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Monash Bioethics Review

ISSN 1321-2753
Volume 33
Number 1

Monash Bioeth. Rev. (2015) 33:29-44
DOI 10.1007/s40592-015-0017-z

Springer

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ON GAMETES AND GUIDELINES

The limits of evidence: evidence based policy and the removal of gamete donor anonymity in the UK

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Published online: 3 March 2015

Abstract This paper will critically examine the use of evidence in creating policy in the area of reproductive technologies. The use of evidence in health care and policy is not a new phenomenon. However, codified strategies for evidence appraisal in health care technology assessments and attempts to create evidence based policy initiatives suggest that the way evidence is used in practice and policy has changed. This paper will examine this trend by considering what is counted as 'good' evidence, difficulties in translating evidence into policy and practice and how evidence interacts with principles. To illustrate these points the removal of gamete donor anonymity in the UK in 2005 and the debates that preceded this change in the law will be examined. It will be argued that evidence will only ever take us so far and attention should also be paid to the underlying principles that guide policy. The paper will conclude with suggestions for how underlying principles can be more rigorously used in policy formation.

Keywords Public policy · Gamete donor anonymity · Evidence based policy · Evidence based medicine · Principles · Reproductive technologies

1 Introduction—the rise of evidence in medicine and policy

The rise of evidence based movements that attempt to ground practice in some form of evidence, and the rhetoric that has surrounded this, has been a dominant trend in both medicine and public policy in the last 20–30 years. Arguably, the use of evidence to make decisions is not a new concept. However, the way evidence is

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conceptualised and how it is operationalised in practice have changed and this section will give a brief overview of these changes.

In providing this overview of the use of evidence in both clinical medicine and public policy it must be noted that the term 'evidence' incorporates many different kinds of 'data' or information. In clinical medicine evidence might be the results of a randomised control trial that indicate the effects of a particular treatment, or an economic assessment of two different treatment regimes. The views of stakeholders can also be a form of 'evidence' and public consultation has become a feature of both changes in medical services and social policy initiatives. Therefore, there are many different types of evidence that may be brought to be bear on policy and clinical decisions and what is counted as relevant or sound evidence and how the different forms are prioritised is a 'political' decision (Marston and Watts 2003). In the example of policy formation I draw on, changes to gamete donor anonymity, many different forms of evidence were used ranging from user, public and clinician/professional views; clinical evidence of welfare of the child to international legal comparisons. This illustrates that in policy debates there are a multitude of competing 'evidences' and how to weight these to produce a sound policy outcome requires making a judgment about what evidence is seen as important and relevant.

1.1 Evidence based medicine

The aim of EBM is to ground medical practice on good evidence so that the treatments patients receive are both the most effective and the least harmful. In this way, patients, so it is claimed, will get the 'best' medical treatment based on the current state of knowledge. When evidence based medicine (EBM) started to become common currency in the early 1990s it was readily accepted, at least in principle, as it rests on an innocuous truism, a point amusingly made by a modern Socrates questioning Enthusiasticus, a supporter of EBM. 'I thought that all doctors were trained in the scientific tradition, one tenet of which is to examine the evidence on which their practice is based. How then does this new evidence based medicine differ from traditional medicine?' (Grahame-Smith 1995, p. 1126) EBM did not differ from traditional medicine because it insisted that medical practice should be based on evidence, rather EBM took a different definition of good medical evidence and what constituted the appropriate mechanisms for finding and evaluating that evidence. As Davidoff argued, 'what has changed in clinical medicine in recent decades is the very nature of clinical evidence itself' (1995, p. 727).

As medical evidence has changed, with more reliance on experimental methods such as randomised controlled trails (RCTs), so have ways of appraising evidence. One way of formulating good or better evidence is to use systematic reviews. These synthesise the results of a number of studies to overcome the possible bias of relying on one study's results and produce a meta-analysis of the results. To foster this kind of evidence development, The Cochrane Collaboration was established in 1992. This produces Cochrane Reviews, systematic reviews of primary research in health care and policy to inform practice.

EBM now underpins the development of policies and guidelines in many medical systems. In the UK various bodies have been established to set standards and

policies for the National Health Service (NHS). The National Institute of Clinical Excellence (NICE), for example, was set up to systematically appraise evidence on medical interventions, drugs and treatment pathways.

1.2 Public policy and evidence

Policy makers have also embraced a concept of evidence based policy (EBP). Like EBM, EBP seems, prima facie, to be a good thing and it is hard to imagine policy being made that ignored evidence or did not seek to engage in any form of evidence review. Florence Nightingale is often said to be one of the first people to point out the need for evidence when she criticised the British Parliament for not thinking about the effects of the policies it implemented, calling them 'all experiment' (McDonald 2003). Blair's Labour government coined the term 'what matters is what works,' and questioned what they called 'ideology based decision-making'. Instead the, 'government must be willing constantly to re-evaluate what it is doing so as to produce policies that really deal with problems; that are forward-looking and shaped by the evidence rather than a response to short-term pressures' and make, 'better use of evidence and research in policy' (Blair and Cunningham 1999, p. 15 & 16). The Campbell Collaboration, an organisation similar to the Cochrane Collaboration, was established in 2000 to provide systematic reviews of the research evidence on social interventions, such as crime and justice, education and social welfare.

