REPRODUCING PREGNANCY

REPRODUCING PREGNANCY: RISK AND RESPONSIBILITY IN RESEARCH DURING PREGNANCY

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Lay Abstract

This dissertation explores the idea of pregnancy as site of risk. It argues that pregnancy is best characterised as a state that is simultaneously healthy and at risk. The tension between these two ways of understanding pregnancy is central to many ethical issues related to pregnancy. This study identifies ideas about pregnancy that impede clinical research during pregnancy. The first major finding of the project is the identification of stigma about pregnancy and pharmaceuticals arising out of the mid twentieth century pharmaceutical scandals. The second major finding is how ideas of health and risk construct pregnancy as women's initiation into 'responsible motherhood' and the corresponding surveillance, pressures and expectations that align with the narrative. This thesis recommends that stakeholder education needs to include a broader range of issues including the effect of stigma, the bias towards inaction, and the role of social narratives of good mothering and maternal responsibility.

Abstract

This dissertation explores the bioethical construction of pregnancy as site of risk and argues that pregnancy is best characterised as sitting in a constant state of tension, as simultaneously healthy-normal-natural and risky. This tension and how it is acknowledged or ignored is a significant factor in many ethical issues centered upon pregnancy. Using a genealogical analysis, this study identifies features of the social discourse around pregnancy that impede clinical research during pregnancy despite both policy changes and educational campaigns emphasising the benefits and importance of such research.

The first major finding of the project is the identification of stigma about pregnancy and pharmaceuticals arising out of the mid twentieth century pharmaceutical scandals. This stigma continues to distort the perception of risk during pregnancy, such that the risk of inaction during pregnancy is significantly undervalued and the risk of actions—particularly pharmaceutical interventions—is overestimated. This is related to both the exclusion of pregnant women from pharmaceutical research, and an accompanying tendency towards medical over-intervention in childbirth. The second major finding is how narratives of health and risk construct pregnancy as women's initiation into 'responsible motherhood' and the corresponding surveillance, pressures and expectations that align with the narrative. Pregnant women's desire to act in their child's best interest and the knowledge that not only acting or choosing 'wrong' may harm their child, make women less inclined to both take risks and/or act outside of conventional norm.

This thesis recommends that successful, stakeholder education needs to widen to include a broader range of issues including the effect of stigma upon risk perception, the broader bias towards inaction, and the normative strength of social narratives of good mothering and maternal responsibility.

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Preamble

Parts of Chapters Five and Six have been published as “Better Safe Than Sorry: Risk, Stigma, and Research During Pregnancy.” In: Baylis F., Ballantyne A. (eds) *Clinical Research Involving Pregnant Women*. Research Ethics Forum, vol 3. Springer, Cham 2016

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Healthcare Equality: Pregnancy and Pharmaceuticals

> Greater than 98% of medicines have no, or insufficient, safety data or pharmacokinetic data to guide dosing during pregnancy.
>
> Baylis & Ballantyne *Missed Trials, Future Opportunities*

High quality information about the safety and efficacy of pharmaceuticals is a central pillar of modern health care. However, this information is not available with regards to pregnant women despite more than 90% of women using pharmaceuticals during pregnancy.[1] This lack of knowledge arises because it is difficult to transfer knowledge developed in studies conducted in non-pregnant populations to pregnant populations, or sometimes even between studies on pregnant women at other stages of pregnancy. This problem of extrapolation occurs because of bodily differences arising from pregnancy, most significantly the presence of the fetus and the metabolic changes associated with pregnancy.[2] The issue is further exacerbated by the disproportionate understudying of pharmaceuticals during pregnancy to the point where "pregnant women may be the most underrepresented group in the entire clinical research process."[3] The central question driving this thesis is: if we know we ought to do more pharmaceutical research on pregnant women, why don't we? In an attempt to answer the question this thesis explores how pregnant women came to be underrepresented in pharmaceutical research, why they continue to be underrepresented despite the best efforts of many, and to indicate some ways in which pharmaceutical research during pregnancy can be encouraged.[4]

[1] Mitchell et al., "Medication Use during Pregnancy, with Particular Focus on Prescription Drugs."
[2] Lyerly, Little, and Faden, "Reframing the Framework"; Lyerly, Little, and Faden, "The Second Wave"; Baylis and MacQuarrie, "Why Physicians and Women Should Want Pregnant Women Included in Clinical Trials."
[3] Foulkes et al., "Clinical Research Enrolling Pregnant Women," 2011, 1430; Fisk and Atun, "Systematic Analysis of Research Underfunding in Maternal and Perinatal Health."
[4] A difference can be drawn between pharmaceutical research during pregnancy and knowledge of the safety and efficacy of pharmaceuticals during pregnancy. However, I would argue they are similar enough in practice for the difference between them not to matter when the overall end goal is ensuring equality of access to

A key question we need to be asking is are the reasons pregnant women are being excluded relevant, are they based on issues of safety and consent, or is an injustice against pregnant women being perpetrated. There are many reasons to promote pregnant women as research subjects – most significantly accurate, effective medical treatments – but, as with any other study population, there can also be good reasons to limit their participation as research subjects, such as their safety and the safety of their fetuses.[5] The harms of both inclusion and exclusion of pregnant women from some or all research must therefore be evaluated. The risks and costs of undertaking research during pregnancy must be balanced by the expected gain in medical knowledge around the safety and efficacy of pharmaceuticals during pregnancy, and consideration of specific risks arising from the unique physiological circumstances of pregnancy given serious attention. At the same time the potentially significant harms that arise from a lack of systematic knowledge about pharmaceuticals during pregnancy must also be considered. A systematic and sustained pharmaceutical research program is a way to ensure high quality healthcare. Yet the current system excludes the production of information that would benefit pregnant women. Pregnant women, like any subpopulation, deserve high quality healthcare also. A robust and systematic approach to researching the efficacy and safety of pharmaceuticals during pregnancy is needed to support the health of pregnant women and it is an injustice that it continues to not be in place.

There are safe, evidence based, high quality treatments for most causes of ill-health specific to pregnancy, such as high blood pressure and gestational diabetes. However, this is not the case when it comes to the causes of ill-health not specific to pregnancy, for instance

healthcare for pregnant (and breastfeeding) women. The phrase 'pregnant women' is used throughout. While I recognise that trans men and male identified people can become pregnant the phrase 'pregnant people' not only sounds awkward but also downplays the relationship between gender and pregnancy which is a central feature of will be important to the ethical analysis in Chapter five.

[5] For the sake of simplicity, the term 'fetus' will be used (inaccurately) during all phases of pregnancy from conception until delivery. Using the technical medical terms for the different stages of pre-birth development obscures the shared social features of 'fetuses' which are central to this project.

cancers and infectious diseases but also chronic conditions such as asthma, epilepsy, depression and other mental illnesses. Between 1980 and 2011 less than 10% of the pharmaceuticals developed were studied sufficiently such that evidence based recommendations as to their safety and efficacy for use during pregnancy could be made.[6] This is a problem for two reasons: first, because without knowledge about potential fetal harms we cannot safely prescribe pharmaceuticals to pregnant women. There is an additional level of complication in that toxic or teratogenic harm to the fetus may not be apparent for years or even decades after a pharmaceutical is administered. Second, the pharmacokinetic and pharmacodynamic profile of pregnant women often differs from the non-pregnant population, and can also vary throughout the stages of pregnancy.[7] This is due to the host of physiological changes that occur during pregnancy and which are relevant to drug metabolism including: "increased cardiac output and plasma volume, decreased gastric emptying and intestinal transport and increased renal excretion."[8] Pregnancy results in bodily changes such as increases in plasma volume, cardiac output and body fat and decreases in serum albumin, all of which affect how drugs are metabolised. This creates the possibility that what is a safe and effective dose for a non-pregnant person will be markedly different from a safe and effective dose for a pregnant woman.[9]

There is also the potential for teratogenicity, when a drug interferes with fetal development, and maternal toxicity, when the fetus is poisoned or otherwise impaired by the manner in which the drug affects the mother, such as reduced kidney function or decreased oxygen supply. Studies in the non-pregnant population cannot always predict how a drug will

[6] Adam, Polifka, and Friedman, "Evolving Knowledge of the Teratogenicity of Medications in Human Pregnancy."
[7] Pharmacokinetic: "how the body absorbs, distributes, metabolises and eliminates a drug." Pharmacodynamic: "Biochemical and physiological effects that a drug may have on the body." (Baylis and MacQuarrie, 2016, p.20
[8] Foulkes et al., "Clinical Research Enrolling Pregnant Women," 2011, 1430.
[9] Kass, Taylor, and King, "Harms of Excluding Pregnant Women from Clinical Research," 43; Morrell, "Maximizing the Health of Women with Epilepsy," 38.

affect a pregnant woman and the fetus. As a result, a drug that is safe and effective in non-pregnant people may be both toxic and/or ineffective during pregnancy. These risks can be minimised via animal model reproductive studies which are required in advance of any clinical pharmaceutical research being conducted during pregnancy.[10] However as with animal model studies in advance of clinical pharmaceutical research in non-pregnant populations there is a chance that potential adverse outcomes for humans will not be identified. The 'best quality' knowledge of drug efficacy and dosages for use during pregnancy can only be gained via interventional clinical research on pregnant women.

While pregnant women are prescribed a wide variety of pharmaceuticals according to therapeutic need, medical practitioners do so largely off-label and from a position of less-than-best practice.[11] Specific drug registries and observational studies such as cohort or case control studies are the most common methods used to study pharmaceutical use during pregnancy; however, when compared to the gold standard interventional method of testing pharmaceuticals, randomised control trials (RCTs), such methods are subject to weaknesses including costs, follow up, recall bias, selection bias, timeliness and insufficient sample size.[12] While good safety and efficacy data can be gathered via observational methods and registries, many pharmaceuticals could be studied during pregnancy in a safe and responsible manner more efficiently using RCTs. It is a matter of healthcare equality that an effort be made towards interventional research during pregnancy in the same way that it is expected, and conducted, in non-pregnant populations.[13] While some interventional research during

[10] Morrell, "Maximizing the Health of Women with Epilepsy," 38; Kass, Taylor, and King, "Harms of Excluding Pregnant Women from Clinical Research," 42.
[11] Baylis and MacQuarrie, "Why Physicians and Women Should Want Pregnant Women Included in Clinical Trials," 20–22.
[12] Gelperin et al., "A Systematic Review of Pregnancy Exposure Registries"; Sinclair et al., "Advantages and Problems with Pregnancy Registries," 2014; Furst, "Comparing the Strengths and Weaknesses of Observational and Experimental Studies Using a Postmarketing Surveillance Study as a Protypic Example."
[13] This argument could also be made for other understudied populations with unique physical circumstances – such as children and the elderly.

pregnancy is conducted there is a pressing need for more, and while many research guidelines and regulations now promote such research, there is still very little interventional research conducted during pregnancy that can generate fast, high quality clinical recommendations about pharmaceuticals use during pregnancy.[14]

A problem of culture

If interventional research is important, why is it so consistently not undertaken? One reason that this project will identify is stakeholder resistance. Many healthcare practitioners, pregnant women, their friends and family, government officials, politicians, and scientists have a distorted perception of what constitutes risk during pregnancy. This distorted perception of risk is such that endorsing, undertaking, legislating, recommending and participating in pharmaceutical research is perceived as too risky during pregnancy.[15] The distortion of risk perception around pharmaceuticals is so strong that sometimes even consuming any pharmaceutical at all is, or recommended to be, avoided.

Closely related to, and complicating, the misperception of the risks associated with taking pharmaceuticals is the notion of pregnancy as an especially vulnerable time. Women and their fetuses are considered particularly vulnerable to harm during pregnancy and thus deserving of greater support and protection. In practice, however, this support and protection often serves to restrict the range of options and choices available to pregnant women, particularly within institutional settings such as biomedical research. This occurs because the increased physical vulnerability associated with pregnancy is conflated with a decreased capacity for autonomy and decision making. When combined these two factors – the

[14] Collectively the following articles have been key in both advocating for and the setting the agenda around pregnancy and the importance of clinical research participation. Several articles in the 2016 book by Baylis and Ballantyne also comprehensively outline the role that policy and legislation have had in impeding clinical research during pregnancy. Baylis and Ballantyne, *Clinical Research Involving Pregnant Women*; Baylis, "Pregnant Women Deserve Better"; Lyerly, Little, and Faden, "The Second Wave"; Lyerly, Little, and Faden, "Reframing the Framework."

[15] Another significant stakeholder, especially in the USA, is the companies who insure drug trials who are particularly risk adverse.

misperception of risk and the misapplication of how pregnant women are vulnerable – help explain some of the gap between desired practice and the actual reality of pharmaceutical research on pregnant women. Most obviously the causes of this misperception of risk and misapplication of vulnerability during pregnancy can be traced back to the 1950s and 1960s and the tragedies associated with pregnant women's consumption of two pharmaceuticals - Thalidomide and DES - which created a stigma around pharmaceutical use during pregnancy.[16]

I argue, however, for the need for a deeper examination of the history of pregnancy: a genealogical enquiry in the Foucauldian tradition, aimed at highlighting the nuances of the social discourse of pregnancy sufficient to understand, and thus overcome, more subtle sources of resistance to research on pharmaceuticals during pregnancy. Rebecca Kukla argues that 'pregnancy' is a story

> mediated and given its shape by the social rituals and practices that make up pregnancy and motherhood, along with the representation and knowledge techniques that expectant new mothers use to understand their own identities and boundaries, those of their fetuses and children, and the substantive, complex, dynamic relationships between them.[17]

Assuming this position abut pregnancy an historical enquiry is key to understanding the contemporary discourse of pregnancy. Contextualising the contemporary discourse in this manner highlights the associated ethical norms and values, which are often only implicit. Broad shifts in society, science, medicine, technology, and politics all contribute to changes in what is considered acceptable, valuable, normal, right and natural during pregnancy and mapping these shifts both contextualises the DES and Thalidomide tragedies and identifies additional barriers to pharmaceutical research. Situating how and why research during pregnancy is not conducted within the framework of a socio-cultural discussion of pregnancy

[16] The case for this point will be made in Chapter Four.
[17] Kukla, *Mass Hysteria*, 4.

highlights the role of the discourse of pregnancy – norms and expectations, narratives and understandings – in producing and maintaining the current impasse. Most importantly situating the problem within a sociocultural framework highlights additional avenues for improving pharmaceutical research during pregnancy that are not apparent via other forms of analysis.

This project explores a specific case study where responsible moral practice requires a re-examination and re-evaluation of when and how morally relevant interventions take place; improving pharmaceutical research during pregnancy requires a critical evaluation of the role of social structures such as political and non-political institutions, formal policies and informal norms in producing ideas and values about pregnancy. I focus on only one excluded population, pregnant women, however my methods are transferable to considering other excluded populations such as children, people with comorbidities and the frail elderly. Similarly, the theoretical argument about the role of healthcare structures and institutions in shaping and producing key normative concepts within wider society, is also applicable beyond a discussion of pregnant women.

Recently, a consensus has emerged around the ethical principles governing research with pregnant women as can be seen in the legal and policy documents discussed in Chapter Four. There remains, however, a disconnection between the policies and guidelines, which provide nuanced support for clinical research during pregnancy, and practice, which shows little change in actual rates of clinical research during pregnancy. [18] In this project I argue that historical changes in five key concepts central to the discourse of pregnancy: risk, health, nature, responsibility and the fetus, are central to social narrative producing the contemporary

[18] The 2016 revisions to the CIOMS guidelines around health related research on humans is the broadest example of the policy shift around research during pregnancy. See 4.2 and 6.1 for a more exhaustive accounting of the policy changes. Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Health-Related Research Involving Humans. Fourth Edition."

disconnection between intention and practice. Once the role of these concepts in inhibiting clinical research during pregnancy is established I ask how we can either change or work with these established narratives of pregnancy to facilitate clinical research. For instance, how can ideas about responsibility and health during pregnancy be harnessed to encourage more research, and how can the process of research participant recruitment improve and correct people's ideas about risk during pregnancy to more accurately reflect the actual balance of risk and benefit of clinical research during pregnancy?[19]

The ethical impact of socio-cultural norms and narratives about pregnancy is felt via their contribution to defining this balance and the ongoing impact this has on the health of women. This thesis discusses the transformation of the ideas of risk, health, nature, responsibility, and the fetus, in response to social, scientific, medical, technological, and political changes. In doing so I highlight the contribution these five concepts make to producing narratives about the possibility and acceptability of pharmaceutical research during pregnancy. What constitutes *health* during pregnancy? What is *natural* during pregnancy? What behaviors and choices are perceived as *risky, or not* during pregnancy? What aspects of pregnancy can pregnant women, health professionals, institutions and governments be held *responsible* for? How is the *fetus* valued and perceived during pregnancy? The answers to each of these questions at a given moment shape the possibility and acceptability of pharmaceutical research during pregnancy in terms of what is included and excluded from policies, what are acceptable or unacceptable research methods, and most importantly via stakeholder perceptions about the urgency, riskiness and value of a given research project.

[19] Another potential avenue to explore here is if there are any advantages to considering ways to make it safer for pregnant women to join? I argue that unless we confront and correct the misperception of safety then there is little benefit to improving safety. The key point is an overconcern and misperception of what safety is. It's reasonable to assume that people in the drug research system will prioritise patient safety

A secondary aim of this project is to highlight the often-overlooked role of social structures in healthcare ethics and in particular their role in both producing and resolving ethical issues such as the one I have identified: problems of structural justice. While there is a wide range of social structures – political and non-political institutions, formal policies and informal norms – those focused upon are strongly associated with biopower. Biopower is here defined as the mechanisms by which the "vital characteristics of human existence," such as birth, death and illness, are made the object of political strategy in order to manage the collective population.[20]

Hospitals, scientific endeavours, demography and tools of governance are all key sites that mediate and facilitate our interaction with 'pregnancy' and produce 'pregnancy' as a social discourse: they shape how we think about and value pregnancy. Furthermore, as new social, scientific, technological, and political innovations occur over time they do so within the context of these social structures and as these social structures shift so do the available scripts or understandings of 'pregnancy.'[21] The genealogy of pregnancy highlights the role played by the social structures of science, medicine and governance in producing pregnancy as a discourse.[22] What needs to be remembered in attempts to improve clinical research during pregnancy is that clinical research, like the other social structures studied in this project, is also a discourse, a social construct, a powerful site for the production of a wider

[20] Foucault et al., *The Birth of Biopolitics*; Rabinow and Rose, "Biopower Today," 196; Foucault, *Security, Territory, Population*, 1.

[21] Thus although the first section of historical discussion takes place before the advent of the modern nation state and the political will to manage demographics, when biopower formally arose according to Foucault, I argue that the incorporation of pregnancy into the medicalised model of health began with the development of obstetrics as a medical speciality in the early modern era situating all pregnancies as a site of health to be managed and improved by medicine and thus was a significant early event in the incorporation of reproduction into the political space. Therefore, the biopolitical era began earlier than Foucault identified in that it was integral to the rise of the nation state rather than a consequence of the development of the nation state.

[22] One key social structure that I fail to touch on is the economic and business structures that govern pharmaceutical research, production and consumption. An exploration of the contributions of business and economics to the narrative forces influencing pharmaceutical research during pregnancy would simply add on another very large and unwieldy layer of analysis and one that I am unqualified to provide.

discourse of pregnancy, setting norms for how pregnancy is valued – or not – as a social practice, how pregnant women are heard – or not, and in general greatly influencing wider discourse of what is considered, healthy, normal, risky and responsible during pregnancy.[23]

Why a Genealogy?

Having introduced the problem of pharmaceuticals and pregnancy I will briefly explain the aim of the historical component of this project presented in Chapters Two through Four. During discussion of the historical material I am guided by a Foucauldian genealogical approach exemplified by philosopher Ladelle McWhorter's genealogies of race and gender in the USA which embeds biopower and the contingency of historical trajectories in her critiques of current discourse around gender and race.[24] Genealogies emphasise the way in which historical events shape discourses and produce norms, narratives and scripts. My historical genealogy of pregnancy aims to better contextualise the current discourse of pregnancy, to identify how, rather than support, aspects of the current discourse inhibit clinical research during pregnancy. Emphasising the mutability and contingency of 'pregnancy' better situates an attempt to challenge and reconfigure those aspects of 'pregnancy' which currently do disservice: those scripts, narratives and stories that promote the exclusion of pregnant women from clinical research for reasons other than safety.

The social, scientific, medical, technological, and political developments – the histories – discussed throughout the genealogy contribute to the discourse of pregnancy by being the framework upon which people experience pregnancy. Overall my genealogy is heavily dependent on two histories of pregnancy: those of Rebecca Kukla and Claire Hanson, both of whom emphasise the ethical implications of cultural representations of pregnancy and

[23] Feminist theory provides the framework of empirically grounded theory and overall language of scripts, discourses, and narratives that I have adopted. See especially Margaret Urban Walker's *Moral Understandings* and feminist bioethics especially Lindemann and Verkerk's *Naturalised Bioethics.*
[24] McWhorter, "Sex, Race, and Biopower"; McWhorter, *Racism and Sexual Oppression in Anglo-America*; McWhorter, "Decapitating Power."

pregnant women. The work of both these thinkers is central to my linking a contemporary ethical issue – pharmaceutical research and pregnancy – to the broader historical discourse of pregnancy.

In the service of contextualising the sociocultural norms underling the problem of research during pregnancy I produce a genealogy of pregnancy focused upon elucidating the role of social, scientific, medical, technological, and political developments in shaping the discourse of pregnancy using a series of five key intermediary concepts – risk, health, nature, responsibility and the fetus. Genealogies are histories of the present, aiming to clarify and contextualise a current discourse via discussion of its history. The genealogy presented in Chapters Two through Four highlights various norms and narratives centred upon these five key ideas of risk, health, nature, responsibility and the fetus, emphasising how they are produced via historical events and continue to shape our current thoughts and experiences of pregnancy. Many of these narratives have been individually discussed elsewhere, particularly in feminist and medical histories centred upon pregnancy and medicine, or maternity and parenting. Tracing their collective historical trajectory and relationships to each other while also emphasising their influence upon shaping key social structures and institutions that continue to govern the relationship between pregnancy and medicine today highlights how collectively they continue to work to impede clinical research during pregnancy.

These case studies highlight instances when understandings of the fetus and what was considered safe, healthy, natural, and chosen in the context of pregnancy shifted in a significant manner, such that the overall discourse of pregnancy changed. Pregnancy entered the domain of medicine during the early modern era when accoucheurs replaced midwives in caring for pregnant and birthing women, thus situating ‘pregnancy’ as a time of healthcare need. In the nineteenth and early twentieth centuries the range of interventions available to manage ‘health ‘and ‘risk’ during pregnancy proliferated and notions of what is natural, or

not, during pregnancy also began to shift. As demographic patterns shifted towards smaller family sizes the social and economic value of reproduction to nation states increased and maternal health during pregnancy and fetal wellbeing became increasingly prioritised both as a focus of scientific and medical research and via targeted funding for health and social services. In line with wider social shifts in risk discourse around environmental management and exposure to substances, and precipitated by the Thalidomide and DES tragedies, a significant upheaval occurred beginning in the 1950s and continuing well into the 1980s whereby risk avoidance became a dominant paradigm governing the interactions of pregnancy and medicine. While for the most part this played out via recommendations to minimise or eliminate exposure to risky substances – cigarettes, alcohol and certain foods - this narrative of risk avoidance as precaution has also shaped expectations, policies and practices around pharmaceuticals during pregnancy including pharmaceutical research.

My final chapters draw together and apply the insights gained in the genealogy. In Chapter Five I discuss the contemporary iterations of the five key concepts and the features key to understanding pharmaceuticals and pregnancy. Chapter Six builds on Chapter Five by first exploring the narratives of risk and responsibility in contemporary policies, about research during pregnancy. It then examines the role of the narratives produced by these policies to five concepts in structuring the experiences of the stakeholders involved in pharmaceutical research during pregnancy. Over the last decade the systems – the policies and practices – to encourage and conduct pharmaceutical research during pregnancy have been developed and are now widely in place. What remains is the need to actually improve the overall rate of research and this requires persuading the various stakeholder groups– medical professionals, scientists, research ethics boards and pregnant women – to participate. What is clear is that simply communicating the benefits of such research is insufficient.

Enacting change will require specific and sophisticated educational initiatives and Chapter Six outlines practical changes that could be made.

Chapter Six draw upon insights from the genealogy to better understand why interventional research during pregnancy is not conducted and what needs to be changed or communicated differently to successfully persuade stakeholders to engage in clinical research. Based upon findings from other stigmatised technologies such as vaccines that have similar issues with risk perception I argue for more targeted and careful interactions with research participants during the recruitment and consent processes that are shown to increase the accuracy of risk communications. In addition, education for clinical researchers and research ethics board members ought to include a specific discussion of the role of social norms and narratives such as maternal responsibility and good mothering, how they influence and shape people's decision making around clinical research during pregnancy and how this impacts people's perception of risk and acceptable behaviours during pregnancy. This project started off with a basic dilemma: if we know we ought to do more pharmaceutical research on pregnant women why don't we? Through a consideration of the wider discourse of pregnancy and its relation to ideas of risk, health, nature, responsibility and the fetus, I present new insight into why more clinical research is not conducted during pregnancy. [25f]

[25] This is a project within naturalised feminist bioethics, an approach that calls for greater contextualisation and greater use of data in bioethical debates. Feminist bioethicists adopting the naturalised approach argue that this is required in order to understand "moral judgement and moral agency in terms of natural facts about ourselves and our world." While naturalised feminist bioethics has been primarily applied to clinical bioethical issues there is no reason not to apply the same methodology to issues in research ethics. Lindemann, Verkerk, and Walker, *Naturalized Bioethics*, 1.

ONE: Theorising pregnancy and structural injustice.

> Pregnancy has been used as a location to project social anxieties and to exert social control.
>
> Armstrong *Conceiving Risk, Bearing Responsibility*

1.1 Key concepts

Pharmaceutical research during pregnancy has only been identified as ethically problematic in retrospect.History has conspired to set up the norms and expectations of pregnancy – the discourse of pregnancy – such that research was not considered safe or suitable. The potential harms of research participation were considered greater than the harms arising from a lack of knowledge about safe and effective treatments and it was wrongly assumed that research upon the non-pregnant population would yield sufficient information for how drugs would work on pregnant women, an assumption only proven wrong in retrospect. While steps can be and now have been taken to encourage pharmaceutical research during pregnancy there remains a lingering gap between policies and practice that is attributable to particular ideas about risk, health, nature, responsibility and the fetus during pregnancy. This section introduces the idea that this is a problem best characterised as a structural injustice. I then move on to discuss social structures and the role of science, medicine and governance in producing the problem– themselves social structures – that make it a structural injustice. Third I introduce in more detail the five key concepts of risk, health, nature, responsibility and the fetus that are traced throughout this project. Fourth and finally, I finish with a discussion of the relationship between narrative scripts and discourses.

A Structural Injustice

The imbalance in pharmaceutical research with regards to pregnancy is a structural injustice, a particular form of harm that arises indirectly as a result of the background social structures

shaping the discourse rather than from individuals making decisions that harm themselves and others. Structural injustices are harms that arise as a (usually unintentional) consequence of the systems and processes, institutions, policies, laws, and practices that are required to have a functioning society. How we fund, value and discuss education, health, infrastructure and businesses (to cite a few examples) impacts people in myriad ways. Despite apparently neutral language and values, the patterns of allocation created by our social structures have different impacts upon and consequences for different social groups. For already disadvantaged social groups the impact of these patterns of distribution is *broad* across many areas of their lives and can create more serious and/or long lasting financial, physical and psychological damage that compounds upon lives that are already harder than those of other social groups.[1] These patterns of allocation can also cause harms that impede people in specific *narrow* ways, such as in the case of pregnancy and pharmaceuticals where the structural practices and patterns make unavailable a resource, in this case pharmaceutical-based healthcare, which is accessible to others. While both broad and narrow cases are the same kind of injustice – structural – they are different in scope. Examining one particular structural injustice that is narrower in scope may provide insight into the more complex structural injustices by mapping how seemingly distantly related or beneficently intended changes to patterns of allocation, such as changing particular policies or practices, promotes or lessens particular structural injustices. The question is how do institutions, policies, laws, and practices perpetuate the lack of pharmaceutical research during pregnancy and how ought they to be changed to promote such research instead.

[1] Young, "Political Responsibility and Structural Injustice"; Young and Nussbaum, *Responsibility for Justice*. These are the types of structural injustice most often discussed in the context of racism and sexism.

Social Structures

An aspect of the problem of clinical research during pregnancy that has been understudied is the role that social structures play in producing norms and narratives. Tracing and explaining how norms and narratives are produced and shaped within social structures are central to my argument as these cultural norms and narratives are key to understanding why there is a lack of clinical research during pregnancy. Young provides a comprehensive articulation of social structures as

> [T]he confluence of institutional rules and interactive routines, mobilisation of resources, as well as physical structures… constitute the historical givens in relation to which individuals act, and which are relatively stable over time…serve as background conditions for individual actions by presenting actors with options; they provide 'channels' that both enable action and constrain it.[2]

How do policies and practices, both institutional and informal, shape and inform the experiences and expectations of and about pregnancy in relation to pharmaceutical research? How do social structures encourage and discourage pharmaceutical research during pregnancy and how can we reconfigure them to encourage more research? At the core of this project are the social structures that shape our experience of the world. By social structures I mean both political and non-political institutions, and both the formal policies and laws and informal norms that are produced within the structures.

Social structures, political and non-political institutions, formal policies and informal norms, play an important role in maintaining and transforming configurations of power. Institutions such as hospitals, research groups, government departments, NGOs and advocacy and professional groups play key roles in the discursive pathway of pregnancy.

> Law, custom, tradition and institutional authority, expertise and discursive boundaries interweave in a sturdy set of barriers that contain or disqualify the speech of some individuals in hierarchical social and political arrangements, or restrict the effect of their speech to limited domains of social interaction.[3]

[2] Young, "Responsibility and Global Justice," 111.
[3] Walker, *Moral Understandings : A Feminist Study in Ethics*, 229.

Highlighting the way in which power relations function within discourse to strengthen or discount different sources of narrative contribution is a key aspect of the production of the discourse of pregnancy: the uneven degree to which different narratives and narrative sources are taken up within a discourse or how much any given narrative contribution is heard.

Since the nineteenth century science and medicine

have increasingly become dominant structures shaping social narratives and norms. Thus, it comes as no surprise that science and medicine are also significant to the story of pregnancy and have become increasingly influential within pregnancy as a discourse over the same period. While they are by no means the only structures and interpretative frameworks significant to pregnancy, medical and scientific discussions are a key site in which the explicit and implicit narratives about pregnant women and fetuses, and their relationship, can be examined. This project will trace these social narratives beginning in the seventeenth century when the 'public' interest in pregnancy intensifies and childbearing and pregnancy, parenting and reproduction became increasingly important topics of social and political commentary linked to social, economic and scientific changes. As Kukla argues "despite the ongoing, reasonably constant themes of permeability, craving, purity and corruption across our last 2,500 years of imagining female reproductive bodies…the medical and cultural status of mothers' bodies went through a profound transformation during the second half of the eighteenth century," a transformation that she links to the rise of the enlightenment social and political ideals and the rise of modern science.[4]

By drawing together key historical events and trends identified by social and medical historians, social and anthropological works about medicine and science, and primary texts about pregnancy, this project aims to draw specific attention to how the discourse around a

[4] Kukla, *Mass Hysteria*, 6. While Kukla identifies the mid eighteenth century as a critical juncture in the discourse of pregnancy I will argue in the next chapter that the key changes to the discourse of pregnancy in English speaking countries begin in the Seventeenth Century with obstetrics.

particular type of subject, 'pregnant women', is shaped by a series of historical developments. In each of the chosen historical examples the discourse of pregnancy is reconfigured by shifts in ideas about risk, health, nature, responsibility and the fetus. These concepts mediate the discourse of pregnancy at given moments by influencing the available scripts about pregnancy. These scripts structure how we consider pregnancy, how we interact with and value pregnant women and how pregnant women consider and value themselves; collectively the various relations that constitute the discourse of pregnancy. Each concept is central to understanding changes in the narrative of pregnancy and assists in articulating the relationship between specific social, political and scientific events and the discourse of pregnancy. Thus, they help explain shifts in norms (changes to the available scripts) about what is right and natural during pregnancy and thereby also help understand and articulate changes in how both people and social structures interact with pregnant women, why what we expect of pregnant women changes, how pregnant women understand themselves and what pregnant women expect of themselves.

Medical, scientific, technological, and political developments lead to "changes in the conduct and management of pregnancy" and these changes provide evidence of social and moral shifts in the ideas and ideals available within the scripts and narratives of pregnancy.[5] Overall, I aim to emphasise the malleability of the discourse of pregnancy in response to social, scientific, medical, technological, and political developments. While I primarily wish to discuss how the current discourse of pregnancy functions to impede clinical research during pregnancy, I also aim to highlight the role clinical research itself as a socially and politically embedded technology in shaping the discourse of pregnancy. I want to suggest that this historical examination of pregnancy is significant for understanding both the ebb and flow of the implicit moral valuation of pregnant women into the present day and also how

[5] Ibid.

contemporary shifts and conflicts in moral valence can relate to social-political changes and policies that have little obvious direct connection to pregnancy. In particular, attention to the depiction of pregnant women in medical, scientific and policy texts highlights the implicit moral valuations of pregnant women throughout the period of analysis. The genealogy charts both *social* and *moral* changes in the discourse of pregnancy in order to better illuminate the present.

It is worthwhile to consider how and why pregnancy is a site of such powerful and authoritative stories – why are norms and narratives, stories and scripts about pregnancy so forceful? Their strength derives in part from pregnancy's dual role as a site of both physical and cultural reproduction.[6] As a central and positive event in many people's lives, pregnancy is part of passing on cultural practices to the next generation.[7] In the modern era it is also a site of civic reproduction and the continuous supply of future citizens to reproduce the nation state, citizens who have been steeped in the civic norms and practices of their country.[8] Kukla takes this social, cultural and political centrality of pregnancy as a jumping off point to emphasise how "our ways of imagining and representing bodies have ethical, political, practical, and medical repercussions for those bodies."[9] My genealogy aims to build upon Kukla's premise and illustrate and contextualise how the rise of new social, scientific, medical, technological, and political structures and events shape the boundaries and content of the discourse of pregnancy as mediated by risk, health, nature, responsibility and the fetus.

Shifts in the content and boundaries of these concepts thus can change not just the cultural imaginary of pregnancy, how pregnancy is understood and interpreted, but also the ethical imaginary, what is morally permissible during pregnancy. These imaginaries, or conceptual spaces, are produced within the specific social, scientific, medical, technological,

[6] Hanson, *A Cultural History of Pregnancy*, 83–103.
[7] Tsolidis, "The Role of the Maternal in Diasporic Cultural Reproduction: Australia, Canada and Greece."
[8] Yuval-Davis, *Gender and Nation*.
[9] Kukla, *Mass Hysteria*, 3.

and political, practices and structures, associated with pregnancy. In turn these practices and structures reshape and reconfigure the boundaries of the imaginaries. Shifts in the boundaries and thus in the content of the cultural and ethical imaginaries can have real repercussions such as a lack of knowledge about the safety and efficacy of pharmaceuticals during pregnancy. Each of the changes examined considers exactly this: how the development produces shifts in both the morally 'acceptable' and the conceptually 'possible' boundaries associated with pregnancy via the intermediary concepts of risk, health, nature, responsibility and the fetus.

The Five Concepts

My genealogy presents not a broad discussion of pregnancy but rather focuses on a series of discrete events that shifted the circulation and uptake of five key ideas within the discourse of pregnancy: risk, health, nature, responsibility and the fetus. In particular I aim to highlight how what is considered safe, risky, healthy, natural, responsible, and thus normal and right during pregnancy inhibits clinical research during pregnancy and how attempts to improve rates of clinical research during pregnancy need to be refined to either work with existing norms and narratives of pregnancy or use more sophisticated techniques to counter and overcome aspects of the current discourse. Contextualising the lack of pharmaceutical research during pregnancy in this manner highlights both barriers and potential sites of intervention for resolving the issue.

My interest in the ethics of pregnancy and pharmaceutical research started in debates about pregnancy and vulnerability.[10] How the label of vulnerable was used to exclude

[10] In the interest of restricting scope, I only touch briefly on the other ideas such as vulnerability which also impact on the discourse of pregnancy in ways relevant to pharmaceutical research. I link vulnerability into this discussion where relevant via the concepts of risk and responsibility. I do not trace it directly as an extensive literature already exists around pregnancy and vulnerability and within the context of the most recent clinical research guidelines issues arising from the linking of pregnancy and vulnerability have been adequately addressed. See Ballantyne and Rogers "Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research" in *Clinical Research Involving Pregnant Women* for a detailed account.

pregnant women from pharmaceutical research, and the lively academic debate about how to improve the situation. In particular there has been a focus on how to remove the negative connotations vulnerability has for the autonomy of pregnant women while ensuring the safety of pregnant women. I felt, however, that resolving this issue of defining pregnant women as vulnerable (or not) was insufficient to both explaining and fixing the broader problem of pharmaceutical research during pregnancy and decided to look for other concepts that were contributing barriers to research during pregnancy. I first looked at a range of contemporary guidance and regulatory documents governing human research practices which allowed me to identify the five key concepts and then expanded my research historically as I attempted to understand how and why they took their current contradictory forms. The final five concepts of risk, health, nature, responsibility and the fetus that I settled upon were the minimum number I found necessary to explain why we don't do pharmaceutical research on pregnant women even when know we ought to. They are a way of framing and connecting across different historical eras and academic disciplines my attempt to answer the question: if we know we ought to do more pharmaceutical research on pregnant women why don't we?

Each concept discussed is a complex discourse in its own right. At any given point 'risk' includes notions of risk perception, risk management, uncertainty, quantifiability and both population (epidemiological) and individual risk. 'Health' includes notions of ill health, wellbeing, disorder and disease. 'Nature' in this discussion is focused upon ideas of naturalness and sits in opposition to 'artificial' or to processes that are governed via technology. 'Responsibility' includes ideas of control, blame, accountability, duty, vulnerability and the division of obligations, and reflects ideas about how autonomy is ascribed, both to the self and others, and reflects assumptions about the moral status and capacities of individuals. 'The fetus' includes all points of development between conception and birth and the maternal-fetal relationship, and reflects assumptions around the moral value

and status of the fetus both as an individual and in conjunction with pregnant women. Risk, health, nature, responsibility and the fetus all function to constrain and construct how we as a group think and act about pregnancy: the cultural imaginary of pregnancy. I struggle to provide more detail than this on each of these concepts or unpack them further at this stage as doing so is a central component of the genealogical section of this thesis where emphasising their mutability over time and the contestableness of their interpretation at a given moment is a central premise of this project. This project is a discussion of key historical moments when the very meanings of these five concepts change. Explaining how and why these changes occur in an attempt to shed light on the current discourse of pregnancy.

Scripts

Social structures encourage and discourage particular practices because they structure interactions between individuals and thus contribute towards constructing particular scripts that seem *right* for such relationships.[11] For instance a doctor and a pregnant woman will have a particular relationship when meeting in a clinic as compared to having a chance meeting on the street: the range of interactive options is constrained differently depending on the context of particular social structures around them. Similarly, the pregnant woman choosing to give birth at home or in a hospital has a different range of options available to her in each space – interaction with other people is not always necessary for social structures to impact people's actions and choices. Life can be understood as a continuous sequence of experiences taking place within the context of particular social structures, often many at the same time. When social structures change with time and geography, so too do people's understandings about themselves, others, and the world.

For example, the introduction of a new government initiative to build and run standalone birthing units, staffed primarily by midwives rather than doctors and nurses,

[11] Not just between individuals but also towards oneself.

would both represent and influence shifts in the discourse of pregnancy and reproduction. The development of a new social structure such as a birthing unit includes not just the physical space but the policies and regulations, norms and narratives, that brought it into being and promotes (or not) its continued existence. Such a unit is atypical in the USA, where professionalised midwifery is rare, and hospital based births attended by obstetricians are the norm; it is slightly more common in Canada and Australia where mixed midwife-physician-obstetrician care is the norm; and is very common in countries like the Netherlands and New Zealand where professionalised midwife-led care is the norm.

This geographic unevenness in lead maternity carers both reflects and reinforces differences in the balance of narrative contribution of several of the key concepts explored in this project – *risk, health* and *nature.* Hospital based childbirth, and its risk management focus, leads to higher rates of technological intervention in birth which reinforces the way in which pregnancy and childbirth are perceived to come with increased health risks. In contrast, midwife led care emphasises the normalness of pregnancy, framing it as a natural, healthy endeavour.[12] Thus differing policies, structures and practices among nations reinforce and encourage both overt and subtle differences in the norms of expectation and practice within the discourse of pregnancy. However, regardless of their particular arrangement the five key concepts remain the same – risk, health, nature, responsibility and the fetus – the balance of their contribution to the discourse of pregnancy differs.[13]

The range of channels or interactive script options that the doctor, midwife and pregnant women have today are similar to the range available in each scenario five years ago because the wider political, medical, scientific and technological changes have been small

[12] This is an overly reductive simplification. It is not a tidy binary between the norms supported by 'midwifery' and 'medicine' but rather a matter of 'more' and 'less' supportive. See section 2.1 for further discussion.
[13] Another example of this phenomenon is the differences between countries in debate and regulation about abortion which has a similar effect in causing differences in the balance between the key concepts of the fetus and responsibility.

and gradual. However, the range of scripts on offer now differs significantly from that available fifty years ago because both policy and practice have changed significantly. There have been many political, medical, scientific and technological shifts that have changed what, and how, we think about pregnancy. Thus, temporal variability in the range of channels or scripts about pregnancy within the context of various social structures is a key aspect of tracing how people's understanding of pregnancy has changed over time.

The scope of this genealogy includes English speaking North America, the UK, New Zealand and Australia. While they have some contemporary and historic differences, they also have many more similarities to their discourses of pregnancy arising from their shared linguistic, cultural and colonial histories. At various instances this genealogy of pregnancy narrows geographic focus to talk about specific events in specific countries or continents, in order to illuminate how a change to the discourse of pregnancy arose but these changes flow outwards to influence the wider group of countries. Furthermore, contemporary pharmaceutical research during pregnancy is an international endeavour and patterns of colonisation and social, scientific and cultural exchange make this grouping logical. Being able to highlight geographic and cultural difference between these regions and countries allows further emphasis of the contingency and malleability of the ideas examined throughout the following chapters.

Examining geographic and temporal changes in a discourse such as pregnancy are ways to trace the malleability and contingency of the locally available scripts and norms (values upon which scripts are based). Thus, the range of options, or potential scripts, that individuals and groups consider possible shifts in time and space depending on particular historic, social and political events, and as new events occur over time that shift social structures and power relations, such as medical, scientific, technological developments. Medical, scientific and technological developments upset existing social structures and power

dynamics shifting people's understanding of the world and what is possible within it – thus changing the scripts available. To draw on a well-studied example, historically as technologies like embryology and ultrasound imaging developed which allowed people to visualise the fetus, the discourse of fetal personhood and the status of the fetus has changed the particular scripts available to people about how they can understand a fetus. While these technologies are by no means the only factor influencing the discourse of fetal status, being able to 'see' a fetus, and its resemblance to born persons, cannot help but impact how we think about them and how we talk about them more formally in law and politics.

The DES and Thalidomide regulatory failures, another example that will be discussed in Chapter Four, shifted medical policies and practices to limit pregnant women's access to pharmaceuticals, a reasonable response but one with unanticipated consequences for pharmaceutical research.[14] Medical and scientific policies changed in response to events around DES and Thalidomide, shifting the range of scripts available about pregnancy in a way that emphasises the riskiness of pregnancy, the vulnerability of the fetus and the potential for in utero damage. Not only did medical professionals become reluctant to give pregnant women pharmaceuticals, but pregnant women became reluctant to consume them and more widely people began to consider what other previously unconsidered things could constitute a risk for pregnant women – alcohol and smoking being the most obvious. *Risk* in pregnancy shifted from only being a concern when something went wrong with the pregnancy to being a worry about all choices made about all aspects of even the most normal, healthy pregnancies.[15]

While contextualised and nuanced accounts of maternity have been developed for many minority groups, the ethical and policy implications of both the particular narratives

[14] See 4.1 - 4.2 for detailed discussion.
[15] See Section 4.3 for a detailed discussion.

and their multiplicity need to be considered.[16] A feature of all social structures is that they group and categorise individuals. A key feature of many of the institutions that developed in the twentieth century is both the manner in which they allocate individuals into social categories and the importance they place in doing so.[17] Demography and the collection of demographic data via social structures and institutions stabilised the boundaries of social categories.

1.2 Pregnancy as Identity

> Feminist bioethicists can never avoid asking the question, how does this work in the lives of real women and men, and in the current political frameworks in which we exist?
>
> Scully, *From Theory to Method*

Contrasting and comparing 'pregnancy' with other categories of identity, such as those associated with race, sexuality, or disability, highlights both the unique aspects of pregnancy as an identity – in its social functioning and relationship to health – and how (and how not) this project compares with the equality and justice movements of other categories of identity. In order to make an argument that the exclusion of pregnant women from clinical research is a structural injustice it is necessary to examine the aspects of pregnant women as a group identity that make it an identity category that can be discriminated against. Identifying the similarities and differences between pregnancy and other identity categories illuminates how a lack of pharmaceutical research upon pregnant women is a health inequality best characterised as a structural injustice.

[16] McCall, "The Complexity of Intersectionality." Following McCall this project assumes an orientation towards intersectionality of intercategorical complexity and adopts "existing analytical categories to document relationships of inequality among social groups and changing configurations of inequality along multiple and conflicting dimensions. McCall distinguishes this form of intersectionality scholarship from two others, those which are anticategorical and intracategorical that study ever more layered and neglected identities.
[17] This point is expanded in Chapters three and four.

A genealogy of pregnancy is potentially a different kind of thing, or level of analysis, than more common topics of genealogical analysis such as race, sexuality, criminality, military discipline and pedagogy.[18] It is worthwhile to consider the similarities and differences between pregnancy and other categories of identity that are disadvantaged on the basis of age, gender, class, ethnicity, sexuality and disability. While pregnancy shares many similarities to other social categories that also mediate structural injustices upon group members it has some significant differences that make wholesale application of theory and policy from the 'isims' impossible. Where race and sexuality are categories for identifying a collective group of kinds, pregnancy is only a kind, there is no collective that pregnancy as kind belongs to commonly used, although perhaps one could be created artificially by stringing words together: women-organised-in-terms-of-their-current-reproductive-status. In this instance, disability is similar to pregnancy and is also a kind, one whose collective is even harder to identify than that of pregnancy due to dispute over what 'disability' actually identifies and the normative implications of how the identity is defined.

