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INCLUSION AND EXCLUSION IN WOMEN'S ACCESS TO HEALTH AND MEDICINE

SUSAN DODDS

Abstract

Women's access to health and medicine in developed countries has been characterized by a range of inconsistent inclusions and exclusions. Health policy has been asymmetrically interested in women's reproductive capacities and has sought to regulate, control, and manage aspects of women's reproductive decision making in a manner unwitnessed in relation to men's reproductive health and reproductive decision making. In other areas, research that addresses health concerns that affect both men and women sometimes is designed so as not to yield data relating to the ways in which women's physiology and gendered location may affect their experience of the condition and its response to treatment, despite a literature on the significance of sex and gender differences in health research. This paper draws on the situation in Australia to explore the ethical significance of these inconsistencies as failing the ideals of high-quality medical research and evidenced-based health care.

Key words: Feminism, Gender, Women's health, Sex differences, Health research

Introduction

But first we must ask: what is a woman? "Tota mulier in utero", says one, 'woman is a womb.'

—SIMONE DE BEAUVOIR, *THE SECOND SEX* (1949)

Feminists, at least since de Beauvoir, have argued that although there are salient physical differences between men and women that affect their lives, possibilities, and social agency; as persons, women should not be reduced to uteruses. The negative social implications of assuming that the only salient features of womanhood concern reproductive capacities are obvious: women who bear children may be viewed simply as mothers and hence, only ambivalently as citizens (Kerber 1976). If women are understood to be "properly" mothers, then, when they are considered outside of maternal and domestic relations, they can be viewed as "disorderly," "unnatural," "dangerous," that is, as threats to civic order (Pateman 1980). Equating gender with sexual functioning has two effects: first, an excessive focus on the significance of reproductive capacity and second, "gender blindness"—a failure to recognize the many less obvious ways in which gendered assumptions shape attitudes, institutions, and social practices that shape all aspects of social and personal life (Minow 1990).

Feminist bioethics has drawn attention to the gendered power relations latent in medical practice with particular attention to the ways in which maternal health, reproduction, and childbirth have been medicalized in a manner that often limits women's autonomous choice and control (Sherwin 1992; Tong 1997; Dodds 2000). At the same time, feminist bioethicists have sought to articulate an approach to feminist bioethics that avoids biological reductionism and has the tools for identifying the ethically salient effects of gender in health care beyond reproduction (Wolf 1996).

Given the wealth of feminist literature on the dual perils of biological reductionism and gender blindness, it may seem unnecessary to reopen this discussion in relation to health care services and medical research in industrialized democracies. Unfortunately, policy surrounding medical research and political priorities in health services suggest that feminist interventions have done little to penetrate health policy, at least thus far. In this paper, I use the example of Australia to show how law, regulation, and policies surrounding health and medical research in an advanced capitalist state (not unlike several others) contribute to the perpetuation of a biological understanding of women's embodiment, as well as gender blindness to the impact of ill health and therapies.

Women's health policy initiatives

In recent years, gender has been evident in policy discussions about health in a very specific range of cases. By and large, gender is recognized as relevant to health policy only where it relates to specific physiological differences between men and women; disproportionately those related in some way to sexual and reproductive health, for example: sexually transmitted infections (STIs); breast, cervical, or ovarian cancer; infertility; perinatal health; childbirth (especially rates of caesarian deliveries); and menopause. In these areas, gender appears to be equated with differences in sexual function. It is only where policy initiatives explicitly seek to take the full array of factors relevant to gender into account and draw on a social conception of health and well-being that women's health begins to be understood in a manner that avoids this degree of biological reductionism.

For example, in the context of Australian health policy, sexual, reproductive, and women's health policies and programs generally are associated with sexually differentiated health matters. Despite the launch of a national women's sexual health policy in 1989 (Commonwealth Department of Community Services and Health 1989)¹ and a Commonwealth health department report recommendation for a comprehensive national sexual and reproductive health strategy (McCallum, McDonald, and Neilson 2000), there is currently no overarching national women's health policy. Rather, each state determines its own health policies and priorities within Commonwealth and state health funding arrangements. In South Australia (SA), for example, the *South Australian Women's Health Policy* (South Australia 2005) covers both sexual and reproductive health. The policy uses the terms "sexual health" and "reproductive health" in relatively narrow ways, however. The reproductive health strategies associated with the SA policy emphasize support for "reproductive rights," and the thrust of the sexual and reproductive health policy initiatives is directed to pregnancy-related health concerns.²

By contrast, the state of Victoria has developed a better-integrated and more gender-sensitive women's health policy. The Victorian *Women's Health and Well-being Strategy* (2006) provides clearer recognition that both sexual health and women's health extend beyond reproduction and that sexual and reproductive health should be encompassed within a broader social understanding of well-being. The goal of the *Women's Health and Wellbeing Strategy* is broadly and socially construed, rather than narrowly focussed on health and medicine:

The . . . Strategy aims to improve the health and wellbeing [sic] of Victorian women, with particular attention to the links between gender, diversity and disadvantage. (Victoria 2006a, 2)

In the policy and action plan, sexual and reproductive health are understood as interrelated and not reducible to either disease or pregnancy status:

