Reproductive BioMedicine Online (2014) **29**, 516–523

www.sciencedirect.com
www.rbmonline.com

ARTICLE

Assisted reproductive technology in the USA: is more regulation needed?

Lucy Frith [a,*], **Eric Blyth** [b]

[a] *Department of Health Service Research, University of Liverpool, Block B, Waterhouse Building, Brownlow Street, Liverpool, L69 3GL, UK*; [b] *School of Human and Health Sciences, University of Huddersfield, Queensgate Huddersfield, HD1 3DH, UK*

* Corresponding author. *E-mail address:* L.J.Frith@liverpool.ac.uk (L Frith).

Lucy Frith is Senior Lecturer in Bioethics and Social Science at the University of Liverpool. She has a taught medical ethics to medical students and healthcare professionals for a number of years, and has a particular interest in combining empirical methods with ethical analysis. Her research focuses on the social context of ethical and healthcare decision-making and uses multi-disciplinary approaches to address complex ethical and social problems. Research interests include women's health, pregnancy and childbirth, reproductive technologies (gamete and embryo donation), use of evidence in medical practice, and organizational ethics. She is empirical ethics section editor of the journal *Clinical Ethics*.

Abstract The regulation of assisted reproductive technologies is a contested area. Some jurisdictions, such as the UK and a number of Australian states, have comprehensive regulation of most aspects of assisted reproductive technologies; others, such as the USA, have taken a more piecemeal approach and rely on professional guidelines and the general regulation of medical practice to govern this area. It will be argued that such a laissez-faire approach is inadequate for regulating the complex area of assisted reproductive technologies. Two key examples, reducing multiple births and registers of donors and offspring, will be considered to illustrate the effects of the regulatory structure of assisted reproductive technologies in the USA on practice. It will be concluded that the regulatory structure in the USA fails to provide an adequate mechanism for ensuring the ethical and safe conduct of ART services, and that more comprehensive regulation is required.

KEYWORDS: American Society for Reproductive Medicine (ASRM), assisted reproductive technologies, infertility treatment, legislation, policy, regulation

Introduction

The regulation of assisted reproductive technologies is a contested area. Some jurisdictions, such as the UK and a number of Australian states, have comprehensive regulation of most aspects of assisted reproductive technologies; others, such as the USA, have taken a more piecemeal approach and rely on professional guidelines and the general regulation of medical practice to govern this area (Ory et al., 2013). In this paper, we argue that such a laissez-faire approach is

http://dx.doi.org/10.1016/j.rbmo.2014.06.018
1472-6483/

inadequate for regulating the complex area of assisted reproductive technologies, and conclude that more comprehensive regulation is required.

The aim of this paper is to give a perspective on regulation of assisted reproductive technologies in the USA and compare it with other jurisdictions with very different regulatory systems and approaches to government intervention, drawing heavily on examples from the UK. The purpose here is not to argue that the solutions and approaches to regulation adopted in other countries, particularly the UK, could be applicable to the USA. We recognize that the American socio-political context in which assisted reproductive technologies operate, attitudes towards government intervention, particularly at federal level, and the funding structure of US health care means that national legislation on assisted reproductive technologies, such as exists in the UK, is highly unlikely to be either practical or ideologically acceptable to most stakeholders in the USA. Our purpose is merely to open up the discussion by using examples of radically different regulatory systems, with a view to finding compromises between regulatory oversight and the autonomy and privacy of practitioners and users that would be acceptable in the USA. Regulatory structures and provisions are not set in stone, and the lively debate in the UK over the Government's plans to abolish the Human Fertilisation and Embryology Authority (HFEA), with strong arguments on either side (Johnson, 2013), show that these matters are never completely resolved even by comprehensive legislation.