An important difference between pregnancy and disability for instance is between the desirability and value placed upon them by both individuals and policy. A strong dominant narrative flows through the discourse of pregnancy in which reproduction, and thus pregnancy, is viewed as a particularly 'good' or valuable thing in itself. It is only when people consider pregnancy in combination with other aspects of identity – to do with age, race, income, relationship status, and mental or pre-existing health conditions – that people express reservations and less positive narratives or scripts are mobilised. Thus, multiple narratives can be held concurrently - doubt about an unemployed, single, young woman becoming pregnant but also that pregnancy is a valuable social good.[19] This 'valuing' of

[18] McWhorter, *Racism and Sexual Oppression in Anglo-America*; McWhorter, "Sex, Race, and Biopower"; Foucault and Hurley, *The History of Sexuality*; Foucault, *Discipline and Punish*.
[19] Kaplan, *Not Our Kind of Girl*, 3–7.

pregnancy is important because it helps rule out abstract resistance to the additional financial expenditure as a source of the impediment to clinical research during pregnancy: it is not perceived as unfair, or additional benefit above and beyond what pregnant people *deserve.* Desert is a concept seldom considered in relation to pregnancy and marks a unique point of difference from other categories of social identity even when consideration is limited to other groups differentiated on physiological-biological difference.[20] Considering how pregnancy differs is important because obtaining the additional resources required to overcome an inequality can be a significant barrier to overcoming structural injustice and this indicates it may be less of an issue during pregnancy.[21]

Pregnant women as a group are not socially disadvantaged. While many accounts of structural injustice emphasise the benefit to other groups that arise out of a structural injustice, I would argue that the case of pregnancy and pharmaceuticals indicates that while common, that other groups benefit, or are perceived to unjustly benefit, is not a necessary feature of structural injustices.[22] Real or perceived disparities of benefit are rather an additional barrier that needs to be overcome in order to resolve structural injustices. There is very little negative association with 'pregnancy' as it (for the most part) marks a positive state of difference from the 'normal' population; it is a good, valuable and desirable difference. The perceived deservingness of pregnant women is paralleled to a lesser extent by people with disabilities who are also often accepted as a group deserving of extra resources. The greater willingness to provide additional resources to pregnant women and disabled people in general also arises because disability and pregnancy are not only 'biological' but

[20] Desert – what a person is deserving of.
[21] For instance, inequalities between black and white Americans arising out of the Atlantic slave trade and contemporary social and political resistance to targeted resource allocation to reduce these inequalities.
[22] In theory it could be argued that not researching on pregnant women allows the distribution of resources to increase research on other populations; however, I have never seen this proposed as a feature of the problem in the literature describing and analysing the lack of clinical research during pregnancy.

also occur across all racial ethnic and class groups. Margaret Urban Walker, in her discussion of stereotype and identity, argues that stereotypes are often used to diminish moral regard.[23] However in this case study the social value placed upon pregnancy makes it heightened moral regard instead.[24]

Drawing on Jackie Leach Scully's theorising of 'disability' highlights other aspects of the disanalogy between pregnancy and other categories of identity. Scully argues that there is a "conceptual difference between disability and gender, class, ethnicity, or sexuality, whether these are considered to be ontological or socially constructed categories."[25] In particular Scully emphasises that while each of these categories has a biological component, they are not biologically determined. She argues that this is because "the consequences of membership [in these categories] have more to do with cultural appraisals than with biology per se."[26] The distinction Scully is driving at here is that the biological component of disability (and pregnancy) is of central importance in a way it is not for categories such as race and sexuality. This analysis however sits in tension with a genealogical approach where the focus is on highlighting the way in which 'pregnancy' is the product of systems and structures, of discourse and practice, a socially constructed category. As with all categories pregnancy is not just a biological kind but also a social kind, an identity centered on a particular unique biological transformation of the body where those identified as pregnant will traverse a set of bodily changes over time within particular social contexts.[27] A key aspect of this genealogy will be highlighting how the physical changes wrought upon the process of pregnancy by technologies – pain relief, ultrasound imaging, caesarean sections –

[23] Walker, *Moral Understandings : A Feminist Study in Ethics*, 203.
[24] It is worth noting that often the subject of concern-focus-moral regards seems not to be a woman but her fetus and that in some circumstances moral regard for a pregnant woman is actively rejected in favour of prioritising moral regard for the fetus. See sections 4.4 and 5.4 for a fuller accounting of this phenomena.
[25] Scully, "Admitting All Variations?," 56.
[26] Scully, 56.
[27] For discussions of the social construction of race and gender see Butler "Gender performativity"

influence the discourse of pregnancy (pregnancy as a social kind) emphasising how such transformations reconfigure the discourse.

Scully emphasises that the biological component of disability is normatively significant because disability is defined in relation to health and thus to the provision of health care for disabled people.[28] This link between the biological and the identity category or 'kind,' 'health' and the provision of healthcare, also holds for 'pregnancy'. Pregnancy qua pregnancy is 'healthy' in that pregnancy is not a disorder making someone sick or ill, yet pregnant women need specific and targeted healthcare resources to ensure that this remains the case. Antenatal monitoring and safe childbirth are matters of 'health' but not treatment per se, because pregnancy is natural rather than disordered or in need of fixing. However, as I argue, the dominant narrative within the discourse of 'health' is 'treatment' of disorder and the unnatural and unhealthy. This then creates ambiguity and tension in the framing of pregnancy in terms of health particularly given the increased risks of pregnancy.

It is within this context of health and pregnancy that Scully's point about the importance of the biological-ness to the identity category needs to be considered. The structural injustice around the provision of healthcare during pregnancy is specifically linked to tension in the relationship between 'pregnancy' and 'health', where health is predicated on a particular idea of biological difference (in the sense of an unhealthy or disordered body for illness or for pregnancy just simple difference). The discourse of health and its relation to biology, disorder/disease and nature is thus of key importance for understanding pregnancy, particularly the way pregnancy is encoded and discussed in policy and governance documents that regulate the provision of health care. Consequently, another theme that will be explored throughout the genealogy is how changes in the relationship between 'health' and 'disease'

[28] Some other 'kinds' also have complex relations to 'health' for example people who identify as trans and ethnic and minority groups with high risks for certain hereditary diseases. However, disability is by far the most similar to pregnancy in actually being shaped by the discourse of health.

influence notions about 'risk' and 'pregnancy.' Alongside responsibility and the fetus, these three ideas of heath, risk and nature are central to changes in the provision of healthcare during pregnancy and also central to pregnancy as an identity category. Clinical research during pregnancy is an important part of ensuring health and one of the core impediments to research during pregnancy is the norms that have arisen out of the interactions of discourses of health, risk and responsibility throughout the twentieth century that make such research during pregnancy seem unacceptable and unsafe.

1.3 Biopower and Genealogy

The current problem of pregnancy and clinical research can be improved by considering the story of pregnancy so far. There is a broad alliance in support among regulators, researchers and practitioners in favour of improving the available knowledge about the safety and efficacy of pharmaceuticals during pregnancy but in practice the research required to establish the body of knowledge still only occurs at a very low rate.[29] While others focus on legal, economic and policy solutions to the conundrum of pharmaceutical research during pregnancy, I examine the contribution of current sociocultural norms, narratives, notions and scripts about pregnancy and how the five key ideas shape policy and practice.[30] In order to do so I draw upon insights from feminist epistemology, critical race theory, and medical and feminist history, whose shared emphasis on power, narrative, and discourse offer ethical orientation and empirical grounding for my genealogical history of pregnancy and link it into the ethical analysis provided in Chapter Five.

The historical approach is underpinned by a Foucauldian genealogical framework and its account of power and biopower as a lens to understand and interpret the production of

[29] For instance, the Second Wave Initiative in the USA, and the 2014 changes to the TCPS in Canada and the 2016 update to CIOMS guidelines health based human subject research.
[30] Baylis and Ballantyne, *Clinical Research Involving Pregnant Women*.

norms, narratives and scripts. Foucauldian genealogies highlight the contingency of a historical discourse such as 'pregnancy,' and provide insight into a contemporary discourse.[31] While the ideas presented in this section are originally developed in the work of Foucault, they find their most productive articulation for the current project in the work of feminist authors. In particular I have been guided by the work of Ladelle McWhorter, who draws upon Foucault, and particularly his discussion of power, to produce a genealogy of race in the USA.[32] She subsequently develops a genealogical analysis of sex which she places in parallel with her genealogy of race in order to highlight how both phenomena "developed together in relation to similar political forces in the eighteenth and nineteenth centuries."[33] Her work is useful as an overall model of genealogy, an approach best explained in practice, as a guide to the key biopolitical forces in the eighteenth and nineteenth centuries and also in order to illuminate how 'race' and 'sex' differ from 'pregnancy'. What follows in this section is a discussion of key concepts of the approach as modeled by McWhorter – power, biopower, discipline and genealogy.

Genealogy

Genealogies are histories intended to critique the present. A genealogical history of pregnancy thus aims to illuminate pregnancy in the current moment and help explain how and why we have the current discourse of pregnancy and pharmaceuticals. Genealogical methods can be used to place issues of structural injustice within a historical context that highlights how the injustice arose and emphasise the particular scripts, narratives and discourses that continue to perpetuate the injustice. Genealogical analysis is a way for ethical theory to integrate and account for the role of history in the production of meaning and values. Genealogies provide accounts of the world that can illuminate the systems and processes by

[31] Foucault and Hurley, *The History of Sexuality*; Foucault, *The History of Sexuality, Vol. 2*.
[32] McWhorter, *Racism and Sexual Oppression in Anglo-America*.
[33] McWhorter, "Sex, Race, and Biopower."

which moral values are embedded on particular people and objects in the world in response to social, scientific, medical, technological, and political developments. Genealogy attempts:

> [T]o illuminate the contingency of what we take for granted, to denaturalise what seems immutable, to destabilise seemingly natural categories as constructs and confines articulated by words and discourse.[34]

Genealogy is a way of writing a history that highlights the mutability and social constructedness of 'pregnancy' via the five concepts: an account of how pregnancy as a social category came into its current state. It is an account that does not try to be comprehensive but rather to emphasise key events that had a meaningful impact on how we currently consider and value pregnancy.

Genealogies highlight the way in which a category – pregnancy, sexuality, race or gender – is not a natural thing but rather the product of systems of discourses and practices that are central to the functioning of modern society. For instance in the *History of Sexuality* Foucault emphasises the role of 'sexuality' as a category that structures and produces the human experience "directing social relations, classifying and examining bodies, authorising and legitimizing specialised knowledges and experts."[35] Focusing this genealogy of pregnancy upon the social, scientific, medical, technological, and political developments that inform it by structuring people's experience of pregnancy, in themselves or others, highlights the way in which pregnancy (at least the way we experience it) is not only natural in itself but also a socially contingent experience and concept. Historicising pregnancy creates distance from our experience of living within the discourse. In this instance a genealogy of pregnancy creates conceptual space to re-evaluate all aspects of the pharmaceutical research process and identify any assumptions about pregnancy that could lie in the way of change towards more just practices.

[34] Crowley, "Genealogy."
[35] Foucault, *The History of Sexuality, Vol. 2*, 3, 6, 10–12; Crowley, "Genealogy."

Power

Following Foucault, McWhorter emphasises that power ought not to be understood as analogous to an object, something "that can be possessed and passed around" and instead as more like an 'event': "Power is something that happens. It is a kind of tension that emerges when people have different goals or perspectives or conflicting projects."[36] This Foucauldian tradition, with its emphasis on power arising as a consequence of relationships between people in culturally specific circumstances, is ideal for contextualising the history of pregnancy. Contextualising the historical discourse in turn illuminates the contemporary discourse of pregnancy and the five concepts, emphasising the ethical consequences of shifts in the discourse. McWhorter emphasises that power struggles occur via people's attempts to "act on each other's bodily actions" and that power thus conceived is not just the formation of limits on people's actions but also creative in that it posits and produces reality as part of the process of struggle and negotiation.[37] However, to take up this understanding of power within the context of the problem of pharmaceuticals and pregnancy highlights the way in which power struggles are not just about intentional actions but more about the production of discourses in society. It is also worth mentioning here the notion of cultural hegemony and how we accept the status quo and things the way they are because they seem natural, right and normal.[38] Few people are intentionally acting to impede research with regards to pregnancy and pharmaceuticals, rather power is forming limits upon 'pregnancy' via shifting discourses of third-party concepts of risk, health, nature, responsibility and the fetus that make the current moment seem natural.

[36] McWhorter, "Sex, Race, and Biopower," 42.
[37] McWhorter, 42.
[38] Hall, "The Problem of Ideology-Marxism without Guarantees."

In an account of Foucauldian genealogy that emphasises the relationship between genealogy, power and practices of knowledge production, Una Crowley argues that "[c]conceptions of truth and knowledge are fundamentally products of power." Power is the network "between institutional practices, bodies and systems of thought." Power does not just place limits upon people's actions but also structures "the ways things are thought about, how people see themselves and others, and how they relate to the world around them."[39] Translated into the language of epistemology, power is thus a term for the productive force that creates, manipulates and structures the boundaries of knowledge in response to specific historical events. The productive and creative aspect of power is key to understanding how everyday lived reality changes moral values while maintaining a key aspect of moral discourse: the appearance of moral values as distant and apart from particular instances of culture. The formation, maintenance and malleability of moral values and practices of valuing always adhere on particular subjects and objects in particular societies.

While power relations are mostly in a state of constant change, for some periods of time, in some specific discourses, the power relations expressed in the particular cultural narratives producing institutions, theories, identities and routines will remain temporarily stable arrangements characterised by an equilibrium in which "the forces in play in a given situation oppose each other repeatedly in exactly the same ways at exactly the same points, so that the situation looks stable."[40] For instance, as traced in Chapter Two, until the early twentieth century ideology around the relative values of a woman and a late stage fetus was stable in this manner.[41] The socially and medically accepted norm was to save the health and future reproductive capacity of a woman even if it meant killing a late stage fetus.[42] It took the substantive demographic, political and technological shifts at the beginning of the

[39] Crowley, "Genealogy."
[40] McWhorter, "Sex, Race, and Biopower," 43.
[41] This may differ in countries and regions outside of the scope of this history.
[42] See Chapter Two for a full account

twentieth century that will be discussed in Chapter Three for this ideology to shift towards valuing every particular fetus and a willingness to take risks with a woman's health and future reproductive capacity.[43] Historically the relative valuing of fetus and woman was relatively stable with few people giving thought to the (potential) issue as challenging or problematic beyond the immediate sorrow of losing a child. As I will argue, the shift in the relationship between a woman and her fetus occurred in substantial part because of technological improvement: it became possible to save both a woman and her fetus without unreasonable risk to the woman.

By contrast, from the twentieth century onwards, the relationship between a woman and her fetus is constantly shifting – a product of a dynamic, constantly fluctuating discourse – as rapid changes in reproductive and bio-genetic technologies and the internationally influential prominent position of abortion in mainstream US political discourse constantly reshape the discourse of pregnancy. In most contemporary discourses the "configurations of power" are constantly changing and thus constantly contributing to dynamic and complex shifting in sets of social structures (political and non-political institutions, policies and norms), while also situating the relationships between individuals and individual senses of self in a state of flux.[44] Cumulatively this constant social flux reconfigures the imagined boundaries of reality (our understanding of the world, our relationships and ourselves) and thus has also shifted the potential meanings of pregnancy beyond what was previously considered possible – morally, scientifically or socially.

Biopower

A Foucauldian framework and its specific interpretation and attention to 'power' also provides a specific orientation to my subject matter, as the people involved in reproduction

[43] This shift will be taken up at greater length in sections 3.1-3.3.
[44] McWhorter, "Sex, Race, and Biopower," 43.

are situated at a particularly potent site of intersection between the power regimes of biopower and discipline. While pregnant women are the group most impacted by this intersection, all those involved in the particular processes of bearing and raising children are affected. Biopower denotes a particular set of networks of organisation, and is orientated towards governance and the power relations between individuals, groups and social structures: "to produce and intensify and direct vital forces rather than to limit and coerce what already exists."[45] Discipline, on the other hand, is the manner in which the social narratives produced by these networks are internalised and reproduced in the bodily practices and decisions of individuals. Reproduction, as conceived here, thus includes not just the continuation of individual family units and lines but also the continuation of groups via structures such as culture, state, and religion.

The majority of critical scholarship around pregnancy focuses on discourses of power within a disciplinary context: how particular practices associated with being pregnant are internalised in a way that limits and constrains a woman's understanding of herself, not just in terms of potential options but in terms of the perceived *acceptability* of particular options, for example eating certain foods. In contrast, eugenics, reproductive technologies, child-raising, and even the fetus – all discourses of reproduction broadly conceived – are more often than not critically situated as explicitly social practices within frameworks of regulation and norms, frameworks that constitute biopower. One aim of this work is to redress this imbalance in the study of pregnancy, which I argue is particularly important given, as Hanson argues, pregnancy's "peculiar susceptibility to regulation and social control." This susceptibility is not so peculiar when considered in terms of the importance of pregnancy to the social and cultural continuation of social groups, and social systems, and thus as a site of power contestation: not the least between the autonomy, responsibilities and desires of

[45] McWhorter, *Racism and Sexual Oppression in Anglo-America*, 13.

particular pregnant women and social, cultural and governmental desires for continuation. McWhorter asks "What was race historically speaking? Where had it come from? How did it become available for biopolitical transformation and use? How did those relationships evolve as the biopolitical structures, institutions, and discourses that fostered and connected them evolved?"[46] By using a genealogical historical approach the subsequent chapters aim to discuss these questions in relation to pregnancy emphasising biopower rather than discipline.

Attention to biopower and the role of structures of governance in shaping the discourse of pregnancy is of central importance to any genealogy of pregnancy in the modern era. As will be discussed in Chapters Three and Four the increasing focus of structures of governance upon reproduction explains the strength and dominance of narratives of good parenting and responsible maternity that are so forceful in the contemporary discourse of pregnancy. In this vein, Kukla highlights how pregnant and fetal bodies in eighteenth and nineteenth century medical texts are depicted as "dynamic entities that need to be *governed* and *ordered*" as opposed to "a given, static entity with a fixed 'nature'" as they were viewed in earlier eras. Kukla highlights a series of historical authors whose titles use *govern*, *governance* and *order* for actively managing maternal, fetal and infant bodies.[47] In what she calls a foreshadowing of Foucauldian terminology and sensibilities these texts focus on ordering not just behaviour or emotions but material bodies. While making a similar point to Kukla, McWhorter however singles out the late eighteenth century as the period when *all* bodies were reconfigured from "collections of parts that interact in space" to "temporal spaces that develop over time."[48] In conjunction with the development of statistical mathematics this shift in the understandings of bodies revolutionised the way people thought

[46] McWhorter, 13.
[47] Kukla, *Mass Hysteria*, 20.
[48] McWhorter, "Sex, Race, and Biopower," 44.

of both themselves and their work, a point that will be developed further in Chapters Three and Four.

While Kukla situates pregnancy as a story, Claire Hanson draws parallels between the physical and cultural mutability of pregnancy; emphasising the role that broader structures of interpretation play in producing the discourse of pregnancy, the rise of science and medicine as dominant social paradigms, and changes in the norms, expectations and practices around politics and governance. From the early twentieth century, pregnancy increasingly became the focus of governance, which given the prominence of the paradigm of medical science made pregnancy something to be categorised and catalogued, evaluated and improved. Improving and maintaining reproduction became a central function of states, and governance practices arose which aimed to not only improve the lives of women and their future children but also to reproduce the best sorts of people in an efficient manner, thus maximising the interests of nation states via practices of biopower. For example, the rise of child and maternal public health units as an early government priority will be discussed in Section 3.1. This shift towards the narrative production of pregnancy and reproduction within the context of biopolitics and biopower as produced by the framework of science, medicine and governance will be a key theme charted throughout the genealogical section of this project.

Within this framing, debates such as that between midwives and obstetricians in the early modern period are not only struggles over who ought to care for women during childbirth – the power-as-object-being-struggled-over interpretation – but as an event, or ongoing series of events, in which "the exercise of power produces social forms, institutions, routines, and even beliefs, theories, and self-images."[49] Thus the early conflict between midwives and obstetricians didn't just affect how pregnant women were cared for but also the boundaries of the scope of practice for each of these groups, how and where they would go

[49] McWhorter, 43.

on to organise into professional groups and what each group (and individuals within them) would come to regard as important.[50] In turn these developments had implications for the subsequent discourse of pregnancy into the present day, in particular for example shaping ideas about spheres of responsibility and authority during pregnancy and childbirth, and setting norms of authority and credibility about what the different groups can speak about.

[50] Similarly, the current antagonisms over access to abortion in the USA has widely impacted a wide variety of social and political discourses – health care insurance, access to reproductive health services and acts as a major platform for organising both political and religious ideologies. Furthermore the polarisation of this debate in the USA has spilt over into the politics and popular culture of other countries. Saurette and Gordon, *The Changing Voice of the Anti-Abortion Movement*, 308–10.

TWO: 1671-1880 Medicine

> [W]omen must maintain complete moral as well as physical hygiene if they were to reproduce satisfactorily.
>
> Claire Hanson, *A Cultural History of Pregnancy*

The early modern period was marked by a series of significant changes within the practice and management of medicine. In England the founding of a college of physicians created an institution that began to register and regulate the skill and knowledge of physicians and midwives.[1] The formation of medical colleges and the proliferation of medically oriented institutions together with the rapid proliferation of printing technology also facilitated the standardisation of shared norms, expectations, conceptual knowledge and orientation towards care. Collectively these changes set the scene for key social, scientific, medical, technological, and political developments to increasingly influence the discourse of pregnancy via the concepts of risk, health, and responsibility. This chapter traces narratives of risk, health, and responsibility in obstetrics, midwifery and medicine between 1671 and 1880, highlighting how scientific and medical innovations such as the development of psychiatry, the advent of anaesthetics and tension between midwives and obstetricians shifted the discourse of pregnancy towards what we are familiar with today. The overall theme of this chapter is the movement of pregnancy into the domain of health, and how this movement exposed 'pregnancy' to further changes within 'health'. This shift opened up the conceptual space that ensured and obligated governments, medical professionals and scientists to have a say in both 'pregnancy' and individual pregnancies while reinforcing existing systems of gender, race and class via appeal to science at a time when they were being challenged.

[1] This was in direct contrast to earlier forms of midwife registration that focused upon the moral character of the individual and was often used as a form of financial support for morally upstanding widows, regardless of their midwifery experience.

2.1 Midwives vs. Obstetricians

The foundation of obstetrics in early modern Europe, and particularly England, is significant for understanding the foundations of contemporary issues about pregnancy and childbirth. The period marks a paradigm shift in 'pregnancy' which begins to be framed as a health issue. Early debates about suitable birth attendants, mental health and the use of pain relief demonstrate how the ideological space around pregnancy was negotiated. Such changes shape 'pregnancy', introducing new narratives and voices to shift ideas about risk, health, nature, responsibility and the fetus during pregnancy and thus shifting what is normal, right, natural and safe during pregnancy. During the early modern period male midwives and physicians with a specialty in obstetrics began to attend an ever increasing number of births.[2] Initially these male midwives and physicians only attended members of the aristocracy, but by the nineteenth century obstetrics had become available to an ever widening class of people who could now afford to call for a doctor.

During this period, the most prominent English language debate regarding pregnancy was the political contestation between female midwives and early obstetricians.[3] The first mass-published text in English specifically on pregnancy, *The Midwives Book*, was authored by midwife Jane Sharp in 1671. Republished four times by 1725, Sharp's book interweaves references and recommendations from other medical sources with her own experiences and opinions to provide practical guidance specific to mother, father and midwife throughout the

[2] In contrast to earlier periods when the norm was for women to attend births.
[3] The decreasing cost of paper, and widening use of mass printing methods, led to the rapid proliferation and mass publication of a range of texts in the early modern period which gave public voice to authors on both sides of the debate.

various stages: conception, pregnancy, birth and postnatal care.[4] Sharp was writing at a time when, in the words of Elaine Hobby:

> [M]ost British women had their babies at home. They were attended by female gossips, and a female midwife, and the vast majority of confinements had a happy result: 80-85 percent of babies survived at least for a few years, and a woman's cumulative risk of dying in childbed, through her probable six or seven pregnancies, was less than 10 percent.[5]

What distinguished Sharp from her predecessors was the manner in which she spoke to this lived context of childbirth. Midwifery manuals prior to Sharp's were not the work of contemporary practitioners but were translations of continental authors who drew heavily on the ideas and work of Galen, Hippocrates and Aristotle. While Sharp still drew heavily on the work of other authors, particularly Nicholas Culpepper, the gloss and spin she placed on the material is significant in terms of how it politically and morally situated pregnant women and other women involved in the pregnancy and birth – most notably midwives but also gossips (the non-expert women friends and family who attend the birth to support the pregnant woman and assist the midwife). As Hobby argues "For all the parallels between *The Midwives Book* and its male equivalents…the differences in detail result in a fundamental shift in the way in which sexuality and gender are conceptualized…challenging the paradigm that reads women's bodies as if they are an inferior, inside out version of the male."[6] Hence, while Sharp echoes much of the standard advice provided in other midwifery manuals, she also endorses a specific *political* position in favour of female midwives, decrying the burgeoning practice of obstetric medicine. The stakes of such exchanges between women midwives and the growing numbers of their male counterparts were financially significant, as attendance on wealthy women was lucrative, particularly for physicians who could charge

[4] Hobby and Sharp, *The Midwives Book, or, The Whole Art of Midwifry Discovered*. See Hobby's introduction for further social context about the book.
[5] Hobby and Sharp, xv.
[6] Hobby and Sharp, xxviii.

significantly more than midwives. Physicians who attended births had the perceived benefit of formal university training in anatomy, general medicine and obstetrics.[7] There were distinct differences in the services provided by obstetricians compared to midwives including venesection (bloodletting), drugs (opioids) and forceps – and frequently all three. What ought not to be forgotten in all this discussion is that pregnant women were choosing in ever increasing numbers to be attended by obstetricians rather than midwives, because the interventional approach of obstetricians was perceived as the safer and more successful alternative. The 10% risk of death and far higher risk of disability during birth, and women's knowledge of these very real and ever present risks, made them desire to mitigate it wherever possible.[8]

Sharp can be considered paradigmatic in the debates between female and male midwifes that continued well into the eighteenth century, as the discourse of obstetrics became established.[9] These debates dealt with many of the same issues and terms as those initially staked out by Sharp and illustrate the contestation of 'pregnancy' in three ways. First, Sharp situates female midwives as experts whose knowledge and practice was (and could be) on par with that of male midwives and whose practical experience was valuable both in standard and abnormal births.[10] In doing so, Sharp is in stark contrast to her male interlocutors, who positioned female midwives as ignorant, uneducated and lacking an

[7] Leavitt, *Brought to Bed*, 40. However this education for men was strongly theoretical, due to strong social taboos and an emphasis on procedures conducted by touch without looking. While I call this obstetrics, this was a label the discipline would only grow into over time. Contemporaries called such men accoucheurs or male midwives.
[8] Leavitt, 28. As is reflected in the letters and journals of people during this period.
[9] The historical continuation of these themes can be seen, for example in the mid-century exchange between William Smellie and Elizabeth Nihell. Similar debates were also reproduced outside England particularly in North America, where, beginning in the 1760s, male physicians began replacing midwives in the birthing rooms of the urban elites in the belief that this ensured better quality of care. William Shippen returned from study in London and Edinburgh in 1762 to private practice in Philadelphia and established the first set of systematic lectures about midwifery, including anatomy during pregnancy, for male students. As in England, physicians had more formal medical education in anatomy and physiology and provided services that midwives did not, including more active intervention in labour and pain relief. Smellie, *A Treatise on the Theory and Practice of Midwifery*; Nihell, *A Treatise on the Art of Midwifery*; Hanson, *A Cultural History of Pregnancy*, 23.
[10] Hobby and Sharp, *The Midwives Book, or, The Whole Art of Midwifry Discovered*, xxiii.

understanding of the relevant anatomical knowledge.[11] The second way in which Sharp's political positioning manifests is in her interpretation of the leading medical model of the day, humoral theory, which suggested that women were constitutionally colder than men and thus more prone to disease. Whereas Willoughby understood this as evidence for women's inferiority, Sharp interpreted it to mean that women simply required greater care from their physicians. Thirdly and finally, Sharp can be contrasted to contemporary male authors in that she did not prescribe one method or birthing position as the ideal for all women.

The most significant consequence of the shift towards obstetrics from a current perspective is the increase in the degree of intervention perceived as normal and necessary, at even the least complicated birth. This shift served to both destabilise the perceived naturalness of pregnancy and childbirth and integrate 'pregnancy' ever more firmly into the domain of 'health' and healthcare. A major theme of the medical debates over pregnancy both in these early years and subsequently is a contestation between pregnancy as natural or in need of active health management. This is not to say that increasing use of medical intervention is a bad thing; indeed, the use of interventional technologies such as forceps and pain relief made childbirth a safer and more pleasant experience for all. Rather, what is significant here is an increasing tendency towards active intervention and management in childbirth that was a significant shift in the discourse of pregnancy and echoes of the debate continue to have practical and ethical consequences in the discourse of pregnancy today.[12]

[11] Willughby, *Observations in Midwifery*; Mauriceau, *The Diseases of Women with Child ...*

[12] This can be seen in the social status and professionalization of midwives in various countries today. In the USA midwives are largely unregulated and few births are attended by midwives. Birth in the USA has a very high rate of medical intervention even for women who desire the minimal possible degree of medical intervention. In contrast New Zealand has a tightly regulated and professionalised body of midwives who attend most low risk pregnancies. Low risk births in NZ have much lower rates of intervention than in the USA. This is an example of an international phenomenon around the impact of the structuring of prenatal and birth care practices upon pregnancy outcomes. Davis et al., "Planned Place of Birth in New Zealand"; Mbuagbaw et al., "Health System and Community Level Interventions for Improving Antenatal Care Coverage and Health Outcomes"; Soltani and Sandall, "Organisation of Maternity Care and Choices of Mode of Birth."

The transition of pregnancy into the domain of healthcare increased as more and more aspects of pregnancy became an issue of health and in need of active medical intervention.

The rise of obstetrics was an early step in the incorporation of the discourse of pregnancy into the discourse of health. A process that continued as medical techniques and technologies made risk and health during pregnancy something increasingly 'manageable'. While new possibilities for intervention made pregnancy increasingly safe and risks more manageable this correspondingly integrated pregnancy more and more into becoming an issue of healthcare and thus reimagined pregnancy as a phenomenon needing management.[13] To be clear I am by no means arguing that this transition was a problem or ought not to have occured; simply that the strengthening ties between pregnancy and healthcare brought about a significant change in 'pregnancy' that would only increase as in the twentieth century governance institutions became increasingly concerned with reproducing the nation, and pregnancy and childbirth become increasingly medicalised in public health attempts to promote the health and safety of both mother and child. The rise of obstetrics as a discipline tied 'pregnancy,' 'reproduction' and 'childbirth' into debates in health and medicine which were also undergoing radical transformations. This was the beginning of the incorporation of 'pregnancy' into medicine, and correspondingly towards 'health' and away from 'nature.' Once the discourse of pregnancy became situated within a medical context broader shifts and developments within discourses of health and disease came to impact the discourse of pregnancy.

2.2 Anaesthesia

Where risk is often identified as the dominant narrative of pregnancy in the twentieth century, Leavitt cites fear as overwhelmingly the dominant narrative associated with pregnancy

13

throughout the eighteenth and nineteenth centuries. [14] Within this setting of both perceived and actual risk Leavitt documents a narrative of "fear of death arising from pregnancy and childbirth" not just in the accounts of individual pregnant women and their families but also in fiction, medical literature, government documents and advice columns. She argues that, for this reason, from the birthing women's perspective pain relief was *the* development in nineteenth century obstetrics. Furthermore, it was the acceptance of male birth attendants for urban middle and upper class women, as discussed in the previous section, which made the widespread uptake of ether and chloroform during birth possible.[15] *Fear* can be understood as an early expression of *risk,* when the risks involved in childbearing in the nineteenth century were both high and unquantified. Anaesthesia mitigated women's fears about the pain of childbirth in a time when uncertainty abounded: there was little understanding of how to prevent or treat the major complications of pregnancy, and mortality and morbidity rates remained high.

Pain relief was one area where a reliable technological intervention was available during childbirth and many people – both women and obstetricians – jumped to use it and thereby minimise a major area of fear around childbirth: the pain. However, the patterns of usage and acceptance of anaesthesia and pain relief during pregnancy were mixed. Many of the issues in anaesthetic use arose from careless or faulty administration and this was acknowledged within medical journals at the time: "The rapidity with which anesthesia drugs were adopted in obstetrics produced an absence of standardisation about drug dosages."[16] Anaesthesia during childbirth was often administered in ways that seemed reckless to contemporary physicians, much less to the modern mind, and it was normal for family members, husbands and even the patients themselves, to drip ether or chloroform onto a cloth

[14] Leavitt, *Brought to Bed*, 21.
[15] Leavitt, 116.
[16] Leavitt, 123.

and hold it to the woman's nose. While not framed in the language of 'risk' which did not enter common usage until the twentieth century, the health risks associated with ether and chloroform were also widely known: increased danger of hemorrhage, protracted labor, decreased contractions and newborn breathing difficulties.[17] It is thus useful to establish the 'risk' involved in pregnancy and birth prior to the twentieth century that made anaesthesia such an attractive option. Birth prior to the twentieth century was (from a current perspective) a risky business that almost all women had to experience. The dominant expression of this concern was not risk – a twentieth century concept – but fear. Fear of death and disability during childbirth was a frequent narrative found in both public and private communications about childbirth by both men and women. Fear was an omnipresent discourse in childbirth; fears of death, disfigurement and most prominently long hours of pain. Technologies that could reduce or combat these fears were enthusiastically adopted by many and anaesthesia was one of the most successful.

Prior to the twentieth century women spent between half to three quarters of their life between marriage and menopause pregnant or breastfeeding. On average, women had eight live births, and thirteen to fifteen pregnancies in total was not uncommon. Approximately one third of children did not survive past their fifth birthday.[18] While mortality rates were high among those who got sick, and the very young and old, deaths during childbirth were, Chamberlain argues, different: "[d]eath in relation to childbirth was mostly in fit young women who had been quite well before becoming pregnant. They died, often leaving the baby, and other children in the family from previous births, with a widowed husband."[19] The four major causes of maternal mortality were puerperal pyrexia (childbirth fever), haemorrhage, convulsions (eclampsia) and illegal abortion. Prior to the twentieth century

[17] Leavitt, sec. Practical Notes.
[18] Leavitt, *Brought to Bed*; Hanson, *A Cultural History of Pregnancy*.
[19] Chamberlain, "British Maternal Mortality in the 19th and Early 20th Centuries," 559.

there are no hard statistics available regarding risk of death in childbirth or from complications of pregnancy, however indications are that both maternal and neonatal morbidity and mortality were decreasing during the eighteenth and nineteenth centuries. In England the maternal mortality rate between 1700 and 1750 has been estimated at 1,050 deaths per 100,000 live births. Between 1750 and 1800 this rate dropped to 750 deaths per 100,000 and then to 500 deaths per 100,000 between 1800 and 1850.[20] As a point of comparison in Canada through the period 2007-2010 the maternal mortality rate was 7.5 per 100,000 live births approximately a 100 fold decrease from the early nineteenth century.[21]

A key aspect of the wider project of modernity was focused upon enacting extensive social, political and technological reform to eliminate pain and suffering from the everyday human experience.[22] The extension of pain relief into obstetrics with the discovery of ether's anaesthetic properties needs to be considered within this broader cultural trend towards modernity as a mode of engagement with the world. While opium had been around for centuries, and its derivatives, morphine and codeine, were isolated prior to 1809, shifts in the wider perception of the meaning and significance of pain that occurred during the nineteenth century created the cultural space for the possibility and acceptability of pain relief during pregnancy.[23] For reasons unknown, opioids were not considered as an option for obstetric pain relief until the advent of twilight sleep in 1902, despite their widespread use to treat other sources of pain for everything ranging from smallpox, to dementia, to colic.[24] The strengthening of a 'modern' engagement with the world can be seen both in the diminishing

[20] Chamberlain, 559–62.
[21] Government of Canada, "Maternal Mortality in Canada Fact Sheet (1996-2010) - Public Health Agency of Canada."
[22] Caton, "'In the Present State of Our Knowledge,'" 779.
[23] Caton, 779.
[24] Leavitt, "Birthing and Anesthesia," 147–48. Twilight sleep was the combination of morphine and scopolamine used in the early twentieth century that provided both an analgesic effect and memory loss of the childbirth. Previously the only option was to be fully knocked out.

opposition to pain relief during childbirth throughout the nineteenth century and in the increasing tendency to frame opposition as a medical matter, an issue of safety rather than, as initial interlocutors would, a matter of morality or religion.[25]

Beginning in 1847 with James Simpson's use of chloroform on a woman in labor, the anaesthetics ether and chloroform were the first drugs to be used extensively on pregnant women primarily for pain relief during birth and labor. With the advent of pain relief, a previously unconsidered critical question about the nature of pregnancy and birth arose: just because birth was a naturally painful event does this mean pain is (or ought to be) a necessary part of the birthing process? Prior to Simpson's discovery of chloroform, the question was inconceivable but afterwards it rapidly became a topic of public debate. Opponents argued that pain relief in childbirth was "improperly enabling woman to avoid one part of the primeval curse" and quoted Genesis 3.16 against him "In sorrow thou shalt bring forth children," which Simpson countered with an alternative sermon in favour: "if God has *beneficently* vouchsafed to us a means of mitigating the agonies of childbirth, it is His evident intention that we should employ these means."[26] The interchange between Simpson and his interlocutors, like the earlier debates between midwives and physicians, illustrates the way in which a novel technological innovation can upset established norms and conceptual boundaries, in this instance what is natural, necessary and normal during pregnancy.

By the late nineteenth century the use of anaesthesia during childbirth would come to have wider variation in practitioner use than any other obstetric technology. [27] While some physicians enthusiastically used anaesthesia on all their patients, many others only used it at

[25] Caton, Frölich, and Euliano, "Anesthesia for Childbirth," 25.
[26] Simpson, *Anaesthesia, or the Employment of Chloroform and Ether in Surgery, Midwifery, Etc.*, 120; Hanson, *A Cultural History of Pregnancy*, 11.
[27] Leavitt, *Brought to Bed*, 119.

the request of the women they attended and still others refused to provide pain relief during pregnancy even when requested, due to the belief that pain was a desirable aspect of labour.

> Despite the early encouraging results, both perceptions of safety and patterns of anesthesia use varied enormously throughout the second half of the nineteenth century. The medical journals reported both safe and hazardous results of ether and chloroform in midwifery.[28]

For instance, Charles D. Meigs of Philadelphia actively campaigned against the use of both chloroform and ether both for general safety concerns and because he believed that inhibiting pain would obscure the progress of the labor from birth attendants, making them less effective.[29] In contrast another physician argued that never in forty years of practice had he seen "the least evil result to mother or child."[30]

The debate around the use of pain relief in childbirth and the resulting tension over the acceptability of the practice demonstrates the instability of the discourse of pregnancy and the seemingly arbitrary deployment of narratives of pregnancy as normal or pathological depending on the needs and aims of the person mobilising the categorisation. This is indicative of the already noted wider trend whereby pregnancy was becoming reframed in terms of 'health'. Increasing acceptance of anaesthesia for obstetric uses was part of the trend toward the normalisation of technological intervention during pregnancy and birth, tied to the rise of obstetric medicine. The trend would accelerate in the nineteenth and twentieth centuries with the widespread uptake of interventional practices such as ergots to stimulate labor, and episiotomy and forceps, often prophylactically. The increased pain caused by these interventions led to even higher rates of anaesthesia use even in minimally complicated vaginal births.

The development of anesthesia was only one of the many social, scientific and political changes that altered the discourse of pregnancy during the nineteenth century.

[28] Leavitt, 119.
[29] Leavitt, 117.
[30] Leavitt, 119.

Another change that will be discussed in the following section, and will shift the discourse of pregnancy, was the rise of psychiatry and mental health and in particular the linking of nervous disorders and hysteria to the reproductive capacity of women, particularly white middle and upper class women. Symptoms of these nervous disorders were perceived to include not just emotional extremes but also many of the physical symptoms of childbirth. In many circumstances physicians saw anaesthesia use as essential to soothing a female nervous system put out of joint by pregnancy. [31] Thus the pain relief provided by anaesthesia came to be considered by many doctors a form of necessary and specialised care for women in labour: a soothing of the nerves.[32] Hanson argues that the "mental perception of the ability to shape the birth experience became even more important in the second half the nineteenth century, when anesthesia emerged as the newest birthing panacea and physician interventions became more routine."[33] This was a significant conceptual shift from the earlier pre-anaesthesia period of history. The cultural space in which pregnancy and being pregnant was conceived, the discourse of pregnancy, was significantly modified by the development and use of chloroform and ether as anaesthetics during pregnancy. While forceps and other means of manual assistance for delivery work assisted the birth attendant in their work, pain relief fundamentally modified the experience of childbirth by alleviating the 'symptoms'.

With the possibility of pain relief, once again the way in which pregnancy and childbirth were valued and understood shifted as the conceptual space and possibilities transformed. Anaesthesia, more so than any other particular nineteenth century medical technology, became a symbol of the benefits of science, and the place of physicians in birthing rooms. Anaesthesia's impact was overwhelmingly positive in that it primarily reduced or removed labour pains, a major source of anxiety and fear for birthing women. It

[31] Love, "Relief from Pain in Labor."
[32] Leavitt, *Brought to Bed*.
[33] Hanson, *A Cultural History of Pregnancy*, 50.

was extremely noticeable and obvious to birthing women and their communities in a way that advances such as antisepsis are not easily apparent even though they far more dramatically contributed to decreasing rates of maternal mortality. Making childbirth less risky and lowering rates of maternal and fetal mortality and morbidity are the reason that the vast majority of technologies to manage childbirth have been adopted. Techniques and technologies such as forceps and caesarian sections lower the medical risks of childbirth; in contrast anaesthesia modified the *experience* of childbirth for women, decreasing or removing pain and making them feel safer – changing the perception, if not the distribution, of risk.

2.3 Mental Health

> It is needless to recall to your mind how the very beginning of pregnancy is announced in many cases by peculiar nervous phenomena. During the entire term the imagination of the woman often becomes exalted or depressed. Her disposition is irritable. In many cases she is continually between two fires; upon the one side the greatest gloom, upon the other an excessive joy. Suspicion, jealousy, general sensitiveness are present, which under other conditions are never dreamed of. Nervous pains abound, migraine, facial neuralgia, toothache, itching in various parts of the body, together with smarting and other evidence of irritation of the peripheral extremities of the nerves. The most grave nerve troubles sometimes are present; eclampsia, chorea and often mania. Truly we have evidence in favor of the thought that pregnancy is a severe test to the stability of the nervous system.
>
> I.N. Love, *Relief from Pain in Labor*

As obstetric medicine settled into a discrete discipline with its own traditions, norms of practice and governing bodies, the nineteenth century also saw the rise of a medical discourse of mental health, which initially connected with ‘pregnancy’ via the notion of maternal impressions.[34] This section discusses the move away from a discourse of maternal impression and into the rise of psychiatry and mental health in the nineteenth century. These

[34] Hanson, 26.

developments changed both the scope and types of narratives available within the discourse of pregnancy, most significantly redefining maternal responsibility during pregnancy with regards to ensuring fetal health and the wellbeing of the future child. Part and parcel with this new narrative of responsibility came a new type of risk during pregnancy, the risk not just of things going wrong but of wrong choices.

'Maternal impressions' was the belief that a child's development could be influenced by the sensory experiences and imagination of pregnant women and was a dominant explanatory paradigm for 'monstrous births' as far back as ancient Greece. However, maternal impressions had its medical heyday just prior to the rise of psychiatry, in the sixteenth through eighteenth centuries.[35] The 'impressions' could take multiple forms and extremes of interpretation and influence, from those obviously routed in folklore – if a women smelt sweet things during pregnancy the child would have a sweet disposition – to the more extreme where women's experiences and fears about the monstrous were the cause of children born with gross physical abnormalities.[36] Although there was significant shame and moral condemnation associated with the advent of a monstrous birth, until the eighteenth century medical texts were "remarkably free of any political rhetoric about the burden of monstrous births or the civic importance of producing healthy babies, and also of any larger judgemental rhetoric concerning maternal vice, beyond blaming it for poor fetal outcomes."[37] While there was disagreement within the medical profession over the doctrine of maternal impression there was unanimity both in obstetrics and midwifery that strong emotions were to be avoided.

As a consequence of the emphasis on avoiding strong emotions, women's responsibility for ensuring a healthy pregnancy – including control of her emotional state and

[35] Kukla, *Mass Hysteria*, 13.
[36] Wilson, "Eighteenth-Century 'Monsters' and Nineteenth-Century 'Freaks,'" 5.
[37] Kukla, *Mass Hysteria*, 19.

environmental exposures –was being increasingly emphasised. Thus 'maternal impressions' cannot be read simply as a "tool for controlling women's mobility and policing their character" because it also imparts responsibility, and thus a degree of agency, upon pregnant women.[38] If a woman is responsible for managing her appetites and ensuring her experiences are positive while pregnant then it is not possible for a woman to be either only a neutral environment for growing men's seed or incubating God's will, she must be to some degree an agent actively able to control her experience of pregnancy.[39] While the significance of this reading should not be overstated it is nevertheless important to recognise how early the narrative of personal responsibility during pregnancy arose. Its presence in contemporary pregnancy discourse is not new. However, it is also indicative of how intimately ideas about maternal responsibility for fetal health and wellbeing become tied to the integrating of 'pregnancy' into 'health'.

The mid 1800s also saw the medicalization of mental illness via two other means: the rise of mental asylums and the increasing belief that organic disorders were the root cause of mental illness. Mental asylums served to formalise and standardise norms and narratives of mental illness via increased standardisation of treatments and diagnosis. They helped situate mental illness as a medical matter, an actual illness to be treated by medical professionals, rather than some other form of disorder: for instance a spiritual matter or chosen immoral behaviour.[40] This was part of the increasing distinction between illness and disease that developed during this era where illness most often occurs in the medical context as reports of symptoms, such as in narrative case histories about particular patients, while diseases were a more abstract classification. The nineteenth century classificatory trend in the wider sciences helped give rise to more refined disease categories which in turn strengthened the distinction

[38] Kukla, 19.
[39] Kukla, 18.
[40] Foucault, *Madness and Civilization*.

between illness – a behaviour pattern involving mental and/or physical symptoms - and disease – the definition given by physicians to collections of illness symptoms.[41] In 1835, James Prichard, a prominent physician specialising in psychology, advanced his theory defining moral insanity as a particular set of mental illnesses of which the insanity of pregnancy was part. He claimed these disorders arose from social and psychological triggers, "a morbid perversion of the natural feelings, affections, inclinations, tempers, habits, moral dispositions and intellect."[42] The link between the insanity of pregnancy and the earlier idea of maternal impressions can be seen in Prichard's work when he writes: "a strong predisposition to madness has arisen from some accidental fright sustained by the mother during pregnancy."[43] While not a conception of mental illness based in organic disorder, this was a break from earlier understandings in that it clearly posits a causal mechanism based on the experiences of the patient. Between 1820 and 1830 the notion that pregnancy is associated with "extreme despondency and even mental derangement" entered obstetrics texts and Prichard's work indicates the connections between maternal impressions and the insanity of pregnancy.[44] This was the integration and transformation of a central aspect of maternal impressions, the experiences of mothers being transmitted to their fetus, into medicine via new and specific diagnostic criteria: harmful maternally derived emotions.

