

Patient-oriented research to support decision-making in pregnancy hypertension

by

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Abstract

Background: Pregnancy hypertension is a common, potentially fatal condition. New guidance recommends ‘tight’ control of pregnancy hypertension over ‘less-tight’ control. However, guidance also suggests that treatment recommendations consider patient preferences. This dissertation aims to understand how to support patients and providers to make preference-congruent and informed decisions about pregnancy hypertension management.

Methods: First, a mixed-methods study, including a best-worst scaling task, of patient preferences for pregnancy hypertension management was conducted. Next, a systematic review built upon ancillary findings by assessing emotion in patient decision aids (PtDAs) for decisions during pregnancy. Using results from the preferences study, the subsequent study re-analyzed the Control of Hypertension in Pregnancy Study (CHIPS) trial using a patient-oriented composite endpoint. A PtDA was developed and assessed for quality and effectiveness. Lastly, a preliminary study explored emotion-regulation in patient decision-making.

Results: The mixed-methods preference study ($n=210$) found that individuals prioritised seven outcomes when choosing how to manage pregnancy hypertension. Latent class analysis identified three preference profiles (a profile comprises participants with similar preferences). Each profile placed different importance on each outcome: 1) ‘*equal prioritisers*’ valued the outcomes equally; 2) ‘*early delivery avoiders*’ prioritised avoiding delivery before 34 weeks; and 3) ‘*medication minimisers*’ prioritised avoiding medication. A systematic review of 39 PtDAs found that most did not address emotion. Reanalysis of the CHIPS trial using a weighted patient-oriented composite endpoint found that while both strategies yielded equal outcomes for *equal prioritisers*; ‘tight’ control produced better outcomes for *early delivery avoiders*; and ‘less-tight’ control produced better outcomes for *medication minimisers*. A prototype PtDA that incorporated these profiles was assessed ($n=99$) as very acceptable and clear, and significantly improved knowledge. The preliminary emotion study ($n=107$) found that individuals’ beliefs about their own ability to regulate emotions may limit the benefit of a PtDA.

Conclusions: Patient preferences for management of pregnancy hypertension can be broadly described by three profiles. ‘Tight control’ is well-suited to only two of these profiles, emphasizing the importance of shared decision-making in reaching treatment

decisions. A PtDA for pregnancy hypertension may help patients make more informed decisions. Future work should explore how to include emotion in PtDAs.

Lay Summary

High blood pressure (BP) in pregnancy is common and sometimes fatal. Pregnant people and their care providers must choose how to manage high BP. However, little research has considered patient preferences and needs when making this decision. This research aimed to understand patients' priorities for management of high BP in pregnancy and develop tools to help them make a decision. To accomplish these aims, this work included interviews, surveys and a review of published literature. The findings showed that individuals prioritised seven health outcomes and medical interventions when choosing a treatment approach, and that which approach was best was not always the same. Instead, which treatment approach was best changed depending on each person's priorities. A decision aid to help patients choose a treatment approach improved knowledge and may be useful for patients. Additionally, emotion may be an important factor for people making this decision.

Preface

Rebecca Kathleen Metcalfe was the principal person responsible for identifying and designing this program of research, completing data collection and data analysis, interpreting the results and writing the chapters. The content of all chapters represents the work of the candidate with the oversight, input, and feedback of supervisors Drs. Bansback and Harrison and supervisory committee members Drs. Magee and Singer. Ms. Mary Lewisch contributed throughout as a patient partner.

In recognition of the many ways in which individuals identify individually and with pregnancy, this dissertation uses inclusive language. The language framing pregnancy is complex and changing. Initial study materials developed in collaboration with participants referred to gendered terms like ‘women’ and ‘mothers’. When these materials are quoted in the dissertation, these terms are retained. Similarly, the term ‘patient’ is used throughout this work as it is neutral with regards to gender/parent identity. Using the term ‘patient’ also aligns this work with the shared decision-making literature and patient-oriented research efforts around the world.

Parts of the analysis in Chapter Two were presented at the Vancouver Health Economics Meeting in 2019, the International Shared Decision Making Conference in Quebec City in 2019, the 41st Annual North American Meeting of the Society for Medical Decision Making in Portland in 2019, and the 2nd Annual Meeting of the BC Support Unit in Vancouver in 2019. Feedback received at these conferences was incorporated into the work presented in Chapter Two. This work was also published in the *Canadian Journal of Cardiology* in 2020 (volume 36 p. 775-779). Ms. Metcalfe contributed to the research design, conducted the data collection and analysis, and drafted the manuscript. Drs. Bansback and Harrison contributed to the design and data analysis and the creation of the manuscript. Drs. Magee and Singer and Ms. Lewisch contributed to the research design and drafting the manuscript.

The analysis presented in Chapter Three was presented at the 42nd Annual North American Meeting of the Society for Medical Decision Making in 2020 (virtual conference). It has been submitted to a peer-reviewed journal for publication and is currently under review.

The analytic plan for the work presented in Chapter Four was presented at the Vancouver Health Economics Meeting in 2018 and the completed analysis was presented at Canadian Student Health Research Forum in 2021 (virtual conference).

Chapter Six presented here is different from initial plans. Ms. Metcalfe was awarded a Friedman Scholarship (~\$24,000) to study in the Netherlands for seven months. During this time, Ms. Metcalfe planned to adapt the patient decision aid presented in Chapter Five to include emotion regulation strategies and compare the adapted tool to the original tool. This planned work was cancelled due to the COVID-19 pandemic. Instead, Chapter Six presents a survey study of emotion and patient decision-making.

The work presented in this dissertation received ethics approval from the UBC Behavioural Research Ethics Board (H17-01194 and H18-02675).

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List of Abbreviations

BP	Blood pressure
BW	Birthweight
BWS	Best-worst scaling
CHIPS	Control of Hypertension in Pregnancy Study
CI	Confidence interval
CIHR	Canadian Institute of Health Research
CPS	Control Preferences Scale
DCE	Discrete choice experiment
DERS-18	Difficulties with Emotion Regulation Scale - 18 item
EBM	Evidence-based medicine
ERQ	Emotion Regulation Questionnaire
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
IPDAS	International Patient Decision Aid Standards
OR	Odds ratio
PMDS	Preparedness for Decision-making Scale
RCT	Randomised controlled trial
SDM	Shared decision-making
STAI-6	State-trait Anxiety Inventory - 6 item
SUS	System Usability Scale
WKS	Weeks

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Chapter 1: Introduction

1.1 Pregnancy Hypertension

1.1.1 Defining Pregnancy Hypertension

Pregnancy hypertension and its related disorders are a leading cause of death during pregnancy worldwide.¹ Hypertension itself is one of the most common complications of pregnancy.¹ It affects 5-10% of pregnancies in Canada and is associated with increased morbidity, including increased risk of stroke and seizures (i.e., eclampsia) for the pregnant individual (note: this dissertation uses inclusive language, see preface), as well as increased risk of early delivery and restricted growth for the infant.²⁻⁴

Hypertension Canada defines hypertension in pregnancy as a diastolic blood pressure (BP) of ≥ 90 mmHg or a systolic BP of ≥ 140 mmHg.⁵ When these readings increase during pregnancy to ≥ 110 mmHg or ≥ 160 mmHg, respectively, the hypertension is classified as severe. Because of the increased risk of stroke, severe hypertension is considered a medical emergency, and it requires immediate intervention with antihypertensive medication to lower BP.^{2,5,6}

Pregnancy hypertension can be pre-existing (also called chronic) or gestational.² Pre-existing hypertension is defined as hypertension with an onset before 20 weeks of pregnancy.^{2,5} Conversely, gestational hypertension is defined as onset at or after 20 weeks of pregnancy.^{2,5} In Canada, gestational hypertension is more common than pre-

existing hypertension.³ A significant proportion of individuals with pregnancy hypertension develop a more serious condition called pre-eclampsia.^{1,2,5}

In addition to increased short-term risk, emerging evidence suggests that those who experience pregnancy hypertension are at increased risk of negative health outcomes later in life.⁵ Longitudinal findings from the Netherlands show that individuals with pregnancy hypertension have a two- to eightfold increased risk of future chronic hypertension.⁷ A recent review found that the odds of developing cardiovascular disease for individuals with gestational hypertension were 1.67 times the odds for individuals without a hypertensive disorder, and that these odds increased in a dose-response-like fashion for those with moderate and severe pre-eclampsia.⁸ Likewise, individuals with past gestational hypertension have increased odds of stroke (odds ratio [OR] = 1.83; 95% confidence interval [CI] = 1.79-4.22) compared to those with no history of hypertension.⁸ The long-term impacts of pregnancy hypertension are not limited to the cardiovascular system; pregnancy hypertension is also associated with an increased risk of renal disease. A follow-up study of more than one and half million individuals who gave birth in Canadian hospitals from 1993 to 2003 found that individuals with pregnancy hypertension, including pre-eclampsia, had a significantly increased risk of hospitalization for end-stage renal disease (adjusted hazard ratios of

3.3, 4.6 and 4.7 for gestational hypertension, unspecified hypertensive disorders during pregnancy, and pre-eclampsia, respectively).⁹

The rate of pregnancy hypertension has increased over the past decades.^{3,10} This increase is likely due to a rise in chronic conditions, like diabetes, among people of child-bearing age, as well as an increase in the average age at pregnancy.^{11,12} Without changes to these factors, it is likely that the prevalence of pregnancy hypertension will continue to rise.

1.1.2 Medical Intervention for Pregnancy Hypertension

Medical management is recommended to mitigate the risks associated with pregnancy hypertension. At present, there are two primary treatment approaches: 'less-tight' control which aims to control BP while minimising antihypertensive therapy, and 'tight' control which aims to normalise BP.^{2,13} There has been considerable debate about which of these two approaches produces better outcomes. Consistent evidence from small trials shows that 'tight' control is associated with better outcomes and fewer complications, such as eclampsia and stroke, for the pregnant person.^{14,15} However, studies have been inconsistent regarding findings about infant outcomes. While some have found that 'tight' control increases risk of being born small for gestational age and

the need for high-level perinatal care, others have found no increased risk for the infant.¹⁶

A large-scale international, pragmatic randomised controlled trial (RCT)—called the Control of Hypertension in Pregnancy Study (CHIPS) trial—was conducted to address methodological issues with previous studies, such as small sample size, and to determine whether less-tight or ‘tight’ control most improved outcomes for both infants and pregnant individuals.¹⁷ The trial found no statistically significant differences in the primary outcome for infants or for pregnant individuals. However, data showed significantly more participants developed severe hypertension with ‘less-tight’ control compared to ‘tight’ control (41% and 28% respectively, $p < 0.001$). As a result of these findings, as well as similar results from a recent systematic review,¹⁵ guidance now promotes ‘tight’ control of pregnancy hypertension.^{5,6,18,19} Nonetheless, Canadian guidelines also recommend that practitioners “consider patient preferences, values, and clinical circumstances when determining how to best apply these guidelines to individual patients”.⁵ Consequently, treatment decisions should consider individual values, not simply the average risk estimates that inform clinical guidelines. However, this recommendation comes with no guidance on implementation. The issue of how to integrate individual values into treatment recommendations for management of pregnancy hypertension is the subject of this dissertation.

1.2 Decision-making in Medicine

1.2.1 Evidence-based Medicine

Evidence-based medicine (EBM) is the primary model of medical decision-making used in Western medicine today.²⁰ The term was first used in the early 1990s by Gordon Guyatt, who sought to change clinical decision-making so that priority was given to what the evidence showed was effective instead of what authorities dictated.^{21,22} Previous approaches had emphasised individual clinician's intuition and clinical experience.²³ EBM reduced this emphasis and instead prioritised systematic examination of evidence as the basis for clinical decision-making.²⁴

EBM has quickly gained a foothold in the medical community. Using an EBM approach requires clinicians to track emerging research and to synthesise new evidence with their current knowledge base.²⁰ However, with more than 2.5 million scientific articles published every year, it is a challenge for clinicians to keep pace with new findings.²⁵ This task is made more challenging because many studies are not well executed: many use flawed methods or make conclusions beyond their findings.²⁶ Furthermore, not all studies are applicable to all patient populations within a given disease area. As a result, tools have proliferated to support EBM. For example, Grading of Recommendations, Assessment, Development and Evaluations (GRADE), is a framework developed to

systematically summarise the quality of evidence on a given topic.²⁷ These summaries can then be used to inform clinical decisions. Likewise, Cochrane, which emerged from the EBM movement, is an international non-profit organization that coordinates comprehensive systematic reviews to synthesise the body of evidence on a given health topic.²⁸ The goal of Cochrane is to make evidence accessible to care providers and patients making medical decisions with the belief that this will aid decision-making and improve decision quality. In the context of pregnancy hypertension, both Cochrane reviews and GRADE have informed the development of clinical guidance.

Although these are important information classification tools that can support decision-making, they only address gaps in knowledge and, like EBM, they do not address the multitude of other factors that influence clinical decision-making. While knowledge can be a barrier, evidence suggests that other factors may be more salient barriers to EBM in clinical practice.²⁹ For example, studies trying to identify factors underlying unnecessary imaging for lower back pain have found that physicians generally have a clear understanding of when imaging is recommended and when it is not.³⁰ Instead, many studies have implicated relational concerns in physicians' failure to implement imaging guidelines. Physicians report: that they worry that patients will be upset if they do not receive imaging; that they believe patients will find it difficult to accept imaging guidelines; and that they feel inclined to comply with patient requests in

order to protect the physician-patient relationship.³⁰⁻³⁴ These concerns extend beyond imaging for lower back pain. A qualitative study investigated physician perception of a recent initiative—the Choosing Wisely Campaign—to improve adherence to evidence-based clinical guidelines.²⁹ The authors found that physicians did not perceive the initiative to be effective because it only addressed knowledge and did not address the other drivers of unnecessary testing, such as time pressure during clinical encounters, and uncertainty about optimal care pathways.

Of note, one negative consequence of EBM is that it may make maintaining strong clinician-patient relationships more difficult; adherence to inflexible rules may result in care that centers system-level needs (like cost reduction) rather than patient needs.³⁵ Likewise, while EBM tools, like clinical guidelines, may describe the best treatment on average, they do not describe the best treatment for all individuals.³⁶ Indeed, some argue that these blanket recommendations do not leave room for individual patient preferences,³⁷ and, in the absence of guidance on how to consider patient preferences in treatment decisions, guidelines may make clinicians more likely to ignore patient preferences.³⁸

Importantly, there are many clinical decisions where EBM may be of limited use. For example, while some treatment decisions have a clear best option, many are preference-sensitive, meaning that there is no best alternative.³⁹ EBM, with its focus on harms and benefits, does not help individuals to make these types of treatment decisions which are necessarily based on individual values. Furthermore, the way in which EBM prioritises certain types of information presents challenges. Namely, EBM places RCTs at the top of the evidence hierarchy. However, RCTs routinely use restrictive criteria that limit the generalizability of findings. For instance, a review of the representativeness of RCT samples found that RCT participants tended to be lower risk than real-world patients, and that RCTs frequently excluded older patients and those with co-morbidities.⁴⁰ Speaking to this, a recent systematic review found that on average 77% of excluded participants from RCTs were excluded because of comorbidities.⁴¹ In Canada, one in three individuals has a chronic condition⁴² and almost one in six has two or more chronic conditions.⁴³ Consequently, given the high prevalence of chronic conditions and multimorbidity, it is unclear to what extent EBM alone could support real-world decision-making, even if knowledge were the primary driver of inappropriate care.

In summary, while EBM is an important step forward to increasing the likelihood that treatment decisions are informed, it is not sufficient to ensure quality

decision-making that both considers the evidence and is aligned with patient values. Shared decision-making (SDM) tries to address these issues.

1.2.2 Shared Decision-making

Shared decision-making (SDM) is a process through which clinicians and patients collaborate to come to treatment decisions: patients are experts on their own experiences and values, and care providers are experts in the evidence supporting different treatment options. SDM has been driven to the forefront of discussions on healthcare as a result of recent quality-improvement initiatives prioritising patient-centered care. For example, the Government of British Columbia, in its Ministry of Health's strategic plan,⁴⁴ identified patient-centered care as the first of eight priorities. SDM is seen as one way in which patient-centered care can be realised in everyday practice and care quality can be improved. Experts have referred to SDM as the "pinnacle of care", and they have argued that the confluence of SDM and EBM are essential for high quality healthcare.⁴⁵ Indeed, SDM provides a way for clinicians to incorporate evidence into individual consultations and to reconcile that evidence with patient preferences and values to ideally arrive at quality treatment decisions.

In addition to improving care quality, SDM has been proposed as a way to improve healthcare outcomes and decrease healthcare costs.⁴⁶ For example, it has been

proposed that SDM may increase the alignment between patient values and treatment choices, and consequently improve medication adherence;⁴⁷ low medication adherence is a common cause of poor outcomes.^{48–50} Although some studies have found that SDM has improved outcomes or reduced costs—for example in knee replacement surgery—in general, these improvements have failed to materialise.^{51,52} However, studies show that SDM does consistently improve patient-reported outcomes, as well as the decision-making process. Recent reviews have found that SDM improves patient satisfaction, reduces anxiety and decisional conflict, and increases confidence in the decision made and knowledge.^{51,52} Moreover, these benefits may be greater for socially disadvantaged individuals (i.e., those made vulnerable by socioeconomic status, racism, lack of education or low-literacy, or geography).⁵³

Despite these benefits and quality initiatives, SDM is often not implemented.^{54,55} The 2018 NHS Adult Inpatient Survey found that almost half of patients were not as involved in decisions about their care and treatment as they would like to have been.⁵⁶ Similarly, a review of SDM studies found overall low levels of patient-involving behaviours in clinical encounters.⁵⁷

Research suggests that implementing SDM can be difficult. Time constraints, as well as a lack of training and structure, are all common reasons that SDM does not take place.^{58,59} It should be emphasised that both patients and care providers can struggle

with SDM. For patients, it can be hard to be sure which treatment components and health outcomes are most important, and for clinicians, it can be hard to convey complex health information in an accessible manner and to find ways to understand what is important to patients. Tools that support SDM, such as patient decision aids (PtDAs), can help address these issues by creating structure for conversations about treatment decisions and providing information in an accessible manner.

1.2.3 Patient Decision Aids

Patient decision aids (PtDAs) are tools to help individuals better understand treatment options and ultimately help them make decisions that are most in keeping with their preferences and values. PtDAs are often used to support SDM, as they can provide a structure through which patients and clinicians are able to collaborate. Established through an international Delphi consensus of experts in patient decision-making, the IPDAS outlines best practices for PtDAs, including guidance on development, content selection and presentation, and effectiveness.⁶⁰

In addition, the International Patient Decision Aids Standards (IPDAS) list seven minimum criteria that must be met for a tool to qualify as a decision aid. The PtDA must: (i) describe the condition related to the decision; (ii) describe the decision that needs to be considered; (iii) identify the target audience; (iv) list the options; (v) provide

information about the positive features of the options; (vi) provide information about the negative features of the options; and (vii) help patients clarify their values for outcomes of options by asking patients to think about which positive and negative features of the options matter most to them, or by describing each option to help patients imagine the physical, social, and/or psychological effects.

The IPDAS do not specify any particular medium for PtDAs. As a result, PtDAs can take many forms. Most commonly, PtDAs are paper-based – often a one- to two-page hand-out or booklet – but they can also be audio recordings, videos, video games, or increasingly, interactive webpages.⁶¹

A significant body of evidence support the use of PtDAs. A Cochrane Review of 105 studies of PtDAs for diverse medical decisions concluded that high quality evidence shows that PtDAs increase knowledge and decrease decisional conflict related to feeling uninformed and indecisive about personal values.⁶¹ Additionally, PtDAs reduced the proportion of patients who were undecided and improved patient-clinician communication.⁶¹

Further research conducted to assess PtDAs in the context of pregnancy has found similar results. A recent systematic review and meta-analysis found that PtDAs for decisions in obstetrics and gynecology significantly improved patient knowledge, reduced patient anxiety, and minimised decisional conflict.⁶² Reviews examining PtDAs

for decisions made during pregnancy specifically found similar results.^{63,64}

Additionally, a scoping review found that PtDAs for decisions in pregnancy are generally of high quality when evaluated using the IPDAS criteria.⁶⁵ These results support the use of PtDAs for health decisions during pregnancy.

1.2.4 Patient Preferences & Preference Elicitation

1.2.4.1 Patient Preferences

As made clear by tenets of SDM, making quality treatment decisions often requires an understanding of patient preferences and values. While occasionally one treatment option will be dominant, that is, superior on all metrics, this is rarely the case. Instead, most treatment decisions require making complex trade-offs between different outcomes or treatment requirements. For example, more effective treatments for relapsing-remitting multiple sclerosis tend to have more side effects than less effective treatments.⁶⁶ Thus, treatment choice depends on the relative value each patient places on the anticipated benefits (i.e., effectiveness) and risks (i.e., side effects).⁶⁷

These value-based decisions are often complex and involve trade-offs in time. For instance, a decision might be made to live with side-effects in the present for increased benefits in the future, or to provide treatments that improve quality of life while shortening expected lifespan. In addition to comparing present and future

benefits and harms, many treatment decisions require patients to make trade-offs about certainty, often because of uneven information (i.e., more data about one treatment than other) and/or low quality information.

These types of decisions can be difficult, not only because of their inherent seriousness, but also because they require people to engage in affective forecasting and imagine what they might value in the future given a variety of hypothetical scenarios. Research shows that when people engage in this kind of thinking they are susceptible to a number of biases, including projection bias (assuming preferences will remain stable over time) and present bias (the tendency to give more weight to outcomes closer to the present time), both of which can lead to lower quality decisions.⁶⁸⁻⁷⁰

In addition to the challenges patients face in determining their own preferences and values, clinicians can also struggle to identify patient priorities and treatment preferences in a consultation. These preferences can sometimes be formed with inaccurate information;⁷¹ and clinicians can sometimes struggle to accept their patients having different preferences than they themselves have.^{72,73} Consequently, a growing body of research focuses on identifying patient preferences, with the goal of informing clinical decision-making and treatment development.

1.2.4.2 Preference Elicitation

Initially developed for marketing, preference elicitation is a growing field in healthcare research. Its purpose is to understand how patients value health outcomes and treatment requirements (herein referred to as ‘treatment characteristics’), either individually, or as a set or profile. More simplistic methods of preference elicitation use techniques common to many fields, such as Likert-scales and ranking tasks. These approaches are often familiar to patients and as a result require little piloting, but these benefits come at a cost. By allowing patients to give all treatment characteristics the maximum importance score, Likert-scales can obscure variability in patient values. In contrast, ranking tasks can create variability where none exists because they do not allow patients to indicate when characteristics are in fact valued equally. Lastly, the simplicity of these tasks makes them more susceptible to response bias, and particularly social-desirability bias and demand characteristics.⁷⁴

More complex approaches, such as discrete choice experiments (DCEs) and best-worst scaling (BWS) tasks, address these issues and provide insight into how individuals make trade-offs between outcomes. In DCEs, participants are presented with a series of choice sets, each showing two or more treatment profiles made up of varying treatment characteristics.⁷⁵ The participants then indicate which of these treatment profiles they prefer. In BWS tasks, the choice sets simply present a list of

treatment characteristics and participants indicate which characteristic is best and which is worst in each choice set. Both of these tasks yield relative weights (herein ‘weight’ is used to refer to the relative importance of outcomes on a scale that sums to 100, where a weight of 60 for outcome A is twice as important as a weight of 30 for outcome B). As a result, the relative importance of treatment characteristics can be directly compared to each other.^{76,77} Additionally, the task formats make them less susceptible to response bias. On the other hand, these tasks are more cognitively taxing than simpler approaches and may not be appropriate for all populations.

Because tasks can only accommodate a finite number of treatment characteristics, qualitative work is an important component of all preference elicitation tasks. This work should focus on identifying which characteristics of a decision are most important to the patient.^{78,79} Rigorous qualitative work is integral to the validity of preference elicitation tasks. Without it, tasks may miss key treatment considerations that shape patient preferences, and thus they would fundamentally misrepresent what patients value and how they make trade-offs between treatment characteristics.

1.2.5 Incorporating Patient Preferences into Clinical Trials

Identifying patient preferences and engaging in SDM can help clinical decision-making and increase the likelihood that any given decision reflects patient values. However,

even with these tools, it can be difficult to know how best to integrate patient values with clinical evidence. According to GRADE, RCTS produce the highest quality clinical evidence.⁸⁰ Unfortunately, interpreting these data in particular can be challenging because RCTs often use multiple endpoints. Multiple endpoints are used because treatments often have more than one outcome of interest, and treatments may have differential impacts on outcomes of interest.^{81,82} For example, a treatment may decrease deaths but increase strokes. However, the meaning of a significant treatment effect in an RCT that uses multiple endpoints is unclear: the treatment could significantly improve any one or all of these outcomes; some or possibly none of these outcomes. As a consequence, it can be very difficult for a clinician to interpret results from trials that use multiple outcomes meaningfully, let alone apply them to treatment decisions that consider patient values.^{83,84} Composite endpoints are one way that RCTs assess multiple outcomes simultaneously. For example, RCTs of cardiovascular conditions often use major adverse cardiac events (MACE) as the primary composite outcome. MACE is not a single outcome, but rather it is comprised of multiple outcomes, often including death, myocardial infarction, stroke and hospitalization.^{83,85}

Statistical guidance indicates that composite endpoints should be composed of equally important components.⁸² Nonetheless, concerns have been raised that there is often an imbalance in the importance (or weight) of

components, but this imbalance is not reflected in the statistical analysis.⁸⁶ Indeed, research shows that the least important outcomes used in clinical trials tend to occur more frequently than the most important outcomes.^{81,82,87} As a result, significant findings are often driven by changes in the outcome that is valued the least, with little to no change in the outcomes that are valued the most.

It should be noted that criticisms have not only been levelled against how the components are valued in statistical analysis, but also whose values are used.⁸⁸ As a result of these criticisms, combined with mounting evidence demonstrating the importance of patient values in treatment,⁸⁹⁻⁹¹ recent work has tried to address the issue of patient values in composite outcomes. For example, Ferreira-González et al. conducted a systematic review of RCTs, in which they assessed the extent to which composite outcomes used in cardiovascular RCTs published in major medical journals varied in importance to patients.⁸¹ Additionally, studies have used multiple preference elicitation methods to assess the importance of cardiovascular endpoints to patients relative to clinical trialists⁹² and clinicians.⁹³ In general, these studies have found that patients place different value on endpoints than clinicians or trialists.

In addition to the arbitrary way in which weights are often determined, the components of composite outcomes are most often chosen by clinicians and researchers, and these components may differ from the endpoints that patients value.⁹⁴ Although

studies that identify the components that patients value are increasingly conducted in healthcare research,⁹⁵ this work has only been applied to clinical trials in a limited way.

Importantly, composite components and component weights may offer an opportunity to improve both the relevance and interpretability composite endpoints. Work has begun to explore best methods for using patient values to weight composite components appropriately. For example, Tong et al. used a DCE to elicit patient preferences for composite components used in a longitudinal cohort study.⁹⁶ After finding differences between patient values and those applied in the study analyses, the authors reweighted the time-to-event analysis and found that using patient weights yielded a smaller marginal effect of the treatment than the conventional analysis. Similarly, using a BWS task, Udogwu et al. assessed patient preferences for common orthopaedic trauma outcomes and weighted simulated trial data.⁹⁷ They found that including patient values attenuated the magnitude but not direction of the effect. These studies show that incorporating patient preferences into trials is feasible and can alter interpretation.

One approach that has not yet been explored is selecting composite components based on patient values and then weighting each component to reflect its relative importance. This approach would have the advantage of focusing results on outcomes that are of importance to patients and are likely to change decision-making. Using

patient-oriented composite endpoints could help clinicians interpret and apply evidence to clinical decisions, as significant findings would indicate that one treatment is better aligned with patient values than another.

1.2.6 Emotion & Decision-making in Medicine

Emotion is a complex construct. Lakoff referred to emotion as a *contested concept*.⁹⁸ While everyone agrees that emotion exists, the scientific definitions and descriptions of emotion vary considerably. Despite this scientific dispute, most definitions of emotion describe it as an internal experience consisting of physiological, cognitive and behavioural components.⁹⁹ Individuals may experience and label emotions differently, but essentially all individuals experience emotion throughout their daily lives, and emotion is involved in many complex processes, including decision-making. In a comprehensive review, Lerner and colleagues describe the deep relationship between emotion and decision-making.¹⁰⁰ Emotions guide and bias conclusions, alter what factors are considered and how deeply, and shape goal-setting and interpersonal decision-making. The authors conclude that “emotion and decision-making go hand in hand.”¹⁰⁰ In health, these conclusions are supported by numerous studies. For example, in the long term, emotion contributes to health behaviours like smoking,¹⁰¹ alcohol and drug use,^{102–105} and overeating;^{106,107} in the short term, emotional states can influence

risky sexual behavior,^{108,109} and the interaction of stress and fear can lead to avoidance of health information.¹¹⁰

As the experience of emotion varies across individuals, it follows that individual factors can also influence the relationship between emotion and decision-making. For example, Apkarian and colleagues compared individuals with and without chronic pain.¹¹¹ They found that those with chronic pain had poorer emotional decision-making, as assessed by an emotional decision-making task, but there were no differences in measures of attention, short-term memory and general intelligence. Likewise, You et al. found that compared to older adults, younger adults' decision-making was more influenced by negative emotions.¹¹² Further, they found that this difference could be explained by differences in how younger and older adults regulated their emotions.

In addition, studies on patient experiences support the importance of emotion in health behaviours. In a 2014 study of telephone helplines in cancer care, Ekberg and colleagues concluded that help-seekers' emotional support needs were intertwined with their informational needs.¹¹³ Speaking to this, a mixed-methods study of shared decision-making in breast cancer found that high levels of emotional arousal were the most common barrier to patient participation in shared decision-making.¹¹⁴ Qualitative findings from the development of a decision aid for treatment of multiple sclerosis are similar; participants reported that the feeling of being overwhelmed made it difficult to

engage in early discussions about treatment options. Given the evidence, it is clear that emotion has a profound impact on health decision-making in numerous ways—from health behaviours themselves to how patients engage with the decision-making process.

Despite the evident importance of emotion in decision-making, it is often not addressed explicitly in patient decision-making. For example, a seminal theoretical paper on shared decision-making in clinical practice¹¹⁵ acknowledges that emotion is an important component of SDM. However, it does not include emotion in its proposed model of SDM. Similarly, an international interdisciplinary working group identified emotional competency as one of two core competencies for shared decision-making,¹¹⁶ yet the IPDAS for the development of PtDAs do not provide guidance on if or how to address emotion.^{60,117}

The absence of emotion in models of patient decision-making extends to models of clinical decision-making. Early models of decision-making failed to explicitly address emotion^{118,119} and instead proposed clinical decision-making as an entirely rational process in which care providers weigh the risks and benefits of each option.¹²⁰ However, a recent review found that emotion is highly involved in clinical decision-making and that it has important implications for patient safety.¹²¹ Addressing this, a qualitative study found that emergency room physicians and nurses report a wide variety of emotions in response to patient-, hospital- and system-level factors, and that providers

were concerned about the impact of negative emotions on clinical decision-making.¹²² A mixed-method study had similar findings: emergency department nurses and physicians reported that emotions—particularly negative emotions like anger— influenced their clinical decision-making. In contrast, positive emotions increased provider engagement.¹²³ Despite this work, acknowledgement of emotion in clinical decision-making is variable,¹²¹ and consequently explicit consideration of emotion is likely missing from providers' formal training.

1.3 Overall Aim of Thesis

In the context of the literature reviewed, the overall aim of this work is to support patients and clinicians to make value-congruent and informed decisions about how to manage pregnancy hypertension. The research questions addressed in each chapter are outlined in Table 1.1.

Table 1.1. Chapter-specific research question

Chapter	Title	Aims	Research Question(s)
2	Patient Preferences and Decisional Needs When Choosing a Treatment Approach for Pregnancy Hypertension	Describe and quantify patient preferences for management of pregnancy hypertension	<ol style="list-style-type: none">1) What outcomes and treatment requirements do individuals prioritise when choosing a strategy for management of pregnancy hypertension?2) What is the relative importance of the

			prioritised outcomes and treatment requirements?
3	How Do Patient Decision Aids Address Emotion? A Review of Patient Decision Aids in Pregnancy	Describe the way in which emotion is addressed in PtDAs	<p>3) Do subgroups of patient preferences exist? If so, how does the relative importance of prioritised outcomes and treatment requirements differ between subgroups?</p> <p>1) What percentage of PtDAs for decisions in pregnancy include emotion?</p> <p>2) Which emotions are included?</p> <p>3) How is emotion framed?</p> <p>4) What percentage of PtDAs for decisions in pregnancy include strategies for managing emotions?</p>
4	Integrating Patient Preferences into Randomised Controlled Trials Using Composite Outcomes	Describe existing methods for weighting composite endpoints and assess the impact of integrating patient weights into analysis of the CHIPS trial	<p>1) What methods have been proposed for weighting composite end points?</p> <p>2) Do the results of the CHIPS trial change when a patient-oriented composite endpoint is used?</p> <p>3) Do the results of the CHIPS trial change when patient values are used to weight a patient-oriented composite outcome?</p>
5	Development and Pilot Testing of a	Develop and evaluate a PtDA for	<p>1) What is the acceptability and usability of the</p>

	Patient Decision Aid for Pregnancy Hypertension	pregnancy hypertension	PtDA for pregnancy hypertension? 2) Does the PtDA for pregnancy hypertension improve knowledge? 1) What is the relationship between specific facets of emotion and emotion regulation and patient decision-making?
6	Generating Hypotheses: A Preliminary Exploration of the Role of Emotion in Patient Decision-Making	Generate and test preliminary hypotheses about the role of emotion and emotion regulation in patient decision-making	

1.4 A Patient-Oriented Research Approach

The research presented in this dissertation takes a patient-oriented approach. Patient-oriented research is “a continuum of research that engages patients as partners, focusses on patient-identified priorities and improves patient outcomes.”¹²⁴ Recent initiatives have highlighted the importance of patient-oriented research. Internationally, INVOLVE was established in 1996 in the United Kingdom to support patient and public involvement in health research,¹²⁵ and in 2010 the Patient Protection and Affordable Care Act in the United States launched the Patient-Centered Outcomes Research Institute.¹²⁶ In Canada, the Canadian Institutes of Health Research (CIHR) recently launched the Strategy for Patient-oriented Research.¹²⁴ Its goal is to increase patient engagement and respond to patient identified healthcare priorities. Evidence indicates that patient-oriented approaches improve treatment uptake and adherence, as well as

patient satisfaction.^{127,128} Further, a patient-oriented approach can add validity and rigor to research processes.^{129,130}

A fundamental difference in patient-oriented research methods as compared to more traditional methodology is the starting point. In traditional methods, the research starts with a literature review. In contrast, patient-oriented research starts with patients. As a result, rather than beginning, as is traditional, with a literature review, this dissertation starts by listening to patients to gain a better understanding of their preferences and needs.

Another fundamental difference in patient-oriented research is the composition of the research team. CIHR states that patient-oriented research is “conducted by multidisciplinary teams in partnership with relevant stakeholders.”¹²⁴ Relevant stakeholders include the CIHR funded provincial and territorial patient-oriented research groups, called SUPPORT Units, as well as patients, researchers, policy and decision-makers, health organizations and other institutions like universities and charities. Unlike other approaches in which patients only contribute as participants in studies, in patient-oriented research, patient partners are a crucial part of the research team; their expertise and lived experience can change not only the research questions but also the research methods. The team that contributed to this work was composed of diverse stakeholders including a patient partner, a clinical trialist and statistician, a

specialist in hypertensive disorders of pregnancy who has co-authored national and international clinical guidance on management of pregnancy hypertension, and two health economists specialising in patient preferences and decision science. Parts of this research were also supported by the BC SUPPORT Unit.

Additionally, substantial effort was made throughout this project to ensure a diversity of patient perspectives were represented. Particular attention was paid to include perspectives of patients from across British Columbia, rather than just the Greater Vancouver Area, and of patients receiving care from non-physician care providers, as these perspectives are often missed in studies of health concerns in Canada.

Figure 1.1: Flowchart showing the connection between dissertation chapters

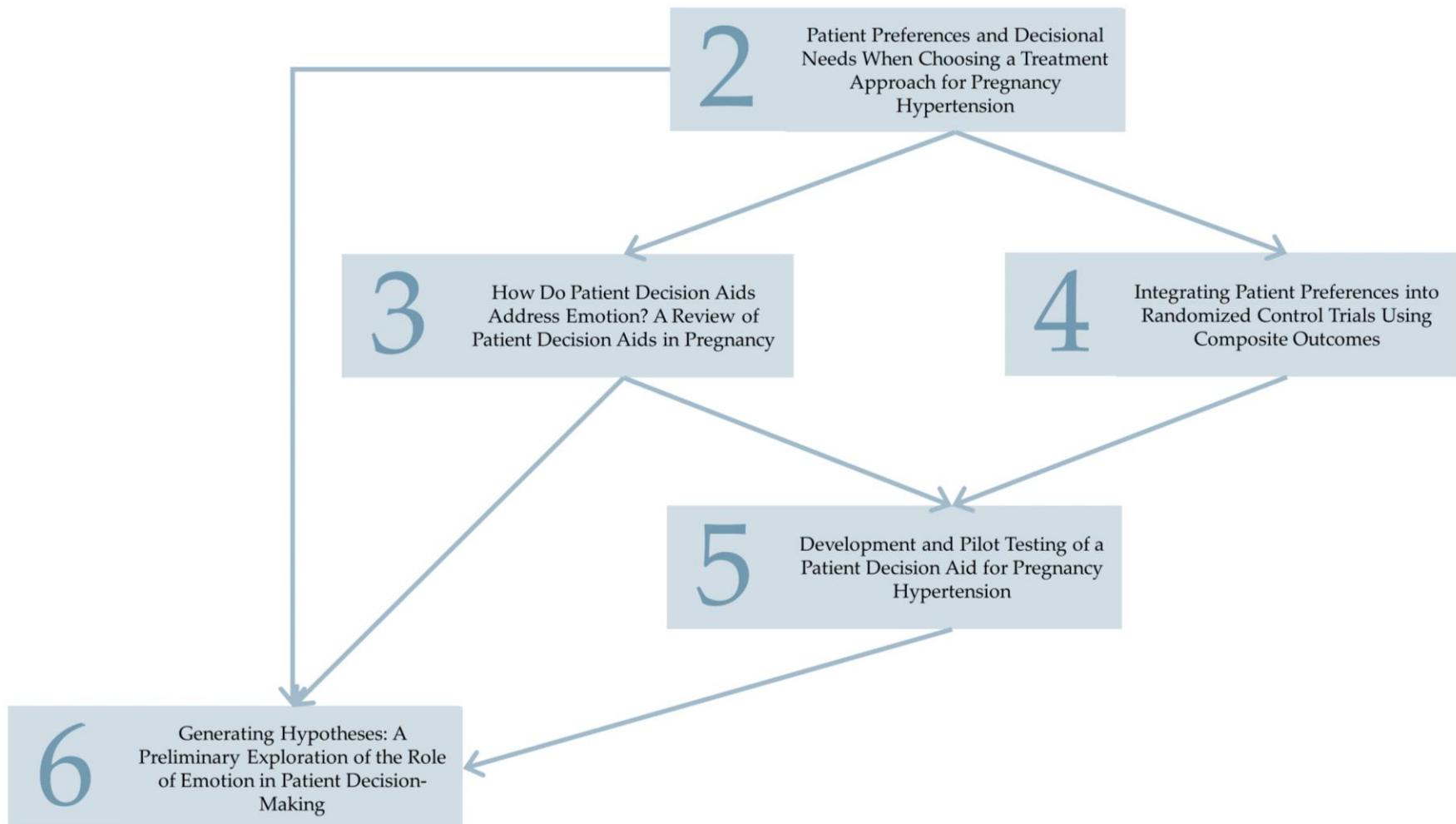
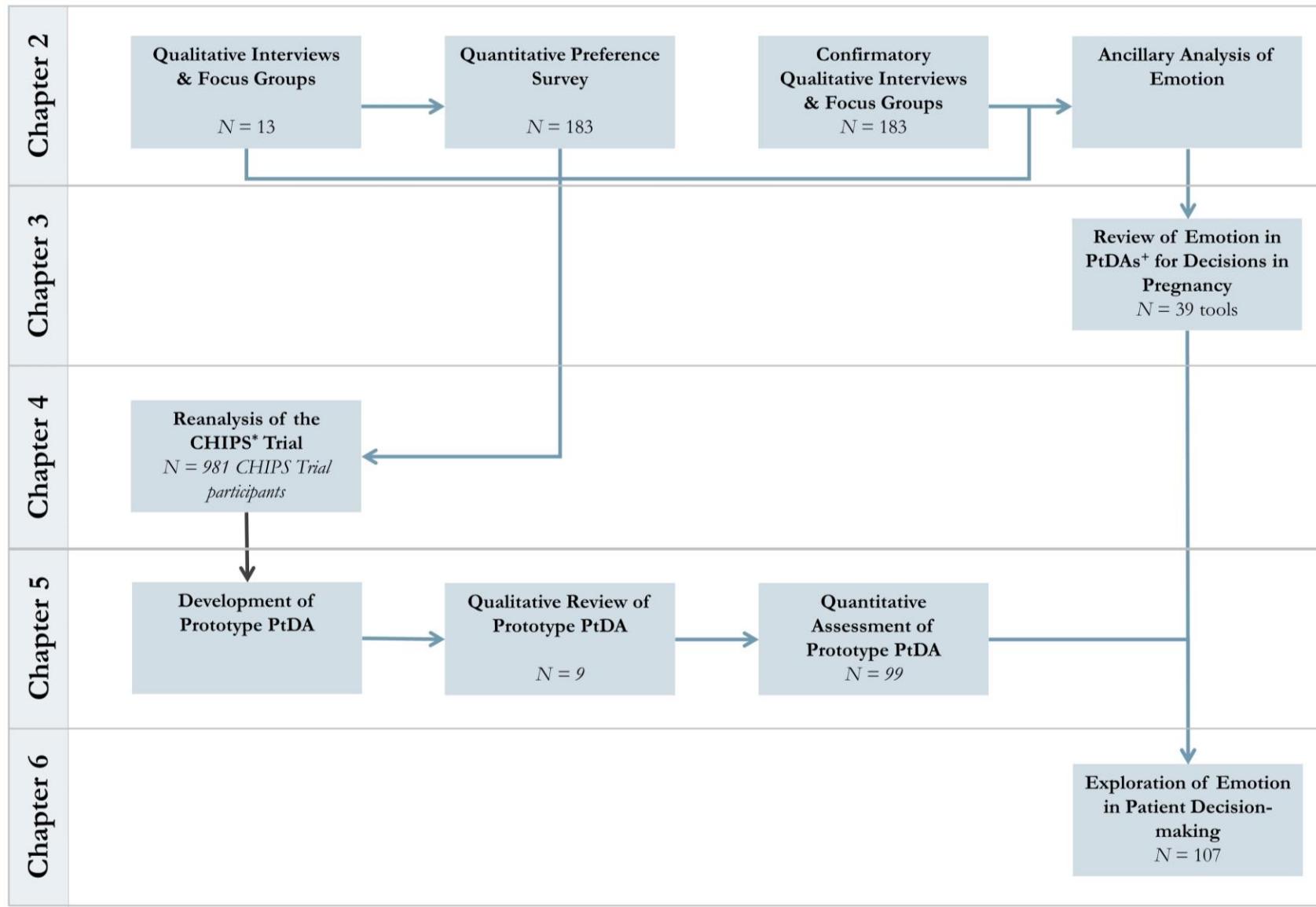


Figure 1.2: Chart showing the specific steps and sample sizes within each chapter



1.5 Dissertation Outline

Pregnancy hypertension is a common, and potentially fatal, condition with lifelong consequences. While the CHIPS trial provides evidence that ‘tight’ control reduces risk of severe hypertension without increasing risk to the fetus, decisions on how to manage pregnancy hypertension must still incorporate patient preferences. At the outset of this work, it was unknown which health outcomes and treatment requirements were most important to individuals with pregnancy hypertension. Moreover, no tools existed to support patients or clinicians in reaching a decision. Figure 1.1 provides an overview of the relationship between subsequent chapters and Figure 1.2 provides an overview of the steps within each chapter.

