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Leighton Pitter

Medical University of South Carolina

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WHAT IS THE EFFECT OF TELEHEALTH AND THE INTERNET OF MEDICAL THINGS (IOMT) ON OUTCOMES WHEN USED IN AT-RISK PREGNANCIES: A SCOPING REVIEW OF THE COMPONENTS OF REMOTE MATERNAL MONITORING FOR HYPERTENSIVE DISORDERS THAT CAN SUCCESSFULLY BE DONE VIA DIGITAL TECHNOLOGY?

BY

Leighton Pitter, DHA (c), MPA

A doctoral project submitted to the faculty of the Medical University of South Carolina
In partial fulfillment of the degree
Doctor of Health Administration
In the College of Health Professions

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I. Acknowledgments

I have reached a pivotal moment in my career and education, which took me twenty-five years to achieve. I am grateful to God and the supportive people who have helped me. My mother, Madgeline, had always known I would become a doctor since I was baptized. My brother Learie, my sons Josiah and Ari, Aunt Pam, Ms. Oliveen, Ms. Vasquez, Devaine, Audrey, Dean, Shakira, and my family, both in Jamaica and the United States, have all played a vital role in my success.

My accomplishments are not my own but result from the support and inspiration of two significant women in my life: my mother, Madgeline, and my wife, Mariecia. Both women have inspired, encouraged, nurtured, and tolerated me (because sometimes I can be a handful 😊). I am divinely favored to have these two amazing women be the wind beneath my wings to help me reach the zenith of my education. Mariecia, my love, my partner, my best friend, and my champion, words cannot express the depths of my love for her. Through all trials and tribulations, she has sustained me and our family with poise, grace, and keen intelligence. As a man, I may be the head of the household, but as the woman, Mariecia is the neck of our household, and she turns the head whichever way she pleases and always guides our family with love, compassion, integrity, strength, and humility.

I thank my dissertation committee members, Abby Swanson Kazley, PhD, Ngozi Nwankpa, MD, and Kevin Keith Wiley, PhD. I also want to acknowledge Mary Dooley, PhD, Eva Karp, PhD, and my colleagues at New York City Health + Hospitals, including Pedro Alex Castillo, Evelyn Nieves, and Akinola Fisher, MD, who helped me bring my dissertation idea to life. Lastly, I want to thank my cohort, who took this journey with me to reach the peak of our educational pursuits. The ambitious and intelligent women and men who make up my cohort embody the words of the poet Henry Wadsworth Longfellow: “The heights by great men (and women) reached and kept were not attained by sudden flight, but they while their companions slept, were toiling upward in the night.”

WHAT IS THE EFFECT OF TELEHEALTH AND THE INTERNET OF MEDICAL THINGS (IOMT) ON OUTCOMES WHEN USED IN AT-RISK PREGNANCIES: A SCOPING REVIEW OF THE COMPONENTS OF REMOTE MATERNAL MONITORING FOR HYPERTENSIVE DISORDERS THAT CAN SUCCESSFULLY BE DONE VIA DIGITAL TECHNOLOGY?

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Chairperson: Abby Swanson Kazley, PhD
Committee: Ngozi Nwankpa, MD
Kevin Keith Wiley, PhD

II. Abstract

IoMT (Internet of Medical Things) is an emerging technology that facilitates individualized remote e-health services to improve patient's quality of life and satisfaction while decreasing healthcare expenditures. The objective of this scoping review is to explore the usage of IoMT and remote patient monitoring (RPM) in at-risk pregnancies for hypertensive disorders to mitigate pregnancy-related complications. IoMT and other devices in an intelligent health system can meaningfully ameliorate maternal care management in the United States (U.S.). Wearables and nearables, subcategories of IoMT, can be utilized to facilitate patient-centered care and promote excellence in health maintenance/management through a holistic continuum of care approach while decreasing maternal mortality and morbidity in the U.S., which currently has the highest maternal mortality ratio/rate (MMR) among all western nations. IoMT and RPM can leverage the Quadruple Aim framework, the current gold standard in U.S. healthcare service delivery, and exist at the convergence of the different dimensions of care. The four tenets of the Quadruple Aim in delivering high-quality healthcare are to (1) Improve population health, (2) Lower healthcare costs, (3) Enhance patient experience, and (4) Improve care team well-being.

Key Terms: Maternal Mortality Ratio/Rate (MMR), Pregnancy-associated mortality, Pregnancy-related mortality, Maternal Health Complications, Maternal Health Disparities, Pregnancy-related Hypertensive Disorders, Hypertensive Disorders of Pregnancy Preeclampsia, Eclampsia, Remote Patient Monitoring (RPM), Internet of Medical Things (IoMT), Wearables, Nearables, Maternal Care Deserts, Digital Determinants of Health (DDoH)

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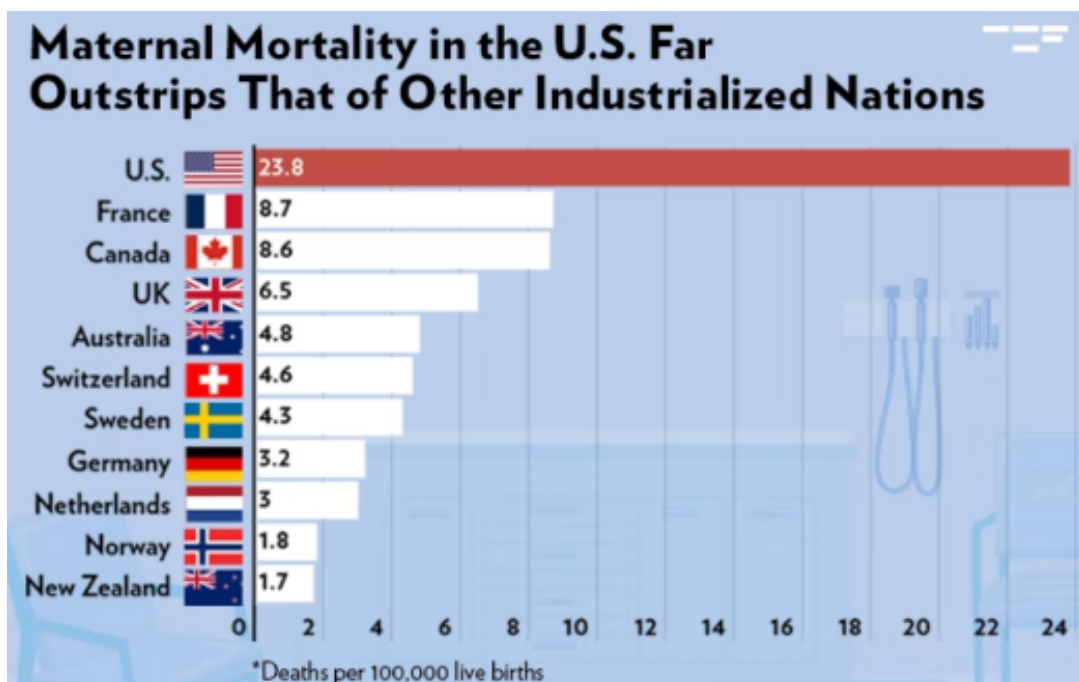
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Chapter 1

Introduction

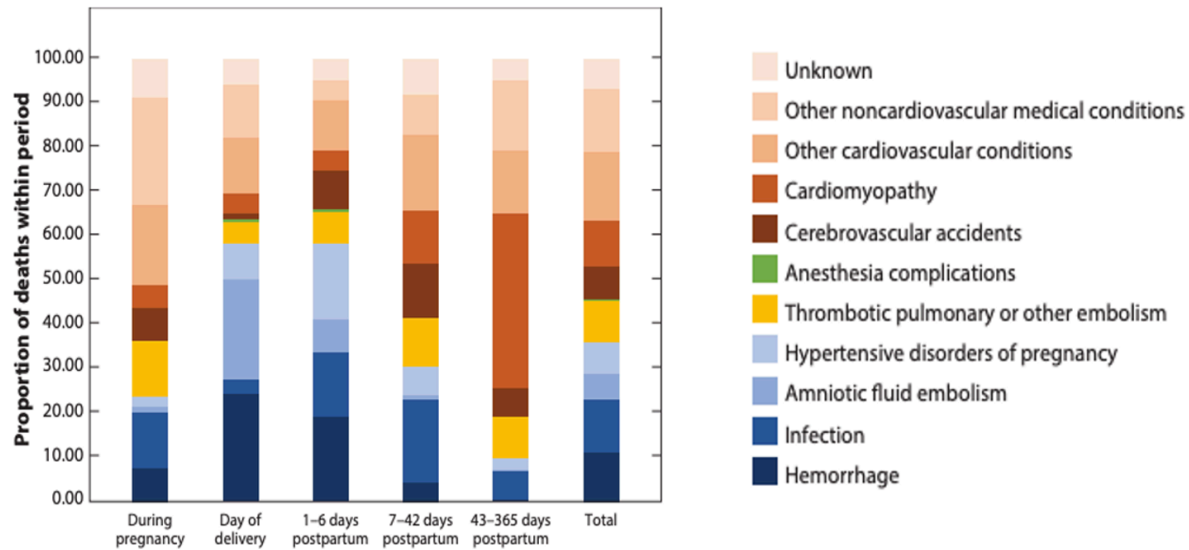
III. Background

Among all industrialized nations, the United States (U.S.) has the highest maternal mortality rate (MMR) (Gunja, 2022). According to recent data, only the Dominican Republic, a developing country, and the United States, a first-world country, reported a considerable upward trend in MMR (Declercq & Zephyrin, 2020). Between 2019 and 2021, 2,820 women died in the U.S. as a direct result of pregnancy or complications associated with pregnancy, and 84% of these deaths were preventable (Centers for Disease Control and Prevention, 2023). In 2021, 1,205 women died from complications, as compared with 861 in 2020 and 754 the year before that (CDC, 2023). The leading causes of maternal deaths in the U.S. were attributed to cardiac and coronary conditions, hypertensive disorders (hypertension, preeclampsia, eclampsia, postpartum preeclampsia, eclampsia, cardiovascular hypertension), infections, hemorrhage, and several other chronic medical conditions (CDC, 2022).