The gradual shift away from maternal impressions towards mental health was influential in transforming the narrative of maternal responsibility in pregnancy, and expectations of what counted as good maternal behaviour. The incorporation of wellbeing

[41] Theriot, "Women's Voices in Nineteenth-Century Medical Discourse."
[42] Hanson, *A Cultural History of Pregnancy*, 62.
[43] Prichard, *A Treatise on Insanity and Other Disorders Affecting the Mind*, 124. Prichard also wrote on evolution and heredity and recommended the insane not breed so as not to pass on the condition to their children. While Prichard recognised the insanity of pregnancy as categorically different, a limited condition that would resolve itself soon after birth, he nevertheless included the insanity of pregnancy in the wider belief that the insane should not breed. Prichard's and his contemporaries' writings on mental illness were also significant because they are some of the earliest texts to contain proto-eugenic sentiments. This was an early iteration of the notion that only the right sort of people ought to breed. See also Hanson, A Cultural History of Pregnancy, 65.
[44] Hanson, *A Cultural History of Pregnancy*, 61.

during pregnancy into 'mental health' medicalised the condition of maternal mental health. 'Medicalization' served to internalise the issue into the identity of pregnant women in comparison to maternal impressions which were something that occurred to women who were pregnant. This shift was consistent with the drive and direction of capitalism in early nation-states where costs (like ensuring mental wellbeing) were externalized onto individuals and away from the collective, and the powerful people who both directed and profited from the emergent system.[45]

The practical impact for women however was that the shift towards mental health transformed expectations around maternal responsibility by encouraging "women to internalise the medico-social view of their responsibility for pregnancy and, in consequence, to discipline their emotions and adopt 'appropriate' (constrained) behaviour."[46] Women felt obligated to manage their pregnancy appropriately, to be careful and responsible, because to not do so was to invite the possibility of something going wrong. This was a new type of concern about *quantifiable risk* during pregnancy, one more sensitive to human agency and more focused upon 'responsibility' and women's choices, activities and emotions, not just the more nebulous and unquantified risks of everyday life. While at the time this shift would not have been conceived of as *risk*, the origins of contemporary discourse of risk and responsibility can be traced to discursive shifts during this period. While there are risks in life that we cannot control, risk as identified in the context of contemporary pregnancy is almost always about risk management and thus arises within the context of choice and responsibility.[47] The shift of responsibility for ensuring a 'healthy' pregnancy towards pregnant women arising from this discourse is an early symptom of the rising intertwined

[45] Foucault, *The History of Sexuality*, 118–19.
[46] Hanson, *A Cultural History of Pregnancy*, 28.
[47] As will be discussed in the next chapter the language of risk was not used prior to the twentieth century as conceptually it is strongly tied to the rise of population statistics which arose at the turn of the nineteenth century; however, the relationship between risk, agency and responsibility that would develop has its roots in this moment.

paradigms of capitalism and science and the functioning of biopower in the service of nation-states built upon these paradigms. This theme will be explored further in Chapter Three. However, the following discussion of the relationship between 'responsibility' and 'health' must be understood within this context.

Following Foucault, it has been widely recognised that medical institutions and taxonomies have significant power to regularise and normalise behaviour, produce and constrain not just what people want but also what they consider possible, acceptable and good. The incorporation of maternal impressions into medical discourse was significant beyond its contribution to ideas about maternal responsibility, because the shift in the discourse of maternal responsibility also further integrated pregnancy into the domain of health. Prior to the incorporation of maternal impressions into medical discourse, pregnancy without debilitating symptoms could only be considered healthy. However, once it was established that good self-governance in pregnancy – responsibility – was required in order to avoid monstrous births then pregnancy became a site that required constant health management. Pregnancy no longer required symptoms of ill health in order to need monitoring of health. All pregnancies now fell within the jurisdiction of medicine.

A common idea in feminist history of medicine is to argue that "disease categories, particularly in relation to mental illness, have reflected and enforced male physicians' preconceptions about normal, neurotic or insane female behaviour."[48] I want to highlight however how norms produced within medical discourse not only shape medical professionals' values and perceptions. They are also extremely influential – dominant even – in wider social discourse. Thus, feminist historians' identification of the relationship between disease categories around mental illness and physicians (a wholly male profession during this period) is critical but the normative implications are wider still. The way diseases are

[48] Hanson, *A Cultural History of Pregnancy*, 60.

categorised and diagnosed by physicians also influences how women understand their own behaviours, symptoms and illness and how others – not just physicians but friends, family and non-health related policies and treatises – categorise and value women and their capacities.

The rise of maternal mental health and the nervous disorders associated with pregnancy thus further strengthened and transformed key trends in the discourse of pregnancy as traced throughout this project. The rise of new ideas about maternal responsibility for ensuring fetal health through self-management of emotions and environmental exposure transformed narratives of maternal responsibility. The introduction of maternal mental health also highlights how 'risk-management' was entering into pregnancy in the nineteenth century and pregnancy was being further enfolded into the domain of health by setting pregnancy up as in constant need of health monitoring because risky or problematic pregnancies no longer required symptoms of ill health to be identified as such.

As with previous events that bound pregnancy into medicine via narratives of health and responsibility, the shift towards attending to mental health during pregnancy, and even more so the rise of hysteria discussed in the next section, further entrenched the obligation and expectation that governments and medical professionals would have a say both in 'pregnancy' and the pregnancies of individual women. As religion receded as a justificatory mechanism for maintaining social and economic hierarchies this is an example of how science was intruding into many areas of life to justify and produce the same norms around gender, race and class that would maintain the social system.

2.4 Hysteria

While insanity was understood as the most serious manifestation of mental illness during pregnancy by far the most common diagnosis was hysteria: an episode of excessively strong

emotion. A core diagnostic category within mental health until the mid-twentieth century, hysteria was an exclusively female disease associated with the uterus whose symptoms were primarily reproductive – prolapsed uterus, diseased ovaries, and difficult and prolonged childbirth.[49] Initially a catchall diagnosis for a large collection of symptoms and disorders, by the late nineteenth century the diagnostic criteria narrowed to coalesce around a particular ideal of middleclass white femininity as delicate and ornamental.[50] Hysteria provides another case study in which a medical development contributes to the narrative shifts in the key concepts traced throughout this project, health, risk, nature, responsibility and the fetus. Hysteria also provides an example of another important phenomenon in the production of discourse, centered upon intersectionality and the impact that differences in race and class can confer upon women's experiences of pregnancy.

Not only do discourses apply unevenly to individuals over time and space but to individuals of differing social identities within the same time and place. Consideration of the broader discourse of pregnancy, one that includes as many minority narratives and experiences as possible, is required in order to better parse the normative impact of concepts such as risk, health, nature, responsibility and the fetus. No matter how forceful or strong a narrative, script or norm about pregnancy, it will interact with individuals differently depending on other components of their identity such as race, class, ability and sexual orientation. In this way pregnancy is only one of many aspects of an individual's broader intersectional identity. In order to take the ethical issues at the center of pregnancy and pharmaceutical research seriously there is a need to include non-dominant narratives and scripts about pregnancy and consider how social structures interact with more than the dominant (white middleclass heterosexual able-bodied) engagement with pregnancy. The

[49] Tasca et al., "Women And Hysteria In The History Of Mental Health," 114.
[50] Prichard, *A Treatise on Insanity and Other Disorders Affecting the Mind*, 226.

non-uniform impact of the norms and narratives about pregnancy on women from different backgrounds – social, economic, racial, and ethnic – is an important feature of contemporary clinical research during pregnancy. As such the exclusion of black women from the diagnosis of hysteria provides insight into the interactions of pregnant black women with the health and medical system in the late nineteenth and early twentieth century and also sheds light on aspects of the problem with the contemporary issue of clinical research during pregnancy. The vast majority of scholarship in the history of pregnancy talks only about white, middle or upper class, non-immigrant pregnant women. Briggs' discussion of hysteria is one of the few to address racial and class differences in the discourse of pregnancy prior to the 20th century.[51] As such I include this discussion to highlight the importance of race and class to narratives of pregnancy, an issue still significant to the problem of pregnancy and pharmaceuticals today particularly the relationship between risk assessment, institutional trust and race, class and immigration

The production and application of hysteria as a medical diagnosis was intimately linked not just to discourses of gender and reproduction, but also nationhood and race. This framing not only set up a justificatory narrative for opposing the nascent women's rights movement as causing potential maternal and fetal harms, but was also a component of early eugenic narratives about who ought to reproduce. Feminist historians, such as Leavitt, have argued that the nineteenth century proliferation of hysteria diagnosis occurred in response to two substantial cultural shifts: industrialisation and the rise of the women's rights movement and an attempt to reaffirm previous gender practices in the face of social changes that were challenging and shifting ideas about what women could and ought to do.[52] However Briggs argues that hysteria also encoded and reinforced norms about race and class, not just gender.

[51] Briggs, "The Race of Hysteria,"
[52] Leavitt, *Brought to Bed*.

The process of industrialisation in western countries in the nineteenth century was a period of rapid social change producing different life opportunities for not just white women but also non-whites, immigrants and poor people. As such 'hysteria' was, Briggs argues, an 'idiom of distress' an attempt to push back against change and adhere to prior norms and expectations. In hysteria this "cultural conflict over the meaning and content of 'womanhood' was written on the body," as much a response to cultural shifts in discourses of race and class as it was about the rise of industrialisation and women's rights.[53] In hysteria, a wide catalogue of symptoms was rendered coherent by the power of the perceived cultural crisis; it was "[b]oth sign and symptom of conflict over the cultural meaning of gender."[54] Hysteria was a real physiological condition but it was the ways in which symptoms were collected, sorted and interpreted within the specific cultural context that made it an 'idiom of distress.'

The diagnostic concept of *overcivilization* was central in limiting the scope of *hysteria* application to middle and upper class white women, thereby reinforcing the boundaries of race, class and gender that were fragmenting under the force of social changes. Hysteria only tended to be diagnosed in women considered overcivilized, those of a weak, fragile and nervous temperament, traits that tended to cluster in middle and upper class white women. In contrast physicians tended to label non-white and working class women as "strong, hardy and prolifically fertile."[55] Racial hierarchies and the distinction between 'civilised' and 'savage' races were developed and reinforced by the diagnosis (or not) of hysteria as the diagnostic criterion aligned with existing racial prejudices. Being considered overcivilized also implied that a woman had a refined character and good breeding thus serving to support class boundaries. In deploying such stereotypes of race and class in their work medical

[53] Briggs, "The Race of Hysteria," 246..
[54] Briggs, 247.
[55] Briggs, 249. Racial hierarchies were being produced and reinforced via a wide variety of areas of medical and scientific discourse– anatomy, physiology and, from the beginning of the twentieth century, in population statistics and the burgeoning field of public health.

professionals made the label of 'overcivilized' inapplicable to non-white and working class women. Alongside the discursive work of race, 'overcivilization' also worked to reinforce gender and class stereotypes that supported the status quo. Hysteria also worked to discourage middle and upper class women from engaging with the nascent women's rights movement by medicalising education in middle and upper class women. It did so via 'scientific' narratives which argued education could worsen nervousness and weakness in overcivilized women. [56] Thus, the narrative went, education not only made women sick, hysterical, it also thereby put their reproductive capacity and future children at risk of harm.

Beyond providing a 'legitimate' scientific argument against early feminism, the narrative also reconceptualised "these forms of white women's struggle for social and political autonomy from white men as a racial threat… it encoded white women's transgressive behaviours as a danger to the future of 'the race.'"[57] In this manner, late nineteenth century worries over decreasing birth rates among white women became linked with eugenic sentiments to produce racist (in the USA) and anti-immigrant (in the UK) policies and arguments to produce a narrative of 'endangered whiteness.' This narrative constructed political engagement among women as harmful and set up a narrative by which responsible women didn't engage. Thus, *hysteria* during the nineteenth century worked to reinforce narratives that supported traditional boundaries of race, class and gender against the alternative narratives made possible by the social changes wrought by industrialisation and the enlightenment. The case study of hysteria makes a point about the invisibility of women who were not white from popular social, medical, scientific and political discourse, which can be extrapolated to apply beyond hysteria to historical reproductive discourse more broadly. Briggs' work points both to the way in which ideas and ideals about race and class

[56] Briggs, 250.
[57] Briggs, 250.

were filtered and produced via discourses related to pregnancy and conversely the way race and class contribute to the narratives and norms, ideas and ideals, of pregnancy.

The deployment of racial and classed assumptions also served to exclude many women from obstetrics more generally. Briggs' analysis of medical case notes and journals from the USA in the mid to late nineteenth century illustrate how the use of racially coded language such as 'hard' and 'insensate' characterised African American and Indigenous women as giving birth easily. While 'fragile', 'weak', 'nervous' white women were obviously in need of obstetric and gynecological services, 'hard' and 'insensate' non-white women did not need obstetric assistance due to their perceived robustness, linked, no doubt, to them being less 'civilised', more like animals. There was "a fully articulated counter-account of the impossibility of hysteria in rural, immigrant, non-white, and 'savage' women."[58] Franklin Newell, an obstetric specialist from Harvard medical school in the early twentieth century, provides a paradigmatic example:

> [I]n spite of the unfavourable condition of her bringing up, poor food, privations, and hard work, comes to maturity a strong healthy woman…The working woman goes through her pregnancy with little or no trouble…she ordinarily comes to labor in good physical condition to endure the strain, and goes through perhaps a hard labor without reacting unduly either to the pain or the muscular effort which she undergoes, and usually without aid of anaesthetics delivers herself safely.[59]

However, in conflict with this narrative of robustness, non-white and lower class women actually had higher rates of childbirth mortality and morbidity for a combination of factors including less access to medical professionals, geographic isolation and midwives with less training.[60]

The perception of black, indigenous, poor and immigrant women as tougher and less prone to hysteria in the nineteenth century made them considered ideal subjects for

[58] Briggs, 257.
[59] Newell, "The Effect of Overcivilization on Maternity," 535; Leavitt, *Brought to Bed*, 67.
[60] Briggs, "The Race of Hysteria," 260.

experimentation. Much of the foundational knowledge of gynecology and obstetrics was developed using slave women in the USA who were specifically purchased for conducting experimental gynecological and obstetrical surgical procedures because of their perceived robustness and inability to feel pain: "Innovation… depended on the belief in black and poor women's 'underdeveloped' nervous systems."[61] For example in 1879 Robert Harris compiled a list of one hundred cases where Caesarean sections had been done in the USA, the majority of which were conducted of black slave women in the south.[62] Prior to the widespread use of anaesthesia and the development of antiseptic practices in the 1880s the caesarean was a highly risky surgical procedure that was seldom attempted except as a daring experiment: English records show 27 attempted caesarian sections in the year 1842 of which two mothers survived. The *nature* of black and white women was thus constructed as fundamentally different.

Pregnant women come from many social groups, and *pregnancy* and the norms of maternity play out differently for different women. Historical events that occurred specifically or mainly to particular groups continue to resonate with women from those groups today in morally relevant ways. Group specific historical events in other discourses shape 'pregnancy' but often not the dominant overall discourse of pregnancy, which was (and is) shaped primarily by the experiences of middle and upper class white women. [63] Well into the twentieth century, black women in the USA had a fraught relationship with medicine: one

[61] Briggs, 262–63.
[62] Harris, "Article III. A Study and Analysis of One Hundred Caesarean Operations Performed in the United States, during the Present Century and Prior to the Year 1878."
[63] Another overlapping example is the collection of mid-twentieth century research scandals perpetrated against black people. People with physical and mental disabilities, homeless and indigenous groups continue to shape the experiences of pregnant women who also identify as members of these groups in morally relevant ways while having little impact on how white middle class women experience pregnancy except via the research ethics guidelines developed in response to the scandals.

that was exacerbated by continued practices of dubious experimentation and poor treatment.[64] Even after the end of slavery, during the Jim Crow period, and as late as the 1960s, many black women in the South preferred older midwives, they distrusted younger black midwives because of their association with and training by white medical professionals.[65] Furthermore particularly in the rural south black women did not fit into the trend both in the USA and abroad of ever increasing rates of hospitalisation during childbirth.

The legacy of the belief about pain and race is still present in US health care today. The impact of historical stereotypes about pain can be seen in high US rates of opioid prescriptions for whites while black people are still less likely to be prescribed opioid pain relief for conditions such as migraines and back pain that are harder to measure objectively.[66] In modern research ethics literature, the legacy of these events is most often framed in terms of lower rates of trust in medicine and medical institutions by minority groups; however more recent work argues for a more sophisticated analysis where such distrust is complicated by other factors including higher rates of deference to authority in less educated populations as well as strong beliefs in community obligations which impact phase one research participation rates in particular.[67]

Pregnancy entered the domain of medicine in the seventeenth century with the rise of obstetric medicine. Over the next three centuries a significant shift in the relationship between pregnancy and health took place as the medical men and their technological and intervention focused approach displaced midwives in the care of pregnant women, particularly white, middle- and upper-class women. Nineteenth century medical science on

[64] Zambrana, "Inclusion of Latino Women in Clinical and Research Studies: Scientific Suggestions for Assuring Legal and Ethical Integrity"; Savitt, "The Use of Blacks for Medical Experimentation and Demonstration in the Old South."
[65] Loudon, *Death in Childbirth*, 311–16.
[66] Tamayo-Sarver et al., "Racial and Ethnic Disparities in Emergency Department Analgesic Prescription"; Olsen, Daumit, and Ford, "Opioid Prescriptions by U.S. Primary Care Physicians From 1992 to 2001."
[67] George, Duran, and Norris, "A Systematic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders"; Fisher and Kalbaugh, "Challenging Assumptions About Minority Participation in US Clinical Research."

obstetrics and gynecology and its application by medical practitioners supported specific racial and gender narratives that maintained the status quo including supporting hierarchies of race, gender and class that were increasingly coming under pressure from new social phenomena such as industrialisation, urbanisation, and the women's rights movement.

The technological and interventional approach to pregnancy and childbirth introduced the framework of *risk* and risk management to pregnancy where proactive monitoring and active management of symptoms and syndromes became increasingly the norm. Collectively these changes cast even the healthiest pregnancy as a site of 'health' in need of monitoring and management, thereby firmly entrenching all pregnancies, and the overall discourse of pregnancy into the domain of 'health' and under the auspices of government and medical professionals who were guided and justified by 'scientific practice and knowledge.' This allowed the pre-existing gender, race and class hierarchies to be reinforced, and to reject challenges to the social order via appeal to science – an 'objective' external arbiter that could justify the social order. The embedding of 'pregnancy' within 'health' increasingly exposed pregnancy to overall trends in 'health' including the new narratives of responsibility for health and wellbeing. This served to cast pregnant women as increasingly responsible for the future health and wellbeing of their children. The shift into 'health' also exposed the discourse of pregnancy to wider trends in medicine including the rise of psychiatry and innovations such as antiseptic technique. Specific changes in the discourse of pregnancy prior to the twentieth century thus were driven primarily by new medical diagnoses such as hysteria, and the advent of specific technologies such as anaesthetics and forceps, that reconfigured how risk, health, and nature interacted with the discourse of pregnancy.

THREE: 1880-1950 Epidemiological transition

> The protection and promotion of the health and welfare of its citizens is considered to be one of the most important functions of the modern state.
>
> George Rosen, *A History of Public Health (1958)*

The social, medical and scientific developments of the eighteenth and nineteenth centuries precipitated a demographic transition that by the early twentieth century would see significant changes in government interest and investment in heath and reproduction. Within the USA and Commonwealth, mortality rates declined, life spans lengthened, and the fertility rate plummeted, and by the 1880s a tipping point was reached that marks a major demographic shift. National populations were still growing but the majority of population growth stemmed from fewer deaths due to improvements in disease management rather than more births.[1] This chapter discusses key aspects of this demographic and epidemiological transition as they relate to pregnancy: First I discuss the rise of antenatal clinics and the introduction of the concept of perinatal risk within public health. These developments more directly embedded the notion of risk management into health care management and introduced new narratives of the fetus, as an individual patient distinct from the pregnant woman.

Second, I discuss how new understandings and technologies centered upon the concept of disease not only radically changed ideas about what health was but that these new narratives transferred into the discourse of pregnancy. This led to shifting ideas about what counted as healthy during pregnancy and most significantly recast how pregnant women were responsible for ensuring fetal wellbeing. This section also discusses the impact the significant changes in maternal and fetal mortality and morbidity had on narratives of risk and safety during pregnancy and childbirth. The third section examines the increasing ability to control

[1] Immigration was the other significant cause of population growth.

fertility in the twentieth century, first via increasingly reliable methods of contraception and then later assisted reproductive technologies (ARTs). Situating these changes within the broader context of industrialisation, urbanisation and the rise of capitalism, I highlight the way the early twentieth century governance structures increasingly focused upon reproduction as a response to the falling fertility rate. Pregnancy's reconceptualization in terms of governance had broad narrative consequences. As pregnancy became a less common event within a woman's life and increasingly a focus of governance not only did the overall social value of pregnancy and fetuses increase but reproduction became increasingly uncoupled from sex and relationships as it became something women could control and choose.

The fourth and final section of this chapter looks at the rise of eugenics as the discourse that represented the confluence of the broader social, political and scientific changes that made the development of reproductively focused public health possible. This section focuses upon the role of eugenics in shaping health and welfare policies in the wake of the falling fertility rates of the early twentieth centuries. The key shifts to the discourse of pregnancy to arise out of these changes were the introduction of control and choice to ideas about fertility and reproduction, the rapid rise in the importance of reproduction to the nation state and the expectation of responsible mothers to ensure a nurturing environment.

By the turn of the century it is no longer possible to single out particular innovations which substantively contributed to shifting the discourse of pregnancy. Instead it becomes necessary to discuss a series of concurrent innovations and events each of which shifted the conceptual possibilities of pregnancy. Each topic in this chapter focuses on a different aspect and manifestation of this relationship between pregnancy, reproduction and public health and charts the discourse of pregnancy during the first half of the twentieth century. The demographic change at the turn of the nineteenth century served to shift ideas of risk, health,

nature, responsibility and the fetus within the context of pregnancy. During this period pregnancy became even more deeply entwined with medicine which in turn served to more firmly situate 'pregnancy' under the banner of health, and under the influence, and even control, of governments, medical professionals and scientists, even as outcomes for pregnant women and their fetuses improved. Pregnancy was more and more becoming something that could be, *should be*, and was, possible to manage; whether to become pregnant and to treat pregnancy symptoms and signs of both maternal and fetal wellbeing, discomfort and disorder via an increasing variety of techniques.

3.1 Public Health

Public health was a key social innovation of the late eighteenth century as municipal administrative bodies attempted to deal with rapidly growing cities and problems arising from intensive industrialisation and urbanisation: environmental management, clean water, roading, waste removal and the placement of cemeteries all became major concerns. In the nineteenth century, public health moved beyond managing the built environment to become increasingly focused on managing the periodic infectious disease epidemics that regularly swept through towns and cities.[2] Three discoveries that improved understanding of infectious diseases were key to this shift in orientation; first, the rise of microbiology in the 1860s when Louis Pasteur formulated germ theory;[3] second, the development of epidemiology beginning with Jon Snow's mapping of a cholera epidemic in 1854 where he traced the epidemic back to a single shared water source thus overturning the miasma theory of disease transmission;[4] and the third key development in public health was the development of the smallpox vaccine

[2] Berridge, Gorsky, and Mold, *Public Health In History*, 27.
[3] The rise of microbiology, germ theory and epidemiology will be discussed further in the next section as the subsequent changes in 'disease' were influential on other aspects of 'health' and 'pregnancy.'
[4] Johnson, *The Ghost Map*.

in the early 1800s and the subsequent investment in infrastructure by state and municipal authorities in order to support vaccine manufacture and distribution.[5]

Collectively these advances, and the new emphasis on combating infectious diseases, broadened the scope of public health to include regular interventions in the lives of individual people as well as managing the collective built environment.[6] Normalising governmental intervention in the lives of individuals to control disease epidemics in the eighteenth century made possible the twentieth century shift towards governments also intervening in pregnancy. Unlike in the modern era, prior to the twentieth century there was little civic investment in the outcomes of pregnancy, which was a matter for midwives, doctors, pregnant women, and their families, not church or state. However, with the spread of public health into intervening in individual people's lives it was not long before public health expanded into regulating and managing other health behaviours including pregnancy.

By the early twentieth century the ideal of public health in many countries included monitoring and support for pregnancy and early childhood. As the role of public health had expanded a new and influential narrative arose: ensuring health was a responsibility of government. Recommendations, regulations and guidance proliferated, and women, children and reproduction were a common focus of these early regulations. As today, policies that emphasise the wellbeing of children align well with public sympathies because (in the abstract) vulnerable, innocent children are always perceived as worthy recipients of social investment.[7] Thus maternal and child health units were an early public policy focus supported by a combination of eugenic pronatalist ideologies of governance and the valued and

[5] Riedel, "Edward Jenner and the History of Smallpox and Vaccination." Smallpox alone killed 400 000 people annually until well into the nineteenth century with a fatality rate between 20-60% that left over one third of survivors blind and many with significant scarring. By the late 1800s smallpox vaccination was mandated in the vast majority of municipalities across most of Europe and North America.
[6] Rosen, *A History of Public Health.*
[7] Faulkner, *The Importance of Being Innocent*, 3–6.

sympathetic status of children.[8] While policies and laws focused on population health had existed prior, a number of factors converged in the twentieth century to produce the upsurge in government interest on health. Most significantly shifts in disease burden, mortality, morbidity and fertility rates will be discussed in the next two sections of this chapter, but collectively they led to a significant and widespread demographic change. The nationalist and eugenic narratives which arose simultaneously, emphasising reproducing the right type of people, and suppressing reproduction in 'the wrong types', were a response to this demographic change and are discussed in 3.4. The effect of these changes on the discourse of pregnancy was pronounced. There was rapid proliferation of laws and regulations intended to promote pregnancy, ensure maternal and fetal wellbeing, and reduce childhood and maternal mortality. These changes integrated pregnancy and reproduction further into 'health' at a time where ensuring the health of populations was becoming increasingly important to governments.

The rise of antenatal/prenatal care and its rapid spread within a framework of public health was a key component of the shift in the social and economic value of reproduction that occurred in the early twentieth century as birth rates declined. The beginning of the twentieth century saw the expansion of systematic antenatal care across the USA and Commonwealth countries.[9] Initial antenatal care clinics were simple, tracking weight gain and fetal movement, but rapidly began to include more complex assessments of risk factors to prevent or reduce birth complications. Antenatal care was portrayed to both the public and medical professionals as an easy way to improve rates of maternal, fetal and infant mortality and

[8] 3.4 will discuss eugenics and its relation to public health in more detail. For now, it is only important to note the link.

[9] Chamberlain, "British Maternal Mortality in the 19th and Early 20th Centuries"; Enkin and Chalmers, *Effectiveness and Satisfaction in Antenatal Care*, 6–7. While such care was central to improving infant mortality rates again there was only the perception of improvement in maternal mortality. J.W. Ballantyne's 1902 Manual of Antenatal Pathology and Hygiene was the first substantive text focused upon antenatal care however Ballantyne focused primarily on the "prevention of monstrosities" with maternal wellbeing being second.

morbidity especially compared to other options, such as professionalising midwifery, improving aseptic techniques and improving the social conditions in which people lived. By 1939 public health services commonly included infant welfare, antenatal and school based clinics and in the 1940s and 1950s governments across the commonwealth and USA expanded the public provision of healthcare, although in a wide variety of ways and with differing priorities.

Well into the twentieth century a common feature of healthcare reform was the exclusion of and failure to consider the health needs of indigenous people and non-white immigrants and this extended to reproductive care. Indigenous people across the Commonwealth and USA were often ignored in data collection, and where medical services were provided there was less funding and lower quality. In line with the explicit and implicit eugenic agenda of the era, government focus with regards to health remained on "improving the quality of the white population;" even when consideration was extended to non-white people in the 1960s and 1970s it failed to consider cultural differences and needs perpetuating the health inequalities founded in the earlier era.[10] The different experiences of non-white people with public health, highlights how and why non-white people today continue to experience the health system differently.

The introduction of nationalised health care schemes in the UK, Canada, NZ, Australia, and to a more limited extent in the USA, was part of a wider expansion of rights discourse within politics and morality. This expansion was epitomised by the Universal Declaration of Human Rights which was ratified by the United Nations general assembly in 1948 and where health was considered an essential right.

Article 25:

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and

[10]. Bryder, "A New World? Two Hundred Years of Public Health in Australia and New Zealand.," 328.

> necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
> *(2)* Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.[11]

In this moment healthcare was presented as a service essential to people's general wellbeing and a service governments were obliged to provide. Provision Two's emphasis on motherhood and childhood as periods when people are entitled to extra assistance is also worthy of note as highlighting the heightened governmental and state concern with reproductive success.

The most significant impact of the rise of public health and antenatal care upon 'pregnancy' was the further tightening of the association between health and pregnancy which justified further government intervention and investment in both 'pregnancy' and individual pregnancies and thus control over 'pregnancy.' Furthermore, the rise of public health also introduced a new level of accountability in the layering of responsibilities owed by pregnant women towards the state. A pervasive narrative shift that occurred within these policies is that they held women explicitly responsible for raising healthy families: investing women with a civic as well as domestic obligation and making them accountable to the state "for ensuring not just the health of their families, but the health of the next generation of citizens."[12] As documented in the sections on mental health and hysteria, the narrative of maternal responsibility was present prior to the twentieth century; however this narrative became more pervasive throughout the twentieth century as policies focused upon maternal and child health proliferated in public health policies and campaigns focused on childhood nutrition, hygiene, vaccination and breastfeeding as well as expectations around self-care during pregnancy. While explicitly situated as being for the benefit of women and children, it

[11] UN General Assemby, "The Universal Declaration of Human Rights."
[12] Kukla, "Ethics and Ideology in Breastfeeding Advocacy Campaigns," 158.

cannot be ignored in how these programs also supported the social agenda of the men in power within the rapidly industrialising modern nation states, their widely held eugenic social agendas about reproducing the right sort of people as the future citizens of these states, and also served to reinforce gender and race based norms about women, femininity and maternity in the face of mass gender, race and class based social upheaval which challenged the previously uncontested dominance of this group of men.

3.2 Disease & Mortality

> …changing perceptions about what causes disease – the nature of risk, behavior, and responsibility – reflect powerful moral beliefs. In turn, these beliefs implicitly and explicitly affect patterns of social behavior and the organization and delivery of health care.
>
> Alan Brandt, *Behaviour, Disease and Health in the Twentieth Century*

Until the early twentieth century infectious diseases such as cholera, smallpox and tuberculosis were the major causes of death in industrialised nations. However, by the mid-twentieth century the majority of deaths in North America, Europe and the Commonwealth had become attributable to a new set of causes: chronic and non-communicable diseases such as heart disease and cancers. This epidemiological transition occurred because of a range of social, scientific and political advances including the rise of public health, improved living standards, and great scientific advances in the understanding of diseases, their causes and methods of transmission: in particular the development of the germ theory of disease.[13] As traced in the prior chapter, the integration of 'pregnancy' into the discourse of health gathered pace as various medical technologies and techniques were becoming more and more integrated into everyday pregnancies. This section explores the role new understandings of

[13] Widespread investments in sanitation – sewers and rubbish collection, improving nutrition among the poor, preventative health measures and ever increasing access to better and better quality medical care from professionals who used ever improving techniques and medicines not only saved lives but also helped facilitate both the epidemiological and demographic transitions.

disease made to improved rates of maternal, fetal and infant mortality and morbidity, making pregnancy a substantially safer, less risky endeavour while also binding 'pregnancy' ever closer to 'health' as more and more treatment options for the disorders of pregnancy and childbirth arose. I then explore the broader discursive impact of the transition towards non-communicable diseases and how the shifting narratives of 'disease' impacted the discourse of pregnancy by redefining the boundaries of what counted as 'health,' what counted as 'risk' and who was 'responsible' for ensuring health and evaluating risk.

While midwife assisted homebirth was still the most common birthing situation into the early twentieth century, birthing practices were changing fast. Hospital based, doctor attended births were becoming increasingly common even for the less wealthy. This was driven both by public desire and medical belief that the active management of labor and birth through the use of technologies was both better and safer.[14] Despite incremental improvement maternal mortality remained stubbornly high in the USA and Commonwealth countries even as overall rates of deaths were rapidly declining for many, including infants.[15] This failure was a source of public outrage that helped mobilise both private and governmental agencies in improving maternal healthcare, improving both the quality of and access to childbirth attendants: midwives, nurses and physicians. The persistence of the high maternal mortality rate also added impetus to the maternal focus of public and preventative health initiatives. The enfolding of pregnancy within the auspices of government, via medicine and science was by no means a conscious power grab by the men in control of these institutions but rather a response to a genuine opportunity to improve people's lives. However, this improvement took place within the context of the dominant hegemonic ideological schema and the

[14] Leavitt, *Brought to Bed*, 5–6.
[15] Loudon, "Maternal Mortality in the Past and Its Relevance to Developing Countries Today," 241 S. The exception to maternal mortality statistics was the countries of northwest Europe which due to the early widespread use of aseptic technique and high standard of midwifery training had significantly decreased rates of maternal morality as early as the 1880s. These countries also had traditions of minimal technological intervention during childbirth.

previously mentioned capitalist oriented emergent nation states where it now became to the advantage of the state, the economy, and the profits of those who owned the means of production to ensure an ongoing pool of future workers-tax payers-citizens.

Maternal Mortality

The major predictor of maternal outcome in childbirth was, and continues to be, whether there is a skilled attendant at the birth. Obstetricians, doctors and midwives could ease breech births, use forceps, and perform craniotomies, episiotomies or suture tears. However until the 1940s they could do nothing to combat the major causes of maternal mortality: puerperal fever, haemorrhage and eclampsia.[16] Puerperal fever – bacterial infection of the reproductive tract post childbirth – was the major cause of sepsis and epidemics periodically swept through lying in hospitals across Europe and North America, where it killed as many as one in four women giving birth.[17] Prior to the widespread use of aseptic and hygiene practices, obstetricians and midwives washing their hands and instruments in between visiting patients, which decreased these epidemics, hospitals had higher mortality rates than home birthing and were not a particularly safe place to give birth.[18] While the benefits of hygiene and antiseptic practice were identified in the mid nineteenth century as key to reducing infectious disease transmission, these practices had little impact upon maternal mortality rates.[19]

The first reason that antiseptic and aseptic techniques had little impact on the overall rate of maternal mortality was because there was significant resistance towards the adoption

[16] Prior to the 1930s there were three major causes of maternal mortality; sepsis (30-50% of overall maternal deaths), toxemia/eclampsia (20%) and haemorrhage (15-20%).
[17] Loudon, *Death in Childbirth*, 46.
[18] De Costa, " The Contagiousness of Childbed Fever," 669.
[19] Holmes, "The Contagiousness of Puerperal Fever"; Semmelweis, *The Etiology, Concept, and Prophylaxis of Childbed Fever*. As early as the 1840s the benefits of aseptic and hygiene practices were promoted by prominent physicians Oliver Wendell Holmes in the USA and Ignaz Semmelweis in Europe. Both men recommended practices such as hand washing and changing one's clothes between patients.

of hygiene practices by doctors, who were not so much opposed to the practices such as handwashing but rather resistant to the general notion that they could be the carriers of disease: doctors "are gentlemen, and gentlemen's hands are clean."[20] Nevertheless by the end of the nineteenth century hygiene practices were well established within hospitals and the human vector for the transmission of puerperal fever was well recognised, in part due to the development and acceptance of germ theory which reduced the 'moral' overtones of being a disease vector. A second reason for the limited impact was that most women still gave birth at home, not in hospital and antiseptic techniques were seldom used in home deliveries. While there was little change in maternal death rates prior to the 1930s public perception was that maternal deaths were declining.[21] Possibly this was because by the end of the nineteenth century the death rate for women giving birth in hospitals was vastly improved and being mostly middle and upper class these white women were exactly the ones who were visible, memorable and related to medical professionals, and government officials, and those on the boards of the charities funding social projects.

Maternal mortality rates did decline rapidly beginning in the mid 1930s, however, as a series of technological developments arose aimed at directly countering the common causes of death in childbirth. First came the development of sulfonamide antibiotics capable of fighting puerperal infections, followed shortly thereafter by penicillin. The effectiveness of antibiotics was such that by 1945 puerperal fever was almost non-existent as a cause of death in childbirth. Shortly thereafter ergometrine was developed to counter postpartum hemorrhage, which alongside the development of universal blood transfusion, significantly decreased hemorrhage, the second most common cause of childbirth related death.[22] The advent of antibiotics also indirectly improved outcomes for the third common cause of death,

[20] Wertz, *Lying-In*; De Costa, " The Contagiousness of Childbed Fever," 670.
[21] Loudon, "Maternal Mortality in the Past and Its Relevance to Developing Countries Today."
[22] Loudon, 246 S.

eclampsia, as early delivery via caesarian section became a safe possibility. At the same time, oxytocin was also identified as a labour stimulus providing an additional means of early delivery. While the diagnosis of pre-eclampsia via its symptoms – proteinuria and hypertension – was possible from the early twentieth century it was only with the advent of safe methods for early birth that it could be avoided.[23] In response to these innovations the rate of maternal mortality plummeted from 40 per 1000 births in 1930, a rate that had remained stable since the nineteenth century, to less than 10 per 1000 births by 1950.[24] However the social impact of these changes upon the perceived safety and riskiness of pregnancy was more complex. Even though the actual improvements in maternal mortality did not occur until the 1940s the perceived safety of pregnancy had been increasing, and thus the perceived risk of pregnancy had been declining, since the mid nineteenth century.

The perceived risks of pregnancy also shifted in response to the rising standard of living in the early twentieth century which improved infant mortality rate – but not maternal mortality. Indeed except under conditions of starvation "[t]here is overwhelming evidence that social and economic conditions were very weak determinants of the levels of maternal mortality."[25] Maternal morbidity and mortality thus declined slightly in the early twentieth century due to the knowledge and technologies available to an increasing number of increasingly skilled birth attendants. As training became standardised and more widespread even those outside of formal training mechanisms improved in knowledge and skills. In conjunction with overall improvements in health and declining rates of infant and child mortality this led to the perception that pregnancy was becoming less risky.

[23] Previously the standard management for preeclampsia- eclampsia was the administration of magnesium sulfate to minimise the convulsions and to await the onset of natural labour. Bell, "A Historical Overview of Preeclampsia-Eclampsia."

[24] Chamberlain, "British Maternal Mortality in the 19th and Early 20th Centuries," fig. 1. After 1950 improved hospital management, medical education and anaesthesia use as well as less interference in normal labors continued to contribute to the improving rates of maternal death.

[25] Loudon, "Maternal Mortality in the Past and Its Relevance to Developing Countries Today," 244 S. While infant mortality rates are strongly influenced by social class we now know that poverty was and is not a primary determinant of maternal mortality.

However, in practice there was an inverse correlation between socioeconomic class and maternal mortality. Working class people and the poor had lower maternal death rates, at least in part because they had less access to physician based obstetric care and relied mainly on midwifery and labored at home. While trained medical professionals attending childbirth reassured women and their families as to the perceived safety of childbirth, middle and upper class women with greater access to such medical support were more likely to give birth in hospitals. Working class women were less likely to get caught up in the hospital based epidemics of puerperal fever that periodically swept through European and North American hospitals. While women who gave birth at home still had a risk of contracting puerperal fever, this risk was significantly less than if they gave birth in hospital.[26]

Infant Mortality

Until the turn of the twentieth century the golden rule of obstetrics was that "the mother's life is always to be more regarded than the safety of the child."[27] However this changed in the twentieth century as it became increasingly possible to save both mother and child thanks to improved methods for intervening in childbirth such as safe caesareans. Declining infant mortality, in conjunction with rapidly falling birth rates and the rise of antenatal care provided as part of a system of public health, led to shifts in the discourse of the fetus. Prior to the demographic shift the high fertility rate and rates of infant death much higher than in western countries today meant that almost everyone shared the experience of child death. In 1880 around 38% of all live-born children died before their fifth birthday. By 1950 this had declined to 12% in Europe and 4% in North America, while today in both North America and Europe less than 0.5% of children die before their fifth birthday.[28]

[26] Chamberlain, "British Maternal Mortality in the 19th and Early 20th Centuries"; Loudon, "Maternal Mortality in the Past and Its Relevance to Developing Countries Today."
[27] Hanson, *A Cultural History of Pregnancy*, 8 Qt Smellie (Vol 1 p280 [London D. Wilson].
[28] Roser, "Child Mortality."

This mortality rate also excludes stillbirths and miscarriages which was a second source of infant death. Today between 10-20% of known pregnancies result in stillbirth or miscarriage and historical rates of stillbirth and miscarriage would have been higher. [29] The third source of infant and fetal deaths was craniotomies and the additional possibility of killing an at term fetus in order to save the mother. Prior to antibiotics, craniotomy was the standard treatment for prolonged childbirth: a procedure of last resort used to save a birthing woman by crushing the fetal scull in order to ease extraction. Until the development of antibiotics, the high likelihood of maternal death from a caesarean section meant the procedure was only used when the mother was already dead or near death. The rate of craniotomy during the eighteenth and early nineteenth century was between 2-6 per 1000 births and in the 1840s there were around 500,000 live births per year in England and Wales, giving somewhere in the range of 1000-3000 craniotomies per year.[30] In conjunction with the higher fertility rates of the nineteenth century these three factors, high child and fetal mortality and fetal death in childbirth, meant most people would have numerous experiences of infant death.

As social, political and medical resources became available to prevent infant and fetal deaths people's exposure to infant and child death declined as infant and child death became increasingly rare. In the discourse of pregnancy, narratives of infant and fetal loss and death as a shared common experience became superseded by healthcare oriented narratives focused on ensuring the safety and wellbeing of fetuses, newborns and infants. Concurrently, as it

[29] American College of Obstetricians and Gynecologists, "ACOG Practice Bulletin. Management of Recurrent Pregnancy Loss. Number 24, February 2001. (Replaces Technical Bulletin Number 212, September 1995). American College of Obstetricians and Gynecologists"; McClure, Goldenberg, and Bann, "Maternal Mortality, Stillbirth and Measures of Obstetric Care in Developing and Developed Countries." According to McClure rates of stillbirth correlate closely to maternal mortality. This stillbirth rate is only an estimate and was found by aligning the pre-twentieth century maternal mortality rate estimated by Chamberlain (2006) against McClure's table 1.

[30] Loudon, *Death in Childbirth*, 135; UK Office for National Statistics, "Annual Data: Live Births." As birth rates declined over the nineteenth and early twentieth century there would have been both a baseline decrease in the relative number of these types of infant and fetal deaths per woman in addition to the decrease in infant and fetal mortality that arose from improved perinatal care.

became possible to actively intervene to save fetuses more and more resources and social attention were focused upon 'the fetus' as the broader idea about what constitutes a fetus shifted.

As discussed in the sections on public health and eugenics, a significant reason for the increasing allocation of resources to fetal and infant health was an increasing concern for the continued wellbeing of each individual child. As women start to have less children individual children became increasingly important to the continuation of the family and the state: "The law of supply and demand was in operation: the successful outcome of a pregnancy became more important as pregnancy itself became scarcer."[31] This is not to say that individual children were not valued by their families prior to the epidemiological transition, simply that as families began to have fewer children more resources (from both state and family) were available to support each individual child. At the same time the fetus was becoming something existent and important in its own right, increasing in value-status-consideration as it became increasingly scarce and more able to be kept alive and healthy through intervention.

The two most significant consequences of this change in the status of the fetus were the rise of narratives in which the fetus was positioned as a patient in its own right, and an associated narrative in which the pregnant woman and fetus are assumed to have separate and sometimes opposing interests.

> One consequence of these changes was an increasing tendency to separate the pregnant woman and fetus. The growing separation of mother and fetus took place along two dimensions, as maternal-fetal antagonism was superimposed on the increasing individualization taking place more generally in society. Concurrently, there was a growing tendency in medicine, law, and society at large to see the pregnant woman and the fetus not only as separate but at odds, their individual welfares distinct and oppositional, rather than mutual.[32]

[31] Hanson, *A Cultural History of Pregnancy*, 9.
[32] Armstrong, *Conceiving Risk, Bearing Responsibility*, 14.

The tendency towards maternal-fetal separation can be seen within medicine in the early twentieth century in the way in which it framed advocacy for specialist antenatal care units within hospitals. Prominent obstetrician J.W. Ballantyne's landmark 1901 article in the *British Medical Journal* "A plea for a Pro-Maternity Hospital," argues for the establishment of such units, however his chief concern was "the prevention of monstrosities [deformations] and the advancement of the fetus's interests" rather than maternal care.[33] Ballantyne's plea represents the rise of new narratives of the fetus, as a patient in its own right: an individual separate from the mother with its own, possibly competing, interests. This was a distinct conceptual shift from the previous century when the dominant narrative representation of the maternal-fetal relationship was one of harmonious symbiosis where maternal and fetal health were understood to be one and the same.[34] This narrative shift occurred not only at the time of a rapidly declining rate of infant mortality (and the perception of a declining rate of maternal mortality and still births), but even more significantly during a period of rapidly declining birthrates.

Disease

The germ theory of disease - the notion that specific microorganisms are responsible for diseases – rose to become the dominant scientific theory of disease in the mid to late nineteenth century (this followed centuries of dominance by miasma theory which held atmospheric impurities were the source of disease). While precursor forms of germ theory had existed in scientific discourse since at least the sixteenth century, support for germ theory grew rapidly over the second half of the nineteenth century, precipitated by two ground breaking research projects: Snow's work on cholera and Semmelweis' studies of childbed

[33] Hanson, *A Cultural History of Pregnancy*; Ballantyne, "A Plea for a Pro-Maternity Hospital"; Enkin and Chalmers, *Effectiveness and Satisfaction in Antenatal Care*, 3.
[34] Hanson, *A Cultural History of Pregnancy*, 8.

(puerperal) fever which lead to new methods for stopping disease transmission.[35] The technological advances in microscope science which made new levels of visualisation possible were also significant. The development of the germ theory of disease was a major scientific advance in our understanding of disease. A particularly ground-breaking aspect of germ theory was the notion of microorganisms - 'germs'- that made people sick with particular illnesses, that these microorganisms could pass between infected individuals, exist or 'live' in different mediums such as water or soil and could infect people or animals indirectly via these mediums. Infectious diseases were poorly understood prior to the development of a germ theory of disease and the subsequent developments of antiseptic technique, vaccinations and antibiotics that germ theory made possible, rapidly reduced transmission and effectively treated infections.