. . . it is more than the absence of disease or unintended pregnancy. It encompasses the capacity to enjoy relationships and express sexuality without feelings of guilt or shame, to have mutually consenting and safe sexual experiences and the capability and freedom to make decisions regarding reproduction. (Victoria 2006b, 26)

Whereas the South Australian policy acknowledges that women's health is affected by physical, social, and environmental factors (South Australia 2005), the Victorian policy documents draw on a more integrated gender and diversity approach that better recognizes that "women's health and wellbeing [sic] are largely determined by the interaction between gender, socioeconomic circumstances and diversity factors" (Victoria 2006a, 3). As such, it is likely that greater attention to the multifaceted interaction of gender, class, and ethnicity on health and well-being would lead to better health outcomes for Victorian women compared with women living in South Australia. Unfortunately, as the South Australian policy has not been fully implemented yet, it is impossible to make a direct comparison of any differences in the health outcomes for women resulting from the different policies in the two states.

Piecemeal attention to the significance of gender within very recent women's health policies reflects a deeper problem within health and medicine. If it is possible for twenty-first-century policy makers in relatively progressive countries to develop policy explicitly directed toward women's health and well-being that fails to acknowledge the complex array of factors affecting gender adequately, it is hardly surprising that medical research (and policy surrounding medical research) has similar limitations. In what follows, I show some of the implications of the failure to attend appropriately to sex and gender for women's health and well-being.

The impact of misdirected attention to sex and gender in health

The policy failings identified previously are likely to have detrimental effects on the quality and availability of health care services, medical knowledge, and ultimately women's health, mortality, and quality of life. First, I argue that there continues to be excessive attention in law and policy discussion surrounding women's fertility and reproductive capacities, at the cost of policy attention to the asymmetric affects of the law and policies. Second, I argue that the lack of attention to research on the differential effects of disease and treatment between men and women means that the quality of medical knowledge and health service

provision overall is diminished. Further, as less is known about the gender-specific effects of conditions affecting (and treatments for) women's health, women (and their clinicians) lack relevant information to make appropriate decisions about how to maintain or improve their (or their patients') health. In light of these factors, there is good reason to revise research ethics guidelines and regulatory processes for approval of therapeutic goods so as to redress the effects of the asymmetric focus on women's reproductive and general health.

Dangerous asymmetries in regulatory debates

In this section I introduce three examples where laws relating to clinical practice or research were developed that affect women's choices and actions asymmetrically. In each case, women's *sui generis* relation to reproduction appears to be used in the justification for asymmetric legal intervention.

The first example of a legal anomaly supporting the view that health and medical matters relating to women's reproductive capacities merit disproportionate scrutiny, arose in relation to access to non-surgical means for terminating a pregnancy. Within Australia, state (rather than national or Commonwealth) law governs legal access to abortion, whereas Commonwealth (national) law regulates pharmaceuticals and therapeutic goods according to the Therapeutic Goods Act 1989. In the 1990s, an Independent Australian Senator, Brian Harradine, used his status in holding the balance of power in the Senate to introduce socially conservative legislation. In 1996, as a result of Senator Harradine's influence, the Australian Commonwealth government passed an amendment to the Therapeutic Goods Act that identified non-surgical abortifacients (mifepristone, RU486) as "restricted goods" and shifted authority for approval of such drugs in Australia from the Therapeutic Goods Administration (TGA) to the Australian Minister for Health. The practical effect of the legal change was to remove the option of non-surgical termination of pregnancy from the range of medical options for Australian women because it politicized ministerial approval of the drug. Abortifacients were the only class of drug regulated in this way.³

There was a strong religious current to the initial public discourse with religious and right-to-life leaders speaking out with the aim of shaping public policy. In later policy debate concerning the removal of the anomalous requirement for ministerial approval, however, this religious concern was transformed into apparently paternalistic concern for the health and well-being of women who might seek out abortifacients (e.g., concerns about the risks of hemorrhage or inadequacy of social support). For example, witnesses to the public hearings on

the 2006 amendment representing religious perspectives raised questions about evidence of the risk of hemorrhage should the drugs be used without medical supervision, even though no argument was made for prescribing the drugs in an unsupervised manner (Senate Community Affairs Legislation Committee 2006). Whereas the 1996 amendment to the Therapeutic Goods Act had the practical effect of removing from women the possibility of legal access to medical termination, the 2006 amendment to the same act allowed non-surgical abortifacients to be evaluated in the same way as any other drug through the Therapeutic Goods Administration. Thus far, however, there has been only very limited access to mifepristone for early abortion in Australia (De Costa et al. 2007).