Information based on Centers for Disease Control and Prevention (CDC), 2020
Source: Rainosek, 2024 and Wang et al., 2023, p. 201

Maternal Mortality in the U.S. During the Period of Antepartum to 365-days Postpartum in Relation to Causes, 2011 – 2015

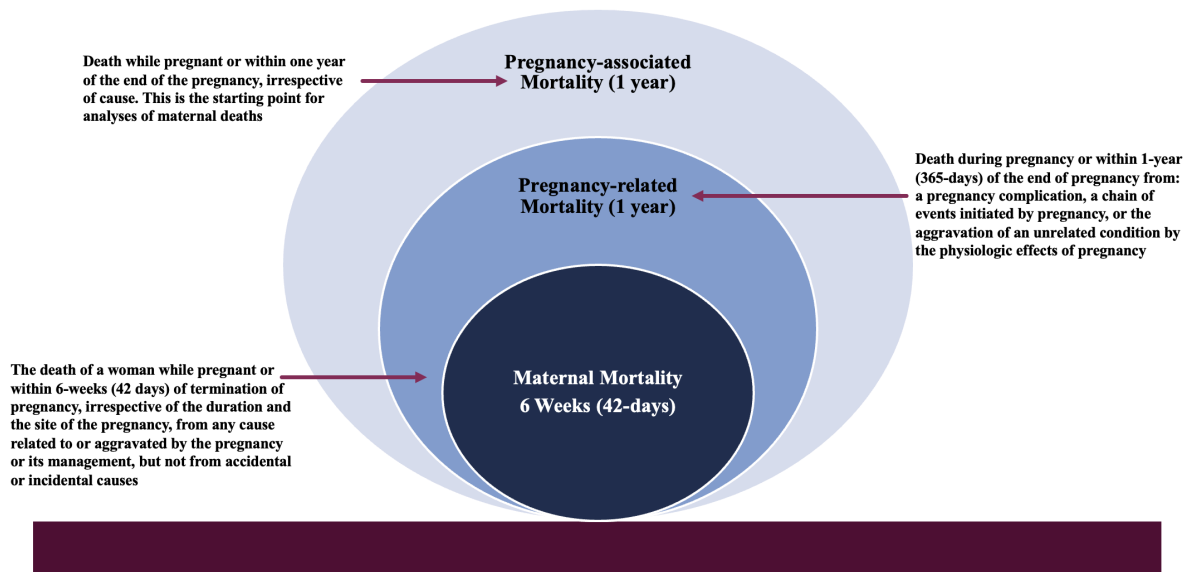


Source: Wang et al., 2023, p. 201

In 2019, all births' total maternal morbidity and mortality costs were estimated to be \$ 32.3 billion (B) (O'Neil et al., 2021). There are three categories of measures utilized to classify maternal death in the U.S. These three classifications are not equivalent but instead use different qualifiers for defining maternal death. The three categories of measures utilized to classify maternal death in the U.S. are:

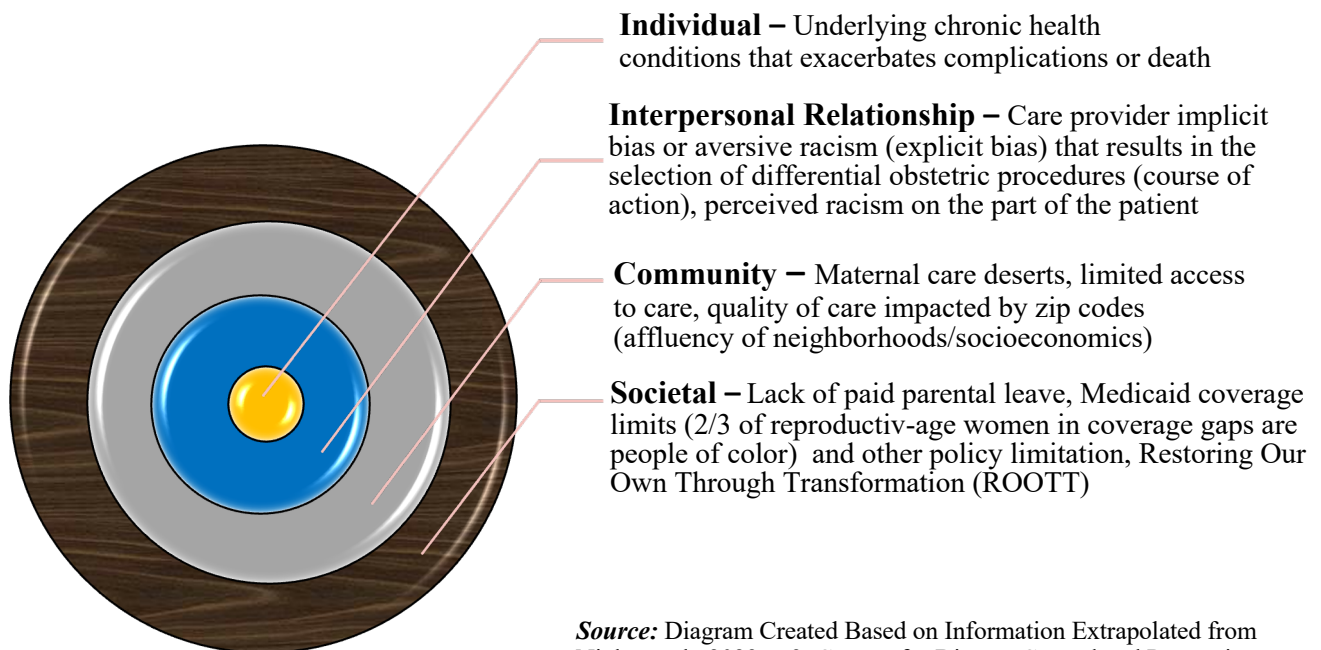
1. ***“Pregnancy-associated mortality:*** *Death while pregnant or within one year of the end of the pregnancy, irrespective of cause. This is the starting point for analyses of maternal deaths.*
2. ***Pregnancy-related mortality:*** *Death during pregnancy or within 1-year of the end of pregnancy from: a pregnancy complication, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy.*
3. ***Maternal mortality rate/ratio (MMR):*** *The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes. Typically, the CDC reports data as a ratio per 100,000 live births. Therefore, MMR refer to the number of maternal deaths per 100,000 live births”* (Hoyert, 2022, p).

Definitions of Maternal Deaths, Pregnancy-related Deaths, and Pregnancy-associated Deaths



Source: Diagram Created Based on Information Extrapolated from Wang et al., 2023, p. 201 & Hoyert, 2022

Root Causes for Maternal Health Complications Using the Social-Ecological Model:

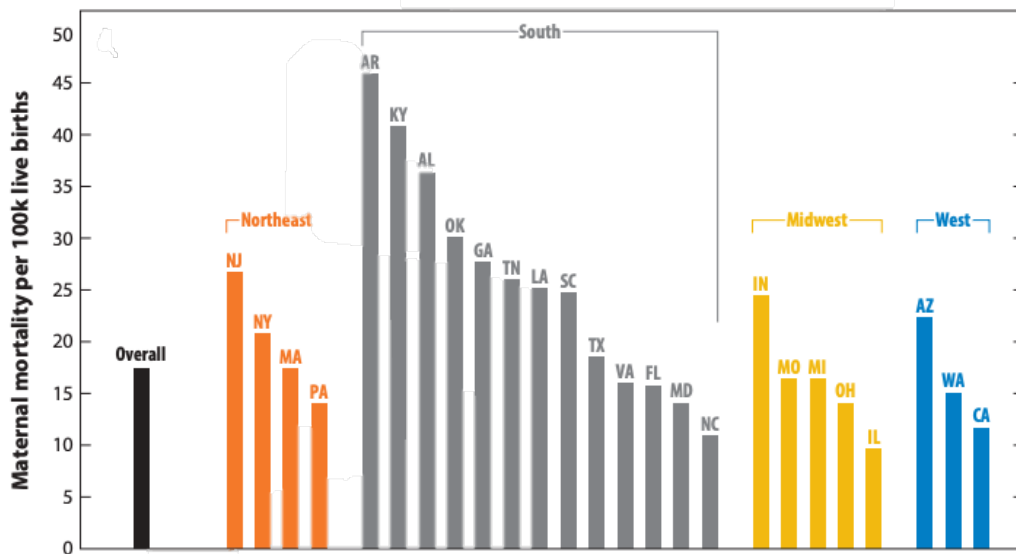


Source: Diagram Created Based on Information Extrapolated from Njoku et al., 2023, p.3, Centers for Disease Control and Prevention (CDC), 2022, Crear-Perry et al., 2021, & Noursi et al., 2020

IV. Problem and Intervention Guided by Research Question(s)

There are vast maternal health disparities in the U.S. that have existed since the U.S. Census Department started collecting data (Kaiser Family Foundation, 2022). Black non-Hispanic and American Indian/Pacific Islander women are 6-8 times more likely than Caucasian women to die from pregnancy-related causes. They are nearly three times more likely to experience severe maternal morbidity than Caucasian and Hispanic women (Katt & Prashar, 2022). The myriad dimensions of the social determinants of health (SDOH) significantly contribute to the disparities in MMR (Crear-Perry et al., 2021). Maternal health inequities are a national issue, and the disparities are magnified and exacerbated in New York and in other areas such as South Carolina, Arkansas, Kentucky, and Alabama that provide healthcare for large socioeconomically challenged minority groups (Li & Huang, 2019). MMR is exceptionally high in the southern and Northeastern regions of the United States (Wang et al., 2023).

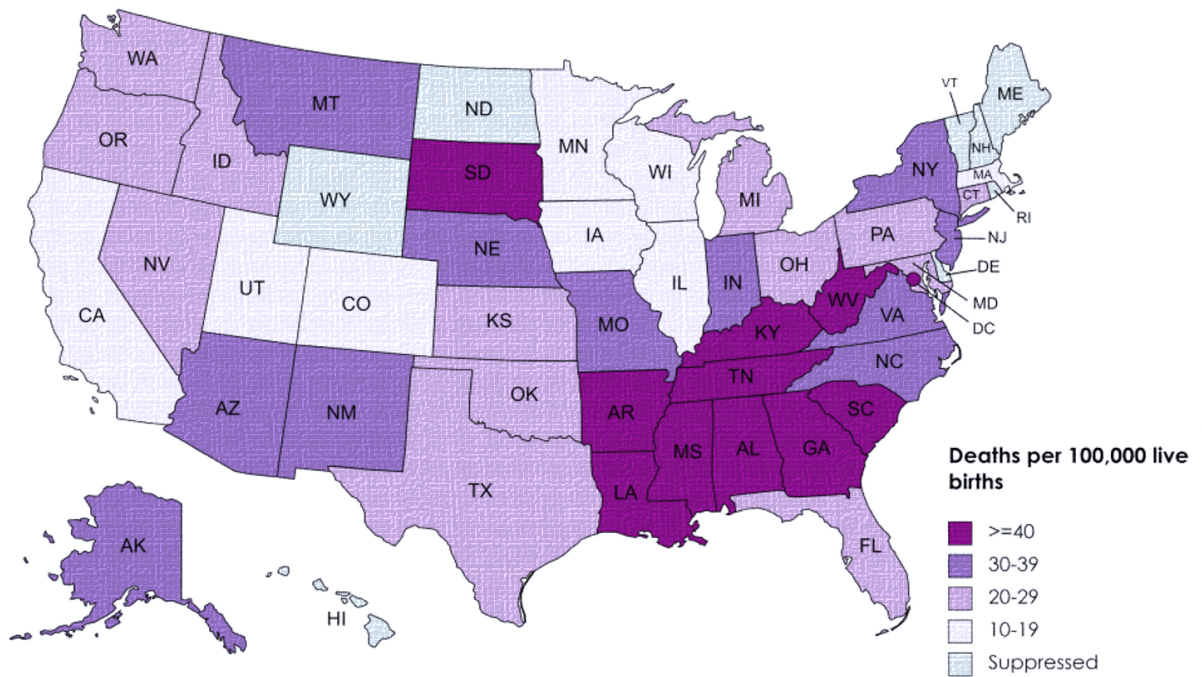
Maternal Mortality in the U.S. During the Period Antepartum to 365-Days Postpartum in Relation to Cause, 2011–2015



States (Divided by Region: Northeast, South, Midwest, West)

Source: Wang et al., 2023, p. 201

Pregnancy-related Mortality Rate by State, 2018 – 2020



Source: Wallace, 2022 Analysis of NVSS Data. All deaths from 2018 – 2020

Despite technological advances in the maternal health landscape, there are vast maternal health disparities in the U.S. that have existed since the Census Department started collecting data (Kaiser Family Foundation, 2022). These technological advances include, but are not limited to, telemedicine and IoMT, which provide for remote patient monitoring and will be discussed in greater detail later in this chapter. Briefly, as previously mentioned, hypertensive disorders hypertension, preeclampsia, eclampsia, postpartum pre-eclampsia, and cardiovascular hypertension are some of the leading causes of complication or death (Centers for Disease Control and Prevention, 2022). Hypertension increases the risk of cardiomyopathy and cardiovascular disease (CVD), which is also another leading cause of complications/death during pregnancy and within 42 days of giving birth (Centers for Disease Control and Prevention, 2022).