Theories of disease causality play a central role in shaping discourses around risk and personal responsibility in 'health.' The influence of 'disease' upon 'health' 'risk' and 'responsibility' can be seen as it became understood that microorganisms, not "moral turpitude, sin and idleness" caused disease.[36] With this new understanding of disease causality and armed with ever improving medicines it became possible for people to intervene and win against diseases previously fatal and this "magic bullet…radically altered both medical and social meanings of disease."[37] In the wake of germ theory's ability to explain infectious disease causality and contagion and success of health initiatives in preventing and treating disease, infectious diseases faded from public awareness, becoming a less dominant, less fear inducing, aspect of 'health'.[38] This occurred because with understanding came the ability to predict how diseases would spread, prevent infections and

[35] Brandt, "Behavior, Disease and Health.".
[36] Brandt, 54–56.
[37] Brandt, 55.
[38] This is not to say that they were not present, simply that they were both less frequent and more treatable and thus less fear inducing. See Brandt for full discussion.

when all else failed more successfully treat them. No longer did governance focus on population based damage limitation and quarantine. Instead the focus became risk management – for governance, and risk evaluation – for individuals. Risk in the context of disease became a quantifiable factor to be managed and evaluated rather than the unknowable and unpredictable uncertainty it was before diseases could be modelled and treated. This paralleled the transformation occurring within 'pregnancy' as increased understanding of reproductive processes and the things that could go wrong caused maternal and infant mortality and morbidity to decline.

The development of germ theory and the associated transformation of 'disease' removed much of both the moral and personal responsibility for disease from the suffering individuals. Infectious diseases had commonly been seen as spreading because of the moral failings of those who become infected. However with the ability to prevent contagion that came with the understanding of how infectious diseases spread, "Disease was no longer seen as *necessarily* reflecting the personal attributes of the sick individual."[39] If microorganisms cause an individual's ill health and these microorganisms attached to people in their everyday life *and* there was an ever increasing number of easy fixes or magic bullets to treat and prevent these diseases then the stigma attached to diseases is vastly reduced.[40] While this narrative that people were not morally responsible for becoming ill originated within the discourse of infectious diseases it rapidly spread outwards into the broader domain of 'health.'

Today this narrative of non-responsibility still underpins the relationship between personal responsibility and health, even as the competing narrative that people are responsible for their health has remerged. In the twentieth century, with infectious diseases

[39] Brandt, "Behavior, Disease and Health," 47.
[40] Stigma will be taken up in detail in 6.1. For now, it is only worth noting that prior to the epidemiological shift infectious diseases likely also fitted the model of stigma I apply to thalidomide and as a consequence subject to substantial misunderstanding, misattributed and distorted causality.

under control, chronic non-communicable diseases arose as the predominant cause of mortality and morbidity. As disease patterns changed so did the pattern of epidemiological inquiry, a movement away from "tracking microbes that were uniformly seen as the "cause" of disease, researchers began to identify *risks:* the social, environmental and behavioural variables that were statistically associated with patterns of chronic disease."[41] These clearly identifiable *risk factors* for conditions such as heart and lung diseases made it possible once again for individual choices and behaviours – lifestyle factors such as smoking, not exercising or eating fatty foods – to be understood as contributing to their own (or their children's) ill health. With the focus of 'health' shifting away from infectious diseases towards chronic and non-communicable diseases ideas about 'risk' and 'responsibility' within the domain of health shifted yet again.

New mathematical techniques such as biostatistics and the subsequent development of controlled prospective trials were central to the rise of this new form of epidemiology focused upon the social, environmental and behavioural factors underpinning chronic and non-communicable disease. Large cohort, long term studies like the Framingham trial into heart disease in Massachusetts in the 1950s allowed epidemiological researchers the "opportunity to explore the relationship of a host of environmental and behavioural variables to patterns of health and disease."[42] While epidemic infectious diseases were still conceptualised as the product of external forces, chronic and non-communicable diseases were increasingly becoming recognised as multifactorial in cause and acquired at least in part through chosen behaviours. This reintroduced the narrative of personal responsibility back into the discourse of health. Contracting a disease was once again, at least in part, a moral failing "a failure to

[41] Brandt, "Behavior, Disease and Health," 60.
[42] Brandt, 60.

take appropriate precautions against publicly specified risks, a failure of individual control, a lack of self-discipline" rather than being outside of personal control.[43]

The shifting relationship between health, risk and personal responsibility can be traced within direct academic theorising about 'health.' The biomedical model of health was developed in the late nineteenth century concurrent with the beginnings of the epidemiological shift and was precipitated by many of the same changes in public health, medical care and scientific innovation. Still dominant today, in a somewhat revised form, the biomedical model posits a range of suppositions: that all illnesses and symptoms are caused by an underlying physical abnormality in the body, that health is the absence of disease, that the patient is the passive and cooperative recipient of treatment and that "the patient is the victim of circumstance with little or no responsibility for the presence or cause of the illness."[44] While early iterations of the biomedical model focused solely on the biophysical aspects of health, by the mid-twentieth century psychological and then social factors also came to be understood as contributing to health. Today this is most often labelled the biopsychosocial model of health but underpinning it are many of the same suppositions about the relationship between health, risk and individual responsibility.[45]

While the epidemiological transition in mortality from infectious to non-communicable disease had little direct connection to the rise of ideas about risk and responsibility within 'pregnancy', it radically shifted the conceptual boundaries of 'health' in relation to risk and responsibility. As discussed in the prior chapter pregnancy was becoming

[43] Brandt, 63.
[44] Wade and Halligan, "Do Biomedical Models of Illness Make for Good Healthcare Systems?"
[45] Wade and Halligan. A simple example that highlights the shift between these models can be seen in the narrative shifts about war veterans. During world war one the symptoms, both physical and psychological, caused by the traumatic experiences of soldiers that often saw them unable to continue in the war, were commonly attributed to 'a lack of moral fibre,' malingering or cowardice. By comparison after world war two, and the integration of psychiatry into healthcare, these same symptoms in soldiers were considered an illness, 'posttraumatic stress disorder', worthy of professional medical assistance and financial support. 'Health' expanded in the twentieth century as psychology integrated into the medical model and the role lifestyle and social factors played within personal responsibility for health also changed.

more and more enmeshed within the discourse of health and thus more sensitive to changes in the overall discourse. Twentieth century changes in the prominence of ideas of risk and responsibility during pregnancy occurred in no small part because of shifts in 'disease' as mediated via 'health.'[46] With the epidemiological transmission, however, a new range and type of risks arose as the role of social, environmental and behavioural factors as causes of disease became apparent. This was significant for 'pregnancy' as it meant that all aspects of pregnancy were now possible causes of fetal ill health. The second half of the twentieth century would be a time where medicine would focus on evaluating these newly apparent risk factors, quantifying the degree of possible harm that could arise and educating stakeholders (pregnant women, medical practitioners, governance organisations and communities) as to the possibility.

Narratives of responsibility for ensuring and maintaining health and the degree to which people, both clinicians and patients, are perceived as responsible for health are impacted by shifts in narratives of disease causation, transmission and treatment. The epidemiological transition from infectious to non-communicable diseases transformed narratives of responsibility in 'health' because of the shift towards behavioural and lifestyle changes as a key source of both prevention and treatment for many non-communicable diseases. The rise of behavioural changes as both prevention and solution to ill-health transformed ideas about responsibility during pregnancy, reshaping how ill health during pregnancy (for woman or fetus) was interpreted and attributed. As birthrates declined, nations became more and more concerned about maintaining the workforce to ensure an expanding industrialised economy based upon skilled labour. The narrative shifts around 'health', 'responsibility' and the 'fetus' that compelled women (who were not at this stage commonly

[46] Lyerly et al., "Risk and the Pregnant Body"; Armstrong, *Conceiving Risk, Bearing Responsibility*.

part of the formal waged economy) to ensure the existence and wellbeing of the future workforce could only benefit nation states, and the powerful men who lead them.

3.3 Controlling Fertility

Rapidly falling birth rates, particularly among white women in the Commonwealth countries and USA, occurred in conjunction with the improvements in morbidity and mortality discussed in the previous section. Collectively these changes had a particularly potent impact upon the discourse of pregnancy. There was a range of causes for the decline in fertility, all stemming from the shift to urban industrial living which reduced the economic benefits of large families.[47] These large scale social changes provided an incentive towards smaller family sizes, for instance married women had new opportunities to take paid work in factories and shops where previously they had been restricted to the household and family owned businesses. While the large scale social changes incentivised people to have smaller families it was an increase in the use, effectiveness and availability of contraceptives and family planning techniques that made the change possible.[48] As much as three quarters of the drop in fertility can be attributed to people using methods of active fertility control.[49] People were becoming increasingly aware of the availability of contraception and the benefits of active family limitation and voluntary motherhood for both women's health and also the economic wellbeing of a family in urban industrialised societies.[50] This section discusses the rise of contraception and the falling fertility rate within the context of twentieth century

[47] Women were also entering higher education and pursuing careers primarily in teaching and nursing but increasingly in medicine, law and other professions.
[48] Brodie, *Contraception and Abortion in Nineteenth-Century America*, 209–16.
[49] Leavitt, *Brought to Bed*, 19.
[50] Thane, "Sexual Politics," 1032.

trends in social and health policy, both the direct impact of decreasing rates of pregnancy upon the discourse of pregnancy and via social policies that focused upon reproduction.

Active fertility control not only changed the pattern of women's lives, but also shifted social and political discourse around reproduction and pregnancy more broadly.[51] As birth rates decreased, pregnancy was no longer a continuous and inevitable part of married life. Active and accurate methods of contraception let women choose (mostly) when and how often they became pregnant which introduced ideas of control and choice into the discourse of pregnancy. While married women still expected to have some children it became increasingly possible to choose how many and this initiated the discursive separation of sex, relationships and marriage from reproduction.

Despite Victorian mores that made sex a forbidden topic of public discussion, family planning and contraceptive methods were both widespread and improving throughout the nineteenth century and there was a lively but low key proliferation of contraceptive knowledge. Both these patterns can be seen in the publications such as Robert Dale Owen's *Moral Physiology* (1831) and Charles Knowlton's *The Fruits of Philosophy* (1832) advising on methods of family size limitation, both of which had multiple editions over many decades. In public contraceptive knowledge also spread by more subtle means including coded advertising, itinerant lectures, conversation with freethinkers and medical practitioners. While Janet Farrell Brodie documents letters between women that contain frank discussions of

[51] Leavitt, *Brought to Bed*, 19. Before the demographic shift a continuous cycle of pregnancy and breastfeeding was the norm. By early twentieth century the fertility rate had dropped to 3.6 children per woman and a slightly higher 5.5 children per woman for Catholic Americans. Numbers were similar in the UK, where birth rates were also steadily declining from 3.5 births per woman in the 1870s to 2.9 births per woman in 1900. While the exact cause of the decrease in the birthrate cannot be known, the significant decreases which occurred within a single generation shows that at least some of the birth control methods used by Victorian women were effective. Guinnane, "The Historical Fertility Transition," 589..

failures and successes of birth control and family planning indicating how family planning and contraceptive knowledge also spread in private although to what extent it is hard to tell.[52]

As discussed in the previous sections ensuring future reproduction and child rearing was increasingly becoming something of value to the state that was worth regulating. Another component of these changes was influencing the fertility rate to ensure a future workforce as after a period of only slow change birth rates were falling rapidly in the late Victorian era. With the rise of the anti-family planning movement contraception became an increasingly prominent topic of social and political backlash. In the USA the peak of this backlash against family limitation was the passing of the Comstock laws in the late 1870s. These laws supported increased fertility by curtailing the circulation of knowledge about methods to avoid pregnancy. They did so by criminalising contraception and making the dissemination of information about sex and contraception illegal as an obscenity. In the UK the same forces were also in play when already existing indecency laws were enforced after a period of laxity. The most prominent example was the 1877 case of Charles Bradlaugh and Annie Besant who were prosecuted for republishing *The Fruits of Philosophy*. However, their prosecution backfired as the publicity around the case served only to repopularise the text on contraceptive options. [53] The anti-family planning, and anti-abortion, movement was a cultural counter response to smaller family sizes and aimed to promote reproduction in white middle and upper class women. It also aligned against the women's rights movement, making sex outside marriage more burdensome for women and reinforced expectations of white middle and upper class women's unwaged labour in childbearing and childcare.

[52] Gordon, *The Moral Property of Women a History of Birth Control Politics in America*, 9; Brodie, *Contraception and Abortion in Nineteenth-Century America*; Walle, "Review of Contraception and Abortion in Nineteenth-Century America. by Janet Farrell Brodie," 376.
[53] As documented above, a wide range of birth control methods existed, and texts discussing the many options, were widespread.

The anti-abortion, anti-family planning movements that developed in the late eighteenth century and strengthened in the early twentieth century were part of the wider cultural response to demographic change where rapidly declining birthrates in the white English speaking populations of the Commonwealth and America saw social and governance groups prioritise reproduction (of the 'right type of people').[54] It is important to note both the eugenic nature and policy shaping capacity that the anti-family planning and anti-abortion movements collectively held as they were influential in both health research and primary care, particularly around reproductive and children's health.[55]

Governmental regulation of contraception (for married people) loosened from the 1930s onwards.[56] Over the subsequent decades the pattern in the Commonwealth countries and USA was ever increasing access to and acceptance of contraception for married women and by the late 1950s most non-Catholic couples used some form of birth control such as diaphragms, spermicides, withdrawal and condom. However, all these methods were relatively fallible and were extensions of technologies that had been available since the late 1800s. Each method also had its own drawbacks, for instance, diaphragms required women to ask for an individual fitting by a medical doctor, while women had to trust a male partner to use a condom. Additionally, these methods also required genital touching which added to people's distaste.[57] Thus the development of the hormonal birth control pill in the late 1950s

[54] Brodie, *Contraception and Abortion in Nineteenth-Century America*, 253.
[55] It was not until after world war two that attempts were made to remove policies with overtones of Nazism and distance themselves from the 'bad' eugenics endorsed by Nazis. Nevertheless, policies promoting selective sterilisation and the removal of children from people with mental disabilities remained in many parts of the world until at least the 1970s. However, the demographic change marked the introduction of pronatalist reproductive policies into governance, where they remain today, albeit with most of the overtly racist and classist aspects of eugenics striped out.
[56] In the USA Margaret Sanger's tireless crusade for safe and legal birth control resulted in the 1937 exclusion of contraception from the Comstock indecency laws and the development of birth control clinics. Similarly, the first birth control societies formed in the UK in the 1920s, forming by the late 1930s the Family Planning Association who could legally provide family planning advice to married women and that were offered as part of the maternal child health units. Other commonwealth countries followed a similar pattern of legalising and promoting contraceptive advice to married women from the 1930s. Leathard, *The Fight for Family Planning*; Bryder, *A Voice for Mothers*; Smith, *Maternity in Dispute*. Watkins, *On the Pill*, 14.
[57] Watkins, *On the Pill*, chap. one.

as a single daily dose oral contraceptive was ground breaking. Not only was it the first novel contraceptive developed since the nineteenth century, but it was simple, effective and disassociated from the sexual act giving women more active control over their reproduction. After successful clinical trials in several countries it quickly became legalised across the USA and commonwealth between 1957 and 1961.[58] Immediately proving popular, the pill had rapid widespread uptake by women.[59]

Even as the development of hormonal birth control provided women with the ability to avoid unwanted pregnancies, at the same time research was underway to assist women to achieve desired pregnancies. While the first known case of successful human donor insemination was back in 1884, it was the second half of the twentieth century that saw a flood of advances. The most widely known example is in vitro fertilisation (IVF) with the first successful human birth in 1977. The 1980s and 1990s saw a flurry of developments in assisted reproductive technologies including controlled ovarian hyperstimulation, improved embryologic technology, intracytoplasmic sperm injection (ICSI), cryopreservation, embryo transfer techniques, and increasing social acceptance of gestational surrogacy and the use of donor eggs and sperm. Today the rates of technologically assisted reproduction range from 1% in the USA to 3% in Australia to 5% in some European countries.[60]

Contraception meant different things to different groups. To middle class women it was a way to break out of housewifery, making possible the option to continue to work after marriage by limiting childbearing.[61] The birth control pill quickly became a symbol of middleclass white women's right to reproductive control. However, condoms remained the

[58] Watkins, *On the Pill*.
[59] Although by the end of the 1960s the pill faced significant criticism from women's groups for its health risks. It is worth noting that these criticisms and concerns occurred after events around thalidomide and DES heightened public awareness of how pharmaceuticals could go wrong. The rapidly shifting expectations around informed consent and the doctor-patient relationship were also core parts of the change.
[60] Connolly, Hoorens, and Chambers, "The Costs and Consequences of Assisted Reproductive Technology."
[61] However, it is likely that the rise of new technologies such as washing machines, vacuum cleaners, and the availability of cheaper readymade clothes, all of which reduced the time required to complete household chores were as causally important to the spread of middleclass women into the workforce.

dominant birth control method for many poor, working class, black and brown women even after the introduction of the pill as they required less money, time and access to doctors. Ideas about reproductive control for poor people continued to have two foci: the continuation of eugenic ideas about limiting reproduction for the less well off as a social good; and the growth of the notion of reproductive control, or family limitation, as a right that all women ought to have.

Birth control and family planning also promoted a shift in the relationship between sex and reproduction, a shift that became more explicit as birth control improved over the twentieth century. Increasingly reliable and widespread forms of birth control made pregnancy no longer the inevitable consequence of sex. In turn the possibility of decoupling sex and pregnancy made pregnancy more and more of a conscious choice. In the early twentieth century such an outlook on sex and reproduction and the conscious choice of small families was mostly limited to the upper classes. However, it rapidly filtered down to other groups throughout the twentieth century as effective birth control became more wide spread.

By the time of hormonal birth control in the 1960s "how people thought about conception, pregnancy, childbirth, and even parenthood [had transformed]. Central to this transformation was the notion of control: women could control the timing, pace, and level of their fertility."[62] This was a shift that had been building throughout the earlier twentieth century and was precipitated by overall demographic changes and technological innovations of the twentieth century, not just shifts in contraceptive use and availability. Today the clear majority of people take for granted that sexually active women can choose whether to have children, yet less than one hundred years ago this idea was unimaginable to all but the most privileged individuals. During the twentieth century reproduction became something women had control over.

[62] Armstrong, *Conceiving Risk, Bearing Responsibility*, 13.

Beyond introducing the possibility of reproductive control, changes in fertility rates and contraceptive availability supported a series of key shifts in the discourse of pregnancy that were also being promoted by the other key social, scientific, medical, technological, and political developments discussed in this chapter. The flipside of the introduction of the idea of choice over whether to become pregnant was that it promoted a narrative of women as more and more responsible for the outcome of their pregnancies. When pregnancy was simply an inevitable regular occurrence in most women's lives, little health maintenance was expected of pregnant women beyond that expected of non-pregnant women. As pregnancy became rarer and new technologies and techniques for minimising fetal risk during pregnancy arose, expectations shifted to place 'responsibility' for maintaining a healthy pregnancy on pregnant women. This is a key shift of 'pregnancy' in the twentieth century, one across all topics in this chapter.

Another key shift mapped in this chapter is the increasing value of reproduction to governments. The changes in contraceptive regulation reflected shifting acceptance and use of contraception, but also highlight how the boundaries of 'responsibility' for reproduction expanded during the early twentieth century to include the state. The state increasingly valued reproduction as a means to ensure economic prosperity and as a consequence increasingly assumed responsibility for it. Overall state reproductive policies had the effect of making pregnancy an increasingly visible endeavour as reproduction became increasingly embedded within politics and the formal and informal social structures of governance, in this case with regulations around access to contraception. Particularly in the first half of the twentieth century, the political focus of reproductive policies was driven by eugenic ideals and contraception was central: economic concerns about maintaining worker populations in the face of falling birthrates and racist-nationalistic ideas about making sure these workers were the right types. This theme will be picked up again in the final section of this chapter.

The development of methods to both enhance and block reproductive capacity was significant to several of the key ideas traced in this project. The primary narrative effected was a shift in how risk was perceived and responded to. However, responsibility was also impacted as expectations around the self-management of health changed. The third impact was a shift in the conceptual possibility around who could potentially need to consume pharmaceuticals and why they might need them. Fourth, these developments also made the relation between 'natural' and 'normal' more complex by introducing the idea that it could be normal (and acceptable) to avoid the natural consequences of sex: reproduction. The development of technological methods to assist in conception and the maintenance of pregnancy similarly created the possibility that pregnancy need not be 'natural' and that, even prior to conception, having children could fall within the sphere of healthcare.

The possibility of controlling birth rates also introduced a new narrative of responsibility associated with pregnancy – the expectation that certain types of women, unmarried, those with mental health issues or addictions, poor women with multiple children already – would and could be responsible and choose not to get pregnant in the first place. New policies and practices around health and social supports built upon this capacity for 'choice' and encoded new expectations and narratives about reproductive responsibility.

As birth rates began to drop in the early twentieth century in response to ever improving methods of contraception, the ability, desire, and expectation to be able to control all aspects of human reproduction at the individual level has increased. The development of hormonal birth control and assisted reproductive technologies facilitated women's ability to control when and how many children they had. Hand in hand with this came the entry of middle- and upper-class women into the workforce and the rise of a new wave of feminism

calling for equality at home and work.[63] These developments contributed to the transformation of all five key ideas this project examines: modern era reproductive technologies redrew the boundaries of what constituted risk, health and nature during pregnancy by changing what was both possible and desirable. The development of technologies to both assist and supress reproduction changed the boundaries around what it was possible to have control and choice over with regards to pregnancy.

3.4 Eugenics

As individual reproductive control became common so too did social and health policies incentivising and regulating reproduction and fertility. This was part of the rise of biopower where networks and organisations, especially nation states, began attempting to regulate, manipulate and incentivise various aspects of reproduction. If people could control whether to have more or fewer children, then states could create policies to influence rates of reproduction. The earliest iteration of this was eugenics: the project of encouraging and discouraging certain types of people from reproducing. The development of birth control and the ability to control rates of reproduction (discussed in the previous section) was a necessary component of the rise of both positive and negative eugenics.[64] But as mentioned previously, contraception was the proximate cause of a demographic change precipitated by a massive shift in what, how, and why, we valued what we valued. The broader social forces driving the massive ideological, physical and social alterations were capitalism, colonialism,

[63] Three key texts representing both the rise of these feminists and their impact are: Marie Stopes, *Married Love or Love in Marriage*. The 19th Amendment to the US Constitution prohibiting states and the federal government from denying people the right to vote on the basis of sex. The Representation of the People Act of 1918 for Great Britain and Ireland which extended the voting franchise to a limited cohort of women over 30 years old.
[64] Positive eugenics was encouraging the 'right' sort of people to reproduce, negative eugenics was discouraging – or actively preventing – the 'wrong' sort of people reproducing.

industrialisation, urbanisation, and science.[65] By both direct and indirect means these forces substantially shifted the discourse of pregnancy most notably the embedding of *reproduction* into not just public health but into governance and the politics of nation states.[66] The development of a political discourse of reproduction in the early twentieth century can be mapped via the rise of eugenics, a 'scientific' discourse that was mobilised and defended by a variety of social groups throughout the late nineteenth and early twentieth century who were invested in the politics of reproduction.

This section briefly outlines the intertwined rise of capitalism and evolutionary theory. I first focus on their role in the rise of eugenics in the late nineteenth century and second, their collective impact upon public policies, particularly the role of eugenics in shaping health and welfare policies in the wake of improvements in contraception and the falling fertility rates of the early twentieth centuries. These changes precipitated three notable changes in the discourse of pregnancy: the introduction of ideas of control and choice to narratives of fertility and reproduction, the rapid rise in the importance of reproduction to the nation state, and the expectation of responsible mothers ensuring a nurturing environment.

Inherent to Laissez-faire, or free-market capitalism is the belief that the best possible world arises via minimal government regulation and free economic markets.[67] Particularly in Britain and its overseas territories the late eighteenth century subsequently saw the rise of the view in political economics that "social security was inimical to economic development" because it went against these capitalist ideals.[68] Within this framework Malthus developed an additional moral argument about the state's obligations towards its populace. He argued that

[65] This is not to say that these forces were not in play prior to the nineteenth century; they were, but the nineteenth century is roughly the period in which their impact was most massive.
[66] Rosen, *A History of Public Health*.
[67] Smith, "An Inquiry into the Nature and Causes of the Wealth of Nations." Influential texts such as Adam Smith's The Wealth of Nations (1776) argued in favour of this minimal state intervention and commerce regulation.
[68] Rothschild, "Social Security and Laissez Faire in Eighteenth-Century Political Economy," 712.

it would be better if governments did not intervene to aid the poor as population growth was about to outstrip food production with catastrophic consequences for the weakest members of society and that intervention would make the catastrophe worse.[69] The nineteenth century was a period of rapid urbanisation and industrialisation as people moved away from small knit communities and the historic charity systems such as those provided by religious bodies and Noblesse oblige declined. In Britain, and its overseas territories, under the moral shadow of Malthus and overwhelming support in the governing classes for laissez-faire capitalism there was tension over whether government ought to step in and provide welfare instead.

While the view against welfare dominated politics for much of the nineteenth century, an alternative political faction slowly developed in favour of governmental welfare. In the nineteenth century authors such as Engels made health an explicitly political and economic issue. In his influential early socialist text *The Condition of the Working Class in England* (1845), an epidemiological survey as well as a political argument, Engels argued that the etiology and population distribution of a range of diseases including typhoid, tuberculosis and rickets had a clear association with waged laborers in industrial English cities and that combating these diseases would require not just direct medical care but also political reform.[70] This emphasis on the role of capitalist economics in producing health inequalities was picked up by the subsequent workers' reform movements in the second half the nineteenth century which advocated for reforming the conditions of factory life including what today we would call a health and safety agenda. These reform movements and the politicians and activists who rose out of them played a significant role in shaping public health in the early twentieth century, pushing governments towards further intervention in health. They developed economic arguments in favour of public health and welfare

[69] Malthus, *An Essay on the Principle of Population*.
[70] Engels, *The Condition of the Working-Class in England in 1844with a Preface Written in 1892*.

interventions, arguing that the strength and prosperity of the nation centered upon a healthy workforce, and thus that ensuring a healthy populace was of national importance.[71]

The linking of health to economics resituated 'health' in two ways. First, providing healthcare was reframed not just as a social good, charity, but also as an economic necessity for nations because a prosperous nation required a healthy workforce. Second, advocating for social and political reforms based upon documented correlations between the social conditions in which people lived and health introduced narratives of *equality* and *rights* into the discourse of health.[72] Collectively these changes made possible the argument that welfare was not charity, but an economic necessity setting up an alternative narrative of welfare within the logic of capitalism. These links between health and economics could occur because of the radical changes wrought by Laissez-faire capitalism upon western thought in how value was assigned to objects and people. As late as the mid-nineteenth century the notion that governments ought to provide welfare to citizens struggling with the basic conditions of life was an alien moral imperative to the vast majority of people who developed and set government policy, the governing class.[73] These arguments about welfare arose within the context of a wider social discourse that was reconciling the emergence of social mobility made possible by capitalism.

New explanations were required for how people obtained worth and proponents of Laissez-faire capitalism turned to science and biology in particular for ideological support.[74] In order to justify this change an explanatory mechanism was needed and attention turned to evolution in order to do so. Both Lamarckist and Darwinist theories of inheritance were

[71] Rosen, *A History of Public Health*.
[72] Today this approach would be labeled the social determinants of health.
[73] Rosen, *A History of Public Health*.
[74] Hawkins, *Social Darwinism in European and American Thought, 1860-1945*; Bowler, "The Role of the History of Science in the Understanding of Social Darwinism and Eugenics.," 274; Leonard, "Mistaking Eugenics for Social Darwinism," 201.

mobilised in support of eugenic arguments for and against groups of people breeding. [75] Three key ideas associated with evolutionary scientific discourse were significant to eugenic science: the 'survival of the fittest' was drawn from Herbert Spencer's theory of social competition in *Principles of Biology* (1864); Francis Galton's development of population statistics; and Darwin's notion of inheritance between generations.[76]

The advent of evolutionary theory in the nineteenth century provided conceptual space for understanding change within (Lamark) and between (Darwin) generations. Evolutionary theory was developed by Charles Darwin in *On the Origin of Species* (1859) and quickly became the dominant account of inheritance. Darwin argued that species arise and become extinct via heritable mutations within the breeding population and in response to environmental selection pressures. Prior to the nineteenth century fatalistic accounts of heredity were dominant, and static natural inherited tendencies were always expected to win out.[77]

The relationship between science and economics was not merely a unidirectional relationship whereby a scientific breakthrough was influencing economic thought; laissez-faire economics was also instrumental in how evolutionary theory developed.[78] In the latter half of the nineteenth century many of the same scientists, writers and politicians debated both evolutionary theory in science, and free market capitalism in economics. This was the beginnings of a trend towards incorporating science and scientific finding into governance in the service of economic aims.[79] While biological trait-based justifications for economic and

[75] Leonard, "Origins of the Myth of Social Darwinism"; Bowler, "The Role of the History of Science in the Understanding of Social Darwinism and Eugenics.," 273. While conceptually, socially and scientifically overlapping, eugenics and Social Darwinism were not synonymous even at the earliest stages.
[76] The enlistment of evolution for particular social policies was not limited to Darwinian evolutionary theory's notion of competition between particular organisms, but also included competition between groups such as nations and races, a la Spencer.
[77] Bowler, "The Role of the History of Science in the Understanding of Social Darwinism and Eugenics."
[78] Bowler, 275.
[79] Leonard, "Mistaking Eugenics for Social Darwinism," 200.

governmental policies would come to a peak in the early twentieth century with eugenics, the broader trend of science-based governance continues today,[80] the most obvious example being the drive towards 'evidence' based policy.[81]

The key impact of eugenics for this project is in the way it used 'science' to make reproduction a matter of public interest and introduced enduring narratives of maternal and governmental responsibility for fetal wellbeing. New ideas about responsibility and moral worth arising out of scientific discoveries around evolution and disease causation were reframing health, stripping away the old fatalistic narratives of ill-health and introducing new 'scientific' explanations. Being ill was something caused by environments and could more and more often be overcome or avoided via public health measures. Eugenic ideology provided impetus for a wide range of social and economic policies premised on improving health. However, they were grounded in a framework of promoting or impeding the right 'fit' or wrong 'unfit' people from reproducing. To the modern viewer the logic employed to separate the 'fit' and the 'unfit' can seem peculiar and based upon assumptions about the ideological and physical and mental superiority of wealthy nineteenth century northern Europeans.

Eugenics introduced a new discursive thread into nationalism premised on ideas about who ought to be reproducing in order for the country to succeed. At its most extreme the aim of eugenics was to "promote fertility of the better types which the nation contains, whilst diminishing the birthrate among those which are inferior."[82] Within eugenic policies there was a focus on encouraging and supporting the 'right' types of people to have children while discouraging or restricting others from having children. The ever-growing infrastructure of the nation - hospitals, sanitariums, asylums, pensions, and publicly funded prenatal care

[80] Leonard, "Origins of the Myth of Social Darwinism," 37.
[81] Pawson, *Evidence-Based Policy*.
[82] MacKenzie, *Statistics in Britain, 1865-1930*, 18 quoting Leonard Darwin (1926).

initiatives - was part of this project. Eugenics, and its sorting of people into the fit and unfit reinforced existing social divisions providing a 'scientific' and 'health' based argument against 'inferior' groups.

Following World War One eugenics began increasingly to emphasise biological accounts of race, incorporating these accounts into hereditary explanations of ill-health. [83] During the economic depression of the 1930s this transformed eugenics-derived initiatives into the policies for which they are today known such as euthanasia and sterilization of 'inferior groups': minorities, those with physical or mental disabilities, addicts, criminals, sex workers and those born out of wedlock.[84] The discussion of hysteria from the previous chapter is an excellent example of the breadth and duration of eugenic influence in shaping not just medical narratives of pregnancy and reproduction, but the ongoing interactions and experiences of people of colour with medicine and science. Another example can be seen in how mother and child health units more often than not ignored or excluded communities of people of color, rural areas, and non-English speaking immigrants either by accident or design. For instance, in New Zealand the mandate of the Plunket society to improve mother and child health did not include Maori communities until well into the twentieth century.[85] Indigenous communities were simply ignored as 'not the right sort of people' to encourage and support in reproducing. Again, this exclusion highlights the racism underpinning eugenics which even in its most moderate iteration focused upon ensuring that the 'right sorts' were reproducing.

Throughout the eugenics era there was a tendency, for both moral and pragmatic reasons, to focus policies on supporting children, pregnant women and new mothers, and the

[83] Hawkins, *Social Darwinism in European and American Thought, 1860-1945*, 234.
[84] Hawkins, 233.
[85] Bryder, *A Voice for Mothers*. There was a specific organisation for Maori health that included a mandate for maternity care but it lacked the specialist focus and comprehensive care of Plunket.

reproducing woman became a figure of central importance within the actively governed nation state.[86] This significantly shifted the conceptual boundaries of *reproduction* to include overtones of national, as well as family, continuity. The flipside of this increasing importance of reproduction was a corresponding increase in the scope of responsibility of pregnant women, medical professionals, nurses, social workers and even policy makers. Reproduction was a matter of politics, serious 'public sphere' business, and by the early twentieth century both new and old institutions were shifting orientation to regulate reproduction. The notion of the pregnant woman as a figure of central importance within the nation is extant as early as the late eighteenth century, for instance in Rousseau's Emmaline.[87] However what I want to highlight is how ideas about women's roles as reproducers of the nation - both physical and cultural - are by the early twentieth century both normalised and embedded into social structures and institutions. The consequence of this shift was most pronounced in the increased value placed upon fetal and infant wellbeing.[88] But there also were a number of other impacts including making it increasingly advantageous for many nation states to enact social policies in the arena of welfare and public health.

Eugenics and the increasing importance it placed upon 'nurture' introduced new narratives of parenting emphasising the importance of making the right active parenting choices – those that were nurturing.[89] Parents could now be held responsible, by themselves, their community and the state for their children's future health and wellbeing. Consequently, the way in which children were brought up became a matter of importance to the state and

[86] While this parallels the North American Christian narrative about the role and responsibility of women in reproducing both the family and culture, the origin, or force, of the narrative differs in the context of the nation state. These are complimentary sources and structures that both support a particular narrative of women and reproduction but of differing origin and location.
[87] Kukla, *Mass Hysteria*, 30–34.
[88] However, all of the social, scientific, medical, technological, and political developments discussed in this chapter contributed to the increasing social and moral value of the fetus.
[89] While initially eugenic policies involved supporting and incentivising reproduction in the right types of people by the 1920s it also included supporting birth control clinics targeting the poor and the sterilisation of people with disabilities.

policies regulating acceptable ‘nurture’ arose. While many of these were supportive, such as welfare or public education, others were punitive, removing children from ‘unsuitable’ or ‘unnurturing’ environments – forced adoptions for out of wedlock pregnancies, residential boarding schools for indigenous children. Thus, although families have always attempted to ensure the wellbeing of their children, eugenics shifted both parental and public monitoring towards the active management of children and their surroundings. The trend towards active management of children, and expectation of nurture, also extended to the management of pregnancy and the environment of pregnant women. Alongside a narrative of state responsibility for ensuring the nurture of children, valuing nurture also created obligations and new notions of what parents, especially pregnant women and mothers, were responsible for.

This was the rise of what Foucault would come to identify as the modern iteration of biopower: government taking an interest in the continuation of the nation by encouraging both formal policies and informal cultural mores that encouraged the right type of people to reproduce. While many authors use this definition of biopower exclusively, as earlier discussed McWhorter argues for a broader, less historically contingent, definition that better fits her understanding of Foucault’s definition of power and provides a better definitional equivalent to discipline. Biopower is about power relations within the network of social institutions and discipline is about power in relation to particular bodies.

This chapter has explored how and why pregnancy was incorporated into the healthcare system. Driven by a desire to make pregnancy and childbirth a safer experience for both women and children, the twentieth century saw everyday pregnancy become more and more incorporated into the medical system via practices such as prenatal care and hospital births. As birthrates dropped the social importance of reproduction increased. This led to the roll out of nationalised healthcare, particularly programs that supported women and children

within the context of the increasing social value of reproduction. These programs, situated firmly within the narratively authoritative realm of medicine, were (and are) the dominant site of interaction between pregnant women and the social structures and institutions thus far discussed. One consequence of the increased integration of pregnancy into 'health' was a corresponding exposure to shifts in the discourse of health: As new interpretations and ideas about healthy and unhealthy experiences, practices and choices arose so too did corresponding narratives of pregnancy, thus shifting what constituted good and bad experiences, practices, and choices, during pregnancy. In the twentieth century pregnancy became a state of being that required systematic healthcare assistance in order to be done 'right'.

The first half of the twentieth century saw a host of social, political and scientific changes that reconfigure the discourse of pregnancy. Urbanisation, industrialisation and an unprecedented improvement in the quality of living experienced by most people living in Europe, North America and Australasia led to a host of demographic changes including rapidly declining birthrates and huge decreases in maternal and infant mortality and morbidity. Diseases and complications that had previously led to death in the vast majority of cases became treatable via simple and cost-effective measures arising out of both scientific advancements and the rapid up-skilling of medical professionals. This improvement in the quality of life arose within the context of a shift towards state supported and funded education, healthcare, and welfare support where governments were invested in promoting a healthy population. Cumulatively the most pronounced effect these changes had was to make pregnancy a far less risky endeavour and to reconfigure the social perception of the fetus. However, it also set pregnancy up as a time of increasing surveillance and monitoring as more and more factors became linked to ensuring infant and maternal health, radically reconfiguring narratives of maternal responsibility during pregnancy. These trends would

continue in the latter half of the century as pregnancy became less and less risky, rates of maternal and fetal survival continued to improve albeit at a lesser rate, and maternal responsibility and the expectation of being a 'good mother' became ever more complex and contradictory. Public health moved from interventions in the built environment aimed at maintaining community wellbeing to providing preventive care for individuals over the course of the nineteenth century. In the twentieth century, driven by social, scientific, medical, technological, and political developments such as eugenics, improved understandings of the mechanisms of health and disease leading to declining mortality rates, increasing rates of more accurate forms of birth control leading to declining fertility rates, and increasing state provisions for health and education, all contributed to changes in 'pregnancy'. The primary site of mediation for these changes was via public health interventions in chid health, family planning and women's health.

FOUR: 1950-2016 Pharmaceuticals and the rise of risk culture

While the discourse of pregnancy in the first half of the twentieth century was dominated by the demographic transition and the entry of structures of governance into reproduction, the key influence upon 'pregnancy' in the second half of the twentieth century was the rise of a 'risk culture' both in broader society and specifically with regards to pregnancy. Section 4.1 discusses two landmark pharmaceutical cases where there was a failure to establish the safety of the drugs Thalidomide and DES. These failures were central to the discourse of pregnancy and its interactions with 'health' and 'research'. Section 4.2 highlights the subsequent impact of these failures of medical safety on healthcare regulation and research. These two events occurred during a formative period in health research and thus shaped not only ideas about the fetus, risk and responsibility during pregnancy, but have also strongly influenced regulation and practice in health research into the current day. The final two sections of this chapter explore different aspects of the rise of risk culture and how it was channeled into particular ideas of risk management, risk avoidance and precaution during pregnancy in the wake of the Thalidomide and DES tragedies. In 4.3 I discuss the rise of risk culture more broadly, first within epidemiology and then the parallel development of the precautionary principle within governance and policy. Finally I end with a discussion of the impact of the growing cultural dominance of 'risk' and its role in producing new categories, such as the perinatal interval, and the regulation and monitoring of risk and safety during pregnancy.

In 4.4 I examine the rise of risk culture specifically within the context of obstetric medicine and how prenatal care expanded to include evaluation of risk factors. While research into 'the disorders of pregnancy' continued, increasingly medical attention became paid to the specialised management of non-pregnancy related disorders during pregnancy; both mental and physical chronic health issues, infectious diseases and cancers. With the rise of fetal medicine in the 1960s, attention also began to be paid to the fetus as a patient with

particular needs and illnesses that could be treated in utero. As always, the focus of this chapter is on how, why and to who's advantage, these events shifted ideas of risk, health, nature, responsibility and the fetus in relation to pregnancy and pregnant women and the impact this had on how pregnancy was encoded, experienced, interpreted and valued. Since the 1950s many social, scientific, medical, technological, and political developments have also contributed to the discourse of pregnancy: abortion politics, prenatal care practices and changes to healthcare funding to name a few. However, it is impractical to discuss all of them and their impact upon the discourse of pregnancy is widely discussed elsewhere. This chapter finally also moves the discourse of pregnancy into the present and the current moment within which the problem of pharmaceutical research during pregnancy is taking place.

4.1 Pharmaceutical Disasters

In the middle of the twentieth century, two key events changed the way that medical science conceived of pharmaceutical research and use, particularly in relation to pregnancy. It is estimated that between eight and twelve thousand children were prenatally affected by exposure to Thalidomide during the 1950s, similarly, a forty-fold increase in the risk of cancer was recorded in women prenatally exposed to diethylstilbestrol (DES) in the 1940s, 1950s and 1960s.[1] As will be discussed later in this section these events shifted the broader discourse of pregnancy by changing the standards of what was unsafe or risky during pregnancy, reconfiguring the permeability of the boundary between a woman and her fetus, and in the subsequent regulation changed shifting notions of autonomous capacity during pregnancy.

[1] Knightley and Times of London, *Suffer the Children*; Swan, "Intrauterine Exposure to Diethylstilbestrol."

Evidence Based Medicine

The introduction of formalised and standardised methods of medical research was a key component of the transformation of medicine during the twentieth century. This shift culminated in the late twentieth century with the rise of the evidence based medicine (EBM) movement which aimed to provide a "systematic approach to analyze published research as the basis for clinical decision making."[2] The pharmaceuticals DES and Thalidomide both arose within the context of EBM and so did the subsequent research reforms that were in part a response to the tragedies arising from the two pharmaceuticals. The application of scientific methodology to the study of the safety and effectiveness of medical treatments was a significant shift in medical practice, research and regulation. Most significantly the development of EBM linked the idea of risk to both medical treatment and research. While there has always been an understanding of medical treatments as uncertain, with the introduction of EBM and scientific methods of study, and most importantly quantification of the uncertainty of both the safety and efficacy of particular interventions, this uncertainty was transformed into risk. Here risk is a *known degree of uncertainty* that has been calculated from prior statistical analysis of an intervention's effectiveness and safety in a population.

While the term 'evidence based medicine' can only be traced back to the mid-1990s, practices identifiable as EBM have existed since at least the 1970s.[3] The Western European enlightenment saw the rise of scientific journal keeping and mass published books – such as the obstetrics text discussed earlier – and beginning in the late nineteenth century the development of textbooks and peer reviewed journals. However, despite a developing culture of research this did not translate into immediate changes in practice. Rather, as in the case of antiseptic techniques, it was a slow transition based on accumulating evidence from multiple

[2] Sackett and Rosenberg, "The Need for Evidence-Based Medicine."
[3] Sackett et al., "Evidence Based Medicine," 71.

sources over many decades.[4] By the mid twentieth century, the trend towards the treatment of health care as a subject of scientific enquiry was established, primarily due to the development of more complex statistical methods and data analysis techniques. The biggest breakthrough was, however, the development of randomised clinical trials (RCTs) in the 1930s: a new application of these statistical advances. The key features of RCTs were the use of randomisation to reduce allocation bias and the use of standardised treatment regimens for all trial participants, alongside reporting of particulars of the trial methodology used.[5]

However, despite the existence of randomized clinical trials, laboratory trials that emphasised causal mechanisms remained the dominant form of research influencing whether a drug came to market well into the 1950s. Advances in human anatomy and physiology as well as disease pathophysiology made laboratory sciences and causal mechanism dominant – how and why certain medical practices worked, or did not:

> The proof of newer [1930s-1940s] therapies did not rely on empirical clinical testing, but on the demonstration that they behaved according to scientific laws and principles, which could be established under a microscope, in a test-tube, or in a laboratory animal.[6]

It would be well into the 1950s before RCTs began their rise to dominance within medical research as considerations of efficacy and safety became prioritised, and clinical research and biostatistical analysis, rather than laboratory research, came to influence medical practice.[7]

It is within this context, where a whole host of new avenues of inquiry and intervention were becoming available, that the DES and Thalidomide medical safety failures

[4] Claridge and Fabian, "History and Development of Evidence-Based Medicine," 548–49. For example research indicated that patients who did not undergo bloodletting had better survival rates; however, for the vast majority of physicians this research did not translate into immediate change of practice but rather it gradually fell out of practice over decades.
[5] Theobald, "Effect of Calcium and Vitamins A and D on Incidence of Pregnancy Toxemia." The first of these trials was a 1931 comparison into the treatment of tuberculosis with Sanocrysin when compared to an untreated control group and included both physician and patient blinding and the allocation of patients via coin flip. A second trial published in 1937 into pregnancy toxemia examined the impact of calcium and vitamins A and D on the disorder, and by the early 1940s, randomised trials were an established study methodology that was rapidly gaining popularity
[6] Bryder, "The Medical Research Council and Clinical Trial Methodologies before the 1940s."
[7] Bryder.

occurred. The dominance of clinical research methods made possible decisive answers about the usefulness and practicality of new pharmaceutical treatments, and regulatory structures arose for getting these treatments efficiently to the biggest market possible. Most importantly for this project however, *uncertainty* about treatment efficacy and safety became quantifiable as *risk* and thresholds of acceptable risk for research – high, low and minimal - could be established and regulated. Early EBM was part of a counter reaction to the ever-increasing expectation of a treatment for every illness that arose during the early twentieth century and the proliferation of interventions of questionable effectiveness. The practices of EBM are linked to the rise of public health and epidemiology: as driven by the needs of populations rather than individuals that arose in the early twentieth century as 'health' became integrated into practices of governance. EBM became the main way in which healthcare systems ensured that only safe, efficient and effective treatments were provided.[8] However, the switch to EBM would come too late for the thousands of pregnant women who ingested Thalidomide, DES, or took hormonal pregnancy tests.[9]

Thalidomide

In 1956 Thalidomide was introduced as a general sedative and promoted in particular for use as an antiemetic during morning sickness based on the explicit promise that it was extremely safe and impossible to overdose. Indeed, Thalidomide was considered so safe that most countries approved it for over-the-counter sale. Developed during World War Two by German pharmaceutical company Grunenthal, Thalidomide, also known as Contergen or Distival, was marketed and distributed under licence worldwide. In countries where it was not approved by pharmaceutical regulators, such as New Zealand, the USA and Austria,

[8] Cochrane, *Effectiveness & Efficiency*.
[9] For a comprehensive discussion of the problem modern EBM has with avoiding structural biases against women see Rogers, "Evidence-Based Medicine and Women." She demonstrates how biases arise not just during research production but also via the methods of analysis and in the application of resulting guidelines.

pregnant women still ingested Thalidomide, albeit in more limited volumes, within the context of clinical trials, as free samples from physicians, and during overseas travel. It is worth noting that, unlike today, the safety information on which regulatory approval was given was drawn solely from Grunenthal's own claims to the safety and efficacy of Thalidomide. Later scrutiny would show not just problems with the quality of these studies but a troubling pattern of the suppression of reports of side effects.[10] As was standard at the time the evidence provided about its benefits was primarily focused upon a causal mechanism rather than safety and efficacy, with Thalidomide being an analogue to an existing sedative, glutethimide.[11]

The prescription of Thalidomide to pregnant women came to an abrupt stop in 1962 when it was withdrawn from use in all countries due to mounting evidence of fetal death and disfigurement. Birth defects retrospectively linked to Thalidomide had been seen as early as 1956, however it took over five years for the connection between Thalidomide and the rise in the rare birth defect phocomelia, to be identified. Thalidomide was identified as the source of the phocomelia simultaneously by two physicians; a gynecologist in Australia, and a pediatrician in Germany. Following identification as a teratogen that caused gross malformations and neuropathy, Thalidomide was withdrawn from sale in all markets within twelve months. Yet despite this prompt withdrawal, sources estimate the toll of Thalidomide to have been approximately 10 000 neonatal deaths; and a significant number of miscarriages and still-births as a high rate of fetal death can be assumed for those fetuses with the most severe defects.[12]

In addition to its high fatality rate, Thalidomide has also been held responsible for a range of other negative health consequences. Beyond the significant mortality rate,

[10] Knightley and Times of London, *Suffer the Children*.
[11] Sneader, *Drug Discovery*, 367.
[12] Knightley and Times of London, *Suffer the Children*; Silverman, "The Schizophrenic Career of a 'Monster Drug.'"

worldwide estimates of the effects of Thalidomide are that "~40 000 [pregnant women] developed peripheral neuropathy (numb hand and/or feet); and, ~8000 to 12 000 infants were born malformed, of these, ~5000 survived beyond childhood."[13] While phocomelia (severe limb malformation) is the side effect most widely associated with Thalidomide, there is a range of other malformations found in the children of women who were prescribed Thalidomide, including eye and ear defects (micropthalmia and coloboma), genital abnormalities and internal organ defects, particularly of the kidneys, lungs, intestinal tract and heart.[14]

Today, the approval of Thalidomide for use during pregnancy remains one of the most widely noted examples of a failure of medical regulation resulting in widespread adverse drug reactions. For instance, Briggs' Drugs in Pregnancy and Lactation, currently in its ninth edition and one of the most popular clinical reference tools for prescribing for pregnant women, opens its introduction with a discussion of Thalidomide and its legacy for drug regulation before moving on to DES in order to highlight the length of time that such adverse effects can take to arise and the complicated nature of identifying adverse drug reactions during pregnancy.[15] While the use of DES preceded widespread use of Thalidomide, the twenty-year lag between ingestion and symptoms meant that its consequences would not be realised until after events around Thalidomide had captured worldwide attention.