In keeping with a patient-oriented approach, the first major component of this dissertation is a qualitative investigation of individuals’ preferences for management of pregnancy hypertension. Through semi-structured interviews and focus groups, this qualitative work aimed to identify the health outcomes and treatment requirements that changed individuals’ preferences for tight or ‘less-tight’ control. These results were then used to inform the development of a quantitative preference elicitation survey to determine the relative importance of each of the outcomes and treatment requirements identified in interviews and focus groups as important to decision-making. In addition, the survey explored decisional needs and preferences for decision support tools and

SDM. Because the initial qualitative work primarily included individuals living in the Greater Vancouver Area, after the preference survey, additional qualitative interviews were conducted to understand the extent to which earlier findings could be generalised to individuals with pregnancy hypertension outside of the Greater Vancouver Area. Like the initial qualitative work, these interviews focused on identifying the health outcomes and treatment requirements that would change preferences for management of pregnancy hypertension. The preference work is reported in detail in Chapter Two of this dissertation.

Although the primary objective of the qualitative work was to identify the outcomes and treatment requirements of most influence to decision-making, it became clear through the interviews that emotion was an important component of the decision-making process for individuals with pregnancy hypertension. As this dissertation used a patient-oriented lens, it was important to explore this patient identified priority and further consider emotion in patient decision-making. After finding little research on emotion in PtDAs or the role of emotion in SDM, a systematic review was conducted to identify if and how emotion is addressed in PtDAs for decisions in pregnancy. The systematic review is presented in Chapter Three.

One of the challenges for SDM is integrating evidence with patient values in order to come to decisions. Thus, part of this project endeavoured to apply the new

findings on individual's preferences for management of pregnancy hypertension and develop tools for clinicians and patients.

To facilitate interpretation of trial results for clinicians, different methods for incorporating patient preferences into trial results were reviewed and a new approach proposed. Specifically, a patient-oriented composite endpoint was created from the outcomes and treatment requirements identified as important in Chapter Two. This composite endpoint was weighted to reflect the relative importance of each composite component to patients. Different preferences weights were tested to examine if and how patient preferences changed the interpretation of the CHIPS trial results. This work is presented in Chapter Four.

In order to support patients, the findings from Chapter Two were used to inform the development of a PtDA for those choosing between 'tight' control and 'less-tight' control. The PtDA presents information on pregnancy hypertension and the risks and benefits of each treatment approach. Additionally, it includes tasks to help individuals identify the aspects of the decision that are most important to them, and information to support conversations with their care providers. The PtDA used results from the quantitative preference study to order information and make the tool more relevant to the patient: the information that is most important to the patient is presented first. Chapter Five details the development process; this process included qualitative

assessment of the PtDA and a preliminary evaluation of the PtDA's acceptability and usability, its relationship to decisional conflict and preparedness for decision-making, and its impact on patient knowledge.

The final chapter of the dissertation addressed emotion in patient decision-making. Results from the systematic review presented in Chapter Three found that no best practices exist on if and how to address emotion in PtDAs. Furthermore, research on the role of emotion in patient decision-making in the context of SDM is limited. Thus, Chapter Six used a cross-sectional survey to explore the role of emotion and emotion regulation in patient decision-making with the aim of generating testable hypotheses for future work.

Chapter 2: Patient Preferences and Decisional Needs When Choosing a Treatment Approach for Pregnancy Hypertension

2.1 Introduction

As reviewed in Chapter One (Section 1.1.2), clinical guidance for management of pregnancy hypertension encourages care providers to consider patient preferences and values when making treatment recommendations. However, no studies of individual's preferences for management of pregnancy hypertension have been conducted to date. Consequently, this chapter explored individual's preferences and decisional needs when they are choosing how to manage pregnancy hypertension.

2.2 Background

Research in other areas shows that patient preferences are often not homogenous, and instead patient subgroups can have different preferences and priorities (e.g. Lynd et al., 2016; Mundal et al., 2021; Ostermann et al., 2020¹³¹⁻¹³³). In pregnancy hypertension, it is likely that at least some patient preferences may be at odds with the clinical guidance, given that 'tight' control is associated with increased usage of antihypertensive medication, and that studies have found that individuals are generally reluctant to use medication during pregnancy.¹³⁴ Importantly, variability in preferences is not limited to patients: physician preferences may vary too. A survey conducted at the end of the

CHIPS trial found that more than 40% of participating clinicians were undecided as to whether they would recommend tight or ‘less-tight’ control.¹³⁵ Ultimately, then, the treatment decision depends on the value that each person places on both the health outcomes and the treatment requirements.

Despite the relatively high prevalence of pregnancy hypertension and the importance of patient preferences when choosing a management approach, no research has examined individuals’ preferences and priorities for management of hypertension, characteristics that may predict a preferred management approach, or, for that matter, preferences for decision support. Elucidating these factors may facilitate clinicians’ support of patient decision-making, particularly when patient preferences differ from their own,^{72,73} or when they are based on inaccurate information.¹³⁶

The objective of this chapter is to explore, with regard to the management of pregnancy hypertension, individuals’ treatment priorities, treatment preferences, and decisional needs, in order to inform the development of decision tools that could facilitate clinician consultations and assist patients in making value-congruent decisions about management of pregnancy hypertension.

2.3 Methods

2.3.1 Overview

A sequential mixed-methods approach was used to study individuals' preferences for management of pregnancy hypertension. First, qualitative methods were used to identify what characteristics of the treatment decision were most important and also to explore individuals' decisional needs and preferences for decision support. Second, quantitative methods were used to determine the relative importance of each of the characteristics identified in qualitative work. Statistical methods were used to identify preference subgroups and predictors of patient preferences. Third, confirmatory qualitative work was conducted to determine the generalizability of the initial qualitative findings. Lastly, an analysis of both the initial and confirmatory work was conducted to explore the relationship between emotion and decision-making. Table 2.1. describes each of these phases and the methods used.

Table 2.1: Four phases of the mixed-methods investigation of preferences for management of pregnancy hypertension

Purpose	Data collection	Data	Analysis
A 1) Identify the treatment considerations that were most important to child-bearing individuals when	Semi-structured focus groups and interviews	Transcripts from interviews and focus groups	1) Constant comparison to identify important treatment considerations

	choosing a treatment approach		
B	<p>1) Quantify the relative importance of each of the treatment considerations identified in Phase A</p> <p>2) Identify subgroups of patients that vary in how they prioritise the identified treatment considerations</p> <p>3) Identify predictors of preference for tight vs. 'less-tight' control</p> <p>4) Quantify decisional needs and preferences for decision support</p>	<p>Cross-sectional, online survey</p>	<p>Survey responses to:</p> <ul style="list-style-type: none"> • A preference elicitation task • Multiple choice questions <p>1) Traditional count analysis for the preference elicitation task</p> <p>2) Latent class analysis of preference elicitation task results</p> <p>3) Logistic regression predicting treatment preference (tight vs. 'less-tight' control)</p> <p>4) Descriptive statistics to describe patterns of decisional needs and support preferences</p>
C	<p>1) Address sampling limitations from Phase A by assessing the extent to which the treatment characteristics identified in Phase A represent</p>	<p>Semi-structured interviews</p>	<p>Detailed notes taken during interviews</p> <p>1) Constant comparison to identify important treatment considerations</p>

		the preferences of child-bearing individuals outside the Greater Vancouver Area
D 1) Describe the different ways in which participants from Phases A & B described emotion as part of decision-making in pregnancy hypertension	None	Detailed notes taken during interviews and focus groups conducted as part of Phase A and C. 1) Descriptive analysis

This study was reviewed and approved by the Behavioural Research Ethics Board (H17-01194 and H18-02675) at the University of British Columbia. This work was supported by the Canadian Institutes of Health Research under grant MCT 87522 and by the BC SUPPORT Unit. Funders did not have any input on the design, analysis or results of the study.

2.3.2 Phase A: Identifying Important Treatment Considerations

Focus groups and individual interviews were conducted to identify the treatment characteristics (also called attributes) that individuals valued most when choosing a treatment approach for pregnancy hypertension, and to explore their decisional needs.

Participants were recruited using posters placed online (e.g., Facebook groups, online forums) and in the Greater Vancouver Area (e.g., libraries, community centres, and hospitals). Individuals were eligible to participate if they were: (i) currently pregnant or had been pregnant within three months of the screening interview at which consent was obtained; (ii) at least 18 years of age; (iii) able to consent and to read, write and speak in English; and (iv) able to attend an interview or focus group in the Greater Vancouver Area.

2.3.2.1 Focus Groups & Interviews

Focus groups and one-on-one interviews followed a semi-structured interview guide. The interview guide was based on two literature reviews. The first of these identified three qualitative studies on pregnancy hypertension,^{135,137,138} all of which focused on the experience of having had pregnancy hypertension. None of these studies focused on treatment decision-making. The second review identified randomised controlled trials comparing 'less-tight' and 'tight' control. This review ultimately focused on the CHIPS trial as it is the most recent and large-scale study with high internal (i.e., randomised and controlled) and external (i.e., open and pragmatic) validity.¹⁷ A patient partner reviewed and provided feedback on the interview guide. Based on these reviews, and on discussions with clinicians, statisticians involved with the CHIPS trial, and decision-scientists, a list of 14 treatment-differentiating attributes was developed to generate

discussion in the interviews and focus groups. Focus groups and individual interviews were conducted until saturation was reached. Member-checking was used throughout the focus groups and interviews to ensure alignment between participants' understanding of their own experiences and qualitative data collected.

2.3.2.2 Data Analysis

All interviews were transcribed. Data analysis followed Coast and colleagues' methodology for developing health related attributes for use in discrete choice experiments.^{78,79} Consequently, constant comparison, in an iterative manner, was used to identify attributes that participants viewed as most important. After each interview, notes were reviewed and compared with notes from the preceding interviews. Between interviews, comparisons were reviewed with the research team. When an attribute was consistently identified as unimportant, the attribute was removed from the list of treatment differentiating attributes and not raised explicitly in subsequent interviews. If any conflict or uncertainty existed around the importance of an attribute, the attribute was retained.

2.3.3 Phase B: Quantifying the Relative Importance of Treatment Considerations and Decisional Needs, and Identifying Preference Subgroups and Predictors of Preference for ‘Tight’ vs ‘Less-tight’ control

Based on the qualitative work from Phase A, a survey was developed to determine child-bearing individuals’ preference for ‘tight’ or ‘less-tight’ control of BP in pregnancy, how they prioritise potential treatment requirements and adverse outcomes as part of their decision-making, and how they would like to be supported in their decisions.

Participants from across Canada were recruited from an independent survey research panel and were eligible to participate if they: (i) self-identified as currently pregnant; (ii) were at least 18 years of age; (iii) and could consent based on their ability to read and write in English. Responses were collected in August and September of 2018.

2.3.3.1 Survey

The survey had four components: (i) collection of demographic information; (ii) information provision and knowledge assessment; (iii) a best-worst scaling task (BWS) to identify treatment priorities; and (iv) a decisional needs assessment to determine how best to support individuals choosing a pregnancy hypertension management approach. To ensure the survey was accessible and easy to understand, the project patient partner

reviewed all information provided and it was tested in focus groups and interviews.

The full survey is included in Appendix A.

2.3.3.1.1 Survey Development

First, demographic information was collected. It consisted of personal characteristics (e.g., age, education), health status related to common conditions in current and past pregnancies (e.g., gestational diabetes), and published predictors¹³⁹ of severe hypertension, pre-eclampsia, preterm birth and small for gestational age infants (e.g., parity, race/ethnicity, antihypertensive medication use).

Second, the information was provided to the participants, and their knowledge was assessed to ensure familiarity with the topic before completing the BWS task. In this section, participants reviewed information about each of the characteristics identified in qualitative work and then answered a question to determine their understanding of the information they had just read. These questions are presented in Table 2.4 as part of the results. Questions were reviewed by a specialist in pregnancy hypertension (LAM). After answering each question, participants were provided corrective or affirmative information, depending on the accuracy of their responses.

Third, a Case 2 type BWS task was chosen to elicit the prioritisation of attributes. BWS is a stated preference technique that allows researchers to determine which treatment attributes are most important to participants.¹⁴⁰ In a BWS task, each

participant is presented with a series of choice sets composed of decision attributes, and then asked to identify the most and least important attributes in each choice set. Case 2 was chosen because it is less cognitively taxing than other choice-based methods, and it allows each attribute to be compared against the other attributes considered.⁹⁵ The BWS task used a balanced incomplete block design of seven choice sets, each containing four attributes. For each choice set, participants indicated which attribute was “most important” and “least important”. All participants completed the same choice sets. Attributes were assigned values from the ‘less-tight’ and ‘tight’ control arms of the CHIPS trial.¹⁷ These values were used because this strategy of antihypertensive-based titration of BP to a target BP is what is clinically recommended, rather than a strategy of antihypertensive therapy (regardless of resultant BP) vs. placebo/no therapy (unless BP is severely elevated) as in other RCTs.¹⁵ Each attribute was described as a decrease in the probability of the attribute occurring if one treatment was chosen over the other (e.g., ‘A decrease in the risk of severely elevated blood pressure throughout pregnancy from 41 in 100 women to 28 in 100 women’). In keeping with risk communication best practice¹⁴¹, all attribute descriptions included: (i) an icon array depicting the outcome risk for each treatment; and (ii) the same denominator (i.e., 100; Figure 2.1). No treatment names were used in the descriptions. After the BWS task, participants were

shown a table listing the attributes and their values for 'less-tight' and 'tight' control (with treatment names removed) and asked which treatment they preferred.

Finally, decisional needs and preferences (e.g., type, delivery and format of health information) identified in qualitative work were assessed using multiple choice questions, including 5-point Likert scale questions anchored at "Strongly Agree" and "Strongly Disagree", and visual analogue scales.

Figure 2.1: Example choice set from the BWS task

Most important	Medication	Least important
<input type="checkbox"/>	<p>A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100. This is a decrease of 17 in 100 women taking medication.</p> <ul style="list-style-type: none"> ● will take high blood pressure medication ● will take high blood pressure medication if they use a given treatment ● will not take high blood pressure medication 	<input type="checkbox"/>
<hr/>		
<input type="checkbox"/>	<p>Severely Elevated Blood Pressure Throughout Pregnancy A decrease in the risk of severely elevated blood pressure throughout pregnancy from 41 in 100 to 28 in 100. This is a decrease of 13 in 100 women having severely elevated blood pressure.</p> <ul style="list-style-type: none"> ● will have severely elevated blood pressure throughout pregnancy ● will have severely elevated blood pressure throughout pregnancy if they use a given treatment ● will not have severely elevated blood pressure throughout pregnancy 	<input type="checkbox"/>
<hr/>		
<input type="checkbox"/>	<p>Caesarean Delivery A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100. This is a decrease of 4 in 100 women having a Caesarean delivery.</p> <ul style="list-style-type: none"> ● will have a Caesarean delivery ● will have a Caesarean delivery if they use a given treatment ● will not have a Caesarean delivery 	<input type="checkbox"/>
<hr/>		
<input type="checkbox"/>	<p>Blood Transfusion A decrease in the risk of blood transfusion from 3 in 100 to 1 in 100. This is a decrease of 2 in 100 women needing a blood transfusion.</p> <ul style="list-style-type: none"> ● will need a blood transfusion ● will need a blood transfusion if they use a given treatment ● will not need a blood transfusion 	<input type="checkbox"/>

2.3.3.2 Sample Size

At present, there are no formal sample size calculations for BWS tasks.⁷⁶ Nevertheless, research indicates that a study should include 10 participants per attribute level to allow for sufficient degrees of freedom during analysis.¹³¹ Given that seven attributes and levels were identified in qualitative work, a target sample size of 200 was set. This sample size followed recommendations, allowed subgroup analyses, and provided a margin for incomplete or invalid responses, while simultaneously balancing a need for precision with recruitment feasibility.^{142,143}

2.3.3.3 Data Analysis

Responses to demographic and decisional needs questions were analysed descriptively. Statistical analyses explored the relationship between treatment preference and knowledge and history of pregnancy hypertension (in a past or current pregnancy), as it was anticipated that individuals with a history of pregnancy hypertension would be more knowledgeable than those with no such history. Mean knowledge scores between groups were compared using t-tests.

A simple count model was first used to calculate the weights for the BWS analysis.¹⁴⁰ Subsequently, latent class modelling in Latent Gold 5.1 was used to determine if subgroups with different treatment priorities (i.e., preference profiles) could be identified.¹⁴⁴ Analyses followed Collins and Lanza's guidelines for latent class

analysis in behavioural health applications.¹⁴⁵ Latent class models were compared using Bayesian information criterion.

Logistic regression identified predictors of treatment preference and multinomial logistic regression identified predictors of the preference profiles identified through latent class analysis. Due to small cell sizes, categorical variables were dichotomised based on overall sample cell-counts, with the aim of maintaining categories with a plurality or majority of the cell-counts. Potential predictors were identified based on bivariable statistics and plausibility, and entered into univariable regression. Variables with a p-value < 0.20 were included in multivariable analysis using backwards stepwise logistic regression with an inclusion criterion of p < 0.10. Likelihood ratio tests and the Bayesian information criterion were used to compare models.

2.3.4 Phase C: Confirmatory Qualitative Interviews

The initial interviews and focus groups were conducted primarily with people living in the Greater Vancouver Area. In order to assess the extent to which findings could be generalised to those outside the Greater Vancouver Area, additional interviews were conducted. These interviews mirrored the initial interviews, and aimed to identify which characteristics of treatment were the most important to individuals outside the Greater Vancouver Area when choosing how to manage pregnancy hypertension.

Participants were recruited using posters placed online (e.g., Facebook groups, online forums) and through the BC Midwifery Network. Individuals were eligible to participate if they: (i) were currently pregnant or had a history of pregnancy hypertension; (ii) were at least 18 years of age; and (iii) could consent, and read, write and speak in English. Interviews were conducted through video conferencing (e.g., Skype) or by telephone.

2.3.4.1 Data Analysis

Interviews were audio-recorded and detailed notes were taken. Data analysis followed the same procedures as the initial qualitative interviews (see Section 2.3.2.2 for further details). Constant comparison, in an iterative manner, identified attributes participants viewed as most important.^{78,79} The finalised list of attributes identified was compared to the list of attributes identified in the initial analysis conducted as part of Phase A.

2.3.5 Phase D: Ancillary Qualitative Analysis

Although outside the initial scope of this work, it became evident that emotion was being mentioned regularly in interviews and focus groups on decision-making about management of hypertension in pregnancy. Previous review of the literature had found little describing individual experiences making decisions about hypertension in pregnancy. Consequently, detailed notes from all qualitative work (initial and

confirmatory) were reviewed. Analysis was descriptive in nature and focused on describing the different ways in which individuals included emotion when discussing this decision. Quotations from participants were obtained from audio recordings and review of transcriptions, where available. As previously, findings were reviewed with the research team to assess validity.

2.4 Results

2.4.1 Phase A: Identifying Important Treatment Considerations

Thirteen people participated in two focus groups and five individual interviews. Most participants (69%; n = 9) were 35 years of age or older and more than half (54%; n = 7) reported an annual household income above \$75,000. All but one participant was from Greater Vancouver Area.

2.4.1.1 Important Considerations for Choosing a Treatment

Constant comparison analysis of focus groups and interviews identified seven treatment differentiating attributes (of fourteen) that participants stated were important to them when considering a treatment approach for pregnancy hypertension: (i) risk of severely elevated blood pressure throughout pregnancy; (ii) risk of pre-eclampsia; (iii) risk of HELLP Syndrome; (iv) likelihood of taking medication during pregnancy; (v) likelihood of Caesarean delivery; (vi) risk of delivery before 34 weeks; and (vii) the risk

of the baby being born small for gestational age. In addition to the outcomes included in the list of treatment differentiating attributes, participants identified death of the infant and the pregnant individual, and severe infant outcomes as important overall. Event rates from the CHIPS trial for these outcomes were nearly identical. When presented with the event rates from the CHIPS trial for these outcomes, they were no longer perceived as relevant to the decision. Table 2.2 shows the attributes that were excluded and the reasons for their exclusion.

Table 2.2: List of seven excluded attributes and the reason for their exclusion

Attribute	Reason for Exclusion
Risk of Serious Complications for the Pregnant Person (e.g., stroke, blood transfusion)	Participants were not comfortable grouping stroke and blood transfusion together, and indicated a concern about stroke, but not about blood transfusion. Review of the trial data identified one stroke event overall, thus the incidence of stroke was too low to include a risk estimate.
Risk of Delivery Before 37 weeks	Participants were aware that they could deliver after 34 weeks in most local hospitals. Participants reported that they were concerned about early delivery, but not with 37 weeks as the cut-off. Based on this feedback, delivery before 34 weeks was included in subsequent focus groups and interviews.
Risk of an Emergency Room Visit	Participants did not feel that this was an important attribute because it did not indicate the severity of the reason for the emergency room visit. Participants did note that it would be helpful to normalise emergency visits in the patient decision aid with a statement like, "It is not uncommon for women with high blood pressure in pregnancy to visit the emergency room at least once during their pregnancy."

Risk of ≥ 1 Hospital Admissions (not including delivery admission)	Participants did not feel that this was an important attribute, both because the difference between the two treatment groups was small (2%), and because they stated that they were happy to receive care if they needed it.
Risk of Needing to Decrease Activity Level During Pregnancy	Some participants said that this could be important if it meant needing to take a leave of absence from work and/or bedrest. However, participants said that given the ambiguity of "decrease activity level" it was not important. Additionally, participants were confused that more individuals in 'tight' control decreased activity than individuals in 'less-tight' control.
Risk of Caesarean Delivery Without Prior Labour or Induction	This attribute was not considered to be important by participants in the focus groups or the interviews. Avoiding caesarean delivery was a very important consideration for a subset of participants, but it was not important whether or not that caesarean was preceded by labour or induction.
Risk of Having Blood Pressure that is Higher than Normal	Some participants felt that this was important because they anticipated experiencing anxiety from knowing that they had an elevated blood pressure. However, this concern was low overall, and participants indicated that it was better captured by concern about severe high blood pressure throughout pregnancy.

Following review of the seven attributes with an expert in hypertensive disorders of pregnancy (LAM), a decision was made to remove risk of HELLP Syndrome as this is a specific form of pre-eclampsia, which was already included. Additionally, risk of blood transfusion was added as this was considered an important intervention for care providers. The final attributes included in the BWS task were: (i) risk of severely elevated blood pressure throughout pregnancy; (ii) risk of pre-eclampsia; (iii) risk of

blood transfusion; (iv) likelihood of taking medication during pregnancy; (v) likelihood of Caesarean delivery; (vi) risk of delivery before 34 weeks; and (vii) risk of the baby being born small for gestational age.

2.4.2 Phase B: Quantitative Survey

In total, 183 people completed the survey. Approximately one third had experience of hypertension in a past pregnancy, and approximately one quarter reported current pregnancy hypertension, usually treated with antihypertensive therapy (46/51, 90.2%). Most participants were 25-34 years of age, Caucasian, born in Canada, and had completed post-secondary education (Table 2.3). The vast majority had a reported annual income of at least CA \$35,000. Most participants were recruited at <20 weeks' gestation (mean = 17.5 weeks). Approximately half of all participants had a prior pregnancy; few were smokers. Participants were evenly divided in preferences for tight and 'less-tight' control (see section 2.4.2.3 for further discussion).

Table 2.3: Preference survey sample characteristics

	Overall Sample		Preferred Treatment	
	N	%	'less-tight' control N = 90	'tight' control N = 93
Hypertension in current or past pregnancy				

Yes	54	29.7	31.5	28.0
Age				
Less than 25 years	14	7.7	10.0	5.4
25 to 29 years	45	24.6	23.3	25.8
30 to 34 years	63	34.4	37.8	31.2
35 to 39 years	35	19.1	15.6	22.6
40 years or older	26	14.2	13.3	15.1
Race/Ethnicity				
Aboriginal or Indigenous	3	1.6	2.2	1.1
African American or Black	8	4.4	4.4	4.3
Asian	38	20.8	26.7	15.1
Biracial, Mixed race, or Other not listed here	3	1.6	3.3	--
Caucasian	120	65.6	56.7	74.2
Hispanic or Latina	4	2.2	2.2	2.2
South Asian	6	3.3	3.3	3.2
Prefer not to say	1	0.5	1.1	74.2
Country of Birth				
Canada	146	78.5	77.5	78.5
Education				
High School or below	30	16.4	18.9	14.0
College Diploma or Technical/Trade School	52	28.4	33.3	23.7
University	66	36.1	31.1	40.9
Professional Qualification	35	19.1	16.7	21.5
Income				
Under \$35,000	23	12.6	16.7	8.6
\$35,000 to \$75,000	63	34.4	41.1	28.0
Over \$75,000	90	49.2	38.9	59.1
Prefer not to say	7	3.8	3.3	4.3
Previous Pregnancies				
0	97	52.7	42.7	50.5
Conditions in Previous Pregnancy[†]				
Gestational Diabetes	24	24.7	29.4	19.6
Hypertension	29	29.9	29.4	30.4
Pre-eclampsia	8	8.3	7.8	8.7
Conditions in Current Pregnancy				
Gestational Diabetes	32	17.5	25.6	9.7

Hypertension	50	27.3	27.8	26.8
Pre-eclampsia	11	6.0	6.7	5.4
Current Medication				
Antihypertensives	46	25.1	22.2	28.0
Aspirin	52	28.4	30.0	26.9
Folic Acid or Prenatal Vitamins	157	85.8	84.4	87.1
Other Medications	54	29.5	30.0	29.0
Smoke Cigarettes During Current Pregnancy				
Yes	13	7.1	11.1	3.2

^aOnly asked of those who reported a previous pregnancy (N = 86)

2.4.2.1 Knowledge

On average, participants answered 3.9 (± 1.8) out of 7 knowledge questions correctly (see Table 2.4). Participants with current or past pregnancy hypertension had significantly lower mean knowledge scores (3.4 ± 1.8 out of 7) than did participants with no such history (4.1 ± 1.8 out of 7; $p = 0.01$), and they also performed more poorly on six of the seven knowledge questions.

Table 2.4: Proportion of participants correctly responding to knowledge questions

	Overall Sample		Treatment Preference			
	N	%	'less-tight' control	'tight' control	N	%
Question 1: Women with high blood pressure have...						
An increased risk of complications for the baby	63	34	37	41	26	28

An increased risk of complications for the woman	28	15	16	18	12	13
The same risk of complications as women with normal blood pressure in pregnancy	17	9	8	9	7	8
*Both a) and b)	77	42	29	32	48	52
Question 2: Women with severely elevated blood pressure during pregnancy are:						
Have the same risk as women without severely elevated blood pressure throughout pregnancy	11	6	9	10	2	2
Less likely to deliver early	24	13	16	18	8	9
*More likely to experience seizures and strokes	102	56	43	48	59	63
Both a) and b)	46	25	22	24	24	26
Question 3: Which one of the following statements is true about women with pre-eclampsia?						
They always have symptoms, such as headache or abdominal pain.	30	16	22	24	8	9
They can be diagnosed in early pregnancy.	26	14	18	20	8	9
*They may be admitted to hospital for monitoring.	100	55	41	46	59	63
None of the above are true.	27	15	9	10	18	19
Question 4: Please indicate which of the following statements is TRUE about taking medication for high blood pressure during pregnancy:						
Mothers who take antihypertensive medications during breastfeeding have to monitor their babies' heart rates.	19	10	12	13	7	8
Taking antihypertensive medication during breastfeeding can negatively impact development of the baby's brain.	28	15	20	22	8	9

Taking antihypertensive medication during breastfeeding is never recommended.	22	12	14	16	8	9
*The commonly-used antihypertensive medications can be taken during breastfeeding.	114	62	44	49	70	75
Question 5: Please choose the ONE best option to describe a baby who is born small for gestational age:						
*The baby can have short-term health problems.	68	37	30	33	38	41
The baby is never normal.	5	3	5	6	0	0
The baby is smaller than all other babies born at the same point in pregnancy	79	43	33	37	46	49
The baby will definitely have long-term health problems	31	17	22	24	9	10
Question 6: True or false: Almost all babies born before 34 weeks need to spend time in the neonatal intensive care unit before they can go home.						
False	25	14	11	12	14	15
*True	158	86	79	88	79	85
Question 7: During and after delivery, women may receive blood transfusions because of:						
Severe anemia	17	9	12	13	5	5
Bleeding associated with high blood pressure	10	5	6	7	4	4
A postpartum hemorrhage (sudden and very heavy bleeding after birth)	56	31	34	38	22	24
*All of the above	100	55	38	42	62	67

*denotes the correct answer

2.4.2.2 Treatment Priorities Among Key Outcomes

Initial analysis of BWS responses found no clear treatment priority. All attributes received a relative weight ranging from 12% to 17% (Table 2.5).

Table 2.5: Relative weights from traditional count analysis of best-worst scaling responses

Attribute	Relative Weight
Decrease risk of severely elevated blood pressure throughout pregnancy from 41% to 28%	0.13
Decrease risk of pre-eclampsia from 49% to 46%	0.12
Decrease risk of blood transfusion from 3% to 1%	0.17
Decrease likelihood of taking medication from 94% to 77%	0.14
Decrease likelihood of caesarean delivery from 51% to 47%	0.16
Decrease risk of delivery before 34 weeks from 16% to 13%	0.15
Decrease risk of baby being born small for gestational age from 20% to 16%	0.13

Latent class analysis identified three distinct groups of treatment priorities (i.e. preference profiles; Table 2.6). ‘Equal prioritisers’ (n = 114, 62% of respondents) assigned roughly equal weighting to all seven attributes (range 8-20%). ‘Early delivery avoiders’ (n = 44, 23% of respondents) prioritised reducing the risk of delivery before 34 weeks. ‘Medication minimisers’ (N = 25, 14% of respondents) prioritised reducing the likelihood of taking medication.

Table 2.6: Treatment priorities for 3 preference profiles identified in latent class analysis

Attributes	Profile 1 “Equal Prioritisers” N = 114	Profile 2 “Early Delivery Avoiders” N = 44	Profile 3 “Medication Minimisers” N = 25
Decrease risk of severely elevated blood pressure throughout pregnancy from 41% to 28%	0.11	0.20	0.20
Decrease risk of pre-eclampsia from 49% to 46%	0.15	0.16	0.10
Decrease risk of blood transfusion from 3% to 1%	0.20	0.02	0.00
Decrease likelihood of taking medication from 94% to 77%	0.14	0.02	0.58
Decrease likelihood of caesarean delivery from 51% to 47%	0.13	0.02	0.04
Decrease risk of delivery before 34 weeks from 16% to 13%	0.18	0.42	0.02
Decrease risk of baby being born small for gestational age from 20% to 16%	0.08	0.16	0.05

2.4.2.3 Preference for ‘Tight’ or ‘Less-tight’ Control of BP

When shown a de-identified table comparing ‘tight’ and ‘less-tight’ control on each of the seven attributes and asked which treatment they preferred, participants were evenly divided. Half of participants preferred ‘tight’ control (n = 90, 49%) and half (n = 93, 51%) ‘less-tight’ control. In univariable logistic regression, there were five variables associated with preference for ‘tight’ control: (i) knowledge score; (ii) race/ethnicity; (iii)

education; (iv) preference profile as identified by the latent class analysis; and (v) number of weeks pregnant (Table 2.7). Three of these were independently associated with preference for 'tight' control in multivariable analyses: Caucasian ethnicity; a university education or professional qualification; and higher knowledge scores.

Table 2.7: Treatment preference for tight (vs. less-tight) control: odds ratios from univariable and multivariable logistic regression

Predictor	Univariable			Multivariable		
	OR	95% CI	p-value	OR	95% CI	p-value
Knowledge Score						
Increasing (continuous)	1.43	1.19-1.70	0.001	1.37	1.15-1.65	0.001
Race/Ethnicity						
Not Caucasian	Ref			Ref		
Caucasian	2.22	1.20-4.17	0.011	2.38	1.18-4.55	0.016
Education						
High School/Trade School	Ref			Ref		
University/Prof. Qualification	1.77	0.98-3.20	0.057	1.95	1.02-3.70	0.037
Latent Class Analysis Preference Profile						
'Equal Prioritisers' and 'Medication Minimisers'	Ref			--	--	--
'Early Delivery Avoiders'	2.13	1.05-4.32	0.038	--	--	--
Number of Weeks Pregnant						
Increasing (continuous)	1.03	0.99-1.06	0.090	--	--	--

2.4.2.4 Multinomial Logistic Regression

Multivariable analysis found no meaningful predictors of preference profile. Results are presented in Appendix B.

2.4.2.5 How Individuals Want to Make Decisions

Most participants stated that they would prefer to hear information about pregnancy hypertension from their doctor (79%), and almost all (82%) wanted that information if they were at risk for pregnancy hypertension, even if they had not yet developed hypertension (Table 2.8). Most participants preferred a digital format (website: 51%; app: 20%) rather than a paper format (30%; booklet: 18% or a one-page pamphlet: 12%). Although most participants (59%) preferred individualised risk information (even recognising that it may be less accurate compared with average information that is very accurate), a substantial minority expressed no preference (24%) or a preference for more accurate, average information (18%). The majority of participants felt that it would be helpful to read about other people's experiences of pregnancy hypertension (86%), and that a separate version of information for partners and other family members or friends would be useful.

Very few participants preferred their doctor to make the final decision about treatment, either with (6%) or without (1%) their input. About half of participants (48%) preferred to make the final decision about treatment themselves after considering their

doctor's opinion, while roughly equal proportions preferred making the decision with their physician (22%) or independently (24%).

Table 2.8: Participants' self-reported decisional needs

	N	%
Prefer to receive information from... (check all that apply)		
Doctor	145	79
A nurse involved with my care	34	19
My midwife	27	15
Community care nurse	13	7
Another health organization or health program (e.g., prenatal classes; first start program)	12	7
A patient group or support group	5	3
I would like to receive this information...		
Only if I had developed high blood pressure	33	18
Only if I were at risk for developing high blood pressure	150	82
Prefer to receive information on maternal hypertension as...		
A website I can access on any device	93	51
An app for my phone or tablet	37	20
A booklet	32	18
A 1-page pamphlet	21	12
Prefer to receive information...		
At the end of my doctor's appointment	91	50
Before my doctor's appointment	75	41
During my doctor's appointment	17	9
I would rather have less accurate information that considers my individual characteristics than have very accurate information that is about the average person.		
Strongly agree	50	27
Somewhat Agree	58	32
Neither Agree nor Disagree	43	24
Somewhat Disagree	24	13
Strongly Disagree	8	4
It is helpful to read about other women's experiences with a health issue.		
Strongly agree	97	53

Somewhat Agree	61	33
Neither Agree nor Disagree	18	10
Somewhat Disagree	6	3
Strongly Disagree	1	1
It is helpful to have information for me, and a separate version of the information for my partner or other close family members or friends.		
Strongly Agree	68	37
Somewhat Agree	62	34
Neither Agree nor Disagree	35	19
Somewhat Disagree	12	7
Strongly Disagree	6	3
Preference for Shared Decision-making		
I prefer to leave all decisions regarding treatment to my doctor	2	1
I prefer that my doctor makes the final decision about which treatment will be used but seriously considers my opinions	11	6
I prefer that my doctor and I share responsibility for deciding which treatment is best for me	40	22
I prefer to make the final decision about my treatment after seriously considering my doctor's opinion	87	48
I prefer to make the decision about which treatment I receive	43	24

2.4.3 Phase C: Confirmatory Qualitative Interviews

Fourteen participants completed interviews about their preferences and priorities when considering a treatment for pregnancy hypertension. The majority of participants lived outside the Greater Vancouver Area ($n = 10$; 79%), had completed post-secondary school ($n = 13$; 93%) and were currently pregnant ($n = 11$; 71%). Three (21%) had a history of pregnancy hypertension.

2.4.3.1 Important Considerations for Choosing a Treatment

Constant comparison analysis of interviews identified the same seven treatment differentiating attributes as important; however, why attributes were considered important varied slightly from previous interviews. For example, while all participants reported concerns about early delivery given the increased risk for the infant, this concern was amplified for participants living in more rural settings due to the extended travel time required to reach hospitals equipped to provide a high level of neonatal care.

2.4.4 Phase D: Ancillary Qualitative Analysis

Descriptive analysis of detailed notes taken during data collection for Phase A and Phase C identified three ways in which emotion was discussed in relation to the decision-making process: (i) information-seeking and avoidance; (ii) taking emotional cues from others; and (iii) anxiety caused by treatment requirements.

1) Information-seeking and Avoidance

Participants reported that emotion impacted how they engaged with health information. For example, some participants reported that health information would increase their anxiety and consequently, they avoided any non-essential health information.

"I feel sometimes I freak-out with more information." (Participant 20)

In contrast, other participants said that they preferred more information, so that they could prepare themselves emotionally for potential events.