Digital technology, in its many forms, is changing how healthcare is delivered, facilitating a continuum of care, and serving as a tool to improve health and nonhealthy outcomes (Khalil et al., 2019). The utilization of telehealth via telemonitoring for the management of hypertensive disorders of pregnancy includes screening, surveillance, and monitoring to prevent disease progression or indicate elevated risks of adverse health events once diagnosed (Khalil et al., 2019). Telehealth uses digital information technologies (computers, smartwatches, smartphones, tablets, etc.) to access healthcare services remotely to manage one's health (May Clinic, 2024).

The ability to provide remote patient monitoring via the Internet of Medical Things (IoMT), including wearable and nearable devices, can help improve health outcomes, mitigate complications, and decrease the chance of death (Bartal & Sibai, 2022). IoMT is the healthcare subset of the Internet of Things (IoT), which focuses specifically on medical devices and applications with internet connectivity, biosensors, and a wide range of applicability (Mathkor et al., 2024). IoMT has integral multirole applications in healthcare by enhancing precision, consistency, reliability, and the productivity of medical devices (Mathkor et al., 2024). Nearables are devices such as smartphones placed near the body, and wearables such as smartwatches and blood pressure cuffs are worn on the body (Yoon & Choi, 2023). Both wearables and nearables use biosensors with transmitting capabilities and, along with IoMT, are expeditiously evolving for wide application in “smart” healthcare systems (Di Rienzo & Mukkamala, 2021). Wearables and nearables have made it possible to track at-risk patients in real-time, and these individuals can be contacted via a telehealth platform without countless onsite in-person visits to healthcare providers. The biosensor technology in these devices gives healthcare professionals greater access to larger volumes of data to analyze, allowing for more precise personalized treatment plans, which include alerts of any adverse changes in blood pressure, glucose levels, or heartbeats while at home, sleeping, etc. (Yoon & Choi, 2023).

RPM and IoMT can reduce health expenditures by limiting the overutilization of the emergency room and allowing pregnant women to seek help before they are in crisis. This is especially important for women who live in maternal health deserts and have limited access to care. It also benefits working women who cannot keep up with weekly visits with their obstetrician, midwife, or other providers. Collecting data through the combination of RPM and wearables/nearables while storing the information in the cloud databases for real-time analysis and application has been found to provide cost savings. A study published in North America in 2019 on telemonitoring of hypertension found that women who measured their blood pressure remotely and then relayed the results to their provider for advice were able to produce cost savings in healthcare expenditures. Telemonitoring saved \$2.50 for every \$1.00 spent compared to in-person monitoring at healthcare facilities (Khalil et al., 2019, p. 657).

Chapter 2

Literature Review

V. Disparities In Maternal Health

Maternal health disparities exist throughout the United States, with variations in maternal mortality rates at the state and regional levels, as illustrated in the chart on Page 8 (Wang et al., 2023). Medical risk factors, demographics, and political factors such as state-level policies and healthcare infrastructures influence these disparities. Social factors also play a significant role in maternal healthcare disparities, with the social determinants of health (SDOH) contributing to notable disparities in maternal mortality rates (Crear-Perry et al., 2021). According to Health People 2030, SDOH is defined as environmental factors that affect individuals' health and quality-of-life risks and outcomes (Office of Disease Prevention and Health Promotion, n.d.). The five dimensions of SDOH are (1) Economic stability, (2) Education access and quality, (3) Healthcare access and quality, (4) Neighborhood and built environment, and (5) Social and community context (Office of Disease Prevention and Health Promotion, n.d.). The SDOH ecosystem impacts the environment in which people are born, live, worship, and play (The White House – Domestic Policy Council Office of Science and Technology Policy, 2023). Over the last decade, a concentrated effort has been made to identify the root causes of maternal health disparities (Crear-Perry, 2021).

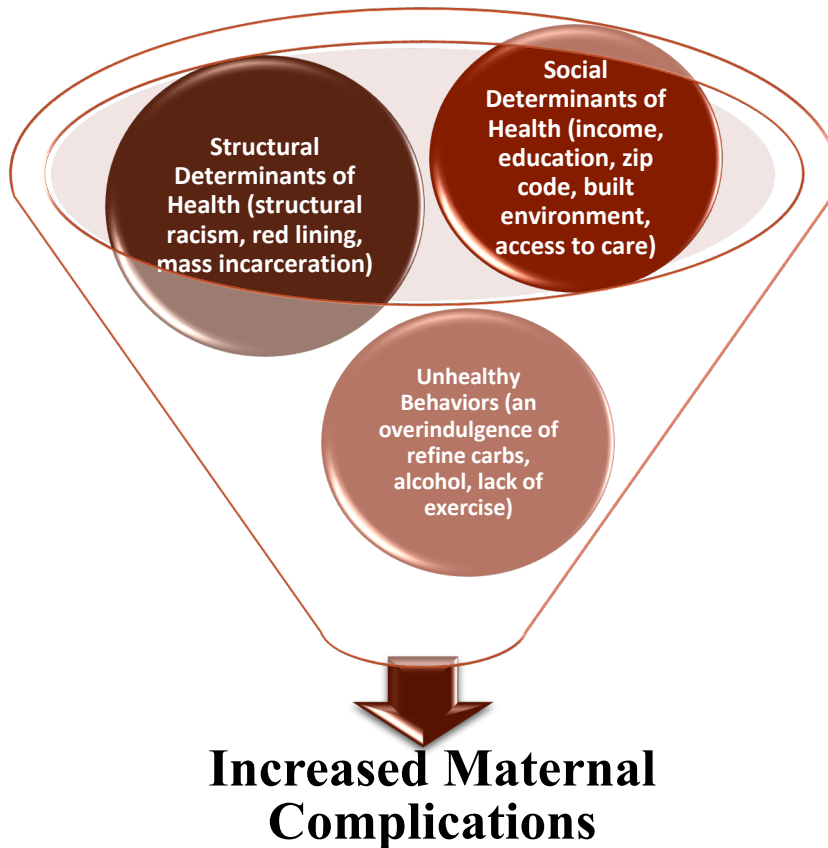
In November 2023, the White House under the Biden–Harris Administration published a fifty-three-page playbook that examines the different layers of SDOH and all the accompanying implications. The playbook highlights the correlation between housing insecurity, which increases the probability of homelessness, increases the rate of adverse health outcomes for both pregnant mothers of color, and complications for their fetuses (The White House – Domestic Policy Council Office of Science and Technology Policy, 2023). The Biden–Harris Administration has allocated resources to be used to focus on efforts to increase screening for conditions associated with the SDOH, such as hypertension, diabetes, and other risk factors that may induce adverse health

outcomes for antepartum and postpartum women. Demonstrated research, in conjunction with the playbook, illustrates the fact that women of color have higher rates of asthma, obesity, diabetes, hypertension, pregnancy complications, and premature death as compared to non-Hispanic Whites due in part to social and economic factors. In the last two decades, more emphasis has been on non-health factors that affect maternal health and exacerbate disparities (Phillippi & Kantrowitz-Gordon, 2023).

In 2016, Jessica Roach developed a theoretical framework that explored the intersectionality of the different dimensions of institutional racism, structural racism, environmental racism, and the SDOH of black maternal health, including neighborhood characteristics that impact safety, as well as access to care, income, education, housing, and food security (Phillippi & Kantrowitz-Gordon, 2023). Restoring Our Own Through Transformation (ROOTT) is the name of the theoretical framework that Roach developed (Phillippi & Kantrowitz-Gordon, 2023). According to Roach, several key characteristics of the healthcare system in the U.S. have contributed to health disparities: (1) Barriers to care as a direct result of income/finances and a lack of primary care physicians (ex., maternal care deserts) (2) Unhealthy behaviors such as overindulgence in refined carbs, lack of exercise, easy access to drugs and alcohol as a result of the built environment (there is an abundance of liquor stores in low-income neighborhoods) (3) Gaps in educational attainment (Crear-Perry, 2021). Roach surmised that:

"By only focusing on clinical and behavioral risk factors in individuals, we utilize a narrow purview that these risk factors experienced are due to actions of the individual rather than systemic and structural racism causing women to experience poor birth outcomes. In fact, it is the perception of Black families related to constructs such as poverty, education, housing instability, and race as a health risk factor that continues to validate the so-called social determinants of health, rather than address the structural and institutional policies that have created them and therefore, the consequences of their impact" (Roach, n.d.).

Jessica Roach Theoretical Framework: Restoring Our Own Through Transformation (ROOTT)



As the use of technology in the medical landscape continues to grow and evolve rapidly, healthcare professionals, healthcare administrators, policymakers, local leaders, and community advocates must be cognizant of a new dimension of SDOH, Digital Determinants of Health (DDoH). If utilized correctly, technology can effectively bridge the gaps created by SDOH. However, it can also mistakenly be used to widen health disparities instead. This can be the case, especially given the fact that the target population for this intervention is women in urban and rural settings who may already be at a disadvantage due to limited access to care because of location in maternal care deserts, time constraints/restraints, limited/lack of internet access, which is required for most remote patient monitoring devices. Digital Determinants of Health (DDoH) is an umbrella term that encompasses concepts and terms such as technological accessibility, digital literacy,

algorithm bias, and poverty (Public Library of Science (PLOS), 2023). DDoH is broad in scope. However, at its core, DDoH focuses on how technology in healthcare can decrease barriers to care and promote better healthcare service delivery more effectively and efficiently (Public Library of Science (PLOS), 2023).

Since the COVID-19 pandemic, digital technology has become increasingly interwoven within healthcare to complement in-person doctors' visits. Preexisting health disparities can be further exacerbated and reinforced by digital technologies. As discussed, previous work on SODH has illustrated how economic, sociodemographic, and political factors affect people's interactions with their built environment. However, with the rapid evolution of telehealth, telemedicine, and the accompanying technologies of IoMT coupled with the application of remote patient monitoring, which is driving the growth of precision medicine, special consideration must be given to individual's interaction with technology because of SODH and how this interaction influences health outcomes (Chidambaram et al., 2024). If a framework for Digital Health Equity is developed to keep pace with the swift digitization of healthcare, steps can be taken to lessen health disparities instead of making them worse (Richardson et al., 2022).

Maternity Care Desert

Pregnancy-related complications are also high in states with less money marked for maternal health and in rural areas located in maternity care deserts (Sonenberg & Mason, 2023). Maternity care deserts are "counties where there is a lack of maternity resources, where no hospitals or birth centers are offering obstetric care and no obstetric providers" (Tanne, 2023, p. 1). Due to funding constraints, there have been many closures of hospitals and other healthcare facilities offering care and support for pregnant women (Tanne, 2023). Over 400 maternity service delivery facilities closed between 2006 and 2020 due to a human capital shortage and financial solvency (Sonenberg & Mason, 2023, p. 1). In the United States, eleven health systems announced

the closure of their obstetric services, citing staffing challenges and low birth volumes between March and June 2022 (Sonenberg & Mason, 2023, p. 1). For comparison, the U.S. has reported an MMR rate nearly three times the rate in France, the high-income country with the second-highest MMR (Sonenberg & Mason, 2023, p. 2). Except for Canada, the U.S. has fewer maternal care professionals, including obstetricians and midwives, than other high-income countries (Sonenberg & Mason, 2023). The number of midwives in the United States is 4 per 1,000 births vs 25 to 68 midwives per 1000 births in other high-income nations, which also adds to the development of maternal care deserts (Sonenberg & Mason, 2023, p. 2).