A second area where law has been used to govern medical practice and women's health choices, in areas specifically related to women's reproductive and sexual health concerns, is access to assisted reproductive technologies (ARTs). In this case the differences between the approaches taken in different Australian states reflect the range of international responses to ARTs. Some states (Victoria, South Australia, and Western Australia) have specific legislation governing access to reproductive technologies; other states have no legal regulation of ARTs. In these states, access to ARTs is governed by the National Health and Medical Research Council's *ART Guidelines* (NHMRC 2004; 2007), the Fertility Society of Australia's Reproductive Technology Accreditation Committee *Code of Practice* (RTAC 2002), and the clinical ethics guidelines of specific hospitals and private clinics that determine which patients have access to which treatments. Victoria, however, had passed a law in the mid-1980s covering all ARTs, the Infertility (Medical Procedures) Act 1984. The Victorian legislation originally included a definition of infertility that formed the basis for access to ARTs in that state, where infertility was defined in relation to a heterosexual couple living in a marital or de facto marital relationship who had tried for two years to achieve a full-term pregnancy. In 1995 the Infertility (Medical Procedures) Act was replaced by the Infertility Treatment Act 1995. The new act reduced the waiting period for access to ARTs, but retained the restriction of treatment to women who were married or in a de facto relationship with a man. Unmarried and lesbian women sought to challenge the heterosexual and marital restrictions on access to ART under the Commonwealth Sex Discrimination Act 1984. Ultimately, a clinician brought a legal challenge to the Victorian law on the grounds that the restrictions were inconsistent with the Sex Discrimination Act (Del Villar, 2000, discussing *McBain v. State of Victoria* [2000] FCA 1009). This challenge was successful. The Commonwealth Government debated creating an explicit exception to the Commonwealth Sex

Discrimination Act for the Victorian legislation based on concerns for the best interests of the child but ultimately accepted the Federal Court's determination. The Infertility Treatment Act was amended in light of the decision, and the Victorian Law Reform Commission reviewed and made recommendations concerning access to ARTs in Victoria (Victorian Law Reform Commission 2007).

The third example of asymmetric legal intervention concerns public policy about medical research, an area that usually is governed by guidelines and professional standards rather than explicit law. In the absence of outrageous and well-publicized unethical practice, there is little evidence that citizens lack trust in the laws, regulations, and guidelines governing medical research and the practices of health researchers. Where there has been significant public attention to the practices of medical researchers, it often has been because of the overtly discriminatory and harmful impact of the research. In the absence of outrages such as the Tuskegee study in the United States (NHMRC n.d.) and the New Zealand National Women's Hospital cervical cancer study (Coney and Bunkle 1988), internationally, there is a high level of public confidence that medical research is regulated in a manner that will protect both participants in research and health consumers (the people whose treatment will be affected by the research findings). This public confidence relies on the recognition that most industrialized countries adopted the World Medical Association's *Declaration of Helsinki* (WMA 1964), adopted research ethics review processes grounded in national or internationally accepted guidelines on research ethics, and have a regulatory framework for registering pharmaceutical and other therapeutic goods and trust that these measures are adequate to protect against grossly unethical research practice.

In countries like Australia, the United Kingdom, Canada, and the United States, there has been very little demand for legal regulation of human research, with one area of notable exception: research that involves human embryos or use of human ova in research involving cloning or the development of chimeric embryos (human ova fertilized by non-human sperm). For example, in Australia, research involving human participants generally is governed by national ethical guidelines (e.g., NHMRC 2004; 2007 and NHMRC, Australian Research Council [ARC], and Australian Vice Chancellors' Committee [AVCC] 2007) rather than national law. The only area where medical research practice is regulated by national law, in addition to national ethical guidelines, is in relation to embryo research and cloning—through two acts, the Research Involving Human Embryos Act 2002 (amended 2007), and the Prohibition of Human Cloning Act 2002 (amended 2007, now called the Prohibition of Human Cloning

for Reproduction Act). These laws primarily affect the scope of medical research and the actions of researchers with respect to embryos; namely, they determine which embryos can be used in research and how access to embryos is regulated. The public debate initially was framed as a contest between science and religion concerning the moral status of the human embryo. However, this concern shifted (in the eventual regulatory debates, especially in the 2005 Legislative review) to include a discussion of the risks to women who might be donors of ova or embryos and the potential that women might be exploited by markets in embryos and ova (see Dodds 2004; Australian Government 2005).

These three examples of areas where law was used to shape medical research, health practice, and women's access to health services demonstrate an asymmetric interest in women as sexual, reproductive beings in a manner that is likely to hinder women's interests and to perpetuate a reductive equation of the concept of "woman" to "reproduction." In the next section, I explore the other side of the equation, that is, whether current research ethics guidelines and regulatory approval processes for pharmaceuticals can draw attention to gaps in our knowledge about the effects of sexual or gender difference on disease and health treatments.

Mind the gap: Do we know what treatments to recommend to women?

Feminist bioethicists have drawn attention to the ways in which research has paternalistically excluded or limited women's participation in research on the grounds that participation in research may adversely affect (potentially) pregnant women or the development of a fetus in utero (Dresser 1992; Baylis, Downie, and Sherwin 1999). Where women have been included in research as participants, it has tended to be research on women's reproductive capacities, again reinforcing the biological reduction of woman to potential childbearer (Inhorn and Whittle 2001). An effect of the general exclusion of women from participation in research concerning wider health and illness has meant that when physicians treat patients who are women, they act without adequate relevant evidence from prior research to know whether those women "will be helped, harmed or not affected at all by numerous therapies now endorsed as 'promoting health'" (Dresser 1992, 24). In particular, Dresser was concerned to demonstrate the error of excluding women from research because it was thought that greater homogeneity of the research participant population would make the research findings more robust and more generalizable. Given that clinical research is intended to provide practitioners, patients, and those allocating health budgets with the information required to

determine which treatments are safe and effective for health conditions for all of those people who may suffer those health conditions (or be offered those treatments), data based only on a portion of the population who could be affected is simply inadequate and cannot be generalized to the whole (diverse) population with any confidence (Dresser 1992).