2 Using evidence in practice

There are three important issues to consider when thinking about EBM and EBP: what counts as 'good' evidence; how can evidence be translated into practice; and what is the role of underlying guiding principles. I shall consider these in turn.

2.1 What counts as 'good' evidence?

How to determine what evidence is valuable and how to assess the quality of the evidence are key questions for EBM and EBP. There are a number of types of evidence and evidence producers that might be relevant in medicine and policy: academic research, commercial research bodies, statistical reports, policy evaluation, economic modelling, and expert knowledge (committees and advisory groups), lay knowledge (public consultations), and service user input for example. As Marston and Watts note the relative status of these different forms of evidence is important and often lay knowledge is given less priority in policy making than expert views and research evidence. Therefore, 'far from being a neutral concept, evidence-based policy [and medicine] is a powerful metaphor in shaping what forms of knowledge are considered closest to the 'truth' in decision-making processes' (2003, p. 146).

As Greenhalgh et al. note in their critique of EBM, the evidence has become 'distorted by vested interests.'

> the drug and medical devices industries increasingly set the research agenda. They define what counts as disease….They also decide which tests and treatments will be compared in empirical studies and choose (often surrogate) outcome measures for establishing "efficacy" (2014, p. 2).

What gets to be researched and counted as evidence is not a value neutral accumulation of facts and these 'facts' can be seen as social constructions. There are many levels on which facts could be argued to be social constructions (Latour and Woolgar 1986). Molewijk et al. (2004) give an example of how the production and presentation of 'scientific' information contain normative values and the information presented to patients on relative risks and benefits of treatments is not value neutral but inherently normative. Therefore, even in the area of clinical research, evidence is not necessarily divorced from the social context in which it was created.

Utilising EBM and EBP involves making choices over what kind of evidence is seen as worthy of influencing decisions. In clinical research evidence hierarchies have been created to grade the relative strength of evidence. Systematic reviews often only include what are deemed as high quality studies conducted using certain study designs such as RCTs. However, as EBM and EBP have developed there has been a questioning of evidence hierarchies and the recognition that good evidence cannot be determined by study design alone (Guyatt et al. 2008a, b). Consequently, there have been moves to construct 'matrixes of evidence' that focus on the question of 'does this work?' rather than 'is the evidence of good quality?'

The Grading of recommendations, assessment, development and evaluation (GRADE) group have considered how evidence might inform a course of action and move from a sole consideration of the quality of evidence to how applicable and useful the evidence is in formulating a recommendation. They argue for the inclusion of values and preferences and recognise that when applying evidence to practice how different groups value particular outcomes versus risks is very important. As Guyatt et al. note:

> Given the paucity of empirical examinations of patients' values and preferences, well resourced guideline panels will usually have to rely on consultation with individual patients and patients' groups to gain insight into patients' values. Less well resourced panels must rely on their intuitive impressions of these values. In either case, when a recommendation is particularly dependent on values and preferences, panels must state the values underlying their decision (2008a).

This represents a change in what kinds of 'data' are seen as useful evidence and the move to include users and stakeholders in guideline development is part of the evolution of EBM and EBP. NICE involves the public and patients in its guidelines by: giving opportunities to comment on proposals, joining a NICE committee, or suggesting topics for guidance for example. Patient groups can also be involved in guideline development. Such stakeholder involvement can be particularly useful in social policy, as the acceptability of interventions and policies to the user groups is an important part of their success. This involvement raises issues about the function and utility of using this kind of evidence in decision-making processes

(see Frith et al. 2014). Are patients' views useful because they present neglected viewpoints? Or, at the level of public policy, is such public involvement important because it extends the democratic process of decision-making? What is appropriate and useful public involvement depends on the context and the type of decision under consideration. However, it is now a widely accepted view that public and patient involvement is critically important for health and social policy development (Williamson 2014), and the main difficulty is how to organise it effectively to create evidence that is useful for policy making.

2.2 Translating evidence into practice

In reality policy is more 'evidence-influenced' or 'evidence-aware' than evidence based (Nutley and Walter 2002). There are numerous problems with translating evidence into practice. First, there is the problem for EBM and EBP of how research evidence can be actually used in everyday practice and there is a huge body of research into how that 'translational gap' can be bridged (Rycroft-Malone and Bucknall 2010). Second, there is often simply not the evidence available to enable all treatment or policy decisions to be based on evidence. Many medical interventions have never been the subject of a clinical trial or any kind of research. In social policy the areas of uncertainty are arguably even greater as there are unlikely to be well conducted RCTs (or other forms of research) and there are many circumstances where such experimental research designs would be difficult to carry out due to ethical, practical and/or financial reasons. Further, most social policy initiatives are not starting from scratch, they are policy changes rather than policy initiatives. These policies have to amend or incorporate existing measures so meaningful studies would have to be based in a specific context to capture this contextual sensitivity and therefore the results might not be generalizable (Pawson 2006).