According to a report on maternal health published by the March of Dimes, the U.S. has an estimated 5.6 million women living in areas with limited access to obstetrics care (Tanne, 2023, p. 1). A study conducted in Georgia found that of the 1,910,308 reproductive-aged women living in the state, an estimated 150,563 (7.9%) of them live more than 50 miles from critical care obstetric (CCO) services (Meredith et al., 2023, p. 1). Additionally, the study found 104,158 (5.5%) reproductive-aged women live in maternity care deserts, with 38,202 (2.0%) living both more than 50 miles away from CCO services and in a maternity care desert (Meredith et al., 2023, p. 1). High-quality maternity care is vital in decreasing pregnancy complications (March of Dimes, 2022). Teaching academic healthcare centers such as the Medical University of South Carolina, University of Mississippi Medical Center, etc., serve as the only referral source for high-risk pregnancies in rural, smaller states, and many of these expecting mothers must travel several hours for prenatal visits (Jones et al., 2023). Due to geographical and financial limitations, these women experience treatment delays, which further jeopardize their health outcomes (Jones et al., 2023).

Given the fact that more than 60,000 women experience life-threatening maternal morbidity each year in the United States, it is crucial to take steps to mitigate adverse health outcomes (Wang et al., 2023, p. 200). There is an association between where women live (zip

code) and their risk for developing complications antepartum or postpartum (McKoy, 2023). Women living in zip codes that fall within the lowest median household income range or giving birth in hospitals in the South or the Midwest Census regions reported the highest rate of pregnancy-related complications (Ford et al., 2022). Washington D.C., California, Nevada, New Jersey, and New York are the states with the highest rates of severe maternal morbidity (SMM) (McCoy, 2023). State-level complications varied when considering race and ethnicity (McCoy, 2023).

Alaska, New York, and New Jersey had the highest SMM rate among Black Medicaid patients, as compared with New Mexico, North Dakota, and Utah, which had the lowest rate (McCoy, 2023). California, West Virginia, and South Carolina had the highest SMM rates among white Medicaid patients compared to Utah, North Dakota, and Maine, which had the lowest rates (McCoy, 2023). Based on the study published in the journal *Obstetrics & Gynecology*, which analyzed maternal health outcomes among Medicaid insurance recipients, found that SMM rates, or near-miss deaths, varied drastically by both race/ethnicity and state (McCoy, 2023). Given the prevalence of eclampsia, a hypertensive disorder, intervention steps should be taken to decrease the rate of pregnancy complications associated with hypertension. Hypertension is also a contributing factor in the complications related to pregnancy-associated cardiovascular disease (Jones et al., 2023).

Snapshot of Difference in Mortality Between Races and Zip Codes

In addition to race/ethnic differences in maternal health outcomes, several studies have illustrated an age-related racial gap as well (Wang et al., 2023). Maternal mortality disparity widens exponentially starting in the mid to late twenties, which demonstrates the “weathering effect,” a rapid deterioration of overall and reproductive health during childbearing years among black women (Wang et al., 2023, p. 202-203). National data from the CDC shows that Black non-

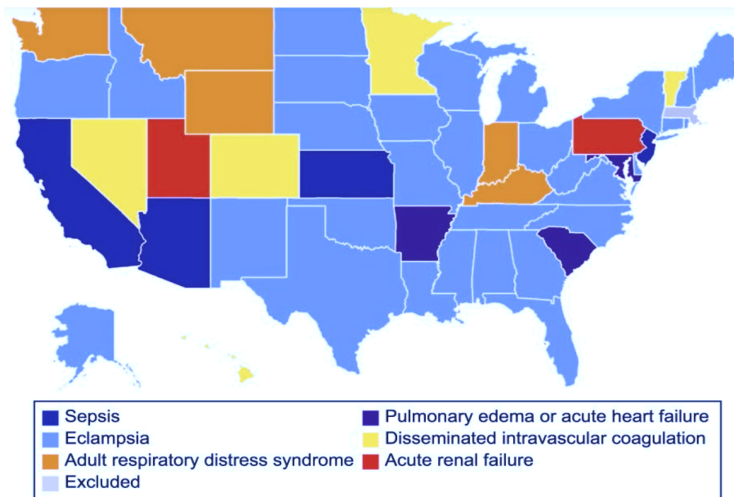
Hispanic women are three times more likely to die from pregnancy-related causes than women of other ethnicities or races (Declercq & Zephyrin, 2020). These differences attribute to variations in medical risk factors and behaviors (Wang et al., 2023). Maternal health inequities are a national issue, and the disparities are magnified and exacerbated in cities such as New York that serve a large Black and Brown population with low socioeconomic standing (Li & Huang, 2019). In New York City, Black Non-Hispanic and American Indian/Pacific Islanders are 6-8 times more likely than Caucasian women to die from pregnancy-related causes and three times more likely to experience severe maternal morbidity than Caucasian women (Katt & Prashar, 2022).

There is also a difference in the causes of pregnancy-related death among various races and ethnicities. For example, maternal deaths, specifically among Black and American Indian/Alaska Native women, are disproportionately due to cardiomyopathy and other chronic medical conditions such as hypertension and diabetes (Wang et al., 2023). The causal relationship for these variances is not completely clear. Still, these differences imply that some of these deaths or complications can be prevented by screening for and the management of preexisting medical conditions (Wang et al., 2023). A diagnosis with a chronic disease, such as hypertension, heart disease, Type II diabetes, lupus, chronic kidney disease, asthma, etc., before pregnancy is correlated with an elevated risk for complications during pregnancy (Sonenberg & Mason, 2023).

Disparities in socioeconomic status and the impact this factor has on the built environment, which also influences access to healthcare across one's lifespan, may contribute to the differences in the type of complication experienced (Wang et al., 2023, p. 202-203). To explore the relationship between the built environment and socioeconomic status and to give some depth context to the discussion on a city level, the focus will use New York City as a brief case study due to its population and because it has one of the poorest counties in the country, the Bronx (Chasen, 2022). Most of these pregnancy-related deaths in New York City occurred among women on Medicaid

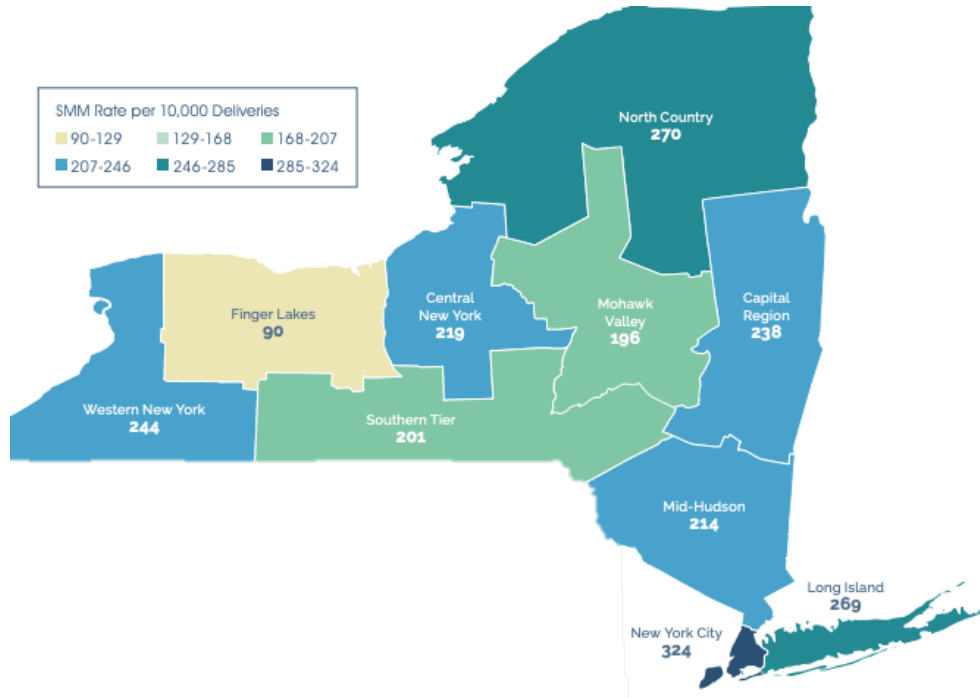
(New York State Department of Health, 2018). Medicaid provides comprehensive health coverage for eligible lower-income people (Rudowitz et al., 2023). Based on extrapolated data from the Vital Statistics, NY State Dept. of Health & Bureau of Vital Statistics NYC DOHMH in 2021, in NYC, the borough with the highest MMR in Brooklyn, with an MMR of 295.6 deaths per 10,000 deliveries, and the Bronx, with an MMR of 255.3 per 10,000 deliveries ("State of maternal mortality and morbidity in the Bronx — The Bronx health link," 2021). A large portion of the Bronx community districts have severe maternal morbidity rates higher than the average NYC rate of 270.2 per 10,000 births ("State of maternal mortality and morbidity in the Bronx — The Bronx health link," 2021). The MMR average in New York State is 20.9 maternal deaths, and the New York City average is 22.9 as compared to the Bronx with an average of 36.2 Maternal deaths per 10,000 births ("State of maternal Mortality & Morbidity in the Bronx" 2021).

**National Snapshot of States Affected by Eclampsia and other Pregnancy-related Complications
(Illustrates the Prevalence of Eclampsia Across the Country)**



Source: Mcoy, 2023, p. 1

Severe Maternal Morbidity Rates by Region of New York State: 2018



Source: Wheelock et al., 2020, p. 8

Data for Image Extrapolated from New York State Health Foundation Analysis 2011-2018 New York Statewide Planning and Research Cooperative System (SPARCS) Data. It represents the Number per 10,000 births. Ex: NYC 324 per 10,000 births

VI. Hypertensive Disorders of Pregnancy (HDP)/Pregnancy-associated Hypertension

Hypertensive Disorders of Pregnancy (HDP) or gestational hypertension is characterized as blood pressure equal to 140/90 mmHg or greater after twenty weeks of pregnancy (Matthew et al., 2023, p. 119). Women with pregnancy-associated hypertension do not have protein in their urine or other kidney problems, and it usually dissipates either closer to delivery or by 20 weeks postpartum (Traub et al., 2024). HDP includes chronic hypertension and gestational hypertension (both preeclampsia and eclampsia) (Henderson et al., 2023). Preeclampsia and eclampsia will be discussed in greater detail in the next section. According to the CDC guidelines, chronic hypertension means that at least 20 weeks before pregnancy, a woman has a documented history of having high blood pressure greater than 120/80 (Centers for Disease Control and Prevention

CDC, 2023). The incidence of hypertension before pregnancy leads to an elevated chance of developing preeclampsia during the second or third trimester or eclampsia postpartum (Traub et al., 2024).

In the U.S., incidences of pregnancy-associated hypertension have increased by 25% over the last two decades and currently affect 5–10% of all pregnancies (Jones et al., 2023, p. 1192). Hypertension accounts for 15% of all maternal deaths in the U.S. because it is the underlying cause of intracerebral hemorrhage (Jones et al., 2023, p. 1192). The condition of untreated high blood pressure is a preventable cause of intracerebral hemorrhages (Wright, 2022). Hypertension is the most prevalent medical condition during pregnancy and is identified as one of the leading causes of perinatal and maternal mortality/morbidity worldwide (Malha et al., 2024). On average, four million women give birth each year in the U.S., and an estimated 240,000 are affected by hypertension (Malha et al., 2024, p. 501). It is a crucial risk factor for stroke (Malha et al., 2024).