According to Dresser, the exclusion of women who might be, could become, or were pregnant could not consistently justify exclusion of all potentially or actually pregnant women from clinical research. She argued against treating pregnancy as *sui generis*. Instead, she argued for advising men and women of the potential risks to fertility and fetal development that might result from participation where they are known, for acknowledging the limits of knowledge about effects on fertility or fetal development, and to suggest effective contraceptive methods. Ultimately, however, she argues that men and women should be allowed to decide as a matter of informed choice whether to take those risks, to use an effective contraceptive method, or to refuse participation. Finally, she argued that men or women should be excluded from participation *only* if there were known risks, where participation in the research was unlikely to be of benefit to the participant, and where reproduction was likely (Dresser 1992).

In the United States, in an attempt to redress the gap in knowledge about conditions affecting men and women (and people of color) and about effective treatments, the National Institutes of Health have adopted a policy on publicly funded research that creates a presumption of inclusion of women (and people of color) in the design of health research and a requirement that researchers attend to the gender implications of their research in funding applications and study design (NIH 1994). Recent research in Australia addresses the question of whether current policy and practice in Australia protects against inappropriate sex-specific research and demonstrates that an unacceptably high level of published Australian research involved inappropriate exclusion of women or men from research (Rogers and Ballantyne, this issue).

There is evidence of a range of conditions that are experienced by both men and women in which women are affected by the condition (or its treatment) differently from men. A recent article on this subject has noted:

It has, however, been recognised since the 1990s that marked differences exist in patterns of health and in conditions that affect both men and women: some conditions are more prevalent or more serious in one sex than in the other, have different risk factors for men and women or require different interventions. These differences may stem from specific biological characteristics of women

and men (reproductive, genetic, hormonal, and metabolic features; sex), or from differences in socially constructed variations in the daily lives of women and men (gender), which interact in complex ways. (Moerman et al. 2007, 107)

Moerman et al. make a distinction between sex (as biological characteristics) and gender (socially constructed practices shaping the daily lives of men and women). Although this distinction has come under scrutiny among feminists (see Butler 1993) on the grounds that both concepts are social constructs, and the features characteristic of them are understood and mediated through social processes (e.g., the study of physiology, medical research), there are good reasons for distinguishing those features that are more readily identifiable in the narrow medical "laboratory" context (e.g., hormone activity, metabolism) from those that are more obviously socially mediated (e.g., occupation, social relations, socialization). Research that attends to both sides of this distinction is important if we are to develop appropriate responses to *both* the significance of differences that are readily measurable in the research lab using models of normal male and female biochemistry *and* to those, such as occupational practices, that are only recognizable if one attends to the lived experience of men and women as socially embedded persons.

Among the conditions listed by the Australian Bureau of Statistics as the leading causes of death (cancers, ischaemic heart disease, stroke, diabetes [ABS 2004]), it is known that there are sex or gender differences in clinical manifestations, risk factors, and responses to treatment between men and women in heart disease and diabetes, as well as in responses to pain (Pinn 2003b). Men and women experience HIV infection and progress to AIDS in different ways, with different mortality rates. Women and men experience the most prevalent form of mental illness, depression, in different ways with different responses to therapies. Women have different rates of incidence and experience different effects from musculoskeletal disease, where they are affected differentially by osteoarthritis, osteoporosis, and sports injuries (Pinn 2003b). The differential responses to musculoskeletal disease readily demonstrates the significance of both biological differences and differential social roles for the health of men and women. The differences experienced can be due to biological differences in musculoskeletal structure (bone density, effects of menopause) and in part, also can be due to gender differences, for example, to participation in contact sport, occupational risks, or to the combined effects of differences in sex and gender.

It is important to avoid the assumption that gender differences should be attended to only where women and men experience a condition at similar rates. There are some conditions that are experienced only rarely by women, but the

likelihood of the condition being life threatening is much higher. In these cases in particular, the exclusion of women from research (e.g., on the grounds that it would be too difficult to recruit a statistically significant sample) could mean that women who suffer the condition have no access to well-informed treatment or information about their condition. One such condition is abdominal aortic aneurysm (AAA). The prevalence of AAA is six times lower in women compared with men (Scott, Bridgewater, and Aston 2002), but the risk of mortality from AAA is higher for women than men (Norman et al. 1998). The reasons for this are not clear but may involve some sex-based differences, as well as gender-based differences in the treatment of women with cardiovascular disease. Research on AAA based on a male-only sample will fail to address the significant risk of death from this condition for women. Similarly, screening programs that ignore the risk of AAA for women could increase women's risk of death.⁴

The current research ethics guidelines in Australia, *National Statement on Ethical Conduct in Human Research* (NHMRC, ARC, and AVCC, 2007) do not explicitly require researchers or human research ethics committees (HRECs) to attend to gender in the design and review of research; further, both the *National Statement* and the regulatory guidelines for approvals of therapeutic goods in Australia (Therapeutic Goods Administration 2006) directly comment on gender only in relation to potential pregnancy. These limitations are ethically significant because they may contribute to poor health outcomes for women due to limited research on how conditions or treatments affect women or due to inappropriate treatment of the conditions that women suffer.