"I want to know the worst things. It's terrifying but...maybe knowing it in that sense is better because then we are avoiding bad surprises." (Participant 19)

2) Taking Emotional Cues from the Care Provider

While some participants found information could induce or alleviate stress, others said that they based their emotional response to the situation on their care provider's response.

"I just feel like if my healthcare provider is kind of more, um, like showing more concern or stress about something, um, then that would make me more worried." (Participant 4)

Another participant reported not only taking cues about negative emotions from their doctor but also positive emotions.

"I didn't really react to my diagnosis [of high blood pressure] because my doctor was so low-key." (Participant 20)

3) Anxiety Caused by Treatment Approaches

Several participants commented on how the different treatment requirements would impact their mental health. Some participants perceived 'less-tight' control as being more anxiety-inducing.

"If I was aiming for something ideal, I think I would worry less, 'cuz I knew I was trying my best to go get out of the danger zone, so with the 'less-tight' control I think I would worry every day. "Oh, am I in the danger zone?" "Am I getting close to the severe zone?" But if I were on 'tight' control, I think every day I would just follow the treatment as much as I could." (Participant 1)

However, others perceived 'tight' control as causing more anxiety.

"I think that if I was in a 'tight' control situation it almost would have been made my anxiety worse, because I wasn't getting to that ideal blood pressure." (Participant 2)

2.5 Discussion

This work shows that child-bearing individuals in BC prioritised seven treatment-differentiating outcomes and interventions related to control of BP in pregnancy, and that the outcomes prioritised were the same for people living in and outside the Greater Vancouver Area.

Survey findings suggest that pregnant people in Canada are divided in which method of BP control they prefer for pregnancy hypertension, in contrast to new evidence-based treatment recommendations (i.e., 'tight' control) from Hypertension Canada to control BP in pregnancy.⁵ Most participants reported no specific focus regarding particular adverse outcomes, when they are making decisions about BP

control. Of note, a distinct minority focus on avoidance of antihypertensive medication. Most (but not all) participants wish to receive information in digital format (vs. paper), have a conversation with their doctor, and undertake shared decision-making. The need for shared decision-making is highlighted by the fact the few participants wished to have the BP control chosen for them. Further, the finding that prior pregnancy hypertension was associated with lower knowledge scores, suggests that SDM may be important for those who may be familiar with the different treatment approaches as well as those who are learning about them for the first time.

It should also be acknowledged that, although outside the scope of the initial research questions, qualitative work identified emotion as an important part of the process of choosing how to manage pregnancy hypertension.

Strengths of this study include reliance on well-validated and robust qualitative and quantitative health economic methods to understand individuals' treatment preferences and priorities, and their decisional needs. The initial qualitative work was validated and assessed for generalizability through a second set of interviews. Additionally, the use of latent class analysis allowed identification of preference profiles that would have been obscured using a traditional analytical approach. This work was conducted in collaboration with a patient partner who contributed to all parts of the research, providing a patient's perspective on materials and methods, and thus

increased the accessibility of the survey and interview materials. Furthermore, all survey participants received the same educational material and corrective or confirmatory feedback in response to knowledge-assessment questions; consequently, errors in understanding were corrected before participants completed the preference task.

Limitations of this study include a focus solely on individuals in BC who spoke a high-level of English in the qualitative work; it is possible that people in other provinces may have prioritised different outcomes. The relatively small sample size may have limited the number of preference profiles identified, and no information was collected on some potentially important predictors of preference for tight or 'less-tight' control, such as strength of support network and proximity to a hospital providing high-level care. For the BWS task, we used outcome rates from a single, albeit high-quality RCT (i.e., CHIPS) rather than from the relevant Cochrane systematic review. This choice was justified by the fact that CHIPS studied the current clinical approach, and trials did not report all outcomes relevant to participants from the qualitative work (e.g., the likelihood of needing to take antihypertensives in pregnancy). Furthermore, relative differences in outcomes rates for severe hypertension, pre-eclampsia, Caesarean delivery, very preterm birth, and SGA infants were similar where available.¹⁵ Additionally, as survey responses were collected approximately four months after the

Hypertension Canada guidance was published, it is unlikely that preferences identified here were informed by the guideline themes. However, past or current pregnancy hypertension (vs. no pregnancy hypertension) did not predict treatment preference, suggesting that the guidelines had little, if any, influence on study findings. Finally, despite the BWS task being one of the least cognitively taxing preference elicitation tasks, the approach may still have been too difficult for all participants to complete accurately, offering an alternative explanation for the 'equal prioritisers' group. However, participants were provided with information assessed for readability by other patients, making it likely to be more accessible than materials that are usually distributed. This difficulty may therefore reflect the true challenge of decision-making for pregnancy hypertension and further emphasises the importance of decision support tools.

This is the first study to explore individuals' preferences and views about decision-making around BP control in pregnancy. While there is currently no validated tool to support these decisions, support tools for other conditions in pregnancy (primarily prenatal diagnosis and mode of delivery) improve knowledge, reduce anxiety, and reduce decisional conflict,^{63,64,146} and these improvements are reflected in higher quality decisions. Patients who use decision support tools are more likely to make evidence-informed and value-congruent decisions.^{147,148} This study highlights the

need for such tools and these data indicate that this is relevant to everyone with pregnancy hypertension, and not just those experiencing pregnancy hypertension for the first time. Importantly, ancillary qualitative findings suggest that emotion may be an important factor in decision-making during pregnancy. This finding, and its implications for decision support tools, should be explored further.

2.5.1 Conclusions

Pregnant people in Canada want to be involved in decisions about their BP control. The majority of pregnant people are not averse to taking antihypertensive therapy when they are made aware of both the potential benefits and the potential risks. The more knowledgeable individuals are, the more likely they are to understand the importance of ‘tight’ control, as recommended by Hypertension Canada.⁵ Future research should focus on development of a decision support tool to aid clinicians and patients in evidence- and value-based decision-making about BP control in pregnancy.

Chapter 3: How Do Patient Decision Aids Address Emotion? A Review of Patient Decision Aids in Pregnancy

3.1 Introduction

The quantitative component of Chapter Two identified that individuals had heterogeneous preferences for management of pregnancy hypertension. Thus, clinicians will need to work with patients to integrate patient values into treatment recommendations. As reviewed in Chapter One (Section 1.2.3), patient decision aids (PtDAs) are tools to support patients and clinicians in shared decision-making. Two recent reviews assessed the quality and impact of PtDAs for decisions in pregnancy^{62,65} but neither considered emotion. Through the qualitative research presented in Chapter Two, it became apparent that emotion was an important factor in how individuals make decisions about management of pregnancy hypertension. Thus, the purpose of this chapter is to review how emotion is addressed in existing PtDAs for pregnancy.

3.2 Background

The preference-sensitive decisions made throughout pregnancy are unlike other health decisions, in that they involve the well-being of both the pregnant person and the fetus. Due to limited research with pregnant populations, patients and care providers routinely rely on low-quality evidence to inform choices during pregnancy.^{149,150} Further

complicating decision-making is the psychosocial stress that is common in pregnancy. This results from the stressful events and/or responses to them (e.g., anger or frustration),¹⁵¹ and it is magnified in high-risk pregnancies requiring additional diagnostic and/or therapeutic choices.^{152–154} Despite these challenges, research consistently shows that patients want to be actively involved in health decisions during pregnancy.^{155–157}

SDM is an evidenced-based approach in which care providers and patients collaborate to make preference-sensitive decisions.^{115,158} SDM is ideally initiated by clinicians, and relies on clinicians' emotional and risk communication competencies.^{116,159} PtDAs support SDM by providing a structure through which clinicians and patients share knowledge of treatment options and patient values.⁶¹ As outlined in Chapter One, recent reviews have found that many PtDAs have been developed for decisions during pregnancy: they improve knowledge, reduce decisional conflict,⁶² and are generally of high quality.^{60,65}

Of note, a recent theoretical review paper supports the importance of emotion in patient decision-making.¹⁶⁰ The authors posit that differences in how individuals manage their emotional responses – what is often called emotion regulation – may alter how they engage with healthcare decisions. Further, they argue that for some individuals, their beliefs about their ability to regulate emotions, and their tendency to

use suppressive emotion regulation strategies, could interrupt decision-making by leading individuals to defer making a decision altogether. The authors suggest that given this work, emotion-regulation specifically may be an important consideration in PtDAs.

Given that decisions made during pregnancy are made under psychosocial stress, and emotion is a fundamental component of decision-making, emotion should be an important consideration in PtDAs.¹¹⁶ Yet, there are no formal recommendations for how to address emotion.

This systematic review aimed to identify the frequency with which PtDAs for pregnancy include emotion, which emotions are acknowledged, and where they are incorporated in the decision tool. Additionally, it assessed how emotion was framed when it was included in the decision tool, and whether explicit emotion regulation strategies were included.

3.3 Methods

3.3.1 Search Strategy

A librarian-guided systematic search of published literature was conducted in MEDLINE/PubMed, CINAHL, EMBASE and PsycINFO, without date restrictions. Keywords and Medical Subject Headings terms were divided into two themes.¹⁶¹ Theme

1 (obstetrics) focused on the medical condition and included the following terms: obstetrics; gynecology; pregnancy; matern*; gestation*. Theme 2 (decision aid) focused on decision tools, and it included the following terms: decision aid; decision tool; decision support; shared decision-making. The search terms were stratified and combined by theme (Figure 3.1).

A grey literature search was conducted for pregnancy-related PtDAs in the Ottawa Hospital A to Z Inventory,¹⁶² the Ottawa Hospital Decision Aid Library

Figure 3.1 Search strategy for CINAHL

#	Query	Limiters/Expanders	Last Run Via	Results
S12	S3 AND S11	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S11	S8 OR S9 OR S10	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S10	DAT	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S9	(decision* n3 (aid* or tool* or instrument*))	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S8	S6 AND S7	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S7	(tool* or instrument*)	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S6	S4 OR S5	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S5	(MH "Decision Making, Patient+") OR (MH "Decision Making, Clinical") OR (MH "Decision Making+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S4	(MH "Decision Making, Patient+") OR (MH "Decision Making, Shared") OR (MH "Decision Support Techniques+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S3	S1 OR S2	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S2	obstetric* or pregnan* or birth or childbirth or antenatal or prenatal or matern* or gestation*	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S1	(MH "Pregnancy+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search	Display

Inventory (DALI),¹⁶³ and the Option Grid Database.¹⁶⁴ The Ottawa Hospital A to Z Inventory includes tools that: meet the minimum set of IPDAS criteria to be a PtDA; have been updated in the past five years; include references, and are publicly available. In contrast, the Ottawa Hospital DALI is less restrictive and includes all decision aids that developers have submitted, regardless of IPDAS criteria. A complementary Google search followed established methods.^{165,166} Terms describing pregnancy (e.g., pregnancy, maternal) and tool (e.g., decision aid, decision tool) were combined and the first ten pages of results reviewed.

3.3.2 Inclusion and Exclusion Criteria

Tools were included if they addressed a health decision made during pregnancy, were in English, and were “interventions designed to help people make specific and deliberative choices among options (including the status quo), by making the decision explicit and by providing (at minimum): information on options and outcomes relevant to a person's health status; and implicit methods to clarify values”.⁶¹ Tools were excluded if they addressed decisions made before or after pregnancy (e.g., family planning; breastfeeding).

3.3.3 Article Review

Two independent researchers (RKM & NB) reviewed the search results and screened titles, abstracts and keywords. Any disagreement was resolved through discussion or consultation with other team members. After screening, full-text review ensured that eligibility criteria were met. When a PtDA was not available, the corresponding author was contacted directly.

3.3.4 Data Extraction

Each PtDA was assessed for words that expressed emotions. All instances of a word or phrase (e.g., anxiety; emotionally difficult) were extracted, and both the basic emotion (e.g., anxiety and worry) and PtDA section (e.g., values clarification) were coded (e.g., under “fear”¹⁶⁷⁻¹⁶⁹ and patient stories, respectively).

Atheoretical open-coding was used to describe different ways in which emotions were addressed. Categories were created using inductive coding. Based on studies in behavioural economics and previous research on framing in PtDAs,¹⁷⁰ “positive framing” and “negative framing” were treated separately when categorising how emotion was mentioned. Categories were not mutually exclusive and a decision aid could be coded in multiple categories.

Lastly, each PtDA was assessed for emotion regulation strategies. PtDAs were assessed as providing strategies to regulate emotions if they included strategies that were explicitly intended to help individuals modulate emotional responses (e.g., "If you feel yourself becoming overwhelmed, it may be helpful to take a break or try some breathing exercises").

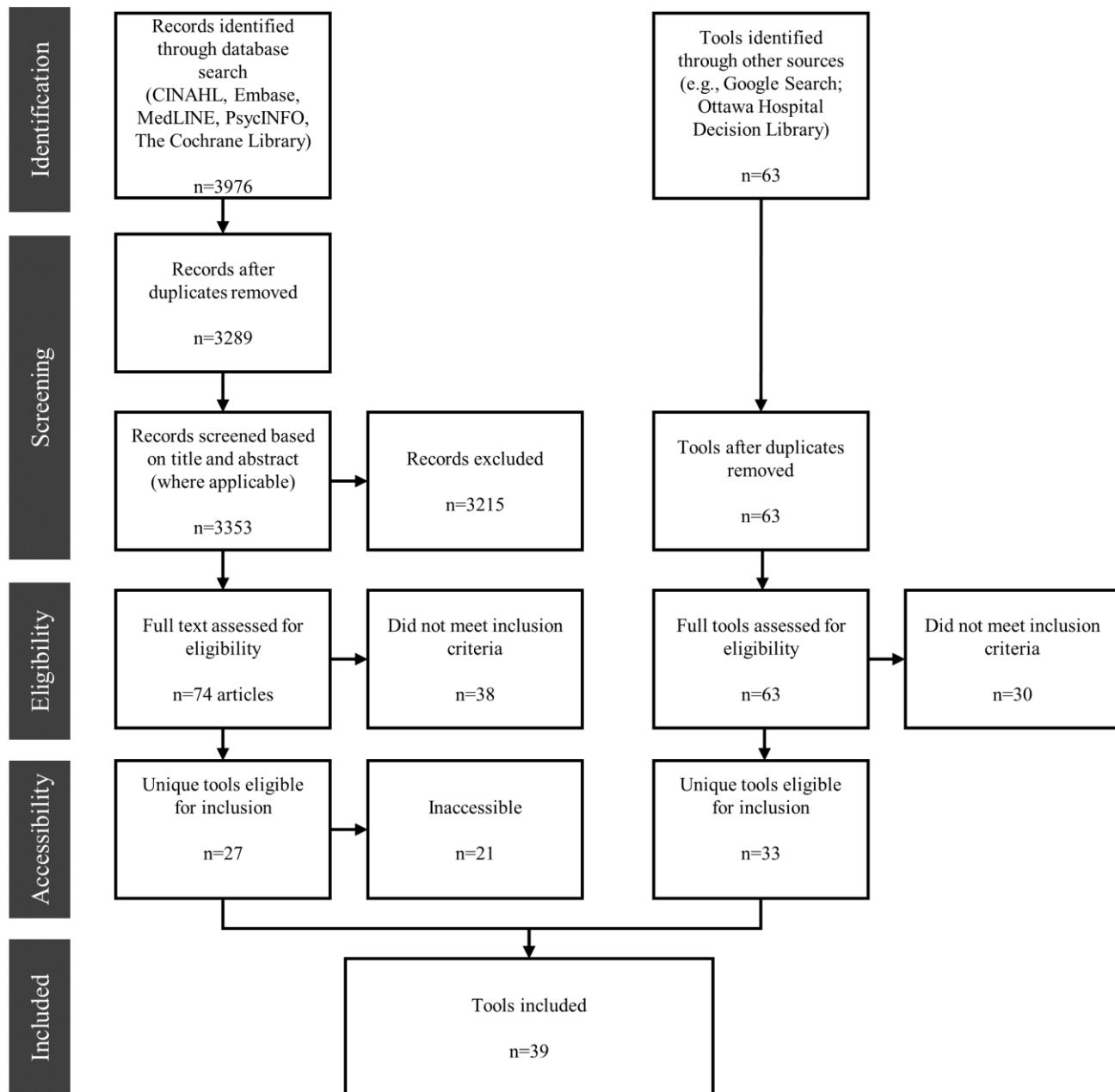
3.4 Results

3.4.1 Search Strategy

Of 3,289 unique articles identified by literature search, 36 studies of 27 unique PtDAs met the inclusion criteria (Figure 3.2). Of the 27 PtDAs, only six decision aids were accessible. A grey literature search yielded an additional 63 potential PtDAs, of which 30 were excluded because they were not available in English, or were not technically PtDAs (e.g., educational material).

Almost all of the 39 PtDAs addressed decisions about prenatal testing ($n = 18$; 47%)¹⁷¹⁻¹⁸⁸ or birth ($n = 17$; 44%)¹⁸⁹⁻²⁰⁴ few addressed health conditions experienced by the pregnant person ($n = 3$; 8%)²⁰⁵⁻²⁰⁷ or multiple pregnancy ($n = 1$; 3%)²⁰⁸. Most of the 17 PtDAs came from Healthwise ($n = 7$),^{175-178,199,201,208} Midwives Information and Resource ($n = 2$),^{174,180} or were adaptations of the same decision tool ($n = 3$).^{172,179,181}

Figure 3.2: PRISMA flowchart of the stage of the search process



3.4.2 Inclusion of Emotion

Of 39 PtDAs, 44% (n=17)^{171–181,190,191,199,201,205,208} included emotion. Most were PtDAs for prenatal testing (n=11; 61%). There was variability in how often emotion was mentioned within a PtDA (median: 7; IQR: 2.5-9.5; Table 3.1)

Table 3.1: Summary of patient decision aids reviewed and emotions included

Decision Type (N)	Title	Year ^a	Mentions Emotion	Primary Emotion Mentioned			
				Anger	Fear	Happiness	Sadness
Labour & Delivery (17)			4	0	4	1	0
1.	Birth Choices: What is best for you...Vaginal or Caesarean Birth? ²⁰⁴	2011					
2.	Birth Place Decisions ¹⁸⁹	2014					
3.	Birthing your placenta - choosing how to birth your placenta - a decision aid for women having a vaginal birth ¹⁹⁴	2012					
4.	Breech Decisions Film ¹⁹⁰	2015	✓		✓		
5.	Choices about epidural - a decision aid for women having a vaginal birth ²⁰⁰	2012					
6.	Choices about episiotomy - a decision aid for women having a vaginal birth ¹⁹⁵	2010					
7.	Choosing how to birth your baby - a decision aid for women with a previous caesarean section ¹⁹⁶	2011					

8. Choosing your positions during labour and birth - a decision aid for women having a vaginal birth ¹⁹⁷	2012				
9. Failure to progress in labor: Delivery options. ¹⁹³	2018				
10. Monitoring your baby during labour - a decision aid for women having a vaginal birth ¹⁹⁸	2012				
11. My Baby is Breech ¹⁹²	2016				
12. Pregnancy: Should I Have an Epidural During Childbirth? ¹⁹⁹	2017	✓	✓	✓	
13. Pregnancy: Should I Try Vaginal Birth After a Past C-Section (VBAC)? ²⁰¹	2017	✓	✓		
14. Thinking About Having Your Labor Induced: A Guide for Pregnant Women. ¹⁹¹	2009	✓	✓		
15. Thinking about VBAC: Deciding what's right for me ²⁰²	2015				
16. Using a bath or pool during first stage labour - a decision aid for women having a vaginal birth ²⁰⁹	2011				
17. Vaginal birth after C-section (VBAC) guide ²⁰³	2018				

Health Conditions (3)

1

1

1

0

0

18. A Shared Decision-Making Tool for the Treatment of Perinatal Opioid Use Disorder (OUD) ²⁰⁶	2015	✓	✓	✓		
19. Epilepsy: medication options when considering pregnancy ²⁰⁵	2015					
20. High blood pressure in pregnancy decision aid ²⁰⁷	2019					
Multiple Pregnancy (1)		1	0	1	1	1
21. Multiple Pregnancy: Should I Consider a Multifetal Pregnancy Reduction? ²⁰⁸	2019	✓		✓	✓	✓
Prenatal Testing (18)		11	0	10	9	1
22. A Decision Aid: Testing in Pregnancy for Fetal Abnormalities ¹⁷¹	2004	✓		✓	✓	
23. Amniocentesis test: yes or no? ¹⁸⁴	2016					
24. An Aid to Decision-Making for Prenatal Screening ¹⁷²	2019	✓		✓	✓	
25. Decision Aid Calculator ¹⁸²	2014					
26. Down syndrome screening test: yes or no? ¹⁸⁵	2016					

27. GaP Study Decision Aid: Choosing between extended and targeted prenatal information ¹⁷³	2014	✓	✓	
28. Is my baby alright? Screening in pregnancy ¹⁷⁴	2005	✓	✓	✓
29. Making decisions about screening for Down syndrome in pregnancy ¹⁸⁶	2017			
30. Pregnancy: Should I Have Amniocentesis? ¹⁷⁵	2019	✓	✓	✓
31. Pregnancy: Should I have an early fetal ultrasound? ¹⁷⁶	2017	✓	✓	✓
32. Pregnancy: Should I Have CVS (Chorionic Villus Sampling)? ¹⁷⁷	2017	✓	✓	
33. Pregnancy: Should I Have Screening Tests for Birth Defects? ¹⁷⁸	2017	✓	✓	✓
34. Prenatal Testing Options for Your Pregnancy: Patient Decision Aid ¹⁸⁷	None Provided			
35. Screening for Down's syndrome, Edwards' syndrome and Patau's syndrome ¹⁸⁸	2018			
36. Should I take the SIPS/IPS test to screen for Trisomy 21 (Down syndrome)? ¹⁷⁹	2019	✓	✓	✓

37. Ultrasound scans -- what you need to know ¹⁸⁰	2008	✓	✓
38. What are my options regarding prenatal screening tests?; <i>Quelles sont mes options concernant le test de dépistage prénatal?</i> ¹⁸¹	2017	✓	✓
39. Your choice: Screening and diagnostic tests in pregnancy. ¹⁸³	None	Provided	

^aThe year may differ from the reference year when the tool was developed for a study and the study publication followed.

3.4.3 Types of Emotion

Most emotions described were negative (Table 3.2). Sixteen PtDAs (94%)^{171–179,181,190,191,199,201,205,208} included fear emotions, like worry (10 PtDAs, 58%; 29 instances)^{175–178,181,190,191,199,201,208} and anxiety (8 PtDAs, 47%; 20 instances)^{171–174,176,179,181,205} (e.g. "Women who don't take the test may be anxious"). Four PtDAs mentioned stress and fear (24%).^{172,176,179,208} and sadness and anger (2 PtDAs,^{181,208} 12% and 1 tool,²⁰⁵ 6%, respectively).

Eleven PtDAs (65%) mentioned positive emotions (e.g., "Those who have a low risk result are reassured"),^{171,172,174–176,178–181,199,208} and/or non-specific emotions (e.g., "emotional recovery").^{171–173,175–178,199,201,205,208} One PtDA (6%) exclusively addressed positive emotions.¹⁸⁰

Table 3.2: Type and frequency of emotions included in PtDAs

Emotion	Instances		PtDAs
	n	n	
Anger	1	1	6%
Anger	1	1	6%
Fear	68	16	94%
Worry	29	10	59%
Anxiety	20	8	47%
Stress	9	4	24%
Fear	4	4	24%
Concern	3	2	12%
Nervous	2	2	12%
Unsettled	1	1	6%
Happiness	17	11	65%
At ease	4	3	18%

Excitement	2	2	12%
Feel Good	1	1	6%
Feel Reassured	10	6	35%
Sadness	10	2	12%
Depression	2	1	6%
Grief	2	1	6%
Guilt	2	1	6%
Regret	1	1	6%
Sadness	1	1	6%
Feel terrible	1	1	6%
Non-specific	25	11	65%
Difficult Emotions	1	1	6%
Emotional Recovery	1	1	6%
Emotionally Difficult	2	1	6%
Feel Conflicted	1	1	6%
"Feelings"	18	8	47%
Mood Change	2	1	6%

3.4.4 Location in PtDA

When included ($n = 17$ PtDAs), emotion was addressed in multiple sections. More than half of PtDAs included emotion during values clarification (e.g "I'm worried about the risks involved with an epidural").^{171,175–178,181,199,201,208} Almost half ($n = 8$; 47%) included emotion: (i) when providing information about the options (e.g. "These results can be difficult to deal with, but your healthcare provider will be available to support you and help you understand what these results might mean");^{171–173,176,180,190,191,208} and (ii) when comparing the risks and side effects of options (e.g. "The test can create a lot of stress and anxiety").^{172,173,176,178,179,181,205,208} Three PtDAs addressed emotion when describing risks and side effects, but not benefits (Table 3.3).^{173,179,205}

Table 3.3: Section of each PtDA that included emotion

PtDA Section	PtDAs	
	n	%
Values Clarification	9	53%
Comparing Options	8	47%
Risks & Side Effects	8	47%
Benefits	5	29%
Information Provision	8	47%
Patient Stories	6	35%
Comparing Options - Benefits	5	29%
General Description of the Decision	2	12%
Knowledge Assessment	1	6%

3.4.5 Publication Date and Authorship

The PtDAs reviewed were published between 2004 and 2019. There was no difference in average date of publication for tools that addressed emotion compared to tools that did not. Most authors published only a single PtDA, but seven authors created multiple tools. For six of these authors, all tools were uniform in either including emotion or not including emotion. Only one author (Option Grid) had variability in whether their PtDAs included emotion; Option Grid included emotion in one of four PtDAs.

For authors that included emotion, there was variation in how often and where in the PtDA emotion. However, PtDAs authored by Healthwise systematically included emotion at certain points (e.g., all seven Healthwise authored PtDAs reviewed included

the phrase “Your personal feelings are just as important as the medical facts” in the values clarification instructions).

3.4.6 Framing

Inductive coding identified three primary ways that emotion was framed in PtDAs: as (i) a consequence; (ii) a motivator; and (iii) a general consideration (Table 3.4).

Most commonly, emotion was framed as a consequence of choosing a given option (12 PtDAs, 71%; 57 instances),^{171–176,178,181,201,205,208} either by increasing a negative emotion (10 PtDAs, 57%; 25 instances),^{171–174,176,178,181,201,205,208} avoiding or reducing a negative emotion (8 PtDAs, 47%; 17 instances),^{172,176,178,181,201,201,205,208} or by providing reassurance or peace of mind (8 PtDAs, 47%; 15 instances).^{171,172,174–176,178,181,201}

Additionally, emotions were framed as the motivation for a given decision (7 PtDAs, 41%; 28 instances).^{175–178,191,199,201} Most often, the presence of a negative emotion was stated as a motivation for choosing one option over another (7 PtDAs, 41%; 18 instances).^{175–178,191,199,201} The absence of an emotion was also provided as a motivation for a decision but less frequently (5 PtDAs, 29%; 10 instances).^{175,177,178,199,201}

Lastly, emotions were framed as a general consideration or contextual factor in the decision (11 PtDAs, 65%; 23 instances).^{171–173,175–178,190,199,201,208}

Table 3.4: Framing of emotion in PtDAs

Framing	Instances	PtDAs	
	<i>n</i>	<i>n</i>	Example
Emotion as a consequence of a given option	57	12	
Increasing a negative emotion	25	10	"Being told that you are in a 'high-risk' group can cause a lot of anxiety."
Avoiding or reducing a negative emotion	17	8	"Not doing the test can avoid the anxiety and stress of making a decision about continuing or ending the pregnancy if the fetus has T21."
Providing reassurance or peace of mind	15	8	"If the test doesn't show any problems, you may feel more at ease during your pregnancy."
Emotion as a Motivation	28	7	
Presence of an emotion as motivation for choosing a given option (especially during values clarification)	18	7	"I'm worried about the risks involved with an epidural."
Absence of an emotion as motivation for choosing a given option (especially during values clarification)	10	5	"I'm not worried that something might be wrong with my baby."
Emotions as a general consideration	23	11	"Either choice can be emotional and complex."

3.4.7 Emotion Management Strategies

None of the PtDAs reviewed provided explicit strategies to manage emotions.

3.5 Discussion

This study assessed the prevalence of emotion in PtDAs, using pregnancy as a case study. The review found significant variation in whether and how emotion was included. Fewer than half of PtDAs for decisions in pregnancy included emotion, and when they did it was most often fear emotions, like worry and anxiety. There was no standard approach to including emotion, such as whether it was described: positively or negatively; in relation to harms or benefits; or in which section(s) of the PtDA it would be placed. Likewise, framing of emotion varied significantly across tools. Most frequently, emotion was framed as a consequence of choosing a given option. None of the tools reviewed included explicit emotion regulation strategies.

There are potential explanations for variation in the inclusion of and type of emotion in PtDAs for decisions during pregnancy. Firstly, empirical evidence of the impact of including emotion in PtDAs does not exist: although much research demonstrates the instrumentality of emotion in decision-making,^{100,210} little work has been extended to decision support tools. Based on early results in non-clinical populations, researchers have theorised that emotion may be an important element to include in PtDAs,¹⁶⁰ but they have yet to investigate this in a healthcare context. Perhaps as a result of this gap in knowledge, the inclusion of emotion has not been formally recommended or included in PtDA development guidelines. Of note, given this context

and the lack of attention paid to emotion in PtDAs, it is likely that this variation is not intentional, and instead is the consequence of the absence of a systematic approach for including emotion.

An alternative explanation may be that the relationship between emotion and decision-making is complex. Not all individuals experience the same emotions in response to the same event (e.g., a diagnosis), and the way in which emotion impacts decision-making depends on the type of emotion and the context.²¹¹ Emotions can help (e.g., improve attention) or hinder (e.g., reduce information processing) decision-making.²¹¹ SDM is built on effective communication of risk and relational or emotional competencies. While it may be that emotion is best addressed on an individual basis during SDM in a clinical encounter when care providers can adapt responses to meet the emotional needs of each patient, this would rely on care provider awareness of the impact of emotion on decision-making. Including emotion in PtDAs would increase the likelihood that emotion is considered explicitly during SDM.

Importantly, an opportunity may exist for PtDAs to provide emotional support to patients making healthcare decisions. Substantial research supports the efficacy of training^{212,213} to improve emotion regulation skills, even with limited instruction.²¹⁴ Thus, incorporating optional emotion regulation skills into PtDAs may be of benefit, particularly for individuals who have difficulty with emotion regulation or tend to use

suppressive strategies. Explicit emotion regulation strategies have been shown to be effective at reducing emotional arousal.^{212,213,215} Distraction strategies, such as visualising a daily task, could be easily incorporated into paper-based decision aids. As more decision aids move to an online format, more complex strategies, like mindful awareness, could be included as an additional resource. Future work should explore the role of emotion and emotion regulation in patient decision-making, and empirically investigate the relationships between decision quality and emotion regulation, as proposed by Carpenter and colleagues.¹⁶⁰

Limitations to this study include the restriction of inclusion criteria to PtDAs during pregnancy. Although the qualitative work (Chapter Two) that prompted this review was conducted in the context of pregnancy, stress and emotion are not unique to pregnancy. In recent studies, patients with breast cancer and patients with multiple sclerosis both reported that high levels of emotion made it harder to discuss treatment options with care providers.^{114,216} However, it is possible that contextual factors, such as expected long-term outcome, would change whether or not emotions are addressed in PtDAs for other health decisions and potentially limit the generalizability of these findings.

Nevertheless, regardless of disease context, emotion likely impacts every step of patient decision-making, suggesting that emotion is broadly important for SDM and

PtDAs.¹⁶⁰ Additionally, as research on SDM and patient decision-making evolves, so too do PtDAs. Because more than half the tools reviewed were published in the past five years, decisions in pregnancy provided an opportunity to assess how emotion is addressed in current tools and, as a consequence, the findings from this review are more likely to reflect recent evidence and best practices.

The findings from this review are supported by well-validated methods. The search strategy was developed and tested with the help of a reference librarian. Recognising that not all PtDAs are disseminated through peer-reviewed literature, an extensive complementary grey literature search was conducted and included three of the largest PtDA repositories.

3.5.1 Conclusion

Emotion is instrumental to decision-making. Despite this, the majority of PtDAs created for health decisions during pregnancy did not address emotion, and none included explicit strategies to help patients manage emotional responses. Future studies should explore the relationship between emotion regulation and decision-making and assess whether incorporation of discrete emotion-regulation skills improves patient decision-making.

Chapter 4: Integrating Patient Preferences into Randomised Controlled Trials Using Composite Outcomes

4.1 Introduction

Chapter One (Section 1.2.5) outlined the challenges that composite endpoints present for interpretation of randomised controlled trial (RCT) results. One approach that has been considered is weighting composite endpoints to reflect patient values. Chapter Two quantified the relative importance of different treatment requirements and outcomes. Consequently, this chapter examines ways in which the values elicited in Chapter Two could be integrated with trial results to support decision-making and assess whether the application of weights and composite components reflecting patient values to the Control of Hypertension in Pregnancy Study (CHIPS) trial impacts interpretation of trial results.

4.2 Background

A composite outcome combines multiple outcomes into a single measure. In health research, composite outcomes are commonly used to provide a more holistic test of a treatment's effect on a disease. For example, some diseases have multiple pathways and thus a thorough evaluation of treatment effectiveness requires measuring change on all pathways. Additionally, diseases with a single pathway may have multiple clinically

significant outcomes, and these outcomes can be differentially affected by treatment. If a study were limited to just one outcome, for example mortality, it may miss significant changes in other important outcomes, like hospitalizations. In addition to clinical benefits, composite outcomes can be beneficial to trial design as they improve a study's statistical power by increasing the number of observable events. As a result, composite outcomes are used widely.

More recently, however, concerns have been raised about composite outcomes. Specifically, it is common for components of composite outcomes to have varying levels of importance (e.g., hospitalization vs. death), but this variation is not reflected in the statistical analysis.⁸² Often, instead of assigning weights that reflect the relative importance of each composite component, all components are assigned no weight, which is effectively equal weight. Indeed, as reviewed in Chapter One, statisticians caution that composite components should have equal clinical significance for an unweighted (or equally weighted) composite endpoint to be valid.⁸¹ As a result, it can be difficult to interpret the results of trials that use composite outcomes.⁸³ Consider a composite outcome with two components, a significant finding could mean a positive result on one outcome, or the other outcome or both, but it is also possible that neither outcome would reach statistical significance on its own. To address these problems, recent work has explored methods to incorporate weights into clinical trial analyses.

The purpose of this chapter is to review the different methods for developing and implementing composite outcomes in RCTs, including: (i) which component outcomes are included; (ii) how component weights are determined; (iii) what statistical methods can be used; and (iv) an assessment of how incorporating patient values may influence the interpretation of study results.

To explore these considerations, a case study of the CHIPS trial is used. The CHIPS trial used composite endpoints to assess the impact of two treatment approaches on individual health and infant health. The chapter begins with a review of the existing composite outcome methods, then presents a case study using a new method for developing composite outcomes. This work aims to answer the question: how does integrating patient values into composite outcomes impact the interpretation of RCT results?

4.3 Review of Methods for Composite Outcomes

Researchers and statisticians have developed different methods to integrate importance weights into clinical trials so that composite component importance is reflected in the final analysis. However, as of yet none has gained wide use. Although superficially simple, the question of how best to integrate importance weights raises corollary issues.

Specifically, before getting to the statistical task of how to integrate importance weights, one must answer more nuanced methodological questions:

1. How are composite components selected?
2. How are composite weights determined?
3. Whose values do composite weights reflect?

Here the current literature that speaks to these three questions is synthesised, followed by a review of published methods for integrating weights.

4.3.1 How Are Composite Components Selected?

Composite components are usually selected by trialists. The criteria for selection vary but generally multiple endpoints are chosen to reflect the full course of a disease, to ensure comparability with other studies, and/or to improve statistical efficiency. While these are sound scientific criteria, they are not the only criteria through which endpoints could be selected. Indeed, these criteria may miss endpoints that are important to patients, as patient, clinician and researcher values often differ.²¹⁷

Studies that identify what patients value are increasingly conducted in healthcare research but much of this work has yet to be applied to clinical trials. Of note, many of these studies have identified that both clinical outcomes, and clinical processes or treatment requirements, are important to patients.²¹⁷ For example, a recent

study found that when considering treatment for multiple sclerosis, most patients prioritise avoiding rare serious adverse events (SAEs) and symptom improvement but a significant minority prioritised both avoiding rare SAEs and route of treatment administration (i.e., oral medication vs. injection vs. infusion).¹³¹ Similarly, a study of preventative treatment options for rheumatoid arthritis found that, after the decision-making process and risk and benefits, patients and first degree relatives of patients prioritised route of treatment administration over certainty of the evidence.²¹⁸ While clinical outcomes are frequently included in composite endpoints, clinical and treatment processes, such as route of administration, are almost never included. However, these process considerations can influence patient willingness to undertake a treatment, even if that treatment offers superior health outcomes. Consequently, it may be important to include these aspects of treatment in a composite endpoint. To date, no studies have examined the impact of using a patient-oriented composite end-point made up of patient-identified components. Such an approach may allow for an endpoint that reflects both the outcome and process aspects of treatment that matter to patients.

4.3.2 How Are Composite Weights Determined?

There are several ways to determine composite component weights. The choice of method for determining weights is often related to the approach used to integrate

outcomes and weights. However, it is important to consider the validity of each approach on its own, in the context of its specific advantages and disadvantages.

4.3.2.1 Ranking Tasks

In this approach, individuals are asked to rank each composite component from most to least important. Ranking tasks have a long and established history in preference elicitation.²¹⁹ They are generally easy for participants to complete; studies that use ranking have a very low rate of data failure.^{74,220} Because ranking is a common everyday task, it can be completed quickly and little piloting is needed.

However, ranking tasks have clear disadvantages. Because they use an ordinal scale, rankings provide information on the preferred order but they obscure the magnitude of the difference. For example, imagine a patient who ranks three considerations as follows: 1) route of administration; 2) side effects; and 3) cost of intervention. According to this ranking, route of administration is most important and cost is least important, but it is unclear how important each consideration is and how much more important each consideration is than those with lower ranks. Additionally, ranking tasks ignore the interaction between outcomes, and these interactions may influence preferences. Using the same example, it is possible that route of administration is considered as the most important variable, but if presented with a low-cost treatment with few to no side effects, route of administration might be ranked

as least important. Lastly, ranking tasks often do not allow individuals to assign no rank to components that are not at all important to them. As a result, ranking tasks can force value on to components that are not valued.

4.3.2.2 Attribute Weighting

Attribute weighting is an approach in which individuals assign value to each composite component; those values are then summed and the assigned value is divided by the sum of the values to create a weight. Attribute weighting can be explicit, for example a constant sum task, or implicit, for example a best-worst scaling (BWS) task. In a constant sum task, participants are given a set number of tokens or points to distribute to the different components to reflect their relative values. In this task, participants state explicitly which components they value most and how much they value them relative to the other components. In contrast, in a BWS task, participants are shown a series of choice-sets each showing a different combination of components. For each choice-set, participants are asked to indicate which component is most important to them and which component is least important. The importance weights for each component are then calculated based on the number of times each number was ranked most important and least important across choice-sets.

Unlike ranking, attribute weighting approaches like BWS and constant sum tasks provide cardinal values on an additive scale. As a result, weights can be directly

compared to one another and the magnitude of the difference in importance of components is known. Although more taxing than ranking tasks, attribute weighting approaches are less cognitively burdensome than more complex preference elicitation tasks, such as discrete choice experiments (DCEs). They are easy for participants to understand and easy to administer. However, these approaches also have limitations. Like ranking, they are unable to account for interactions between composite components, and can force value onto components that are not valued. Lastly, these tasks are often unfamiliar, and are susceptible to framing effects. Consequently, developing attribute weighting tasks requires extensive pilot-testing which can be quite time consuming.

4.3.2.3 Health State Valuation

In this approach individuals are shown a series of choice-sets. In each choice-set, individuals are asked to consider two hypothetical health states and asked to select the profile that they prefer. The two health states are described using the same attributes (e.g., frequency pain is experienced) but the level (e.g., daily, weekly, monthly) of some or all attributes varies. The profiles vary across choice-sets. By comparing responses across choice-sets for a sample of individuals, it is possible to calculate a value for the health state described in each profile.