DES

> Really? Yes…desPLEX to prevent abortion, miscarriage and premature labor. Recommended for routine prophylaxis in ALL pregnancies… bigger and stronger babies too. [16]

[13] Silverman, "The Schizophrenic Career of a 'Monster Drug,'" 406.
[14] Silverman, 405.
[15] Briggs, Freeman, and Yaffe, *Drugs in Pregnancy and Lactation*.
[16] The above quotation first appeared in an advertisement by the Grant Chemical Company in the June 1957 issue of the American Journal of Obstetrics and Gynecology. Dutton, *Worse Than the Disease*.

First synthesised in 1938 as an estrogen mimic, diethylstilbestrol, or Stilbestrol, (DES) created excitement in the medical community as the first cost effective, potent, synthetic estrogen. A rapid research agenda was quickly launched for a wide range of sex hormone disorders and by 1941 the benefits of DES were firmly established with over 257 publications of its clinical effectiveness in conditions ranging from acne, gonorrhea and cancer treatments, to lactation suppression and menopausal disorders.[17] At this time, husband and wife team of Harvard researchers Olive and George Smith along with colleague Priscilla White developed a theory on the relationship between estrogen and progesterone during pregnancy. They posited a mechanism by which DES acted and thereby proposed a means to identify the disorders and deficiencies that DES could potentially treat. [18] After confirming the theory in animal models, White successfully used DES to increase fetal survival rates from between 40-60% to over 90% in a small group of diabetic women.[19] Building on White's success, Smith and her husband developed a large scale trial in the general population where they found a range of fetal and maternal benefits from DES supplementation for a very broad range of risky pregnancies.[20] Prior to the Smiths' study DES was often prescribed off-label in order to improve health during pregnancy, but on the basis of their findings in 1947 the FDA officially approved DES to prevent miscarriage.[21]

In 1953, the Smiths' research was overturned when William Dieckmann failed to replicate their results in a larger scale blinded control study.[22] The Smiths' original study had

[17] Dutton, 35–36; Davis, "A Clinical Study of Stilbestrol"; MacBryde et al., "The Synthetic Estrogen Stilbestrol."
[18] Smith and Smith, "Prolan and Estrin in the Serum and Urine of Diabetic and Nondiabetic Women during Pregnancy, with Especial Reference to Late Pregnancy Toxemia."
[19] White, "Pregnancy Complicating Diabetes," November 1949; White, "Pregnancy Complicating Diabetes," May 19, 1945; White et al., "Prediction and Prevention of Late Pregnancy Accidents in Diabetes"; White and Hunt, "Pregnancy Complicating Diabetes"; White and Hunt, "Prediction and Prevention of Pregnancy Accidents in Diabetes."
[20] Smith, "Diethylstilbestrol in the Prevention and Treatment of Complications of Pregnancy"; Smith and Smith, "The Influence of Diethylstilbestrol on the Progress and Outcome of Pregnancy as Based on a Comparison of Treated with Untreated Primigravidas."
[21] Dutton, *Worse Than the Disease*, 35–36.
[22] Dieckmann et al., "Does the Administration of Diethylstilbestrol during Pregnancy Have Therapeutic Value?"

not been blinded: they had selected a cohort of pregnant women at a major Boston hospital for supplemental treatment with DES and used as a comparison the general population of pregnant women at the same hospital whom they did not attend. Dieckmann attributed the difference in study findings to the higher quality medical care sustained by the Smiths' patients in comparison to the general patient population. Nevertheless, DES continued to be prescribed for general neonatal wellbeing and it is worth noting that Dieckmann's study did not find any harms associated with prescribing DES.[23] Dieckmann's study is an example of the developing standards of clinical research.

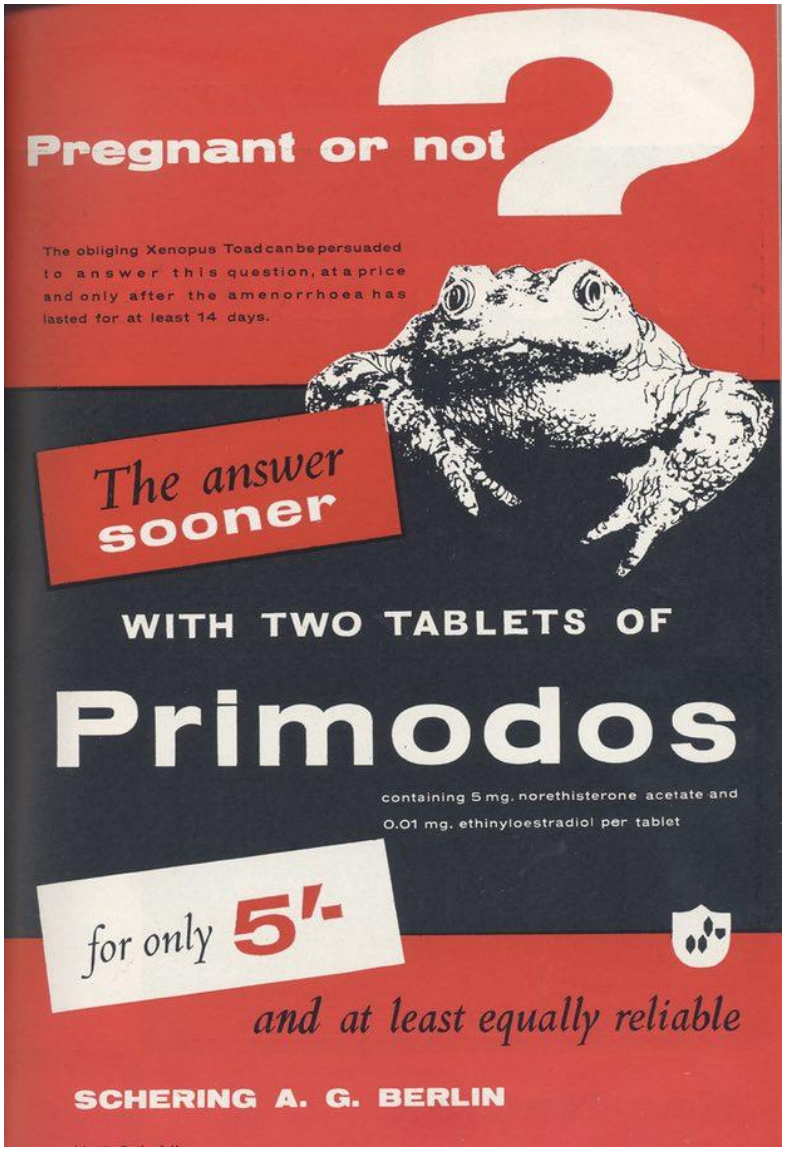
The situation changed in 1970 when Herbst, a student of the Smiths, reported on a cluster of six cases of an extremely rare vaginal clear cell adenocarcinoma in adolescent girls around New England. Upon investigation using a case control study methodology, Herbst discovered that all the young women in the subject group had mothers who took DES during pregnancy while none of the mothers of the thirty-two control subjects did. Subsequent work over the next few years, including follow-ups on all patients of the Smiths, and the establishment of a national US registry for these types of cancer confirmed the association between prenatal exposure to DES and cancer.[24] Moreover, while clear-cell adenocarcinoma was the first health problem identified in the daughters of women given DES, further consequences have subsequently been identified in both male and female first and second generation offspring, including increased cancer risks and a range of issues that make conceiving and carrying their own pregnancies more difficult.[25]

The impact of DES on offspring has subsequently been shown to follow a dose-response curve where the severity of effects relates to the gestational stage at which the mother was prescribed DES. It has been estimated that about 1 in 1,000 DES daughters will

[23] Dieckmann et al.
[24] Herbst, "Diethylstilbestrol and Adenocarcinoma of the Vagina"; Herbst, Ulfelder, and Poskanzer, "Adenocarcinoma of the Vagina."
[25] Swan, "Intrauterine Exposure to Diethylstilbestrol."

develop clear cell adenocarcinoma – the most widely-known consequence of DES – about 40 times the risk of the general population and that they can do so at any age between their teens and late forties. Monitoring of, and research on, the health of the children and grandchildren of DES patients continues today and new health issues continue to be identified. DES represented the first time an association between prenatal drug exposure and cancer was established and alongside the Thalidomide regulatory failure highlighted the potentially devastating consequences of the use of medications in pregnancy. While there was no immediate panic, knowledge and fear of the new form of risk during pregnancy slowly spread through the wider population.[26]

[26] Swan. Further adverse effects have subsequently been identified in both male and female, first and second generation, offspring of DES-treated women – including increased cancer risks, and a range of issues that make conceiving and carrying their own pregnancies more difficult. Monitoring of, and research on, the health of children and grandchildren of DES patients continues today. As a result of this, new health issues continue to be identified and researched.



An advertisement for Primodos in The Practitioner from the early 1960s marketing campaign aimed at GPs that aggressively targeted the slower, more expensive toad test. Photograph: Practitioner, vol. 185 July 1960. /The Practitioner, Practitioner Medical Publishing Ltd

Hormonal pregnancy testing is another less known case of pregnancy, pharmaceuticals and safety concerns that exhibits many of the same characteristics as the more well-known cases of Thalidomide and DES. Widely available throughout the 1960s Primodos (Duogynon) and Gestest were hormonal pregnancy tests withdrawn from use in the 1970s because of fetal safety concerns. These tests were tablets containing various combinations of ovarian hormones, which caused uterine bleeding in non-pregnant women, and, like DES, were part of the suite of synthetic reproductive hormones that become

available for clinical application throughout the 1940s and 1950s.[27] Many of the particulars of events around hormonal pregnancy testing parallel that of DES and Thalidomide including continued use after initial concerns were raised, inadequate pre-existing safety data, a range of potential effects on the fetus including neural tube defects and malformed limbs, hearts and faces, uncertain mechanisms for the causes of these defects and conflicting study results as to whether these drugs caused the birth defects. It is only in the last few years that supressed evidence of the risks of hormonal pregnancy testing have been released stimulating further discussion after a 1980s review found insufficient evidence that they caused fetal defects.[28]

4.2 Research Regulation

Medical research has shaped the discourse of pregnancy through both the manner in which it has included pregnant women within the research agenda but also via its exclusion of pregnant women – both intentional and unintentional. The intentional exclusion of pregnant women from medical research arose in the 1960s on the back of widespread recognition of the unique risks of pharmaceutical use during pregnancy. While Thalidomide, DES, and hormonal pregnancy tests were developed after the establishment of randomised control trials (RCTs) and occurred within the context of clinical research, they preceded the widespread adoption of the use of RCTs as a standard quality of evidence for the adoption of novel pharmaceuticals. Indeed, it was because of events like these that standards for the clinical adoption of pharmaceutical interventions would change. These tragedies were not only a wakeup call to the potential dangers of pharmaceutical use during pregnancy but were also central in the formation and development of medical research regulation. In particular, these

[27] Gaudillière, "Better Prepared than Synthesized."
[28] Olszynko-Gryn, "Risky Hormones, Birth Defects and the Business of Pregnancy Testing Pt I"; Olszynko-Gryn, "Primodos Was a Revolutionary Oral Pregnancy Test. But Was It Safe?"; Olszynko-Gryn, "The Contentious History of Pregnancy Test Drugs: Will Science Find Its Own Path to the Truth?"

incidents drew attention to safety concerns around the consumption of drugs during pregnancy. Consequently, in the second part of the twentieth century concerns about a repeat of the Thalidomide and DES regulatory failures set the tone for the regulation of not just research into pharmaceuticals but the safety and efficacy agenda for medical research more broadly.

The regulatory changes precipitated by Thalidomide and DES limited who could participate in research, expanded the power and mandate of regulators such as the FDA and, alongside other biomedical scandals, promoted the development of ever more extensive and detailed guidelines and regulations for medical research. The Thalidomide and DES regulatory failures made apparent that maternal ingestion of pharmaceuticals could detrimentally impact a fetus, something that had been discounted prior to this time, and suddenly assessments of risk of pharmaceutical ingestion during pregnancy needed to include an analysis of potential harms to the fetus. The result was almost the complete exclusion of all potentially pregnant women from pharmaceutical research. Furthermore, the way in which regulations to effect this change were structured – the labelling of pregnant women as vulnerable – had an additional impact on ideas about autonomy and responsibility during pregnancy.

Research regulations and guidelines changed worldwide in response to the Thalidomide and DES tragedies.[29] As part of the review following the Thalidomide regulatory failure, the US Drug Efficacy Amendment of 1962 shifted the burden of proof from regulators to manufacturers to prove both the safety and the efficacy of a pharmaceutical before approval for widespread use. This regulatory change greatly increased

[29] The United States was one of the few countries to exclude Thalidomide and insist on further testing. The FDA's concern was with the incidence of peripheral neuropathy in pregnant women prescribed Thalidomide rather than with any potential foetal impacts. The FDA's progress in determining the rate of this side effect was very slow and in the United States clinical research was still ongoing when the foetal malformations were first made public five years after the FDA was first approached to approve Thalidomide (Archer, 1979).

the power of the FDA. Similarly, in the United Kingdom, a Committee on the Safety of Drugs was formed in 1963, followed by a voluntary adverse pharmaceutical reaction reporting system in 1964. Similar legislation was also passed in Europe.[30] In the 1970s, governance of pharmaceutical research became even more sophisticated in response to other research ethics scandals such as the Tuskegee and Willowbrook experiments, both of which were long running, ethically problematic, "research" of questionable quality on vulnerable subpopulations: the mentally ill and poor black men respectively. In New Zealand "the unfortunate experiment" into the non-treatment of cervical cancer was stopped in 1976 although the scandal did not become known to the wider public until the mid- 1980s with the Cartwright inquiry.[31] Almost concurrently, the outcry around the legal struggles of Thalidomide survivors for restitutions peaked, the cancer risks associated with DES became public and there was a public enquiry into hormonal pregnancy tests in the UK. This confluence of events created the perception of 'science' deeply in need of reform, particularly with regard to the rules for research involving *vulnerable* groups.

Tightening of the rules governing clinical research are evident in the 1975 revision of the Declaration of Helsinki. This revision not only added a clause stressing that the interests of research participants should prevail over the interests of science and society, but also introduced an extra layer of oversight by an independent review committee to ensure the quality and ethics of all research involving humans.[32] At the national level, in 1974, the United States formed the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which produced the Belmont report, and also weighed in on the creation of the 1974 law for the Protection of Human Research Subjects.[33] This law

[30] Boxtel, Santoso, and Edwards, *Drug Benefits and Risks*, 65–66.
[31] Bryder, *A History of the "unfortunate Experiment" at National Women's Hospital*; Coney and Bunkle, "An Unfortunate Experiment at National Women's."
[32] Shephard, "The 1975 Declaration of Helsinki and Consent."
[33] Department of Health and Human Services, "45 CFR 46."

specifically included additional regulations for research involving pregnant women (subpart B added in 1975), and later prisoners (subpart C, in 1978) and still later children (subpart D, in 1983). Similarly, the 1977 FDA Guidelines for Industry required the exclusion of women of child bearing potential (i.e., all post-pubertal and premenopausal women) from participation in clinical research except at the latest stages of Phase III trials, and only once safety and efficacy were shown in humans and reproductive studies in animals were complete.[34]

Taken together, these laws and guidelines increased the protections for human participants in clinical research, but they also left a negative legacy, particularly in US law, due to the grouping of pregnant women alongside prisoners and children under the label 'vulnerable populations.'[35] The impact of this labelling was to associate pregnant women who, as a group, have a more complicated range of risks facing their participation in research, with prisoners and children: groups that have a reduced capacity to give informed consent for research participation.[36] The categorisation of pregnant women as a vulnerable population implies that we ought not to conduct research on them without greater safeguards. Pregnant women do need additional considerations in order to safely participate in research. In this sense they are vulnerable because they face unique risks that need to be carefully managed. However, within American legislation, a dominant influence upon pharmaceutical research, the legal requirements of those safeguards are geared towards an assumption that vulnerable populations cannot give an informed consent to research participation. These issues that have

[34] US Department of Health and Human Services and Food and Drug Administration, "Guidance for Industry General Considerations for the Clinical Evaluation of Drugs."
[35] US Department of Health and Human Services and Food and Drug Administration.
[36] Levine et al., "The Limitations of 'Vulnerability' as a Protection for Human Research Participants."

arisen from labelling pregnant women as vulnerable and with reduced capacity to consent have only recently been unpacked and will be discussed in 5.3. [37]

For this discussion, the most significant impact of this labeling of pregnant women is that it muddies the distinction between capacity for consent and potential exposure to greater risk; such labelling therefore contributes to the discourse of pregnancy in which pregnant women have a restricted capacity for autonomy. This legislation, and its practical legacy, also impacts ideas of risk during pregnancy, emphasising that pregnant women should not be exposed to particular types of risk regardless of the actual degree of riskiness, thereby supporting the problematic norm of inaction as precaution. Inaction as precaution, or 'better safe than sorry,' is exactly the idea that it seems to be:a form of risk aversion whereby it seems safer to avoid action than to take it.[38] For example the norm is operative when doctors avoid prescribing, or pregnant women resist consuming, pharmaceuticals for chronic conditions such as epilepsy during pregnancy despite evidence that continuing medication is almost always the safest option for both mother and fetus.[39] Inaction as precaution is one of the key harmful norms this project identifies as impeding pharmaceutical research during pregnancy and will be discussed in more detail throughout chapter five especially in the discussion of risk and stigma. For now, it should simply be recognised that risk discourse during pregnancy is muddled and that this arose in part out of the regulations attendant on the failures of pharmaceutical regulation in the 1950s and 1960s. The key point is that narratives about pregnant women between the 1950s and 1990s reinforced and aligned with an ongoing

[37] Coleman, "Vulnerability as a Regulatory Category in Human Subject Research"; Macklin, "Bioethics, Vulnerability, and Protection"; Rogers and Lange, "Rethinking the Vulnerability of Minority Populations in Research"; Schonfeld, "The Perils of Protection"; Wild, "How Are Pregnant Women Vulnerable Research Participants?"; Ballantyne and Rogers, "Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research." The problem of pregnancy and vulnerability will be discussed further in 5.3.
[38] Lyerly et al., "Risks, Values, and Decision Making Surrounding Pregnancy."
[39] Friedman, Tomson, and Sazgar, "Seizure Medications and Teratogenicity"; Kinney and Morrow, "Epilepsy in Pregnancy"; Campbell et al., "Malformation Risks of Antiepileptic Drug Monotherapies in Pregnancy"; Meador et al., "Pregnancy Registries in Epilepsy A Consensus Statement on Health Outcomes."

narrative of pregnant women as less able to make decisions and choices building on historical characterisations of them as weak, nervous and hysterical.

In the early 1990s, the regulations and guidelines that restricted pharmaceutical testing on pregnant women began to be rolled back in recognition of the need for improved knowledge around pharmaceutical safety and efficacy during pregnancy. [40] At that time, it became apparent that the often unique biological and physiological aspects of pregnancy resulted in pharmacokinetic profiles during pregnancy that can make it impossible to identify the therapeutic dosage for pregnant women based on studies in non-pregnant populations. While the idea of research on drugs during pregnancy became possible from the 1990s onwards, research predominantly focused upon safety and efficacy research for pharmaceuticals to combat a few major diseases such as HIV and cancers. Generally pharmaceutical research during pregnancy remains significantly lower than desirable for ensuring good quality health treatments during pregnancy.[41] However from the 1990s onward, practice began to shift and testing on women and other subpopulations has become more and more the standard internationally.[42]

While most guidelines still limit the participation of pregnant women, a few research guidelines have begun to presume the eligibility of pregnant women for participation in clinical trials, albeit as a specialised population. For example, while the 1993 Council for International Organizations of Medical Sciences (CIOMS) guidelines state that "pregnant women should in no circumstances be the subjects of non-clinical research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the

[40] Matroianni, Faden, and Federman, *Women and Health Research*.
[41] Lyerly, Little, and Faden, "The Second Wave."
[42] Foulkes et al., "Clinical Research Enrolling Pregnant Women," 2011; Levine et al., "The Limitations of 'Vulnerability' as a Protection for Human Research Participants"; Ballantyne and Rogers, "Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research"; Johnson, "When Hypothetical Vulnerability Becomes Actual: Research Participation and the Autonomy of Pregnant Women."

research is to obtain new knowledge about pregnancy or lactation," the 2002 revision of the CIOMS guidelines specifically requires that pregnant women be presumed eligible for participation in research.[43] This represents a complete reversal from previous iterations of CIOMS guidelines. The 2016 CIOMS revision clarifies and strengthens the 2002 position on research involving pregnant and lactating women: "Pregnant and breastfeeding women have distinctive physiologies and health needs. Research designed to obtain knowledge relevant to the health needs of the pregnant and breastfeeding woman must be promoted."[44] Other recent research guidelines, such as the 2014 Canadian Tri-Council Policy Statement, *Ethical Conduct for Research Involving Humans* (TCPS2), go a step further and highlight the risk of exclusion due to "over[ly] protectionist attitudes or practices" and explicitly requires a justification for any exclusion of pregnant women from research.[45] As part of the Canadian initiative a more detailed guidance document was also developed specifically to assist clinical researchers and further facilitate the inclusion of pregnant women in clinical research.[46] Similarly, as part of the 2020 National Institutes of Health (NIH) strategic plan, the Office of Research on Women's Health (ORWH) in the United States recommends the inclusion of pregnant women in health research, and also includes guidance documents for clinical researchers to facilitate this end.[47]

Despite these regulatory shifts, in practice ethics review boards still regard pregnancy as "a near-automatic cause for exclusion" where the most common reason given is that both

[43] Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Biomedical Research Involving Human Subjects," 1993; Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Biomedical Research Involving Human Subjects," 2002.
[44] Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Health-Related Research Involving Humans. Fourth Edition."
[45] Canadian Institutes of Health Research, Social Sciences and Humanities Research Council of Canada, and Natural Sciences and Engineering Research Council of Canada, "TCPS2."
[46] Government of Canada, "Considerations for Inclusion of Women in Clinical Trials and Analysis of Data by Sex - 2013 Guidance Document."
[47] Foulkes et al., "Clinical Research Enrolling Pregnant Women," 2011.

international and national guidelines and regulations provide insufficient, or contradictory information.[48] For instance, in contrast to recent updates to CIOMS, TCPS and NIH documentation, the current Australia *National Statement on Ethical Conduct in Human Research* identifies pregnant women (4.1) alongside children, the mentally ill, intellectually disabled, cognitively impaired, prisoners, and several other categories as requiring not only that research during pregnancy be approved by a full Human Research Ethics Council (HREC) but also that such research be therapeutic unless there is no risk to the fetus (4.1.10). Consequently, today the vast majority of research during pregnancy is post-market studies in the form of retrospective observational studies and adverse event registries that track the use of specific pharmaceuticals during pregnancy, primarily to log potential long-term fetal impacts.[49] However these can be of varying quality and usefulness. Retrospective studies have problems with recall bias and in both registries and retrospective studies the data available can be insufficient, inconclusive, inconsistent and untimely.[50]

4.3 The Rise of Risk

> Both medicine and American society are risk averse; we use medicalization as a strategy to control and manage risk.
>
> E.M. Armstrong, *Conceiving Risk, Bearing Responsibility*

Alongside the implementation of formal standards for regulating and safeguarding research came the rise of epidemiological risk, both as a category for formal evaluation and as a concept in the public and professional discourses of pregnancy. While *risk* has a long history its exact meaning and context of use changed in the mid twentieth century to include

[48] Ells and Lyster, "Research Ethics Review of Drug Trials Targeting Medical Conditions of Pregnant Women"; Lyerly, Little, and Faden, "The Second Wave."
[49] Meador et al., "Pregnancy Registries in Epilepsy A Consensus Statement on Health Outcomes"; Reiff-Eldridge et al., "Monitoring Pregnancy Outcomes after Prenatal Drug Exposure through Prospective Pregnancy Registries"; White, McGready, and Nosten, "New Medicines for Tropical Diseases in Pregnancy."
[50] Ballantyne and Rogers, "Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research"; Baylis and MacQuarrie, "Why Physicians and Women Should Want Pregnant Women Included in Clinical Trials."

overtones of quantifiable uncertainty. Prior to the rise of population statistics, risk was simply a synonym for 'potentially unsafe'. However in the twentieth century risk became something to be managed rather than accepted: the rise of a paradigm in which "[t]here can be no safety without risk," where trial and error could be used to determine which practices were safe or not and the degree of risk quantified.[51] Writing in the late 1980s, Ulrich Beck argued that the rise of risk in the twentieth century was "a systematic way of dealing with hazards and insecurities induced and introduced by modernisation itself," a method for coping with the particular practices and technologies which were expressions of the significant social, technological and political changes that were occurring.[52] While risks from natural disasters had always been present, those external risks were perceived as different from the new types of risks, manufactured risks, which had a high level of human agency involved in both their production and mitigation. Nuclear power plants and high-speed motorways are examples of manufactured risks.[53] While the label 'manufactured risk' does not always fit well into the discourse of health, the twentieth century was notable for the rise of many new medicines and treatments for longstanding causes of ill health. Through better understanding of the human body and the world around us, antibiotics, surgical procedures and pharmaceuticals, people could suddenly avoid, manage or resolve entirely a huge range of previously debilitating and lethal disorders – infectious diseases, cancers, nutritional deficiencies, pregnancy complications. Becoming ill, and having children, were no long as inherently risky as they had been in prior centuries. However, this also set new standards of expectation for the safety of new products and technologies. This was a fundamental change in mindset from understanding all risks as something outside of human control to expecting risks to be quantifiable, manageable and reducible. There is no simple way to identify who benefited or

[51] Wildavsky, *Searching for Safety*.
[52] Beck, *Risk Society*, 21.
[53] Mythen, *Ulrich Beck*.

not from this shift; certainly consumers benefited from a focus on safety and risk mitigation but governments and capital driven systems like business with their tendency to risk management and risk quantification certainly did also.

The spread of quantifiable epidemiological risk in the mid to late twentieth century was bolstered by a series of public disasters; pharmaceutical ones such as the Thalidomide and DES tragedies, and also environmental disasters from nuclear and industrial accidents such as the Love Canal disaster in the USA, the Chernobyl disaster in the USSR and lead poisoning worldwide.[54] From the 1940s scientists developed "an interest in categorising and explaining environmental factors" that caused harm to humans, particularly toxins that had teratogenic impacts on fetuses.[55] Collectively these events and developments introduced a new narrative of risk during pregnancy and by the 1970s, a public discourse had arisen that emphasised the riskiness of chemicals, pharmaceuticals and environmental pollution for human and animal health. In stark contrast to only decades earlier, fetal wellbeing was now perceived to be at risk from environmental exposures during pregnancy and also from substances consumed by pregnant women. The final two sections of this chapter both discuss the rise of modern risk discourse and its impact on pregnancy and in particular the strengthening of the expectations upon pregnant women for the management of good health and optimal fetal development. This section focuses on the broader social changes that lead to the culture of risk while the next focuses specifically upon the rise of risk culture within pregnancy and obstetrics.

A series of very modern disasters between 1960 and 1990 catalysed the contemporary discourse of risk in popular, scientific and governmental discourse and introduced the existence of links between environmental exposure and health impacts, including health

[54] Kahn, "Environmental Disasters as Risk Regulation Catalysts?"
[55] Dron, "Teratology Transformed," 13.

impacts upon people's future reproductive capacity and the possibility of maternal exposure causing fetal impacts. The nascent scientific and medical developments in genetics, particularly around the mechanisms and causes of mutation, introduced a host of new concerns. Beyond the Thalidomide and DES tragedies there was the Love Canal disaster, the Chernobyl nuclear reactor meltdown, and rising rates, and awareness, of childhood lead poisoning.

The Love Canal disaster occurred in upstate New York from the 1970s when people from housing areas built upon former toxic waste dumps in the 1950s began showing higher than average rates of miscarriage, birth defects and cancers. A mass evacuation occurred and subsequently a raft of new regulations were developed for cleaning up environmental disasters.[56] Although only thirty three people died of radiation exposure in the immediate aftermath of the 1986 Chernobyl nuclear reactor disaster, it caused hundreds of other cases of acute radiation sickness and an estimated 4000 additional fatal cancers subsequently.[57] Fear of nuclear exposure has been heightened by the many deaths, reproductive issues and high rates of mutations in animals remaining in the exclusion zone in the area around the reactor. As a result, territory in what is today Belarus, Ukraine and Russia, was evacuated. Similarly, fear about the risks of exposure to 'toxins' in food has been exacerbated by periodic outbreaks of concern about the level of safe and acceptable risk from radiation levels in livestock, fish and soils across many parts of Europe arising from the Chernobyl disaster.[58]

Lead poisoning had been a recognised, although low level, health concern since the end of the nineteenth century; however after the publication of a report in 1967 by the US Departments of Health, Education and Welfare (DHEW) and Health and Human Services

[56] Brown, *Laying Waste*; US EPA, "The Love Canal Tragedy"; Blum, *Love Canal Revisited*.
[57] UNDP et al., "The Human Consequences of the Chernobyl Nuclear Accident A Strategy for Recovery."
[58] Kahn, "Environmental Disasters as Risk Regulation Catalysts?"; UNDP et al., "The Human Consequences of the Chernobyl Nuclear Accident A Strategy for Recovery." While radiation and toxins are different they are often collapsed in public concern about exposure.

(DHHS) it rapidly rose in the public awareness as a preventable source of "death, mental retardation and neurological handicaps" in children.[59] Many countries subsequently moved to remove lead from the environment particularly targeting lead based petrol, paints and water pipes. Countries also developed policies to limit lead exposure, deriving maximum acceptable lead exposure rates for children based upon acceptable levels of risk for various health consequences. Public education into the hazards of lead was also introduced.[60]

Each of these disasters contributed to the development and enrichment of a public discourse of risk. Furthermore, momentum developed among the public, governments, scientists and medical professionals to stem such risks in the future, and to develop rules about acceptable levels of risk. Collectively these disasters strengthened scientific and public knowledge of not just the role that exposure to environmental toxins could have on human health but also the association between maternal exposure and fetal health and development.

The Precautionary Principle

Alongside other events this series of failures also led to the development of the precautionary principle, which was incorporated into policy and guidance documents from the 1980s onwards in order to improve the management of such risks in the future. While the notion of precaution has a long history, the precautionary principle was introduced in the 1970s as an environmental risk management tool and is the codification and adoption into policy, law and treaty of the vague yet common sense aphorism 'better safe than sorry.' [61] Today the precautionary principle is used widely across all areas of human planning and regulation particularly where there is the possibility of impact to human or environmental wellbeing, whereby an action should not take place if there is a significant chance of bad consequences.

[59] Lin-Fu, "Modern History of Lead Poisoning A Century of Discovery and Rediscovery," 24.
[60] Lin-Fu, "Modern History of Lead Poisoning A Century of Discovery and Rediscovery."
[61] United Nations General Assembly, World Charter for Nature; European Commission, "Communication from the Commission on the Precautionary Principle 52000DC0001."

As risk was now something that could be quantified, the degree of acceptable risk for any given practice could also be decreed, managed and evaluated/assessed. The practice of risk management, this new understanding of risk, arose in two ways – in formal legislation via the precautionary principle and in everyday practices and discourse. While the new understanding of risk was incorporated widely into the framing of scientific, health and environmental debates and events during the 1970s and 1980s, this section will focus on the intersection of risk and pregnancy.

There are two iterations of the precautionary principle. The strong interpretation requires that activities should not proceed when potential adverse effects are not understood, where the burden of proof lies upon those proposing to undertake the activity such as pharmaceutical or mining companies, in other words where the degree of risk and its likelihood has not been properly quantified. A prominent iteration is the Wingspread Statement focused upon resource extraction, environmental degradation, toxic environmental releases and their impact upon human health:

> We believe existing environmental regulations and other decisions, particularly those based on risk assessment, have failed to protect adequately human health and the environment - the larger system of which humans are but a part.
>
> We believe there is compelling evidence that damage to humans and the worldwide environment is of such magnitude and seriousness that new principles for conducting human activities are necessary…
>
> When an activity raises threats to the environment or human health, precautionary measures should be taken, even if some cause-and-effect relationships are not fully established scientifically. In this context, the proponent of an activity, rather than the public, should bear the burden of proof.[62]

In contrast the weak interpretation of the principle sets the burden of proof upon those opposing action and also allows consideration of non-risk-based considerations such as economic or social benefit. The precautionary principle is commonly applied when scientific

[62] "Wingspread Statement on the Precautionary Principle."

consensus is lacking, or data is insufficient to draw conclusions, yet there is a plausible mechanism of harm causation. The application of the precautionary principle includes a built in assumption that governments have a responsibility to protect people from such harms.[63] The strong version of the precautionary principle adoption while desirable is hard to implement however, because "the environmental or health risks of a particular action are usually uncertain and occur in the future, while the costs of averting it are often immediate."[64] The regulations discussed in the previous section such as the Declaration of Helsinki (1975), the law for the Protection of Human Research Subjects (USA, 1974) and the early iteration of the Council for International Organizations of Medical Sciences (CIOMS) guidelines (1993) all incorporate aspects of the precautionary principle. In particular it is possible to understand pharmaceutical regulation as fitting within the strong interpretation of the precautionary principle as pharmaceutical developers face the burden of proof in showing safety and efficacy before being allowed to bring a drug to market. The entry of the precautionary principle into public policy is worth noting because it was the formal codification of risk within public policy and continues to structure the discussion of risk today, including in regard to pregnancy and health research policy. The final chapter will discuss both the formal use of precaution and the more informal 'better safe than sorry' iteration.

4.4 Reproductive safety

While the later disasters would strengthen the narrative, the regulatory failure to establish the safety of Thalidomide marked the beginning of the modern iteration of the narrative of risk during pregnancy, particularly with regards to environmental exposures and the absorption of

[63] O'Riordan and Jordan, "The Precautionary Principle in Contemporary Environmental Politics."
[64] Langston, *Toxic Bodies*, 152.

substances into pregnant women's bodies. The new-found awareness of the potentially vulnerable nature of the pregnant body collided with a long-developing belief in maternal responsibility for good fetal outcomes. As detailed in earlier chapters there is a long-standing expectation that women should manage a range of external and internal risk factors, including appetites and emotions, while also ensuring their experiences while pregnant are positive—as seen in the discussion of maternal impressions. Kukla argues that the underlying values and assumptions from maternal impressions still apply in popular, medical and scientific discourse around women and reproduction:

> Many of the maternal impression myths are about female 'selfishness' or about women desiring things for themselves. **In American culture, women who are not selfless, self-sacrificing, and self-abnegating transgress important boundaries.** The ancient notion of maternal impressions continues to hold sway over not just the popular imagination but in many ways the medical imagination as well… Pregnancy crystalizes concern about gender, female identity, motherhood, and work, as well as hopes and fears for children - the next generation, the 'future' of society.[65]

Prior to events around Thalidomide there was no expectation that pregnant women restrict or change their intake of food, drink and other consumables, such as pharmaceuticals, from the regular patterns of consumption that also applied to the non-pregnant population. The Thalidomide regulatory failure precipitated a significant change in the behaviours and considerations that pregnant women were expected to manage. This section details the changes that arose in light of the newly apparent risks of consumption and environment during pregnancy and the consequences this new narrative of risk had upon maternal responsibility and the fetus.

The cultural shift in the perceived safety of pharmaceuticals during pregnancy can be seen in the responses of women questioned by German clinicians before and after the Thalidomide regulatory failure became widely known. In the initial inquiries into the causes

[65] Kukla, *Mass Hysteria*, 17–19. My emphasis

of the phocomelia outbreak when women were asked what they had ingested during their pregnancies, many women failed to mention having taken Contergan (as Thalidomide was branded in Germany) at all. After Thalidomide was confirmed as the source they were re-questioned as to why they had not mentioned it and most answered that they felt the drug was "too innocent to mention on the questionnaire."[66] At the time of the events around Thalidomide, most physicians—and the general population —assumed that the placenta and thus fetus, was impervious to any drugs ingested by the expectant mother — unless the drug actually killed her or was a known abortifacient. Despite findings to the contrary from a few animal studies as early as the 1940s, knowledge that drugs could cross the placental membrane was not widely known by researchers who worked with pregnant humans.[67]

Once the Thalidomide scandal broke, its effect on the perception of pharmaceutical safety was immediate and pronounced. At the 1962 AGM of the British Drug Houses the chairman said "since the discovery of the wholly unforeseen risks attendant on the use of Thalidomide, doctors have become hesitant about prescribing any drugs during the early stages of pregnancy."[68] The beginnings of the shift in the perception of pharmaceutical safety during pregnancy can also be seen in the changes to research regulation as discussed in the previous section. However, in practice actual prescription rates during pregnancy remained stable. This illustrates how changes to regulations and codes do not automatically precipitate changes to beliefs and practices. This can be seen in US sales of DES which held steady at five million doses per annum from its introduction in the 1950s until its withdrawal from the market in 1971.[69] DES was used exclusively during pregnancy and until 1968 was a treatment against "habitual and threatened abortions" as recommended by the Physicians'

[66] Taussig, "A Study of the German Outbreak of Phocomelia," 842.
[67] Greek, Shanks, and Rice, "The History and Implications of Testing Thalidomide on Animals."
[68] Anderson, *Making Medicines*, 257.
[69] Swan, "Intrauterine Exposure to Diethylstilbestrol," S212.

Desk Reference, a free widely-used text distributed annually to all physicians in the USA.[70] The stability in the level of DES prescriptions in the USA throughout the 1960s indicates that while there was a new awareness of the potential dangers of prescribing pharmaceuticals to pregnant women, in practice there was still a need to prescribe pharmaceuticals during pregnancy, not just for treating conditions associated with pregnancy, but also the illnesses of everyday life.[71] Thus, while the formal world of biomedical research and in particular the guidelines and regulations governing such research began to restrict research on pregnant women in an effort to protect them from the newly apparent risks of using pharmaceuticals, in practice doctors were habituated to providing pharmaceutical interventions in the first instance. Furthermore, medical practitioners were faced with pregnant women who wanted and expected medical interventions just like everybody else and thus the rates of prescriptions to pregnant women remained high because in practice the treatment needs of pregnant women remained steady.

This disconnect between on-the-ground practice in terms of what 'risk' is acceptable for 'treating' a pregnant patient and the acceptable level of risk pregnant women can be exposed to during research as decided in policy highlights a distinction in the norms of safety and acceptable risk that will be important in improving clinical research during pregnancy. This difference in acceptable risk for the two scenarios illuminates how specific pharmaceuticals are acceptable if they are used by or given to an individual pregnant woman in service of treating a particular disorder but the overall riskiness of pharmaceuticals is such that pregnant women ought not to participate in research. This difference between specific medicines or treatments and the more general concept 'pharmaceuticals' is one that those attempting to encourage research during pregnancy need to be mindful of. It is a specific

[70] Dutton, *Worse Than the Disease*, 57.
[71] Bonati et al., "Drug Use in Pregnancy"; Doering and Stewart, "The Extent and Character of Drug Consumption during Pregnancy"; Donati et al., "Drug Use in Pregnancy among Italian Women"; Egen-Lappe and Hasford, "Drug Prescription in Pregnancy."

iteration of the importance of specificity and detail in people's decision making, an issue that will be flagged in the final chapter. This also suggests that clinical research during pregnancy is more acceptable if it is conducted secondary to treatment and that best practice research methods like placebo control will not be acceptable. It highlights how difficult it will be to conduct anything other than stage three and four trials during pregnancy. Outreach efforts to improve clinical research during pregnancy need to be mindful of the perceptual gap that most people hold between 'research participation' and 'treatment' and emphasise when 'treatment' is a component of the research in order to encourage participation.

Cigarettes and Alcohol

Beyond creating an instant heightening of caution with regards to pharmaceuticals during pregnancy, the Thalidomide regulatory failure also opened up the possibility of a vast new area of risk that must be managed during pregnancy: consumables. Thalidomide was not the only factor precipitating the awareness of these new types of risk; the disasters detailed in the previous section also contributed to heightened awareness: Thalidomide, DES, lead poisoning, Love Cannel and Chernobyl. The narrative expansion of risk into exposure and consumption can also be seen in spreading awareness of health concerns about long consumed products such as cigarettes and alcohol. The spread in awareness of the risks of alcohol and tobacco consumption while pregnant were the leading edge of a wider reconsideration of risk and safety during pregnancy that occurred in the 1970s and 1980s and occasioned changes to both 'maternal responsibility' and the 'fetus'.

While evidence as to the harms of tobacco was available from the 1920s onwards it was only in 1964 that the Surgeon General's report, which linked smoking to cancer, precipitated a widespread shift in smoking regulation and consumption especially during

pregnancy.[72] The report concluded that there was strong evidence for the detrimental effects of maternal smoking on a fetus, including premature birth and low birth weight, and these findings aligned neatly into the developing paradigm of consumption risk during pregnancy. By the 1969 edition of the Surgeon General's report, the stated risks of maternal smoking began to include higher rates of miscarriage, stillbirth, and neonatal death and by 1979 included SIDS and childhood behavioural disorders.[73] Smoking is notable in that its harms are such that most countries have invested in antismoking campaigns aimed at eliminating across all social groups; however there is often an additional focus on preventing smoking during pregnancy.[74]

Even more than in relation to smoking, a similar pattern of events and shifts in value can be seen in the increasing focus on alcohol consumption during pregnancy between the 1950s and the 1990s. Changes to practices and beliefs around alcohol consumption during pregnancy highlight a series of narrative shifts that occurred in the discourse of pregnancy focused around ideas of risk, health and the fetus. Prior to the 1940s alcohol was not even mentioned in obstetrics texts, but by 1953 it gained mention in a prominent obstetrics text as something to be consumed in moderation as part of a normal diet: "alcohol, as such, is not injurious and need not be eliminated during pregnancy."[75] This recommendation was in line with that given to the wider non-pregnant population. As with smoking, and many other substances, perception of the general safety of alcohol shifted during the 1960s and in 1971 the US National Institute on Alcohol Abuse and Alcoholism (NIAAA) was developed. Research funded by the NIAAA into pregnancy and alcohol use lead to the development of

[72] U.S. Department of Health and Human Services, "Smoking and Health: Report of the Advisory Committee to the Surgeon General."
[73] U.S. Department of Health and Human Services, "The Health Consequences of Smoking - 50 Years of Progress: A Report of the Surgeon General," fig. 4.4.
[74] Ministry of Health NZ, "Pregnancy: Avoid Smoking, Alcohol and Drugs"; Government of Canada, "Smoking and Pregnancy - The Healthy Pregnancy Guide - Public Health Agency of Canada."
[75] Lull and Kimbrough, *Clinical Obstetrics by Members of the Staff of the Pennsylvania Hospital by Lull, Clifford B. and Kimbrough, Robert A. (MD's) - Editors*, 160.

fetal alcohol syndrome (FAS) in 1973 and by 1977 the first formal recommendations to moderate the consumption of alcohol during pregnancy arose in the USA. In 1980 this was developed further into a blanket recommendation that pregnant women, and those considering pregnancy, "should not drink alcoholic beverages and … be aware of the alcoholic contents of food and drugs."[76] New Zealand, Australia, Canada and the United Kingdom subsequently all recognised FAS and also came to recommend pregnant women minimise or completely refrain from consuming alcohol.[77] FAS was redefined as fetal alcohol spectrum disorder (FASD) in 1996 in light of further research that widened the severity and scope in the range of possible fetal symptoms associated with alcohol consumption during pregnancy.

The development of FAS(D) was a marker by which concern about alcohol consumption during pregnancy could be expressed within the legitimising framework of medicine, science and public health. Embedded within the medical concept of FAS(D), as within other explanations for illness, are "deeply held moral convictions about the nature of risk and responsibility for disease."[78] Where Armstrong correctly links this to the moral responsibility for risk and responsibility around disease I wish to take it one step further and consider biopower and the questions about who benefits from the transformation. As discussed earlier with the rise of mental health, the advent of FAS(D) as a diagnosis is another act of medicalization where the situating of an act (alcohol consumption) is transformed into something about an individual; where the risk and responsibility for the act of alcohol consumption is placed firmly upon the individual and away from other actors who conceivably contribute to the act of alcohol consumption such as the state, alcohol businesses and family and friends.

[76] Office of the US Surgeon General, "Surgeon General's Advisory on Alcohol and Pregnancy."
[77] O'Leary et al., "A Review of Policies on Alcohol Use during Pregnancy in Australia and Other English-Speaking Countries, 2006."
[78] Armstrong, *Conceiving Risk, Bearing Responsibility*, 9.