Background

In the USA, forms of assisted reproductive technology regulation exist at federal and state level. At federal level, assisted reproductive technologies are overseen by the Fertility Clinic Success Rate and Certification Act 1992, Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services. Medical practice is also regulated at individual state level. This can include specific regulations on assisted reproductive technologies (in the main relating to insurance coverage). Considerable inter-state variation, however, exists; some states have limited or non-existent regulation and others have more comprehensive oversight. Because of the relative lack of legal regulation at both these levels, professional guidelines and good practice protocols play an important role in overseeing assisted reproductive technology practice. The American Society of Reproductive Medicine (ASRM) and its affiliate, the Society for Assisted Reproductive Technology (SART), offer professional self-regulation through guidelines and codes of conduct for fertility clinics and their staff. Key among these are the ASRM Ethics Committee Reports and Practice Committee opinions (ASRM and SART Practice Committee, 2013; ASRM Ethics Committee, 2004).

The ASRM has consistently asserted that, owing to the existence of this framework assisted reproductive technologies are sufficiently well regulated and there is little need for further intervention (Adamson, 2005; Rebar and DeCherney, 2004). Following a meeting to review the oversight of assisted reproductive technologies, the ASRM produced a report in May 2010 re-stating this position that assisted reproductive technologies are, 'one of most highly regulated of all medical practices in the United States' (ASRM, 2010). We do not necessarily quarrel with that view in this paper, as our purpose is not to examine or compare different regulatory regimes of other areas of medical practice in the USA. The aim is to highlight important omissions in the regulatory structures that govern assisted reproductive technologies in the USA, and to argue that the oversight of assisted reproductive technologies is much less extensive and rigorous than the ASRM claims. Before considering the specifics of US regulation, it is useful to consider what is meant by 'sufficiently well-regulated'. We argue that assisted reproductive technologies are sufficiently well regulated if regulations, which are designed to promote the safe and ethical conduct of these practices, are present and enforceable in some meaningful way and have broad support of all the relevant stakeholders.

Limitations of regulation

At the federal level, the sole statute regulating assisted conception, the Wyden Law (the colloquial term for the Fertility Clinic Success Rate and Certification Act) is limited in scope. It is primarily designed to make publicly available accurate information about fertility clinic success rates by requiring annual data reporting to the CDC. It has been commented, however, that this publically available outcome data can be misleading, and a small number of clinics have reported data in such a way as to give an inflated picture of their pregnancy rates. For example, the analysis by Kushnir et al. (2013) of SART and CDC reporting data showed that some centres were excluding cycles started in women over the age of 38 years. By doing this, these clinics reported significantly better pregnancy rates than average and were able to increase their market share by 19.9%. Kushnir et al. (2013) conclude that future data collection and reporting need to be more patient-centred so that success rates of clinics can be more accurately and fairly compared. The HFEA, for example, organized a public consultation on how clinic success rates should be reported, to allow patients to make the most informed choices when selecting a clinic (HFEA, 2008). The outcomes of this are reflected on the HFEA's website where information is presented in an accessible way to help people understand the meaning of the statistics used in making clinic comparisons and aid them in making treatment choices (HFEA, 2014).

In the USA, such comprehensive data do not exist on clinics, not all of them file reports to CDC, and each year about 12% of them fail to do so. In 2009, 43 clinics did not report (Centers for Disease Control and Prevention, 2011), in 2010, 31 clinics failed to reported (Centers for Disease Control and Prevention, 2012) and, in 2011 (the latest figures available), 30 clinics failed to report (Centers for Disease Control and Prevention, 2013). Data from clinics are also collected by SART on a voluntary basis, and these are shared with the CDC. Not all clinics report to SART either; of those that did, 113 (28.1%) did not report a complete data set (Kushnir et al., 2013). Further, it is unclear if every practising fertility clinic is known to the CDC and therefore included in these figures, as they state: 'We will continue to make every effort to include in future reports all clinics and practitioners providing ART (assisted reproductive technologies) services.' (CDC Website, commonly asked questions reference). Furthermore, the CDC request any