Health state valuation is done using paradigms like discrete choice experiments (DCEs) or modified BWS tasks. These are robust, well-validated methods that have been shown to reasonably predict real-life behaviour.²²¹ Because these tasks provide value estimates of whole-health states, rather than individual attributes, they accommodate interactions and it is possible to identify equivalent health states. In addition, health state valuation tasks can include an “opt out” option which may stop value being forced onto health states or outcomes that are not valued, unlike weighting and ranking tasks. Lastly, the statistical methods used to analyze these types of data yield an error term which can be used to better understand predictors of differences in individual values.

It should be noted, however, that health state valuation tasks are cognitively much more difficult to perform than other approaches because participants need to consider attributes and levels both within and across health states. This difficulty increases as the number of attributes increases. As a result, there are questions about their validity in populations with low literacy and low numeracy. To ensure the task can be completed, extensive pilot testing is needed. In addition, task development is complex as there are specific requirements to ensure a balanced and unbiased design. This complex design requires a complex analysis. While this analysis has benefits in

terms of the precision of the estimates derived, the complexity can be a barrier to the comprehension and application of results.

4.3.3 Whose Values Do Composite Weights Reflect?

Criticisms of composite endpoints have gone beyond *how* weights and components are determined to *whose* values are reflected in the weights used. Significant work has tried to address the issue of patient values in composite endpoints. Ferreira-González and colleagues conducted a systematic review of RCTs to assess the extent to which composite endpoints used in cardiovascular RCTs published in major medical journals varied in importance to patients.⁸¹ Of the trials included in the review, the majority used endpoints that varied in both magnitude of importance to patients and magnitude of effect across components. Furthermore, the review found that components that were most important to patients were associated with smaller treatment effects than components that were less important to patients, suggesting caution in interpretation of results, as they may be driven by less important components.

Several studies have used preference elicitation techniques to assess the importance of common composite endpoints to patients relative to clinical trialists and clinicians; they found important differences. For example, a study comparing cardiovascular patients' preferences and those of clinical trialists found that for patients,

myocardial infarction and stroke were more important considerations than death, whereas trialists prioritised death over myocardial infarction.⁹² Likewise, in a study comparing patient and clinician values, clinicians and patients ranked health outcomes similarly, but patients were less willing to tolerate potential treatment complications.⁹³ Although these studies developed patient weights to better understand their impact on composite endpoints, these weighted endpoints were not applied to trial data.

To date, two studies have attempted to integrate patient-oriented weights into composite endpoints. Ahmad and colleagues used a visual analogue task to determine patient values for a composite outcome commonly used in studies of cardiac catheterization, and then weighted a meta-analysis to reflect these values.²²² They found that when patient weights were used, there was no difference between the two methods of cardiac catheterization. In contrast, when clinician weights were used, one method yielded a better outcome than the other. Similarly, in a study exploring the preferences of orthopaedic trauma patients using simulated trial data,⁹⁷ unweighted time-to-event analysis yielded no difference between treatments, whereas weighted analysis identified one treatment as superior to the other. Both of these studies demonstrate the importance of weights to trial interpretation; however, both have limitations: neither integrated preferences with individual-event data from an actual RCT.

4.3.4 Methods for Integrating Weights

Because of the potential impact of weights on trial interpretation, researchers have proposed multiple ways to integrate importance weights into clinical trials. These approaches are varied and include non-parametric and parametric statistical methods.

4.3.4.1 Global Rank Method

The Global Rank Method was first proposed by O'Brien as a way to weight trial analyses.²²³ The method was developed specifically to address the problem of how to analyze trials with multiple endpoints when sample sizes are small, such as phase 1 clinical trials, where a Bonferroni correction may be impractical.

In the Global Rank Method, each participant is ranked on each outcome; outcomes themselves are not ranked. The ranks for each participant are then summed across the outcomes to create a rank sum. This rank sum score can then be compared across conditions using the appropriate parametric (i.e., *t*-test, ANOVA) or non-parametric (i.e., Mann-Whitney, Kruskal Wallis) test, depending on number of conditions (see Table 4.1).

Table 4.1: Hypothetical data showing ranking and rank sum approach proposed by O'Brien (1984)

Participant	Death	Stroke	Days in Hospital	Rank Sum
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	Outcome	Rank*	Outcome	Rank*	Outcome	Rank*	
$1_{treatment}$	No	1	Stroke	2	15	4	7
	Death						
$1_{control}$	Death	2	Stroke	2	5	3	7
$2_{treatment}$	Death	2	No	1	1	2	6
			Stroke				
$2_{control}$	No	1	No	1	0	1	3
	Death		Stroke				

* Lower ranks indicate better outcomes

Li and colleagues extended the Global Rank Method to accommodate weights. In this extension each outcome is given a weight.²²⁴ The weight of each outcome is then applied to each participant's rank for that outcome. The rank sum score is calculated as the sum of the weighted ranks (see Table 4.2).

Table 4.2: Hypothetical data showing the weighted Global Rank Method proposed by Li et al.²²⁴

Participant	Death			Stroke			Days in Hospital			Weighted Rank Sum
	Weight = 0.5		Weighted	Weight = 0.3		Weighted	Weight = 0.2		Weighted	
	Outcome	Rank	Rank	Outcome	Rank	Rank	Outcome	Rank	Rank	
<i>1</i> _{treatment}	No	1	.5	Stroke	2	.6	15	4	.8	1.9
	Death									
<i>1</i> _{control}	Death	2	1	Stroke	2	.6	5	3	.6	2.2
<i>2</i> _{treatment}	Death	2	1	No	1	.3	1	2	.4	1.7
				Stroke						
<i>2</i> _{control}	No	1	.5	No	1	.3	0	1	.2	1.0
	Death			Stroke						

* Lower ranks indicate better outcomes

An alternative ranking approach has also been proposed.²²⁵ In this approach, a hierarchy of end-points is created and outcomes are placed on a continuum from most favourable to least favourable. Participants are then ranked according to the outcomes they experienced. Patients who experienced worse outcomes are given a lower rank than patients who did not experience those outcomes (See Table 4.3). Ties between participants are broken by time to event when possible.

Table 4.3: Hypothetical data showing the ranking approach described by Felker & Maisel (2010)

Participant	Death (worst)	Stroke (middle)	Days in Hospital (least bad)	Rank Sum
$1_{treatment}$	No Death	Stroke	15	2
$1_{control}$	Death	Stroke	5	4
$2_{treatment}$	Death	No Stroke	1	3
$2_{control}$	No Death	No Stroke	0	1

* Lower ranks indicate better outcomes

Advantages & Disadvantages

Simplicity is one of the main advantages of the Global Rank Method and its extensions. The process for ranking and scoring is straightforward and the final assessment uses common statistical tests that are familiar to researchers and clinicians alike. Indeed, the Global Rank Method is supported by the research community and has been proposed by cardiovascular researchers as a favoured solution to the complexities of composite endpoints. Furthermore, because this method has been used for several decades, albeit

infrequently, established power- and sample-size calculations exist. Lastly, the approach is flexible. It can accommodate small sample sizes and both continuous and ordinal data.

Although the Global Rank Method has been used to analyze some trials, the proposed extensions which allow for patient values to be incorporated (i.e., the weighted Global Rank method and the alternative ranking method) have not yet been applied to real trial data. Additionally, this method does not deal well with missing or censored data. As a result, researchers using this method need to impute or develop rules for generating missing values.

4.3.4.2 Proportion in Favour of Treatment & Win-Ratio

First proposed in 2010 by Buyse, the “proportion in favour of treatment” method is an extension of the U-statistic from the Mann-Whitney test.²²⁶ Using this technique, composite components are ranked from most severe to least severe (see Table 4.4 for an example using the MACE outcomes discussed in the introduction).

Table 4.4: Ranking of MACE outcomes in decreasing severity

Outcome	Rank*
Death	1
Stroke	2
Hospitalization	3

*1 is most severe outcome

Then, each participant in the treatment condition is compared to each participant in the control condition. The comparison starts with the most severe outcome and moves through the outcomes by decreasing severity. The comparison stops at the most severe outcome that differs between the two participants. The comparison is scored 1 if the control condition participant has the most severe outcome compared and the treatment condition participant does not. The comparison is scored -1 if the treatment condition participant has the most severe outcome compared and the control condition participant does not. The comparison is scored 0 if the treatment and control participants compared have the same outcomes. Table 4.5 shows a hypothetical example comparing treatment participant $1_{treatment}$ to control participants $1-3_{control}$.

Table 4.5: Hypothetical comparison and scoring of event data for one treatment participant and three control participants

Participant	Death	Stroke	Hospitalization	Score
$1_{treatment}$	No	No	No	
$1_{control}$	No	Yes		-1
$2_{control}$	Yes	No		1
$3_{control}$	No	No	No	0

A summary statistic called proportion in favour of treatment (denoted Δ) is calculated to measure the general difference between the treatment and control groups. This statistic is the net difference between the number of favourable pairs and the number of unfavourable pairs, divided by the total number of pairs. If the proportion in

favour of treatment is greater than zero, then the treatment is generally considered better than the control. If the proportion in favour of treatment is less than zero, then the treatment is generally considered worse than the control. No confidence interval calculations are provided for the proportion in favour of treatment statistic.

Shortly after Buyse described proportion in favour of treatment, Pocock proposed the win-ratio.²²⁷ The win-ratio uses a similar ranking and scoring method to proportion in favour of treatment. However, instead of a comparison between each treatment participant and each control participant, a matched analysis is conducted with each participant in the treatment group compared to a single participant in the control group. No precise method is provided to match participants. Furthermore, where proportion in favour of treatment scores comparisons as 1, -1, or 0, in the win-ratio approach comparisons are scored as a win, a loss, or a tie, respectively. Once all pairs are scored, the win-ratio is calculated as the number of pairs in which the treatment “won” over the number of pairs in which the treatment “lost”. The proportion of wins can also be calculated as the number of wins divided by the sum of the number of wins and the number of losses. This proportion has an easily-calculated 95% confidence interval. An unmatched analysis which follows Buyse’s approaches closely is also possible but is not recommended by Pocock as it is difficult to obtain confidence intervals for the proportion of wins.

Advantages & Disadvantages

Due to their similarity, these approaches have comparable advantages and disadvantages. Although the example provided uses binary event data, both of these approaches can accommodate time-to-event and continuous data. Additionally, both approaches are relatively straightforward and use ranks which, as described in the introduction, are easier to obtain than other preference data. On the other hand, these advantages must be weighed against their disadvantages. Results using these approaches are highly dependent on censoring distribution, duration of follow-up and competing risks. Furthermore, because of the method of comparison, not all outcomes will be considered in each pairwise comparison, so that important but less severe outcomes may be ignored. Therefore, it can be difficult to interpret the proportion in favour of treatment and win-ratio statistics beyond concluding that the treatment is generally better than the control, or vice versa.

4.3.4.3 Survival Analysis

Survival analyses are common in RCTs. Thus, it is unsurprising that methodologists have explored ways to incorporate weights into these types of analyses. Two author groups have proposed methods for integrating weights into survival analyses: one uses a life-tables approach and compares Kaplan Meier survival curves;²²⁸ the other creates a weighted all-cause hazard ratio.^{229,230} An additional two papers applied patient value

weights to survival analyses, but did not describe the methods they used to incorporate weights.^{96,97}

4.3.4.3.1 Weighted Kaplan-Meier Curves

Armstrong and colleagues proposed a modified Kaplan-Meier approach to account for unevenness in the importance of composite components.²²⁸ In a traditional Kaplan-Meier approach, the survival probability at time_x is calculated as the probability of survival at time_{x-1} multiplied by the proportion of participants at risk that did not experience an event at time_x. Once a participant experiences any of the outcomes included in the composite outcome, they are removed from the analysis. This is reflected in the table below (Table 4.6) in the Number at Risk column. However, despite being removed from the analysis, a participant who experiences a less severe event, for example hospitalization, is still at risk of the more severe events, such as death.

Table 4.6: Traditional Kaplan-Meier approach

Time	Participant	Number at Risk (NNR)	Number Deaths	Number Strokes	Number Hospitalised	Survival Probability
0		20	0	0	0	1
1	A	20	1	0	0	.95
3	B	19	0	0	1	.90
6	C	18	0	1	0	.85
7	D	17	0	0	1	.80

Consequently, Armstrong and colleagues argue it is not appropriate to exclude that participant from the analysis. Rather than removing participants from the number at

risk entirely, they propose that the amount each participant contributes to the number of participants at risk should be discounted in proportion to the severity of the outcome experienced. The maximum weight of events experienced by a participant is limited to one. As a result, when a participant who has previously experienced an event dies, the weight applied to that death is adjusted to account for the previous experience (e.g., Participant D in Table 4.7 had a stroke at Time 3. When Participant D died at Time 9, the weight subtracted from the residual severity score was equal to the weight assigned to death minus the weight assigned to stroke).

Table 4.7: Kaplan-Meier Approach modified to accommodate weights

Time	Participant	Death Weight = 1	Stroke Weight = 0.3	Hospitalised Weight = 0.2	Applied Event Weight	Residual Severity Score (modified NNR)	Proportion of Total (weighted survival probability)
0		0	0	0			
1	A	1	0	0	1	19.0	.95
3	B	0	0	1	0.2	18.8	.94
6	D	0	1	0	0.3	18.5	.93
7	C	0	0	1	0.2	18.3	.92
8	B	0	1	0	0.24	18.1	.91
9	D	1	0	0	0.7	17.7	.89

NNR: Number at Risk

Advantages & Disadvantages

Kaplan-Meier curves are a common analytic method in health trials and have been used for decades. As a result, clinicians and trialists may be more amenable to this approach proposed by Armstrong and colleagues than to less familiar methods for incorporating patient values.

However, this method is not without its challenges. Kaplan-Meier curves do not allow for adjustment for confounders or covariates, and the authors have not provided details on how to extend these methods to accommodate adjustments. Furthermore, the approach assumes multiplicative, rather than additive, interactions when multiple outcomes occur, but the authors do not provide justification for this assumption. It is possible that the interaction of components could be greater or lesser than, or equal to, the sum of the individual weight of the components. It is also possible that this interaction could change with different clinical scenarios. The proposed approach does not allow for flexibility in the type of interaction between outcomes. Lastly, the results from this weighted Kaplan-Meier curve are difficult to interpret and the clinical meaning of a weighted survival probability is unclear.

4.3.4.3.2 Weighted All Cause Hazard Ratio

Recently a weighted-time to all-event analysis has been proposed as an alternative method for incorporating importance weights into trial analyses.^{229,230} This approach

builds on a standard all-event hazard ratio by applying weights to the outcome specific hazards. Table 4.8 shows unweighted and weighted outcome-specific hazards as presented by Rauch and colleagues.²³⁰ In this example, death is given a weight of 0.9, and hospitalization is given a weight of 0.1.

Table 4.8: Example of a weighted time to all-event analysis using data from the CAPRICORN Trial (as presented by Rauch et al.²³⁰)

Outcome	Extrapolated Hazard Ratios	Unweighted Event Time Distributions		Weighted Event Time Distributions
		D _I = 1 - exp(-0.008 * t)	D _C = 1 - exp(-0.0104 * t)	
Death (D)	<u>0.008</u>	D _I = 1 - exp(-0.008 * t)	D _C = 1 - exp(-0.9 * 0.008 * t)	
	0.0104	D _C = 1 - exp(-0.0104 * t)	D _C = 1 - exp(-0.9 * 0.0104 * t)	
Hospitalization (H)	<u>0.0196</u>	H _I = 1 - exp(-0.0196 * t)	H _I = 1 - exp(-0.1 * 0.0196 * t)	
	0.0295	H _C = 1 - exp(-0.0295 * t)	H _C = 1 - exp(-0.1 * 0.0295 * t)	
Composite (CE)	<u>0.0276</u>	CE _I = 1 - exp(-0.0276 * t)	CE _I = 1 - exp((-0.9 * 0.008 + -0.1 * 0.0196) t)	
	0.0299	CE _C = 1 - exp(-0.0299 * t)	CE _C = 1 - exp(-0.9 * 0.0104 + -0.1 * 0.0295) t)	

I = intervention; C = control; t = time

This weighted-time to all-event hazard ratio can be interpreted as the ratio between the weighted average of the cause-specific hazards. The significance of the weighted hazard ratio can be assessed using a weight-based log rank test. This approach is non-parametric and as a result does not make assumptions about the shape of the survival curve; however, it does assume hazards are equal at baseline and proportional.

Advantages & Disadvantages

This approach may be easier than other approaches for trial analyses to accommodate as many trials already use time-to-event or time-to-all event hazard ratios. Additionally, depending on how the weights are determined, and whose values they reflect, the results of trial analyses using this approach may be easier to interpret. Furthermore, using a weighted time-to-all event approach is less susceptible to bias: it is robust in the presence of censoring and accounts for competing risks.

It should be noted, however, that this approach is new and has not yet been applied to any trials. Its statistical properties have only been assessed by the same authors who first proposed this approach. Additionally, this approach is only able to address time-to-event data and cannot be used if binary or continuous variables are collected without time-to-event information. Lastly, this approach is fairly complex statistically and may not be accessible to clinicians.

4.3.4.4 Weighted Meta-Analysis

Ahmad and colleagues developed this weighted meta-analytic approach specifically to create a MACE that reflected patient values.²²² Patient weights were based on results from a visual analogue task and were calculated as the importance attributed to the outcome divided by the importance attributed to death. These weights were then applied to event rate for each MACE component (see Table 4.9). Component weights were then summed to obtain a weighted MACE. This process was repeated for each trial and then treatment arms were compared to yield an odds ratio.

Table 4.9: Hypothetical weighting of event data for two arms of an RCT

		Patient		Weighted Event Rate	Weighted MACE Rate
	Outcome	Importance Weight	Number of Events		
Treatment	Death	1.0	5	5	16
	Stroke	0.3	20	6	
	Hospitalization	0.2	25	5	
Control	Death	1.0	10	10	22
	Stroke	0.3	20	6	
	Hospitalization	0.2	30	6	

Advantages & Disadvantages

The approach proposed by Ahmad and colleagues is relatively straightforward and thus may have higher uptake than other methods reviewed here. However, the

proposed approach is specific to meta-analyses and only provides methods for addressing events at the trial level, rather than at the individual level. Thus, its applicability to individual trials may be limited.

4.3.5 Selecting a Method to Apply to the CHIPS Trial

One of the purposes of this chapter is to explore the impact of integrating patient values into the CHIPS trial. Thus, it is important that the chosen method be well-suited to the context of the CHIPS trial, employ a weighting approach that accurately reflects patient values, and improve the interpretability of results. Unfortunately, each of the methods reviewed presents substantial challenges to these goals (see Table 4.10).

Table 4.10: Summary comparison of reviewed methods for weighting RCTs

Approach	Fits trial context	Accurately reflects patient values	Improves interpretability
Global Rank Method	✓	✗	✗
Win-Ratio & Proportion in Favour	✓	✗	✗
Weighted Kaplan-Meier Curve	✓	✓	✗
Weighted Time-to-all-event analyses	✗	✓	✓
Weighted Meta-analysis	✗	✓	✓

First, although frequently used in clinical trials, survival analyses may present challenges for trials in pregnancy. Because pregnancy is time-limited, trials generally seek to determine if an intervention decreases the risk of a given outcome, but not if an

intervention decreases the time until that outcome occurs. Furthermore, several outcomes commonly used in studies of pregnancy hypertension, such as 'small for gestational age', are time-dependent. Removing time from these outcomes renders them almost meaningless. For example, it is difficult to imagine how to include weight at delivery in a survival analysis and excluding these commonly used variables would decrease comparability with other trials. Thus, the approaches to weighting survival analyses reviewed above are not appropriate for a reanalysis of the CHIPS trial.

The Global Rank Method does not present the same challenges as survival analyses. However, this approach relies on ranks which can misrepresent preferences. Specifically, as reviewed above, because ranks use an ordinal scale, they obscure the magnitude of the difference in importance between outcomes. Thus, two outcomes that would be comparable on an ordinal scale may be represented as being more different than they truly are when ranking approaches are used.

Furthermore, papers on the Global Rank Method do not provide methods for ranking participants, so many different approaches are possible. For example, it is not clear from the literature if participants who do not experience an event should receive a ranking, and if so, what rank should be assigned to those who do experience the event. There are many different possible ranking approaches and each of these approaches can have a significant impact on the outcome of the analyses (see Appendix C for an

example). As of yet, no guidance exists on which ranking approach is most appropriate. This methodological ambiguity calls into the question the validity of results obtained using the Global Rank Method.

The proportion in favour of treatment and win-ratio approaches offer seemingly intuitive summary statistics to evaluate the relative impact of an intervention. However, because not all outcomes are included in all comparisons, the interpretation of these statistics and which outcomes they represent is unclear. Furthermore, because these rely on ordinal rather than cardinal data, they suffer from the same challenges as the Global Rank Method and may obscure or magnify differences in importance between composite components. Additionally, while the win-ratio proposes a simple confidence interval calculation to aid interpretation, this calculation is not appropriate for unpaired data, like that collected in the CHIPS trial. Thus, if these approaches were applied to the CHIPS trial data, it would be difficult to deduce the statistical significance of the summary statistics produced.

Lastly, the method proposed by Ahmad and colleagues (Weighted Meta-analysis) addresses most of the issues reviewed above. Unlike several other approaches, it uses cardinal, rather than ordinal, weights and consequently can more accurately reflect patient values than approach like the Global Rank Method or proportion in favour. Additional, in contrast to the survival analyses reviewed, this method

accommodates binary and continuous data and does not require time-to-event, and thus is well-suited to the data collected in the CHIPS data. However, the approach described focuses on events across trials rather than individual events within a trial.

As a result of these concerns, an extension of the Weighted Meta-analysis approach developed by Ahmad and colleagues is proposed. This approach is extended in three ways. First, instead of using a standard composite endpoint, a patient-oriented composite endpoint consisting of components identified as important by patients is proposed. Second, the approach used by Ahmad and colleagues is adapted to accommodate individual-level data from the CHIPS trial. Thus, the analysis will better reflect the variability in outcomes experienced by participants. Lastly, average patient weights are not considered; instead, the value-weights for each of the preference subgroups identified in Chapter Two are applied and how varying preferences and priorities impact recommended treatment is explored.

4.4 Methods

4.4.1 Overview

Patient preferences for management of pregnancy hypertension were integrated with the individual event data from the CHIPS trial. This study was reviewed and approved

by the Behavioural Research Ethics Board (H17-01194) at the University of British Columbia.

4.4.2 The CHIPS Trial

Data from the 981 participants enrolled in the CHIPS trial with outcome data were used. Inclusion criteria were: 14^{+0} to 33^{+6} weeks' gestation, nonproteinuric preexisting or gestational hypertension, office diastolic BP of 90-105mmHg (or 85-105mmHg if the participants were taking antihypertensive medication), and a live fetus.¹⁷ On average, participants were \approx 34 years of age, enrolled at \approx 24 weeks' gestation. Most (75%) had chronic hypertension, and just over half were taking antihypertensive medication.

The CHIPS trial used two composite outcomes with equally weighted components. The primary composite comprised infant death and need for 48 hours or more of high-level neonatal care in the first 28 days after birth. The secondary outcome comprised severe complications for the pregnant individual (death, stroke, eclampsia, blindness, uncontrolled hypertension, the use of inotropic agents, pulmonary edema, respiratory failure, myocardial infarction, hepatic dysfunction, hepatic hematoma or rupture, renal failure, and blood transfusion) up to six weeks post-partum or until hospital discharge, whichever occurred later. Composite outcomes were analyzed using a mixed-effects logistic-regression model. No clinically or statistically significant

difference was found between the two treatment arms on either composite outcome.

Review of composite component events found almost identical frequencies in each trial arm for the primary and secondary composite components, with the exception of blood transfusion which occurred twice as often in 'less-tight' control as 'tight' control ($n = 16$; 3.2% and $n = 8$; 1.6%, respectively).

4.4.3 Composite Components

To increase the relevance of the trial analysis to patients, a patient-oriented composite outcome was created. The composite outcome comprised the seven health outcomes and treatment requirements identified in qualitative work (Chapter Two) as both important and sufficiently different between treatment arms (i.e., 'tight' control and 'less-tight' control) to influence participants' choice of BP control. The seven binary (present/absent) outcomes included were: antihypertensive medication; severe hypertension; pre-eclampsia; blood transfusion; Caesarean delivery; delivery before 34 weeks; and birth weight below the tenth percentile (also referred to as small for gestational age; SGA).

4.4.4 Component Weights

Chapter Two presented patient value weights for each of the composite components. These weights were collected using a BWS task. Because of the limitations associated with this approach (e.g., cannot accommodate interactions between outcomes), a DCE was considered. However, the DCE was dismissed due to concerns over the cognitive difficulty of the task. Specifically, the majority of participants weighted outcomes equally in the BWS task, which could reflect difficulty with the task itself or difficulty making trade-offs between the health outcomes and treatment requirements. DCE tasks that are too difficult can lead to attribute non-attendance (i.e. some attributes are ignored because participants focus on one or a subset of the attributes to make the task easier) and ultimately threaten the validity of task results. Consequently, the analysis used the weights from the BWS task presented in Chapter Two as this approach is less cognitively burdensome than a traditional DCE.

Equal weights (conventional analysis using 14% weight per outcome) and the weights for the three preference profiles identified by latent class analysis (Chapter Two) were applied. These weights and the event frequencies from the CHIPS trial are presented in Table 4.11.

Table 4.11: The seven CHIPS outcomes prioritised by child-bearing individuals and their event rates in the CHIPS trial, overall and by trial arm*¹⁷

Outcome	Overall (n = 981)	Trial Arm			Profiles based on patient preference weights†		
		'less-tight'			weights ^α	(1) ^α	(2) ^α
		'control' (n = 493)	'tight' control (n = 488)	Equal			
Antihypertensives	837 (85.3%)	379 (76.9%)§	458 (93.9%)§	14%	14%	2%	58%
Severe hypertension	334 (34.0%)	200 (40.6%)§	134 (27.5%)§	14%	11%	20%	20%
Pre-eclampsia	464 (47.3%)	241 (48.9%)	223 (45.7%)	14%	15%	16%	10%
Blood transfusion	24 (2.4%)	16 (3.2%)	8 (1.6%)	14%	20%	2%	0%
Caesarean	481 (49.0%)	231 (47.0%)	250 (51.4%)	14%	13%	2%	4%
Delivery <34 wks	138 (14.1%)	77 (15.7%)	61 (12.6%)	14%	18%	42%	2%
BW <10 th % ile	175 (17.8%)	79 (16.1%)	96 (19.8%)	14%	8%	16%	5%

BW (birthweight), wks (weeks)

* Of the 987 participants randomised in CHIPS, outcomes were available for 981 following 6 withdrawals and losses to follow-up, with the exception of antihypertensive medication for which data were available for 986 participants (Magee et al., 2015)

† Profile (1) was 'equal prioritisers', (2) 'early delivery avoiders', and (3) 'medication minimisers'.

§ The difference between groups was statistically significant at the p<0.001 level.

^α Rounded numbers may not sum to 100%

4.4.5 Statistical Methods

A composite score was derived for each CHIPS participant by multiplying the patient preference weight for each outcome by whether or not the outcome occurred (using 1 if it occurred and 0 if it did not). Thus, higher composite scores indicate worse outcomes (i.e., more highly-weighted events occurred). Mean composite scores between treatment groups were compared using *t*-tests and $p < 0.05$ taken to be statistically significant. This process was repeated with equal weights and with the three sets of preference profile weights.

4.4.5.1 Threshold Analysis

Clinical guidance in Canada, and internationally, recommends ‘tight’ control of pregnancy hypertension. Thus, threshold analyses were conducted for preference profiles that supported ‘less-tight’ control over ‘tight’ control. The purpose of the threshold analysis was to assess the extent to which preference weights would need to shift to yield a finding congruent with clinical guidance (e.g., that the two treatments are equally suited to meeting patient preferences, or that ‘tight’ control is better suited than ‘less-tight’ control).²³¹ The threshold analysis systematically reduced the weight assigned to the most highly weighted composite component and distributed the removed weight across the six other components proportionately to the weight

assigned in preference profile. The proportional weight for a given outcome was calculated as the weight assigned to that outcome divided by the sum of the weights assigned to all of the outcomes except the highest weighted outcome. For example, using Profile 3 weights, the weight assigned to severe hypertension would increase by 0.047 which is equal to 0.01 (the weight reduction) multiplied by the weight assigned to severe hypertension (0.20) and divided by one minus the Profile 3 weight assigned to minimising antihypertensive medication—the highest weighted outcome ($1 - 0.58 = 0.42$). These redistributed weights were calculated for each one-point reduction in the highest weighted composite component. The primary analysis was then repeated for each set of redistributed weights.

4.5 Results

Table 4.12 presents the mean patient preference-weighted composite outcome scores by trial group, according to equal weights or those from each of the three patient profiles, presented in Table 4.11. Of note, severe hypertension (11-20% weight) and pre-eclampsia (10-16% weight) were consistently prioritised by participants in each preference profile group, the importance of taking antihypertensive medication was variable (2-58% weight), blood transfusion and Caesarean had little importance to '*early*

delivery avoiders' (Profile (2)) or '*medication minimisers*' (Profile (3), and only '*early delivery avoiders*' prioritised the outcome of birthweight <10th percentile.

Analysis of the trial data using equal weights in the composite score produced no difference in score between treatment arms (0.35 vs 0.36, $p = 0.670$); the significantly higher frequency of antihypertensive medication use in 'tight' control (94% vs. 77%; Table 4.11) was offset by the significantly higher frequency of severe hypertension in 'less-tight' control (41% vs. 28%). Similar results were found using Profile (1) weights ('*equal prioritisers*').

Using Profile (2) weights ('*early delivery avoiders*'), the apparently lower rate of early delivery (and significantly lower incidence of severe hypertension) in the 'tight' control arm (13% vs 16%), resulted in a lower (better) composite score for 'tight' control (0.24 vs 'less-tight' control 0.28, $p = 0.03$), with use of significantly more antihypertensive therapy in 'less-tight' control contributing little, given the low weighting of this outcome.

Using Profile (3) weights ('*medication minimisers*'), the significantly lower frequency of antihypertensive medication use in less-tight (vs. tight) control (77% vs. 94%), combined with a high weighting (58%) resulted in a significantly lower (better) composite outcome score for 'less-tight' control (0.61 vs 0.68; $p < 0.001$), despite significantly more frequent severe hypertension (20% weight).

Table 4.12: Mean weighted composite score* according to blood pressure control, and *t*-scores for equal weights and each preference profile

	'less-tight' control	'tight' control	differ- ence score	95% CI		<i>t</i> -test results	
				Lower	Upper	<i>t</i>	<i>p</i>
Equal Weights	0.35	0.36	0.01	-0.03	0.02	-0.43	0.668
Profile (1) 'Equal prioritisers'	0.33	0.34	0.01	-0.03	0.02	-0.34	0.731
Profile (2) 'Early delivery avoiders'	0.28	0.24	-0.04	0.002	0.07	2.12	0.034
Profile (3) 'Medication minimisers'	0.61	0.68	0.07	-0.11†	-0.04†	-4.14	< 0.001

*Lower scores indicate fewer highly-weighted events occurred.

† Favours 'less-tight' control.

4.5.1 Threshold Analysis

Of the four primary analyses conducted, only the analysis that used the weights for medication minimisers yielded superior outcomes with 'less-tight' control than 'tight' control. Consequently, a threshold analysis was only conducted for this profile (3). The threshold analysis with proportionally redistributed weights found that once the weight applied to avoiding antihypertensive medication was reduced to 0.41 (from 0.58), 'less-tight' control was no longer the preferred treatment (see Figure 4.1 and Table 4.13).

Figure 4.1: Results from the threshold analysis examining the change required in weight allotted to avoiding medication to change treatment recommendation from 'less-tight' control

Threshold Analysis: Medication Minimisers

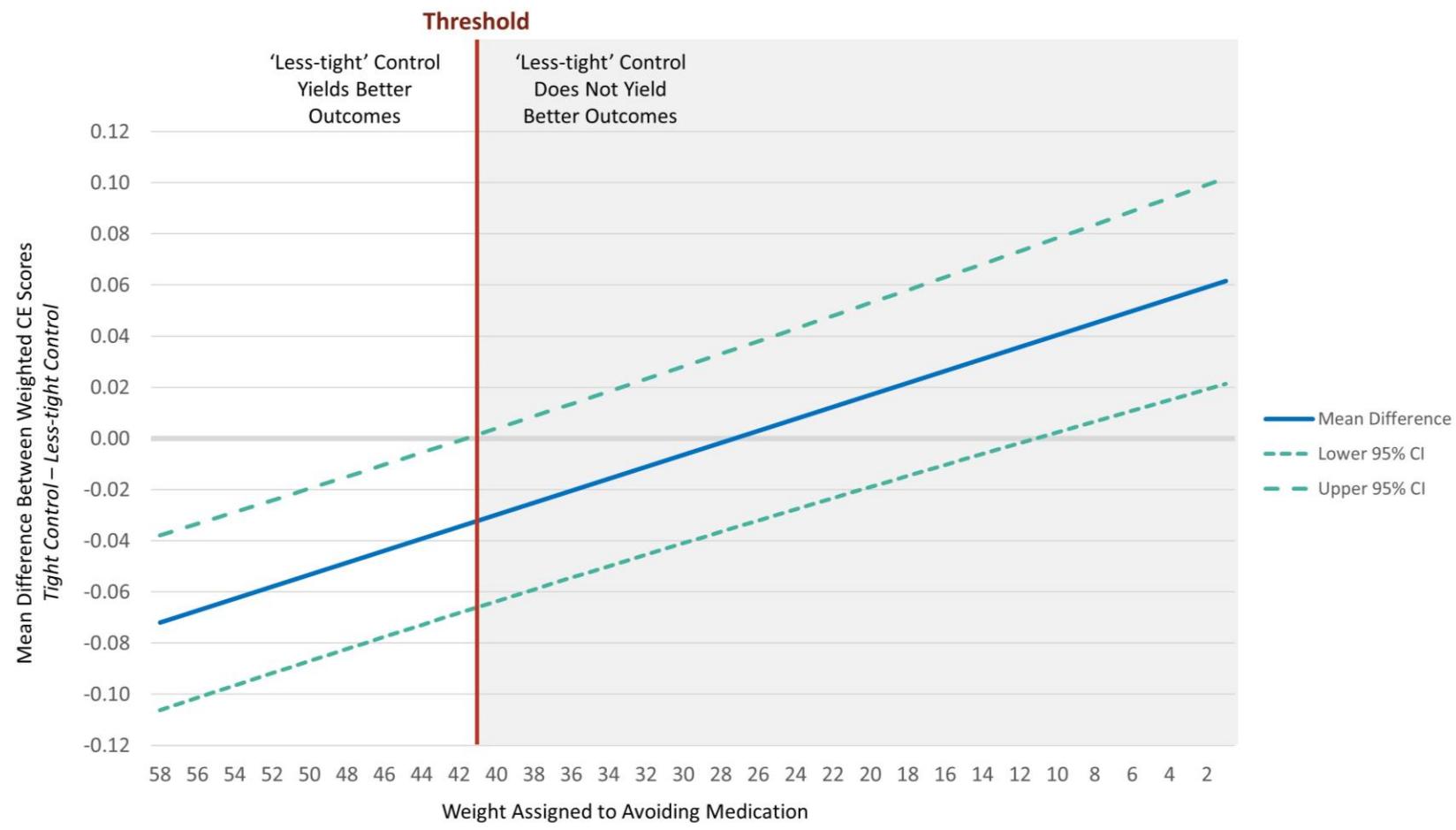


Table 4.13: Weights applied in threshold analysis

Anti-hypertensives	Severe hypertension	Pre-eclampsia	Blood transfusion	Caesarean	Delivery <34 wks	BW <10th % ile
0.580	0.200	0.100	0.000	0.040	0.020	0.050
0.570	0.205	0.102	0.000	0.041	0.020	0.051
0.560	0.210	0.105	0.000	0.042	0.021	0.052
0.550	0.215	0.107	0.000	0.043	0.021	0.054
0.540	0.220	0.110	0.000	0.044	0.022	0.055
0.530	0.224	0.112	0.000	0.045	0.022	0.056
0.520	0.229	0.115	0.000	0.046	0.023	0.057
0.510	0.234	0.117	0.000	0.047	0.023	0.059
0.500	0.239	0.120	0.000	0.048	0.024	0.060
0.490	0.244	0.122	0.000	0.049	0.024	0.061
0.480	0.249	0.124	0.000	0.050	0.025	0.062
0.470	0.254	0.127	0.000	0.051	0.025	0.063
0.460	0.259	0.129	0.000	0.052	0.026	0.065
0.450	0.263	0.132	0.000	0.053	0.026	0.066
0.440	0.268	0.134	0.000	0.054	0.027	0.067
0.430	0.273	0.137	0.000	0.055	0.027	0.068
0.420	0.278	0.139	0.000	0.056	0.028	0.070
0.410	0.283	0.141	0.000	0.057	0.028	0.071
0.400	0.288	0.144	0.000	0.058	0.029	0.072
0.390	0.293	0.146	0.000	0.059	0.029	0.073
0.380	0.298	0.149	0.000	0.060	0.030	0.074
0.370	0.302	0.151	0.000	0.060	0.030	0.076
0.360	0.307	0.154	0.000	0.061	0.031	0.077
0.350	0.312	0.156	0.000	0.062	0.031	0.078
0.340	0.317	0.159	0.000	0.063	0.032	0.079
0.330	0.322	0.161	0.000	0.064	0.032	0.080
0.320	0.327	0.163	0.000	0.065	0.033	0.082
0.310	0.332	0.166	0.000	0.066	0.033	0.083
0.300	0.337	0.168	0.000	0.067	0.034	0.084
0.290	0.341	0.171	0.000	0.068	0.034	0.085
0.280	0.346	0.173	0.000	0.069	0.035	0.087
0.270	0.351	0.176	0.000	0.070	0.035	0.088
0.260	0.356	0.178	0.000	0.071	0.036	0.089

0.250	0.361	0.180	0.000	0.072	0.036	0.090
0.240	0.366	0.183	0.000	0.073	0.037	0.091
0.230	0.371	0.185	0.000	0.074	0.037	0.093
0.220	0.376	0.188	0.000	0.075	0.038	0.094
0.210	0.380	0.190	0.000	0.076	0.038	0.095
0.200	0.385	0.193	0.000	0.077	0.039	0.096
0.190	0.390	0.195	0.000	0.078	0.039	0.098
0.180	0.395	0.198	0.000	0.079	0.040	0.099
0.170	0.400	0.200	0.000	0.080	0.040	0.100
0.160	0.405	0.202	0.000	0.081	0.040	0.101
0.150	0.410	0.205	0.000	0.082	0.041	0.102
0.140	0.415	0.207	0.000	0.083	0.041	0.104
0.130	0.420	0.210	0.000	0.084	0.042	0.105
0.120	0.424	0.212	0.000	0.085	0.042	0.106
0.110	0.429	0.215	0.000	0.086	0.043	0.107
0.100	0.434	0.217	0.000	0.087	0.043	0.109
0.090	0.439	0.220	0.000	0.088	0.044	0.110
0.080	0.444	0.222	0.000	0.089	0.044	0.111
0.070	0.449	0.224	0.000	0.090	0.045	0.112
0.060	0.454	0.227	0.000	0.091	0.045	0.113
0.050	0.459	0.229	0.000	0.092	0.046	0.115
0.040	0.463	0.232	0.000	0.093	0.046	0.116
0.030	0.468	0.234	0.000	0.094	0.047	0.117
0.020	0.473	0.237	0.000	0.095	0.047	0.118
0.010	0.478	0.239	0.000	0.096	0.048	0.120

BW (birthweight), wks (weeks)

4.6 Discussion

This reanalysis of CHIPS trial outcomes incorporates patient values and demonstrates that integrating patient preferences for outcomes and their associated weights into trial analyses is feasible and can identify different management approaches for some individuals, even based on the results of a single trial. These findings suggest that almost two-thirds of participants prioritise adverse outcomes equally, as assumed in the primary CHIPS analyses. However, it should be noted that about one quarter of participants prioritise very pre-term birth, which clearly favours ‘tight’ control, and a distinct minority prioritise minimising antihypertensive medication above other adverse outcomes, making ‘less-tight’ control the most value-congruent BP management strategy for them. Importantly, for those who prioritise minimising medication, the benefit of ‘less-tight’ control, compared to ‘tight’ control, is removed once the weight applied to minimising medication is reduced to 0.41. Put another way, for patients who prioritise minimising medication, ‘less-tight’ control is only more beneficial than ‘tight’ control if reducing the likelihood of taking antihypertensives is allotted more than two-fifths of the decision weight. The methods used to arrive at these findings were adapted from an approach used for integrating patient values into meta-analyses. These methods were selected following a thorough review of existing

methods for weighting RCTs and an assessment of the specific requirements of the CHIPS trial context (i.e., pregnancy) and data.