The advent of FAS(D) was also the expression of a particular set of social norms and narratives during pregnancy about risk, responsibility, the fetus and disease. It is not by chance that FAS(D) was discovered in 1973 - the same year as Roe vs. Wade which made abortion legal in the USA for the first time in the twentieth century and there was a hyper focus on pregnancy across politics, society and medicine within the USA. In Armstrong's words "medical ideas [about FAS(D)] arose out of cultural ferment over gender and motherhood but they also further leavened that ferment."[79] The strength of the expression of this set of narratives that was developed within the discourse of alcohol during pregnancy reflects and reinforces these same narratives in other aspects of discourse around women and pregnancy. FAS(D) was an expression of moral concern about wider social changes over gender roles, good mothering practices, addiction and responsibility and, most contentiously in the USA, the moral and political status of the fetus.[80] Beyond the shifts in the narratives of risk and maternal responsibility, a strengthened narrative of the fetus as a participant in the pregnancy or patient in its own right also arose. The concept of the fetus continued to shift, in part both because of and in response to increasing concerns over risky consumption. Together these narratives shifted the discourse of pregnancy into the contemporary form we experience today.

Obstetrics

Both public facing and expert obstetric guidelines also shifted in this era, most notably by increasing focus upon evaluating and mitigating risks to the fetus. Developments in obstetric practice post-FAS(D) and Thalidomide placed a new focus upon risk management in order to maximise the likelihood of a healthy fetus. Momentum towards a concept of the fetus as an individual had been growing since the early twentieth century. The

[79] Armstrong, 10.
[80] Armstrong, 9–11.

development of maternal-fetal medicine in the 1960s as an obstetric subspecialisation focused upon what today are called high risk pregnancies. These specialists developed technologies to specifically diagnose and treat fetal health issues, technologies such as amniocentesis (1952), precise fetal heart monitoring (1967) and real time obstetric ultrasonography (1971) all of which quickly spread into wider obstetric practice to monitor and test fetal wellbeing in lower risk pregnancies.[81] Actual treatments for fetal ill health were also developed, the first being intrauterine transfusions for Rh incompatibility in 1963, glucocorticoids to speed lung development when preterm delivery is expected (1977), and fetal surgery (1982).[82]

While these practices arose out of obstetric knowledge and practice, it remained the responsibility of pregnant women to actually act to modify the newly apparent risks during their everyday life. Where prior to the 1960s there were no specific recommendations during pregnancy beyond health guidelines that applied to all people, by the 1980s specific dietary and behavioural guidelines were regularly communicated to pregnant women during obstetric visits. This can be seen in the 1978 World Health Organisation Publication *Risk approach for maternal and child health care* which argues for the newly developed 'risk approach' in order to better improve health care services. It goes on to list a wide range of maternal, environmental and cultural risk factors that ought to be considered by healthcare providers in order to identify 'at risk' individuals and groups, and suggests rational methods by which to allocate health care resources to maximise both the health of the overall population and those 'at risk.'[83]

By the late 1980s these risk management strategies had moved beyond medicine and into popular texts on pregnancy. The narratives of fetal safety and risk management became

[81] Kurjak et al., "Scientific and Religious Controversies about the Beginning of Human Life."
[82] Kolata, "Fetal Surgery for Neural Defects"; Pattison, Roberts, and Mantell, "Intrauterine Fetal Transfusion, 1963–90"; Farrell, "Fetal Lung Development and the Influence of Glucocorticoids on Pulmonary Surfactant."
[83] World Health Organization, "Risk Approach for Maternal and Child Health Care."

more sophisticated over time and by the early 1990s were established in pregnancy guides well beyond the USA.[84] Today *fetal safety* and *risk management* are common place concepts present without question in all texts about pregnancy, both medical and popular.[85] For instance, in 1984 the first edition of *What to Expect When You're Expecting,* a consistently top selling text authored "by parents for parents," arose out of the author's concern and confusion about what was and was not safe during her own pregnancy. It was written because of her concern about fetal health threats – *risks* – that she understood "lurked everywhere: in the air we breathed, the food we ate, in the water we drank, at the dentist's office, in the drugstore, even at home."[86] What can be seen here is the (hyperbolic) culmination in popular discourse of the recognition that risks during pregnancy are everywhere and involve everything and the impact that this had on pregnant women who were attempting to be responsible parents.

The 1978 WHO report recommended systematic prenatal care and assessment of risk factors for all pregnant women in a community. The report, the first international guideline to recommend prenatal care for all pregnant women not just those with symptoms of ill-health, can be seen as part of the conceptual shift in healthcare in the mid twentieth century discussed in Chapter Three that saw 'health' change to include systems that ensured the health of population as well as individuals. In obstetric practice the shift to include all pregnant women as in need of health care and evaluation further facilitated the understanding of the fetus as a separate being from the pregnant woman, a patient in its own right: "from thinking of pregnant as something a woman is to regarding pregnancy as something she carries."[87] The rise of the fetus to a patient in its own right both in policy an practice,

[84] Gibson, *Becoming a Mother*.
[85] Government of Canada, "Prenatal Nutrition - Health Canada"; NZ Ministry of Health, "Eating Safely and Well during Pregnancy."
[86] Murkoff, *What to Expect When You're Expecting.*; Dron, "Teratology Transformed," 2.
[87] Armstrong, *Conceiving Risk, Bearing Responsibility*, 11.

supported a narrative of the fetus as an individual with separate interests to that of the pregnant women, ones that could compete and conflict with hers.

The continued shift towards the fetus as a patient in its own right can be seen in the comparison of the 1977 WHO report with a more recent guideline. In the 1977 report all risks and recommendations are framed in terms of the pregnant woman; however in the 2016 *WHO recommendations on antenatal care for a positive pregnancy experience* the outcomes section for each recommendation is split between maternal and fetal outcomes with separate sections for each.[88] It is important to be clear that such documents by no means downplay the role and health of women during pregnancy; pregnancy remains as something situated upon women. However, increasingly throughout this period the fetus is also recognised in a wide range of health related documents as an additional recipient of medical attention - a not entirely separate patient whose health and wellbeing is also of concern. The impact of this was two-fold: the fetal rights movement that gained momentum during the 1980s leveraged the 'fetal patient' in support of their movement, and our understanding of 'the fetus' - what it is, what it needs to be sustained and nurtured, in sum how people viewed our collective and individual obligations and responsibilities toward specific fetuses - again transformed.

Perinatal biostatistics

A core part of public health is developing and tracking detailed population level biostatistics such as infant and maternal morbidity and mortality. Governmental interest in demography began with rough population censuses and the loose tracking of infectious disease outbreaks in the nineteenth century, and by the twentieth century was producing ever more refined categories of analysis. While many new categories and measurements of the health of individuals began to be tracked in the early twentieth century, such as average age

[88] World Health Organization, "WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience."

of death and common causes of death for age groups and subpopulations, one new category stands out with regards to the history of pregnancy: a new measurement of fetal and infant mortality – the perinatal death rate. The concept of the 'perinatal' interval was developed by public health officials in an attempt to better keep track of the death rate in the period ranging between 20-28 weeks gestation to 7- 28 days after birth rather than tracking stillbirths (fetal deaths) and infant deaths in the period after birth separately as had previously been the case.[89] Improving childhood health and reducing child mortality was a goal of increasingly significant importance to governments throughout the early twentieth century and better data about health in the first year of life was one way to help achieve it. A consideration of the rise of the perinatal interval highlights its contribution to changing narratives of the fetus and how 'risk' and risk management became more and more entwined with pregnancy.

Risk was the central organising concept in the development and proliferation of the perinatal interval. From the 1950s onward, new methods of assessing risk became attached to specific individual pregnancies in an attempt to reduce perinatal mortality: "Standardized, population based, routine risk assessment in clinical practice came to saturate pregnancy in succeeding decades, promising an ever-receding utopia of health."[90] This was a change from previous methods of prenatal care, which had proceeded without the backdrop of population-based comparisons. While a pregnant woman (and increasingly her fetus), was always situated within the framework of her social conditions (race, class, marital status, pre-existing disorders), in the twentieth century this framework became quantified in terms of particular 'risk factors' and these risk factors became more and more situated within a body of 'objective scientific evidence' that could be separated from her social location. While in theory these risk factors are 'objective and scientific' it has become increasingly apparent

[89] The recording of stillbirths is still a contentious issue in demography and remains a major confounding factor in comparing neonatal fatality rates between territories with conflicting regulations (such as Canadian provinces and territories).
[90] Weir, *Pregnancy, Risk and Biopolitics*, 3.

how risk factors derived from scientific evidence most often both replicate and reinforce the social features of people's lives.

With a few exceptions most accounts of pregnancy and childbirth focus upon discipline not biopower – even when not couched in those terms. In other words, the focus is disciplinary in that the discussion focuses on changes to the discourse of pregnancy as they impact upon pregnant women, structuring their experiences, expectations and worries. In the context of risk during pregnancy focus thus often centers upon personal responsibility for managing risk factors, and how failure to adequately manage these risks leads to involuntary medical treatment. However, risk is not simply a question of discipline, rather "risk is a technology of both security and discipline," narratives of 'risk' function not just to ensure self-regulation but also to manage populations.[91] What is lost in the overwhelming attention to personal responsibility in making choices about narratives of risk is a consideration of how and why risk and responsibility take this form during pregnancy.

The distinction between the power schemas of biopower and discipline – power over population health vs. power over individual health – is often conflated such that risk is primarily associated with self-regulation at the individual level. But this is problematic because it makes it difficult to discuss how risk functions at the social level:

> the asymmetry between power over population health and power over individual health needs greater emphasis, particularly in the study of risk governance, which is all too often conflated with the self-governance of the neoliberal subject, a move that occludes risk at the level of population, epidemiology and public health.[92]

The best example of this is the predominance of 'individual choice' and 'informed consent' in discussions of risk, but limiting focus to individuals obscures the functioning of risk discourse at the social level. For instance, Weir highlights the importance of considering the relationships between the state and 'responsibility' and the impact this has upon how

[91] Weir, 13.
[92] Weir, 9. The importance of narratives of what is perceived as risky during pregnancy in inhibiting clinical research during pregnancy is a key finding of this project and will be picked up again in the following chapter.

pregnancy is regulated: "because the state is situated as responsible for health of populations there is always tension over whether those who won't govern themselves in accordance with the norms of health can be compelled by law to do so."[93] The lack of analysis of risk as a social discourse is a problem particularly pronounced around discussions of pregnancy. The very real significance of this lack of attention is made urgent by the potential for (or actual) substandard medical care for pregnant women if we do not also explicitly look at risk at the level of social discourse and discuss it in terms of biopower rather than discipline.

The introduction of 'risk' into clinical care not only shifted people's understandings of the dangers and responsibilities of pregnancy – refocusing and reformulating clinical and maternal priorities and experiences – it also contributed to the reordering of our understanding of the fetus. The shift towards risk-based analysis in clinical care ties to the wider point that throughout the twentieth century there is an increasing tendency to treat the fetus as a patient.

> Risk-based prenatal care bound together categories of epidemiological risk with diagnostic information, test results and patient histories; the result was to make standardized prenatal risk assessment into a higgledy-piggledy concatenation of epidemiological and clinical reasoning as risk came to invade the space of patient management, treated as equivalent of any clinical intervention.[94]

Proactive prenatal care aimed at pre-empting health issues and, based in the science of population-based risk assessment, increased as the twentieth century progressed; but more and more frequently medical care was focused on the fetus rather than the pregnant woman, strengthening the structuring of the fetus as patient and thus subject.

The advent of perinatal statistics created a new category, one that complicated our ideas around who counts as a patient by mixing parts of both the pre and post birth timeframes into a single frame. Prior to the late eighteenth century, Western biological

[93] Weir, 16.
[94] Weir, 3.

science lacked a concept of fetal viability as there was no concept of the fetal development beyond quickening: the moment when a pregnant woman first notices fetal movement. Advances in developmental biology at the beginning of the nineteenth century introduced new fetal narratives as the fetus became understood as moving through a series of developmental stages. The introduction of stages of development in conjunction with the concepts of viability and perinatality made it conceptually possible to locate the beginning of human subjectivity at a point prior to birth: "the fetus after viability was implicitly postulated as a living subject whose death was to count and whose health was to be preserved."[95] While the creation of the categories of viability and perinatality refined our ability to track health and facilitate healthcare interventions during early life, they also served to blur what had previously been the definitive threshold at which one becomes a patient – birth.

One consequence was that the availability of narratives of maternal fetal conflict were further strengthened because attention to the fetus as an individual before birth set up the possibility that a fetus could have interests that did not align, or were in competition, with a pregnant woman. The risks to the fetal-individual-patient that needed management during the perinatal period could differ from the risks to the maternal patient. The focus of perinatal statistics was an issue of biopower: "pregnancy [and antenatal care] became a time for routinely conserving and optimizing population."[96] The social discourse of 'risk' after the advent of perinatal statistics thus included the governance needed to ensure population health where the 'population' now included both woman and fetus.

For instance, the inclusion of stillbirths in statistics on perinatal mortality sets them up as preventable deaths at the level of health governance. [97] Conceptually, perinatality and viability changed the scope of what we can consider the early boundary of patienthood,

[95] Weir, 12.
[96] Weir, 6.
[97] Weir, 11.

where patienthood brings with it assumptions about one's status as a moral subject in its own right. There was now the conceptual possibility of fetal subjects in a way there had not been previously. While particular fetuses have always been valued, the advent of the perinatal interval reinforced the narrative of the fetus as an individual within the context of governance, to be valued, evaluated and optimised like any other subject. Fetuses became the subjects of policy and legislative interventions in their own right reinforcing the possibility for fetuses and pregnant women to exist in social and legal tension with each other.

The development of perinatal statistics introduced a number of new narratives into pregnancy, shifting not just 'the fetus' but also introducing a new maternal-fetal relation, conceived as interlinked but individual patients. This, in turn, introduced a new aspect into maternal responsibility: pregnancy as a situation of carrying another individual whose interests may differ from their own. Once the state "is situated as responsible for health of populations there is always tension over whether those who won't govern themselves in accordance with the norms of heath can be compelled by law to do so."[98] The introduction of these narratives shifted the wider discourse of pregnancy: not just pregnant women's experiences and understanding but also of all the medical experts and government officials whose work touched on pregnancy.[99] This shift in 'responsibility' can be traced in the creation of diagnoses such as FAS(D) and the prosecution of pregnant women who consumed drugs on the basis of harm to the fetus became possible. The development of perinatal statistics had its most significant impact in reshaping the discourse of pregnancy within the public sphere setting new norms and expectations about risk, responsibility and who counted as an individual or a patient.

[98] Weir, 16.
[99] Weir, 3.

Fetal Imaging

The epidemiological and demographic shifts of the early twentieth century were the most significant events precipitating changes to the narrative of the fetus in terms of governance and population. However, in terms of changing popular and lay narratives of the fetus, the rising prevalence of fetal images both in everyday and medical contexts had the most impact. Fetal ultrasound was developed in Scotland in 1957; however extensive fetal ultrasound screening programs did not become a widespread practice until the 1970s when the practice was widely adopted in both the UK and USA.[100] The process of fetal imaging is a positive, reassuring diagnostic tool that can improve fetal and maternal health outcomes, which at the same time can exacerbate the perception of conflict between women and their fetuses and reinforce narratives about producing the 'right' sort of child.[101] Within the mainstream media, the publication of Lennart Nilsson fetal photographs on the cover of Life magazine in April 1965 was a pivotal moment.[102] These photos were concurrent with a significant shift in the social conscience of North America, a strong ideological shift towards fetal personhood. Beginning in the 1960s, the idea that if you harmed a pregnant woman you were also harming an additional person, the fetus, arose in both law and popular culture.[103] This shift towards fetal rights sat in apparent tension with the simultaneous movement for the liberalisation of abortion law which would culminate in the USA in the 1971 Supreme Court decision Roe v. Wade which legalised abortion prior to the third trimester.[104] However within the judgement the court recognised and sanctioned the state's "important and legitimate interest in protecting the potentiality of human life;" women's interests are simply preeminent prior to

[100] Nicolson and Fleming, *Imaging and Imagining the Fetus: The Development of Obstetric Ultrasound*.
[101] Mitchell, *Baby's First Picture*.
[102] Stabile, "Shooting the Mother."
[103] Daniels, *At Women's Expense*.
[104] Daniels, 23. Later amended in Casey v. Planned Parenthood to prior to viability.

the third trimester. Thus, the narrative of state interest in its population extending prior to birth and the extension of narrative of 'fetal rights' can be seen in abortion discourse also.

By the 1970s laws intended to recognise the additional harm to the fetus when a pregnant woman was harmed came into effect.[105] By the late 1980s the application of these laws had transformed beyond their original intent and were being used against pregnant women who self-harmed via suicide attempts, drug addiction and alcoholism. While Hanson attributes the shift towards increasing concern for the fetus in situations of tension between maternal and fetal rights to the advent of routine ultrasound, routine ultrasound was only part of the phenomenon of increasing visualisation of the fetus.[106] The role of the visualisation of the fetus and the technological transparency of the maternal body is something extensively discussed by others.[107] For my purposes it is enough to note that the widespread uptake of fetal ultrasound strongly contributed to the rise of the narrative of the fetus as a patient in its own right and helped push back earlier the stage of development at which the fetus is considered to become a patient in its own right and a being that could be harmed in its own right.[108]

Conclusion

Advances in developmental biology, rapidly decreasing morbidity and mortality for both women and their infants, and the advent of methods to visualise the fetus in utero were all central in the reconfiguring of the relationship between women and their fetuses in the twentieth century. However, these advances occurred in a social and political context of intensifying political interest in reproduction. Increasing political interest arose from two

[105] Daniels, 97–131.
[106] Hanson, *A Cultural History of Pregnancy*, 10.
[107] Hanson, *A Cultural History of Pregnancy*; Kukla, *Mass Hysteria*.
[108] Fetal imagery is primarily a tool of diagnosis. While I emphasise the way in which its uptake reinforced narratives of the fetus as an individual in its own right its actual purpose was also often to identify medical conditions in a fetus that recommended it for termination. Fetal imaging technology was both enabler of fetal personhood in the abstract use and a denier of fetal personhood via its role as identifier of fetuses for termination in the specific use.

major social-political trends that were emerging at the time – eugenics and the politicisation of the working class, as discussed in 3.4, which together culminated in governments investing in public health systems heavily invested in reproduction.

The consequence of these events in the latter half of the twentieth century was a complex and conflicting set of expectations around pregnancy. The early guidance documents and regulations (hereafter jointly referred to as guidelines) developed in a climate of response to disaster. They indicate a strength of concern for the safety and well-being of pregnant women and the fetus, despite the rapid recalculation of the maternal-fetal relationship towards greater attention towards the monitoring and intervention in fetal health. Narratives of the fetus also shifted to include consideration of the fetus as a patient in itself with individual interests that could conflict with those of the mother. There was also a move towards the idea of maternal responsibility for ensuring a healthy pregnancy and healthy fetus via active self-management centered around risk avoidance, precaution and significant behavioural modification. However, the most significant shift in the second part of the twentieth century was the rise of risk culture, particularly the rise of the precautionary principle in policy development, the drive towards the quantification of uncertainty, and the development of safety thresholds and population-based health assessments. Within the context of pregnancy this resulted in both improved medical care and health outcomes but also greater routine surveillance of and intervention in pregnancy. The following chapter will use the nuanced, complex and contradictory understanding of pregnancy developed in this historical discussion to illuminate some of the barriers to ensuring a just research agenda during pregnancy.

FIVE: The five concepts today

Multiple strategies are needed to rectify the lack of information about the safety and efficacy of pharmaceutical interventions during pregnancy. Prior to 2010, debate focused upon both practical and ethical justifications over whether research ought to be conducted during pregnancy.[1] Lately, however, focus has shifted towards overcoming barriers to research during pregnancy and in developing practical strategies to ensure such research takes place in a safe and effective manner.[2] Despite increasing awareness on the part of researchers, practitioners, and policymakers of the need for pharmaceutical research during pregnancy, shifts in actual practice have been slow. A recent systematic review by van der Zande of the reported reasons for the continued exclusion of pregnant women from clinical research identified nine themes and areas of concern: fetal safety, collective memory and social controversy, liability, regulation, ethics review board interpretation, research design, willingness to participate, vulnerability and consent.[3]

Initiatives aimed at improving education, and clarifying and enhancing the regulations, policies and supporting documents around research during pregnancy have already been developed.[4] Collectively these steps will also mitigate some of the other

[1] Chervenak and McCullough, "An Ethically Justified Framework for Clinical Investigation to Benefit Pregnant and Fetal Patients"; Lyerly, Little, and Faden, "Reframing the Framework"; Lyerly, Little, and Faden, "The Second Wave"; Baylis, "Pregnant Women Deserve Better"; Little, Lyerly, and Faden, "Pregnant Women and Medical Research"; Allesee and Gallagher, "Pregnancy and Protection"; Briggs et al., "Should Pregnant Women Be Included in Phase IV Clinical Drug Trials?"

[2] Omer SB and Beigi RH, "Pregnancy in the Time of Zika"; Baylis and Ballantyne, *Clinical Research Involving Pregnant Women*; Brandon et al., "Ethical Challenges in Designing, Conducting, and Reporting Research to Improve the Mental Health of Pregnant Women"; Beigi et al., "Performing Drug Safety Research During Pregnancy and Lactation"; Clemow et al., "A Proposed Framework to Address Needs of Clinical Data for Informed Medication Use in Pregnancy"; Campbell et al., "Malformation Risks of Antiepileptic Drug Monotherapies in Pregnancy"; Schonfeld, "The Perils of Protection"; Blehar et al., "Enrolling Pregnant Women"; Endicott and Haas, "The Current State of Therapeutic Drug Trials in Pregnancy."

[3] van der Zande et al., "Fair Inclusion of Pregnant Women in Clinical Research: A Systematic Review of Reported Reasons for Exclusion."

[4] Ells and Lyster, "Research Ethics Review of Drug Trials Targeting Medical Conditions of Pregnant Women"; Canadian Institutes of Health Research, Social Sciences and Humanities Research Council of Canada, and Natural Sciences and Engineering Research Council of Canada, "TCPS2"; Campbell et al., "Malformation Risks

concerns highlighted by Van der Zande about liability, fetal safety, consent and research design and reduce concerns regarding ethics review board interpretation. A literature has also developed around vulnerability and pregnancy that both identifies how and when pregnant women and fetuses need additional safeguards to participate in research, and also when the label is misused and misapplied, and the linking of pregnancy and vulnerability acts as a barrier to research.[5] Researchers have also begun to examine how, why and when women are willing, or reluctant, to participate in research during pregnancy and to make recommendations to overcome misconceptions and to mitigate concerns.[6]

Many of these concerns can be mitigated via targeted educational initiatives which focus on how and why it is important to conduct clinical research during pregnancy. Findings also suggest that such education should be supplemented and supported by revisions to the

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of Antiepileptic Drug Monotherapies in Pregnancy"; Baylis and Halperin, "Research Involving Pregnant Women"; Briggs et al., "Should Pregnant Women Be Included in Phase IV Clinical Drug Trials?"; Modi et al., "Guidance on Clinical Research Involving Infants, Children and Young People"; Clemow et al., "A Proposed Framework to Address Needs of Clinical Data for Informed Medication Use in Pregnancy"; McCormack and Best, "Obstetric Pharmacokinetic Dosing Studies Are Urgently Needed"; Government of Canada, "Considerations for Inclusion of Women in Clinical Trials and Analysis of Data by Sex - 2013 Guidance Document"; Beigi et al., "Performing Drug Safety Research During Pregnancy and Lactation"; World Health Organization, "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants"; Little, Lyerly, and Faden, "Moving Forward With Research Involving Pregnant Women"; Liaschenko, DeBruin, and Marshall, "The Two-Patient Framework for Research During Pregnancy"; Kaposy and Baylis, "The Common Rule, Pregnant Women, and Research"; Foulkes et al., "Clinical Research Enrolling Pregnant Women," 2011; Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Biomedical Research Involving Human Subjects," 2002.

[5] Johnson, "When Hypothetical Vulnerability Becomes Actual: Research Participation and the Autonomy of Pregnant Women"; Coleman, "Vulnerability as a Regulatory Category in Human Subject Research"; Wild, "How Are Pregnant Women Vulnerable Research Participants?"; Rogers and Lange, "Rethinking the Vulnerability of Minority Populations in Research"; Schonfeld, "The Perils of Protection"; Ballantyne and Rogers, "Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research"; Macklin, "Bioethics, Vulnerability, and Protection"; Levine et al., "The Limitations of 'Vulnerability' as a Protection for Human Research Participants"; Bracken-Roche et al., "The Concept of 'Vulnerability' in Research Ethics"; Beattie and VandenBosch, "The Concept of Vulnerability and the Protection of Human Subjects of Research"; Kottow, "Vulnerability"; Kottow, "The Vulnerable and the Susceptible"; Hurst, "Vulnerability in Research and Health Care; Describing the Elephant in the Room?"; Moreno, "The Natural History of Vulnerability"; Luna, "Elucidating the Concept of Vulnerability"; Zion, Gillam, and Loff, "The Declaration of Helsinki, CIOMS and the Ethics of Research on Vulnerable Populations."

[6] Wild and Biller-Andorno, "Pregnant Women's Views About Participation in Clinical Research"; Rodger et al., "Participation of Pregnant Women in Clinical Trials"; Tooher, Middleton, and Crowther, "A Thematic Analysis of Factors Influencing Recruitment to Maternal and Perinatal Trials"; Frew et al., "Recruitment and Retention of Pregnant Women Into Clinical Research Trials"; Norwitz and Greenberg, "FDA Approval for Use of Medications in Pregnancy"; Kenyon et al., "Participating in a Trial in a Critical Situation."

specific policy and guidance documents which remove the ambiguities and contradictions present in the guidance documents developed at the different levels of governance – international, national, provincial or state, and university.[7] In addition to researchers, healthcare practitioners and policy makers, members of research ethics review boards are identified as a key target for specific support in these educational initiatives and guidance documents. The decisions made by these boards vary significantly even within individual countries, and the challenge is only increased because international multisite studies are common in pharmaceutical research in order to obtain the sample size to ensure a statistically significant result.[8]

While these initiatives have made progress in rectifying the problem of clinical research during pregnancy there is an additional dimension to the problem that remains to be resolved. In particular, the themes identified by van der Zande as collective memory and social controversy can be read as a shorthand for the legacy that Thalidomide, DES and other pregnancy related regulatory failures have had in distorting the discourse of pregnancy. Solutions such as policy revision and education of stakeholder groups will be more effective if they start with an understanding of the mechanisms by which 'collective memory and social controversy' act. This chapter builds on the historical discussion in previous chapters to examine these two themes of collective memory and social controversy: how changing ideas about risk, health, nature, responsibility and the fetus perpetuate norms that impede pharmaceutical research upon pregnant women by distorting perceptions of safety, efficacy, desert and need via the legacy of their historical use.[9] This chapter opens with a discussion of pharmaceutical research as a technology. I then go on to discuss risk and the norm of inaction as precaution and the role they play in inhibiting pharmaceutical research during pregnancy. I

[7] van der Zande et al., "Fair Inclusion of Pregnant Women in Clinical Research: A Systematic Review of Reported Reasons for Exclusion."
[8] Ells and Lyster, "Research Ethics Review of Drug Trials Targeting Medical Conditions of Pregnant Women."
[9] Desert is the philosophical term for the condition of being deserving of something.

discuss the stigma regarding pregnancy and pharmaceutical research that arose out the of the DES and Thalidomide tragedies. I finish with a discussion of the other four concepts traced within the genealogy and why they are still important even if they are less overt within the discourse of pregnancy.

5.1 Stigmatised Technologies and Risk

In healthcare the perception of safety is almost as important as actual safety. If people do not think something is safe then they will not risk engagement, interaction or ingestion of a technology or product. When a technology or product is 'known' to improve health this outlook is a problem because people are acting against their own interest. When considering the problem of pharmaceutical research and pregnancy it is helpful to explicitly situate pharmaceutical research as a technology, a tool that mediates relations with the world, assisting in interpretation, sorting, enhancing, refining and providing information.[10] The practice of 'pharmaceutical research' is also a method of knowledge production endorsed, authorised and legitimated by powerful groups namely scientists, medical professionals and governments. Considering pharmaceutical research as a technology endorsed and legitimated by particular groups is beneficial because it explicitly presents it as a tool, a system by which we interpret the world. This view of 'pharmaceutical research' not only emphasises the cultural role of technologies in producing narratives, but also who benefits from this method of endorsing and recommending pharmaceuticals, highlighting how pharmaceutical research supports the social, political, economic and cultural authority of these particular groups and the current system of social organisation.

[10] Verbeek, *Moralizing Technology*; Verbeek, "Materializing Morality"; Achterhuis, *American Philosophy of Technology*.

As well as highlighting whose interests are maintained by the system/technology of pharmaceutical research, situating pharmaceutical research as a technology is helpful because it allows us to draw parallels to other stigmatised technologies and the body of research associated with public health attempts to overcome or accommodate the effects and impacts of risk distortion. For instance, nuclear technologies also have a strong legacy of stigma and of people misestimating both the degree and severity of the risks associated with use and exposure. They also have a long literature of attempts to correct, educate and overcome the misperception of risk around nuclear technology.

According to a cultural model of technology, in mediating experiences technologies also shape behaviours and choices; technologies contribute scripts that shape narratives and discourses: "not only does technology become what it is in and through the interweaving of technology and culture, so does culture and the human beings using the technology."[11] This manner of understanding technology emphasises the relationship of technologies to discourse and their twofold role within the network of discourse both as products and shapers of discourse. Within this understanding of technology, technologies can not only mediate direct experiences of the world but also exist in the background as "absent presences," which "exert more subtle indirect effects upon the way the world is experienced."[12] The influence of a technology can be both direct, as in when people 'use' a microscope, telephone, or eyeglasses to view the world, or indirect as in the mostly 'off label' prescriptions of pharmaceuticals during pregnancy.

Understanding pharmaceutical research as a technology, a tool, in relation to pregnancy, illuminates how it is a significant background presence in shaping people's experience of the world. This is yet another aspect of how, compared to the non-pregnant

[11] Verbeek, *American Philosophy of Technology*, 133.
[12] Ibid, 112.

population, pregnant women are often underserved by healthcare in relation to pharmaceuticals, for instance by highlighting the pharmaceutical research system privileging of certain 'gold standard' methods of evidence production and disvaluing other techniques of evidence gathering such as retrospective studies of off-label usage – a method commonly used to study pharmaceuticals during pregnancy. Emphasising pharmaceutical research as a technology meshes well with the wider orientation of this project highlighting how pregnancy is a discourse made up of ideas and narratives which coexist in tension. The technology of pharmaceutical research is one of the pathways or mechanisms by which these narratives are expressed and shaped. But conversely these narratives – and the balance of tensions between them that influence our overall understanding of pregnancy – can also be shaped and reconfigured via changes to the technology. For example, can retrospective studies be reconfigured to be valued equally to RCTs, and can pharmaceutical research evaluation policies be reconfigured to do the same? If so, this would substantively reconfigure the injustice around pharmaceutical research during pregnancy as pharmaceutical research during pregnancy is primarily conducted via retrospective studies and there would be no need to transition to prospective research designs. Thus, changing the procedures and practices that constitute pharmaceutical research can promote an overall discourse of pregnancy more in line with wider social ideals such as equality.

Another way to understand this socially embedded interpretation of technology is that the practices and policies that collectively make up pharmaceutical research are part of the structures that shape the social environment. A parallel example is roads: not only are there the physical objects that make up roads but also the formal policies and informal norms that govern our interactions with them. *Roads,* in this broader sense, structure how people experience the world, mediating experiences, their commonplaceness making them invisible but influential. Just as *roads* can be changed via law, education and major catastrophe so can

pharmaceutical research. Parallels to more obvious technologies such as roads and considering how and why they are modified makes more obvious how we can manipulate and refine the pharmaceutical research process towards alignment with broader social goals. Technologies can thus be reconfigured, the scripts and influences shifted, in order to counter problematic scripts and narratives: "technologies are always technologies-in-use, and this use context is part of a larger cultural context. This contextuality makes technologies multistable."[13] When use patterns shift or traffic volumes change, changing the road rules, or physical layout, can make roads safer without impeding their existence as things that assist in getting between places. Changes can also be made to encourage shifts in usage types, less cars, more bikes, and walking. Similarly, pharmaceutical research can be changed, the rules modified to make it safer, educational outreach can change how pharmaceutical research is conducted, and policies tweaked to encourage different types of research or research on different groups. Collectively these individual changes can change the wider discourse of pregnancy by rebalancing the distribution of ideas/narratives contributing to the discourse.

There are a number of strands to the discussion in this chapter: the norm of inaction as precaution arises out of, and contributes to, the stigma around pharmaceuticals during pregnancy; the experiences of other stigmatised products and technologies which could provide us with strategies and insight into how to correct the misperception of risk during pregnancy; the role of existing norms of health, nature, responsibility and the fetus; and finally the guidance and regulatory documents that structure the inclusion of pregnant women in pharmaceutical research. Collectively these strands help to identify where and how to next target efforts to change the status quo around pharmaceutical research during pregnancy.

[13] Ibid, 134.

5.2 Risk, Stigma and the Norm of Inaction as Precaution

Risk, or calculated uncertainty, has become an increasingly central frame of interpretation since the 1970s and, as such, a clear understanding of the way we value, interpret, avoid and calculate risk is key to improving pharmaceutical research during pregnancy. *Risk* shapes many of the central facets of clinical research during pregnancy, for instance where clinical equipoise is situated, what constitutes acceptable safety thresholds for conducting research, permissible study designs, how pregnant women are thought to be vulnerable, values and ideas around fetal safety and the willingness of researchers and pregnant women to participate. Each of these factors relies upon norms: about acceptable levels of safety and uncertainty during pregnancy; about what is considered healthy and natural during pregnancy; the types of activities and outcomes that pregnant women, researchers and clinical professionals are considered responsible for, and about the fetus and the maternal-fetal relationship. In sum the historical narratives of risk, health, nature, responsibility and the fetus play a significant role in shaping the current discourse of pharmaceutical research during pregnancy. This chapter unpacks the intersection of these norms with pharmaceutical research during pregnancy and how they complicate attempts to improve pharmaceutical research during pregnancy.

The perception of risk is key to understanding the slow rate of change in research practices during pregnancy and in shifting the discourse of pregnancy towards a more favourable structure for conducting pharmaceutical research during pregnancy. Speaking to ideas about pregnancy and risk, Anne Drapkin Lyerly takes up the idea expounded in the previous chapter as the precautionary principle when she identifies a pattern of behaviour and practice with regards to pregnancy that she labels “better safe than sorry” – whereby inaction

or avoidance is always preferred to action – that she argues also reflects the historical ideas and ideals about purity and being a good mother explored in prior chapters.[14]

Lyerly's account examines the way in which the discourse of the precautionary principle, and risk management, as discussed in the previous chapter, have come to be expressed in people's behaviour and beliefs about pregnancy. Pregnant women are constantly told in numerous ways to avoid taking particular risks: Don't eat a wide range of foods or drink alcohol and coffee, and in the medical arena, don't undergo 'unnecessary' procedures or take 'unnecessary' drugs.[15] In many instances while policy and evidence suggest moderation, social expectation expects abstinence. Discussing patterns of expectation within the context of alcohol Armstrong states that "[p]regnant women who have even a single drink routinely face harassment, social stigma, and openly voiced reproach from both social intimates and total strangers." [16]

While many everyday recommendations during pregnancy – particularly those that encourage moderated intake, or avoidance of foodstuffs prone to foodborne pathogens – are beneficial to fetal wellbeing, this concern for the wellbeing of pregnant women and their fetuses easily slips into hyper-vigilance and a narrative of over-caution, which can include avoidance of pharmaceuticals, that can actively jeopardise the wellbeing of both pregnant woman and fetus. At its most extreme such hypervigilance causes medical practitioners to strongly discourage a range of practices that are 'known' to be safe for pregnant women under current paradigms of evidence based knowledge, such as the use of diagnostic radiation and flu shots and various pharmaceuticals used to treat conditions such as depression, asthma, and epilepsy.[17] Thus, the 'better safe than sorry/no action is better than action' narrative is entrenched not only in everyday lay understandings of pregnancy and risk, but also in

[14] Lyerly et al., "Risk and the Pregnant Body," 35, 39.
[15] Lyerly et al., "Risks, Values, and Decision Making Surrounding Pregnancy."
[16] Armstrong, *Conceiving Risk, Bearing Responsibility*, 12.
[17] Lyerly et al., "Risk and the Pregnant Body," 36.

medical discourse - clinical practices, training and perceptions of obligation and liability. Pregnant women are often able to recognise as absurd many of the recommendations and general advice given about how to be pregnant.[18] However it is far more problematic when advice comes from within the authority of medicine and instances of incoherence are not recognised because of the unthinking degree of social authority and deference that is so often conferred to medicine.[19]

When risk perception is skewed, the magnitude and sources of potential harm during pregnancy are misconceptualised. An ongoing source of this misconceptualisation is the distorted perception of risk with regards to pregnancy which is a consequence of historic events associated with pregnancy that have created a stigma around consumption during pregnancy.[20] Not only is society in general very risk averse with regards to pregnant women – a reasonable practice – but there is an additional stigma that is distorting people's perception of risk during pregnancy. Events arising from the Thalidomide and DES regulatory failures created a stigma around pharmaceuticals during pregnancy. I argue that identifying the existence of the stigma, understanding both its origin and how it interacts with the general perceptual bias towards considering inaction as safer than action, is key to countering a problematic norm associated with pregnancy, whereby precaution has become conflated with inaction. This norm skews peoples' risk perception in favour of inaction, or 'better safe than sorry,' and is key to understanding and improving research practices during pregnancy. The narrative of inaction as risk avoidance or precaution during pregnancy significantly contributes to the continuing low uptake of research during pregnancy. This is the downside of Thalidomide's legacy of caution: an oversensitivity towards, and misinterpretation of, risk

[18] Nicolson, "Sources of Pregnancy Advice for 21st Century Women."
[19] Scully, *Disability Bioethics*, 157. There is also a false assurance in medical advice, which is taken to be authoritative and 100% certain. This is wholly untrue; even evidence based practice is based on probabilities with confidence intervals rather than absolute certainty.
[20] Jordan and Murphy, "Risk Assessment and Risk Distortion." See the following discussion of stigma in 5.3.

during pregnancy. One way to understand this oversensitivity, and thus the reluctance of all parties to conduct and participate in pharmaceutical research, is through the lens of stigma. There is a stigma around the consumption of pharmaceuticals during pregnancy and understanding how this stigma arose out of the Thalidomide and DES tragedies has the potential to help mitigate the misidentification of risk during pregnancy that continues to occur today. In particular, understanding how a stigma exists around pharmaceutical consumption during pregnancy has the potential to counter the norm of inaction as precaution.

5.3 A model of stigma

The preeminent model for the inscription of stigma arises out of the work of James Flynn and Paul Slovic who argue that perceptions of risk and stigma are closely linked. They propose a model whereby stigma associated with a person, product, technology or place can distort risk perception in the wake of a catastrophe. Flynn and Slovic outline a number of criteria common to those phenomena that develop a stigma, and six of their criteria are applicable to either or both the Thalidomide and DES regulatory failures: it was intended to benefit but instead causes harm; includes a critical hazardous event; strikingly memorable negative imagery; the perception of a failure of hazard management; an unequal distribution across geographic areas and populations; and it was unbounded in magnitude and persistence.[21] This section will examine each of these criteria and evaluate how the Thalidomide and DES tragedies fit their model. Understanding the case of pregnant women and pharmaceuticals in terms of a stigma arising from the Thalidomide regulatory failures helps provide an explanation for the conflation of the very sensible norm of precaution with the often problematic norm of 'no action is safer than action.' When the reluctance to conduct

[21] Flynn, Slovic, and Kunreuther, *Risk, Media, and Stigma*, 3–5.

pharmaceutical research during pregnancy is understood in terms of mistaken risk perception, then the tools of risk communication become available to support, critique and evaluate research during pregnancy.

The first of Flynn and Slovic's criteria is that a stigma is "something that is to be shunned or avoided because it overturns or destroys a positive condition; what was or should be something good is now marked as blemished or tainted."[22] They argue that historically for an object or person to be stigmatised was for it to be considered a hazard; however contemporary stigmatisation is more than simple hazard identification but rather involves the benign or good suddenly turning menacing. Pharmaceuticals are given to increase wellbeing but – as in the cases of Thalidomide and DES – they sometimes instead cause harm, the exact opposite of the intended result of improving ill-health. Thus, the Thalidomide and DES tragedies meet the first criterion required for a technology or product to develop a stigma: something intended for benefit instead causes damage. Flynn and Slovic identify the production and creation of a visual mark as a second common factor in the production of stigma, in particular negative imagery. More so than with DES, which via cancer has an internal impact on the body, the birth defects associated with Thalidomide are a particularly apt illustration of the role of negative imagery in stigma production. The malformations associated with Thalidomide are especially vivid and include the rare and very memorable stunted limb malformation known as phocomelia, which literally translates as 'seal flippers'.[23]

Flynn and Slovic's third criterion for a product or technology to become stigmatised is that there be "some critical event, accident or report of a hazardous condition" which "sends a strong signal of abnormal risk."[24] The Thalidomide and DES catastrophes were

[22] Flynn, Slovic, and Kunreuther, 3.
[23] Silverman, "The Schizophrenic Career of a 'Monster Drug,'" 405.
[24] Flynn, Slovic, and Kunreuther, *Risk, Media, and Stigma*, 4.

definitely a "critical event" in the histories of both pregnancy and pharmaceuticals that still strongly resonates in the cultural memory over 50 years later. Even today, phocomelia remains strongly associated with Thalidomide in contemporary culture, as for instance in Mat Fraser's 2005 *Thalidomide!! A Musical*, and Niko von Glasow's 2008 documentary *NoBody's Perfect*, both of which are by and about people living with phocomelia.[25] Phocomelia was and is the visual reinforcement of Thalidomide as an unnatural and horrific event precipitated by a normally beneficial product. These recent cultural productions and the spate of newspaper articles around the 50 year anniversary also point to the continuing cultural significance of Thalidomide. As a consequence, Thalidomide persists in popular memory in a way few other biomedical scandals have. Another reason for their continued cultural significance is that both DES and Thalidomide have highly organised survivor networks which function at both national and international levels and whose representatives regularly interact with the press and weigh in on social and ethical aspects of bioscientific debates. They also remain directly in the biomedical consciousness because of the ongoing and continuously developing health needs of both DES and Thalidomide survivors and the cohort studies on DES to which almost all offspring of identified DES lineages belong.

Flynn and Slovic's fourth criterion is that the perception of how a hazard is being managed can contribute to whether a stigma arises. One factor that can contribute to the perception of hazard management is whether a background of existing distrust exists. According to Flynn and Slovic, in a society already primed to distrust, people judge more harshly and give less leeway when "concerns about competence, conflicts of interest or a failure to apply proper values and precautions" arise.[26] The Thalidomide and DES regulatory failures arose in a historical moment that was already primed towards distrust: biomedical

[25] Fraser, *Thalidomide!! A Musical*; von Glasow, *Nobody's Perfect*.
[26] Flynn, Slovic, and Kunreuther, *Risk, Media, and Stigma*, 5.

research in general was feeling the impact of public distrust from earlier research scandals during World War Two. This included the atrocities in the name of science conducted by Nazi and Japanese scientists which prompted the formation of the Nuremburg Code, a precursor to the Declaration of Helsinki. The Second World War had been thought to justify taking bigger risks with research subjects but a series of news headlines that emphasised the vulnerable status of the particular groups studied – institutionalised children and adults, conscientious objectors and soldiers – and the horrific studies conducted by the Nazi and Japanese scientists quickly precipitated a cultural shift in what was considered acceptable conduct for biomedical research and who was an acceptable research participant. As noted in previous chapters public distrust was also engendered by the string of localised bioethical scandals that began to snowball from the late 1960s onwards, including the aforementioned Tuskegee and Willowbrook scandals. These scandals coincided with ever increasing public awareness of Thalidomide victims' litigation battles against various drug manufacturers and revelations of the first studies of DES as a potential cause of cancer.

While legislative responses to contain and prevent another incident like Thalidomide had occurred promptly after the first physicians notified authorities, throughout the 1970s via the court cases it became increasingly apparent that Grunenthal, the manufacturer of Thalidomide, had suppressed knowledge of the problem. From as early as 1959 Grunenthal had received internal warnings from staff about the safety of Thalidomide but did not act on them. When the side effects of Thalidomide were first reported, Grunenthal not only consistently denied these findings but also tried to discredit the doctors and prevent their articles from being published in the medical literature.[27] Beyond the families directly affected, the Thalidomide scandal was not widely known to the public in English-speaking countries throughout the 1960s. It was only after a persistent media campaign – particularly

[27] Knightley and Times of London, *Suffer the Children*.

by the Sunday Times of London beginning in the late 1960s – that the story began to surface. Using images of the affected children, the Sunday Times sought to highlight their plight and pressure the UK distributor of Thalidomide to substantially increase the financial compensation on offer. This series of articles, which lasted until the late 1970s and which were syndicated around the English speaking world, and the subsequent book *Suffer the Children*, remain the major source of both popular and academic knowledge about the initial Thalidomide regulatory failures and the subsequent court battles over compensation.[28] The ongoing denial by Grunenthal, the decades of dispute over compensation and apologies and the secrecy around the legal proceedings only heightened public concerns about government and healthcare competence, and increased distrust in the drug companies involved. Today newspapers continue to publish articles releasing new evidence about the drug company's machinations to avoid responsibility and deny the victims justice which only highlights how the distrust and concerns about competence that Flynn and Slovic identify as significant factors in the production of stigma remain strong.[29]

Flynn and Slovic's fifth criterion is that products that become stigmatised also often have an unequal distribution across populations and/or geographic areas. Thalidomide and DES both had very unequal impact, only impacting on those who were pregnant and the children they carried while ingesting the drugs. Even within pregnancy Thalidomide was at its most devastating only when ingested during a short window of ten days. Thus, many women who took Thalidomide while pregnant suffered no harmful consequences, further perpetuating the perceived uneven distribution of harm. Furthermore, as well as being unequally distributed across populations, the Thalidomide regulatory failures also had an unequal geographic impact: occurring primarily in just a few jurisdictions – Germany, the

[28] Knightley and Times of London.
[29] Evans, "Thalidomide."

UK, Canada and Australia with other countries such as the USA and NZ both having relatively few cases. Similarly, DES has also had a very uneven impact both geographically and across populations, and like Thalidomide, DES only causes harmful effects in some of the children of women prescribed DES. DES daughters are 40 times as likely to develop the cancer clear cell adenocarcinoma and are also far more likely to get many other types of cancer or experience problems conceiving and carrying pregnancies to term.[30] As with Thalidomide, only some of the children of women who consumed DES will actually develop cancer and/or have reproductive difficulties. Because of the lag in the onset of symptoms and the identification of their cause, DES was prescribed over a much longer period of time than Thalidomide, thirty years from the 1940s until 1971 in comparison to the approximately five year window of Thalidomide (1956-1962). This makes the window of time in which people could become identified as victims of DES far broader and creates the perception of very uneven distribution. As with Thalidomide, the impact of DES has also been geographically uneven. DES was to a lesser degree prescribed in Australia, New Zealand, Canada and Europe, however the majority of DES prescriptions occurred in the USA – where the initial research for its use during pregnancy was conducted.