Third, how do we decide the evidence is good enough to act upon? As Pawson notes, often time is not given to researchers to fully evaluate interventions and in order for research to influence policy the research has to have been conducted before the initiation of the policy. Oakley gives a fascinating account of some of the practical obstacles facing large scale evaluations of social policy interventions that took place in the US in the 1950s, 1960s and 1970s. One of the main problems was that it was hard to design studies that produced clear findings, on whether the programme (intervention) worked or not, and many studies produced zero effects. 'The initial enthusiasm and commitment of the evaluation community to systematic experimentation was transmuted into despair and despondency when few concrete findings seemed to emerge' (Oakley 2000, p. 232). Therefore, proving something works, or not, is not straight forward in the realm of social interventions. Although this type of experimentation fell out of favour in the US (for this and others reasons), as Oakley observes, this was not due to any inherent problems with applying experimental methods to social interventions, it is possible to do large randomised studies on social interventions—there just has to be the will to fund and support such studies.

2.3 The role of underlying principles

Often what is the best policy or policies to implement are not questions that can be answered by evidence alone. A commitment to a fairer society, or more market mechanisms are philosophical positions that are established by argument rather than evidence. They are often supported by claims that they will improve quantifiable aspects of life—but at root they are beliefs about the world and how one should live. To take a simple example, Archie Cochrane (Cochrane and Blythe 1989) did a case controlled study on whether caning school boys for smoking acted as a deterrent and the results of his study suggested that it did not. This might then suggest a policy of not caning boys for smoking, but this presupposes that the aim of caning was deterrent rather than a mechanism of punishment. If the aim of caning was punishment, then the findings of the study are irrelevant, if the aim was to be a deterrent then the results are a good reason to stop the practice. Therefore, the aims of an intervention are often established by argument and one's principles, and the evidence becomes important when trying to see which means are best to reach those aims.

One initial attraction of EBM and EBP was that values or ideology, as it is called in the policy making arena, are seen as playing less of a role. Underlying the attraction of EBM and EPB is the idea that we will do what works not what is indicated by our ideological stance. The idea that EBM and EBP can eradicate values from the decision-making process has been heavily criticised (Frith 1999; Kerridge et al. 1998; Ashcroft and ter Meulen 2004). Evidence has to be combined with principles and values in order to make decisions, both for practical reasons (the evidence deficit) and for conceptual reasons (that evidence does not tell us what to do). The claim that by using evidence that is of a higher quality, policy and clinical decision making can be more objective and scientific is, arguably, a confusion between two different things, the quality of evidence and the decision. While a decision that is made on the basis of good evidence may be of a higher quality, it will not be more objective in the sense that it is independent of value judgments or our perceptions and priorities. The evidence of effectiveness may form the basis of a very good reason for pursuing a particular course of action, but value judgments are needed to tell us whether we *should* take that course of action and these values are guided by what underlying principles we want to foster. Therefore, policy cannot be solely based on evidence, principles play an important, and inevitable, role in the decision-making process.

Having considered how evidence is used in medicine and policy and the potential difficulties, both practical and conceptual, with making medicine and policy fully evidence based, I now want to look at a specific example of policy formation.

3 Donor anonymity

In April 2005 gamete donor anonymity was removed and all future donors had to donate under conditions of non-anonymity. Donor offspring would, once they reached 18, be able to access identifying details about their donor (assuming they

had been told that they were donor conceived). This was a major change in policy in the field of reproductive technologies. In this section I want to examine how evidence was used in this process, to illustrate the points made above. This account will draw on documents that are publicly available (such as government documents and the responses of professional bodies) that chart the explicitly given reasons for policy change; this does not tell the whole story but rather the 'public' account of why and how the policy was changed, consequently it is recognised that any hidden narratives are not revealed by this account.[1]

The 1991 Human Fertilisation and Embryology Act 1990 (the Act)[2] governs donor conception in the UK.[3] One of the Act's key provisions was the legal protection of donor anonymity. Accepted practice prior to this, at least until the late 1980s, had been to safeguard the donor's identity and also to advise people to keep secret the fact of donor conception both from their social circle and the child (RCOG 1987). The basis of the 1990 Act was The Warnock Committee, set up to consider the new developments in reproductive medicine. The Report challenged the primacy of secrecy on the grounds that secrets in families were unhealthy and donor-conceived people were entitled to some information about their origins. However, they were wary of undermining donor anonymity as there were fears that doing so would compromise family functioning in families that had used donor conception (Department of Health and Social Security 1984).