Clinical practice guidelines have recommended ‘tight’ control of pregnancy hypertension, based on demonstration in the CHIPS trial¹⁷ and other randomised trials¹⁵ of a significant reduction in development of severe hypertension, without an increase in perinatal risk. As severe hypertension is important to individuals as an outcome and is prioritised across preference groups, these findings suggest that ‘tight’ control is appropriate for the vast majority ($\approx 85\%$) of pregnant people.

While integrating multiple outcomes into composites has been considered in cardiology²²² and other fields,⁹⁷ this is the first study to integrate patient weights with individual event data from a high-quality RCT in pregnancy. It is also the first study to employ patient-oriented composite components. These findings show that specifying outcome weights may change the interpretation of trial results when applied to individuals.

The strength of this work lies in its rigorous methods. First, the patient values used in this work were elicited using a well-validated technique and grounded in, and confirmed by, extensive qualitative work (Chapter Two). Second, patient values were integrated by using both patient-identified composite components and their associated patient weights. As a result, it was possible to compare the impact of a patient-oriented

composite alone to a patient-oriented composite weighted to reflect patient values. Comparing these findings to the CHIPS trial results shows that in this instance, the use of a patient-oriented composite without patient weights did not change the interpretation of trial results. However, once patient weights were incorporated, it became evident that the particular management strategy that yielded the best outcomes depended on which composite components were prioritised and to what degree. Lastly, the proposed methods are easily adapted to other trial and non-trial approaches and could be used with other statistical methods that can accommodate confounders and covariates (e.g., linear regression; ANCOVA).

The results of this study should be considered in the context of its limitations. The preference weights used in this study reflect the values of child-bearing individuals in Canada. These preferences may differ in other regions and may be especially influenced by the healthcare system in place. In addition, preferences were identified after the CHIPS trial had been completed; it is possible that different composite components may have been identified as important a priori. However, given that the CHIPS trial results are known and used to inform clinical decisions and practice guidelines, this study's findings are informative for those seeking to make treatment recommendations that align with patient values. Furthermore, the study used patient value weights as assessed by a BWS task which does not allow assessment of

interactions between outcomes. It is possible that participants would have assigned different weight to outcomes if they were evaluated in context with one another, as in a DCE, rather than individually, as in a BWS Type-2 task. However, the BWS was chosen because it is less cognitively taxing than more complex methods like DCEs, and consequently may yield a more accurate assessment of participant values. Additionally, the weights identified by latent class analysis (Chapter Two) represent the average weight applied to each composite component by members of each class. However, it is possible that a given individual's preferences may differ from the preference profiles identified here. The threshold analysis was conducted to address this variation and assess if, and when, shifts in individual preference weights would yield different findings. Finally, the approach used here presents challenges for statistical power. Multiple studies have shown that the most important outcomes are often the least frequent events.^{81,82,87} Composite endpoints are often constructed to enhance power specifically because these events are so rare. Thus, by increasing the relative weight of these events in the composite endpoint, the approach presented here may limit the statistical efficiency gained by composite endpoints. This cost, however, comes with the benefit of improved interpretability.

4.6.1 Conclusion

This chapter reviewed methods for incorporating patient preferences into analysis of RCTs. It then used the CHIPS trial to explore the impact of integrating patient values into analyses on the interpretation of trials results. Integrating a weighted patient-oriented composite endpoint changed the interpretation of the CHIPS trial results: which treatment yielded better results depended on patient values. Future trials with composite endpoints should use specified weights to improve interpretation of trial results.

Chapter 5: Development and Pilot Testing of a Patient Decision Aid for Pregnancy Hypertension

5.1 Introduction

Informed by the results of the CHIPS trial, current clinical guidance for management of pregnancy hypertension promotes ‘tight’ control. However, because the guidelines were based on average risks and benefits, practitioners are encouraged to consider patient preferences and values when making treatment recommendations. Relatedly, findings from Chapters Two and Four show that preferences for management of pregnancy hypertension vary and can change which treatment is most congruent with patient preferences. As of yet, however, no tools exist to help clinicians and patients collaborate on decisions about management of pregnancy hypertension. Consequently, the work presented in this chapter developed and then tested a patient decision aid (PtDA) for pregnancy hypertension.

5.2 Background

Earlier research presented in Chapter Two found that preferences for management of hypertension are heterogeneous: some patients prioritise avoiding early delivery, others prioritise minimising medication even though this increases the risk of severe hypertension, while others had no clear priority. Knowing that these groups of patients

with different preferences exist is an important starting point for shared decision-making. However, clinicians need to work with patients to understand their informed preferences and integrate these preferences with the current evidence in order to make treatment recommendations.^{232,233} As reviewed in Chapter One, PtDAs are tools to help patients and clinicians make informed shared decisions.⁶¹ A significant body of evidence supports the use of PtDAs and has found that patients who use decision aids feel better informed, have a better understanding of their own values, and may more accurately assess treatment risks.⁶¹ Systematic reviews of PtDAs in pregnancy have found that most PtDAs significantly improved patient knowledge, and also reduced patient anxiety and decisional conflict.^{62,64,234}

The objectives of this study were to develop a PtDA to support patients choosing a management strategy for pregnancy hypertension, and to evaluate the PtDA's acceptability, usability and utility, as well as its impact on patient knowledge.

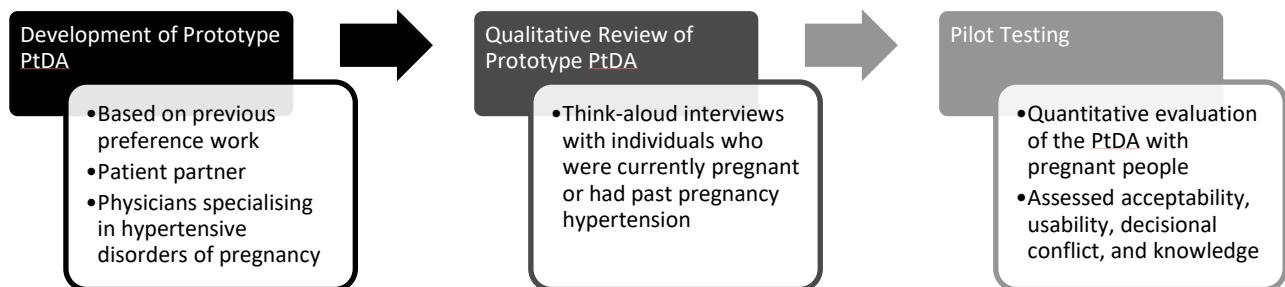
5.3 Methods

5.3.1 Overview

Established processes for the development of PtDAs²³⁵ were followed. An initial prototype was developed based on patient preferences identified in Chapter Two. This tool was reviewed by stakeholders and revised in an iterative fashion. The revised

PtDA was piloted with 99 pregnant people living in Canada. The development process is shown in Figure 5.1. This study protocol was reviewed and approved by the Behavioural Research Ethics Board (H17-01194 and H18-02675) at the University of British Columbia.

Figure 5.1: PtDA development process



5.3.2 Development of the Initial Prototype

The preliminary PtDA was developed in accordance with the guidelines put forth by the IPDAS Collaboration.⁶⁰ The PtDA was developed using an iterative process in collaboration with stakeholders including a patient partner and physicians specialising in hypertensive disorders of pregnancy. The initial paper PtDA prototype was based on focus groups and individual interviews reported in Chapter Two that identified the most important characteristics of the treatment decision.

Based on the systematic review presented in Chapter Three which found that there are no best practices for including emotion in PtDAs, the decision was made to

omit emotion from the prototype, and subsequently explore the impact of adding emotion to the PtDA separately (Chapter Six).

The two literature reviews conducted as part of the initial qualitative work in Chapter Two were used to inform the risk estimates included in the PtDA. The risk estimates included were drawn from the CHIPS trial as it was both the most recent and only large trial identified.¹⁷ Additionally, the CHIPS trial provided the most appropriate risk estimates because it directly compared ‘tight’ and ‘less-tight’ control, unlike comprehensive reviews and meta-analyses which have focused on comparisons between antihypertensive medication for all elevated BP and no antihypertensive medication until BP is severely elevated (usually a diastolic BP of ≥ 110 or a systolic BP of ≥ 160).¹⁵ The patient partner reviewed and provided feedback on the information to be included. Evidence included was based on these reviews, as well as discussion with clinicians and statisticians involved with the CHIPS trial and decision-scientists.

5.3.3 Qualitative Review of the PtDA

Participants were recruited to provide qualitative feedback on the PtDA from the patient perspective. Individuals were eligible to participate if: (i) they were currently pregnant and/or had a history of hypertension in pregnancy; (ii) were at least 18 years

of age; (iii) could read and speak English; (iv) and had not participated in earlier stages of the study. Each participant completed one 45-60 minute think-aloud interview.

To maximise consistency, all interviews were conducted by the same member of the research team (RKM). The interviews were semi-structured and recorded. In addition, the interviewer took notes during each interview and used memoing to record thoughts and impressions before and after each interview. These notes and memos served as the primary data source; audio recordings were consulted as needed to clarify these notes.

During the interviews, the PtDA was presented to participants. Participants were instructed to navigate through the PtDA and state their thoughts about the PtDA aloud. As needed during the interview, the interviewer would prompt the participant on specific aspects of the PtDA that were identified as important by the research team, the physicians, or previous participants. Interviews were designed to solicit feedback on the layout, understandability of the language used, appropriateness of the content, and ease of use. When applicable, participants were presented with previous versions of the PtDA to assess the acceptability of changes that had been made in response to previous participants' suggestions.

5.3.4 Revision & Pilot Testing

The PtDA was revised based on the feedback from the think-aloud interviews. Before pilot testing, the revised tool was reviewed by experts in hypertensive disorders of pregnancy to ensure completeness. Participants were recruited through an independent survey panel provider. Individuals were eligible to participate if: (i) they were currently pregnant; (ii) were at least 18 years of age; (iii) could read, write and provide consent in English; and (iv) lived in Canada.

Before completing the PtDA, participants provided consent and demographic information, and completed five true-or-false knowledge questions adapted from the Chapter Two study to assess baseline knowledge. As part of the decision tool, participants reported their self-identified preference profile (*equal prioritiser; early delivery avoider; medication minimiser; or other*), and completed the 4-item *SURE scale*, a measure of decisional conflict with high levels of sensitivity and specificity.²³⁶

Following the PtDA, participants completed the same five true-or-false knowledge questions to assess change in knowledge, as well as measures of usability, acceptability, and preparation for decision-making. Usability was assessed using the 10-item *System Usability Scale* (SUS).²³⁷ Using a 5-point Likert Scale, the SUS provides a single score ranging from 40 to 100 to assess the subjective usability of a product, with higher scores indicating better usability. Applicable items from the *Acceptability Scale*

were used to assess how well information was presented for specific topics (e.g., risks and benefits) and overall impressions of the PtDA.²³⁸ The 10-item *Preparation for Decision Making Scale* (PDMS)²³⁹ assessed participant perceptions of the usefulness of the PtDA in preparing them to consult with clinicians about a healthcare decision. Like the SUS, the PDMS uses a 5-point Likert scale and items are summed to yield a score from 0 to 100, with higher scores indicating greater perceived preparedness for decision-making. The PDMS is well validated and reliable.²⁴⁰

Data were analyzed using descriptive statistics and t-tests for pre-post comparisons.

5.4 Results

5.4.1 Prototype Tool

The initial prototype tool was paper-based and formatted as a 3-paneled, single-page pamphlet (see Figures 5.2 and 5.3). The prototype PtDA was divided into 5 sections:

- 1) *Information provision.* Using information identified in the literature review, this section described hypertension in pregnancy generally, the two management strategies ('tight' control and 'less-tight' control) and expected treatment requirements (e.g., medication; BP monitoring).

2) *Risks & benefits.* This section presented information on the risks and benefits identified as important by focus groups and in interviews (Chapter Two). Probabilities were expressed as a number out of one hundred (e.g., "Out of 100 women with pregnancy hypertension who choose 'tight' control, it is expected that 28 will develop severely elevated blood pressure") and accompanied by an icon array.

3) *Preference assessment and values clarification.* This section was embedded in the presentation of risks and benefits. A space was provided beside each outcome for participants to indicate which outcomes were important to them.

4) *Frequently asked questions.* This section included additional information and responses to common questions identified in earlier phases of development.

5) *Summary.* The summary included space for participants to identify which aspects of the decision were most important to them, to take notes on other questions they might have for their care provider, and to indicate which treatment approach they preferred.

Figure 5.2: Early prototype PtDA – side 1

Frequently Asked Questions

What kind of medication is prescribed for high blood pressure?
Medication used to manage high blood pressure is called *antihypertensive medication*. Several antihypertensive medications, such as labetalol, methyldopa and nifedipine, are commonly used to lower high blood pressure in pregnancy.

Is the medication safe?
Some antihypertensive medications can be used in early pregnancy and throughout. They have not been shown to increase risk of birth defects, although the evidence is not extensive.

Will I be able to breastfeed if I take high blood pressure medications?
All commonly used antihypertensive medications are acceptable for use in breastfeeding.

Summary

For me, the most important things to consider are:

- 1.
- 2.
- 3.
- 4.
- 5.

I would like more information about/to talk to my doctor about:

High Blood Pressure in Pregnancy

High blood pressure affects 10% of pregnancies in Canada.

Women with high blood pressure in pregnancy and their babies have a higher risk of complications. Treatment is recommended to decrease these risks.

Figure 5.3: Early prototype PtDA – side 2

What is high blood pressure?

- The heart needs to work harder than it normally does
- Puts extra strain on the heart and on blood vessels increasing the risk of stroke a
- A normal blood pressure is 120 over 80. Blood pressure is called 'high' when the top number reaches 140 or the bottom number reaches 90.

What are the risks of high blood pressure in pregnancy?

Most women with high blood pressure in pregnancy have a safe and healthy pregnancy. But, the risk of complications for them and their baby is higher.

Risks to the Baby

- Premature birth
- Being born smaller than most other babies born at the same age
- Needing to stay in the hospital after birth
- Severe complications, like respiratory stress disorder and sepsis
- Pregnancy loss

Risks to the Mother

- Severely elevated blood pressure
- Hospitalization before delivery
- Pre-eclampsia
- Eclampsia which includes seizures
- Stroke

You can lower your risk of these outcomes by working with your doctor to manage your high blood pressure.

Managing High Blood Pressure in Pregnancy

For most women, a treatment approach called 'tight control' is the best way to manage high blood pressure in pregnancy

In tight control, you:

- Aim to lower blood pressure to the normal range

The other approach is called 'less tight control'.

In less tight control you:

- Aim to avoid taking blood pressure medication
- Aim to lower blood pressure but not all the way to the normal range

Both approaches are safe but the risks and benefits are different.

Treatment Requirements

You and your doctor will work together to lower your blood pressure to the target that you choose.

In both tight control and less tight control, your doctor may recommend that you:

- Take medication for high blood pressure
- Monitor your blood pressure at home
- Go on some bedrest

Right now, there isn't enough evidence to support:

- Changes to diet like salt restriction or calorie restriction
- Changes to activities like exercise or workload
- Changes to stress level

Comparing Treatment Approaches

The numbers below are based on the average person. Your risk might be higher or lower based on your characteristics.

If an item is important to you, fill in the star

Severely Elevated Blood Pressure

The risk of severely elevated blood pressure is 13% higher for women choose less tight control.

What does this mean?

This is considered a medical emergency. Women who experience severely elevated blood pressure in their pregnancy have an increased risk of strokes and seizures, early delivery, and the baby needing to stay in neonatal intensive care.

Taking High Blood Pressure Medication

The likelihood of taking medication is 17% higher for women choose tight control.

What does this mean?

Some women prefer not to take medication. Commonly used medications have been in use for more than 30 years with no evidence of harm to the mother or the baby, but only a few studies have been done.

Baby Born Smaller than Expected

The risk of the baby being born smaller than expected might be 4% higher for women who choose tight control.

What does this mean?

The baby is smaller than most other babies born at the same point in pregnancy. A baby may be normal and small, such as when the parents are very small or also be abnormally small because of problems with the placenta and/or poor growth before birth.

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5.4.2 Think-Aloud Interviews

In total, nine individuals completed a think-aloud interview, and seven versions of the prototype decision aid were created. A plurality of participants was White or Caucasian (44%), and most were between 35 and 39 years of age (56%). However, given the small sample size, there was good representation of different racial and ethnic background and ages. Eight participants (89%) were currently pregnant and one (11%) had current or past pregnancy hypertension (Table 5.1).

Participants provided extensive feedback on all components of the PtDA. A primary concern across interviews was lack of concision and complexity of language. Based on this feedback, phrasing was revised and unnecessary words removed. For example, “high blood pressure is a common condition that can affect people of all ages” was removed and “premature birth” was revised to “born early”.

Table 5.1: Participant demographic characteristics

	Think-aloud Interviews N = 9		Pilot Testing N = 99	
	N	%	N	%
Currently Pregnant				
Yes	8	89%	99	100%
Hypertension in current or past pregnancy				
Yes	1	11%	40	40%
Age				
Less than 25 years	0	--	10	10%
25 to 29 years	2	22%	27	27%

30 to 34 years	2	22%	34	34%
35 to 39 years	5	56%	16	16%
40 years or older	0	--	12	12%
Race/Ethnicity†				
Aboriginal or Indigenous	0	--	3	3%
African American or Black	1	11%	7	7%
Asian	2	22%	11	11%
Caucasian or White	4	44%	64	65%
Hispanic or Latina/o	1	11%	4	4%
South Asian	0	--	10	10%
Southeast Asian	0	--	1	1%
West Asian	2	22%	2	2%
Prefer not to say	0	--	0	0%
Prefer to self-identify or other not included here	0	--	1	1%
Education				
High School or below	0	--	14	14%
Some College or University	0	--	17	17%
College Diploma or				26%
Technical/Trade School	1	11%	26	
University Degree or Professional Qualification	8	89%	42	42%
Previous Pregnancies				
Yes	3	33%	45	45%
Current Medication*				
Antihypertensives*	--	--	14	14%
Aspirin*	--	--	13	13%
Folic Acid*	--	--	49	49%
Multivitamin*	--	--	72	73%
Other Daily Medication*	--	--	22	22%

† Numbers do not sum to 100% as participants could endorse multiple categories;

*These questions were not asked to think-aloud interview participants

In addition to revisions to language, significant revisions were made to the layout and instructions. Participants reported that it was not clear that the initial

pamphlet was a decision tool rather than an informational pamphlet, and as a result found the values clarification and summary sections confusing. Instructions were added to clearly identify the PtDA as a tool to aid conversation with a care provider, which made the aim of the tool clearer to participants.

Relatedly, participants did not find the initial values clarification task helpful for determining which treatment strategy they preferred, particularly because some prioritised outcomes and treatment requirements had better risk estimates with 'tight' control, and some had better risk estimates with 'less-tight' control. A more complex values clarification task was added in which participants rated the importance of each outcome or requirement and then which treatment approach they preferred; however, this resulted in similar issues as the initial values clarification task, and participants found it confusing. The final PtDA included a simple clarification task which provided participants space to rate the importance of each outcome or treatment requirement.

Lastly, participants reported that the 3-panel pamphlet was familiar and convenient but that the layout was too busy and the dark colours made the tool look overwhelming. Consequently, several layouts and colour schemes were developed, including different variations on the 3-panel pamphlet as well as a two-sided, unfolded single-page tool to maximise white space.

After the above revisions had been completed, the final PtDA was formatted as an unfolded, double-sided page, with clear instructions at the top of the tool (Figures 5.4 and 5.5). The PtDA included descriptions of the preference profiles uncovered in previous work (Chapter Two), in order to help participants identify their own preferences and values. To maximise white space and improve readability of the tool, the text was limited to essential information only, with a link provided on the tool for individuals seeking more detail and reference materials. The PtDA was assessed at a Grade 7 reading level according to the SMOG Readability Formula.²⁴¹

Figure 5.4: Paper-based PtDA revised based on feedback from think-aloud interviews – side 1

High Blood Pressure in Pregnancy Decision Aid

This decision aid is for people with high blood pressure (BP) in pregnancy. You can use it to help you talk with your doctor about which treatment approach is best for you.

What is high blood pressure?

- The heart needs to work harder than normal
- There is extra stress on the heart and on blood vessels and this extra stress increases the risk of stroke
- A normal blood pressure (BP) is 120 over 80

Normal	High Normal	Mild	Moderate	Severely Elevated
120 over 80	130 over 85	140 over 90	150 over 100	160+ over 110+
High Blood Pressure				

What are the risks of high BP in pregnancy?

Most pregnant people with high BP have a safe and healthy pregnancy. But, the risk of problems for them and their baby is higher.

Baby

- Being born early
- Needing to stay in hospital after birth
- Severe complications, like respiratory distress syndrome and sepsis
- Pregnancy loss

You

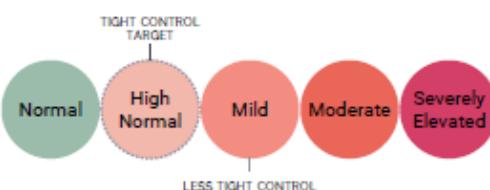
- Hospitalization before delivery
- Pre-eclampsia, when you have high BP & organ damage, and a more serious form called eclampsia
- Severe complications like stroke

You can lower your risk by working with your doctor to manage your high blood pressure

Managing High BP in Pregnancy

For most people, a treatment approach called 'tight control' is the best way to manage high BP in pregnancy.

- Tight Control: Act now to lower blood pressure to the *high normal* range.



What will treatment look like?

No matter what you choose, your doctor may recommend you:

- Take medication for high BP
- Track your BP at home
- Take vitamins or other supplements

Right now, there isn't enough evidence that the items below lower the risk of problems for people with high BP in pregnancy:

- Changing diet, like lowering how much salt you eat or how many calories you eat
- Being more or less active, for example changing exercise or workload
- Lowering stress level

Which approach should I choose?

There is no one best approach. The best approach for you depends on what matters most to you. It may be helpful to know what matters to others. Research found that most pregnant people in Canada fall into one of the 3 groups.

Flip over the page to see how tight control and less tight control compare.

Group 1



What Matters Most?
Avoiding early delivery

Approach:
They may want to talk to their doctor about *tight control*.

Group 2



What Matters Most?
Reducing medication

Approach:
They may want to talk to their doctor about *less tight control*.

Group 3



What Matters Most?
Not yet sure. Lots of things seem important right now.

To learn more, read our FAQ at: <https://tinyurl.com/bpfaqs> & check out our online decision aid at: <https://tinyurl.com/bpdecisiontool>

This decision aid was made by patients, clinicians and researchers at the University of British Columbia and King's College London. The developers have nothing to gain from the decision you make. More information about the development process and a full list of references is available at: <https://tinyurl.com/high-bp>. Last Update: July 2020; Reading Level: Grade 7

Figure 5.5: Paper-based PtDA revised based on feedback from think-aloud interviews – side 2

How to use this sheet

Under "My Rating" you can rate how important each difference is to you. (1 - not at all important to 5 - very important)



This sheet uses icon arrays to show how many people, out of 100, we think would have each outcome.

55 would have the outcome 45 would not have the outcome



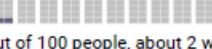
The darker colour shows how many people we think would have the outcome.
The lighter colour shows how many people we think would not have the outcome.

How Do Tight Control and Less Tight Control Compare?

The tables below show the risk of outcomes that were important to women we spoke to. Other outcomes may be important to you. These numbers are based on the average person. Your risk may be higher or lower based on other factors.

My Rating	Description	Tight Control	Less tight Control
Severely elevated blood pressure (BP) A medical emergency. Severely elevated BP increases the risk of other health problems now and later in life.	Out of 100 people, 28 will develop severely elevated BP		Out of 100 people, 41 will develop severely elevated BP
Taking blood pressure medication Often taken everyday, medications prescribed for high BP in pregnancy are considered safe.	Out of 100 people, 94 will take blood pressure medication		Out of 100 people, 77 will take blood pressure medication

The evidence is not clear right now. But based on the evidence, it looks like there is no difference between the treatment approaches or only a small difference between tight control and less tight control on the outcomes below.

My Rating	Description	Risk	If there is a difference...
Born before 34 weeks Most of these babies need to spend time in the hospital. They are also more likely to have health problems.	Out of 100 babies, about 15 will be born before 34 weeks		Slightly fewer people who choose tight control will have a baby born before 34 weeks
Born smaller than most other babies A baby may be normal and small or a baby may be very small because of problems before birth. It is very hard to know why the baby is small before the baby is born.	Out of 100 babies, about 18 will be born smaller than most other babies		Slightly fewer people who choose less tight control will have a baby born smaller than most other babies
Pre-eclampsia A type of high BP that involves internal organs, like the liver and kidneys. This raises the risk of health problems later on.	Out of 100 people, about 48 will develop pre-eclampsia		Slightly fewer people who choose tight control will develop pre-eclampsia
Blood transfusion A person needs a blood transfusion when they lose a lot of blood. Blood transfusions are generally considered safe.	Out of 100 people, about 2 will need a blood transfusion		Slightly fewer people who choose tight control will need a blood transfusion.
Caesarean section/C-section The baby is delivered through a cut in the lower belly. The average person takes 6 weeks to recover from a C-section.	Out of 100 people, about 49 will have a C-Section		Slightly fewer people who choose less tight control will have a C-section

Summary

- I know enough about the risks and benefits of each option
- I am clear about which benefits and risks matter most to me
- I have enough support and advice from others to make a decision
- I feel sure about the best choice for me

When I think about the risks and benefits of both approaches, I prefer:

- Tight Control
- Less Tight Control

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5.4.3 Pilot Testing

To facilitate pilot testing during the pandemic, the paper-based tool was converted to a web-based tool. The web-based tool followed the same presentation order as the paper-based tool, but the online format allowed for adaptability in how information was provided and to whom. Specifically, rather than having the additional information on a separate webpage, the online tool included drop-down boxes that participants could “open” to access more detail on a specific topic. Additionally, because of the issues with values clarification identified in the think-aloud interviews, and evidence that inclusion of preference profiles in PtDAs can facilitate shared decision-making,²⁴² preference profiles were added to the PtDA. After the information was presented, participants were asked to select the preference profile (*equal prioritiser; early delivery avoider; medication minimiser; or no group*) that most aligned with their own preferences (Figure 5.6). Subsequent information was prioritised based on the selected preference profile. For example, for individuals who selected *early delivery avoider*, information about early delivery was prioritised. The full web-based PtDA is available in Appendix D.

Figure 5.6: Screenshot of the preference profiles included in the web-based PtDA

Priority	Action	Action	Action	Action
My top priority is	Delivering after 34 weeks	Taking as little medication as possible	I don't have a top priority yet	Something else
Other things that impact my decision	<ul style="list-style-type: none"> Developing pre-eclampsia Developing severely elevated BP 	<ul style="list-style-type: none"> Developing severely elevated BP 	<ul style="list-style-type: none"> Having a blood transfusion Delivering after 34 weeks 	
These things are less important to me	<ul style="list-style-type: none"> Having a blood transfusion Taking medication 	<ul style="list-style-type: none"> Having a blood transfusion Delivering after 34 weeks 	<ul style="list-style-type: none"> My baby being born smaller than most other babies 	

In total, 99 pregnant people participated in pilot-testing. The majority of participants identified as White or Caucasian ($n = 62$, 62%), had at least one prior pregnancy ($n = 54$; 55%), and had completed university or had a professional qualification ($n = 62$; 62%). More than one third of the participants ($n = 40$; 40%) had a history of hypertension during pregnancy (Table 1).

5.4.3.1 Acceptability and Usability

In general, participants reported high acceptability of the PtDA; all but 2% participants ($n = 2$) reported the overall acceptability of the PtDA to be neutral or better, with 75% of participants ($n = 74$) rating overall acceptability as “Generally positive” or “Very positive”. Almost all participants ($n = 86$; 86%) reported that the PtDA was mostly or entirely clear. For most participants, the PtDA provided the right amount or close to the amount of information they wanted ($n = 73$; 74%); however, for some the tool provided much less ($n = 3$; 3%) or much more ($n = 13$; 13%) information than they wanted (Table 5.2).

The mean SUS score was 62.7 ($s = 18.84$), indicating close to, but slightly below, average usability.²⁴³ Review of demographic characteristics found slightly higher average usability ratings for those who reported completing some college (mean = 70.7) compared to those reporting either more or less formal education (range 57.1 to 63.7). One-way analysis of variance found that this difference was not statistically significant ($F(3, 95) = 1.68, p = 0.18$). No differences were observed by age (mean range: 59.4 to 64.6) or race or ethnicity (mean = 62.8 for White or Caucasian participants and 62.5 for non-White or Caucasian participants; variable dichotomised due to small cell counts).

Table 5.2: Participant ratings of the PtDA's acceptability

	N	%
Overall Acceptability		
Very positive	27	27%
Generally positive	47	47%
Neutral or mixed	23	23%
Somewhat negative	2	2%
Balance and Fairness		
Clearly slanted to 'less-tight' control	4	4%
Slightly slanted to 'less-tight' control	18	18%
Completely balanced	59	60%
Slightly slanted to 'tight' control	13	13%
Clearly slanted to 'tight' control	5	5%
Clarity		
Everything was clear	31	31%
Most things clear	55	56%
Some things unclear	9	9%
Many things unclear	4	4%
Length		
About right	60	61%
Should have been a little longer	38	38%
Should have been much longer	1	1%
Amount of Information		
Much less than I wanted	3	3%
Little less than I wanted	14	14%
About right	53	54%
Little more than I wanted	16	16%
Much more than I wanted	13	13%

5.4.3.2 Preparedness for Decision-making and Decisional Conflict

The mean PDMS score was 70.9 ($s = 20.15$) indicating, that on average, participants reported that the tool would be helpful for preparing to engage in shared decision-making with their physician. Similarly, the majority of participants reported little to no

decisional conflict; 81% of participants ($n = 81$) endorsed all four items in the SURE scale.

5.4.3.3 Knowledge

The overall knowledge score improved significantly after completing the PtDA; the mean score before completing the decision aid was 3.29 out of 5; afterwards, this increased to 4.24 out of 5 ($t = -6.99, p < 0.0001$; 95% CI: -1.22; -0.68).

5.4.3.4 Preferences

Similar to findings presented in Chapter Two, the most common preference profile was *equal prioritiser* ($n = 39$; 40%) followed by *early delivery avoider* ($n = 24$; 25%) and *medication minimisers* ($n = 19$; 20%). A significant minority identified avoiding another health outcome or intervention as their priority ($n = 15$; 15%).

After completing the PtDA, most participants preferred ‘tight’ control ($n = 60$; 61%) to ‘less-tight’ control ($n = 22$; 22%). A minority of participants were unsure of which approach they preferred ($n = 17$; 17%).

5.4.3.5 IPDAS Criteria

The final decision aid met seven out of seven criteria to be defined as a PtDA, and eight out of nine criteria to lower the risk of making a biased decision. The criterion that was not met was the readability criterion. Using the SMOG Readability Formula,²⁴¹ the web-

based PtDA was assessed at a Grade 9 reading level. This higher rating was primarily due to the words: information; decision; and pregnancy.

5.5 Discussion

This study sought to develop and then test a patient-centered PtDA for management of pregnancy hypertension. Overall, the tool was positively received and effective: most participants found the PtDA to be clear and balanced, and after completing the PtDA participants reported low decisional conflict and improved knowledge. Results showed this prototype tool to have slightly below average usability based on scores from the SUS. About one third of participants found the tool to be unnecessarily complex. Despite these challenges, the vast majority of participants reported that they would like to use the tool and that it would be helpful for preparing for SDM with their care provider. Future efforts should focus on simplifying the tool to improve usability.

This work builds on and confirms research on patient preferences for management of pregnancy hypertension presented in Chapter Two, which identified three preference profiles using latent class analysis (LCA). In this study, self-identification of preference profile yielded similar distributions to previous LCA, with *equal prioritisers* comprising the largest group, followed by *early delivery avoiders* and *medication minimisers*. Preference profiles are not exhaustive and are not expected to

describe all individuals' preferences. In this study, a significant minority did not identify with any of these preference profiles. This minority may be a group that could gain particular benefit from SDM as their preferences are not represented in the literature.

Additionally, previous research assessing preferences for 'tight' control compared to 'less-tight' control found that after reading educational material, half of participants preferred 'tight' control and half preferred 'less-tight' control (Chapter 2). In contrast, after completing the PtDA, most participants in this study preferred 'tight' control to 'less-tight' control. This may be an artefact of the sample, or it could be related to differences in framing between the two studies. While the educational material in the previous study did not describe clinical guidelines, the PtDA described 'tight' control as the approach recommended by clinical guidelines. Thus, it may be that placing treatment risks and requirements within the context of clinical guidance influenced participant preferences.

These findings should be considered in the context of the study's limitations. The majority of participants identified as White or Caucasian and reported a high level of education. Consequently, it is possible that the PtDA would not be as effective or acceptable to people from other racial or ethnic backgrounds or with less formal education, although these factors did not impact usability scores. Furthermore, because

participants were recruited from a survey panel, they may not have been as invested in completing the decision tool as patients actively making a decision about how to manage hypertension during pregnancy. It should be noted, however, that 40% of participants had current or past pregnancy hypertension and all participants were pregnant, increasing the likelihood that the tool would be relevant for them. In addition, when presented with the option to complete a longer, more detailed values clarification activity or a shorter one, half of participants chose the longer activity, which suggests that they were engaging with the tool. Lastly, this pilot testing was conducted with a Canadian sample using a tool based on qualitative work with participants in Canada. Findings may not apply to other settings, particularly those with different resources and healthcare structures.

Well-validated methods and patient engagement throughout the development process strengthen these findings. The development process followed the IPDAS guidelines which are based on international review of current evidence and list best practice for PtDA development. Additionally, a patient-oriented approach was used and patients were engaged throughout the development process. Validated qualitative work was used to identify which aspects of the treatment decision were most important to patients. Established preference elicitation methods from health economics were used to determine the relative importance of different treatment considerations and identify

preference profiles. In addition, patient feedback on the prototype tool was solicited both by engaging patient partners during development, and through iterative think-aloud interviews with pregnant people and individuals with lived experience of pregnancy hypertension. These comprehensive steps ensured that the PtDA was relevant for patients with pregnancy hypertension and prioritised the issues that were of most importance to them. Lastly, to improve relevance and reduce fatigue, information was presented to each participant in a way that matched their self-identified priorities, and allowed participants to choose the amount of information the tool would present.

5.5.1 Conclusions

A PtDA for pregnancy hypertension was developed using a patient-oriented approach. Pilot testing of the PtDA with pregnant individuals found the tool to be generally acceptable and perceived as useful for supporting shared decision-making. Knowledge of pregnancy hypertension improved after completing the tool. Future work should aim to improve usability of the PtDA and ensure that its content is accessible to individuals from diverse socioeconomic backgrounds.

Chapter 6: Generating Hypotheses: A Preliminary Exploration of the Role of Emotion in Patient Decision-Making

6.1 Introduction

The systematic review presented in Chapter Three found that no best practices exist for addressing emotion in PtDAs. As a result, the initial purpose of this chapter was to adapt the PtDA presented in Chapter Five to address emotion, and then compare the original tool with the adapted tool. This work was to be conducted during a six-month study abroad term in the Netherlands at Maastricht University supported by the Friedman Scholarship at the University of British Columbia. However, these plans were interrupted by the COVID-19 pandemic. Instead, a survey was conducted to explore the role of emotion in patient decision-making and generate hypotheses for future study.

6.2 Background

Although participants interviewed reported that emotion was important to the decision-making process, as reviewed in Chapter Three, no guidance exists on the how to incorporate emotion into PtDAs, and currently PtDAs for decisions in pregnancy vary considerably as to whether and/or how emotion is addressed. One theoretical paper has explored the relationship between emotion, emotion regulation specifically, and patient decision-making.¹⁶⁰

Emotion regulation is the ongoing process through which individuals manage their emotional responses. Similar to attention, emotion regulation can be automatic (i.e., implicit) or purposeful (i.e., explicit). Emotion regulation strategies are specific ways in which individuals regulate emotions and are broadly categorised into engagement and disengagement strategies.²⁴⁴ When using engagement strategies, individuals approach or interact with emotional experiences, for example by reframing thoughts related to the emotion being experienced (e.g., “All of my plans are ruined” to “Plans change and I can adapt”). In contrast, when using disengagement strategies, individuals avoid emotional experiences, for example by ignoring the emotion being experienced and directing their attention elsewhere (e.g., focusing on a simple task like making tea). Whereas engagement strategies decrease distress slowly, disengagement strategies decrease distress quickly.²⁴⁵ According to the Process Model of Emotion Regulation, which type of strategy is most appropriate depends on the context and the level of distress being experienced. Because engagement strategies work slowly, they may be more appropriate when distress is low. In contrast, because disengagement strategies work more quickly, they may be more appropriate when distress is high. Thus, when emotional responses are high, individuals are more likely to use disengagement strategies. Indeed, research shows that individuals who report higher levels of stress also report a greater tendency to use expressive suppression, a

disengagement strategy in which individuals try to stop any behavioural expression of the felt emotion(s).²⁴⁶⁻²⁴⁸ It is important to note that despite working more quickly, inflexible use of disengagement strategies can be problematic because they impede information processing.^{249,250}

Evidence suggests that high levels of stress in and of themselves can impact decision-making. For example, Preston and colleagues found that anticipatory stress disrupted participant learning in a gambling task: those who were in the stress condition learned the risk contingencies of the task more slowly than those in the control condition.²⁵¹ Building on these findings, a 2008 study found that anticipatory stress impaired performance on a gambling task even when explicit information on risks were provided.²⁵² Conversely, a study comparing individuals with reduced emotional responding to healthy controls found that individuals with reduced emotional responding made more advantageous decisions during a gambling task.²⁵³ These results suggest that high levels of stress can impact decision-making.

Significantly, the impact of stress on decision-making is not uniform.²⁵⁴ Numerous factors can impact the relationship between stress and decision-making. One important factor is the extent to which individuals believe they are able to cope with the stress. In a laboratory experiment, Kassam and colleagues assigned participants to receive social-feedback (either negative or positive) to influence the extent to which they

perceived themselves capable of coping with a stressful task (giving an impromptu speech to the researchers).²⁵⁵ Participants then completed a series of anchoring-and-adjustment questions to assess the extent to which anchoring biased their responses. Participants who received feedback that reinforced their ability to cope with the stressful task adjusted their responses more than participants who received feedback that minimised their ability to cope with the stressful task. Together, the authors concluded that this suggests that individuals' perceived ability to cope may influence the extent to which stress impacts decision-making.

In their theoretical paper, Carpenter and Niedenthal posit that complex health decisions are necessarily stressful and that differences in how individuals regulate their emotions may be related to difficulty with decision-making.¹⁶⁰ Specifically, individuals who rely on disengagement strategies, like expressive suppression, may be less able to engage with decisions and instead be more likely to delay or defer decision-making. Additionally, based on the work reviewed above,²⁵⁵ they propose that an individual's belief in their own ability to regulate emotions may also impact how they engage with decision-making.

Taken together, the evidence and theory reviewed suggest three mechanisms through which emotion and emotion regulation may impact patient decision-making:

(i) high levels of emotional responding or stress; (ii) tendency to use disengagement strategies; and (iii) low belief in ability to cope.

This chapter aimed to explore, in a preliminary manner, each of these three mechanisms in a healthcare context, using knowledge as a proxy for decision-making. Specifically, this chapter aimed to identify the relationship between (i) state-trait anxiety, (ii) tendency to use expressive suppression emotion regulation strategies, (iii) and perceived lack of access to effective emotion regulation strategies and knowledge in a healthcare context.

6.3 Methods

6.3.1 Overview

A cross-sectional survey was conducted to explore the relationship between emotion regulation and patient decision-making. This study protocol was reviewed and approved by the Behavioural Research Ethics Board (H18-02675) at the University of British Columbia.

6.3.2 Participants

Participants were recruited through an independent survey panel provider. Individuals were eligible to participate if: (i) they were currently pregnant; (ii) were at least 18 years of age; (iii) could read, write and provide consent in English; and (iv) lived in Canada.

6.3.3 Survey

This survey was part of a larger study of patient preferences. After consenting to participate in the study, survey participants answered questions about demographic characteristics and preferences for shared decision-making. Participants were then shown information about pregnancy hypertension and asked specific questions about the content. Importantly, the questions were on the same page as the informational content. The information and knowledge questions were previously tested, as described in Chapter Two. At the end of the survey, participants completed measures of anxiety and emotion regulation.

