains publicly invisible despite the commitment to making organisations transparent'.

8 See http://www.public-standards.gov.uk/

9 Kant I. Groundwork of the metaphysics of morals, 1785. In: Gregor MJ (translator) *Kant's Practical Philosophy*. Cambridge: Cambridge University Press, 1996;**4**:439.

10 For more detail on conceptions of autonomy, see O'Neill O. *Autonomy and Trust in Bioethics*. Cambridge, Cambridge University Press, 2002.

11 The problem is not merely that some patients are not competent to consent – a difficulty much written on in medical ethics – but that massive empirical evidence indicates that patients and research subjects with high cognitive competence do not assimilate a significant proportion of the information disclosed to them.

12 This formulation is used in the Nuremberg Code. http://www.ushmm.org/research/doctors/Nuremberg_Code.htm. For a note on the Code's historical context see http://www.ushmm.org/research/doctors/code_expl.htm

13 These thoughts are well-entrenched in international documents. See: The European Convention on Human Rights and Biomedicine, 1997 (http://conventions.coe.int/treaty/en/Treaties/Html/164.htm) which

requires specific and explicit consent to research: 'Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being ... and the necessary consent ... has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.' Similarly, Article 22 of the 2002 revision of the Declaration of Helsinki (http://www.wma.net/e/policy/b3.htm) which requires: 'In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed'. For the history of the Declaration, see http://www.wma.net/e/ethicsunit/pdf/chapter_4_decl_of_helsinki.pdf