The Committee recommended that—on becoming adults—donor-conceived people should be provided with some non-identifying information about their donor. This recommendation was incorporated in the 1990 Act which endorsed the principle of donor anonymity and made provisions for some unspecified non-identifying information about the donor to be released to donor-conceived people reaching the age of 18. Despite maintaining anonymity, the government signalled the possibility of future change and drew parallels with the history of adoption legislation that had allowed adopted people to obtain their birth records in 1976. The government indicated that donor conception might, in time, follow a similar path (Department of Health and Social Security 1987; Bottomley 1990).

Almost a decade after implementation of the 1990 Act, there was a human rights challenge to the 1990 legislation in the English High Court. It was claimed that the statutory enforcement of donor anonymity contravened the right to 'respect for private and family life' guaranteed by Article 8 of the 1950 European Convention on Human Rights (Rose and Another versus Secretary of State for Health and Human Fertilisation and Embryology Authority 2002). While this case was being heard, the government launched a public consultation in December 2001 seeking views on what—if any—information should be provided for donor-conceived people.

The public consultation ended in July 2002 and in early 2003 the government made public the substance of the responses (Department of Health 2003). The consultation received 237 responses from a variety of groups (donors, offspring,

[1] With any social change it is hard to give definitive reasons why such a change happened and there will always be debates over what significance to give certain events and what were the main causes.

[2] The 1990 Act was revised in 2008.

[3] This section draws on Blyth and Frith (2008).

those who had had treatment, clinics and organisations (such as groups representing the medical profession). A significant majority of respondents endorsed the provision of non-identifying donor information to donor-conceived people, 211, while a smaller proportion of respondents, 137, proposed the complete removal of donor anonymity. The reasons given for supporting non-anonymity were: it is a basic human right; to meet emotional needs of offspring; society should not withhold this information; and more openness was needed. The HFEA in its response to the consultation supported greater openness in this area and the removal of donor anonymity. They argued that the potential loss of donors that might result, one of the main arguments used against removing anonymity, was not a strong enough reason to maintain anonymity (HFEA 2002).

The professional associations involved in donor conception were not in favour of the removal of donor anonymity (Blyth and Frith 2008). The British Fertility Society (BFS), for example, in their response to the consultation recommended that non-identifying information was provided. They also noted the lack of evidence in this area and concerns over recruitment. However, they did state that the BFS:

> Generally supports the concept that we move towards a policy of openness about donor anonymity in due course, and recommends a proactive approach in preparing both donors and recipients for this, through the provision of information, advice, support and counselling (BFS 2002).

The overall response to the consultation was limited and the government was particularly concerned about the lack of responses from donors and assisted conception units and it was decided that more evidence should be gathered before any decision was made. Responding to the consultation, the minister for public health, Hazel Blears, said:

> This is a complex and highly sensitive area—where the rights of the child have to be balanced with the rights of the donor. Having carefully considered the consultation responses, and bearing in mind the potential impact that such a measure could have on infertility treatment services, I have concluded that at this stage we need to have a wider debate on this (Blears 2003).

As part of these investigations, a questionnaire designed by the DH was distributed to donors via licensed infertility treatment centres.[4] The questionnaire sought information from donors on:

Their response to the future removal of donor anonymity.
Their willingness to donate should donor anonymity be removed.
Their knowledge of other potential donors.
Their perception of the main issues or question.
Their suggestions for recruiting identifiable donors (Frith et al. 2007).

Of the 133 questionnaires that were analysed, just over one-third (47) of respondents identified concerns regarding the future removal of donor anonymity. A

[4] See Frith et al. (2007) for an analysis of this data.

similar proportion (48) declared they were either not worried about, or were pleased with, the removal of anonymity (Frith et al. 2007).

The Department of Health also surveyed infertility clinics and received 42 responses. Summarising the findings at the HFEA conference in January 2004, Melanie Johnson (Minister for Public Health), said:

> Most, but not all, of the responses to us from UK clinics in our programme of work said that they were opposed to the removal of anonymity. Other clinics were concerned that not enough donors would come forward, or that that not enough of the right donors would come forward, that patients would have to wait longer, that patients wait a long time already, that clinics' services to patients would be impaired, that if anonymity is removed people would not tell their children that they were donor conceived, and that it is not in the interest of the children (Johnson 2004a).

Despite the clinic responses, in the same speech, Johnson announced that with effect from 1st April 2005, all new donors would be required to agree to their identity being disclosed to any individual conceived as a result of their donation, if so requested, once they reached 18 (Johnson 2004a).

4 Discussion

The government highlighted a number of strategies for gathering evidence and issues that needed to be addressed when considering changing the policy on gamete donor anonymity. Johnson summed these up in her speech to Parliament:

> The decision that it is right to remove donor anonymity has been informed by a public consultation on the provision of information to donor-conceived people; a programme of work with clinics and donors; consideration of the position in other countries; and a comparison with the information available to adopted people. We have also listened to the voices of donor-conceived people (Johnson 2004b).