6.3.3.1 Six-item State—Trait Anxiety Inventory (STAI-6)

A modification of the full 20-item STAI,²⁵⁶ the six-item STAI is commonly used in health research to measure both state and trait anxiety.²⁵⁷ State anxiety refers to transient anxiety experienced in the present moment. Trait anxiety refers to anxiety that is more generally representative of an individual's personality. The instrument comprises items about the presence or absence of anxiety which are rated as "not at all", "somewhat", "moderately" or "very much". The six-item STAI has high reliability and construct validity—it is highly correlated with the full 20-item instrument.²⁵⁸

6.3.3.2 Emotion Regulation Questionnaire (ERQ)

The Emotion Regulation Questionnaire (ERQ)²⁵⁹ is a ten-item instrument that measures individuals' tendency to use cognitive reappraisal (an engagement strategy) and expressive suppression (a disengagement strategy). The ten items are scored on a 7-point Likert Scale anchored at 'strongly disagree' and 'strongly agree'. Items form two facets—expressive suppression and cognitive reappraisal—which are scored as a continuous sum of the relevant item responses. The facets are interpreted separately. Translated into 40 separate linguistic versions, the ERQ is widely used in studies of emotion processing and emotion regulation. It shows strong construct validity^{246,259} and both internal and test-retest reliability.^{259,260}

6.3.3.3 18-item Difficulties with Emotion Regulation Scale (DERS-18)

The 18-item Difficulties with Emotion Regulation Scale (DERS-18)²⁶¹ is a self-report questionnaire derived from the original 36-item scale. The DERS-18 assesses individuals' overall difficulties with emotion regulation and their difficulties across six dimensions: nonacceptance of negative emotions; difficulties engaging in goal-directed behaviors when distressed; difficulties controlling impulsive behaviors when experiencing negative emotions; limited access to emotion regulation strategies perceived as effective; lack of emotional awareness; and lack of emotional clarity. Participants rate 18-items on a 5-point Likert scale ranging from "almost never" to

“almost always”. The DERS-18 has strong internal consistency and construct validity.^{261,262}

6.3.4 Data Analysis

Preliminary data analysis used descriptive statistics and correlations. Univariate linear regression was used to assess the relationship between each of the three emotion measures—the expressive suppression facet of the ERQ, STAI-6, and the Strategies subscale of the DERS-18—and knowledge. For each of these regressions, the emotion measure was entered as the predictor variable and knowledge was entered as the outcome variable.

As the constructs assessed in the three emotion measures overlap, a backwards stepwise linear regression was conducted to assess the relationship between all three measures and knowledge score. The backwards linear regression used an inclusion criterion of $p < 0.10$. Bayesian information criterion was used to compare models.

Education was entered as a covariate in the multivariable analysis. Based on review of the distribution of education, and the approach used in Chapter Two, education was dichotomised into individuals with and without a university degree or professional qualification. Chapter Two found that individuals with current and/or pregnancy hypertension had lower knowledge scores than individuals with no history

of pregnancy hypertension. As a result, history of pregnancy hypertension was also added as a covariate. Lastly, because age has been shown to be related to individual differences in emotion regulation, age was included as a covariate as well.^{263–265}

6.4 Results

In total, 107 pregnant people completed the survey. Most participants were between 25 and 39 years of age ($n = 80$; 77%); identified as White or Caucasian ($n = 73$; 68%) and had completed post-secondary education ($n = 74$; 69%; Table 6.1). Slightly more than one third reported experiencing hypertension in a past pregnancy or currently ($n = 39$; 36%).

Table 6.1: Demographic characteristics of survey participants

	Frequency	
	<i>n</i>	%
Hypertension in current or past pregnancy		
Yes	39	36%
Age		
Less than 25 years	16	15%
25 to 29 years	23	21%
30 to 34 years	32	30%
35 to 39 years	25	23%
40 years or older	11	10%
Race/Ethnicity[†]		
Aboriginal or Indigenous	3	3%
African American or Black	8	7%
Asian	13	12%
Caucasian or White	73	68%
Hispanic or Latina/o	3	3%
South Asian	7	7%
Southeast Asian	0	0%

West Asian	1	1%
Prefer not to say	1	1%
Prefer to self-identify or other not included here	1	1%
Education		
High School or below	20	19%
Some College or University	13	12%
College Diploma or Technical/Trade School	28	26%
University Degree or Professional Qualification	46	43%
Previous Pregnancies		
Yes	60	56%
Current Medication		
Antihypertensives	10	9%
Aspirin	25	23%
Folic Acid	52	49%
Multivitamin	71	66%
Other Daily Medication	19	18%

[†]Values may not sum to 100% as participants could indicate multiple responses

Table 6.2 presents mean scores on: knowledge; the Expressive Suppression facet of the ERQ; the STAI-6; and the Strategies subscale of the DERS-18. Participant scores were approximately normal; kurtosis and skewness statistics for all measures were between 0 and |1|.

Table 6.2: Mean scores for knowledge; expressive suppression; state-trait anxiety; and the strategies subscale of the DERS

Measure	Mean	(sd)
Total Knowledge Score	4.7	(1.8)
Expressive Suppression Facet of the ERQ	15.8	(5.7)
STAI-6 Total Score	14.8	(2.7)
Strategies subscale of the DERS-18	7.7	(3.3)

sd: standard deviation

6.4.1 Univariate Analysis

Analysis of the impact of the tendency to use expressive suppression on knowledge scores yielded a significant effect. On average, a one-point increase in expressive suppression scores was related to a 0.075 point decrease in knowledge scores (95% CI: -0.13, -0.02; $p < 0.05$; Table 6.3). Put another way, based on these results it is expected that a person in the bottom decile of expressive suppression scores would answer one more question correctly, out of seven, than a person in the top decile of expressive suppression scores. These results indicate that as the tendency to use expressive suppression strategies increases, performance on the simple knowledge task decreases.

Table 6.3: Results from univariate linear regression with knowledge score as the outcome variable

Predictor	Beta	Error	Standard		95% CI	
			Lower	Upper		p-value
Expressive Suppression (ERQ)						
Increasing (continuous)	-0.075	0.029	-0.13	-0.02	0.01	
STAI-6						
Increasing (continuous)	-0.167	0.062	-0.29	-0.04	<0.01	
Strategies Subscale (DERS-18)						
Increasing (continuous)	-0.145	0.049	-0.24	-0.05	<0.01	

Analysis of the impact of anxiety as measured by the STAI-6 on knowledge yielded a significant effect. On average, a one-point increase in STAI-6 score was related

to a 0.17 point decrease in knowledge scores (95% CI: -0.29, -0.04; $p < 0.01$; Table 6.3). Put another way, based on these results it is expected that a person in the bottom decile of STAI-6 scores would answer one more question correctly, out of seven, than a person in the top decile of STAI-6 scores. These results indicate that higher self-reported state-trait anxiety decreases performance on a simple knowledge task.

Analysis of the impact of perceived access to effective emotion regulation strategies as measured by the Strategies subscale of the DERS-18 on knowledge yielded a significant effect. On average, a one-point increase in Strategies subscale score was related to a 0.15 point decrease in knowledge scores (95% CI: -0.24, -0.05; $p < 0.01$; Table 6.3). Put another way, based on these results it is expected that a person in the bottom decile of Strategy subscale scores would answer one and a half more questions correctly, out of seven, than a person in the top decile of Strategy subscale scores. These results indicate that lower perceived access to effective emotion regulation strategies is associated with decreased performance on a simple knowledge task.

6.4.2 Multivariable analysis

Based on these results, all three emotion measures were entered as predictors in the multivariable linear regression. The final model included the Strategies subscale of the DERS-18 and level of education (full model is shown in Appendix E). On average, individuals with higher scores on the Strategies subscale of the DERS-18 had lower

knowledge scores, after controlling for the effect of education. Put another way, individuals who believe themselves to be less able to effectively manage their emotions performed more poorly on the knowledge task.

Table 6.4: Results from the final multivariable model with knowledge score as the outcome

Predictor	Beta	Standard Error	95% CI		<i>p</i> -value
			<i>Lower</i>	<i>Upper</i>	
Strategies Subscale (DERS-18)					
Increasing (continuous)	-0.153	0.049	-0.250	-0.057	0.002
Education					
High School/Trade School	Ref				
University/Prof. Qualification	0.860	0.324	0.217	1.502	0.009

6.5 Discussion

This study is one of the first to quantitatively explore the role of emotion and emotion regulation in patient decision-making. Based on theoretical models of emotion processes, the primary analysis investigated three potential mechanisms through which emotion and emotion regulation could impact decision-making as measured by a simple knowledge task. Univariate analyses found support for all three mechanisms, and specifically that as the tendency to use expressive suppression and state-trait anxiety increased, and access to emotion regulation strategies perceived as effective decreased, average knowledge scores decrease. When considered together, however, only access to emotion regulation strategies perceived effective significantly predicted knowledge scores after controlling for education. This finding suggests that, in the

context of pregnancy hypertension, an individual's belief about their own ability to cope with emotions has a significant impact on how they engage with educational information in the short term. These results partially support Carpenter & Niedenthal's hypothesis but suggest that it is not simply a tendency to use expressive suppression that interrupts decision-making; instead it is an individual's beliefs about how effective the strategies they use are. In this sample, scores on the Strategies subscale of the DERS-18 and the expressive suppression facet of the ERQ were strongly correlated ($r = 0.536, p < 0.001$). Consequently, it may be that both the tendency to use expressive suppression and an individual's belief about their own ability to regulate their emotions have a significant impact on engagement with education information but the limited sample size did not allow for these effects to be disentangled.

In the context of patient decision-making these findings suggest that individuals who are less confident in their ability to regulate their emotions effectively may benefit less than others from educational material. Importantly, these findings also offer an opportunity to provide support to these individuals. Specifically, providing optional, evidence-based emotion regulation strategies as part of the SDM process, or in PtDAs to support SDM, may improve knowledge transfer. Teaching explicit emotion regulation skills has been shown to be effective^{266,267} and improvements can be seen readily in both clinical and non-clinical populations.²¹⁴

These findings should be considered in the context of their limitations. First, this study used a simple knowledge task as a proxy for patient decision-making. It is clear that this one task could not fully capture the complex process of decision-making. However, information provision is foundational to SDM and quality decision-making. Thus, this task may be a good proxy to study the potential impact of emotion on patient decision-making in the context of PtDAs, specifically. Of note, the knowledge task was not designed to be challenging. For example, each of the questions was asked on the same page as the information which included the answer to the question. That an effect was observed with such a simple task suggests that the effect of these emotional processes on decision-making is robust. Furthermore, the effect may be greater for more cognitively taxing tasks like complex decisions involving trade-offs between health outcomes and treatment requirements.

Second, the cross-sectional nature of this investigation means that the findings only speak to the short-term impact of emotion and emotion regulation on performance on the knowledge task. It is possible that these relationships are different when considering a longer-term perspective. For example, evidence shows that emotional arousal can be helpful for long-term memory consolidation.²⁶⁸ Consequently, a longitudinal study design may have found different results: where this study found in multivariable analyses that self-reported state-trait anxiety was not related to

knowledge scores in the short-term, a longitudinal study may have found that higher state-trait anxiety was associated with increased knowledge scores.

Lastly, sample characteristics may limit the generalizability of these findings. Participants primarily identified as White or Caucasian and were well-educated. The analyses attempted to address this by including education as a covariate, but given the small sample this may not be sufficient to accurately capture this complex relationship in individuals with other demographic characteristics. Similarly, it is possible that interactions exist between the three emotion constructs measured (tendency to use expressive suppression; state-trait anxiety; and access to emotion regulation strategies perceived as effective) but these relationships are obscured by the relatively small sample size.

Despite these challenges, this work presents compelling preliminary evidence for the importance of emotion processes in patient decision-making. These findings are supported by well-validated and reliable measures that have been used regularly in online surveys. Additionally, the survey material was relevant to participants as all were pregnant and more than one third had experienced pregnancy hypertension. Furthermore, participant responses to the knowledge questions suggest a relatively high-level of engagement. Three-quarters of respondents answered most knowledge

questions correctly. Lastly, the range of correct responses across participants suggests that although simple, the knowledge task was able to differentiate participants.

6.5.1 Conclusion

In conclusion, the preliminary evidence presented in this chapter aligns broadly with well-established theory on emotion and emotion processing. These findings support emotion and emotion regulation as an important factor in patient decision-making. Future research should build on this work by using clinical samples, and considering emotion regulation throughout the decision-making process.

Chapter 7: Discussion

7.1 Introduction

This dissertation identified and quantified child-bearing individuals' priorities when choosing how to manage pregnancy hypertension and then developed tools to support patients and clinicians facing this decision. To that end, this dissertation used a patient-oriented research approach and included: a qualitative investigation of individuals' preferences; an elicitation of individuals' preferences to identify the relative importance of key decision characteristics or attributes; a systematic review of how emotion is addressed in PtDAs; a re-analysis of the CHIPS trial incorporating the preferences obtained previously; the development and preliminary testing of a PtDA for pregnancy hypertension; and an exploratory investigation of the relationship between emotion and decision-making in a healthcare context. This chapter reviews the key findings from this dissertation, situates them within the broader literature and health care context, outlines the strengths and limitations of this body of work, and considers the implications for practice and future research.

7.2 Key Findings

The key findings from this dissertation are summarised in Table 7.1.

Table 7.1 Summary of key findings by chapter

Chapter	Finding(s)
Two	<ul style="list-style-type: none"> • Patient preferences for management of pregnancy hypertension are heterogeneous • Most patient preferences fit one of three preference profiles • Patients want to be involved in decisions about management of pregnancy hypertension • Emotion is an important consideration
Three	<ul style="list-style-type: none"> • Most patient decision aids for decisions in pregnancy do not address emotion • No patient decision aids reviewed included emotion regulation strategies
Four	<ul style="list-style-type: none"> • Which strategy for management of hypertension yields the best results depends on patient preferences • For one preference profile, the optimal strategy is not the strategy promoted by current clinical guidance
Five	<ul style="list-style-type: none"> • A patient decision aid for pregnancy hypertension may help individuals make informed decisions
Six	<ul style="list-style-type: none"> • Individuals who perceive themselves as less able to cope with their emotions may benefit less from patient decision aids

The first study presented in this dissertation (Chapter Two) was a mixed-methods investigation of individuals' preferences for management of pregnancy hypertension. Qualitative work identified seven treatment-differentiating treatment attributes that child-bearing individuals prioritised when choosing between 'tight' control and 'less-tight' control of BP: severe hypertension; pre-eclampsia; baby born small for gestational age; delivery before 34 weeks; antihypertensive medication; caesarean section; and

blood transfusion. These findings were then applied in a BWS preference elicitation task. Analysis of the BWS task identified three preference profiles for management of pregnancy hypertension: *equal prioritisers*; *early delivery avoiders*; and *medication minimisers*. Each of these profiles differed in which of the seven treatment attributes they prioritised and by how much.

Additionally, this work explored individuals' decisional needs and preferences for shared decision-making. These results showed that people largely preferred: to receive information about pregnancy hypertension if they were at risk of pregnancy hypertension and before pregnancy hypertension had developed; that information be shared in a digital format (i.e., website or app for tablet or phone); and to make the decision about which BP management strategy to pursue, either with or without their physician's input.

Lastly, through review of notes and transcripts from qualitative work it became apparent that emotion was an important factor in individual decision-making about management of pregnancy hypertension. In many ways, it is unsurprising that emotion was identified as it is a long established to have an important role in decision-making in general. However, because emotion is often not considered in preference studies or the development of PtDAs, it was not part of the initial conception of this dissertation work. An ancillary analysis of focus groups and interviews described ways in which emotion

arose when participants talked about choosing a BP management strategy. When participants talked about emotion, they discussed the way in which emotion impacted their information seeking behaviour, either by causing them to seek-out more information or to avoid information. Additionally, participants shared that they would take their emotional cues from their care provider, and assess the extent to which they should be concerned or worried based on their care provider's level of worry. Lastly, participants discussed different ways in which the management strategies themselves would cause anxiety. For example, for some, 'tight' control was perceived as reassuring; whereas for others, the lower target BP in 'tight' control was perceived as a source of stress.

The second study (Chapter Three) presented in this dissertation built on these ancillary findings, and looked at if and how emotion is addressed in PtDAs for decisions during pregnancy. The systematic review cast a broad net and included the published academic literature as well as tools available online that had not been studied. Results found that most PtDAs for decisions in pregnancy did not address emotion. The tools that did, varied in which emotions were addressed, how they were addressed, and where in the tool they were included (e.g., information provision, or values clarification). None of the tools reviewed provided emotion management regulation strategies. This was the first study of emotion in PtDAs. These findings were

unsurprising given that emotion is not included in the international guidance on PtDA development, or in leading models of SDM. However, an abundance of research from social sciences, including psychology, sociology, and economics, and shows that emotion is a core component of decision-making and further work in the healthcare context is needed.

The third and fourth studies (Chapter Four and Chapter Five, respectively) examined ways in which the findings from the mixed-methods study in Chapter Two could be applied to support both clinicians and patients in choosing how to manage pregnancy hypertension. Specifically, these studies sought to help decision-makers integrate patient preferences and values with the existing evidence on the risks and requirements associated with ‘tight’ control and ‘less-tight’ control.

The third study reviewed existing methods for weighting RCT analyses to incorporate importance weights, and then adapted one of these measures to assess the impact of patient values on interpretation of the CHIPS trial. This adapted approach employed both patient preferences weights and used a patient-oriented composite component comprised of the seven treatment attributes identified in qualitative work (Chapter Two). Results showed that which treatment was most aligned with patient preferences varied by preference profile. For *equal prioritisers*, neither treatment approach was significantly better than the other, and presumably, choice would be

guided by clinical guidance. However, ‘tight’ control was best aligned with the priorities of *early delivery avoiders*, and ‘less-tight’ control was best aligned with the priorities of *medication minimisers*. The finding supporting ‘less-tight’ control for *medication minimisers* was driven by the amount of weight placed on avoiding antihypertensive medication. For *medication minimisers* avoiding antihypertensive medication made-up 58% of the decision. A threshold analysis assessed by how much the weight allotted to avoiding antihypertensive medication would need to decrease for ‘less-tight’ control to no longer be the treatment that best suited *medication minimisers*’ preferences. The analysis found that if avoiding antihypertensive medication accounts for 42% of the decision or more, ‘less-tight’ control yields better outcomes. However, if avoiding antihypertensive medication accounts for less than 42% of the decision, the treatment approaches are either equivalent or ‘tight’ control yields better outcomes.

Taken together with the findings from Chapter Two, these results show that ‘tight’ control, the approach recommended by national and international clinical guidance, is the preference congruent recommendation for approximately 85% of people with pregnancy hypertension (i.e., *equal prioritisers* and *early delivery avoiders*), and this percentage may increase depending on the weight that individual *medication minimisers* place on avoiding antihypertensive medication. Of note, this was the first study to

assess the impact of patient-oriented composite outcome *and* patient-value weights on the interpretation of RCT results.

To support SDM, a PtDA was developed for individuals choosing between 'tight' control and 'less-tight' control (Chapter Five). Preliminary testing of the PtDA found that overall the tool was positively received and effective. The majority of participants reported that the PtDA was clear and balanced. After completing the PtDA, participants had low decisional conflict and improved knowledge. However, the PtDA was found to have slightly below average usability scores. These scores were not related to age, level of education, or race/ethnicity. One potential reason for the below average usability scores may be the usability measure used. The SUS was designed to assess the usability of systems²³⁷ and as a result it may be less well-suited to studies of standalone interventions like PtDAs. The results from this study provide good evidence that a PtDA for pregnancy hypertension would confer benefit by improving patient knowledge.

The final study (Chapter Six) built on the findings from Chapters Two and Three on emotion in decision-making, and reported a preliminary investigation of mechanisms through which emotion may impact decision-making in a healthcare context. Based on theoretical models of emotion, emotion regulation and decision-making, the study assessed state-trait anxiety, the tendency to use expressive

suppression strategies to regulate emotions, and lack of access to emotion regulation strategies perceived as effective as mechanisms through which emotion may impact patient decision-making, as measured by a simple knowledge task. In independent analyses, all three mechanisms were associated with performance on the knowledge task. However, multivariable analysis found that only the Strategies subscale of the DERS-18 (lack of access to emotion regulation strategies perceived as effective) significantly predicted performance on the simple knowledge task. These results suggest that, in the context of pregnancy hypertension, an individual's belief about their own ability to cope with emotions has a significant impact on how they engage with educational information in the short term. Although preliminary, these findings support the importance of emotion and emotion regulation in patient decision-making and for PtDAs.

7.3 How a Patient-oriented Approach Shaped this Dissertation

This dissertation used a patient-oriented approach to identify, quantify and then apply patient preferences for management of pregnancy hypertension. This body of work was not designed to test whether or not a patient-oriented approach improves research. Instead, despite being a relatively new way of doing research, a patient-oriented approach was chosen because engaging patients in research is an "ethical imperative"²⁶⁹

as patients are ultimately the most impacted by and have the most to lose or gain from clinical health research. Patient-oriented research seeks to answer research questions that matter to patients, engage patients as partners, and improve healthcare.

Historically, research has not always focused on research questions that matter to patients. In the broader health context, for example, a mixed-methods study found that only approximately one quarter of published research articles on organ donation and transplantation in Canada addressed any of the top ten priorities identified by patients and caregivers.²⁷⁰ A similar study found that only 20% of published research in dialysis addressed patient or caregiver priorities.²⁷¹

In general, patients tend to prioritise more holistic considerations and treatment requirements, whereas researchers and clinicians often focus on measures of disease activities and symptoms.²⁷² For example, a study of domains for clinical care in HIV found that, for patients, addressing contextual factors, like HIV stigma, were more important for their health than directly addressing health behaviours. In contrast, physicians prioritised health behaviours above these contextual considerations.²⁷³ Interestingly, these findings parallel results from a study evaluating the Choosing Wisely Campaign. As reviewed in Chapter One, the Choosing Wisely Campaign aims to improve EBM and limit unnecessary testing in part by providing checklists and guidelines on when testing is appropriate. Qualitative evaluation of physician

responses to the Choosing Wisely Campaign found that the campaign was generally not seen as helpful because it did not address the broader contextual issues that shape patient-physician interactions, such as relationship building and limited time for clinical encounters.²⁹ Contextual factors which are often ignored are important for patient engagement with interventions and ultimately have a significant impact on the health benefit that patients receive from interventions.²⁷² Thus, it was important for this work to take a patient-oriented approach to ensure that those contextual factors and treatment requirements that can significantly influence patient engagement were not missed. Considering pregnancy hypertension, while clinicians chose to change guidelines for BP control based on outcomes, this dissertation responded to concerns many individuals have about taking medication and challenged whether this was simply a consequence of treatment decisions or, instead, an important consideration in individuals' decision-making.

The decision to take a patient-oriented approach and center patient values and perspectives fundamentally shaped the course of this dissertation. As discussed in the introduction, as a result of this approach, this dissertation started by speaking with and listening to patients rather than with a systematic review, as is traditional. More significantly, it is only through this approach that emotion was identified as important to patient decision-making in the context of pregnancy hypertension. As emotion is

generally not addressed in the SDM literature or PtDA guidance, it is likely that this important factor would have been missed if a traditional approach, guided by the existing literature, had been used. Listening to patients prompted the systematic review of emotion in PtDAs (Chapter Three) and the preliminary work on mechanisms through which emotion may impact patient decision-making (Chapter Six). Likewise a desire to help patients and care providers understand how preferences impact which treatment best meets patient priorities undergirded the work presented in Chapters Four and Five.

Patient-oriented research involves more than simply focusing on patient priorities. Instead, patient-oriented research changes the research process to engage patients. The literature shows that this engagement happens only very rarely. For example, a review of clinical trials published between 2011 and 2016 found that just 23 out of the 2777 trials reviewed actually engaged patients.²⁷⁴ In this dissertation, patient voices not only impacted the overarching goals of the investigations presented in this dissertation, they also influenced the methods used to achieve these goals. For example, patient feedback was sought throughout the development of the PtDA, both through think aloud interviews with participants, and through conversations with patient partners. Additionally, attempts were made to make sure that interviews and focus groups were accessible to all individuals who were interested in participating. One way

of increasing accessibility was providing the option of remote participation, either by phone or by video conferencing. Offering remote participation removed several barriers to participation, and had the added benefit of making it possible to include the perspectives of participants in different regions of BC. The methods used tried to reduce barriers to in-person participation too. Specifically, many participants had young children and a lack of access to childcare can be a significant barrier to participation. Consequently, participants were offered the option of bringing their children with them to interviews and focus groups.

Furthermore, taking a patient-oriented approach changed the materials used throughout this dissertation. For instance, in the initial qualitative work presented in Chapter Two, participants expressed a desire for information on long-term health outcomes, even though these outcomes are not typically studied in RCTs. As a result, information on long-term health outcomes was included where possible in educational materials, both within surveys and the PtDA. Similarly, antihypertensive medication was often identified as an important treatment attribute, both in interviews and focus groups and in the latent class analysis presented in Chapter Two. Because of this, a Frequently Asked Questions list was developed to address questions about antihypertensive medication in pregnancy.

It is important to note that taking a patient-oriented approach did present some challenges. Research is often very structured, and this approach required greater flexibility. For example, research often takes place during regular business hours on weekdays when patient partners, and participants, are likely to be at work. Likewise, clinical health research regularly takes place in hospitals which may be difficult for patients to access, either due to proximity or cost. During this dissertation research, meetings took place over the phone or via e-mail, as well as outside of business hours and in spaces that were convenient to the patient partner. In addition to the challenges presented by the way in which research is often done, there were challenges associated with what research was being done. While it was easy for the patient partner to contribute meaningfully to parts of this work, like the preference survey and the PtDA (Chapters Two and Five), it was difficult for the patient partner to play a role in the more technical components, like the trial reanalysis (Chapter Four). As patient-oriented research continues to grow as a field, more guidance on best practices for patient partner engagement will be available, and hopefully help to address some of these challenges.

While it is not possible at this point to systematically assess whether taking a patient-oriented approach improved the output of this dissertation, it is clear that this

approach shaped the research process, both in what questions were asked and what methods were used to address them.

7.4 The Challenges of Implementation in Clinical Practice

This dissertation included two applied components (Chapters Four and Five) to help clinicians and patients integrate patient values and preferences with clinical data. While the patient-oriented trial analysis and PtDA may be useful for SDM, the impact of these applications is limited by the extent to which they are actually used in practice.

Implementation of effective interventions is a longstanding challenge in healthcare.

Research suggests that healthcare innovation uptake is rare – only 5% of innovations have significant uptake.²⁷⁵ When innovations are taken-up, it is often after a considerable delay; on average, it takes 14 years for innovations to diffuse.²⁷⁵ Indeed, a recent study of patient decision aids found that 55% of trialed PtDAs had no uptake at all.²⁷⁶ Recent work has focused on barriers to uptake of SDM and PtDAs specifically.^{58,277}

While little research has been conducted on implementation of PtDAs in perinatal health,¹⁴⁶ it is likely that insights on enabling implementation of decision support tools broadly would apply in the context of pregnancy hypertension.

Studies have identified several enablers of implementation. In a review of a ten year PtDA program at a single hospital, Sepucha and colleagues found that providing

patients with direct access to the PtDA, rather than the PtDA only being available through the care provider, and providing the PtDA in multiple formats also furthered uptake.²⁷⁸ A more recent study found that online delivery, organizational endorsement and a design that allows integration into care practices were important implementation enablers.²⁷⁶ Furthermore, reviews of factors affecting implementation of health interventions in general have found that relevance to patients is important to uptake.

Based on these considerations, the PtDA developed and tested in this dissertation is well-positioned for successful implementation. This tool can be accessed by patients directly and is available as a web-app that works on computer internet browsers, and smart-phone and tablet interfaces. A paper version of the PtDA is also available. Importantly, these modes of delivery are the modes in which participants in Chapter Two said they would prefer to receive information on pregnancy hypertension. Furthermore, the web-app facilitates integration into clinical processes—it can be set-up to automatically return a summary of the patient's responses and preferences to the relevant care-provider, and this summary can be integrated into the electronic medical records and patient notes. Additionally, work is currently underway to build connections with patient organizations to help disseminate the tool. Lastly, immense efforts were taken to make sure the PtDA is relevant to patients. This work was

presented in detail in Chapters Two and Five and included an iterative, patient-oriented development process.

Similarly, the trial reanalysis presented in Chapter Four directly addresses care provider-identified challenges with the interpretation and application of trials with multiple and composite endpoints to individual clinical decisions. The inclusion of a threshold analysis may make it easier for care providers to identify when changes in patient preferences may shift recommendations for ‘tight’ or ‘less-tight’ control by gauging how important it is to a given patient to avoid taking antihypertensive medication. Additionally, the patient-oriented methods used increases the probability that the priorities that are most important to a given patient are included in the analysis, and thus the reanalysis may be highly relevant for care providers. Finally, there are ongoing efforts to disseminate this work to care providers by targeting high-impact clinical journals and professional conferences.

However, despite these efforts, successful implementation of health interventions is challenging. A recent review of implementation approaches found that in addition to ensuring that common barriers were addressed (e.g., difficulty accessing the tool for the patient; and difficulty integrating the tool for the clinician), the most successful implementation approaches considered the individual needs of each clinic or system to which the intervention was introduced.²⁷⁹ Consequently, it will be important

for future implementation efforts to account for the specific considerations of individual care settings.

7.5 Emotion and Decision-making

This dissertation adds to the limited literature on emotion and patient decision-making. The work presented in Chapters Three and Six are the first empirical, systematic investigations of how emotion is addressed in PtDAs, and mechanisms through which emotion may impact patient decision-making in the context of PtDAs. Although emotion is acknowledged as fundamental in psychological and sociological models of decision-making (see Lerner et al., 2015 and Burch & Fienberg, 2017 for comprehensive reviews^{100,280}), it is omitted from leading models of SDM. Further, models of clinical decision-making have been slow to integrate emotion.¹²⁰

Emotion was a consistent part of how participants described the decision-making process (Chapter Two) and the results from preliminary mechanistic investigation (Chapter Six) suggest that emotion and emotion regulation are related to performance on a simple knowledge task. Together, these studies provide evidence that emotion impacts patient decision-making. The relationship between emotion and patient decision-making is likely complex, and varies across individuals, contexts, and time. However, given the substantial evidence from other fields of the profound impact of

emotion, this complexity is not a sufficient reason to exclude emotion from research on patient decision-making or models of SDM. Instead, rather than facilitating research by simplifying concepts, excluding emotion may impede progress. If, as suggested in this work, emotion is an important mechanism, excluding emotion may limit the effectiveness of tools to support SDM or attempts at improving SDM. More work is needed to disentangle the relationship between emotion and patient decision-making.

7.6 Strengths

This dissertation includes the first mixed-methods investigation of patient preferences for management of pregnancy hypertension. Given the relatively high prevalence of hypertensive disorders in pregnancy, the results of this study address a significant gap in clinical understanding. A patient-oriented approach was used to build understanding of patient preferences, and develop tools to support patient and care provider decision-making. This approach increased the relevance of the study materials, surveys, and tools to patients, and may have increased the level of participant engagement throughout the study. Furthermore, this approach opened new avenues of investigation, specifically emotion in patient decision-making, which may present opportunities for further honing the effectiveness and relevance of interventions to support SDM, like PtDAs.

The preference work conducted in this dissertation relied on rigorous methods that have been demonstrated to be effective in clinical populations and in the context of health decisions.^{95,281} Further, confirmatory qualitative analyses were conducted to assess the extent to which findings from the initial qualitative study could be generalised beyond the Greater Vancouver Area. Thus, the findings reported here represent perspectives of child-bearing individuals from across British Columbia.

The trial reanalysis presented in Chapter Four is the first study to integrate patient weights with individual event data from a high-quality RCT in pregnancy. It is also the first study to employ a composite endpoint comprised of patient-identified components. Importantly, the trial reanalysis demonstrated that the results of the CHIPS trial could be interpreted differently depending on patient preference profile, highlighting the importance of weights in composite endpoints. This work adapted an approach for weighting meta-analyses.²²² The methods used are robust and were selected to meet the specific context of pregnancy and the data collected in the CHIPS trial. Compared to other existing methods, the adapted methods also maximise the interpretability of findings. Because this approach used a simple *t*-test to compare treatment arms, it is more likely to be understandable and accessible to clinicians and care providers than other more statistically complex approaches. Lastly, the adapted

approach is flexible: it can accommodate parametric and non-parametric data, as well as covariates and confounders if applied to a linear regression or analysis of variance.

The PtDA developed in Chapter Five is the first decision support tool for pregnancy hypertension that has been tested and shown to be effective. The tool was developed following established international guidelines to increase accessibility and decrease bias in decision-making. Review by patients and clinicians throughout development ensured the tool was relevant to patient and provider needs.

7.7 Limitations

The work presented in this dissertation should be considered within the context of its limitations.

The samples used within this dissertation present the largest limitation. Specifically, while a significant proportion of participants had experience with pregnancy hypertension, the majority did not. Particularly in the qualitative work, most participants were pregnant or had a history of pregnancy hypertension, or both, but none had pregnancy hypertension in their current pregnancy. It is possible that this altered the attributes identified in qualitative work; however, a history of pregnancy hypertension did not predict preference for ‘tight’ control vs ‘less-tight’ control or preference profile in the quantitative preference elicitation, suggesting that the

experience of pregnancy hypertension (or not) may not have altered attribute prioritisation. Furthermore, hypertension in pregnancy often appears suddenly, and a treatment plan is developed quickly, so it was reasonable that pregnant people without pregnancy hypertension were interviewed. Moreover, because participants did not have current pregnancy hypertension, they may have been less likely to be influenced by their care provider's preferences for management of pregnancy hypertension, and ultimately provide a more accurate representation of individuals' preferences and decisional needs.

Relatedly, the samples used in this study were geographically constrained. The qualitative work was conducted only with people in British Columbia. It is possible that individuals in different provinces, particularly those with differing prescription medication coverage plans, may have prioritised different treatment attributes, although antihypertensive medications used in pregnancy are all inexpensive and widely available. Similarly, the quantitative surveys presented in Chapters Two, Five and Six were limited to people in Canada. Individuals in other countries may vary in which attributes they prioritise and by how much. This variation may be especially pronounced in countries without universal healthcare and with fewer resources.

Perhaps the most significant limitation is the demographic make-up of study participants. Although participants in the qualitative components of this dissertation

were more racially and ethnically diverse than those in the quantitative components, participants in this work mostly identified as White or Caucasian. An attempt was made to address this limitation in quantitative investigations by including race and ethnicity in statistical analyses where appropriate. However, due to limited representation of non-White or non-Caucasian participants, race and ethnicity was included as a binary variable and investigation of differences between non-White racial and ethnic groups was not possible.

Additionally, participants tended to be highly educated. The survey materials and PtDA followed best practices for risk communication to increase accessibility. For example, risk estimates were presented with icon arrays and, in the PtDA, information that was most important to participants was presented first.²⁸² However, it is unclear to what extent the findings presented here generalise to individuals with low health literacy. Supporting individuals with low health literacy is of particular concern as studies show that low health literacy is associated with poorer health outcomes.²⁸³ Importantly, a systematic review⁵³ found that SDM may be of particular benefit to individuals with low literacy, highlighting the need for PtDAs that consider low health literacy. The material and PtDA presented in this work were primarily text-based. However, research suggests that individuals with low health literacy may benefit most from communication that does not prioritize text, for example spoken animations or

videos.²⁸⁴ Further work should be done to assess the applicability and utility of this work to individuals with low health literacy, and to adapt the materials and tools as needed.

In the quantitative investigation with the largest sample (Chapter Two), race and ethnicity, and level of education both predicted patient preference for 'tight' control (vs. 'less-tight' control). Importantly, these factors are also predictors of more positive experiences with the healthcare system. Given that 'tight' control is the more interventionist approach, it is possible that preferences for 'less-tight' control are driven, at least in part, by a desire to minimise interactions with healthcare, rather than a preference for the outcomes and treatment requirements associated with 'less-tight' control. A fulsome exploration of these sociological and systemic issues was beyond the scope of this study.

The work presented here is highly dependent on the CHIPS trial. Risk estimates from the CHIPS trial were used throughout this dissertation as it is the largest RCT comparing tight and 'less-tight' control to date and has high internal and external validity. Furthermore, many of the risk differences found in the CHIPS trial are similar to those from the most recent Cochrane Review of anti-hypertensive intervention for pregnancy hypertension.¹⁵ However, other RCTs are currently on-going, such as the Chronic Hypertension and Pregnancy (CHAP) Project.²⁸⁵ Should these trials change the

risk estimates significantly, the work presented in this dissertation may be less applicable. That being said, many of the outcomes assessed here are measured in the CHAP project, so it would be possible to update the patient-oriented analysis presented in Chapter Four. An added challenge is that the CHIPS trial was an international study, thus it is unclear to what extent the results apply to pregnant people in Canada specifically. While data on the proportion of participants from Canada are unavailable, almost a third of the CHIPS trial participants were from North America.¹⁷ Furthermore, international trials are commonly used to inform clinical decisions, and the CHIPS trial was used to inform clinical guidance in Canada and internationally.^{5,6,18,19} Thus, applying these international data within a single country as was done in this dissertation likely mirrors clinical practice.

The quantitative assessment of patient preferences presented in Chapter Two forms the basis of much of the subsequent work, including the patient-oriented trial reanalysis (Chapter Four), and the formatting of the PtDA (Chapter Five). This assessment used a BWS task to quantify the relative importance of the different treatment attributes. But, there are limitations with BWS tasks. One issue is that they only capture the relative importance of each attribute independently, and do not capture the impact of interactions, as reviewed in Chapter Four. It is possible that a DCE which can account for interactions between attributes would better capture

individuals' preferences. Nonetheless, a BWS task was chosen because it is less cognitively taxing than a DCE, and as a result the task may have been more accessible to participants than a DCE.

In addition, although outside perspectives were sought as part of the research process, the stakeholder team for this work only comprised one physician and did not include other clinicians, like midwives, who may be involved in an individual's care. Although midwifery and other care is increasingly being sought in British Columbia, professional practice guidelines require physician care (either in part or wholly) for individuals with hypertension during pregnancy.²⁸⁶ That being said, other clinicians, including midwives and doulas, may be part of treatment decisions and could provide insight into this decision-making process. This work tried to address this gap by recruiting participants who sought care from midwives, including participants who were themselves midwives. Similarly, this work may have benefited by having stakeholders with more diverse backgrounds and lived experiences, as well as multiple patient partners to increase the range of patient perspectives contributing to the research process.

Lastly, these studies capture patient preferences at a single moment in time. Two significant recent events may have altered patient preferences for management of pregnancy hypertension. First, the clinical guidance for management of pregnancy

hypertension changed during this dissertation. In June of 2018, Canadian guidance changed to recommend ‘tight’ control of BP. This change in guidance may explain the increase in the proportion of participants preferring ‘tight’ control in Chapter Five (data collected in November and December of 2020) compared to Chapter Two (data collected in August and September of 2018). However, this may also be a result of differences in survey content and methods (i.e., assessing preferences vs. evaluating a PtDA). Second, the COVID-19 pandemic may have shifted preferences and willingness to engage with healthcare. It is well-documented that people have been reluctant to seek care or go to hospital during the pandemic.²⁸⁷⁻²⁹⁰ Preferences may have shifted towards ‘tight’ control if it were perceived as an approach that would limit need for additional care (e.g., by reducing risk of severe hypertension). Thus, the preferences and preference profiles relayed here may not match current patient preferences.

7.8 Lessons for Future Research

Reflecting on the processes that underpinned this research, there are several changes that could be made to strengthen the research and ensure better representation of diverse groups and those with low health literacy.

With the experience and knowledge gained over the past 5 years into the challenges and needs of people from marginalized populations and those with lower

literacy, if this work were to begin again, the recruitment strategies would be revised.

For the qualitative components of the study, it would be important to connect with

community organizations early in the research process to increase the likelihood that

the research findings reflect the preferences of different cultural and racial groups.

Specifically, the recruitment strategy used, made it more likely that pregnant

individuals who tended to lead health decisions during pregnancy, or make them

independently, participated in this study. A more varied recruitment strategy could

have increased representation of individuals who make these health decisions more

collaboratively, for instance with a partner or with family members. Additionally,

recruitment was primarily done through written materials, which likely excluded

individuals who have lower health literacy. Partnering with community organizations

that work with adults with low literacy or difficulty accessing health services may have

addressed this gap. Furthermore, for the quantitative surveys, including health literacy

assessments and recruitment quotas would have allowed for a sufficient sample to

assess any differences in preferences for management of pregnancy hypertension or

effectiveness of the PtDA developed.