NHMRC, ARC, and AVCC National Statement on Ethical Conduct in Human Research (2007)

The Australian guidelines governing all research involving humans provide ethical guidance to both researchers and HRECs charged with the review of health and medical research (among others) through the *National Statement on Ethical Conduct in Research* (NHMRC, ARC, and AVCC 2007). Although the revisions made in the latest version of the *National Statement* extended the scope of the guidelines to "address many issues not discussed in the previous version" (3), the matter of the ethical significance of gender-appropriate research is not directly addressed within the guidelines. There is minimal attention to the need for research to be designed to attend appropriately to gender differences, nor is there any specific requirement to justify exclusion of research populations. Nonetheless, the guidelines do allow researchers and HREC mem-

bers to consider the appropriateness of research design within the provisions regarding the merit and integrity of research and recruitment of research participants. However, the bulk of responsibility for assessing whether the research is designed so as to ensure that generalizations made about the nature of a condition or the efficacy of a treatment are applicable to all those who may be affected (both men and women), largely relies on peer review that occurs outside of the HREC review process. In effect, the current research ethics guidelines are gender blind in a manner that may negatively affect women's health.

In the sections addressing research merit and integrity the *National Statement* acknowledges the ethical significance of research design (emphasis added):

1.1 Research that has merit is:

- (a) *justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities;*
- (b) *designed or developed using methods appropriate for achieving the aims of the proposal;*

1.3 Research that is conducted with integrity is carried out by researchers with a commitment to:

- (a) *searching for knowledge and understanding;*
- (b) *following recognised principles of research conduct;*
- (c) *conducting research honestly; and*
- (d) *disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding. (NHMRC, ARC, and AVCC 2007, §1.1–1.3; emphasis added).*

The text in italics indicates areas that *could* provide a ground for researchers or HRECs to attend to the gender impact of research, given that the capacity for research to "contribute to knowledge and understanding, to improved social welfare and individual wellbeing" will depend on whether the research is designed to provide findings that are appropriately applicable to all those who may be affected by the condition or treatment being studied. However, nothing

in the wording requires researchers to attend to the potential that sex or gender may be a significant variable that requires attention in the design of the research. Further, this section of the *National Statement* explicitly limits the capacity of HRECs to consider whether sex or gender matters are appropriately addressed in research that has been subject to peer review:

1.2 Where prior peer review has judged that a project has research merit, *the question of its research merit is no longer subject to the judgement of those ethically reviewing the research.* (NHMRC, ARC, and AVCC 2007, §1.2; emphasis added)

Thus, it is left up to peer review and research funding bodies to assess the appropriateness or otherwise of sex-based exclusions and inclusions in the design of research and not deemed to be an *ethically salient* aspect of research merit.

A second avenue for researchers and HREC members to assess the significance of gender-exclusion and inclusion arises in the sections of the *National Statement* concerning justice and recruitment of participants.

1.4 In research that is just:

- (a) *taking into account the scope and objectives of the proposed research, the selection, exclusion and inclusion of categories of research participants is fair*, and is accurately described in the results of the research;
- (b) *the process of recruiting participants is fair*;
- (c) *there is no unfair burden of participation in research on particular groups*;
- (d) *there is fair distribution of the benefits of participation in research*;
- (e) *there is no exploitation of participants in the conduct of research*; and
- (f) *there is fair access to the benefits of research.* (NHMRC, ARC, and AVCC 2007, §1.4; emphasis added)

Again, researchers and HREC members *may* be aware of the significance of sex and gender for the generalizability of results and for the value of results from research in improving the health of both men and women through treatments and interventions appropriate to the gender of patients. However, there

is nothing in this section to draw either researchers' or HREC members' attention to the significance of sex or gendered inclusion and exclusion for study design and justification.

In chapter 3.3 of the *National Statement*, which specifically deals with clinical research, there are, again, guidelines relating to research design and recruitment that *could* be read as requiring attention to the sex and gender appropriateness of research that is intended to apply to both men and women:

3.3.3 Researchers should show that:

- (a) *the research is directed to answering a specific question or questions*;
- (b) *there is a scientifically valid hypothesis being tested that offers a realistic possibility that the interventions being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burdens, costs and risks*;
- (c) *the size and profile of the sample to be recruited is adequate to answer the research question*; and

3.3.6 *The research methodology should provide a rationale for the selection of participants and a fair method of recruitment (see paragraph 1.4).* (NHMRC, ARC, and AVCC 2007, §3.3.3–3.3.6)

A strong reading of §3.3.3 (c) would push researchers and HREC members to address the issues raised previously about the appropriateness of the study design to provide sex or gender specific findings applicable to both men and women, but it is likely to do so only if the researchers or HREC members are alive to the significance of sex and gender to medical research design and findings. Nothing within the *National Statement* requires attention to sex or gender *except* where a participant might be, or become, pregnant.

The specific participation of women in research arises in the *National Statement* solely in relation to protection of fetuses in Chapter 4.1, "Women who are pregnant and the human fetus." These sections risk the kind of biological reductionism discussed at the start of this paper and emphasize the potential effects of research on the developing fetus, with secondary consideration given to the welfare of the pregnant woman (for whom experimental treatment may be the only available treatment for her condition). Given that pregnant women who are not participants in research may receive treatments that never have been tested on women during pregnancy, it seems peculiar that the emphasis

on protection of the interests of pregnant women *in research* appears to override the interests of pregnant women who are receiving what effectively are *untested treatments* as clinical therapy.