How the government gathered and used the evidence in this policy debate illustrates the complex issues raised by trying to base policy on evidence. I will relate these specific issues to the wider concerns with EBM and EBP I discussed in the previous section: what counts as good evidence; the difficulties with translating evidence into practice; and the role of underlying guiding principles.

4.1 What counts as 'good' evidence?

The initial type of evidence the government drew on was evidence they had collected themselves on public and stakeholder views. The DH began the policy review by organising a public consultation, a method that has often been used in this area. The HFEA has used public consultations for a number of issues notably sex-selection for non-medical reasons and more recently mitochondrial DNA transfer (HFEA 2012). How useful the evidence gathered from a public consultation is

uncertain, as it is often argued that just because the 'public' agree or disagree with something this should not determine what should be done. However, such consultations are not attempting to provide a democratic decision in the sense the majority agree or disagree, as clearly the 237 responses did not constitute a representative sample of the UK population. Despite the low number of responses, public consultations can confer some legitimacy on a policy decision by providing a form of open process and an indication of the concerns of key stakeholders.

This type of evidence, created by consultations and surveys,[5] raises the problem of what to do with the responses once canvassed; it is unclear what weight to give the different voices and what opinions to take into account. Both the public consultation and the survey of clinics found little support for changing the policy on non-anonymity.[6] Hence, taking stakeholder views as evidence in policy debates is not straightforward: how do we get access to the views of stakeholders adequately (i.e. improve response rates to consultations)? And when we have them what weight do we give them? As seen in this example, the government chose to ignore certain views and prioritise others and the reason for this will be considered below, when underlying principles are discussed.

The DH chose to use this type of evidence, a public consultation and surveys of stakeholder views they conducted themselves, to inform their deliberations, and any evidence appraisal involves choices over what to take as relevant and useful evidence. These choices can always be criticised and disagreements over what counts as the 'right' evidence to use often characterise policy debates. For example, the DH's use of evidence was criticised by the House of Commons Science and Technology Select Committee during 2004 and 2005 in its review of the 1990 Act. 'We regret the Department's poor use of evidence in policy-making and its failure to commission and have published the necessary research underpinning its decision on the removal of donor anonymity' (HoC 2005: Para 154). Which the government countered by arguing they had carried out sufficient evidence gathering and summaries of both the consultation and surveys were provided (DH 2005).[7]

4.2 Translating evidence into practice

The evidence the DH used, public consultation and surveys, was not academic research based on literature reviews or research summaries. This type of evidence is commonly used in policy, where policy makers commission their own research rather than rely on the existing academic literature. Why academic research was not

[5] The lack of response to the public consultation prompted the DH to launch further information gathering in the form of surveys of donors and clinics.

[6] The medical professions' view was similar, not to change the policy and remove donor anonymity. These views were discounted and the medical professional groups used the review of the 1990 Act undertaken by the House of Commons Science and Technology Select Committee during 2004 and 2005 to reinforce their objections (BFS 2004; BMA 2004; RCOG 2004).

[7] The DH did not publish any reports from the surveys of clinics and donors they carried out and the summary of the clinic responses by Johnson was very cursory. The donor responses were only published in 2007 after researchers were allowed access to the data (Frith et al. 2007) and therefore after the decision had been made.

used more rigorously in this debate shows some of the problems with translating academic research findings into practice: existing academic research might not ask the right questions, engage the right stakeholders or address the key issues and therefore not provide the particular answers policy makers are looking for. To gather new data, policy makers often prefer to commission their own research from non-academic organisations because academic research takes a long time, and commercial research companies can move faster and produce reports quicker.

In the light of the criticisms of the DH's evidence use, would a more rigorous, systematic review of the research evidence have led to different policy conclusions? Should the government have commissioned a review of existing research evidence? Such a review might have been, with hindsight, a good idea and would have set to rest some of the criticisms of the policy change. However, practically whether a synthesis of the evidence on this topic would have made a significant difference to the outcome is debatable.

At the time the policy review took place there was a lack of evidence on the effects of donor anonymity in terms of disclosure to offspring, whether a system of non-anonymity is better for donor offspring and the effects of non-anonymity on donor recruitment. As noted above this is a fundamental problem with EBM and EBP, that there is a lack of evidence on which to base many decisions. The Nuffield Report on donor conception, published in 2013, stated that the evidence in this area is still patchy and there was even less evidence over 10 years ago. There do seem to be some trends developing from the current evidence, such as increased disclosure to donor conceived children; telling the child when they are young appears to be beneficial; and both types of family (those who disclose and those who do not) appear to function well (Nuffield 2013). But these trends were not so apparent in the early 2000s. Further, as has been noted (Blyth et al. 2012), evidence in this area is beset with a number of difficulties: much of research is conducted on those conceived from sperm donation and it is a point of discussion if conclusions can be generalised to egg and embryo conceptions; studies often suffer from methodological limitations; and there are few long term follow up studies (Blyth et al. 2012). Therefore, whether there would have been enough evidence and if it would have been classed as robust enough to base policy on is debatable. Using the GRADE criteria, any recommendation made on the basis of this evidence would only have been 'weak'.