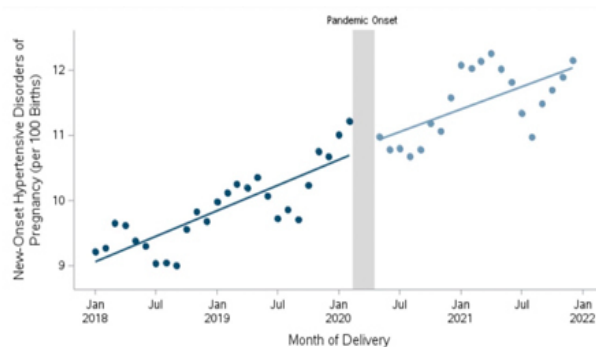
Data has shown that pregnancy-related hypertension disproportionately affects women living in rural areas and minority women (Jones et al., 2023). MMR is higher for minorities and socioeconomically disadvantaged women (Jones et al., 2023). Obesity, diabetes mellitus, and advanced maternal age are risk factors for gestational hypertension (Ford et al., 2022). Among delivery hospitalizations, the prevalence of HDP increased from 13.3% to 15.9% for the period between 2017 and 2019, with women aged 35 to 55 and women who were Black or American Indian and Alaska Native (Santos et al., 2023). An estimated 32% of deaths that occurred during delivery hospitalization had an International Statistical Classification of Diseases and Related Health Problems (ICD) diagnosis code for hypertension (Ford et al., 2022, p. 586).

Recommendations for identifying and monitoring pregnant women with hypertension include measuring blood pressure regularly throughout pregnancy via consistent prenatal visits and self-monitoring. Pregnancy-associated complications and mortality because of preeclampsia,

eclampsia, and other hypertensive disorders are preventable with the implementation of strategies to identify and monitor these women. Timely diagnosis and treatment of hypertension is a requisite for preventing severe complications and mortality (Ford et al., 2022). Early identification of hypertension can help minimize the risk of complications and the need for hospitalizations, which ultimately improve maternal outcomes while reducing morbidity, mortality, and long-term health while decreasing healthcare expenditures. Currently, the best practice for the management of pregnancy-related hypertension is close monitoring via frequent clinic visits or hospitalization until delivery (Ford et al., 2022, p. 1). In most cases, an obstetrician, sometimes in conjunction with a cardiologist, internist, or nephrologist for severe cases, manages most cases of hypertension during pregnancy (Malha et al., 2024).

In the U.S., the cost associated with preeclampsia within the first 12 months after delivery was estimated at over \$ 2 billion (B) (\$1B for mothers and \$1B for newborns) (Bromfield et al., 2023, p. 8). The financial burden of preeclampsia per newborn ranges between \$150K at 26 weeks of gestational age and an estimated \$1.3K at 35 weeks of gestational age (Bromfield et al., 2023, p. 8). Prevention of preeclampsia can help significantly reduce costs after delivery and can ripple over the lifespan of women.

Upward Trend in Incidences of HDP



Source: Everitt et al., 2023 p 1.

Preeclampsia

Preeclampsia is defined as “proteinuric gestational hypertension, characterized by hypertension and organ disorders caused by pregnancy or affected by the current pregnancy” (Hadiyanto et al., 2023, p. 1). It is a multisystemic disorder of pregnancy that affects an estimated 250,000 women in the United States (Roberts et al., 2023, p. 193). It is worth noting that preeclampsia can occur even in the absence of symptoms such as the presence of protein in the urine (proteinuria) or high blood pressure. If the disorder becomes progressively worse and causes seizures, the condition then develops into eclampsia (Hadiyanto et al., 2023). Factors that contribute to preeclampsia include high blood pressure pre-pregnancy, multiple pregnancy, teenage pregnancy, and first pregnancy. Maternity health professionals provide the diagnosis of preeclampsia. Symptoms of preeclampsia include but are not limited to a constant headache that does not subside, seeing spots (flashing lights, floaters, dark spots, or bright spots), blurry vision, changes in eyesight, nausea/vomiting, sudden excessive weight gain, difficulty breathing, pain in the upper abdominal area (Centers for Disease Control and Prevention (CDC), 2023).

Eclampsia

Eclampsia is one of the most severe acute complications of pregnancy, which carries a high morbidity and mortality rate for both the newborn/fetus and the mother (Bartal & Sibai, 2022). Eclampsia is the occurrence of one or “more generalized, tonic-clonic convulsions unrelated to other medical conditions in women with hypertensive disorder of pregnancy” (Bartal & Sibai, 2022, p. S1237). Eclampsia occurs in 0.8% of women with hypertensive disorder (Bartal & Sibai, 2022, p. S1237). On average, eclamptic seizures occur in 2% of cases with preeclampsia, which includes severe features (Bartal & Sibai, 2022, p. S1238). Even though eclampsia is not well understood, it is known that there is a blood-brain barrier disruption with the passage of plasma proteins, ions, and fluid during eclampsia (Bartal & Sibai, 2022).

Acute Maternal Complications in Eclampsia

Complication	% of Cases
Death	0.0 – 1.0
Cerebrovascular Disease	2.0 – 4.0
Heart Failure	3.0 – 9.5
Cardiomyopathy	1.0
Cardiac Arrest	0.5
Aspiration Pneumonia	2.0 – 4.0
Pulmonary Edema	3.0 – 12.0
Placental Abruption	7.0 – 12.0
Acute Renal Failure	3.0 – 8.8
Disseminated Intravascular Coagulation	6.0 – 7.0
Venous Thromboembolism	4.7
Blood Transfusion	24.0

Source: Fishal Bartal & Baha Sibai, 2022., p. S1243

Eclampsia is associated with an even higher risk of maternal morbidity and mortality than preeclampsia. It causes pulmonary edema, placental abruption, acute renal failure, cardiopulmonary arrest, disseminated intravascular coagulation, and aspiration pneumonia. There may be a correlation between a history of epileptic seizures and long-term cardiovascular risk (wang et al., 2023). In addition, there is also the risk of cognitive difficulties related to memory, and some data has suggested that placental growth factor levels in preeclamptic women are superior clinical markers in the prediction of adverse pregnancy outcomes (Bartal & Sibai, 2022). Women with eclampsia reported headaches, visual disturbance, and stomach pain (Bartal & Sibai, 2022). As in the case of preeclampsia, hypertension may be absent in up to 25% of reported cases (Bartal & Sibai, 2022, S1241). Eclampsia typically occurs within 48-72 hours postpartum. (Bartal & Sibai, 2022, S1241-S1242). Some cities, such as NYC, did not start reporting data for eclampsia until 2014 (Xiao et al., 2021, p. 491).

Prevention of preeclampsia and eclampsia includes a low-dose aspirin regimen (dosage ranging from 60-150 mg daily) or other antihypertensive medications for blood pressure, which has been proven to reduce the risk by 10% to 15% (Bartal & Sibai 2022, p. S1244). Early detection of these conditions helps reduce their impact and can be done more cost-effectively via weekly monitoring of women with gestational hypertension or preeclampsia (Bartal & Sibai, 2022, p.

S1244). Several studies have recommended the use of telemedicine and remote patient monitoring via the Internet of Medical Things to help manage adverse health outcomes associated with gestational hypertension.

VII. Technological Solutions for Management of Hypertensive Disorders

Telehealth/Telemedicine

Telemedicine is information communication technology that facilitates the delivery of healthcare services and relays pertinent medical information and education from one location to another regardless of physical distance (Omboni, 2024). The most common use of telemedicine for the management of hypertensive disorders is blood pressure telemonitoring, which enables the remote exchange of blood pressure and other relevant patient information between the patient and healthcare provider via the Internet through video conferencing, text messaging, e-mails, and the integration of Enterprise content management (ECM) (Omboni, 2024).

Telemedicine can be asynchronous (ex., information being re-laid via IoMT devices) and synchronous (ex., video conferencing appointments). Asynchronous and synchronous contact with healthcare providers reduce the need for frequent face-to-face encounters, which is especially important for women who are high-risk hypertensive patients, women who live in maternity deserts or have limited time to attend frequent doctor visits due to other obligations (ex., other children to care for, need to work due to finances or lack of time-off, improved adherence to treatment and quality of life). The use of telemedicine and digital health in patients with difficult-to-treat hypertension increases adherence to medication adherence, and it allows providers to identify issues such as preeclampsia and eclampsia earlier (Omboni, 2024).

Telemedicine uses information telecommunications technologies to support a wide range of medical services related to diagnostic and treatment-related care provided by healthcare professionals (Federal Communications Commission, n.d.). Close monitoring of patients' vitals

after treatment or therapy administration and diagnostic testing are all examples of telemedicine services. Telehealth is like telemedicine, but it includes a broader range of remote healthcare services that extend beyond the doctor-patient relationship (American Academy of Family Practice, 2024). Telemedicine involves services provided by nurses, nurse practitioners, healthcare educators, social workers, pharmacists, chatbots, etc., who instead assist patients with health education, medication adherence, social support, and troubleshooting health issues for patients and their caregivers (Federal Communications Commission, n.d.).

Remote Patient Monitoring/Telemonitoring

Remote patient monitoring (RPM) refers to the ability of healthcare providers and patients to monitor a patient's diagnostics from the comfort of their own home (Health Resources & Services Administration (HRSA), 2023). RPM works synergistically with telehealth because of its interoperability feature. High blood pressure, arrhythmia, diabetes, asthma, sleep apnea, obesity, etc., are a few conditions that can be tracked through RPM in the form of smartwatches, smartphones, tablets, pulse oximeters, blood pressure monitors, blood glucose meters, heart monitors, apnea monitors, etc. (Health Resources & Services Administration (HRSA), 2023). RPM complements telehealth and telemedicine, allowing for continuous patient-centered care. It is a type of telehealth that offers a tangible solution for patient management in rural and other low-health access settings (Agency for Healthcare Research and Quality, 2023). It minimizes interrupting patients' days because in-person visits can be less frequent.

Cellular-enabled blood pressure (BP) devices can more readily transmit the necessary data for patients' BP readings. Consistent patient blood pressure access allows providers to address concerns between visits, leading to better health outcomes. The U.S. Association for the Advancement of Medical Instrumentation (AAMI) has standardized guidelines for measuring machines and sphygmometers (Khalil et al., 2019). Most BP telemonitoring requires patients to

measure their own BP with a validated pregnancy automated machine and then record the results (Khalil et al., 2019). According to the Food and Drug Administration (FDA), validation shows irrefutable proof that a machine or process does what it says while meeting specific requirements (Trail, 2020). Validation is done to ensure that medical devices will work correctly, with no room for harm or error (Trail, 2020).

Some researchers and providers have established a text message-based telemonitoring system that is customized specifically for gestational hypertension, which requires patients to text their BP results, and the telemonitoring system then keeps the results using deep machine learning to provide feedback based on the readings that were received (Khalil et al., 2019). Other healthcare providers and researchers have smartphone applications with Bluetooth capabilities that allow patients to keep a digital record via a cloud-based portal, which providers can access (Khalil et al., 2019, p. 653). The result can then be acted on directly by the patient or healthcare professional, who decides on the best action for BP management.

Ambulatory blood pressure monitoring (ABPM) involves wearing a BP monitor for an extended period of typically 24 hours. ABPM can measure, record, and track blood pressure at selected intervals to provide averages and trends. This type of BP monitoring is frequently used in the general population to diagnose hypertension, and it can distinguish between actual hypertension and white-coat hypertension (elevated blood pressure because of being in the presence of a doctor) (Khalil et al., 2019). One study found that higher ambulatory readings have been associated with microalbuminuria in normotensive women with a previous history of preeclampsia and subclinical echocardiographic changes (Khalil et al., 2019).