4.1.1 The wellbeing and care of the woman who is pregnant and of her foetus always takes precedence over research considerations.

4.1.3 Research involving the woman may affect the foetus, and research involving the foetus will affect the woman. The risks and benefits to each should be carefully considered in every case, and should be discussed with the woman. This must include the effect of the research on the foetus *in utero* (including consideration of foetal stress) and on the child who may subsequently be born. (NHMRC, ARC, and AVCC 2007, §4.1.1–4.1.3; emphasis added)

In summary, although the *National Statement* does not prevent researchers, HREC members, or peer reviewers from raising sex or gender issues concerning the appropriateness of research design and recruitment processes, it does not specifically require that such matters be considered explicitly (as the U.S. NIH policy does). It is appropriate to consider whether the regulations of the Therapeutic Goods Administration ensures that sex/gender considerations are attended to in the drug approval process.

The *Australian Clinical Trials Handbook* (TGA 2006) and the *TGA Note for Guidance on Good Clinical Practice* (GCP) (TGA 2000) provide advice to researchers on the appropriate design of clinical trials for the purpose of establishing the merit and safety of a drug or device that may be approved for use in Australia. In the *Handbook*, there is no specific requirement for a justification to be provided for the design of a study in relation to sex/gender issues. However, in the *GCP*, researchers are required to provide all known effects of and data from studies of the drug on humans, including any information on population subgroups (including gender groupings):

7.3.6 Effects in Humans

Introduction:

A thorough discussion of the known effects of the investigational product(s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacodynamics, dose response,

safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should also be provided regarding results of any use of the investigational product(s) other than from in clinical trials, such as from experience during marketing.

(a) Pharmacokinetics and Product Metabolism in Humans

- A summary of information on the pharmacokinetics of the investigational product(s) should be presented, including the following, if available:
- Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).
- Bioavailability of the investigational product (absolute, where possible, and/or relative) using a reference dosage form.
- *Population subgroups* (e.g., gender, age, and impaired organ function).
- Interactions (e.g., product-product interactions and effects of food).
- Other pharmacokinetic data (e.g., results of population studies performed within clinical trial(s)). (TGA 2000, 41; emphasis added)

These requirements ensure that *if* there are known sex-based or gendered effects of an unapproved drug or other product, then those data will be included in the Investigator's brochure that will be used by HRECs and/or the TGA in reviewing the clinical trial. However, there is no requirement for the researcher to ensure that their clinical trial addresses *whether there may be* relevant sex/gender issues associated with the condition, its treatment, or the drug under investigation.

Given the lack of explicit direction to attend to sex and gender issues in medical research given to researchers, research ethics review committees (RERCs), and drug regulators, there is no guarantee that Australian medical researchers will design their research so as to ensure that findings from the research are applicable to all those who may be clinically affected by the findings. With the rise of evidence-based medicine (EBM) as a basis for clinical decision making over the past decade, together with the moves made in the United States to require explicit justification of study design in light of pertinent sex and gender considerations, it is surprising that relatively little attention has been given to this omission in the

Australian discourse surrounding research ethics and research design. The identification of only reproduction and risks to fetal development as the specific areas meriting sex-differentiated attention in medical research and drug approval processes reduces women to their reproductive capacities in a manner that limits their autonomous possibilities and risks poor health outcomes due to limited knowledge and inappropriate treatments. Failure to attend to the significance of the array of social relations and practices that shape gender in the design of medical research places too much emphasis on biochemistry, and too little on factors (e.g., differences in daily activities, modes of occupational exposure, social supports) that may influence the course of a condition and effectiveness of treatment. In each of these cases, we have reason to believe that failure to attend appropriately to sex and gender in health research can have deleterious effects on health outcomes.

Conclusions

What is the potential significance of these policy gaps and what are the avenues for redress? I have argued that a narrow focus on women's health as reproductive health involves a biological reductionism that allows wider health concerns to be omitted from women's health policy strategies and goals. These wider concerns may be sex-specific (but not related to reproduction) or may be gendered (and hence associated with wider social relations). In either case, they may significantly affect how governments respond to women's health needs and may limit their capacity to recognize significant health issues. Second, I have argued that where legal interventions asymmetrically target women's choices and actions in reproduction (e.g., access to medical abortion, decisions regarding donation of ova or embryos, or access to ART) and not men's, they contribute to a reductionism of women to reproductive capacity. Further, given the legal restrictions that have been developed, the message appears to be that women's choices regarding childbearing and raising children require legal oversight and control; that women who pursue alternatives to the norm of heterosexual childbearer and maternal child caregiver threaten the civil order. These legal asymmetries differentially affect women's autonomy and well-being in the pursuit of health, well-being, and parenting.

In the case of policy surrounding research ethics and approval of drugs, the absence of any explicit policy requirements for attention to sex and gender in the design of a medical research study means that there are likely to be substantial gaps in medical understanding about conditions and diseases that have been studied in a gender-blind fashion. Further, gender-blind study design means that many of those who are receiving tested treatments are doing so on the basis of

data that assumes the generalizability of findings without that generalizability having been proven. As a result, people are receiving treatments where, in fact, the efficacy and safety of the treatment for those patients is not firmly established. Similarly, recommendations about "best practice" clinical management of women with conditions suffered by men and women may not be appropriate to those women. Further, gender-neutral assumptions about the impact of ill health or exposure to harmful substances may overlook the gendered significance of occupational practice, parenting responsibilities, and social relations on such exposure or health conditions. In a country with a robust public health system, these gaps may have a significant impact on the efficient use of medical resources and supports and may directly affect health outcomes.