In addition to revising the recruitment strategies, the study team would be

expanded to include multiple patient partners and a more diverse representation of care

providers. While having a patient partner contribute to this work strengthened the

validity and accessibility of the findings and materials used, one patient partner cannot be expected to represent all patient experiences. Collaborating with multiple patient partners, each with their own lived experience of pregnancy hypertension, would address this concern. Likewise, having a specialist in hypertensive disorders of pregnancy as part of the study team, and receiving feedback on the PtDA from multiple specialists, ensured the study materials were accurate and increased the relevance of this work to clinicians. However, these specialists represent one of several groups of care providers who can be involved in this decision. Care providers with different educational backgrounds and clinical training may approach this decision differently. Evidence from other areas suggests considerable variation in care provider perspectives on birth practices.²⁹¹⁻²⁹³ Furthermore, some evidence suggests that certain types of care providers may be more likely to work with marginalised populations, and this too may influence provider perspectives.²⁹⁴ Thus, if this work were to begin today, in addition to the physician specialist in hypertensive disorders of pregnancy, the research team would include other care providers such as general practitioners, midwives, doulas, and nurse practitioners.

7.9 Implications for Practice

This dissertation has practical implications for patients, care providers and trialists.

First, the results presented here suggest that pregnant individuals want to be engaged in decision-making about management of pregnancy hypertension and that a patient decision aid for pregnancy hypertension can improve patient knowledge. The PtDA developed was well-received overall and may be a useful tool through which patients and clinicians can collaborate to make decisions. Second, the results of the trial reanalysis may support clinicians in understanding how patient values may alter interpretation of trial findings. In specific, the threshold analysis may make it easier for clinicians to understand when patient values may best be served by 'less-tight' control, the approach not recommended by current clinical guidance. Lastly, the trial reanalysis demonstrates both how to integrate patient values into RCT analyses and the impact of these values on interpretation of trial results. The combination of the relative simplicity of the methods adapted here and stark impact patient weights had on trial results may encourage trialists to collect patient value weights when considering composite endpoints.

7.10 Areas for Future Research

Future research should build on this work. Most significantly, studies should examine the extent to which these findings are applicable to individuals from diverse backgrounds and with low levels of numeracy and literacy. Additionally, further testing of the PtDA is warranted to evaluate its impact on decision-quality in a clinical context. Since SDM is a process, and not an outcome, and PtDAs exist to support SDM, further testing should include measures of the quality of clinician-patient communication.

Furthermore, future work should expand on the preliminary findings on emotion in patient decision-making and evaluate individuals who are actually making a medical decision. Ideally this work would be longitudinal and would assess changes in emotion and emotion regulation across the decision-making processes. Such an approach would allow for a more robust understanding of different types of emotion regulation (e.g., antecedent vs reactive) and their relationship to engagement with health decisions.

Additionally, RCTs should routinely include importance weights in analyses of multiple and composite endpoints. Future RCTs should consider collecting importance weights from study participants enrolled in trials a priori. For RCTs that have already been completed, it may be useful to apply patient value weights to existing analyses, or

to include patient-oriented analyses as a sensitivity analysis to assess the robustness of trial results.

Lastly, as discussed earlier in this chapter, the practical significance of these findings is determined by the extent to which they permeate and are implemented in clinical practice. To increase the likelihood that patient preferences would impact practice, the findings from Chapter Two were applied in the reanalysis of the CHIPS trial and in the development of a PtDA. However, these applications too need to be diffused and implemented for them to be impactful. At this time, there is limited guidance on how to facilitate uptake of decision tools in prenatal care. Future work should evaluate whether guidance from other health contexts is appropriate and consider barriers and enablers specific to decision interventions in pregnancy.

7.11 Conclusions

This dissertation reported the first investigation of individuals' preferences for management of pregnancy hypertension, a relatively common and potentially life-ending and life-altering condition for child-bearing individuals and babies. The results suggest that individuals want to be actively engaged in decision-making about management of pregnancy hypertension and that the majority of individuals' preferences can be described by one of three preference profiles. Further, when

integrated with data from the largest RCT to date, these preference profiles change which management strategy is most appropriate. While these findings are not definitive and cannot be generalised to all people with pregnancy hypertension, this dissertation provides insight into what individuals prioritise in the context of pregnancy hypertension, and general guidance on how patient preferences can be integrated with RCT data to improve interpretability of trial results and quality of care.

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Appendices

Appendix A: Preference Elicitation Survey

CHIPS Decision: What is most important when making a treatment decision during pregnancy?

Principal Investigator: Nick Bansback, PhD, Associate Professor

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Anna Hutfield, MBA, Research coordinator

Welcome to the Treatment Decision-Making During Pregnancy Study

Thank you for your interest in this study. Before you decide whether to participate in this study it is important that you understand why the study is being carried out and what it will involve. Please read the information provided carefully.

Who is conducting the study?

This study is being conducted by researchers at the University of British Columbia and the Centre for Health Evaluation and Outcome Sciences.

Who is funding this study?

The study is funded by grants received from Canadian Institute of Health Research for the CHIPS and CHIPS-Child research projects.

Why are we doing this study? The purpose of this project is to find out which factors are most important to pregnant women as they make treatment decisions. This information will help policy makers understand how women make treatment decisions during pregnancy and will help the development of tools to support women during these decisions.

How is the study done?

Participating in this study will involve taking part in one 15 to 20 minute survey that is presented in three parts. In the first part, you will be asked some questions about your demographic background (e.g., your age and gender). In the second part of the survey you will be presented with written information about a health condition and asked to indicate which characteristics of treatment are most important to you and which are least important. In the third part, you will be asked a few more questions about yourself and how you like to receive information. It is best to complete the survey in one sitting, but if you need to, you can pause the study at any point and return to it later.

What will happen with the results of the study?

The results of the study will be shared with others in the health community. To do this, the results will be published in medical and health journals and presented at professional conferences. No one will be able to identify you in any reports or publications as only overall results will be published. If you would like a copy of the results once the study has finished, please contact us

What are the risks of participating?

There are no risks to participating in this study. You do not have to answer a question if you do not want to. Please tell a research team member if you have any concerns.

How will your identity be protected?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your consent unless required by law. All documents will be identified only by code number. Anonymized data will be stored on a network accessible through password-protected computers.

What are the benefits of participating?

You might start thinking about decision-making differently or wish to learn more about the subject. In the future, others may benefit from what we learn in this study. The results of the study will be used by to develop a tool to help support women as they make treatment decisions during pregnancy.

Who can I contact if I have a question or concern about the study?

If you have any questions about what we are asking of you, please contact the Principal Investigator or one of the Project Contacts. Their names and telephone numbers are listed at the top of the first page of this form. If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line at UBC Office of Research Ethics at 604-822-8598, or if long distance, e-mail RSIL@ors.ubc.ca or call toll free 1-877-822-8598.

Participant consent:

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to take part, you may choose to stop participating at any time without giving a reason.[Click here](#) to download a copy of this consent form for your own records.

Clicking the "Next" button below indicates that you consent to participate in this study, and also consent to have your anonymized quotes published in conference posters, peer-reviewed manuscripts, and knowledge translation publications.

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Demographic Questionnaire

We are going to ask you some general questions about yourself and your health.

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Are you currently pregnant?

Yes

No

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How many weeks into your pregnancy are you?

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Please rate your willingness to take medication.

A horizontal slider scale consisting of a thin grey bar with a small square marker in the center, positioned between two text labels.

Not willing at all

Extremely willing

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Please consider the five statements below and select the one that best describes the role you prefer to take when making treatment decisions with your doctor.

- I prefer to make the decision about which treatment I receive
- I prefer to make the final decision about my treatment after seriously considering my doctor's opinion
- I prefer that my doctor and I share responsibility for deciding which treatment is best for me
- I prefer that my doctor makes the final decision about which treatment will be used but seriously considers my opinions
- I prefer to leave all decisions regarding treatment to my doctor

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Learning about high blood pressure in pregnancy

In the next section of the survey, we are going to ask you to read some information about high blood pressure in pregnancy and answer knowledge questions about what you have read, so that we can see if we have communicated the information well.

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High Blood Pressure

High blood pressure is a common condition that can affect people of all ages. When a person has high blood pressure, the heart needs to work harder than it normally does. This means that there is extra strain on the heart and on blood vessels. Because of this extra strain, people with high blood pressure have a higher risk of stroke and heart attacks.

How common is high blood pressure in pregnancy?

Almost 10% of pregnant women have high blood pressure. 1% have high blood pressure before they became pregnant, and for the rest, high blood pressure starts during pregnancy. For 2% of women this high blood pressure develops into a more serious condition called preeclampsia.

What does it mean to have high blood pressure in pregnancy?

Overall, women with high blood pressure in pregnancy have a higher risk of negative outcomes for themselves and their babies. Because of these risks, treatment is often recommended for pregnant women with high blood pressure.

Knowledge question:

Women with high blood pressure in pregnancy have:

- An increased risk of complications for the baby
- An increased risk of complications for the woman
- The same risk of complications as women with normal blood pressure in pregnancy
- Both a) and b)

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Severely Elevated Blood Pressure During Pregnancy

Women with high blood pressure during pregnancy are more likely to have severely elevated blood pressure during their pregnancy.

What does it mean to have severely elevated blood pressure throughout pregnancy?

A blood pressure measurement has two parts and is stated as one number over another, for example 120 over 80. The top number is called the 'systolic' blood pressure, and the bottom number is the 'diastolic' blood pressure. High blood pressure occurs when the top number reaches 140 or the bottom number reaches 90. Severely elevated blood pressure occurs when either the top number is 160 or more, or the bottom number is 110 or more.

Women with severely elevated blood pressure during pregnancy are more likely to experience complications, like seizures and strokes, or other internal organ damage. Women with severely elevated blood pressure during pregnancy are also more likely to both deliver early and have a baby who is born smaller than expected.

Knowledge question:

Women with severely elevated blood pressure during pregnancy are:

More likely to experience seizures and strokes

Less likely to deliver early

Have the same risk as women without severely elevated blood pressure throughout pregnancy

Both a) and b)

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Pre-eclampsia

Women with high blood pressure during pregnancy are more likely to develop pre-eclampsia and eclampsia.

What is pre-eclampsia?

Pre-eclampsia is a type of high blood pressure that develops during pregnancy and goes away postpartum, usually in the weeks after the baby is born. A pregnant woman is diagnosed with pre-eclampsia if she has high blood pressure that has developed in the second half of pregnancy, with either protein in her urine (proteinuria) or other maternal problems, such as headache, seizures, clotting or liver problems. The woman herself may feel nothing at all. This is one of the reasons why regular check-ups in pregnancy are necessary, and always include measurement of blood pressure, urine tests, and questions about how you are feeling.

Women with pre-eclampsia have a higher risk of developing HELLP Syndrome and of having seizures before and shortly after giving birth. These seizures are the primary symptom of eclampsia, a more severe complication. Women who have pre-eclampsia also have an increased risk of heart disease, heart attacks and stroke later in life.

What happens if I develop pre-eclampsia during my pregnancy?

If you develop pre-eclampsia during your pregnancy, your doctor will recommend blood, urine, and ultrasound tests to carefully monitor you and your baby. This may require hospital admission. The purpose of this monitoring is to minimize the risk of complications by timing delivery, either by induction of labour or Caesarean. Delivery is usually necessary within four weeks of the diagnosis of pre-eclampsia, because of problems for mothers, problems for babies, or both.

Knowledge question:

Which one of the following statements is true about women with pre-eclampsia.

They always have symptoms, such as headache or abdominal pain.



They can be diagnosed in early pregnancy.



They may be admitted to hospital for monitoring.



None of the above are true.



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Medication for High Blood Pressure During Pregnancy

Many women with high blood pressure during pregnancy take medication to lower their blood pressure.

How does medication for high blood pressure during pregnancy work?

Medications to reduce blood pressure are called antihypertensives. They work by helping blood vessels relax and widen, or by decreasing the amount or force of blood that passes from the heart into these blood vessels.

Does taking medication for high blood pressure in pregnancy harm the baby?

Several antihypertensive medications, such as labetalol, methyldopa and nifedipine, are commonly used to lower high blood pressure in pregnancy. These medications are used commonly in early pregnancy and throughout. They have not been shown to increase risk of birth defects, although the evidence is not extensive.

There is a wide variety of antihypertensive medications that can be used in pregnancy, with just a few exceptions. These are angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs).

Can women who take antihypertensive medication breast feed?

Yes. All commonly used antihypertensive medications are acceptable for use in breastfeeding.

Knowledge question:

Please indicate which of the following statements is TRUE about taking medication for high blood pressure during pregnancy:

- Taking antihypertensive medication during breastfeeding is never recommended.
- Taking antihypertensive medication during breastfeeding can negatively impact development of the baby's brain.
- The commonly-used antihypertensive medications can be taken during breastfeeding.
- Mothers who take antihypertensive medications during breastfeeding have to monitor their babies' heart rates.

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Small for Gestational Age

Women with high blood pressure in pregnancy are more likely to have a baby who is born small for gestational age (SGA).

What is "small for gestational age"?

Small for gestational age (SGA) is a term used to describe a baby's actual size relative to the expected size, based on being a boy/girl, and when the baby was born. A baby born SGA is smaller than most other babies born at the same point in pregnancy. For example, a baby born at 34 weeks who is SGA is physically smaller than most other babies born at 34 weeks. Another way to say small for gestational age is that the baby is born smaller than expected.

A SGA baby may be normal and small, such as when the parents are very small. However, a SGA baby may also be abnormally small because of problems with the placenta and/or poor growth before birth. It is very difficult for doctors to distinguish between the two types of problems, particularly before the baby is born.

What are the risks if a baby is born small for gestational age (SGA)?

In the short-term (the weeks that follow birth), the risk of problems depends on a number of factors, such as why the baby is SGA and when the baby was born. These problems may include difficulty breathing, low blood sugar, and difficulty maintaining a normal body temperature.

All babies who are born early are at greater risk of problems, the severity of which depends on just how early they were born. For example, a baby born at 36 weeks of pregnancy (with 40 weeks being the due date) is at risk of problems with breathing, feeding, or maintaining body temperature. However, a baby born at 26 weeks, has a risk of death or serious brain problems, for example.

An additional consideration is that in the long-term, babies born SGA may be at greater risk of cardiovascular disease, such as stroke or heart attack, although the risk has more to do with lifestyle after birth (such as diet, weight, smoking, and exercise) than growth before birth.

Knowledge question:

Please choose the ONE best option to describe a baby who is born small for gestational age:

The baby can have short-term health problems.

The baby will definitely have long-term health problems

The baby is smaller than all other babies born at the same point in pregnancy

The baby is never normal.

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Delivery Before 34 Weeks

Women with high blood pressure in pregnancy are more likely to give birth to their baby before 34 weeks. 34 weeks is an important milestone in pregnancy because babies born after 34 weeks are just as likely to survive as full-term babies (defined as those who are born on or after 37 weeks).

What does it mean if a baby is born before 34 weeks?

Almost all babies born before 34 weeks need to spend time in the neonatal intensive care unit (often called the NICU) before they can go home. Being born before 34 weeks means that the baby has less time to develop inside the womb than most other babies. Because they spend less time in the womb, babies born before 34 weeks are more likely to face more health problems and more serious health problems than babies born later. The kind of health problem and the severity of the health problem change based on when your baby is born.

In the short-term, problems may include difficulties breathing (requiring oxygen or ventilation), difficulties feeding (requiring tube or intravenous lines), infection (requiring intravenous antibiotics), bleeding into the brain or other brain problems, or problems with the intestines that process food. The earlier the baby is born, the higher the risks, the greater the chance that the problems will be severe, and the greater the risk that death is a possible outcome.

Knowledge question:

True or false: Almost all babies born before 34 weeks need to spend time in the neonatal intensive care unit before they can go home.

True

False

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Blood Transfusion

Women with high blood pressure in pregnancy are more likely to need a blood transfusion during or after delivery.

What is a blood transfusion?

A blood transfusion is a medical procedure done to replace lost blood. In the procedure, a small intravenous needle is placed into the patient's vein, and blood is put into the patient's body through this needle. The blood the patient receives comes from the hospital blood bank that tests blood for diseases that can be transmitted through blood; the risk of transmission is less than 1 in 100,000 in developed countries.

When would a woman receive a blood transfusion?

In developed countries, most blood transfusions are given during or after delivery, and are considered a life-saving intervention. Blood loss is most often caused by hemorrhage (sudden and very heavy bleeding) that is usually after delivery of the baby and placenta, related to the womb not contracting properly after delivery or high blood pressure. Less often, blood transfusion may be required due to clotting problems, bleeding before birth, or particularly in less-resourced settings, severe anemia (low blood iron).

Are blood transfusions safe?

Blood transfusions are generally safe, but the risk of complications is never zero. This is why women must provide written consent for blood transfusion.

Knowledge question:

During and after delivery, women may receive blood transfusions because of:

Bleeding associated with high blood pressure

A postpartum hemorrhage (sudden and very heavy bleeding after birth)

Severe anemia

All of the above

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Your choice

Now that you have read through the material, we would like to ask you some questions. For this task, you will be shown a list of four items, and asked to select the item that you would most like to avoid, and the item that you would least like to avoid.

Here's an example to get you started.

Example task

Example Question 1

Imagine you are planning to buy a new refrigerator.

Below is a list of refrigerator features. Please read the features carefully. Thinking only about the features below, select the feature that is most important to you, and the feature that is least important to you.

In this example, the person has selected *Stainless steel* as the most important feature, and *Energy efficient* as the least important feature to them.

Most important	Refrigerator Feature	Least important
	Energy efficient	<input checked="" type="checkbox"/>
	Automatic ice-maker	
	Adjustable shelves	
<input checked="" type="checkbox"/>	Stainless steel	

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Instructions

Imagine that you are visiting your doctor for a routine check-up during your pregnancy, and your doctor tells you that you have high blood pressure. Your doctor then tells you about your options. Each option has different characteristics.

On the next pages, some of these characteristics are presented in lists of 4 characteristics. For each list, please indicate the characteristic that is most important to you, and the characteristic that is least important to you when choosing a treatment for high blood pressure during your pregnancy.

Question 1 of 7

Most important		Least important
<input type="checkbox"/>	Blood Transfusion A decrease in the risk of blood transfusion from 3 in 100 to 1 in 100. This is a decrease of 2 in 100 women needing a blood transfusion. <ul style="list-style-type: none"><input checked="" type="radio"/> will need a blood transfusion<input type="radio"/> will need a blood transfusion if they use a given treatment<input type="radio"/> will not need a blood transfusion 	<input type="checkbox"/>
<input type="checkbox"/>	Caesarean Delivery A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100. This is a decrease of 4 in 100 women having a Caesarean delivery. <ul style="list-style-type: none"><input checked="" type="radio"/> will have a Caesarean delivery<input type="radio"/> will have a Caesarean delivery if they use a given treatment<input type="radio"/> will not have a Caesarean delivery 	<input type="checkbox"/>

Most
important

Least
important



Medication



A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100.

This is a decrease of 17 in 100 women taking medication.

- will take high blood pressure medication
- will take high blood pressure medication if they use a given treatment
- will not take high blood pressure medication



Severely Elevated Blood Pressure Throughout Pregnancy



A decrease in the risk of severely elevated blood pressure throughout pregnancy from 41 in 100 to 28 in 100.

This is a decrease of 13 in 100 women having severely elevated blood pressure.

- will have severely elevated blood pressure throughout pregnancy
- will have severely elevated blood pressure throughout pregnancy if they use a given treatment
- will not have severely elevated blood pressure throughout pregnancy



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Instructions

Imagine that you are visiting your doctor for a routine check-up during your pregnancy, and your doctor tells you that you have high blood pressure. Your doctor then tells you about your options. Each option has different characteristics.

On the next pages, some of these characteristics are presented in lists of 4 characteristics. For each list, please indicate the characteristic that is most important to you, and the characteristic that is least important to you when choosing a treatment for high blood pressure during your pregnancy.

Question 2 of 7

Most important		Least important
<input checked="" type="checkbox"/>	Caesarean Delivery A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100. This is a decrease of 4 in 100 women having a Caesarean delivery.	<input type="checkbox"/>
	<ul style="list-style-type: none">● will have a Caesarean delivery● will have a Caesarean delivery if they use a given treatment● will not have a Caesarean delivery 	
<input type="checkbox"/>	Delivery Before 34 Weeks A decrease in the risk of delivery before 34 weeks from 16 in 100 to 13 in 100. This is a decrease of 3 in 100 babies being born early.	<input type="checkbox"/>
	<ul style="list-style-type: none">● will deliver before 34 weeks● will deliver before 34 weeks if they use a given treatment● will not deliver before 34 weeks 	

Most important

Least
important



Pre-eclampsia



A decrease in the risk of pre-eclampsia from 49 in 100 to 46 in 100.

This is A decrease of 3 in 100 women developing pre-eclampsia.

- will develop pre-eclampsia
 - will develop pre-eclampsia if they use a given treatment
 - will not develop pre-eclampsia



Severely Elevated Blood Pressure Throughout Pregnancy



A decrease in the risk of severely elevated blood pressure throughout pregnancy from 41 in 100 to 28 in 100.

This is a decrease of 13 in 100 women having severely elevated blood pressure.

- will have severely elevated blood pressure throughout pregnancy
 - will have severely elevated blood pressure throughout pregnancy if they use a given treatment
 - will not have severely elevated blood pressure throughout pregnancy



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Instructions

Imagine that you are visiting your doctor for a routine check-up during your pregnancy, and your doctor tells you that you have high blood pressure. Your doctor then tells you about your options. Each option has different characteristics.

On the next pages, some of these characteristics are presented in lists of 4 characteristics. For each list, please indicate the characteristic that is most important to you, and the characteristic that is least important to you when choosing a treatment for high blood pressure during your pregnancy.

Question 3 of 7

Most important		Least important
<input type="checkbox"/>	Blood Transfusion A decrease in the risk of blood transfusion from 3 in 100 to 1 in 100. This is a decrease of 2 in 100 women needing a blood transfusion. <ul style="list-style-type: none"><input type="radio"/> will need a blood transfusion<input type="radio"/> will need a blood transfusion if they use a given treatment<input type="radio"/> will not need a blood transfusion 	<input type="checkbox"/>
<input type="checkbox"/>	Delivery Before 34 Weeks A decrease in the risk of delivery before 34 weeks from 16 in 100 to 13 in 100. This is a decrease of 3 in 100 babies being born early. <ul style="list-style-type: none"><input type="radio"/> will deliver before 34 weeks<input type="radio"/> will deliver before 34 weeks if they use a given treatment<input type="radio"/> will not deliver before 34 weeks 	<input type="checkbox"/>

Most important

Least
important



Pre-eclampsia

A decrease in the risk of pre-eclampsia from 49 in 100 to 46 in 100. This is A decrease of 3 in 100 women developing pre-eclampsia.

- will develop pre-eclampsia
 - will develop pre-eclampsia if they use a given treatment
 - will not develop pre-eclampsia



Small for Gestational Age

A decrease in the risk of the baby being born smaller than expected from 20 in 100 to 16 in 100.

This is a decrease of 4 in 100 babies being born smaller than expected.

- will be born small for gestational age
 - will be born small for gestational age if a given treatment is used
 - will not be born small for gestational age



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Instructions

Imagine that you are visiting your doctor for a routine check-up during your pregnancy, and your doctor tells you that you have high blood pressure. Your doctor then tells you about your options. Each option has different characteristics.

On the next pages, some of these characteristics are presented in lists of 4 characteristics. For each list, please indicate the characteristic that is most important to you, and the characteristic that is least important to you when choosing a treatment for high blood pressure during your pregnancy.

Question 4 of 7

Most important	Least important
<input type="checkbox"/>	<input type="checkbox"/>
Blood Transfusion	
A decrease in the risk of blood transfusion from 3 in 100 to 1 in 100. This is a decrease of 2 in 100 women needing a blood transfusion.	
<ul style="list-style-type: none"><input type="radio"/> will need a blood transfusion<input type="radio"/> will need a blood transfusion if they use a given treatment<input type="radio"/> will not need a blood transfusion	
	
<hr/>	
<input type="checkbox"/>	<input type="checkbox"/>
Caesarean Delivery	
A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100. This is a decrease of 4 in 100 women having a Caesarean delivery.	
<ul style="list-style-type: none"><input type="radio"/> will have a Caesarean delivery<input type="radio"/> will have a Caesarean delivery if they use a given treatment<input type="radio"/> will not have a Caesarean delivery	
	

Most
important

Least
important



Medication



A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100.

This is a decrease of 17 in 100 women taking medication.

- will take high blood pressure medication
- will take high blood pressure medication if they use a given treatment
- will not take high blood pressure medication



Small for Gestational Age



A decrease in the risk of the baby being born smaller than expected from 20 in 100 to 16 in 100.

This is a decrease of 4 in 100 babies being born smaller than expected.

- will be born small for gestational age
- will be born small for gestational age if a given treatment is used
- will not be born small for gestational age



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Instructions

Imagine that you are visiting your doctor for a routine check-up during your pregnancy, and your doctor tells you that you have high blood pressure. Your doctor then tells you about your options. Each option has different characteristics.

On the next pages, some of these characteristics are presented in lists of 4 characteristics. For each list, please indicate the characteristic that is most important to you, and the characteristic that is least important to you when choosing a treatment for high blood pressure during your pregnancy.

Question 5 of 7

Most important	Least important
<input type="checkbox"/>	<input type="checkbox"/>
Caesarean Delivery	
A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100. This is a decrease of 4 in 100 women having a Caesarean delivery.	
<ul style="list-style-type: none"><input type="radio"/> will have a Caesarean delivery<input type="radio"/> will have a Caesarean delivery if they use a given treatment<input type="radio"/> will not have a Caesarean delivery	
	
<hr/>	
<input type="checkbox"/>	<input type="checkbox"/>
Delivery Before 34 Weeks	
A decrease in the risk of delivery before 34 weeks from 16 in 100 to 13 in 100. This is a decrease of 3 in 100 babies being born early.	
<ul style="list-style-type: none"><input type="radio"/> will deliver before 34 weeks<input type="radio"/> will deliver before 34 weeks if they use a given treatment<input type="radio"/> will not deliver before 34 weeks	
	

Most
important

Least
important



Medication



A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100.

This is a decrease of 17 in 100 women taking medication.

- will take high blood pressure medication
- will take high blood pressure medication if they use a given treatment
- will not take high blood pressure medication



Severely Elevated Blood Pressure Throughout Pregnancy



A decrease in the risk of severely elevated blood pressure throughout pregnancy from 41 in 100 to 28 in 100.

This is a decrease of 13 in 100 women having severely elevated blood pressure.

- will have severely elevated blood pressure throughout pregnancy
- will have severely elevated blood pressure throughout pregnancy if they use a given treatment
- will not have severely elevated blood pressure throughout pregnancy



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Instructions

Imagine that you are visiting your doctor for a routine check-up during your pregnancy, and your doctor tells you that you have high blood pressure. Your doctor then tells you about your options. Each option has different characteristics.

On the next pages, some of these characteristics are presented in lists of 4 characteristics. For each list, please indicate the characteristic that is most important to you, and the characteristic that is least important to you when choosing a treatment for high blood pressure during your pregnancy.

Question 6 of 7

Most important		Least important
<input type="checkbox"/>	Delivery Before 34 Weeks A decrease in the risk of delivery before 34 weeks from 16 in 100 to 13 in 100. This is a decrease of 3 in 100 babies being born early. <ul style="list-style-type: none">● will deliver before 34 weeks● will deliver before 34 weeks if they use a given treatment● will not deliver before 34 weeks 	<input type="checkbox"/>
<input type="checkbox"/>	Pre-eclampsia A decrease in the risk of pre-eclampsia from 49 in 100 to 46 in 100. This is A decrease of 3 in 100 women developing pre-eclampsia. <ul style="list-style-type: none">● will develop pre-eclampsia● will develop pre-eclampsia if they use a given treatment● will not develop pre-eclampsia 	<input type="checkbox"/>

Most
important

Least
important

Small for Gestational Age

A decrease in the risk of the baby being born smaller than expected from 20 in 100 to 16 in 100.

This is a decrease of 4 in 100 babies being born smaller than expected.

- will be born small for gestational age
- will be born small for gestational age if a given treatment is used
- will not be born small for gestational age



Severely Elevated Blood Pressure Throughout Pregnancy

A decrease in the risk of severely elevated blood pressure throughout pregnancy from 41 in 100 to 28 in 100.

This is a decrease of 13 in 100 women having severely elevated blood pressure.

- will have severely elevated blood pressure throughout pregnancy
- will have severely elevated blood pressure throughout pregnancy if they use a given treatment
- will not have severely elevated blood pressure throughout pregnancy



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Instructions

Imagine that you are visiting your doctor for a routine check-up during your pregnancy, and your doctor tells you that you have high blood pressure. Your doctor then tells you about your options. Each option has different characteristics.

On the next pages, some of these characteristics are presented in lists of 4 characteristics. For each list, please indicate the characteristic that is most important to you, and the characteristic that is least important to you when choosing a treatment for high blood pressure during your pregnancy.

Question 7 of 7

Most important		Least important
<input type="checkbox"/>	Blood Transfusion A decrease in the risk of blood transfusion from 3 in 100 to 1 in 100. This is a decrease of 2 in 100 women needing a blood transfusion. <ul style="list-style-type: none">● will need a blood transfusion● will need a blood transfusion if they use a given treatment● will not need a blood transfusion 	<input type="checkbox"/>
<input type="checkbox"/>	Pre-eclampsia A decrease in the risk of pre-eclampsia from 49 in 100 to 46 in 100. This is a decrease of 3 in 100 women developing pre-eclampsia. <ul style="list-style-type: none">● will develop pre-eclampsia● will develop pre-eclampsia if they use a given treatment● will not develop pre-eclampsia 	<input type="checkbox"/>

Most
important

Least
important



Medication



A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100.

This is a decrease of 17 in 100 women taking medication.

- will take high blood pressure medication
- will take high blood pressure medication if they use a given treatment
- will not take high blood pressure medication



Small for Gestational Age



A decrease in the risk of the baby being born smaller than expected from 20 in 100 to 16 in 100.

This is a decrease of 4 in 100 babies being born smaller than expected.

- will be born small for gestational age
- will be born small for gestational age if a given treatment is used
- will not be born small for gestational age



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Treatment Choice 1

The table below shows the characteristics of the two recommended treatments for high blood pressure in pregnancy. Please read through the characteristics of the two treatments carefully.

If you had to choose one, which treatment would you prefer?

	Treatment A <input type="checkbox"/>	Treatment B <input type="checkbox"/>
❶ Small for Gestational Age	<p>16 out of 100 babies will be born small for gestational age.</p> <ul style="list-style-type: none"> ● will be born small for gestational age ● will not be born small for gestational age 	<p>20 out of 100 babies will be born small for gestational age.</p> <ul style="list-style-type: none"> ● will be born small for gestational age ● will not be born small for gestational age 
❷ Delivery Before 34 Weeks	<p>16 out of 100 women will deliver before 34 weeks.</p> <ul style="list-style-type: none"> ● will deliver before 34 weeks ● will not deliver before 34 weeks 	<p>13 out of 100 women will deliver before 34 weeks.</p> <ul style="list-style-type: none"> ● will deliver before 34 weeks ● will not deliver before 34 weeks 
❸ Caesarean Delivery	<p>47 out of 100 women will have a Caesarean delivery.</p> <ul style="list-style-type: none"> ● will have a Caesarean delivery ● will not have a Caesarean delivery 	<p>51 out of 100 women will have a Caesarean delivery.</p> <ul style="list-style-type: none"> ● will have a Caesarean delivery ● will not have a Caesarean delivery 
❹ Blood Transfusion	<p>3 out of 100 women will need a blood transfusion.</p> <ul style="list-style-type: none"> ● will need a blood transfusion ● will not need a blood transfusion 	<p>1 out of 100 women will require a blood transfusion.</p> <ul style="list-style-type: none"> ● will need a blood transfusion ● will not need a blood transfusion 

	Treatment A <input type="checkbox"/>	Treatment B <input type="checkbox"/>
Pre-eclampsia	<p>49 out of 100 women will develop pre-eclampsia.</p> <ul style="list-style-type: none"> ● will develop pre-eclampsia ● will not develop pre-eclampsia 	<p>46 out of 100 women will develop pre-eclampsia.</p> <ul style="list-style-type: none"> ● will develop pre-eclampsia ● will not develop pre-eclampsia
Severely Elevated Blood Pressure Throughout Pregnancy	<p>41 women out of 100 will have severely elevated blood pressure throughout pregnancy.</p> <ul style="list-style-type: none"> ● will have severely elevated blood pressure throughout pregnancy ● will not have severely elevated blood pressure throughout pregnancy 	<p>28 women out of 100 will have severely elevated high blood pressure throughout pregnancy</p> <ul style="list-style-type: none"> ● will have severely elevated high blood pressure throughout pregnancy ● will not have severely elevated high blood pressure throughout pregnancy
Medication	<p>77 out of 100 women will take medication during their pregnancy.</p> <ul style="list-style-type: none"> ● will take high blood pressure medication ● will not take high blood pressure medication 	<p>94 out of 100 women will take high blood pressure medication during their pregnancy.</p> <ul style="list-style-type: none"> ● will take high blood pressure medication during their pregnancy ● will not take high blood pressure medication during their pregnancy



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Earlier in the survey we showed you information on 7 different characteristics of treatment for high blood pressure in pregnancy.

This is a different way of showing how important characteristics are to you. Using the sliders below, please indicate how important each characteristic would be to you if you were choosing a treatment for high blood pressure in pregnancy.

For some people, all of these characteristics might be important to consider when choosing a treatment. For others, only 1 or 2 characteristics might be important. If a characteristic is not at all important, slide the slider all the way to the left, and the characteristic will be removed from the pie chart.

Medication



0 (Not important) 10 (Very important)

Severely Elevated Blood Pressure Throughout Pregnancy



0 (Not important) 10 (Very important)

Pre-eclampsia



0 (Not important) 10 (Very important)

Blood Transfusion



0 (Not important) 10 (Very important)

Caesarean Delivery



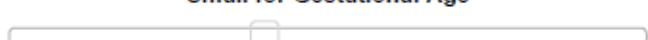
0 (Not important) 10 (Very important)

Delivery Before 34 Weeks



0 (Not important) 10 (Very important)

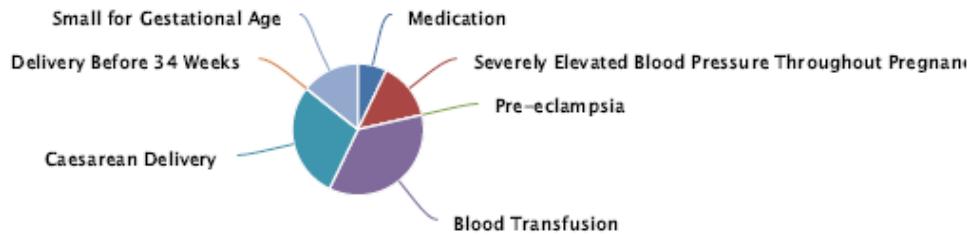
Small for Gestational Age



0 (Not important) 10 (Very important)

The relative importance of each attribute

Relative Importance



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Individualized Task

In this first part of the survey we showed you general information based on the population as a whole. In this next section we are going to show you information based on your own characteristics.

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Section 2: Individualized Information

In this part of the survey, you will complete a similar task to the one you just finished. In this task, however, you will be shown information that is specific to people with similar characteristics to you.

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What is your age?

Less than 25 years

25 to 29 years

30 to 34 years

35 to 39 years

40 years or older

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How do you identify?

Aboriginal or Indigenous

African American or Black

Asian

Caucasian

Hispanic or Latinx

South Asian

Biracial, Mixed race, or Other not listed here

Prefer not to say

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Have you experienced any of the following during your current pregnancy? Please check all that apply.

Gestational diabetes

Hypertension

Pre-eclampsia

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Is this your first pregnancy?

Yes

No

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Have you experienced any of the following during a past pregnancy? Check all that apply.

Gestational diabetes

Hypertension

Pre-eclampsia

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Are you currently taking Aspirin? Aspirin is sometimes also called acetylsalicylic or ASA.

Yes

No

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Are you currently taking folic acid or prenatal vitamins?

Yes

No

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Do you take medications to manage high blood pressure?

Yes

No

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Do you take any daily medications, not including Aspirin and high blood pressure medication?

Yes

No

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Have you smoked cigarettes during this pregnancy?

Yes

No

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In the month before your pregnancy, how much did you weigh?

Please answer in pounds. If you only know your weight in kilograms, click here (<https://www.google.ca/search?q=convert+kg+to+lbs&oq=convert+kg+to+&aqs=chrome.1.69j0l5.5615j1j7&sourceid=chrome&ie=UTF-8>) to open a link to a convert your weight to pounds.

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How tall are you?

Please answer in inches. For example, someone who is 5 feet 6 inches would enter 66 in the text box. You can use the table below to help determine your height in inches.

Feet and inches	Inches	Centimeters
4 ft 6 in	54 in	137 cm
4 ft 7 in	55 in	140 cm
4 ft 8 in	56 in	142 cm
4 ft 9 in	57 in	145 cm
4 ft 10 in	58 in	147 cm
4 ft 11 in	59 in	150 cm
5 ft 0 in	60 in	152 cm
5 ft 1 in	61 in	155 cm
5 ft 2 in	62 in	157 cm
5 ft 3 in	63 in	160 cm
5 ft 4 in	64 in	163 cm
5 ft 5 in	65 in	165 cm
5 ft 6 in	66 in	168 cm
5 ft 7 in	67 in	170 cm
5 ft 8 in	68 in	173 cm
5 ft 9 in	69 in	175 cm
5 ft 10 in	70 in	178 cm
5 ft 11 in	71 in	180 cm
6 ft 0 in	72 in	183 cm
6 ft 1 in	73 in	185 cm
6 ft 2 in	74 in	188 cm
6 ft 3 in	75 in	191 cm
6 ft 4 in	76 in	193 cm

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In the next set of questions, you will be asked to complete the same task as before. However, the risks will be different. The risks you see will be specific to you and were calculated using the information you just provided.

Please read each question carefully before making your selection.

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Imagine that you are choosing a treatment for high blood pressure during your pregnancy.

Considering only the four characteristics below, please choose the characteristic that is most important to you and the characteristic that is least important to you when making a treatment decision.

Question 1 of 7

Most Important	Least Important
<input type="checkbox"/>	<input type="checkbox"/>
<p>Severely Elevated Blood Pressure Throughout Pregnancy</p> <p>A decrease in the risk of severely elevated high blood pressure throughout pregnancy from 46 in 100 women to 32 in 100 women.</p> <p>This is a decrease of 14 in 100 women having severely elevated high blood pressure throughout pregnancy</p> <ul style="list-style-type: none"><input type="radio"/> will have severely elevated blood pressure throughout pregnancy<input type="radio"/> will have severely elevated blood pressure throughout pregnancy if they use a given treatment<input type="radio"/> will not have severely elevated blood pressure throughout pregnancy 	
<input type="checkbox"/>	<input type="checkbox"/>
<p>Medication</p> <p>A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100.</p> <p>This is a decrease of 17 in 100 women taking medication.</p> <ul style="list-style-type: none"><input type="radio"/> will take high blood pressure medication<input type="radio"/> will take high blood pressure medication if they use a given treatment<input type="radio"/> will not take high blood pressure medication 	
<input type="checkbox"/>	<input type="checkbox"/>
<p>Caesarean Delivery</p> <p>A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100.</p> <p>This is a decrease of 4 in 100 women having a Caesarean delivery.</p> <ul style="list-style-type: none"><input type="radio"/> will have a Caesarean delivery<input type="radio"/> will have a Caesarean delivery if they choose a given treatment<input type="radio"/> will not have a Caesarean delivery 	

Most
Important

Least
Important

Blood Transfusion

A decrease in the risk of blood transfusion from 3 in 100 women, to 1 in 100 women.

This a decrease of 2 in 100 women needing in a blood transfusion.

- will need a blood transfusion
- will need a blood transfusion if they use a given treatment
- will not need a blood transfusion



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Imagine that you are choosing a treatment for high blood pressure during your pregnancy.

Considering only the four characteristics below, please choose the characteristic that is most important to you and the characteristic that is least important to you when making a treatment decision.