Internet of Medical Things (IoMT)

IoMT, which falls under the larger umbrella of the Internet of Things (IoT), includes wearable devices and other remote devices that operate via a sensory network. The concept of IoT

was first introduced in 1999 by Kevin Ashton, a pioneer in sensor technology (Gabbai, 2015). Ashton referred to IoT as a system “embedded with sensors and actuators that communicate with computing systems via an internet of wired or wireless networks—allowing the physical world to be digitally monitored or even controlled” (Revathy & Mangaiyarkkarasi, 2023, p. 1). IoT encompasses a variety of physical devices with an internet connection (Maleh et al., 2023). Home appliances, factory devices, smartwatches, and healthcare devices are examples of IoT. Artificial intelligence (AI) can also be used in IoT applications (Ahsan, 2023).

The AI feature allows programable intelligence to learn, process, and reason information like humans to maximize efficiency and efficacy (Kapoor et al., 2023). This feature is highly beneficial for monitoring the BP of pregnant women. According to researchers Nozari, Szmelter-Jarosz, & Ghahremani, IoT functions as a digital nervous system, and AI functions as the brain of that system. IoT has been described as the apotheosis of the next generation of new and innovative information technologies working synergistically together. The applications of IoTs are vast, and IoT innovations can be found in research, finance, healthcare, etc.

A sub-category of IoT is IoMT, which focuses on applications in the healthcare landscape. IoMT is the Medical Internet of Things (MIoT) (Maleh et al., 2023). IoMT is a system comprised of software applications and intelligent medical devices (Ahsan, 2023). Medical devices, remote medical devices, and wearables (devices that can be worn on the body) are IoMT devices that connect to the internet to gather, share/transmit, and process digital information. IoMT devices facilitate patient data collection in real-time, including, but not limited to, receiving alert notifications and supporting patient monitoring. The information is transmitted directly to smartphones, tablets, computers, or a wearable device like a smartwatch/smart wristband. In addition, some wearables/nearables can transmit information directly to patients’ EHR/EMR and

send real-time alerts to healthcare providers prompting emergency assessments (CareSimple, 2022).

1. Operational Implications of IoMT

Most IoMT have four layers that are necessary for optimal functionality. These layers are:

(1) Perception Layer – the data collection system that includes data sources such as mobile applications, health monitoring devices, and other smart objects. The data sources are infused with sensors that can communicate with smart devices via infrared, GPS, radio frequency identification (RFID), and cameras (Dwivedi et al., 2022). These sensors can detect environmental changes and recognize the location, demographics, magnitude, etc. The detected changes are then converted to digital information and sent via wireless and wired networks transmitting infrastructures that can store and memorize the data.

(2) Gateway Layer – entails connectivity to a wireless personal area, local area, or wide area networks including, but not limited to, Bluetooth, Wi-Fi, radio frequency, or global system for mobile communication (GSM) that do not require connectivity, etc.

(3) The Management Service/Data Storage Layer – provides data/user management and data analysis of large amounts of data in random access memory (RAM) to speed up the ability to make decisions

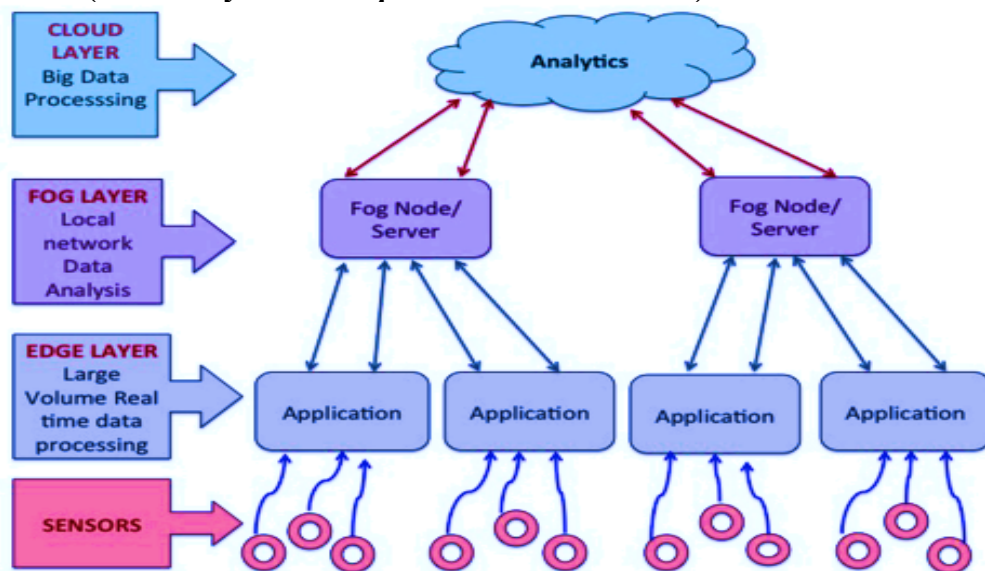
(4) Application/Service Layer – is where the interpretation of data occurs via deep machine learning and the AI can monitor changes and trends in the collected and stored data (Dwivedi et al., 2022). See the following two figures for a snapshot of the various layers. All layers depend on a 5G network and cloud computing technologies. 5G combines IoMT, artificial intelligence, and cloud computing synergistically. The three arms of IoMT are (1) data cloud centers, (2) body sensor networks (3) gateways. IoMT provides better healthcare services to faraway stakeholders. Gateways function similarly to a central hub between the data cloud center and medical devices (Ahsan, 2023).

The Four Layers Involved in the IoMT Framework



Source: Diagram created based on Dwivedi et al., 2022, p. 302-305

Data Processing Layer Stacks of IoMT (*****All Layers Are Dependent on 5G Network**)



Source: Dwivedi et al., 2022, p. 302 -306

2. Financial Implications of IoMT

Several financial implications are linked with implementing an RPM program in any healthcare setting. First, financing the program must be considered. Second, there is the cost associated with hardware for machines and the necessary in-house infrastructure required to

monitor the data. In addition, it will be an added duty for obstetrics personnel. It will be optional to hire new personnel staff specifically for this task. IoMT and A.I. can impact the insurance sector by developing a precise picture of the actual treatment need based on IoMT and AI-supported devices, resulting in personalized health insurance plans, which have the potential to lower insurance premiums required by predicting the likelihood of future claims (Dwivedi et al., 2022). To be covered by Medicaid, wearables and nearables must be clinically validated by the U.S. Food and Drug Administration (U.S. Centers for Medicare and Medicaid Services, 2024).

As mentioned in the previous paragraph, given the structure of Medicaid and other federal-state laws, it must be determined if federal funding can be captured and, if so, how much. For example, the amount of coverage provided varies from state to state and city by city, with some states providing no coverage for self-measured blood pressure devices (American Medical Association, 2023). For comparison, as of March 2023, NYC Medicaid covers \$50.50 for a self-measuring blood pressure cuff for individuals with a clinical diagnosis of uncontrolled high blood pressure (American Medical Association, 2023). However, unlike Maryland, New York City has yet to have a current IoMT program specifically for blood pressure monitoring (Berg, 2023). The IoMT home devices or wearables Medicaid covers require validation by the American Medical Association (AMA) for clinical accuracy (Berg, 2023). A complete listing of AMA can be found online at <https://www.validatebp.org/> (American Medical Association, 2023). Given the limitations due to the lack of Medicaid coverage, another financial consideration is the reimbursement criteria for RPM devices (Berg, 2023).

As outlined in the September 2022 “New York State Medicaid Expansion of RPM for Maternal Care,” RPM usage is permitted during antepartum and postpartum pregnancy but requires adherence to strict guidelines (New York State Department of Health, 2023). Possible funding sources include capturing a small portion of the \$65 million that the Biden Administration

has earmarked to address the maternal health crisis in the country (U.S. Department of Health and Human Services, 2023). Since NYC Health + Hospitals is a non-profit organization, funding sources for the initiative via the National Institute of Health grants can be explored, and city and state funds earmarked for improving population health can be targeted. Politics and political agendas directly affect Medicaid spending, QALY determinations, and the cost-effectiveness of treatments for hypertension and pregnancy disorders.

The average cost of standard in-person blood pressure monitoring per patient is \$420 compared to \$309 per telehealth patient (Niu et al., 2021, p. 7559). It was found that using RPM via IoMT resulted in a cost saving of \$93 per patient (Niu et al., 2021, p. 7555). With an estimated 333,253 pregnant women diagnosed with hypertension per year, the use of telehealth, RPM, and IoMT has the potential to result in significant cost savings in the U.S. (Niu et al., 2021, p. 7565). It has been estimated that the application of telehealth, IoMT, and RPM can result in a \$31 million cost reduction per year (Niu et al., 2021, p. 7560). In conjunction with RPM and IoMT, telehealth has resulted in a 3% decrease in hospital readmission, reducing healthcare expenditure (Niu et al., 2021, p. 7560). It was also found that this intervention resulted in an increase in QALY of 41.76 compared with 41.70 for conventional in-person blood pressure monitoring (Niu et al., 2021, p. 7558). For reference, one quality-adjusted life year (QALY) is the equivalent of 1 year of life in perfect health, which is how years of healthy living are quantified (Andrade, 2024).

3. Patient Experience Perspective of IoMT

IoMT adds to the patient experience because it offers high-quality, cost-effective, and less invasive care management that certainly appeals to patients, healthcare professionals, healthcare executives, and political actors worried about the rising cost of healthcare (Dwivedi et al., 2022). IoMT, medical wearables/nearables, and other RPMs allow patients to achieve quality personalized care in rural areas and other areas lacking specialists. Busy working mothers/women

can receive care remotely, increasing the likelihood of identifying an issue in the early stages. A patient's health status can be monitored anywhere in the world with reliable internet. It is worth noting that a smaller number of RPM devices do not require access to the internet, for example, the Ideal Life Blood Pressure Manager device (Oben et al., 2023). RPM is becoming patient-centered care as more patients face difficulties visiting their physicians for monitoring/testing. These sensors, linked with network processors and microcontrollers, can communicate with central servers to establish alarm systems that can make decisions via algorithms and deep machine learning. Several studies highlighted in the Literature Review (Chapter 2, p. 12 – 40) will focus on the dimension of patient experience perspective of IoMT, RPM, and telehealth.

4. Strengths of IoMT

IoMT facilitates personalized patient-centered care by allowing for remote monitoring. This can save money by decreasing the length of stay and readmission rates, thus increasing the quality of life. IoMT enhances data collection and improves health outcomes through technology optimization in intelligent health systems. It can minimize the disruption to patients' lives and facilitate the continuum of care.

5. Challenges of IoMT implementation

Challenges to IoMT include that it is a complex system to maintain and requires personnel, software, and hardware infrastructures, which need to be improved or are in the infancy of development for public health systems. After countless hours of scanning the research, it was found that IoMT is highly dependent on the internet, and there are privacy concerns and questions about how to keep patient data safe from cyber-attacks and data breaches. Governance on the federal level to ensure HIPAA adherence needs to be improved.

6. Clinical Implications of IoMT

Categories of IoMT include clinical wearables, such as 24-hour blood pressure monitors, blood pressure watches, glucose monitors, personal emergency response wearables, etc. Other devices include point-of-care devices and in-hospital devices. In-house IoMTs send patients' medical data collected at home to healthcare providers via RPM devices, telehealth platforms, and personal emergency response systems (PERS). One example of an in-house IoMT that can be used in managing hypertensive disorders in pregnant women is the remote device CareSimple. CareSimple is a remote blood pressure monitoring system that integrates with patient health records (CareSimple, 2022).