In light of these considerations, I conclude with five recommendations. The first is addressed to Australian health ministers (Commonwealth and State): the time has come to revive the promise of the 1989 national women's health policy (Commonwealth Department of Community Services and Health 1989) with a new overarching women's health policy covering, but not reduced to women's sexual and reproductive health, as well as developing an effective approach to identifying and responding to the full array of health issues facing women in Australia. Such a policy would serve as a guide and check on state and local health service policy and practice and could be reviewed, nationally, to assess its effectiveness (in responding to women's health needs) and scope (in light of new research and health challenges). The design of such a policy should include not only population health experts, health economists, and clinicians, but also those whose work addresses the lived experience of women (counsellors, welfare advocates, unionists, community service providers, etc.), so as to ensure appropriate attention to the gendered experiences shaping women's health.

The second recommendation is addressed to law reform commissioners, citizens, and their parliamentary representatives. I recommend that we demand of law makers when developing laws that differentially affect women, their opportunities, and choices, that they justify any such differential laws, and in particular, that reproductive differences between men and women should only be accepted as justification for differential legal restrictions where those differences are directly salient to the matter under consideration. That is, we should demand of lawmakers that they demonstrate that there is something relevantly different about the situation at hand that merits the imposition of asymmetric law (merely pointing to a woman's uterus should not be deemed sufficient). Clearly, considerations of the welfare of children are important in discussions

about reproductive technologies, but those considerations should not be used arbitrarily to restrict women's but not men's choices, actions, and welfare.

My final three recommendations are addressed to the process of ethical review of medical research and approval of pharmaceuticals and hence, to the NHMRC and TGA. Third, that the *National Statement* be revised to explicitly require of medical researchers conducting clinical trials that the researchers justify their study design and inclusion and exclusion criteria in light of considerations of the evidence of differences between men and women (or among any other sub-populations) in the experience of conditions, the progression of the disease, and response to treatment. Fourth, that researchers seek out evidence of any sex/gender differences in relation to a condition or its treatment as part of their study design. Finally, fifth, that the TGA require of those seeking approval of a drug or device in Australia that they provide evidence of the efficacy for all relevant populations that may be affected. These recommendations will contribute to an improvement in our knowledge about health, disease, and appropriate therapies. They may directly improve the quality of treatments available to men and women and may also improve the efficient use of medical resources.

Notes

1. A change of government in the 1990s saw the abandonment of the national policy.
2. The implementation of the SA Sexual and Reproductive Health Strategy has been delayed since 2007.
3. The anomaly was removed in 2006, after Senator Harradine retired from politics, following a further amendment to the Therapeutic Goods Act that repealed ministerial authority.
4. I am grateful to Wendy Rogers for suggesting this example.

References

- Australian Bureau of Statistics. 2004. Australian social trends, 2004. Canberra: Commonwealth of Australia. <http://www.abs.gov.au/> (accessed 15 February 2008).
- Australian Government. 2005. Legislation Review: *Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002*. Reports. Canberra, December 2005.
- Baylis, Françoise, Jocelyn Downie, and Susan Sherwin. 1999. Women and health research from theory to practice to policy. In *Embodying bioethics*, ed. Anne Donchin and Laura M. Purdy, 253–68. Lanham, MD: Rowman & Littlefield.
- Beauvoir, Simone de. 1972. *The second sex*. Trans. H. M. Parshley. Harmondsworth: Penguin.
- Butler, Judith. 1993. *Bodies that matter: On the discursive limits of "sex."* New York: Routledge.
- Commonwealth Department of Community Services and Health. 1989. *National women's health policy, advancing women's health in Australia*. Canberra: Australian Government Publishing Service.
- Coney, Sandra and Phillida Bunkle. 1988. *The unfortunate experiment: The full story behind the inquiry into cervical cancer treatment*. Harmondsworth: Penguin.
- de Costa, Caroline M., Darren B. Russell, Naomi R. de Costa, Michael Carette, and Heather M. McNamee. 2007. Introducing early medical abortion in Australia: There is a need to update abortion laws. *Sexual Health* 4 (4): 223–26.
- Del Villar, Katrine. 2000. *McBain v. State of Victoria*: Access to IVF for all women. Research note 3 2000–2001. <http://www.aph.gov.au/library/pubs/rn/2000-01/01RN03.htm#1> (accessed 2 May 2008).
- Dodds, Susan. 2000. Choice and control in feminist bioethics. In *Relational autonomy in context: Feminist perspectives on autonomy, agency and the social self*, ed. Catriona Mackenzie and Natalie Stoljar, 213–35. New York: Oxford University Press.
- . 2004. Women, commodification and embryonic stem-cell research. In *Biomedical ethics reviews: Stem cell research*, ed. James M. Humber and Robert F. Almeder, 151–74. Totowa, NJ: Humana.
- Dodds, Susan, and Rachel Ankeny. 2006. Regulation of HESC research in Australia: Promises and pitfalls for deliberative democratic approaches. *Journal of Bioethical Inquiry* 3 (1–2): 95–107.
- Dresser, Rebecca. 1992. Wanted: Single, white male for medical research. *Hastings Center Report* 22 (1): 24–29.
- Inhorn, Marcia C. and K. Lisa Whittle. 2001. Feminism meets the "new" epistemologies: Toward an appraisal of antifeminist biases in epidemiological research on women's health. *Social Science and Medicine* 53 (5): 553–67.
- Kerber, Linda. 1976. The republican mother: Women and the enlightenment—an American perspective. *American Quarterly* 28 (2): 187–205.
- McCallum, L., J. McDonald, and D. G. Neilson. 2000. *Analysis of current national sexual health related activities, policies and programs funded by the Commonwealth: Consultation of the appropriateness and scope of a national sexual health strategy*. Canberra: Commonwealth Department of Health and Aged Care.
- Minow, Martha. 1990. *Making all the difference: Inclusion, exclusion and American law*. Ithaca: Cornell University Press.
- Moerman, C. J., J. A. Haafkens, M. Söderström, E. Rasky, P. Maguire, U. Maschewsky-Schneider, M. Norstedt, D. Hahn, H. Reinert, and N. McKeivitt. 2007. Gender equality in the work of local research ethics committees in Europe. *Journal of Medical Ethics* 33: 107–112.
- National Health and Medical Research Council. 2004. *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*. Canberra: Commonwealth of Australia.