The sixth and final factor common among those products that develop a stigma is that the initial precipitating event should have an impact that is "unbounded in the sense that its magnitude and persistence over time is not well known."[31] Not only were many of the Thalidomide babies born with phocomelia and other serious disabilities, but over 50% of these children died by their fifth birthday. Furthermore, estimates of the number of people affected vary significantly. Within survivor networks and in popular discussion there continue to be ongoing fears of Thalidomide having harmful effects into a second generation.

[30] Swan, "Intrauterine Exposure to Diethylstilbestrol."
[31] Flynn, Slovic, and Kunreuther, *Risk, Media, and Stigma*, 5.

It is only in the last decade that the teratogenicity mechanism of Thalidomide has been identified and these fears begin to dissipate. Unlike Thalidomide where concerns about second generation impact are being laid to rest, the impact of DES – higher rates of cancers and reproductive issues – has been clearly identified in the second generation.[32] Furthermore the major impact of DES is an increased likelihood of cancer across people's entire life. Consequently, more so than Thalidomide, DES can be perceived to have apparently unbounded magnitude and scope. With Thalidomide, while only some children were impacted, it was immediately apparent either at birth or shortly after. In comparison DES daughters are in their 60s and still getting cancer at increased rates in comparison to the general population.[33]

The incidents involving DES and Thalidomide thus fit well within the model of stigma proposed by Flynn and Slovic in that: they involved products that were intended to benefit, but instead caused harm; included critical hazardous events; included strikingly memorable negative imagery; there was the perception of a failure of hazard management; they were unequally distributed across geographic areas and populations; and were unbounded in magnitude and persistence. Understanding the consequences of the Thalidomide and DES tragedies in terms of stigma is important for current efforts to increase the quality and quantity of research during pregnancy. This is because when a product or technology is stigmatised it produces a distorted perception of risk around that product or technology. In turn a distorted perception of risk during pregnancy is a major contributing factor to the pregnancy norm previously identified as problematic: inaction as precaution. Identifying the sources and causes of the stigma and the distorted perception of risk during pregnancy is an important step on the way to correcting the distortion and enabling increased

[32] Blatt et al., "Ovarian Carcinoma in an Adolescent with Transgenerational Exposure to Diethylstilbestrol"; Brouwers et al., "Hypospadias."
[33] Swan, "Intrauterine Exposure to Diethylstilbestrol."

research during pregnancy. So too is the link it provides to other stigmatised technologies where knowledge can be drawn from other attempts to correct the misperception of risk in the wake of stigma.

In a solo-authored article, Slovic argues that there are four ways that the adverse impacts of stigma can be minimized: preventing stigmatizing events, reducing perceived risk, reducing the social amplification of stigmatizing messages, and reducing the impacts o stigma.[34] Given the impossibility of preventing already realised stigmatising events, the reduction of both perceived risk and the social amplification of the stigmatizing message would seem the most useful to consider for pregnancy and pharmaceuticals. Improving these two factors would, in turn, lead to a reduction in the fourth factor: a reduction in the impact of the stigma. It is worth noting that, unlike in Slovic's proposal, with regards to consuming pharmaceuticals during pregnancy it is not a matter of reducing the perceived risk as much as modifying risk perception so that people can accurately evaluate the risks of both action and inaction. Stigma is however only one of the factors impeding research during pregnancy. While it is important to situate sections 6.2 and 6.3 within the stigma-risk perception framework, risk is far from the only source of the problem. The other concepts traced throughout this project of health, nature, responsibility and the fetus, also contribute significantly to the continued lack of research during pregnancy. It is the impact of the relationship of pregnancy to all five of the key concepts when considered collectively, that creates a discourse of pregnancy that impedes research.

The Thalidomide and DES tragedies were the precipitating factor in creating a stigma around pharmaceutical use during pregnancy and a key cause of distorted risk perception about how we ought to act and what is safe to consume during pregnancy. Framing pharmaceutical use during pregnancy in terms of stigma helps explain the social and

[34] Flynn, Slovic, and Kunreuther, *Risk, Media, and Stigma*, xiv.

psychological dynamics at play within the issue of risk perception around pregnancy. In addition, situating the Thalidomide and DES tragedies in terms of stigma explains how the norm of precaution during pregnancy mutated into the notion that inaction and avoidance are the safest choices during pregnancy. The harms of Thalidomide and DES struck unexpectedly and were the consequence of products thought to be safe. It is easy to see how the precautionary reaction to such an event would be that it was better to avoid everything that could possibly have a similar outcome until better comprehension of the issue and causes is reached. However, fifty years after the tragedies we have both an understanding of the biological and social mechanisms which caused the issues. We also have enacted institutional mechanisms to ensure that pharmaceuticals are only provided to pregnant women after an appropriate level of safety is established and when women and their clinicians have evaluated the benefits and risks of treatment.

5.4 Responsibility, health, nature and the fetus

The linking of stigma and the mid-century pharmaceutical tragedies highlights the role these events had in creating barriers to pharmaceutical research during pregnancy not just via the stigma and legacy of distorted risk perception but also directly via the policy changes discussed in 4.2. *Good reasons* for excluding pregnant women from participating in pharmaceutical research should be similar to reasons for excluding other populations from research studies: safety, and an accurate picture of possible risks vs. possible benefits. *Bad reasons* include inaccurate notions about the capacity of pregnant women for autonomy, false assumptions about the health needs of women during pregnancy, overly coercive narratives of ‘good’ maternity and responsibility, and legal and political spillover from abortion politics codifying particular understandings of the fetus. Many of these ‘bad’ reasons for the

exclusion of pregnant women from clinical research arise out of the historical discourse of pregnancy. To use Van der Zande's categories, they are 'reasons' mistakenly arising because of collective memory and social controversy. Instead, the discourse needs to shift to recognise biomedical research as a powerful site at which to enact broader social changes to the discourse of pregnancy and that changes need to be made in order to improve clinical research during pregnancy. The final two sections of my thesis attempt to do just this and start suggesting changes that can be enacted within biomedical research which may promote a discourse of pregnancy more conducive to research. This section however specifically highlights the aspects of the key narratives traced throughout this project that currently impede clinical research during pregnancy.

The five key ideas/narratives explored in this thesis all play a significant role in shaping how research policies are written, interpreted and used: situating pregnancy and research within the context of a genealogy of pregnancy presents not just a history of pregnancy but, as discussed in Chapter One, aims to highlight the context and contingency of the contemporary discourse of pregnancy. The genealogy has highlighted how and why some specific ideas and values are emphasised within the current discourse of pregnancy and pharmaceutical research and not others, and also what has been taken for granted or not considered at all. While over the last decade there has emerged a strong literature advocating the importance and value of including pregnant women in pregnancy research, less work has been done on what needs to be changed to promote further inclusion.[35] In the previous chapters I have made the case that the narratives circulating within and around the discourse of pregnancy produce particular ideas that serve to shape beliefs, policies and practices about what is acceptable, valuable, right, good, risky, normal, healthy and responsible during

[35] Baylis and Halperin, "Research Involving Pregnant Women"; Baylis and Ballantyne, *Clinical Research Involving Pregnant Women*.

pregnancy. This section draws together the diverse historical content of the previous chapters in order to discuss the most relevant aspects of each key idea for the contemporary problem of pharmaceutical research during pregnancy.

Responsibility

As discussed in the previous sections, risk is the most overtly influential of the five narratives being considered in this project. However, I cannot emphasise enough the importance of narratives of reproductive responsibility in setting the norms about the acceptability and possibility of pharmaceutical research during pregnancy. As Loften argues "there are few things as imperative in contemporary Western society as right parenting decisions" a statement that holds as true in 1916 as in 2016 when she wrote it.[36] Throughout Chapters Three and Four I chart a key transition in reproductive discourse within the twentieth century, a shift in the narrative of responsibility for reproduction, one that is also often characterised as the rise of 'intensive parenting'. This trend is exemplified by the 1980s popularity of pregnancy self-help books and guides that emphasise the maternal role, and maternal responsibility, in having the best and healthiest pregnancy.[37] By the end of the twentieth century the phenomenon of 'intensive parenting' is well documented: a "good middle-class mothering required an unprecedented amount of time, energy, and financial resources to meet an expanding list of children's needs."[38] What this project seeks to emphasise is that a key driver behind this practical shift in parenting style was the strengthening of a particular narrative of maternal responsibility: good mothers did these things for their children because that is what was required of them to have successful children. While most often this phenomenon plays out during childhood, the narrative pressure to be a responsible mother – to do all the things that are best for your child – starts

[36] Lofton, "Religion and the Authority in American Parenting," 807.
[37] Hays, *The Cultural Contradictions of Motherhood*.
[38] Wall, "Mothers' Experiences with Intensive Parenting and Brain Development Discourse."

before birth. As also highlighted in the genealogical chapters, the rise of intensive parenting was also supported by changing patterns of reproduction: contraception and delayed and chosen maternity, smaller family sizes and increased governmental investment, oversight, regulation and support into ensuring that subjects reproduced 'well.'[39]

It is important to therefore keep in mind the way in which decisions around the participation of pregnant women in pharmaceutical research are also decisions about parenting and women wanting to do the best by their child by acting as a (responsible) good parent. Particular cultural narratives of responsible maternity play out in different ways in line with ethnic and class norms; however, what is shared across all groups is the strength of force of the narrative. The depth of the influence of expectations of 'maternal responsibility' in governing the choices and behaviours of everyone in society (not just pregnant women) is what needs to be emphasised. According to the Canadian guidelines for ethical research, the TCPS 2, part of being a responsible researcher is being "familiar with the cultural, social and economic circumstances of prospective participants, groups or communities."[40] Thus there is an obligation on the part of researchers, policymakers, and ethics boards to understand some of the key social forces that influence people's decision making processes. I therefore argue that when dealing with research involving pregnant women this needs to include a broad comprehension of the narrative strength of maternal responsibility and the way this plays out in the pressure to be a good mother: "parents are now understood – by policymakers, parenting experts, and parents themselves – as 'God-like', and wholly deterministic in an individual child's development and future."[41] This understanding of parenting and the particular expectations about maternal responsibility that constitutes and drives it is a key social norm impacting research during pregnancy.

[39] Where 'well' connotes ensuring fetal and child health through responsible parental choices.
[40] Canadian Institutes of Health Research, Social Sciences and Humanities Research Council of Canada, and Natural Sciences and Engineering Research Council of Canada, "TCPS2," sec. 4.7.
[41] Faircloth, "Intensive Parenting and the Expansion of Parenting," 24.

Closely linked to the narrative of maternal responsibility is another narrative traced throughout this project – the increasing value placed by governance structures upon ensuring reproduction via mechanisms of 'health'. Pregnancy and reproduction have always been highly socially valued activities, deemed worthy of additional resources, considerations and allowances; however, in the early twentieth century the value of reproduction to the state – both economic and otherwise – became apparent and mechanisms of governance increasingly contributed to the discourse. Two insights drawn from the genealogy about governance structures and health are important for reconsidering the context of clinical research and pregnancy. First, the targeting of reproduction as a site of economic and social investment has made pregnancy a highly regulated space. Second, narratives produced within governance structures are particularly powerful in their discursive influence. Thus, stakeholders researching and regulating clinical research during pregnancy need to be aware of how their work is producing, and reproducing, an authoritative narrative of pregnancy. In what they research, how they interact with and portray research participants, regulators, research ethics boards and researchers are making statements that will have an impact upon the discourse of pregnancy.

I also highlight these points to draw attention to the ratcheting up effect this 'governance interest' has had upon 'maternal responsibility'. While most discussion within this chapter centers upon the key ideas of risk and responsibility, the other concepts are also in play shaping the discourse of pregnancy just in less overt roles. Risk and responsibility are simply the dominant frames by which pregnancy is engaged with in clinical research: the discourses of safety-benefit (risk) and autonomy/free choice (responsibility) are simply overwhelmingly dominant within health research. These are the two strands that primarily define the acceptability of research: is it safe? Is it chosen? The other key concepts discussed throughout this project – health, nature and the fetus, are also present.

Health and Nature

The concept of health sits behind the entire intersection of the discourses of pregnancy and clinical research, structuring, defining and driving the entire system of interpretation of the relationship. In the current moment, 'health' is conceived of as a social and political good/right, something that states are obliged to support people in achieving.[42] The governance obligation to support and improve health provides impetus for continued clinical research which has been settled upon as the best way to increase the effectiveness and efficiency of healthcare. Via its dynamic relationship to 'nature,' 'health' sets up the possibility for clinical research as 'health' and 'nature' are two of the key narratives that set the boundaries of what is defined, or not, as healthy-natural or as symptoms-sickness-disease-disorder – and thus what gets researched, or not. The narrative of the nature-naturalness of pregnancy itself is also at play within this dynamic in laying out the expectations around clinical research and pregnancy.[43] As it does in relation to health, narratives of nature-naturalness set up what is normal and acceptable during pregnancy and what is not. In turn what is normal and acceptable during pregnancy sets the baselines for 'harm' and 'risk,' and thus the way in which various disorders and complications of pregnancy are prioritised for treatment and clinical research.

[42] United Nations General Assembly, "The Universal Declaration of Human Rights."

[43] The concept of "wellness", a close parallel use to that of "health" and "nature", has been discussed extensively in the context of biopower due to the widespread proliferation of corporate wellness programs. There is an extensive commentary around both the biopolitical functioning of such wellness programs and how they shift the onus of work, responsibility and obligation onto individual people to ensure their wellness in the corporate context, as a mechanism to save corporations costs, and to increase their efficiency with minimal corporate effort. The structural logic by which responsibility and obligation for health/wellness is placed upon pregnant women parallels that of workers in corporate wellness projects. However, the concept of wellness is seldom mobilised in the context of pregnancy and the unique nature of pregnancy as "natural" and a site of health/wellness makes it easier to discuss in terms of health and nature rather than wellness.
Interestingly in the last few years another related concept - *wellbeing* - has come to the fore in accountability structures associated with governments where there is an expectation to ensure that government spending supports not just GDP but a host of social and environmental measures. For more detailed discussion of these links see Weijers and Morrison, "Wellbeing and Public Policy"; Nadesan, *Governmentality, Biopower, and Everyday Life*; Hull and Pasquale, "Toward a Critical Theory of Corporate Wellness."

'Health' is also increasingly something that individuals are expected to maintain via adopting particular lifestyle choices such as diet changes, exercise and activities that support mental wellbeing. This creates a wider cultural narrative of responsibility for health. Interventional research into effective education and support methods for lifestyle changes has increasingly become central to achieving and maintaining individuals' overall health and this new area of clinical research has had an impact upon the overall discourse of 'health'. This has had a complicated impact upon the discourse of pregnancy, the most relevant being how obesity, excessive gestational weight gain and diabetes – which are to differing degrees common 'lifestyle related' complications of pregnancy – are increasingly regarded as a matter of personal responsibility.

The fetus

The fetus is perhaps the most conflicted and overtly political of the five concepts I have identified as key contributors to the discourse of pregnancy. As discussed in Chapters Two through Four, medical advances such as safe caesarians, fetal imaging, fetal surgery and increased survival rates for younger and younger babies born early have all contributed to the idea of the fetal patient and a shift in the relative values of the pregnant woman and fetus. Today, a host of common fetal disorders can be both identified and treated before birth and there is rarely the need to choose between saving a pregnant woman or her fetus. Clinical research during pregnancy today includes not just studies designed to improve or manage the health of pregnant women but also protocols where fetuses are the target of a health intervention. Collectively these developments have increased expectations of fetal wellbeing and shifted what constitutes the 'minimal risk': a key notion in setting the permissibility for an avenue of research, and defined as "the probability and magnitude of harms implied by participation is no greater than those encountered by participants in those aspects of their

everyday life that relate to the research."[44] As I have established in the genealogy, prior to the twentieth century rates of mortality and morbidity for both pregnant women and fetuses were much higher than they are in high income countries today. The everyday risks were much higher and thus so was 'minimal risk.' In this sense pregnancy is part of a wider shift towards improved health across all populations. What was unique to pregnancy is that this transformation, and the corresponding medical breakthroughs, overwhelmingly strengthened within medical discourse the narrative of saving both mother and fetus. No longer was there a requirement to choose between one and the other except under increasingly rare circumstances.

Another key avenue by which narratives of the fetus influence clinical research during pregnancy is via abortion discourse. The USA, with its extreme focus upon, and rhetoric around, abortion, sets the international tone of narratives of the fetus. The USA is a major centre for pharmaceutical research and the ongoing, increasingly polarised, high profile debates around abortion have spilled over into clinical research during pregnancy in a number of ways. Most obviously they influence how, and whether, both research guidelines and stakeholders provide for abortion when fetal defects are detected. This divisive debate over abortion has also acted as a touchstone for political mobilisation by Christian Conservatives in the USA at all levels of government, both directly influencing US policies touching on the fetus and also by strengthening narratives with an extremely narrow view of who and how people should reproduce.[45] The narrative of the fetus promoted by this particular brand of Christian conservatives – that a fetus is equally (or more) valuable than a pregnant woman – is extreme. Christian conservatives also tend towards fatalism about overcoming ill health – a

[44] Canadian Institutes of Health Research, Social Sciences and Humanities Research Council of Canada, and Natural Sciences and Engineering Research Council of Canada, "TCPS2," sec. 2B.
[45] Lewis, *The Rights Turn in Conservative Christian Politics*, 96–98; Jimenez, "The Impact of the Conservative Protestant Movement on Social Policy"; Burack, "Keeping Government out of My Medicare and in Her Uterus."

return to the earlier discourse of disease and health discussed in 3.2 – further complicating how research into both maternal and fetal ill-health are viewed and valued.

The possibility of Christian conservative narratives of the fetus to arise and become a dominant stream within reproductive discourse is explained in part by the social and political developments discussed in the genealogy. The wider Christian conservative discourse of reproduction is a successor to the eugenic discourse with their shared emphasis upon reproducing the right sort of people – it has mutated into a new and still highly racialized account about who, how and why certain people should and should not reproduce. The Christian conservative movement has been widely influential in US and international policy in issues such as abortion and contraception. Here their political power has tied accommodation for their particular views on abortion and contraception to funding for both health care and health research. The narrative of the fetus promoted by Christian conservatives is extreme, yet potent in effect when combined with other shifts in fetal discourse and has had an influence upon both the fetal narratives incorporated in clinical research policies and the way in which people who are not Christian conservatives think about and value the fetus.[46]

Each of the five narratives I have identified plays a greater or lesser role in shaping the practice and regulation of clinical research during pregnancy. As was seen in the genealogy, they tend to function in particular clusters or collectives depending on the aspect of the discourse being considered. The importance of risk is in part that it is almost always in play working with each of health, responsibility and the fetus to shape their functioning. In

[46] Expression of Christian conservative valuing of the fetus is by no means straightforward or linear in its relationship to pharmaceutical research during pregnancy. Christian conservatives will often provide social and financial assistance to women to support them to not abort. However, they still often oppose research involving pregnant women, that would likely support the health of women and their fetuses, on the grounds of risk to the fetus and the potential chance that it will lead to fetal death or disfigurement and thus more likelihood of abortion. A common feature of both scenarios however is that the fetal rights concept is often being mobilised by Christian conservatives in contexts that override or diminish the autonomy of pregnant women rather than enhance it, in line with the wider Christian patriarchy ideology prevalent in American evangelical Christians.

contrast, nature is the least prominent concept functioning within the discourse of pregnancy, often only functioning within the same narrative moment as health. The most dominant clusters are risk-health and risk-responsibility/-fetus. Within the theme of collective memory and social controversy stigma/ risk perception is the most significant feature that is inhibiting clinical research during pregnancy. The second most important feature arising out of the discussion of the five key concepts is the current narrative of maternal responsibility/good mothering (as tied to the fetus and risk) that also make a significant contribution to inhibiting pharmaceutical research during pregnancy. The value of exploring each of the other concepts within the genealogy primarily lies in explicating how they interact with these two. Understanding how and why we have the current ideas of health, nature and the fetus assists in denaturalising and contextualising the current discourse of pregnancy. Understanding the history of how these concepts have been mobilised in relation to pregnancy explains how current ideas centered upon risk and responsibility inhibit pharmaceutical research during pregnancy.

SIX: Pregnant women and pharmaceutical research

> There remains an unhealthy reluctance to involve pregnant women in clinical trials, a legacy of decades.
>
> Foulkes, *Clinical Research Enrolling Pregnant Women*

Clinical research during pregnancy is inhibited by tensions within and between the five key concepts traced in this project – risk, health, nature, responsibility and the fetus. Within specific guidance documents countering, minimising or eliminating particular problematic instantiations of narratives can sometimes be effective – as demonstrated with the example of vulnerability. However, the five ideas traced by this project are central within the discourse of pregnancy and need to coexist in order to accurately represent pregnancy as it is understood today, for instance as an event that is simultaneously risky but also healthy and natural. Likewise, the idea of responsibility is tied up in supporting autonomy which is an important ethical value core to informed consent and closely associated with personhood, dignity and liberty also.

Pregnancy *is* a natural and normal part of life, thus *healthy.* However, pregnancy often comes with extra health complications – sometimes minor, sometimes serious. Things can and do go wrong during pregnancy at a greater rate than for other adults in the same age range. Pregnancy is thus risky and consequently additional monitoring by health professionals is recommended as standard practice for all pregnancies, because, as discussed in 4.4, in the modern era many of the health complications arising during pregnancy can be managed or resolved if caught early. Rather than eliminate particular 'problematic' narratives, policies, procedures and guidelines need to accept and support the balance of tensions within and between the five narratives.

6.1 Health guidance documents

The discourse of pregnancy, particularly in the context of health research, thus needs to incorporate all five narratives. This section explores current policies and other guidance documents about pregnancy, particularly those focused upon research during pregnancy. It reflects upon the role played within these documents by the five key narratives explored in this project: risk, health, nature, responsibility and the fetus - and examines how the reform of pharmaceutical research during pregnancy is complicated by the need to balance the value added to the discourse of pregnancy by each of the five narratives. I aim to highlight how the five key ideas are balanced within current research guidance documents pertaining to pregnancy. Overall, I want to emphasise that while careful policy writing is important, it is limited as a tool for improving clinical research during pregnancy. This is because of the influence of the pre-existing stigma about pharmaceutical consumption during pregnancy and the overall human cognitive bias towards perceiving inaction as precaution in producing perceptions of risk and responsibility during pregnancy. It is also of limited effect because of the strength and social forcefulness of narratives of good and responsible mothering. Refinements to the way in which research guidance documents are written can support a discourse of pregnancy more conducive to clinical research, as will be seen in the case of vulnerability where it has been possible to remove reference to vulnerability in the context of pregnancy entirely. However, the key concepts I have focused upon – particularly risk and responsibility – are central and necessary within clinical research and thus must be retained. Where the discussion of vulnerability will indicate how research guidance documents can be modified to more effectively encourage clinical research during pregnancy, this section highlights the limits of such an approach.

Pregnancy needs to be represented as healthy and natural not only within policy documents; to do otherwise invites additional anxiety and potential over-medicalization. However, often within the same document, pregnancy also needs to be represented as risky to indicate it as a time when increased monitoring and screening is appropriate and when it is normal to require extra medical interventions including pharmaceuticals. Medical depictions of pregnancy thus need to represent three narratives – health, nature, and risk – in balance.[1] At the very least authors and authorities need to consider how they present the balance of these three key norms which are so influential upon readers in shaping our experience of pregnancy. Texts mindful of this balance can be seen in many online health portals providing guidance about pregnancy:

> The healthier you are in pregnancy the healthier your baby is likely to be…The majority of women have normal, uncomplicated pregnancies and deliveries. However your LMC [lead maternity carer] will be watchful for pregnancy complications, including gestational diabetes and high blood pressure.[2]

> Your body has a great deal to do during pregnancy. Sometimes the changes taking place will cause irritation or discomfort, and on occasions they may seem quite alarming. There is rarely any need for alarm, but you should mention anything that is worrying you to your maternity team… During your pregnancy, you'll be offered a range of tests, including blood tests and ultrasound baby scans. These tests are designed to help make your pregnancy safer, check and assess the development and wellbeing of you and your baby, and screen for particular conditions. [3]

These examples are taken from the official pregnancy guidance of two different countries, NZ and the UK, and are specifically targeted to the general population rather than healthcare providers. They show balance between the different aspects of pregnancy, as natural-normal-healthy while simultaneously also presenting as normal the attitude towards risk during pregnancy represented by the extra precautions of medical attention, screening and

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[1]

[2] Auckland District Health Board, "Maternity Services – Information about Diabetes and High Blood Pressure during Pregnancy."

[3] National Health Service (NHS) UK, "Common Pregnancy Problems - Pregnancy and Baby Guide - NHS Choices."

monitoring that is routine during pregnancy within high income countries. Each site attempts to balance presenting the 'normal everyday' side effects and symptoms of pregnancy and how to mitigate them, with sections on 'the danger signs' and 'when to seek help' to provide advice and support for when things go seriously wrong. Similarly they balance explaining why screening for various maternal and fetal conditions is both low risk and important while still supporting and informing women with positive or uncertain screening outcomes via links to more detailed information: "If antenatal screening tests find a possible problem."[4] The public face of pregnancy guidance is especially mindful about representing the different facets of pregnancy and of maintaining a balance between the healthy-natural and risky-intervention narratives.

Similarly, the 2016 edition of the CIOMS regulations governing health research is extremely careful in how they represent pregnancy, and overall very conducive to narratives that encourage research during pregnancy. The commentary to Guideline 19 goes as far as to detail the complex history of pregnant women and research and then clearly outline negative consequences of excluding pregnant women from research. Guideline 19 requires that when there is no potential individual benefit for a pregnant woman or her fetus the risks of research participation must be minimal. If the research must be done on pregnant women and the social value of research is particularly compelling then a small increase above minimal risk is deemed permissible.[5] Minimal risk is defined as either comparable to the risks experienced in daily life or during routine physical and psychological examination with a caveat that it is the everyday life or routine examination of a healthy adult not the population being studied.[6] The CIOMS guidelines are the highest level international guidelines available focused upon clinical research and produced under the joint umbrella of the UN and WHO alongside many

[4] National Health Service (NHS) UK.
[5] Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Health-Related Research Involving Humans. Fourth Edition," 71.
[6] 12; Kopelman, "Minimal Risk as an International Ethical Standard in Research," 354–57.

national and international professional medical bodies. They are also linked to further guidance by many national level health research groups. I would argue that they set the overall standard for clinical research regulations and represent best practice. In coming decades, as individual countries update their clinical research guidelines, I expect that they will come into line with the CIOMS guidelines.

The Guideline goes on to state that when there is no expectation of personal benefit from research participation there is a difference in the degree of risk permitted in regard to pregnant women as opposed to non-pregnant consenting adults – the risks must be *minimal* rather than *minimised*. While this different standard for research that won't benefit pregnant women or their fetus is questionable, it is unlikely to impede efforts to improve either healthcare equity or rates of research during pregnancy in the short to medium term as very few studies conducted during pregnancy are not either of potential benefit or minimal risk. The minimal or near minimal risk requirement is a reasonable response to the heightened pharmacokinetic and pharmacodynamic uncertainty about pharmaceuticals during pregnancy.

There are only two potential impacts arising out of the difference between the minimal risk that pregnant and minimised risk that non-pregnant individuals are permitted within the CIOMS guideline 19. First it potentially limits the study design options for any given research question. While there is never only one study design that can provide good quality healthcare information, restrictions such as the one in guideline 19 of CIOMS can make information gathering more expensive, slow, resource intensive and only provide lower degrees of certainty or narrower applicability.[7] All of these features can delay improvements in the provision of healthcare for a population and progress towards health equity, and when

[7] The requirement that pregnant women or their fetus benefit or the research may only be minimal (a level comparable to the exposures that arise through everyday life) limits the options for clinical study design in a number of ways, for instance by precluding certain study designs. The more restrictive risk profile that is acceptable also would likely require a higher level of monitoring of individuals involved in the study and tighter compliance practices. The overlapping requirement of pregnancy and a specific disorder is a low frequency event thus it may take years to build a sample size large enough to determine a finding from a study.

dealing with a population such as pregnant women, who are already relatively underserved, then this is a potential issue to keep in mind. Second the difference between minimal and minimised risk potentially reinforces the norm that pregnant women are somehow less able to make responsible choices and have less autonomy than non-pregnant people as they are not able to choose for themselves whether a higher level of risk is acceptable. Alternatively, it assumes that they will not or presumes they should not be offered high risk interventions which is also problematic and paternalistic. However, the potential likelihood of such narrative reinforcement is greatly reduced by the detailed commentary countering such assumptions and instead emphasising the need for additional care in research during pregnancy because of the heightened physical-medical risks during pregnancy. The difference between the focus of the different phases of pharmaceutical research, most notably Phase I – which has a safety focus, and phase II and III's effectiveness focus - should be highlighted here. I am not making the case for inclusion of pregnant women in the initial Phase I phase where the overall safety of a pharmaceutical is being established; rather that the safety of a pharmaceutical for use during pregnancy be determined once initial safety assessment, and perhaps even preliminary effectiveness, have been established in the non pregnant population.

As discussed in 4.2, when there is an expected benefit to pregnant women or their fetus, the 2016 CIOMS guidelines require that the risks of participation not outweigh the potential individual benefits. This is the same risk-benefit ratio considered acceptable for all adults capable of informed consent. However, there is an additional caveat for research during pregnancy:

> Research in pregnant and breastfeeding women must be initiated only after careful consideration of the best available data from preclinical research in pregnant animal

> models, research in non-pregnant women, retrospective observational studies, and pregnancy registries.[8]

This is a far more precise outline of the permissible balance of risks and benefits than in the earlier 2002 guidelines. This increase in detail is likely a response to the high level of uncertainty and widespread variability over acceptable levels of risk during pregnancy that has been documented within ethics review boards.[9]

The additional caveat draws specific attention to the role that, in practice, observational studies and registries can play in clinical research during pregnancy, emphasising both the value of such information and the gathering methods themselves. However, it is worth noting that because of the significant lack of pharmaceuticals approved for use during pregnancy highlighting the role of retrospective observational studies and registries assumes, and possibly tacitly endorses, off label drug prescription. As I outlined in the introduction these registers imply that women are being prescribed pharmaceuticals during pregnancy in situations where there ares no best practice guidelines around safe and effective dosage – an injustice that should not be promoted as a long term solution.

In contrast, a similar discussion in relation to non-pregnant adult research subjects makes no mention of observational studies or registries, only preclinical and early phase studies. Furthermore, the caveat supports a narrative of the heightened social value of pregnancy via its requirement that research on pregnant women come after studies in non-pregnant populations in order to minimise risk. This is not necessarily a problematic narrative to reinforce, and a reasonable precaution given the heightened complexity of drug reactions

[8] Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Health-Related Research Involving Humans. Fourth Edition," sec. 19.
[9] Ells and Lyster, "Research Ethics Review of Drug Trials Targeting Medical Conditions of Pregnant Women"; Ballantyne, "New Zealand Needs Guidelines for the Safe and Responsible Inclusion of Pregnant Women in Medical Research."

during pregnancy. However, it provides yet another example of how policies can and do implicitly reflect and reinforce the high social value of reproduction.[10]

Vulnerability

The most illuminative discourse for understanding how guidelines can be modified to be conducive to supporting research during pregnancy is the discourse of vulnerability. Until the late 2000s pregnant women have been included as a vulnerable population in all the key medical research guidance documents discussed in this project. As discussed in 4.2, beginning in the 1970s as part of the response to the Thalidomide and DES tragedies most research policies and guidelines grouped pregnant women, alongside children and prisoners, as 'a vulnerable population' worthy of special protections during research participation.[11] However unlike the other groups, pregnant women have the capability to give an informed consent to participate in research because they can recognise that they face increased risk. In contrast neither children nor prisoners can provide free informed consent because of respective concerns for capacity and coercion. In many jurisdictions this definition of 'vulnerable' eventually expanded to include people with intellectual disabilities and even students – any group who was perceived to either lack capacity or to be potentially coerced. By the early 2000s it became increasingly apparent that assigning pregnant women the status of a vulnerable population, given current definitions and use of 'vulnerable' in research was

[10] Even when such policies are a reasonable response to the more complex safety assessment required of pharmaceuticals during pregnancy.
[11] US Department of Health and Human Services and Food and Drug Administration, "Guidance for Industry General Considerations for the Clinical Evaluation of Drugs."

problematic.[12] By the decade's end, the consensus was that there was a serious problem conflating pregnant women with other vulnerable populations for whom there are issues of coercion and capacity around consent for research participation.[13]

Over the last decade 'vulnerability' has been purposefully removed from many policies governing research during pregnancy because of the way it clashes with the more valuable narratives of responsibility and autonomy. Removing pregnant women from the list of vulnerable research populations and finding alternative methods to indicate the increased risks associated with research during pregnancy is a first step to improving rates of research during pregnancy. Separating vulnerability from pregnancy in research policies decreases the circulation of a particularly problematic narrative of reduced capacity for consent and autonomy during pregnancy: a particularly problematic iteration of the narrative of responsibility. Furthermore it also reduces the likelihood of continued confusion for researchers and ethics review committees about the permissibility of more-than-minimal-risk research during pregnancy.[14] This section briefly outlines first the problem of labelling pregnant women a vulnerable population and then outlines current usage of vulnerability with regards to pregnancy and research in the guidance documents literature highlighting the new emphasis within CIOMS 2016 Guidelines and TCPS2 on ensuring groups such as pregnant women have access to the benefits of research participation.

Pregnant women have been historically included as a vulnerable population because they face more extensive risks in research participation than many other populations. As discussed in the introduction, part of the issue is the constantly changing physiological

[12] Weijer, "Research Involving the Vulnerable Sick"; Macklin, "Bioethics, Vulnerability, and Protection"; Levine et al., "The Limitations of 'Vulnerability' as a Protection for Human Research Participants"; Kottow, "The Vulnerable and the Susceptible"; Kottow, "Vulnerability."
[13] Wild, "How Are Pregnant Women Vulnerable Research Participants?"; DuBois et al., "Restoring Balance"; Rogers, Mackenzie, and Dodds, "Why Bioethics Needs a Concept of Vulnerability"; Schonfeld, "The Perils of Protection."
[14] Ells and Lyster, "Research Ethics Review of Drug Trials Targeting Medical Conditions of Pregnant Women."

complexity that characterises pregnancy and differing pharmacokinetic and pharmacodynamics profiles from the non-pregnant population. While pregnant women face unique risks when agreeing to become research subjects there is nothing arising out of pregnancy that makes pregnant women less able to evaluate these potential risks and benefits for themselves and their fetus – they have the capacity. Similarly, there is nothing specific to being pregnant that makes it a coercive situation.[15] While pregnant women face additional risks when participating in medical research that the non-pregnant do not, they are not 'vulnerable' in the same manner as other 'vulnerable' populations – pregnant women have the capacity for informed consent and are not in coercive circumstances. Labeling pregnant women vulnerable in research documentation reinforces a discourse of pregnancy unconducive to research during pregnancy in that it supports narratives of pregnant women as lacking the capacity for making decisions and as thus unable to take responsibility. However, this is not to say that pregnancy is never a vulnerable time, rather that the association in this particular context reinforces incorrect narratives of the capacity and autonomy of pregnant women – depicting them as less able to make 'good' choices and be responsible.[16] Paradoxically it is treating and depicting pregnant women as less able to make such choices and be responsible that can make pregnant women more vulnerable by undermining both the self-trust, and the trust of other people, that pregnant women can make good decisions.

The impact of being presumed 'less able' or less autonomous, less capable than non-pregnant people has the potential to expand into narratives of pregnant women's decision making capacity in other aspects of their medical and social lives. The cases where baristas

[15] I will argue in the following paragraph that potentially a form of social coercion may be in play during pregnancy, but it arises out of pressure from wider social narratives of responsible maternity rather than the power imbalances within interpersonal interactions as with prisoners and students.
[16] Rogers, Mackenzie, and Dodds, "Why Bioethics Needs a Concept of Vulnerability"; Ballantyne and Rogers, "Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research"; Rogers and Lange, "Rethinking the Vulnerability of Minority Populations in Research."

and bartenders refuse to serve pregnant women alcoholic or caffeinated drinks can be considered in relation to the autonomous capacity of pregnant women.[17] While those refusing to serve pregnant women probably do not consider their refusal to serve as making assumptions about the autonomy of pregnant women, instead framing it as a concern about the health of the fetus, it nevertheless is. It is worth noting how the discourse of pregnancy supports the acceptability of other people intervening in the decision making of pregnant women when it is unacceptable in regard to other groups of people (who are not intoxicated).

Research on vulnerable populations has additional barriers and safeguards to ensure the safety and protection of such research populations. The inclusion of pregnant women as a vulnerable research population directly contributed to low rates of research during pregnancy, and removing the inaccurately cast safety net of vulnerability from pregnancy will improve research during pregnancy in the future. Eliminating links between vulnerability and pregnancy in clinical research guidance documents supports improved rates of pharmaceutical research during pregnancy and improves healthcare equity for pregnant women. Although individual pregnant women, like members of any other cohort, can be vulnerable in one or more of the ways identified above, these individual vulnerabilities do not transfer to the population of pregnant women as a whole.[18] It is possible that pregnant women as a group could be deemed *socially* vulnerable because "patriarchal social structures have historically and systematically excluded women from those aspects of society that are

[17] Smith, "Pregnancy Police"; McPhate, "Bartenders Can't Refuse Pregnant Women Alcohol, New York City Says"; Millard, "I'm Pregnant -- Just Serve Me Some Coffee And No One Gets Hurt"; Marsden, "Pregnant Woman 'humiliated' by Barman's Refusal to Serve Her Glass of Wine."

[18] Two options seem to present themselves: either vulnerability should be redefined so as to be capable of including pregnant women, or we should accept that pregnant women are not a vulnerable population. If we consider the previously discussed concerns over the current perception of risk during pregnancy, then there is an additional reason for disassociating pregnancy from vulnerability. The labelling of pregnant women as a vulnerable population perpetuates a stereotype about pregnant women as less able than "normal" people. Examining how vulnerability is defined and applied in medical research policy provides a clear example of how a social structure – legislation about biomedical research – influences both what pregnant women regard as good decisions about their lives and also the wider social perception of what is right and good during pregnancy.

responsible for leadership, policy formation, resource allocation and decision making."[19] As often argued in contemporary equality discussions, it is not only important that members of traditionally excluded groups participate in high status work and governance endeavours but that representations of them doing so circulate. Discursive representation – a narrative contribution to discourse – is as important to long term equality efforts as voice. In this way pregnant women could be socially vulnerable via narratives of misrepresentation of their capacity, and the subsequent internalisation and continued expression of such narratives by pregnant women, those they interact with, and as expressed in guidance documents and policies concerned with pregnancy. Such narratives can however be countered by ensuring representation of pregnant women as capable individuals.

While the issue with capacity is centered upon misrepresentation, I argue there is more potential for concern centered upon a weak type of coercion.[20] As discussed in Chapters Three and Four, over the twentieth century there has been a strengthening narrative of maternal responsibility for ensuring 'good' reproductive outcomes – both in ensuring health during pregnancy and wider child development. However, this narrative is a particular iteration of a 'toxic maternity' harmful in its coercive potential to influence the choices in ways counter to the interests of pregnant women.[21] This narrative intersects with vulnerability to undermine the narrative of pregnant women as capable decision makers in a complex manner – both reducing perception of the capacity while strengthening expectations of responsibility (and correspondingly, blame).

[19] Travers and Bennet, "Aids, Women and Power," 64.
[20] It arises out of pressure from a perception of general social expectation around what constitutes maternal responsibility rather than the power imbalances within interpersonal interactions as with prisoners and students.
[21] Kupers, "Toxic Masculinity as a Barrier to Mental Health Treatment in Prison," 716–19; Ramírez, "'What You Do to Children Matters'"; Radstone, "Social Bonds and Psychical Order." Drawing on Kimmels' landmark work on masculinity Kupers develops an account of toxic masculinity as the harmful aspects of hegemonic masculinity that promote problematic behaviours. This is the theoretical basis for the smaller literature on toxic maternity.

A similar concern has been raised by Lyerly regarding the historic circumstances that produced contemporary norms about risk and pregnancy. She argues that the historical beliefs that circulated about pregnant women continue to influence the current beliefs of 'society in general' as well as individuals regarding the capabilities of pregnant women. Thus, not only could these beliefs discourage pregnant women from participating in research trials because of misperceptions about safety and appropriate behaviours, but pregnant woman who do agree to be research subjects could face social condemnation not just from the public but also within the biomedical professions. [22] This speaks to the many points of the perpetuation of narratives about risk and responsibility with regards to pregnancy within the biomedical sphere: resistance in creating pharmaceutical trials that include pregnant women, research ethics boards in giving protocols ethics approval, and medical staff in enrolling research participants. This theme will be returned to in the following section when I discuss stakeholder engagement. The labeling of pregnant women as vulnerable within research guidance documents is just one pertinent example of the role of social structures in shaping narratives of pregnancy.

The well-intentioned attempts within research guidelines to protect *vulnerable* populations, whose memberships are perceived as at greater risk or less able to protect their own interests – prisoners, old people, women, poor people and children, – have, until recent years, discouraged research on these populations. An attempt to protect people less able to protect themselves from being unfairly burdened with research has also closed off access to the benefits of research and worsened healthcare equity. The health benefits to populations participating in clinical research trials are undeniable: an increased likelihood of recovery, and knowledge about the dose ranges, safety, efficacy and feasibility of drugs.[23] Recent

[22] Lyerly et al., "Risk and the Pregnant Body"; Lyerly et al., "Risks, Values, and Decision Making Surrounding Pregnancy."
[23] Lippman, *The Inclusion of Women in Clinical Trials*, 9; Lyerly, Little, and Faden, "The Second Wave."

updates to guidelines such as CIOMS and TCPS2 have thus developed more sophisticated accounts of the importance of fair access to research participation that emphasise appropriate and inappropriate use of 'vulnerability' and its relationship to the key notions explored in this project.

In light of the shifting consensus within bioethics about pregnancy and research vulnerability, the most recent updates of major policy documents, including CIOMS and TCPS2 have been revised to explicitly exclude pregnant women from being categorised as a vulnerable research population, and often include commentary explaining why. Prior to 2010 analysis of international policies and guidelines show few explicit definitions of vulnerability. Instead, as I said in Chapter Four, readers are left to assume the sources of said vulnerability from a definition drawn from who is defined as vulnerable.[24] Between the 2002 and 2016 updates of the CIOMS guidelines, the definition of vulnerability was radically redrawn to include a more complex and nuanced discussion of vulnerability that was in line with recent developments in the academic discourse. This included specific attention to the reasons people were vulnerable within the context of research, as not able to protect their own interests for

> innate reasons or because of particular features of their circumstances including when people are marginalized, stigmatized, or face social exclusion or prejudice that increases the likelihood that others place their interests at risk, whether intentionally or unintentionally.[25]

Similarly, TCPS2 has an updated definition of vulnerability as

> A diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited decision-making capacity or limited access to social goods, such as rights, opportunities and power.

In 2002 the focus of CIOMS guideline 13 *Research involving vulnerable persons* emphasises the vulnerable as classes of people who lack capacity and resources to protect their interests,

[24] Bracken-Roche et al., "The Concept of 'Vulnerability' in Research Ethics."
[25] Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Biomedical Research Involving Human Subjects," 2002.

or who would struggle to protect their own interests. By 2016 CIOMS Guideline 15 *research involving vulnerable persons and groups* lays out the more sophisticated understanding of vulnerability that had developed in the intervening years as involving "judgments about both the probability and degree of physical, psychological, or social harm, as well as a greater susceptibility to deception or having confidentiality breached."[26]

The refining of 'vulnerability' as a category within biomedical research guidelines over the last 10 years has been driven by recognition of the role it has played in distributing the benefits of health research: "Equity in the distribution of the benefits of research requires that research not disproportionately focus on the health needs of a limited class of people."[27] In response to the research scandals of the mid twentieth century, the focus of initial editions of research guidelines was on protecting 'the vulnerable' from the burdens of health research. By the 2000s the impact of such protection had become apparent and guidelines began to emphasise the health inequities that resulted from such 'protections'. While the 2002 CIOMS Guideline provides vulnerability as an example of reasonable cause precluding participation (Guideline 8), in contrast the 2012 NZ Guidelines (4.5, 5.26-5.27), the 2014 Canadian TCPS (Chapter four) and the 2016 CIOMS Guidelines (3, 17-19) all emphasise that vulnerability cannot be used as a reason for exclusion:

> As a consequence of such exclusions, information about the diagnosis, prevention and treatment of diseases that afflict such groups is limited. This has resulted in a serious injustice. Since information about the management of diseases is considered a benefit to society, it is unjust to intentionally deprive specific groups of that benefit.

The emphasis has shifted to foreground inclusion as the default stance in research, including people from vulnerable populations, and recognising that inclusiveness might require additional resources and time. The issue of underrepresentation and the refined account of

[26] Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Health-Related Research Involving Humans. Fourth Edition."
[27] The Ethics Working Group on ZIKV Research & Pregnancy., "Pregnant Women & the Zika Virus Vaccine Research Agenda: Ethics Guidance on Priorities, Inclusion, and Evidence Generation."

vulnerability have together flipped the logic so that 'vulnerability' is not grounds for not including groups in research and instead researchers are required to justify the exclusion of populations from their project rather than only justify the case for who is included and why the population has been chosen for the study: "The need to redress these injustices by encouraging the participation of previously excluded groups in basic and applied biomedical research is widely recognized."[28]

All these policy shifts to support more research on pregnant women have arisen out of a systematic campaign for change. As mentioned above the problem of 'vulnerability', and the drawbacks of excluding vulnerable groups of people from research, was identified in the academic literature in the early 2000s and by the late 2000s vulnerability was being emphasised as a factor in the continued exclusion of pregnant women from research and this recognition was spreading into clinical research guidelines. Within research guidelines, vulnerability was the first narrative to be recognised as a direct cause of low rates of research during pregnancy. In 2009 in the USA the Second Wave Initiative was formed by Lyerly, Little and Faden advocating for "the responsible inclusion of pregnant women in medical research.[29] Since then, alongside other key feminist biomedical professionals and ethicists in many countries, a steady stream of articles in prominent medical journals and submissions to research policy being updated and reviewed has occurred advocating for change to policy to nuance the use of vulnerability in the context of pregnancy and to advocate for a rebalancing of risk and autonomy in the context of pregnancy and clinical research.[30]

[28] Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Health-Related Research Involving Humans. Fourth Edition."
[29] "The Second Wave Initiative."
[30] Kukla, *Mass Hysteria*; Little, Lyerly, and Faden, "Moving Forward With Research Involving Pregnant Women"; Lyerly, Little, and Faden, "Reframing the Framework"; Baylis and Halperin, "Research Involving Pregnant Women"; Ballantyne and Rogers, "Pregnancy, Vulnerability, and the Risk of Exploitation in Clinical Research."