Wearables and Nearables

Wearables are devices that are worn on the body. In contrast, nearables are placed near the body. Wearables work with nearables, such as putting a phone near a Freestyle Libre sensor. Wearables for intelligent healthcare systems collect patient health (Bhatt & Sharma, 2023). Wearables have a variety of embedded sensors that gather and analyze medical data using the various sensors, allowing users to continue their daily lives with minimal interruption (Khozouie & Malekhoseini, 2023). Smartphones, smartwatches, and fitness bands are examples of wearable IoMT. Smartphones and tablets can also be categorized as nearables. These devices have applications that are loaded onto them to allow for continuous monitoring of pregnancy-associated hypertensive conditions. Wearable devices make it easier to continuously obtain vital signs such as insulin levels, blood pressure, or heart rate over time (Epstein & McCoy, 2023).

A smartwatch that is clinically validated wearable is the Omron HeartGuidie device, which is a Class III medical device (Smith et al., 2023). The Apple smartwatch is also a wearable that has received FDA approval. However, it is not a clinically validated device. It requires other devices that connect to the smartwatch to provide more accurate readings because it cannot

measure BP alone (Roberts, 2024). The Apple Watch is interoperable with other blood pressure devices and is instead considered a Class II medical device (Song, 2023). The following is a list of different categories of validated devices:

1. ***Class I*** devices are low-risk devices. Examples include bandages, handheld surgical instruments, and nonelectric wheelchairs.
2. ***Class II*** devices are intermediate-risk devices. Examples include computed tomography (CT) scanners or infusion pumps for intravenous medications.
3. ***Class III*** devices are high-risk devices that are very important to health or sustaining life. Examples include pacemakers and deep-brain stimulators” (Jin, 2014).

Wearable devices are a cost-effective, feasible, and scalable way to collect patient vitals with low participant burden (Epstein & McCoy, 2023). Wearables facilitate early detection of potential health complications and provide mothers-to-be with greater peace of mind throughout prenatal and postnatal care (Revathy & Mangaiyarkkarasi, 2023). As telemedicine and telehealth visits have become more prevalent in pregnancy care, wearables’ and nearables’ role in health maintenance will continue to grow. Women in maternity deserts can benefit from wearable IoMT that facilitates remote patient monitoring (DeNicola et al., 2020). Artificial intelligence (AI) is another technological advance transforming pregnancy care. As the use of artificial intelligence continues to evolve rapidly and the field of precision medicine continues to grow, the ability to analyze vast quantities of data will give healthcare professionals new perspectives on personalized patient treatment plans (Revathy & Mangaiyarkkarasi, 2023). AI and deep machine learning allow for the maximization of IoMT. By increasing the number of blood pressure measurements under different conditions, wearable monitors allow for a more accurate and holistic view of patients’ health. The field of nanotechnology continues to grow as well and will enhance IoMT.

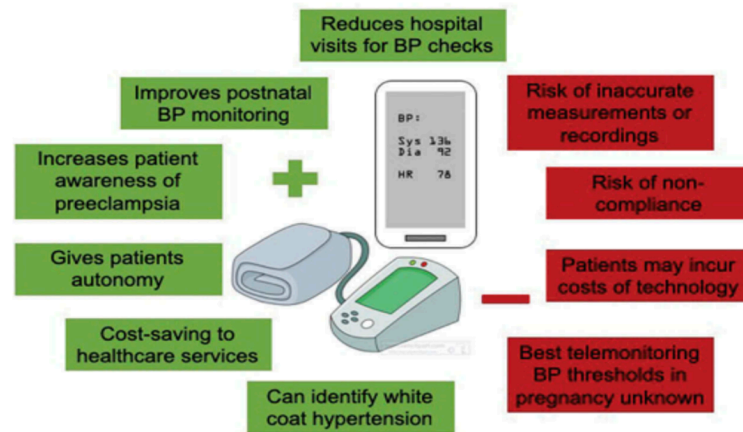
The Alignment of RPM, IoMT Filling the Gap in Care for Gestational Hypertension

The primary diagnosis of preeclampsia and eclampsia are based entirely on urine tests and blood pressure for proteinuria, which can be done remotely (Hadiyanto et al., 2023). Early

diagnosis and treatment of high blood pressure are necessary mitigation steps to reducing maternal complications. Advanced computing research such as the Internet of Medical Things (IoMT) and Machine learning (ML) are now technological tools that can be used to manage better and, hopefully, one day solve the health problem of pregnancy-associated hypertension (Hadiyanto et al., 2023). Machine learning algorithms are currently in the infancy of being used to assist healthcare providers in managing preeclampsia and eclampsia. Developments in IoMT combined with technologies such as artificial intelligence, machine learning, and cloud computing allow these technologies to be integrated and used holistically to treat hypertensive pregnancy disorders. These technologies improve diagnoses, disease management, and progression (Hadiyanto et al., 2023). Providers can now apply patient-centered care and precision to a larger population.

RPM is an excellent tool for monitoring the physiological vital signs of pregnant patients. The diagnosis of preeclampsia can be dramatically improved with the use of e-health interventions such as RPM and IoMT. Information technology can support the decrease in prevalence or the prevention of the disease and the development of the associated complications (Hadiyanto et al., 2023). As mentioned by many experts, early detection and management of hypertension in pregnancy is imperative to improving health outcomes and decreasing healthcare expenditure because of pregnancy-associated hypertension (Hadiyanto et al., 2023)

Advantages and Disadvantages of Telemonitoring Based



Source: Khalil, 2019, p. 659

According to the Kaiser Family Foundation (KFF) Peterson-KFF Health System Tracker, the cost of healthcare expenditures has been increasing exponentially over the last four decades (Telesford et al., 2023). Any corrective measures that can be taken to cut the \$32.3B price tag associated with maternal mortality and morbidity will be value-added (Telesford et al., 2023). Cities throughout the country have taken steps to improve MMR and morbidity. For example, the New York City Council passed a package of bills in 2021-2022 to address systemic inequities that affect women by expanding maternal health services for Blacks, Indigenous People, and Hispanics (NYC City Council 2022). At the request of the Bronx Borough President, Vanessa L. Gibson, Public Advocate Jumaane Williams led the efforts of the “Introduction Law 86” and the annual Maternal Mortality and Morbidity Report, which is mandated per Local Law 188 of 2018 (The New City Council, 2018). Introduction Law 86 requires a city agency designated by the New York City mayor to deliver public education on NYC’s standards of “respectful care at birth” through community outreach and facilitate the “Maternal Bill of Rights” (The New York City Council, 2022). It resulted from Local Law 188 of 2018, which requires the tracking and publishing maternal health data (The New York City Council, 2018).

As a result of the exponential growth in the usage of telemedicine during the COVID-19 pandemic, telemedicine has proven to be an indispensable tool to complement patient-centered healthcare (Doraiswamy et al., 2020). A review of forty-one studies showed that the application of telehealth strategies for delivering more effective maternal healthcare to mitigate complications has garnered mixed results (Parsons & Althuis, 2022). One review identified three studies that focused on hypertension and the utilization of telehealth (Parsons & Althuis, 2022). This paper is a scoping review to assess maternal health disparities and determine if the utilization of digital technology can complement in-person maternal healthcare delivery to decrease the complications of pregnancy-related hypertensive disorders, with particular focus placed on preeclampsia and eclampsia. The overarching objective is to determine if remote patient monitoring (RPM), including the digital intervention of telehealth and IoMT, can effectively manage maternal patients to limit complications and reduce MMR.

Telehealth is an emerging field of study, and the results of applying RPM wearables and nearables of IoMT to maternal health management have been mixed (Dwivedi et al., 2021). Therefore, further analysis and synthesis of existing studies are required to explore this relationship. Stakeholders in RPM include Centers for Medicare and Medicaid Services, Congress, healthcare administrators, obstetrics healthcare professionals, pregnant women, partners/spouses, women who have recently given birth, and their families and friends. The list of stakeholders has a vested interest (personal, professional, or financial) in the effective management of hypertension antepartum and postpartum. Thus, the research question is:

What is the effect of telehealth and the Internet of Medical Things (IoMT) on outcomes when used in at-risk pregnancies: A Scoping Review of the components of remote maternal monitoring for hypertensive disorders that can successfully be done via digital technology?

VIII. Studies on the Utilization of Wearables and Nearables in the Management of Pregnancy-associated Hypertension Across Various Dimensions

Of the 16,669 articles screened for inclusion in this literature, only 21 studies fit the inclusion criteria for this scoping review. The studies varied in methodology and scope, ranging from non-randomized cohort studies, feasibility studies, mixed-method pilots, comparative studies, and prospective studies to scoping reviews and a systematic review. One multivariate retrospective cohort study found that RPM for preeclampsia did not decrease readmission rates (Bronner et al., 2023). However, the study did find that women were more likely to be re-admitted to the hospital for preeclampsia with severe features than the preintervention patient group (Bronner et al., 2023). This finding implies that there is an increased need to monitor women with preeclampsia post-discharge (Bronner et al., 2023). Five studies found that the intervention of telehealth (RPM with IoMT) improved patient outcomes (Results Section p. 51 – 62).

One recent study published by Forna et al. found a statistically significant correlation between the intervention RPM program and better postpartum BP control (Forna et al., 2024). These women also experienced improved linkage to clinical care postpartum compared to historical controls of in-person visits, which may explain why their blood pressure was better controlled (Forna et al., 2024). Another study found that the show rates for telehealth visits were higher than traditional in-person visits, which may also contribute to improved patient outcomes and better linkage to care (Sanghavi et al., 2022). A systematic study of forty-seven studies by DeNicola et al. found that the literature also illustrated that telehealth interventions were correlated with better maternal health outcomes for women diagnosed with gestational hypertension (DeNicola et al., 2020). DeNicola and her team identified one study where there was a reduction in preeclampsia among women with gestational hypertension (DeNicola et al., 2020).

Four of the studies focused on the feasibility of the cost dimension of RPM. One study conducted an expansive investigation into this aspect. The study found using RMP via IoMT to be cost-effective in managing postpartum hypertensive disorders (Niu et al., 2021). A two-way sensitivity analysis was conducted from a hospital's perspective, with data from a non-randomized controlled trial comparing RMP to standard outpatient blood pressure monitoring. Women with a diagnosis of HDP were given a blood pressure monitor, Bluetooth tablet, and a scale to enable them to submit their vitals daily. The outcomes for these women were compared with those treated with the standard in-person protocol. It was found that telehealth RPM significantly reduced postpartum readmissions (Niu et al., 2021). The study also found higher quality-adjusted life years and concluded that telehealth resulted in cost savings and was cost-effective. On average, the cost per patient for telehealth was \$309, compared with \$420 per patient using standard in-person monitoring (Niu et al., 2021, p. 7556). Telehealth was also found to reduce the cost associated with hospital readmission (Niu et al., 2021, p. 7556). The average cost for women who had to be hospitalized was \$10,999, and the average admission cost was \$14,401 for non-RPM. The readmission rate was cut by 3.0% or higher with standard monitoring (Niu et al., 2021, p. 7559). The researchers found that the Incremental Cost-Effectiveness Ratio (ICER) was less than zero, which is better for reimbursements. ICER is the difference in costs between two strategies compared to the difference in effectiveness, and it is expressed as a ratio that quantifies the trade-offs between resources spent and patient outcomes gained (Kitschen et al., 2022).

Several studies explored health equity (Results Section p. 51 – 62). Arkerson et al. found that RPM promoted health equity and that there was a statistical difference ($p < 0.001$) for blood pressure ascertainment within ten days post-discharge for women with HDP, which has the potential to promote more significant health equity (Arkerson et al., 2023, p. 856). RPM patients were discovered to have a higher rate of postpartum blood pressure than with in-office surveillance

(Arkerson et al., 2023, p. 855). RPM helped identify more patients at risk for postpartum complications than traditional surveillance, which could provide linkage to the necessary care sooner. Another retrospective cohort study found that telehealth visits improve the attendance of post-hypertension visits among non-Hispanic Black women, thereby improving health equity and decreasing health disparities (Khosla et al., 2022). Lee and Brayboy found that low-cost IoMT technologies should be further developed and expanded to include wearables and nearables to increase access to prenatal screening, which is lower cost. Lee and Brayboy found that the completion rate for in-person clinic visits was 32%, as compared with telehealth visits, and the findings were statistically significant ($p < 0.001$) (Lee & Brayboy, 2022, p. 394).