4.3 The role of underpinning principles

A key element in policy debates is the underlying principles that are used, how the debate is framed and who is seen as the main party to safeguard. In the case of the debate over donor anonymity policy, the main party was donor offspring. As Johnson said: 'Our conclusion is that the interests of the child are paramount (Johnson 2004b). This focus on the best interests of the child produced by gamete donation is something that is justified by argument rather than appealing to evidence. The government chose to frame the debate in terms of the best interest of the child rather than the best interests of the medical profession (and the smooth operation of their donation programmes) or the best interests of those going for treatment. The best interests of the child was seen as being promoted by the child's

right to know identifying information about their donor and this became one of the main arguments used in the debate. As Blears said at the time of the public consultation: 'I think there is a strong argument in principle that donor conceived children are able to find out the identity of their donor' (Blears 2003). It is such 'in principle arguments' that play a key role in policy debates and frame the questions that evidence is brought into answer. Therefore views that did not support non-anonymity, such as those of the medical profession, were not taken into account and evidence on donor recruitment issues became redundant.

Drawing parallels with adoption was another area that was addressed by argument rather than evidence and was used in support of the law change. Johnson when setting out the policy change to Parliament said:

> The position of donor-conceived people should be aligned more closely with that of adopted people, with access to identifying information about their donor when they reach age 18 (Johnson 2004b).

The legitimacy of drawing such parallels have extensively been debated (Frith 2001). Clearly, the parallel is not an exact one, but what one chooses to see as similarities or differences is very much dependent on one's perspective on the issue of donor anonymity and which underlying features of both practices one choses to focus on. Those who argue for greater information giving in donor conception see the parallel as a strong one and those who see gamete donation more akin to a medical technique to create a pregnancy see it as weak. Therefore, how applicable evidence from other areas is and the value of making comparisons between different practices, are debates that are highly influenced by the underlying principles that are felt to be important.

5 Applying principles in policy debates

If this point about the importance of principles is accepted, then how can principles be appropriately incorporated in policy developments? One of the attractions of EBP was that it would move policy away from vested interests and ideological commitments to produce policy that worked. As was noted above evidence is crucial in determining what works, but deciding what to do, what we want to work, is a question that cannot be answered by the evidence alone. The fear with appealing to principles or value judgments is how do we adjudicate between these different principles? How do we make a decision on which principles to adopt and how do we defend different ethical world views? How, in essence, do we deal with moral pluralism?

Moral pluralism is often seen as a feature of modern life (Rawls 1993; Parker 2000). Engelhardt's (1996) argues that the secularisation of western societies has had a profound effect on the ability of a society to institute any widespread moral advice or policies.

> The Enlightenment hope of secular bioethics has gone aground on the postmodern recognition of competing moral narratives and accounts, among which choice in a principled fashion has not proved possible without begging

> the question of which moral vision should give guidance. The question has then become whose moral consensus should be recognized as the moral consensus to guide policy (2002, p. 10).

For Engelhardt, as there is no general moral vision or position, any agreement will only be partial to those who uphold the underlying position. Those who hold another position will be left out and what comes to be the prevailing policy is largely a matter of power and politics rather than morals.

In answer to Engelhardt's problem of a lack of a common moral vision that besets policy decision-making, Moreno contends that there is enough common ground in society to allow the formulation of a consensus on policy decisions. Moreno argues that, 'the moral authority of consensus in bioethics must be understood within the framework of liberal political philosophy to which our society subscribes' (1995, p. 143). In Moreno's view bioethical consensus is justified by 'honouring' principles that arise out of a political liberalism and that such principles are upheld by our society.[8] Moreno uses Rawls' term 'over-lapping consensus', that members of a pluralistic society will agree on some values, but will not all agree on the same ones. For Moreno, as long as the group broadly upholds liberal values, such as respect of personal autonomy, and accords, 'with the general conditions that govern the conduct of this kind of process' (1995, p. 63) then the group has as much moral authority as is possible in a liberal society. Thus, according to Moreno, this is the 'moral vision, in Engelhardt's sense, on which moral consensus on policy decisions can be based.

I agree with Moreno that we can have agreement on certain substantive values and that these can be debated and discussed to see which principles we want to uphold in any particular policy decision. The HFEA, for example, in its review of gamete donation policies in 2011, set out a list of key principles that they thought should guide the review (such as welfare of the child, altruism and fairness) (HFEA 2011). Althought, as Wilkinson says there are problems with such an approach,

> When we appeal to 'ethical principles', their meaning needs always to be clearly stated. If this does not happen—if we do not get beyond listing keywords—it will be hard to tell whether the policies generated are consistent, justified, and based on sound ethical reasoning (Wilkinson 2011).