- . 2007. *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (as revised in 2007 to take into account the changes in legislation)*. Canberra: Commonwealth of Australia.
- . n.d. *Ethical standards and review of research involving humans—a brief historical context*. Canberra: Commonwealth of Australia.
- National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee. 2007. *National statement on ethical conduct in human research*. Canberra: Commonwealth of Australia.
- National Institutes of Health. 2001. NIH Policy and guidelines on the inclusion of women and minorities as subjects in clinical research. http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm (accessed June 18 2008).
- Norman, Paul E., James B. Semmens, Michael M. D. Lawrence-Brown, and D'Arcy J. Holman. 1998. Long term relative survival after surgery for abdominal aortic aneurysm in Western Australia: Population based study *BMJ* 317: 852–56.
- Pateman, Carole. 1980. The disorder of women: Women, love, and the sense of justice. *Ethics* 91:20–34.
- Pinn, Vivian W. 2003. Expanding the frontiers of women's health research—US style. *The Medical Journal of Australia* 178 (12): 598–99.
- Reproductive Technology Accreditation Committee. 2002. *Code of practice for centres using assisted reproductive technology*. Melbourne: Fertility Society of Australia.
- Rogers, Wendy and Angela Ballantyne. 2008. When is sex-specific research appropriate? *International Journal of Feminist Approaches to Bioethics*, this issue.
- Scott, R. A. P., S. G. Bridgewater, and H. A. Ashton. 2002. Randomized clinical trial of screening for abdominal aortic aneurysm in women. *British Journal of Surgery*; 89 (3): 283–85.
- Sherwin, Susan. 1992. *No longer patient: Feminist ethics and health care*. Philadelphia: Temple University Press.
- Senate Community Affairs Legislation Committee. 2006. *Therapeutic Goods Amendment (Repeal of ministerial responsibility for approval of RU486) Bill 2005*, Public Hearings Friday 3 February 2006 (Melbourne); Monday 6 February 2006 (Sydney).
- South Australia. 2005. South Australian women's health policy. Adelaide: South Australia Health. <http://www.health.sa.gov.au/Default.aspx?tabid=62> (accessed 12 February 2007).
- . 2007. Strategic health plan 2007–9. http://www.saplan.org.au/images/pdf/South_Australia_Strategic_Plan_2007.pdf (accessed 9 May 2008).
- Therapeutic Goods Administration. 2000. Note for guidance on good clinical practice (CMP/ICH/135/95) Annotated with TGA Comments. Commonwealth Department of Health and Aged Care. Canberra. <http://www.tga.gov.au/docs/html/ich13595.htm> (accessed 18 February 2008).
- . 2006. *Australian clinical trials handbook*. Canberra: Commonwealth of Australia.
- Tong, Rosemarie. 1997. *Feminist approaches to bioethics*. Boulder, CO: Westview Press.
- Victoria. 2006a. Victorian women's health and wellbeing strategy stage two: 2006–10. Melbourne: Victorian Department of Human Services. http://www.health.vic.gov.au/vwhp/downloads/whws_stage2.pdf (accessed February 2007).
- . 2006b. Victorian women's health and wellbeing strategy stage two: 2006–10 action plan January 2007–June 2008. Melbourne: Victorian Department of Human Services. <http://www.health.vic.gov.au/vwhp/wellbeing/actionplans.htm> (accessed February 2007).
- Victorian Law Reform Commission. 2007. *Assisted reproduction and adoption: Final report*. Melbourne: Victorian Law Reform Commission.
- Wolf, Susan. M., ed. 1996. *Feminist bioethics—beyond reproduction*. New York: Oxford University Press.
- World Medical Association. 1964. Declaration of Helsinki, <http://www.wma.net/e/policy/b3.htm> (accessed March 2007).