A key difference between the 2002 CIOMS Guideline 8 and the 2016 Guideline 3, both of which outline research participation and distributive justice, is that the 2016 guideline explicitly spells out how "in cases where the underrepresentation of particular groups results in, or perpetuates, health disparities, equity may require special efforts to include members of those populations in research." It then lists such populations as including children and adolescents, women, and pregnant and breastfeeding women. In contrast, the earlier CIOMS guidelines make no mention of the problem of underrepresentation as an issue of distributive justice.

Similarly, the preamble to TCPS2 Chapter four *Equity and Fairness: inappropriate inclusion and exclusions* highlights the harms that can arise from inappropriate exclusions:

> Over-protectionist attitudes or practices of researchers or REBs, whether intentional or inadvertent, can exclude some members of society from participating in research. The exclusion of individuals, groups or communities may constitute a failure to treat them justly.

Furthermore article 4.7 TCPS2 links such inappropriate exclusion specifically with 'vulnerability' and categorically rejects vulnerability as an acceptable circumstance for automatic exclusion. Instead this guideline emphasises the need to consider the specific context of both research and participant, rather than the group they belong to. With regards to pregnancy, TCPS2 emphasises the need to include consideration of the harms of exclusion as well as risk of inclusion.

> In considering research on pregnant or breastfeeding women, researchers and REBs shall take into account foreseeable risks and potential benefits for the woman and her embryo, fetus or infant, as well as the foreseeable risks and potential benefits of excluding pregnant or breastfeeding women from the research.[31] (my emphasis)

This additional commentary is a direct attempt to counter the narrative of inaction-as-safest-option that is prevalent with regards to 'pregnancy'. Overall, both CIOMS and TCPS use

[31] Canadian Institutes of Health Research, Social Sciences and Humanities Research Council of Canada, and Natural Sciences and Engineering Research Council of Canada, "TCPS2," sec. 4.3. My emphasis.

commentary upon the primary guidelines to provide context and additional guidance to researcher and ethics review boards. The benefit of doing so is to reduce ambiguity, which is particularly important as their most recent versions are both attempting to establish a new cultural norm of research during pregnancy as possible, safe and responsible. If the cultural norms or discourse of pregnancy are causing the problem, then one method to encourage pharmaceutical research during pregnancy is to attempt to change the norms. Particularly in this case it seems that the current norms benefit only pharmaceutical corporations who might be expected to provide additional research (and thus spend additional money) upon physiologically distinctive subpopulations such as – children, teenagers, the elderly and pregnant women - in their applications for approval of novel pharmaceuticals. For all other parties the benefit of norm change would be a net positive in the form of more effective and efficient health care for pregnant women. 6.2 explores how stakeholders can be persuaded to conduct and participate in research during pregnancy via specific attention to methods of communication that can overcome and correct misperception around risk and challenge ideas of responsibility that harm rather than help.

Research ethics guidelines have not been uniformly reformed to support research during pregnancy. As a result, low rates of research persist regarding pregnancy. For instance, the *New Zealand Guidelines for Interventional Studies* (2012) make no mention of pregnant and breastfeeding women within a sophisticated and lengthy discussion of vulnerability (5.28-5.35) neither including nor excluding them from the category. However the definition includes as vulnerable people who "may be particularly susceptible to harm…because of their health status."[32] Thus while researchers and ethics boards educated to the specific problem of pregnancy, vulnerability and clinical research would not be impeded

[32] NZ National Ethics Advisory Committee, "Ethical Guidelines for Intervention Studies: Revised Edition," sec. 5.28.

from approving clinical research during pregnancy, those without specific knowledge in the area might hesitate to either initiate or approve many clinical research projects aiming to improve health during pregnancy, as these research guidelines place additional safeguards and limitations on research with vulnerable populations. Indeed, a recent article in the NZ Medical Journal by a NZ ethics review board member makes this point:

> One might assume that the general tone of New Zealand guidelines facilitates reasonable inclusion of pregnant women in New Zealand health research simply because they do not prescribe any specific limits on research with pregnant women ... In my experience, this is not the case. I have served on the Central Ethics Committee for 3 years, and in my view pregnant women are still routinely excluded from research without any justification. Often it is the case that pregnant women are excluded from studies for conditions known to affect them, where there is a high likelihood that they will be receiving treatment in the community off-label. Researchers rarely offer any justification for exclusion.[33]

Given the narrative contexts of risk and responsibility during pregnancy which are coded into the NZ guidelines discussion of vulnerability, such as minimisation of risk (5.30), and protecting the interests and avoiding exploitation of vulnerable people (5.31), it would be even easier to assume that pregnant women are vulnerable, even though I doubt the guidelines authors intended such an inclusion.[34]

Vulnerability is a good example of a narrative that can be explicitly removed from association with pregnancy within the context of research in order to both facilitate more research during pregnancy and support a more coherent overall discourse that better aligns with a considered account of pregnancy. However, ethics guidelines need not just to remove pregnancy from association with vulnerability; they also need to explicitly outline their supportive position on research during pregnancy in order to avoid ambiguity, mistaken assumptions of vulnerability and to counter the forceful impact of the stigma around pharmaceuticals during pregnancy and the perceptual bias towards ‘inaction as safety’.

[33] Ballantyne, “New Zealand Needs Guidelines for the Safe and Responsible Inclusion of Pregnant Women in Medical Research.”
[34] Ballantyne.

Attempts to improve rates of research during pregnancy via institutional changes such as including updating policies, must do so while first maintaining the balance of ideas and norms about the health status and naturalness of pregnancy. Second, these attempts must also balance continuing to reinforce sensible depictions of the health risks of pregnancy. Third, potential changes must promote a sensible allocation of responsibility during pregnancy, i.e. what pregnant women can and cannot be held responsible for during pregnancy in areas such as ensuring health, risk assessment, and making decisions. Fourth, any changes need to also reflect acceptable narratives about the moral status of the fetus and the degree of risk perceived as acceptable to expose the fetus to. Fifth and finally all this must take place while these narratives are in continuing flux, and some – particularly the *fetus* – are particularly contentious.

Guidelines, particularly guidelines accompanied by commentary, can support research during pregnancy. These guidelines can be a site of positive narrative contributions to a discourse in which research during pregnancy is the norm. Given the current discourse of pregnancy and in particular the biased perception of the risks of action during pregnancy (as opposed to inaction) alongside the stigma around pharmaceutical consumption during pregnancy there needs to be specific discussion of pregnancy (and other relevant populations) within the contexts of risk, vulnerability, distributive justice and health equity. Common elements of the most effective guidelines are: (1) specific endorsement of research during pregnancy as the presumptive norm and the exclusion of pregnant women from research participation as an exclusionary criterion to be questioned by ethics review boards, (2) emphasis on the need to consider the risks and harms of exclusion in order to counter the bias towards the assumption of inaction as safety, (3) a more nuanced definition of vulnerability that disassociates pregnancy and the increased risk faced by pregnant women from association with, and thus assumption of, incapacity or social disadvantage. Effective and

supportive guidelines are only the first step however; effective stakeholder education is also required. Education about the benefits of clinical research during pregnancy but also education that shapes and supports an overall discourse of pregnancy conducive to research during pregnancy, are needed.

6.2 Stakeholder engagement

> Existing psychological, social, cultural, health, and socioeconomic factors…greatly affect how individuals interpret health risk communications, as well as their willingness and ability to act in a timely manner.
>
> Vaughan and Tinker, *Effective Health Risk Communication*

As discussed in Chapter Four, the Thalidomide and DES regulatory failures had a significant impact on the trajectory of pharmaceutical research, and in shaping the boundaries of what was considered normal, acceptable and safe with regards to pharmaceutical research. Nowhere can this be seen more clearly than in the history of pregnancy and clinical research. As discussed in 5.2, norms and practices arising from background relations with technologies are often unintentional, the accidental by-product of interaction between artefacts, individuals and societies. Pregnant women have been excluded from research because the discourse of pregnancy sets up both pharmaceutical consumption and research as riskier than inaction and this has had an unforeseen effect on health equity. Faced with a problem set up in this way, it is necessary to restructure the interaction of humans and technology to produce scripts, norms and narratives to instead encourage safe high quality research during pregnancy. This requires that both policies and practices around the technology of 'pharmaceutical research' change to include understandings of how narratives of risk, responsibility, health, nature and the fetus function in pregnancy and work to either promote alternative accounts of these concepts or work out how to use existing narratives to promote behaviour supportive of developing a systematic body of knowledge around pharmaceutical effectiveness and safety during pregnancy.

Having discussed the reforms already occurring within policy and pregnancy in regard to contemporary health guidance documents in 5.3, this section examines how practice must also actively work to shift narratives of responsible maternity and overcome and counter the norm of inaction as precaution in order to correct the distorted risk perception of

pregnancy. Understanding how and why risk is misperceived during pregnancy, and how this misperception often takes the specific form of a belief that inaction is safer than action, will improve rates of research and participation. In turn, this would assist in shifting norms and narratives regarding 'responsibility' and participating and conducting pharmaceutical research during pregnancy.

More than simply risk-benefit analysis is required when discussing the ethics of pharmaceutical research during pregnancy. Rather there needs to be consideration for how technologies and other social structures promote and deny certain scripts – those that promote health equity through safe and effective pharmaceutical research. The concrete practices that constitute the interaction of pharmaceutical research and pregnancy need to be reconfigured in order to counter broader problematic narratives and norms about what is considered risky and responsible, natural and normal, healthy or not, during pregnancy. This section integrates insights drawn from the genealogy of pregnancy in previous chapters about risk, health, nature, responsibility and the fetus into a discussion of how best to engage stakeholders to shift practice towards conducting more clinical research during pregnancy. I argue that educational initiatives targeting the three key stakeholder groups, ethics review boards, pregnant women and researchers, are the first step. However, this education cannot simply focus upon why clinical research is valuable but needs to educate stakeholders about the specific norms and narratives within the discourse of pregnancy that are impeding research. There needs to be an emphasis upon how various norms and narratives about pregnancy are being reinforced, contradicted or ignored and present concrete strategies to overcome the problem. While education is not going to change the norms around pregnancy by itself it is one of many components that needs to occur in order for change to arise. This section highlights the three key narratives that are impeding clinical research during pregnancy – responsibility and risk (two of the key concepts identified in this project) and

structuring the problem as one involving a stigmatised technology. I then discuss communication strategies that may be effective in reforming these narratives to better encourage research during pregnancy, particularly strategies already in play with regards to other stigmatised technologies such as vaccinations. First however a brief discussion of the third key stakeholder group: industry.

Industry and governance groups:

Low rates of pharmaceutical use while pregnant can be detrimental to the health of pregnant women; however, identifying and separating out the origin and force of the problematic norm of inaction can also help explain why the problems around pregnant women and pharma research have only been recently taken up as a serious concern. It can also help explain why there remains a continued lack of progress in this area despite broad attempts within the healthcare system to address the issue and guidance documents and regulations that actively endorse such research. We often use the term the pharmaceutical *industry* unthinkingly, and overlook how industries can generate, shape and reinforce norms as well as producing products. Pharmaceutical industries always are driven by profit generation and the norms, value and products they produce will always be oriented towards the maximisation of profit as limited by the constraints of regulations that apply to the industry. A key method of norm production within the pharmaceutical industry is via the advertising and marketing of pharmaceutical products, for instance the medium used and who is or is not represented within the ad.[35] But norm production and shaping also occurs via the regulations and policies surrounding the pharmaceutical industry, particularly those policies and regulations that govern clinical trials - for example whether it is normal for depression and anxiety to be treated primarily via drugs rather than therapy or both therapy and drugs. While drug

[35] Bristor, Lee, and Hunt, "Race and Ideology"; Williamson, *Decoding Advertisements*; Cortese, *Provocateur*.

marketing both to clinicians and consumers has a role in producing this norm so do clinical trials whose economic and regulatory systems are set up to make drug research more attractive than studies into the effectiveness of therapies. Perhaps the tendency to avoid clinical research on pharmaceuticals during pregnancy makes pregnancy one of the few areas where the range of therapeutic options being tested in clinical research is not biased in favour of evaluating pharmaceuticals at the expense of other potential therapies.

Research during pregnancy is less appealing to industry both because recruitment is more difficult and also financial profits for industry smaller than studies for the same pharmaceutical in the regular population. There is little economic incentive to conducting clinical research during pregnancy. The current economics of contemporary medical research and production provide no incentives for, and many barriers to, pharmaceutical companies. As discussed earlier the unique physiological circumstances of pregnant women, most notably the presence of a fetus but also specific pharmacokinetic and pharmacodynamic changes that continue through pregnancy and into the post-natal period, make the bulk of pharmaceutical research conducted on the non-pregnant only partially applicable. Furthermore the constant physiological change and the presence of the developing fetus make undertaking pharmaceutical research on pregnant women a complex endeavour, as the safety and efficacy of pharmaceuticals varies throughout a pregnancy, and furthermore safety guidelines require long term follow up to continue to watch for developmental impacts that may not be immediately apparent.[36] Thus not only is research addressing pregnant women at all stages of pregnancy needed to ensure good data collection about safety and efficacy, but there is a need for long term tracking and follow up before safety can be ensured. These requirements make pharmaceutical research upon pregnant women both resource intensive

[36] Foulkes et al., "Clinical Research Enrolling Pregnant Women," 2011; Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), "International Ethical Guidelines for Health-Related Research Involving Humans. Fourth Edition."

and very expensive. Pregnant women make up only a very small proportion of the overall population who may need to consume a pharmaceutical. Collectively these features of research during pregnancy disincentivize the pharmaceutical industry for encouraging or supporting research during pregnancy as it is very high cost and low margin research. Change will thus likely need to be regulated upon the industry.

Furthermore, particularly in the USA, where a significant proportion of pharmaceutical research is conducted, there are also concerns about legal liability if either mother or fetus are harmed during the research, as OBGYNs are not only a medical specialty against which malpractice suits are often brought but claimant payouts are on average the largest of malpractice suits against any medical specialty.[37] Thus there are significant economic costs and delays beyond those usually accrued in pharmaceutical research. However, regulations can and have been used to shift liability in other areas, and there is no reason to think that this could not also be the case.[38] Financial, legal and regulatory incentives could be reconfigured towards encouraging or requiring research during pregnancy and given the already heavily regulated environment for pharmaceutical research there is little reason to think that such changes could not be made.

Pregnant Women

> In general, researchers should be familiar with the cultural, social and economic circumstances of prospective participants, groups or communities.
>
> Section 4.7 of the TCPS 2

Responsibility is a narrative key to improving stakeholder engagement in pharmaceutical research. As discussed in 5.2 pregnant women are held responsible for their pregnancies by themselves and others in an intense and often conflicting manner. A key question that needs

[37] Jena et al., "Malpractice Risk According to Physician Specialty"; Hale, "Legal Issues Impacting Women's Access to Care in the United States—the Malpractice Insurance Crisis."
[38] Kaposy and Lafferty, "Overcoming Liability Concerns in Vaccine Trials Involving Pregnant Women"; Mastroianni, "HIV, Women, and Access to Clinical Trials."

to be considered in all attempts to engage pregnant women in research is, how will women who participate in research during pregnancy be perceived by their families and communities? Will they be considered responsible mothers making good choices or poor mothers making bad choices, being lazy or reckless or selfish? For instance, statements such as "A baby's health depends largely on how the mother treats her body during pregnancy" are both normalised and widespread in public health engagement.[39] As I have argued, the contemporary discourse of pregnancy places significant expectations upon women to act moderately and change their behaviour and choices before, during and after, pregnancy in order to ensure fetal health and safety.

Analysis and evaluation of public health messaging shows time and time again the importance of recognising the social, cultural and economic barriers structuring women's 'choices' and how narratives setting norms and expectations about maternal responsibility must be considered for public health interventions to be effective. Initiatives targeting pregnant women need to move beyond assuming that 'choice' and evidence of the benefit of an initiative are all that is needed to improve maternal and fetal/child health. Time has shown this to be an insufficient and ineffective solution. In order to address this situation, we first need to consider how the allocation of responsibility is complicated by distortion in risk evaluation and perception arising from the stigma and the norm of inaction as precaution, as was discussed in 5.2. There is also a second dimension to the narrative of responsibility during pregnancy: How the autonomous capacity of pregnant women is structured in law, policy and expectation, and in particular for this project, the relationship between autonomy and informed consent.

A significant problem with the current overall discourse of responsibility in relation to health arises when attempts are made to enact social policies to change unhealthy behaviours.

[39] Kukla, "Ethics and Ideology in Breastfeeding Advocacy Campaigns," 158.

Many of these policies assume that people will modify their behaviour if an explanation is provided as to how it will negatively impact (or improve) their health, or that of their child. Thus, there are negative public service announcements (PSAs) telling women not to drink, smoke, or take illegal drugs, all of which are associated with an increased risk of adverse effects for the fetus and positive PSAs encouraging breastfeeding, and a wide variety of other health promoting behaviours. While simple broadcast advertising will work to a degree, such strategies will not work for a significant proportion of women because of the norms they have internalised about how to be responsible during pregnancy. These attempts to modify behaviour fail because they work against, and fail to take account of, how 'responsibility' functions in the wider discourse of pregnancy, particularly in structuring 'choice'. Chapters Two through Four reveal how 'responsibility' is perceived and allocated around pregnancy and how it shapes various 'choices' as acceptable, risky, natural and normal. The uncritical assumption that telling women to modify their actions in particular ways will produce the desired outcome is predicated upon the norm of individual responsibility taken to an extreme and a complete failure to consider and account for the social contexts that produce the behaviors.

Breastfeeding campaigns provide an excellent parallel example of a health intervention campaign that often fails to consider the impact of social and material circumstances upon women's choices. There is ample scientific evidence that, all being equal, breastmilk is the healthiest nutritional choice for infants and health education campaigns aim at clearly communicating this to pregnant and breastfeeding women. When no change in breastfeeding rates occurs in response to a campaign it is interpreted as a communications failure, that women are not hearing the message. However, according to Kukla, in the USA where breastfeeding rates are particularly low among racialised groups, women know that breastfeeding is best; what campaigns are failing to do is either identify or

attempt to mitigate the socio economic and structural barriers that make breastfeeding difficult for many women. She highlights how campaigns present breastfeeding as the responsible choice, situating breastfeeding as something exclusively under women's control rather than subject to a huge range of factors outside women's control.[40]

Kukla's analysis of breastfeeding highlights how important it is to ensure that efforts to recruit pregnant women do not rely simply on persuading pregnant women to 'do the right thing,' and make the responsible choice to ensure their child's health. Rather recruitment efforts need to focus on structural barriers that make women less able to participate. This includes not only physical and social barriers to participation that are commonly considered in high quality research recruitment strategies, but to also explicitly work to counter the misperceptions arising from the particular social norms and narratives about pregnancy explored in this project. While this type of approach, inclusiveness by overcoming structural disadvantages, is often present in research practices, it is particularly important to consider how the narrative of good and responsible mothering is also being mobilised in attempts to recruit pregnant women into research.

Currently norms and narratives about health and risk are tightly linked to narratives of individual responsibility, reinforcing the idea that "individuals *can* and *should* exert fundamental control over their health through careful and rational avoidance of risks."[41] However, as discussed in Chapter Three, this particular approach to health, risk and responsibility has not historically always been the case. The current emphasis on personal responsibility for health and making 'healthy choices' arises out of neoliberal ideology and "denies broader social responsibilities for health and diseases" and ignores the manner in which individual "behaviour itself is, at times, beyond the scope of individual agency."[42]

[40] Kukla, "Ethics and Ideology in Breastfeeding Advocacy Campaigns."
[41] Brandt, "Behavior, Disease and Health," 68.
[42] Brandt, 68.

Making good choices is a duty individuals choose and when they don't choose well the assumption is they are choosing to take risks with their health and are "considered ignorant, stupid, or self-destructive."[43] According to Brandt in his discussion of 'choice' in the context of health and disease in the twentieth century this "notion that simple self-denial can solve a complex social problem" is the expression of a central cultural belief in individual self-determination and individual responsibility.[44] As these values have strengthened in the late twentieth century the right to health has transformed into the duty to be healthy.

This presumption about responsibility and choice in 'health' is expressed within recommendations around obesity, weight gain during pregnancy, exercise and nutrition.[45] However, examination of the evidence supporting the recommendation reveal a disconnect, as this recommendation arises from meta-analysis of studies into supported interventions to change diet and exercise behaviours rather than of the effectiveness of counselling women as to the health importance of diet and exercise during pregnancy.[46] As most women know the health benefits of breastfeeding so do most obese and overweight people know the health benefits and risks associated with being overweight and the recommended diet and exercise modifications.[47] Education around the specific health risks of obesity and excessive weight gain during pregnancy is appropriate during antenatal care as women often lack knowledge about the specific risks. However, such education focused counselling should not be conflated with an effective intervention for reducing excessive weight gain or improving poor

[43] Brandt, 69.
[44] Brandt, 69. While Brandt is discussing the USA and these values are especially dominant there I argue that due to their cultural and regulatory similarities Brandt's argument applies equally to the other countries considered in this project: Australia, New Zealand, the UK and Canada.
[45] World Health Organization, "WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience," 15–17; Ministry of Health NZ, "Guidance for Healthy Weight Gain in Pregnancy."
[46] Muktabhant et al., "Diet or Exercise, or Both, for Preventing Excessive Weight Gain in Pregnancy."
[47] Shub et al., "Pregnant Women's Knowledge of Weight, Weight Gain, Complications of Obesity and Weight Management Strategies in Pregnancy," fig. 3.

nutrition as evidence suggests actual changes in outcomes requires sustained and supported interventions.[48]

As with breastfeeding, this example aligns with Brandt's argument about cultural assumptions around responsibility, health and behavioural choices, and continues to ignore the role of structural impediments while conflating education with intervention. There is an inbuilt assumption within (neo)liberal ideology that all it takes is education and people can and will change their behaviours. When dietary and exercise changes are recommended for a pregnant woman they should be in line with the evidence – additional supported interventions with nutrition and exercise specialists who have knowledge of how particular social and structural factors impede change.[49] The recommendation for counselling as a solution for preventing excessive gestational weight gain indicates how strong the narrative of responsibility for health is particularly when the changes needed are related to patterns of consumption and 'lifestyle.'

Obese women are another group of women who could be excluded from pharmaceutical research during pregnancy if care is not taken. People who are obese or overweight going into a pregnancy are at increased risk for many complications during pregnancy and birth, and for some adverse neonatal outcomes, and are often labelled a high risk population. However overweight and obese women make up between 30-50% of all pregnancies and it would be important to only exclude such women from research participation after careful weighing of the risks and benefits. This is especially important given that in high income countries obesity increasingly correlates with membership in

[48] Shub et al., "Pregnant Women's Knowledge of Weight, Weight Gain, Complications of Obesity and Weight Management Strategies in Pregnancy"; World Health Organization, "WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience," 15–17.
[49] Furness et al., "Maternal Obesity Support Services: A Qualitative Study of the Perspectives of Women and Midwives."

socioeconomic disadvantaged populations.[50] Thus there is the potential to further disadvantage people already more likely to have poorer health outcomes during a pregnancy. Given the impact that variations in weight and percentage body fat composition can have on pharmacokinetics – even outside of pregnancy – it is important that overweight and obese women be included in pharmaceutical research during pregnancy, as they represent a significant proportion of overall pregnancies in high and middle income countries.

A more serious example of the consequences of an emphasis on individual responsibility for health can be seen in the stream of accusations and convictions for murder, and attempted murder, which have been made against pregnant women addicted to illegal drugs and alcohol.[51] While addiction is often perceived as simultaneously both a disease and a moral failing, in the case of addicted pregnant women and mothers the discourse of moral failing and blame is particularly strong. The narrative of maternal responsibility and 'choice' intertwines here with a script emphasising fetal rights and status that conflicts with attempts to frame mental health and addiction as a health issue that people can be supported through. Most notably however the discourse ignores all the ways in which society contributes to the situation: difficulties accessing birth control, abortion services, prenatal care and addiction services being only the most obvious. When policies and practices start with the assumption that people can choose to make healthy decisions then, as with the cases of addiction, breastfeeding education and diet and nutrition during pregnancy, they ignore the practical and material barriers that make women unable to make the *healthy* and *responsible* choice. Narratives about personal responsibility and making healthy choices can become particularly toxic in conjunction with the expectation of 'good mothering.'

[50] Shub et al., "Pregnant Women's Knowledge of Weight, Weight Gain, Complications of Obesity and Weight Management Strategies in Pregnancy."
[51] Armstrong, *Conceiving Risk, Bearing Responsibility*, 9; Flavin and Paltrow, "Punishing Pregnant Drug-Using Women"; Paltrow and Flavin, "Arrests of and Forced Interventions on Pregnant Women in the United States, 1973–2005."

While for the most part the narratives of risk and pregnancy play out in policies via acceptable safety thresholds and other assumptions, the impact of these narratives upon practice also needs to be considered when developing strategies to recruit pregnant women into research. How does the way in which pregnant women are engaged with during study recruitment presume choice is the major barrier to recruitment? When efforts are directed towards presenting the benefits of research during pregnancy the role of other factors in impeding research can be downplayed. The most significant of these is the distorted risk perception arising out of the stigma attached to pharmaceutical use during pregnancy and the broad cognitive bias towards the norm of inaction as precaution.

Researchers and Ethics Review Committees

> Interventions during pregnancy are likely to engage sets of values and interests that are deeply held, particularly prone to intense ideological and cultural pressures and highly variable.
>
> Rebecca Kukla, *Equipoise, Uncertainty and Inductive Risk*
>
> .

Engagement and education efforts focused on researchers, clinicians and research ethics board members need scrutiny similar to that focused upon pregnant women. Efforts to improve rates of research often assume that researchers and ethics boards need only factual guidance as to the benefits and risks of research during pregnancy in order to change behaviours and ‘make the right choice.’ However, the additional social and material barriers that influence behaviour need to be recognised and targeted. Engagement and education focused on researchers and ethics boards needs to emphasise the significance of narratives of ‘good mothering’ to research during pregnancy and encourage researchers towards recruitment strategies that emphasise links between research participation and good and responsible mothering.

Awareness is needed on the part of researchers and ethics boards about how stigma and cognitive bias towards inaction around pharmaceutical use during pregnancy shapes people's perceptions of 'pregnant women'- not just how the norms about risk and responsibility during pregnancy impact women's rates of participation but also in how they shape researchers' recruitment strategies and research designs. The role and influence of these norms on funders will also need to be explored as funders will need to provide the additional funding required to design and implement studies that include pregnant enrollees. These considerations point to a need for wider engagement than only with pregnant women but to include families and maybe key community members in stakeholder education initiatives. Given the significance of the *good mothering* narrative in the lives of many women, and the consequences when women are seen to deviate from it, efforts to ensure that research participation is perceived by wider society as a responsible choice for *good mothers* will be needed. Whenever pregnant women decline research participation, or even pharmaceutical use, the role of the narrative of responsibility and good mothering needs to be considered and addressed.

Research design is conducted by researchers who are also stakeholders. Thus, the majority of strategies discussed earlier in the chapter for raising awareness around perceptual biases and inhibitory social norms will also assist in improving research design. Nevertheless, clinical research design has several features worthy of specific note. First the background knowledge and values that can be assumed to be held by people who design research is far more limited and uniform than those who participate in research. While the backgrounds of researchers will (hopefully) differ in many aspects including race, class and ethnicity, researchers undergo reasonably uniform and extensive education and training. Thus, targeting education and highlighting the role of perceptual biases and the key norms associated with pregnancy and reproduction could be incorporated into sessions on specialised

subpopulations with less of the concerns about uptake and belief issues that complicate stakeholder engagement of other groups.

The different ethical imperatives of clinical research and treatment also need to be considered. If techniques borrowed from other stigmatised technologies are used to encourage stakeholder participation in research then there is need to carefully consider the more stringent requirements of informed consent for research participation, rather than more ethically straightforward provision of healthcare. Compared to health interventions such as vaccinations, the balance of information provided and understanding required for informed consent for research on pregnant women is significantly different.

The opportunity for education and individual engagement present during pharmaceutical research also represents a site for broader intervention to correct misperceptions about responsibility, risk and health during pregnancy. Understanding pharmaceutical use during pregnancy as a stigmatised technology adds nuance to the continued resistance by pockets of both the public and healthcare practitioners to pregnant women taking pharmaceuticals. Relating pharmaceutical use during pregnancy to the literature on stigma creates links to other stigmatised technologies and products about which people also have significantly skewed perceptions of risks. Most notably this includes nuclear technologies, genetically modified foods, and vaccinations. The persuasiveness and success of different techniques for educating stakeholders as to the balance of risks and benefits of these technologies and products have been investigated and evaluated.[52] Those working to improve rates of research during pregnancy via education ought to draw on their findings. These studies find that there are specific techniques that work to correct risk perception and

[52] Bak, "Education and Public Attitudes toward Science"; Gaskell et al., "GM Foods and the Misperception of Risk Perception"; Lee, Scheufele, and Lewenstein, "Public Attitudes toward Emerging Technologies Examining the Interactive Effects of Cognitions and Affect on Public Attitudes toward Nanotechnology"; Saba and Messina, "Attitudes towards Organic Foods and Risk/Benefit Perception Associated with Pesticides"; Whitfield et al., "The Future of Nuclear Power."

misperception and integrating findings from the wider literature on risk would save reinventing the wheel.[53] In particular, communication and education efforts around the safety and importance of childhood vaccinations parallels that of pharmaceuticals and pregnancy as the risk misperception centers upon distorted beliefs about the safety and risks associated with non-action and overcompensating with regards to concerns for the risk of vaccination. Vaccination is similarly a discourse centered upon children and infants, making healthcare decisions to their benefit and the use of pharmaceuticals.[54] Studies into vaccination practices also highlight the role of socioeconomic factors in variations of the persuasiveness of different methods.

Communication around vaccinations has been extensively studied in recent decades and many of the findings from this literature are applicable to improving communication practices with pregnant women at the recruitment stage of clinical research because both situations involve correcting a misperception of risk. Not only will better communication of the risks and benefits of research participation improve recruitment, but several of the suggested strategies would also act as an intervention into combating the broader problematic norm of inaction as precaution. Research specifically into vaccination communication suggests that people reluctant to vaccinate are not persuaded by the presentation of facts and numbers in an adversarial or authoritative manner but rather that guided conversation about concerns and priorities is more persuasive.[55] Thus it is unlikely that presenting pregnant women with an overly factually focused argument will be persuasive in recruiting them into research.

[53] Aakko, "Risk Communication, Risk Perception, and Public Health"; Breakwell, *The Psychology of Risk*; Breakwell, "Risk Communication"; Fischhoff et al., "Risk Perception and Communication."; Pidgeon, Kasperson, and Slovic, *The Social Amplification of Risk*.
[54] In the post-Wakefield era vaccines also probably fit many of Slovic's criteria for a stigmatised discourse.
[55] Leask et al., "Communicating with Parents about Vaccination."

More general research into risk evaluation and health decision making also emphasises the way in which risk is evaluated in a non-rational manner, "consistently overestimating the dangers and undervalue[ing] the benefits" of action.[56] This suggests that the norm of inaction as precaution functions more widely than in just pregnancy, although I would argue that pregnancy is an instance of this norm at its most extreme. The solution thus is not providing additional risk statistics because the primary issue is not a matter of people miscalculating risk and does not shift decisions. Rather the norm of inaction as safety is part of a broader cognitive bias that needs to be countered. Studies report success with efforts focused on educating people about cognitive bias itself, its sources and consequences. Thus, it would be beneficial to include as part of research recruitment strategies a broader discussion of cognitive bias, risk misperception and the norm of inaction as precaution and the outcomes specific to pregnancy that arise from these features. Integrating a discussion of these features into medical education by developing a discussion of both cognitive biases and the role of cultural norms in shaping what people consider safe, acceptable and normal for various social groups could also help. A simple method would be the creation of case studies in both clinical and research ethics highlighting the implications of these features of the social world which could provide both the vocabulary and skills for identifying the issues arising. A series of examples could be used including vaccinations, mental health, addictions and pharmaceuticals and pregnancy.

Another important finding from studies into risk communication in both HIV/Aids and vaccinations is that there is a strong preference for personal face to face communication and discussion; people prioritise personal knowledge and experience when it comes to "judging the trustworthiness of risk information."[57] Thus personalisation, real testimonials

[56] Alaszewski and Horlick-Jones, "How Can Doctors Communicate Information about Risk More Effectively?"
[57] Alaszewski and Horlick-Jones; Pidgeon et al., "Perceptions of and Trust in the Health and Safety Executive as a Risk Regulator"; Petts and Niemeyer, "Health Risk Communication and Amplification"; Calman, Bennett, and Corns, "Risks to Health."

from those who have benefited from pharmaceutical research during pregnancy and situating risk information within specific real examples that outline the costs and benefits of both participating and not participating would all improve recruitment. Evidence also shows that groups who have the least trust in government and authorities are the least likely to respond to generalised public health campaigns.[58] In order to ensure diverse representation across socio-economic groups in research, additional attention will be required to recruit a diverse array of individuals in order not to repeat the general problems of representative recruitment within the specific context of pregnancy.

The current discrepancy in the USA for maternal mortality, and many other markers of good health between black and white women, speaks to the importance of attention to such details in order to not reinforce and exacerbate already present socio-economic disadvantages.[59] However this is not a problem specific to pregnant women and, as with any other research agenda, balance must be sought between ensuring rates of participation high enough to ensure findings are applicable to minority populations, and minimising additional burdens upon already disadvantaged people. This also points to another issue specific to countries, such as the USA, where many people lack access to healthcare and research participation can ensure access to healthcare. Carefully managed research participation could be an ethically permissible way to extend antenatal, pediatric and postnatal care to disadvantaged populations.[60] However this would need further analysis to determine whether the provision of otherwise unlikely healthcare to women and children from disadvantaged backgrounds in the USA could be considered as a factor in the primary risk-benefit analysis

[58] Larson et al., "Addressing the Vaccine Confidence Gap"; Vaughan and Tinker, "Effective Health Risk Communication About Pandemic Influenza for Vulnerable Populations."
[59] Creanga et al., "Pregnancy-Related Mortality in the United States, 2006–2010."
[60] Benatar, "Reflections and Recommendations on Research Ethics in Developing Countries"; Emanuel et al., "What Makes Clinical Research in Developing Countries Ethical?"

for approving the research. [61] Particularly in the US context of the history of unethical research in minority populations, to do otherwise could ghettoise research during pregnancy into primarily being conducted upon minorities and exacerbate already existing issues of institutional trust.[62]

The key findings of this project in terms of stakeholder engagement are that the stigma around pharmaceuticals during pregnancy exacerbates and works in conjunction with the cognitive bias towards a perception that inaction is precaution. Countering this bias does not require additional or more sophisticated information to be presented to pregnant women in order to persuade them to participate in research. Rather it requires the education of all stakeholders into cognitive bias using already existing techniques from other areas of health that grapple with issues of stigma and risk misperception such as vaccination and HIV. The education could be built in at different places including in medical and health research education, research ethics board training, and participant recruitment.

Furthermore, specific attention needs to be paid to ensuring the inclusion of minorities and disadvantaged groups in research during pregnancy. Maternity narratives intersect in complex ways with ideas of good mothering, responsibility, and health also contributing to low rates of research during pregnancy. Techniques for participant recruitment should be mindful of these particularly forceful narratives, avoid assumptions about the choices of pregnant women and work to promote and support the psychological health of women rather than exacerbating/promoting burdens of expectation about good mothering. Problems arising from narratives of good and responsible mothering are particularly pronounced for women from minority and disadvantaged backgrounds who are often excluded from representation in

[61] Fisher and Kalbaugh, "Challenging Assumptions About Minority Participation in US Clinical Research"; Boutin-Foster et al., "Ethical Considerations for Conducting Health Disparities Research in Community Health Centers."
[62] George, Duran, and Norris, "A Systematic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders."

contemporary discourse of maternity and healthcare, have demographic and health differences that represent specific research priorities, and for whom research participation raises additional burdens and balances of risk and benefits.

Conclusion

Pregnancy is ideally positioned to express many social ambiguities and cultural tensions. It is an everyday normal, natural event experienced by millions of people every year. On the other hand, pregnancy often requires additional medical support, ranging from the incidental to life changing long term medical care and even death. In between these extremes sits a wide range of side effects and complications arising from the bodily changes of pregnancy, from banal discomforts to those that threaten the life or long term wellbeing of mother and fetus, and it is in the midrange that the majority of pregnancies lie. It is also within this midrange that the most serious impacts of the socio-cultural perception of pregnancy are felt. Today those who are seriously ill while pregnant get treatment, or when they don't receive treatment it is either remarkable or controversial. Pregnancy is a remarkable, life changing event, that is accompanied by a series of minor discomforts for almost everyone who experiences it: heartburn, aches and pains as the body copes with the extra stresses and strains of accommodating the growing fetus. There is unlikely to be harm or long term consequence when women choose, or are advised, not to alleviate these discomforts. However, for the unlucky few the aches and pains, signs and symptoms, are more serious, the 'choice' not to medicate can become more fraught. Where does the balance lie between acceptable discomfort and pain that stresses the body, or depression or anxiety such that it impacts ongoing wellbeing? Moreover, many people have significant yet well managed health conditions before they are pregnant – type one diabetes, asthma and epilepsy – and need to continue treatment throughout their pregnancies.

The relationship between pregnancy and clinical research has shifted tremendously within the time I worked upon this project. When I started in 2009, clinical research during pregnancy was only just beginning to be widely discussed as a problem and the drive to increase rates of clinical research during pregnancy was only beginning. In the USA the

Second Wave Initiative had just been formed in 2009 by Lyerly, Little and Faden, advocating for "the responsible inclusion of pregnant women in medical research."[1] The problem of 'vulnerability', and the drawbacks of excluding vulnerable groups of people from research had been identified in the early 2000s, and by the late 2000s vulnerability was being emphasised as a factor in the continued exclusion of pregnant women from research and this recognition was spreading into clinical research guidelines. Within research guidelines, vulnerability was the first narrative to be recognised as a direct cause of low rates of research during pregnancy. Thus, I set out to explore whether other key concepts within the discourse of pregnancy might similarly be impeding clinical research during pregnancy. I settled upon health, risk, nature, responsibility and the fetus as likely candidates as these concepts are all central to the discourse of pregnancy – how pregnancy is discussed, valued and conducted – particularly at the intersection of pregnancy and healthcare. In contrast, as I draw this project to a close in 2019 there is not only widespread recognition of the health equity problem faced by pregnant women that has arisen out of the exclusion of pregnant women from clinical research, but also international momentum for resolution including the updated policy guidelines for clinical research during pregnancy and educational initiatives targeting researchers and ethics review committees. A number of projects studying the attitudes of stakeholder groups to clinical research during pregnancy are also underway or recently complete.[2] Others are attempting to improve health equity during pregnancy via observational research and improved and wider use of pregnancy registries.[3] While many essential and

[1] "The Second Wave Initiative."
[2] Ballantyne et al., "The Experiences of Pregnant Women in an Interventional Clinical Trial"; Baylis and Ballantyne, *Clinical Research Involving Pregnant Women*; Ells and Lyster, "Research Ethics Review of Drug Trials Targeting Medical Conditions of Pregnant Women"; Wild and Biller-Andorno, "Pregnant Women's Views About Participation in Clinical Research."
[3] Burt, "Evidence-Based Pregnancy Registries"; Sinclair et al., "Advantages and Problems with Pregnancy Registries," 2014; Margulis et al., "Effects of Gestational Age at Enrollment in Pregnancy Exposure Registries"; Gelperin et al., "A Systematic Review of Pregnancy Exposure Registries"; Freeman, *Psychotropic Medication Use during Pregnancy*; Campbell et al., "Malformation Risks of Antiepileptic Drug Monotherapies in Pregnancy."

practical steps are being taken to improve clinical research during pregnancy this project is unique in attempting to step back and consider the wider social discourse of pregnancy and the narrative barriers that are impeding research during pregnancy.

In the time I worked upon this project I gave birth to twins which designated my pregnancy automatically high risk: under the care of an obstetrician and highly monitored with very frequent scans to check fetal growth. I needed pharmaceuticals while both pregnant and breastfeeding for nausea and high blood pressure. In the end I was induced at 36 weeks because the smaller twin had stopped growing and I was developing preeclampsia. A twin pregnancy also meant they recommended I receive an epidural because of the high likelihood of caesarean with twin pregnancies. Indeed, at one stage I was close to experiencing the worst of both options when I was almost rushed to an operating theatre to give birth to the second twin by caesarean as there were concerns about her heart rate dropping on the monitors my abdomen was covered with. However, in the end I gave birth to both children with the assistance of forceps although this required several IVs, an episiotomy and shortly afterwards an iron transfusion because of blood loss during the birth. Two weeks in the neonatal unit because of problems regulating temperature and feeding and we were off home where they are now happy healthy children.

What I mean to highlight with this litany of detail is that I experienced a highly medicalised pregnancy and childbirth, experiencing many of the interventions and problems touched upon in the genealogy. A series of complications that could have been serious if not caught early were effectively identified and treated. We were all fine. I appreciate how this was not always the case. Not so many generations back in my partner's family tree are several sets of twins who died at birth; even my uncle who was 'the smaller twin' only one generation back had a precarious start. Clinical research about safe and effective medical interventions in pregnancy, especially frequent antenatal monitoring, was a significant factor

in how my experience differed from my grandmother's and why our outcome was so different from earlier generations.

I also experienced marked cognitive dissonance writing Chapters Four and Five while pregnant. I had all this knowledge about the cultural expectations and norms around pregnancy. During the birth I was thinking 'this is that cascade of interventions I read so much about'. Even though I knew about the misperception of risk and safety during pregnancy I still found myself choosing to follow the norms, making very conservative choices about caffeine and alcohol. Despite knowing how, and why, my risk perception was somehow 'off'. My knowledge often sat oddly with my choices and experiences even as I talked through this double vision about risk with my wonderful midwife. Even holding all this knowledge and with a sophisticated understanding of the relationship between medicine and pregnancy I couldn't or wouldn't break with the pattern. My experience, despite extensive knowledge, was little different from those who lacked the same understanding. The strengths of these norms and narratives centered upon pregnancy are well documented, particularly those centered on ideas of risk and responsibility. It will require systematic and institutional changes to overcome the lack of evidence based knowledge for pharmaceutical use during pregnancy.

Some of these changes have occurred. Today, robust examples of good policy encouraging research during pregnancy exist in the form of Canada's 2014 TCPS2. This was the first set of guidelines to specifically address the exclusion of pregnancy from clinical research and emphasise the importance of including pregnant and breastfeeding women in research and refining the complex relationship between 'vulnerability' and pregnant women. TCPS2 also more broadly shifts the balance of consideration of protections and risk for vulnerable individuals to include consideration of the harms arising to populations from being excluded from research. These changes occurred late in the drafting process, only being

incorporated because of advocacy in the December 2009 round of draft consultation.[4] By the time of the 2016 CIOMS Guidelines the reconfiguration of the relationship between pregnancy and clinical research had undergone refinement with emphasis on the injustice of exclusion from research and the need to state that pregnancy was not something that made people vulnerable. In the time between these updates of research guidelines, an increasing international discussion had taken place within bioethics including numerous conference panels and an edited collection to which I contributed.[5] Despite these improvements there is still a lack of change and the socio-cultural norms of pregnancy have been identified as a next step site for intervention.[6]

The genealogical analysis creates a better understanding of why there continues to be a lack of clinical research during pregnancy despite both policy changes and educational campaigns emphasising the benefits and importance of research during pregnancy. Perhaps even more importantly it provides insights into the additional changes needed to facilitate higher rates of clinical research during pregnancy by highlighting the barriers and complications created by stigma, risk misperception, the dominance of the norm of inaction-as-safety, the unique tension between health, nature and risk during pregnancy, the fetus, and expectations from all parties around what constitutes good and responsible motherhood. Each of these features has been identified within the genealogy as shaping the current discourse of pregnancy and as a factor that is impeding clinical research during pregnancy.

The most significant outcome of this project is identifying the existence of a stigma about pregnancy and pharmaceuticals arising out of the mid twentieth century pharmaceutical scandals. This stigma continues to distort the perception of risk during pregnancy, such that

[4] "Public Comments on the Revised Draft 2nd Edition of the TCPS (December 2009)"; "2008 Draft of TCPS2."
[5] Baylis and Ballantyne, *Clinical Research Involving Pregnant Women*; "Enrolling Pregnant Women: Issues in Clinical Research."
[6] van der Zande et al., "Fair Inclusion of Pregnant Women in Clinical Research: A Systematic Review of Reported Reasons for Exclusion."

the risk of inaction during pregnancy is significantly undervalued and the risk of actions – particularly pharmaceutical interventions – is overestimated. While the distorted perception of risk is the predominant concept impeding safe and effective research into pharmaceuticals and pregnancy, each of the other concepts also plays a role. The discourse of pregnancy is best characterised as sitting in a constant state of tension, as simultaneously healthy-normal-natural and also risky. This tension and how it is acknowledged or ignored is a significant factor in many ethical issues centered upon pregnancy. The balance of health and risk and the precise ways these narratives are mobilised within the discourse of pregnancy has real impact not just on how and why pregnant women have been excluded from pharmaceutical research – under-intervention – but also the tendency towards medical over-intervention in childbirth. Pregnancy is women's initiation into 'responsible motherhood' and the corresponding surveillance, pressures and expectations that align with the narrative. It is helpful to understand this narrative of responsible maternity as sitting on top of the overall discourse of pregnancy influencing women's decisions via self-surveillance and the expectation that they are being watched. This works with pregnant women's desire to act in their child's best interest and the knowledge that not only acting or choosing 'wrong' may harm their child to make women less inclined to both take risks and/or act outside of conventional norm.

The final sections of this project discussed what can be drawn from the collective insights gathered via the genealogy. First examining how health, risk, responsibility, nature and the fetus are reinforced within particular documents and how the presence of these concepts within the discourse of pregnancy are central components of modern pregnancy. While over the last decade the formal research documentation and policies have been updated to support research during pregnancy there is still a lack of actual research taking place. This is because such documents and policy can only be part of any attempt to shift the discourse of pregnancy towards promoting research during pregnancy. I conclude by making some

recommendations about what will and will not work as techniques to improve pharmaceutical research during pregnancy. Relevant stakeholders must be educated about the problem, and as demonstrated by other discourses dominated by narratives of risk and stigma, it is not enough simply to educate people about the benefits of research during pregnancy. Rather, to be successful, such education needs first to include a broader range of issues including education about the effect of stigma upon risk perception, the broader bias towards inaction, and the normative strength of social narratives of good mothering and maternal responsibility, and to target researchers, ethics board members, pregnant women, and even possibly their friends and families. This is not a quick fix strategy for resolving the problem of research during pregnancy; however, it is one that can be enacted in parts, broken down into components and refined or enhanced further. There are already existing regulatory and educational associations via which this specific educational bundle could be rolled out, many of which already provide ongoing education for researchers, and medical professionals. Pregnant women and the problem of under-inclusion could be presented as a case study in research ethics, one that highlights a wide range of issues including the importance of checking one's own biases and presuppositions, the importance of detailed planning for how to best engage potential research participants and a more critical engagement with the overall practice of evidence based medicine.

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