Despite this criticism, I would argue that this is a good start, at least by setting out some basic principles that we think should underpin policy, they can begin to be debated and subject to scrutiny. Work in empirical ethics can be a robust way of approaching such scrutiny by: ascertaining and understanding the principles that people think are important in particular situations; for seeing how they are actually constructed and used in practice; for developing more context specific principles to guide action; and articulating their meaning more clearly (Frith 2012). While this will not lead to complete agreement, at least if the underlying principles are articulated then a more open debate can be had over their appropriateness and if they have been actualised in practice and this, in my view, will lead to more robust policy decisions.

[8] Also see Strong (1999) who argues that as a society we share enough moral values to make agreement possible.

6 Conclusion

The case of the removal of gamete donor anonymity demonstrates some of the obstacles to applying evidence in practical policy making. Often it is simply that the evidence does not exist on the matter in question, other times it is insufficient to conclusively demonstrate what course of action is the best one. However robust or lacking one's evidence base is, there is still the prior question of what the ends of policy should be and what guiding principles should inform that policy debate. With donor anonymity, the debate was underpinned by a conception of the best interests of the child and rights of an individual to information. Once the debate was framed in this way, evidence on questions such as, 'would donor recruitment suffer?' became largely irrelevant. In public policy, principles and values will always play an important role in determining what the appropriate ends of policies should be and in what direction policy should be guided. These underlying principles should be explicitly debated, as they are the fundament issues at stake in any policy debate.

References

Ashcroft, R., and R. ter Meulen. 2004. Ethics, philosophy and evidence based medicine. *Journal of Medical Ethics* 30: 119. doi:10.1136/jme.2003.007286.

Blair, T., and J. Cunningham. 1999. *Modernising government*. London: Prime Minister and Minister for the Cabinet Office.

Blears, H. 2003. Keynote address to human fertilisation and embryology authority, annual conference, January 28, London.

Blyth, E., and L. Frith. 2008. The UK's gamete donor 'crisis': A critical appraisal. *Critical Social Policy* 28(1): 74–95.

Blyth, E., M. Crawshaw, C. Jones, and L. Frith. 2012. Donor conceived peoples' views and experiences of their genetic origins: A critical review of the literature. *Journal of Law & Medicine* 19(4): 769–789.

Bottomley, V. 1990. House of commons debates, proceedings of the committee on the human fertilisation and embryology bill 15 May, col 199.

British Fertility Society. 2002. Publication of consultation document on donor anonymity and British fertility society's response. http://www.fertility.org.uk/news/pressrelease/02_08-donor_anonymity.html. Accessed 13 Feb 2015.

British Fertility Society. 2004. Memorandum from the British Fertility Society, Appendix 9. Ev 216. In House of Commons Science and Technology Committee (2005) 'Human Reproductive Technologies and the Law' Fifth Report of Session 2004-05. Vol II: Oral and Written Evidence http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7ii.pdf. Accessed 13 Feb 2015.

British Medical Association. 2004. Memorandum from the British Medical Association. Appendix 12. Ev 228. ibid.

Cochrane, A., and M. Blythe. 1989. *One man's medicine: an autobiography of Archie Cochrane*. London: BMJ Books.

Davidoff, F., K. Case, and P. Fried. 1995. Evidence-based medicine: Why all the fuss? *Annals of Internal Medicine* 122(9): 727.

Department of Health. 2003. Donor information: Providing information about gamete or embryo donors: Responses to consultation. 28 January. http://www.dh.gov.uk/assetRoot/04/07/18/43/04071843.pdf. Accessed 13 Feb 2015.

Department of Health. 2005. Donor information: Providing information about gamete and embryo donors, Govt response to House of Commons Select Committee Report. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/browsable/DH_5401581. Accessed 13 Feb 2015.