Question 2 of 7

Most Important	Least Important
<input type="checkbox"/>	<input type="checkbox"/>
Pre-eclampsia	
A decrease in the risk of pre-eclampsia from 44 in 100 women to 41 in 100 women. This is a decrease of 3 in 100 women developing pre-eclampsia.	
<ul style="list-style-type: none"><input type="radio"/> women will develop pre-eclampsia<input type="radio"/> women will develop pre-eclampsia if they use a given treatment<input type="radio"/> women will not develop pre-eclampsia	
	
<input type="checkbox"/>	<input type="checkbox"/>
Severely Elevated Blood Pressure Throughout Pregnancy	
A decrease in the risk of severely elevated high blood pressure throughout pregnancy from 46 in 100 women to 32 in 100 women. This is a decrease of 14 in 100 women having severely elevated high blood pressure throughout pregnancy	
<ul style="list-style-type: none"><input type="radio"/> will have severely elevated blood pressure throughout pregnancy<input type="radio"/> will have severely elevated blood pressure throughout pregnancy if they use a given treatment<input type="radio"/> will not have severely elevated blood pressure throughout pregnancy	
	
<input type="checkbox"/>	<input type="checkbox"/>
Delivery Before 34 Weeks	
A decrease in the risk of delivery before 34 weeks from 34 in 100 women to 29 in 100 women. This is a decrease of 5 in 100 women delivering before 34 weeks.	
<ul style="list-style-type: none"><input type="radio"/> will deliver before 34 weeks<input type="radio"/> will deliver before 34 weeks if they use a given treatment<input type="radio"/> will not deliver before 34 weeks	
	

Most
Important

Least
Important

Caesarean Delivery

A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100.

This is a decrease of 4 in 100 women having a Caesarean delivery.

- will have a Caesarean delivery
- will have a Caesarean delivery if they choose a given treatment
- will not have a Caesarean delivery



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Imagine that you are choosing a treatment for high blood pressure during your pregnancy.

Considering only the four characteristics below, please choose the characteristic that is most important to you and the characteristic that is least important to you when making a treatment decision.

Question 3 of 7

Most Important	Least Important
<input type="checkbox"/>	<input type="checkbox"/>
<p>Pre-eclampsia</p> <p>A decrease in the risk of pre-eclampsia from 44 in 100 women to 41 in 100 women. This is a decrease of 3 in 100 women developing pre-eclampsia.</p> <ul style="list-style-type: none"><input type="radio"/> women will develop pre-eclampsia<input checked="" type="radio"/> women will develop pre-eclampsia if they use a given treatment<input type="radio"/> women will not develop pre-eclampsia 	
<input type="checkbox"/>	<input type="checkbox"/>
<p>Delivery Before 34 Weeks</p> <p>A decrease in the risk of delivery before 34 weeks from 34 in 100 women to 29 in 100 women. This is a decrease of 5 in 100 women delivering before 34 weeks.</p> <ul style="list-style-type: none"><input type="radio"/> will deliver before 34 weeks<input checked="" type="radio"/> will deliver before 34 weeks if they use a given treatment<input type="radio"/> will not deliver before 34 weeks 	
<input type="checkbox"/>	<input type="checkbox"/>
<p>Blood Transfusion</p> <p>A decrease in the risk of blood transfusion from 3 in 100 women, to 1 in 100 women. This is a decrease of 2 in 100 women needing a blood transfusion.</p> <ul style="list-style-type: none"><input type="radio"/> will need a blood transfusion<input checked="" type="radio"/> will need a blood transfusion if they use a given treatment<input type="radio"/> will not need a blood transfusion 	

Most Important		Least Important
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Small for Gestational Age



A decrease in the risk of the baby being born smaller than expected from 62 in 100 babies to 55 in 100 babies.

This is a decrease of 7 in 100 babies being born smaller than expected.

- will be born small for gestational age
- will be born small for gestational age if a given treatment is used
- will not be born small for gestational age



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Next

Imagine that you are choosing a treatment for high blood pressure during your pregnancy.

Considering only the four characteristics below, please choose the characteristic that is most important to you and the characteristic that is least important to you when making a treatment decision.

Question 4 of 7

Most Important	Medication	Least Important
<input type="checkbox"/>	<p>A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100. This is a decrease of 17 in 100 women taking medication.</p> <ul style="list-style-type: none"><input type="radio"/> will take high blood pressure medication<input type="radio"/> will take high blood pressure medication if they use a given treatment<input type="radio"/> will not take high blood pressure medication 	<input type="checkbox"/>
<input type="checkbox"/>	<p>A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100. This is a decrease of 4 in 100 women having a Caesarean delivery.</p> <ul style="list-style-type: none"><input type="radio"/> will have a Caesarean delivery<input type="radio"/> will have a Caesarean delivery if they choose a given treatment<input type="radio"/> will not have a Caesarean delivery 	<input type="checkbox"/>
<input type="checkbox"/>	<p>A decrease in the risk of blood transfusion from 3 in 100 women, to 1 in 100 women. This a decrease of 2 in 100 women needing in a blood transfusion.</p> <ul style="list-style-type: none"><input type="radio"/> will need a blood transfusion<input type="radio"/> will need a blood transfusion if they use a given treatment<input type="radio"/> will not need a blood transfusion 	<input type="checkbox"/>

Most
Important

Least
Important

Small for Gestational Age

A decrease in the risk of the baby being born smaller than expected from 62 in 100 babies to 55 in 100 babies.

This is a decrease of 7 in 100 babies being born smaller than expected.

- will be born small for gestational age
- will be born small for gestational age if a given treatment is used
- will not be born small for gestational age



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Imagine that you are choosing a treatment for high blood pressure during your pregnancy.

Considering only the four characteristics below, please choose the characteristic that is most important to you and the characteristic that is least important to you when making a treatment decision.

Question 5 of 7

Most Important	Least Important
<input type="checkbox"/>	<input type="checkbox"/>
<p>Severely Elevated Blood Pressure Throughout Pregnancy</p> <p>A decrease in the risk of severely elevated high blood pressure throughout pregnancy from 46 in 100 women to 32 in 100 women.</p> <p>This is a decrease of 14 in 100 women having severely elevated high blood pressure throughout pregnancy</p> <ul style="list-style-type: none"><input type="radio"/> will have severely elevated blood pressure throughout pregnancy<input type="radio"/> will have severely elevated blood pressure throughout pregnancy if they use a given treatment<input type="radio"/> will not have severely elevated blood pressure throughout pregnancy 	
<input type="checkbox"/>	<input type="checkbox"/>
<p>Delivery Before 34 Weeks</p> <p>A decrease in the risk of delivery before 34 weeks from 34 in 100 women to 29 in 100 women.</p> <p>This is a decrease of 5 in 100 women delivering before 34 weeks.</p> <ul style="list-style-type: none"><input type="radio"/> will deliver before 34 weeks<input type="radio"/> will deliver before 34 weeks if they use a given treatment<input type="radio"/> will not deliver before 34 weeks 	
<input type="checkbox"/>	<input type="checkbox"/>
<p>Medication</p> <p>A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100.</p> <p>This is a decrease of 17 in 100 women taking medication.</p> <ul style="list-style-type: none"><input type="radio"/> will take high blood pressure medication<input type="radio"/> will take high blood pressure medication if they use a given treatment<input type="radio"/> will not take high blood pressure medication 	

Most
Important

Least
Important



Caesarean Delivery



A decrease in the likelihood of Caesarean delivery from 51 in 100 to 47 in 100.

This is a decrease of 4 in 100 women having a Caesarean delivery.

- will have a Caesarean delivery
- will have a Caesarean delivery if they choose a given treatment
- will not have a Caesarean delivery



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Imagine that you are choosing a treatment for high blood pressure during your pregnancy.

Considering only the four characteristics below, please choose the characteristic that is most important to you and the characteristic that is least important to you when making a treatment decision.

Question 6 of 7

Most Important	Least Important
<input type="checkbox"/>	<input type="checkbox"/>
Pre-eclampsia	
A decrease in the risk of pre-eclampsia from 44 in 100 women to 41 in 100 women. This is a decrease of 3 in 100 women developing pre-eclampsia.	
<ul style="list-style-type: none"><input type="radio"/> women will develop pre-eclampsia<input type="radio"/> women will develop pre-eclampsia if they use a given treatment<input type="radio"/> women will not develop pre-eclampsia	
	
<input type="checkbox"/>	<input type="checkbox"/>
Severely Elevated Blood Pressure Throughout Pregnancy	
A decrease in the risk of severely elevated high blood pressure throughout pregnancy from 46 in 100 women to 32 in 100 women. This is a decrease of 14 in 100 women having severely elevated high blood pressure throughout pregnancy	
<ul style="list-style-type: none"><input type="radio"/> will have severely elevated blood pressure throughout pregnancy<input type="radio"/> will have severely elevated blood pressure throughout pregnancy if they use a given treatment<input type="radio"/> will not have severely elevated blood pressure throughout pregnancy	
	
<input type="checkbox"/>	<input type="checkbox"/>
Delivery Before 34 Weeks	
A decrease in the risk of delivery before 34 weeks from 34 in 100 women to 29 in 100 women. This is a decrease of 5 in 100 women delivering before 34 weeks.	
<ul style="list-style-type: none"><input type="radio"/> will deliver before 34 weeks<input type="radio"/> will deliver before 34 weeks if they use a given treatment<input type="radio"/> will not deliver before 34 weeks	
	

Most
Important

Least
Important



Small for Gestational Age



A decrease in the risk of the baby being born smaller than expected from 62 in 100 babies to 55 in 100 babies.

This is a decrease of 7 in 100 babies being born smaller than expected.

- will be born small for gestational age
- will be born small for gestational age if a given treatment is used
- will not be born small for gestational age



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Imagine that you are choosing a treatment for high blood pressure during your pregnancy.

Considering only the four characteristics below, please choose the characteristic that is most important to you and the characteristic that is least important to you when making a treatment decision.

Question 7 of 7

Most Important	Least Important
<input type="checkbox"/>	<input type="checkbox"/>
Pre-eclampsia	
A decrease in the risk of pre-eclampsia from 44 in 100 women to 41 in 100 women. This is a decrease of 3 in 100 women developing pre-eclampsia.	
<ul style="list-style-type: none"><input type="radio"/> women will develop pre-eclampsia<input type="radio"/> women will develop pre-eclampsia if they use a given treatment<input type="radio"/> women will not develop pre-eclampsia	
	
<hr/>	
<input type="checkbox"/>	<input type="checkbox"/>
Medication	
A decrease in the likelihood of taking medication from 94 in 100 to 77 in 100. This is a decrease of 17 in 100 women taking medication.	
<ul style="list-style-type: none"><input type="radio"/> will take high blood pressure medication<input type="radio"/> will take high blood pressure medication if they use a given treatment<input type="radio"/> will not take high blood pressure medication	
	
<hr/>	
<input type="checkbox"/>	<input type="checkbox"/>
Blood Transfusion	
A decrease in the risk of blood transfusion from 3 in 100 women, to 1 in 100 women. This a decrease of 2 in 100 women needing a blood transfusion.	
<ul style="list-style-type: none"><input type="radio"/> will need a blood transfusion<input type="radio"/> will need a blood transfusion if they use a given treatment<input type="radio"/> will not need a blood transfusion	
	

Most Important

Least Important



Small for Gestational Age

A decrease in the risk of the baby being born smaller than expected from 62 in 100 babies to 55 in 100 babies.

This is a decrease of 7 in 100 babies being born smaller than expected.

- will be born small for gestational age
 - will be born small for gestational age if a given treatment is used
 - will not be born small for gestational age



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Treatment Choice 2

The table below shows the characteristics of the two recommended treatments for high blood pressure in pregnancy. The figures below are based on the information you provided earlier. Please read through the characteristics of the two treatments carefully.

If you had to choose one, which treatment would you prefer?

	Treatment A <input type="checkbox"/>	Treatment B <input type="checkbox"/>
i Pre-eclampsia	<p>44 out of 100 women will develop pre-eclampsia.</p> <ul style="list-style-type: none"> ● will develop pre-eclampsia ● will not develop pre-eclampsia 	<p>41 out of 100 women will develop pre-eclampsia.</p> <ul style="list-style-type: none"> ● will develop pre-eclampsia ● will not develop pre-eclampsia 
i Blood Transfusion	<p>3 out of 100 women will require a blood transfusion.</p> <ul style="list-style-type: none"> ● will need a blood transfusion ● will not need a blood transfusion 	<p>1 out of 100 women will require a blood transfusion.</p> <ul style="list-style-type: none"> ● will need a blood transfusion ● will not need a blood transfusion 
i Severely Elevated Blood Pressure Throughout Pregnancy	<p>46 out of 100 women will have severely elevated blood pressure throughout pregnancy.</p> <ul style="list-style-type: none"> ● will have severely elevated blood pressure throughout their pregnancy ● will not have severely elevated blood pressure throughout pregnancy 	<p>32 out of 100 women will have severely elevated blood pressure throughout pregnancy.</p> <ul style="list-style-type: none"> ● will have severely elevated blood pressure throughout their pregnancy ● will not have severely elevated blood pressure throughout pregnancy 

	Treatment A	Treatment B
Medication	<p>77 out of 100 women will take blood pressure medication during their pregnancy.</p> <ul style="list-style-type: none"> • will take high blood pressure medication • will not take high blood pressure medication 	<p>94 out of 100 women will take blood pressure medication during their pregnancy.</p> <ul style="list-style-type: none"> • will take high blood pressure medication • will not take high blood pressure medication 
Caesarean Delivery	<p>47 out of 100 women will have a Caesarean delivery.</p> <ul style="list-style-type: none"> • will have a Caesarean delivery • will not have a Caesarean delivery 	<p>51 out of 100 women will have a Caesarean delivery.</p> <ul style="list-style-type: none"> • will have a Caesarean delivery • will not have a Caesarean delivery 
Delivery Before 34 Weeks	<p>34 out of 100 women will deliver before 34 weeks.</p> <ul style="list-style-type: none"> • will deliver before 34 weeks • will not deliver before 34 weeks 	<p>29 out of 100 women will deliver before 34 weeks.</p> <ul style="list-style-type: none"> • will deliver before 34 weeks • will not deliver before 34 weeks 
Small for Gestational Age	<p>55 out of 100 babies will be born small for gestational age.</p> <ul style="list-style-type: none"> • will be born small for gestational age • will not be born small for gestational age 	<p>62 out of 100 babies will be born small for gestational age.</p> <ul style="list-style-type: none"> • will be born small for gestational age • will not be born small for gestational age 



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The following questions will ask you about your values and decisional needs.

The information from this survey will be used to create a tool to provide pregnant women information about high blood pressure in pregnancy. Next few questions will help us decide the best way to design this tool.

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We conducted a series of focus groups and interviews with women in Canada to figure out what they felt were the most important things to think about when choosing a treatment for high blood pressure in pregnancy.

The women we spoke with said these 7 characteristics were the most important things to think about:

- Likelihood of Taking medication
- Risk of preeclampsia
- Risk of blood transfusion
- Risk of severely elevated blood pressure in pregnancy
- Risk of delivery before 34 weeks
- Risk of baby being born smaller than expected
- Likelihood of Caesarean delivery

Are there any other things you think would be important to consider when choosing a treatment?

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Sometimes people need to make very difficult treatment choices during pregnancy. These choices are particularly difficult if someone needs to choose between a treatment that benefits the mother but puts the infant at risk, and a treatment that benefits the infant but puts the mother at risk. Different people have different values and priorities when faced with this decision.

Thinking about your values, please use the slider below to show how you value the mother's health compared to the infants' health.



Only the mother's health should be considered

Only the infant's health should be considered

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If I were receiving information on high blood pressure in pregnancy, I would prefer it to be:

Online – a website I can access on any device

Online – an app for my phone or tablet

Paper – a 1-page pamphlet

Paper – a booklet

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If I were receiving information, I would prefer to receive it:

- Before my doctor's appointment
- During my doctor's appointment
- At the end of my doctor's appointment

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If I were receiving information, I would prefer to receive it from:

Check all that apply.

- | | |
|---|-----------------------|
| My doctor | <input type="radio"/> |
| A nurse involved with my care | <input type="radio"/> |
| A community care nurse | <input type="radio"/> |
| My midwife | <input type="radio"/> |
| A patient group or other support group | <input type="radio"/> |
| Another health organization or health program (e.g., prenatal classes, first start program) | <input type="radio"/> |

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I would like to receive this information:

Only if I were at risk for developing high blood pressure

Only if I had developed high blood pressure

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I find it helpful to read about other women's experiences with the health issue.

-
- Strongly Agree
-
- Somewhat Agree
-
- Neither Agree Nor Disagree
-
- Somewhat Disagree
-
- Strongly Disagree

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It is helpful to have information for me, and a separate version of the information for my partner or other close family members or friends.

- Strongly Agree
- Somewhat Agree
- Neither Agree Nor Disagree
- Somewhat Disagree
- Strongly Disagree

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Next

Most health information you receive is about the average person. For example, on average, 18 in 100 women with high blood pressure will have a baby who is born smaller than expected. This type of average information is generally quite accurate. If you were to randomly interview 100 women who had high blood pressure in pregnancy, 95% of the time between 14 and 22 of them would have given birth to a baby who was smaller than expected.

Unfortunately, this average information does not consider individual factors that may change how likely a given person is to have the outcome. For example, we know that smoking during pregnancy makes it more likely that a baby will be born smaller than expected. So, among women with high blood pressure in pregnancy who smoke, 24 in 100 women will have a baby who is smaller than expected. Unfortunately, this information is less accurate. What that means is that if you were to randomly interview 100 women who smoked and had high blood pressure in pregnancy, 95% of the time between 10 and 38 of them would have given birth to a baby that was smaller than expected.

Thinking about the information above, please rate how strongly you agree or disagree with this statement:

I would rather have less accurate information that considers my individual characteristics than have very accurate information that is about the average person.

Strongly agree

Somewhat Agree

Neither Agree Nor Disagree

Somewhat Disagree

Strongly Disagree

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Thank you for answering all our questions so far. We just have a few more short questions.

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How do you identify?

Female

Male

Non-binary or third gender

Prefer to self-describe

Prefer not to say

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Were you born in Canada?

Yes

No

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Next

What country were you born in?

Back

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What is your annual household income?

Under \$35,000

\$35,000 to \$75,000

Over \$75,000

Prefer not to say

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What is the highest level of education you have completed?

- Primary School
- High School
- College Diploma or Technical/Trade School
- University
- Professional Qualification

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Thank you for completing our survey!

You will now be re-directed to the IPSOS survey completion page.

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[Finish the Survey](#)

Appendix B: Results of Multinomial Logistic Regression

Table B.1: Results of multinomial logistic regression predicting preference profile

Predictor	Beta	Standard Error	95% CI		<i>p</i> -value			
			Lower	Upper				
Profile 2 – Medication Minimisers								
Knowledge Score								
Increasing (continuous)	0.357	0.111	0.139	0.575	0.001			
History of pregnancy								
hypertension								
Yes		Ref						
No	0.980	0.495	0.010	1.950	0.048			
Profile 3 – Early Delivery Avoiders								
Knowledge Score								
Increasing (continuous)	0.209	0.13	-0.046	0.464	0.107			
History of pregnancy								
hypertension								
Yes		Ref						
No	-0.070	0.485	-1.021	0.881	0.885			

Reference: Profile 1 – Equal Prioritisers

Appendix C: Impact of Different Ranking Approaches on Global Rank Method

Results

Figure C.1: Results of the Global Rank Method following Felker & Maisel's ranking approach, allowing ties between participants

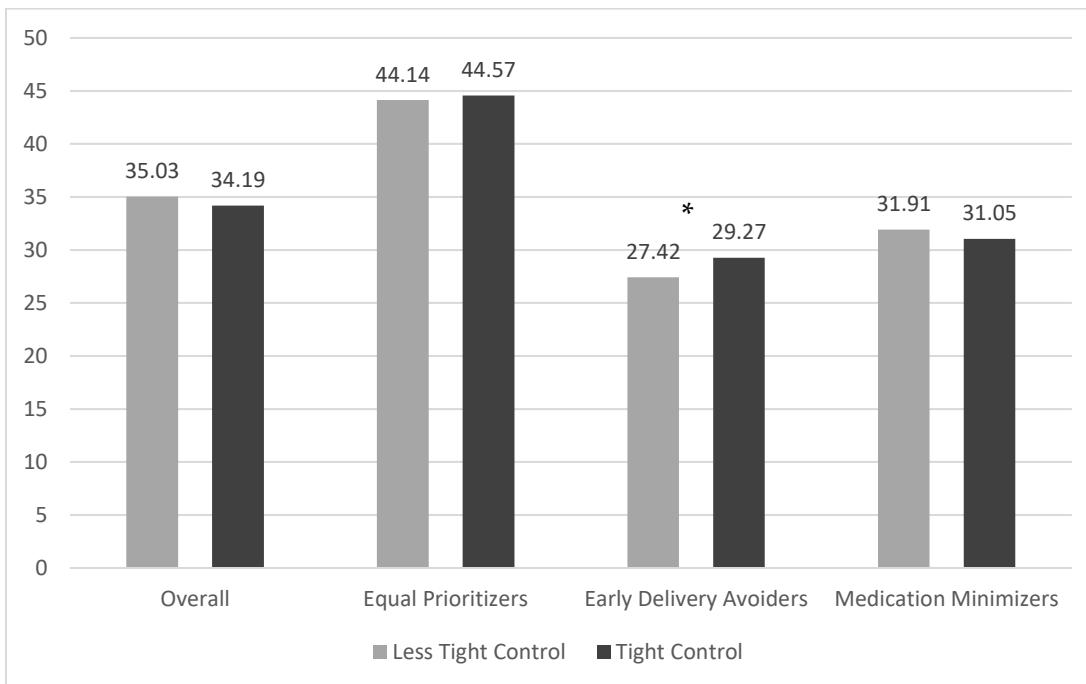
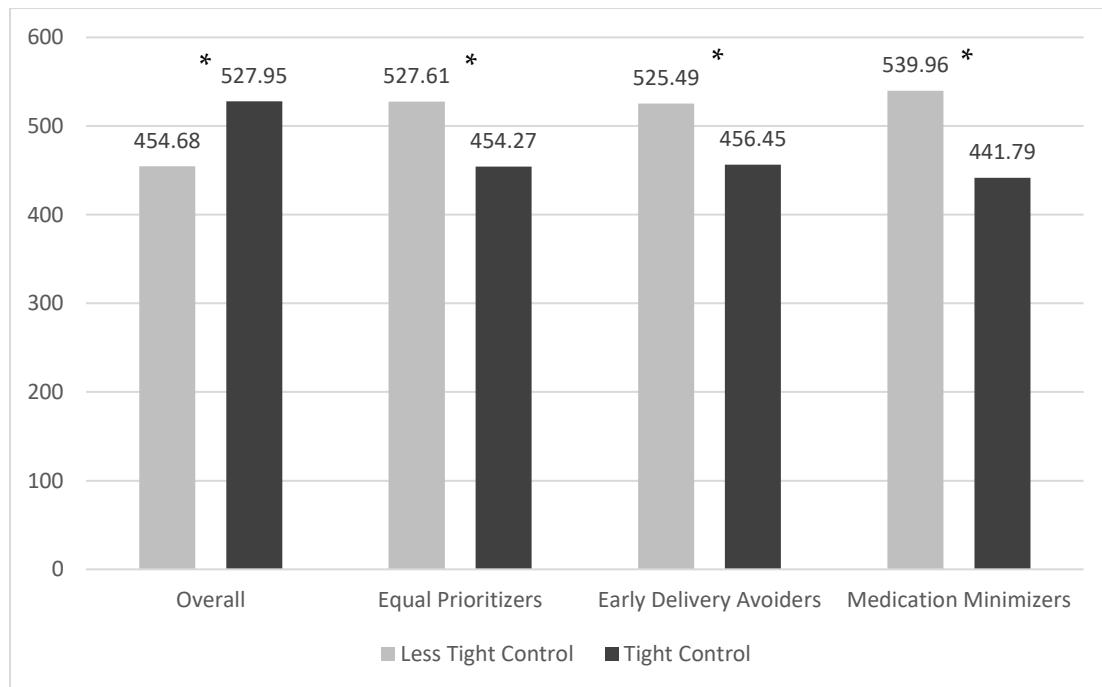


Figure C.2: Results of the Global Rank Method following Felker & Maisel's ranking approach, with ties broken by time-to-event



Appendix D: Web-based Patient Decision Aid (PtDA)

PREGNANCY HYPERTENSION DECISION AID

1. Welcome! 2. About Me 3. My Choice 4. Review 5. Summary

This tool will:

- Provide you with information on high blood pressure in pregnancy
- Ask you some questions about yourself
- Help you think through the decision and figure-out what you value most in this decision
- Provide you with a summary that you can use to talk to your support network and your healthcare providers

Where does the information in this tool come from?

The information in this decision aid comes from the best scientific studies conducted to date. You can find a list of these studies [on our website](#).

*This tool has been developed by researchers at the University of British Columbia and King's College London.
The developers of this decision aid do not have anything to gain from the decision you make.*



Begin

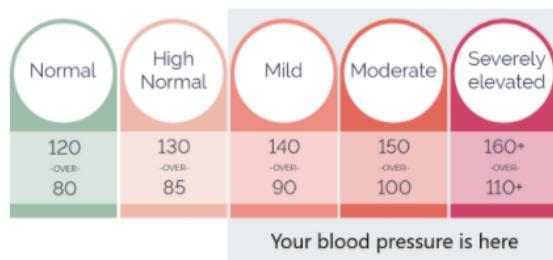


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PREGNANCY HYPERTENSION DECISION AID

1. Welcome! 2. About Me 3. My Choice 4. Review 5. Summary

If your doctor has told you that you have high blood pressure, your blood pressure is in one of the three categories on the right:



+ What is High Blood Pressure?

+ What happens if my blood pressure gets to ____ level?

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PREGNANCY HYPERTENSION DECISION AID

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Most people with high blood pressure in pregnancy have a safe and healthy pregnancy. But, the risk of problems for them and their baby is higher.

— Risks to the Baby

- Being born early
- Being born smaller than most other babies born at the same age
- Needing to stay in the hospital after birth
- Severe complications, like respiratory stress disorder and sepsis
- Pregnancy loss

— Risks to Me

- Hospitalization before delivery
- Pre-eclampsia, a complication that involves high blood pressure and organ damage
- Eclampsia, a complication that includes seizures
- Stroke

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PREGNANCY HYPERTENSION DECISION AID

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For most, a treatment approach called 'tight control' is the best way to manage high blood pressure in pregnancy.

— Tight Control: Act now to lower your blood pressure to the normal range

'Tight' Control: act now to lower blood pressure to the high normal range.



Almost everyone who chooses 'tight' control will take medication at some point in their pregnancy.

— Less-tight Control: Wait and see if your blood pressure becomes very high

When you choose a lower blood pressure goal, you are more likely to take medication. Because of this, some people choose 'less tight' control. In 'less-tight' control, you choose a higher target and start taking medication if their blood pressure becomes moderately high to very high.



Choosing a higher target blood pressure makes it less likely that woman will need to take medication. But most people who choose less-tight control still need to take medication at some point in their pregnancy.

'Less tight' Control: Wait and see if blood pressure becomes moderately high to severely elevated

⊕ What will treatment look like?

PREGNANCY HYPERTENSION DECISION AID

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Understanding the risks, medications and procedures

Below, you can explore different health outcomes that are more likely for people who have high blood pressure in pregnancy. We've organized this information into two main groups:

1. **Known Differences:** These are areas where we know there are differences between tight control and less-tight control.
2. **Unclear Differences:** These are areas where the evidence isn't clear right now. But based on the evidence that we do have, it looks like there is either no difference between tight control and less tight control or the difference is very small.

These numbers are based on the average person. Your risk may be higher or lower based on other factors.

[**+ Known Differences**](#)

[**+ Unclear Differences**](#)

If you'd like to learn more, you explore more using the tabs below or by access our [frequently asked questions page](#).

[**+ Learn More**](#)

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This next section will help you think about which treatment approach matches your preferences best.

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Research in Canada found that most pregnant people fall into one of these groups. Whose preferences are closest to yours?



For them, the most important thing is lowering the chance that their baby will be born before 34 weeks.

For them, the most important thing is lowering the chance that they will need to take medication.

They aren't yet sure what health risks and medical interventions are most important to them.

They know what their priority is, but it isn't avoiding delivery before 34 weeks or medication.

My top priority is ★★★★★	Delivering after 34 weeks	Taking as little medication as possible	I don't have a top priority yet	Something else
Other things that impact my decision ★★★★★	<ul style="list-style-type: none"> Developing pre-eclampsia Developing severely elevated BP 	<ul style="list-style-type: none"> Developing severely elevated BP 	<ul style="list-style-type: none"> Having a blood transfusion Delivering after 34 weeks 	
These things are less important to me ★★★★★	<ul style="list-style-type: none"> Having a blood transfusion Taking medication 	<ul style="list-style-type: none"> Having a blood transfusion Delivering after 34 weeks 	<ul style="list-style-type: none"> My baby being born smaller than most other babies 	

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Group 1

Our best evidence suggests that people who want to reduce their likelihood of delivering before 34 weeks should talk to their doctor about 'tight' control.

Tight control is the treatment approach recommended by current Canadian clinical guidelines. With the evidence available right now, we can't know for sure which treatment approach is better when it comes to reducing the likelihood of early delivery. Our best guess is that fewer women who choose tight control will deliver before 34 weeks or that there is no difference between the two treatment approaches.

You can learn more about delivering before 34 weeks by exploring the FAQs below. If you want to learn more about other outcomes, you can explore those under "Other Priorities".

When you're ready to move forward, click "next".

- + Does having high blood pressure change my expected delivery date?
- + What does it mean if my baby is born before 34 weeks?
- + What is the evidence that tight control may lower my risk of early delivery?
- + Other Priorities

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PREGNANCY HYPERTENSION DECISION AID

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You have two choices now. You can:

Complete 7 questions to help you think about what matters most to you and how your values fit with the treatment options

Skip those questions and start your summary sheet for you and your healthcare provider

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OPPORTUNISTIC HYPERTENSION DECISION AID

X

Values Clarification

In this section, you will be asked some questions to help you compare the two treatment approaches.

Prev Begin

Which option do you prefer?	Tight control	Less tight control	Unsure
-----------------------------	---------------	--------------------	--------

x

What is my risk of developing severely elevated blood pressure in my pregnancy?

Question 1 of 7

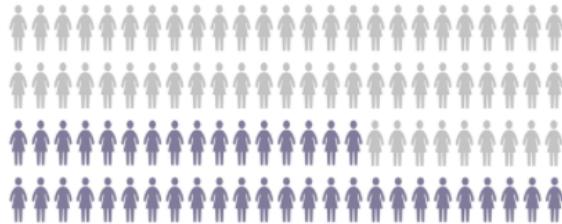
Tight Control

28 out of 100 women who choose Tight Control will develop severely elevated blood pressure in their pregnancy



Less-tight Control

41 out of 100 women who choose Less Tight Control will develop severely elevated blood pressure in their pregnancy



Considering "risk of severely elevated blood pressure" alone, which do you prefer?

Tight Control Less-tight Control Unsure

How much does "risk of severely elevated blood pressure" matter to your decision?

Not Important 1 2 3 4 5 Very Important

Prev

Next

x

What is my risk of developing pre-eclampsia Question 2 of 7

Tight Control

46 out of 100 women who choose Tight Control will develop pre-eclampsia.



Less-tight Control

49 out of 100 women who choose 'Less Tight' Control will develop pre-eclampsia.



Considering "the risk of pre-eclampsia" alone, which do you prefer?

Tight Control

Less-tight Control

Unsure

How much does "the risk of pre-eclampsia" matter to your decision?

Not Important

1

2

3

4

5

Very Important

Prev

Next

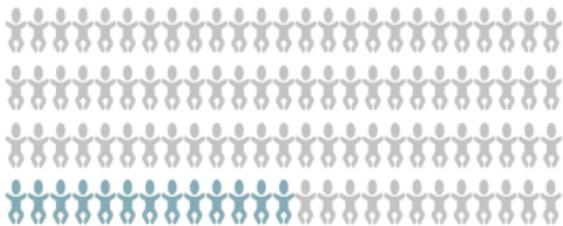
X

What is the risk that my child will be born before 34 weeks?

Question 3 of 7

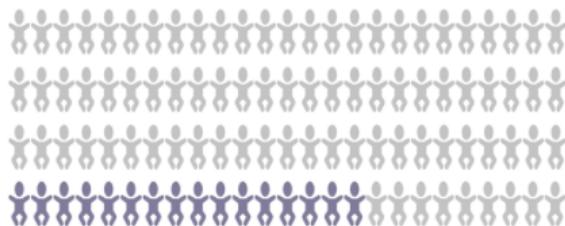
Tight Control

13 out of 100 women who choose Tight Control will have a baby who is born before 34 weeks.



Less-tight Control

16 out of 100 women who choose Less-tight Control will have a baby who is born before 34 weeks.



Considering "delivery before 34 weeks" alone, which do you prefer?

Tight Control Less-tight Control Unsure

How much does "delivery before 34 weeks" matter to your decision?

Not Important

1 2 3 4 5

Very Important

Prev

Next

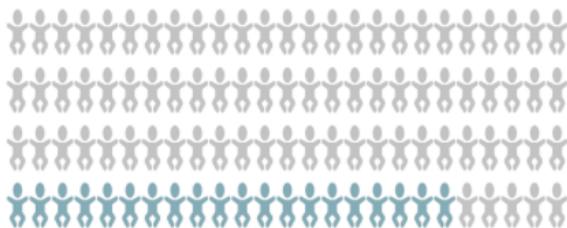
x

What is the risk that my child will be born small for gestational age?

Question 4 of 7

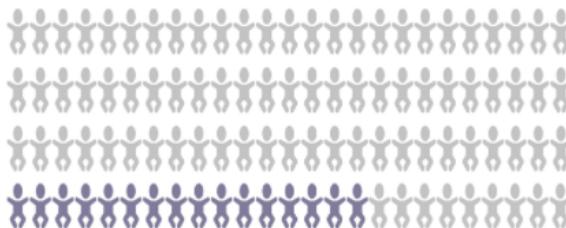
Tight Control

20 out of 100 women who choose Tight Control will have a child born small for gestational age.



Less-tight Control

16 out of 100 women who choose 'Less Tight' Control will have a child born small for gestational age.



Considering "small for gestational age" alone, which do you prefer?

Tight Control

Less-tight Control

Unsure

How much does "small for gestational age" matter to your decision?

Not Important

1

2

3

4

5

Very Important

Prev

Next

x

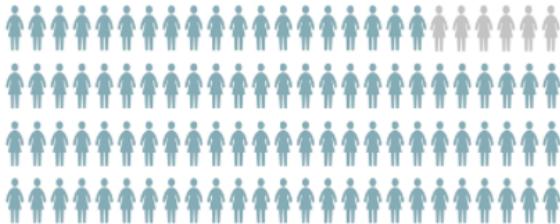
What is the likelihood that I will need to take medication for high blood pressure during my pregnancy?

Question 5 of 7

What is the likelihood that I will need to take medication for high blood pressure during my pregnancy?

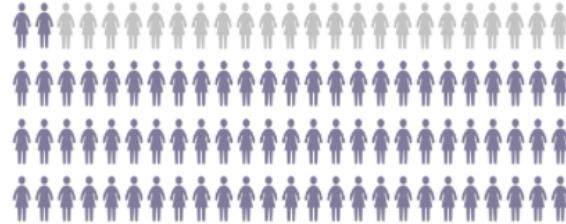
Tight Control

94 out of 100 women who choose Tight Control will take medication for blood pressure during their pregnancy.



Less-tight Control

77 out of 100 women who choose Less-tight Control will take medication for blood pressure during their pregnancy.



Considering "taking high blood pressure medication" alone, which do you prefer?

Tight Control

Less-tight Control

Unsure

How much does "taking high blood pressure medication" matter to your decision?

Not Important

1

2

3

4

5

Very Important

Prev

Next

x

What is the likelihood that I will have a Caesarean section (c-section)?

Question 6 of 7

What is the likelihood that I will have a Caesarean section (c-section)?

Tight Control

51 out of 100 women who choose Tight Control will have a caesarian section (c-section).



Less-tight Control

47 out of 100 women who choose Less-tight Control will have a caesarian section (c-section).



Considering "having a c-section" alone, which do you prefer?

Tight Control

Less-tight Control

Unsure

How much does "having a c-section" matter to your decision?

Not Important

1

2

3

4

5

Very Important

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x

What is the likelihood that I will need a blood transfusion due to blood loss?

Question 7 of 7

Tight Control

1 out of 100 women who choose Tight Control will need a blood transfusion.



Less-tight Control

3 out of 100 women who choose Less-tight Control will need a blood transfusion.



Considering "needing a blood transfusion" alone, which do you prefer?

Tight Control

Less-tight Control

Unsure

How much does "needing a blood transfusion" matter to your decision?

Not Important

1

2

3

4

5

Very Important

Prev

Close

PREGNANCY HYPERTENSION DECISION AID

1. Welcome! 2. About Me 3. My Choice 4. Review 5. Summary



Tight Control

Less-tight
Control

Unsure

Risk Of Severely Elevated Blood Pressure			
Delivery Before 34 Weeks			
Having A C-section			
The Risk Of Pre-eclampsia			
Small For Gestational Age			
Needing A Blood Transfusion			
Taking High Blood Pressure Medication			

Which option do you prefer?

Tight control

Less tight control

Unsure

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PREGNANCY HYPERTENSION DECISION AID

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This final section of the decision aid will put together a summary sheet for you to share with your care provider.

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PREGNANCY HYPERTENSION DECISION AID

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Below are some questions on the information you saw earlier.

	True	False
All people with high blood pressure in pregnancy take medication	<input type="radio"/>	<input type="radio"/>
Babies born to people with high blood pressure in pregnancy will definitely have complications	<input type="radio"/>	<input type="radio"/>
The only way to 'cure' pre-eclampsia is to give birth	<input type="radio"/>	<input type="radio"/>
Almost all babies born at or before 34 weeks need to stay in the NICU.	<input type="radio"/>	<input type="radio"/>
People who have high blood pressure in pregnancy are less likely to give birth early than people without high blood pressure in pregnancy.	<input type="radio"/>	<input type="radio"/>

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How prepared are you to make a decision?

	Yes	No
I feel ready and well prepared to talk to my doctor about this decision	<input type="radio"/>	<input type="radio"/>
I know the risks and benefits of each option	<input type="radio"/>	<input type="radio"/>
I am clear about which risks and benefits matter most to me	<input type="radio"/>	<input type="radio"/>
I have enough support and advice to make a good decision for me	<input type="radio"/>	<input type="radio"/>

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If you had to choose right now, which treatment would you pick?

Tight Control



Less-tight Control



Unsure



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Is there anything else you need before you can make a decision?

Some examples of things you might need:

- To talk to my doctor
- More information on specific outcomes
- To talk to my family and/or love ones
- More time to process the information you've received

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My Decision: High Blood Pressure in Pregnancy

My treatment priorities are...



Avoiding severely elevated BP

After completing this decision aid I...

Feel sure about the best decision for me



Know the benefits and risks of each option



Am clear about which risks matter most to me



Have enough support to make a decision



To make a decision, I need...

My knowledge

1. All women with high blood pressure in pregnancy take medication.
Answer: False - fewer women who choose 'less tight' control take medication.



2. The only way to cure pre-eclampsia is to give birth.
Answer: True - your doctor can monitor your symptoms but there is no treatment.



3. Babies born at or after 34 weeks are just as likely to survive as full-term babies.
Answer: True - but these babies are more likely to need care after birth.



4. All babies born to women with high blood pressure in pregnancy have complications.
Answer: False - many of these babies have no health complications.



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Appendix E: Full Linear Regression Model Predicting Total Knowledge Score

Table E.1: Full linear regression model predicting total knowledge score

Predictor	Beta	Standard	95% CI		<i>p</i> -value
		Error	Lower	Upper	
Expressive Suppression (ERQ)					
Increasing (continuous)	-0.039	0.034	-0.105	0.028	0.253
STAI-6					
Increasing (continuous)	-0.108	0.065	-0.238	0.021	0.101
Strategies Subscale (DERS-18)					
Increasing (continuous)	-0.084	0.060	-0.204	0.036	0.167
Education					
High School/Trade School	Ref				
University/Prof. Qualification	0.852	0.327	0.202	1.501	0.011
Age					
Increasing (continuous)	0.001	0.026	-0.050	0.052	0.973
History of pregnancy					
hypertension					
No	Ref				
Yes	-0.160	0.353	-0.861	0.541	0.652