Department of Health and Social Security. 1984. *Report of the committee of inquiry into human fertilisation and embryology (the Warnock report)*. London: HMSO. Cmnd. 9314.
Department of Health and Social Security. 1987. *Human fertilisation and embryology: A framework for legislation*. London: HMSO. Cm. 259.
Engelhardt, T. 1996. *The foundations of bioethics*, 2nd ed. New York: Oxford University Press.
Frith, L. 1999. Evidence based medicine and general practice. In *General practice and ethics*, ed. L. Frith, and C. Dowrick, 29–44. New York: Routledge.
Frith, L. 2001. Gamete donation and anonymity: The ethical and legal debate. *Human Reproduction* 16(5): 818–824.
Frith, L., E. Blyth, and A. Farrand. 2007. UK gamete donors' reflections on the removal of anonymity: Implications for recruitment. *Human Reproduction* 22(6): 1675–1680.
Frith, L. 2012. Symbiotic empirical ethics: A practical methodology. *Bioethics* 26(4): 198–206.
Frith, L., B. Young, and K. Woolfall. 2014. Patient participation in health care: How can we do it better? *American Journal of Bioethics* 14(6): 17–18.
Grahame-Smith, D. 1995. Evidence based medicine: Socratic dissent. *British Medical Journal* 310: 1126–1127.
Greenhalgh, T., et al. 2014. Evidence based medicine: A movement in crisis? *BMJ* 348: g3725. doi:10.1136/bmj.g3725. (Published 13 June 2014).
Guyatt, et al. 2008a. GRADE: What is quality of evidence and why is it important to clinicians? *BMJ*. doi:10.1136/bmj.39490.551019.BE.
Guyatt, et al. 2008b. Going from evidence to recommendation. *BMJ* 336: 1049. doi:10.1136/bmj.39493.646875.AE.
HFEA. 2002. Response to the department of health's consultation on 'donor information: Providing information about sperm, egg and embryo donors.' http://www.hfea.gov.uk/cps/rde/xbcr/hfea/Donor_Info_response.pdf. Accessed 13 Feb 2015.
HFEA. 2011. Donation review. http://www.hfea.gov.uk/5605.html. Accessed 13 Feb 2015.
HFEA. 2012. Mitochondria public consultation. http://www.hfea.gov.uk/6896.html. Accessed 13 Feb 2015.
House of Commons Science and Technology Committee. 2005. Human reproductive technologies and the law. Fifth report of session 2004–05. Vol I. http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf. Accessed 13 Feb 2015.
Johnson, M. 2004a. Donor anonymity and review keynote address: Human fertilisation and embryology authority annual conference, London. 21 January. http://www.dh.gov.uk/NewsHome/Speeches/SpeechesList/SpeechesArticle/fs/en?CONTENT_ID=4071490andchk=zLzthb. Accessed 13 Feb 2015.
Johnson, M. 2004b. Written ministerial statements Hansard Wednesday 21 January 2004, http://www.publications.parliament.uk/pa/cm200304/cmhansrd/vo040121/wmstext/40121m01.htm. Accessed 13 Feb 2015.
Latour, B., and S. Woolgar. 1986. *Laboratory life: The construction of scientific facts*. Princeton: Princeton University Press.
Kerridge, I., M. Lowe, and D. Henry. 1998. Ethics and evidence based medicine. *BMJ* 316: 1151–1153.
Marston, G., and R. Watts. 2003. Tampering with the evidence: A critical appraisal of evidence-based policy-making. *The Drawing Board: An Australian View of Public Affairs* 3(3): 143–163.
McDonald, L. (ed.). 2003. *The collected works of Florence Nightingale, society and politics, philosophy, science, education and literature*. Ontario: Wilfrid Laurier University Press.
Molewijk, B., A.M. Stiggelbout, W. Otten, H.M. Dupuis, and J. Kievit. 2004. Empirical data and moral theory: A plea for integrated empirical ethics. *Medicine, Health Care and Philosophy* 7: 55–69.
Moreno, J. 1995. *Deciding together: Bioethics and moral consensus*. New York: Oxford University Press.
Nuffield. 2013. Donor conception: Ethical aspects of information sharing. Nuffield Council of Bioethics. http://nuffieldbioethics.org/project/donor-conception/. Accessed 13 Feb 2015.
Nutley, S. Davies, H and I. Walter. 2002. 1- UK. ESRC UK Centre for Evidence Based Policy and Practice: Working Paper 9. http://www.kcl.ac.uk/sspp/departments/politicaleconomy/research/cep/pubs/papers/assets/wp9b.pdf. Accessed 13 Feb 2015.
Oakley, A. 2000. *Experiments in knowing*. London: SAGE.
Parker, M. 2000. Public deliberation and private choice in genetics and reproduction. *Journal of Medical Ethics* 26: 160–165.
Pawson, R. 2006. *Evidence based policy*. London: SAGE.
Rawls, J. 1993. *Political liberalism*. New York: Columbia University Press.

Rose and Another versus Secretary of State for Health and Human Fertilisation and Embryology Authority (2002) EWHC 1593.

Royal College of Obstetricians and Gynaecologists. 1987. *Donor insemination*. London: RCOG.

Royal College of Obstetricians and Gynaecologists. 2004. Memorandum from the Royal College of Obstetricians and Gynaecologists. In House of Commons Science and Technology Select Committee (2005) Human reproductive technologies and the law: fifth report of session 2004–05. Vol II, Appendix 26. Ev 283. op cit.

Rycroft-Malone, J., and T. Bucknall (eds.). 2010. *Models and frameworks for implementing evidence based practice: linking evidence to action*. Sussex: Wiley-Blackwell.

Strong, C. 1999. Critiques of casuistry and why they are mistaken. *Theoretical Medicine and Bioethics* 20(5): 395–411.

Upshur, R. 2013. A call to integrate ethics and evidence based medicine. *Virtual Mentor: American Medical Association Journal of Ethics.* 15(1): 86–89.

Wilkinson, S. 2011. Ethical principles and the HFEA's donation review, Bionews 632, 7th November.

Williamson, L. 2014. Patient and citizen participation in health: The need for improved ethical support. *American Journal of Bioethics* 14(6): 4–16.