An observational study by Hacker et al. found that RPM programs were feasible as they can be integrated easily into current IT structures of healthcare institutions and can be used to assist women living in maternal care deserts (Hacker et al., 2022). Hacker et al., Sarhaddi et al., Khanijahani et al., and Muger et al. focused on the interoperability of IoMT with current healthcare structures (Hacker et al. and Khanijahani et al. 2022). Five other studies found that RMP via IoMT is feasible and scalable. Hauspurg et al. evaluated the feasibility, acceptability, and compliance of an RPM protocol for managing HDP and found that patients were compliant with visits and reported high satisfaction with the care (Hauspurg et al., 2019). In the study, RPM was done via IoMT in conjunction with a nurse who monitored the readings from the IoMT 24 hours per day, seven days per week. Hoppe and her team also found that telehealth with remote blood pressure monitoring was feasible, and 86% of patients reported high satisfaction with RPM (Hoppe et al., 2019, p. 1).

One study by Jones et al. gauged the satisfaction and feasibility of using an integrated model of cellular-enabled RPM devices for blood pressure to manage HDP. The information technology was supported by a 24/7 nurse call center (Jones et al., 2023). If readings were outside

the set range, a nurse would call the patient to triage and provide further instructions. Jones et al. did a mixed-method pilot, including survey administration and semi-structured interviews. The study found that patients perceived RPM as convenient and that the RPM devices were easy to use and wear. Patients reported they received better care and expressed comfort in knowing that their vitals were being monitored remotely by a healthcare professional. Participants only reported concerns about wearing the device and perceiving that it gave higher readings (Jones et al., 2023). Participants were given a cellular-enabled BodyTrace kit. These kits included a BP cuff and weight scale for remote use. While most RPM devices require Bluetooth or Wi-Fi, the BodyTrace device does not. It uses cell towers to transmit participants' BP readings directly to the associated website via built-in cellular transmission capabilities that their healthcare providers can access in real-time (Jones et al., 2023, p. 1192). The device created greater ease and access for study participants (Jones et al., 2023, p. 1192). To date, validation studies on the use of BodyTrace have not been done (Jones et al., 2023).

After scanning the literature in the databases identified in this paper for the last two years, four scoping reviews and one systematic review were determined to specifically focus on the United States and the use of telehealth intervention of RPM via IOMT for the management of pregnancy-related hypertension (Results, p. 51 – 62). Most of these reviews found favorable results that telehealth interventions are a promising tool for managing HDP, but more reviews are required to make the body of literature more robust. One study by Joseph et al. found that the current method of relying on the pregnancy checkbox often led to the misclassification of maternal deaths (Joseph et al., 2024). However, when maternal deaths are identified by requiring the mention of pregnancy, among other causes of death, it shows lower and more stable maternal mortality rates. Moreover, it also results in a decline in maternal deaths caused by direct obstetrical factors (Joseph et al., 2024). It is worth knowing that Joseph et al.'s study was the only one that found that the overall

increase in maternal deaths was an artifact. Most of the data and literature confirms that the U.S. is experiencing a maternal health crisis. There is a definite gap in the literature. More large-scale reviews and, specifically, more pilots to explore this intervention's impact on outcomes, cost, and patient satisfaction are necessary to grasp its scope and applications fully.

Chapter 3

Methodology

IX. Scoping Review

In 2005, Hilary Arksey and Lisa O'Malley introduced the world to the concept/framework of a scoping review in their seminal work, *Scoping Studies: Towards a Mythological Framework* (Arksey & O'Malley, 2005). Since its publication, their article has been viewed over 150,000 times and cited over 12,000 times over the years (Taylor & Francis Online, 2023). To assist with the scoping review process, the Arksey and O'Malley framework highlights the rationale and provides methodological recommendations for conducting a valid and thorough scoping review. Components of a scoping review include (1) Formulating a research question, (2) Examining the current state of research on the topic, (3) Conducting a Needs Assessment for and determining the feasibility of undertaking a more in-depth systematic review, (4) Select relevant studies to synthesize. Then, organize research findings to share clearly and compellingly (5) Highlight any critical gaps in the literature (Westphaln et al., 2021).

At its core, a scoping review categorizes knowledge that includes merging and streamlining information via a systematic approach to identify and synthesize an emerging or existing body of literature on a particular subject matter (Mak & Thomas, 2022). In other words, scoping reviews serve as a preliminary or an initial assessment of the breadth and magnitude of currently available research literature on a topic. The primary motivation for conducting a scoping review is to map the body of work and explore the nature of the literature on a specific topic (Westphaln et al., 2021).

Mapping the range and extent of literature allows for a deeper understanding of an issue. It facilitates developing best practices, which also, in contrast, helps to readily identify gaps in the body of literature on the topic (Westphaln et al., 2021). In addition to identifying gaps, this review helps clarify definitions. A scoping review is more applicable than a comprehensive systemic review to supplement emerging domains in similar literature streams (Touro College, 2023). While

valuable, scoping reviews can be considered helpful precursors to systematic reviews (Munn et al., 2018). A scoping review map and a systematic review collate the best available research on a specific topic (Weill Cornell Medicine, 2023). The Samuel J. Wood Library at Weill Cornell site, last updated in 2023, sums up the differences best:

“A scoping review seeks to present an overview of a potentially large and diverse body of literature pertaining to a broad topic. A systematic review attempts to collate empirical evidence from a relatively smaller number of studies pertaining to a focused research question. Scoping reviews aim to provide a descriptive overview of the reviewed material without critically appraising individual studies or synthesizing evidence from different studies (no risk of bias or meta-analysis/statistical pooling is performed). In contrast, systematic reviews aim to provide a synthesis of evidence from studies assessed for risk of bias.”

Scoping reviews can be found utilizing several databases, including Cochrane Library, EMBASE, PubMed, Google Scholar, etc. Scoping reviews can be done on various topics, such as maternal health. After exploring the multiple databases, several reviews were found on the topic of outcomes for at-risk pregnant women. Though small, there have been scoping reviews on the digital interventions of telehealth, including the usage of the Internet of Medical Things (IoMT) in the management of the health of pregnant women. IoMT is an emerging technology that facilitates individualized remote e-health services that aim to improve patient quality of life, improve patient satisfaction, and decrease health expenditures (Atmojo et al., 2020). IoMT and other digital devices can leverage maternal care meaningfully (Lawry, 2023). Specifically, monitoring at-risk pregnant women for developing a hypertensive disorder is a possible step to help address the issues in maternal health. IoMT, which falls under the larger umbrella of the Internet of Things (IoT) and includes wearable devices and other remote devices that operate via a sensor network, is a tool that can be utilized to mitigate adverse maternal health outcomes.

Eligibility Criteria for Inclusion Studies in Scoping Review

This review includes articles that involve the utilization of RPM to support early detection and management of pregnancy-related hypertensive disorders, as well as studies that were conducted postpartum. The reviews focused on studies written in English. They were conducted in the United States, with particular attention placed on studies that include the digital intervention of IoMT, remote patient monitoring, and telehealth (See Chapter 2, Section 7 for the distinctions between these terms). The goal was to include original and primary research studies in observational studies, non-randomized cohort studies, experimental studies, quasi-experimental studies (differences-in-differences (D-In-D)), and study protocols. Articles published between January 2017 and October 2023 were included since this is the period before, during, and after the COVID-19 pandemic.

Research Methods

An extensive scoping review was done, including an exploration of information from the Cochrane Database of Systematic Reviews (CDSR) and an investigation of other relevant studies to gain insight into the following research question: *What is the effect of telehealth and the Internet of Medical Things (IoMT) on outcomes when used in at-risk pregnancies: A Scoping Review of the components of remote maternal monitoring for hypertensive disorders that can successfully be done via digital technology?* The CDSR is the leading database for systematic reviews in healthcare, and it offers a vast resource of high-quality information on the effectiveness of various healthcare interventions (Cochrane Library, 2023).

A manual internet-based search of Cochran Library, PubMed, Wiley Online Library, Embase, and Google Scholar for English language publications using relevant terms was conducted to capture peer-reviewed literature on the subject. Search terms will include hypertensive disorders and remote patient monitoring, preeclampsia and telehealth in the United

States, preeclampsia and telehealth and other remote digital monitoring technologies in the U.S., postpartum preeclampsia in telehealth, pregnancy-related hypertension, pregnancy-related cardiovascular hypertension, and hypertensive disorders of pregnancy. Search terms are listed in the Abstract. The search strategy was developed with the assistance of professors specializing in healthcare research at the Medical University of South Carolina, and a medical doctor whose specialty is maternal health was consulted. Another reviewer was considered and included to add rigor to the review. The PRISMA approach was used to review current literature in addition to a manual search. PRISMA emphasizes the reporting of reviews and evaluating the effects of interventions. For the context of this paper, PRISMA was utilized to verify the manual findings. Covidence, a web-based tool for reviews and meta-analyses, was used with PRISMA to streamline the inputs.

For the manual search, articles identified were screened and categorized based on the type of study (cohort, correlational, longitudinal, inductive, etc.), intervention, and results to conduct a deeper analysis. Titles, abstracts, and content related to IoMT in healthcare were screened, and duplicate articles were excluded. Relevant references from selected articles were considered as well. The Critical Appraisal Skills Programme (CASP) checklists were used as a tool during the manual article screening process. There were four key components of interest in the articles: target population (pregnant women), health condition (pregnancy-related hypertensive disorders, preeclampsia/postpartum preeclampsia, eclampsia, postpartum eclampsia, and hypertensive disorders of pregnancy), location (external to healthcare facilities in the United States), and the intervention digital remote patient monitoring technologies (telehealth/IoMT). The information was then reviewed to identify overarching themes.

The field can benefit from more reviews being conducted on the topic. After analyzing the literature on the subject, the intervention of telehealth and the accompanying IoMT have been

mixed (Gajarawala & Pelkowski, 2021). More significant questions have been raised about the well-documented barriers to access to stable internet or privacy for the utilization of telehealth, which then encompasses the issues surrounding disparities and social determinants of health (Bailey et al., 2021). Problems have arisen about using telehealth in pregnancy in general for both at-risk and non-risk pregnancies. A more in-depth scoping review will further explore the literature on issues of using telehealth and IoMT for both at-risk and non-at-risk pregnant women.

X. Validity

A second reviewer was enlisted to increase internal validity and limit bias. In addition to manual searches, the PRISMA approach was applied in the scoping review, including using Covidence to improve the review's robustness.

XI. Strengths and Limitations

The strength of a scoping review is that it collates existing and evolving bodies of literature and allows for synthesis to identify gaps in the literature and areas for future development and empirical work (Mak & Thomas, 2022). Scoping reviews are easily replicable, and the methods are transparent (Mak & Thomas, 2022). However, there are limitations to the scoping review. For example, selecting search terms for a comprehensive search strategy, especially for emerging literature, can be complex, with varying terms for the same topic. The narrow range of included studies (only in the U.S.) may have impacted the external validity. Scoping reviews are labor-intensive and time-consuming and require multiple reviewers. This scoping review had only two reviewers, which may adversely affect the rigor of the review work. Finally, researchers may interject bias and only want to include papers that support their position.

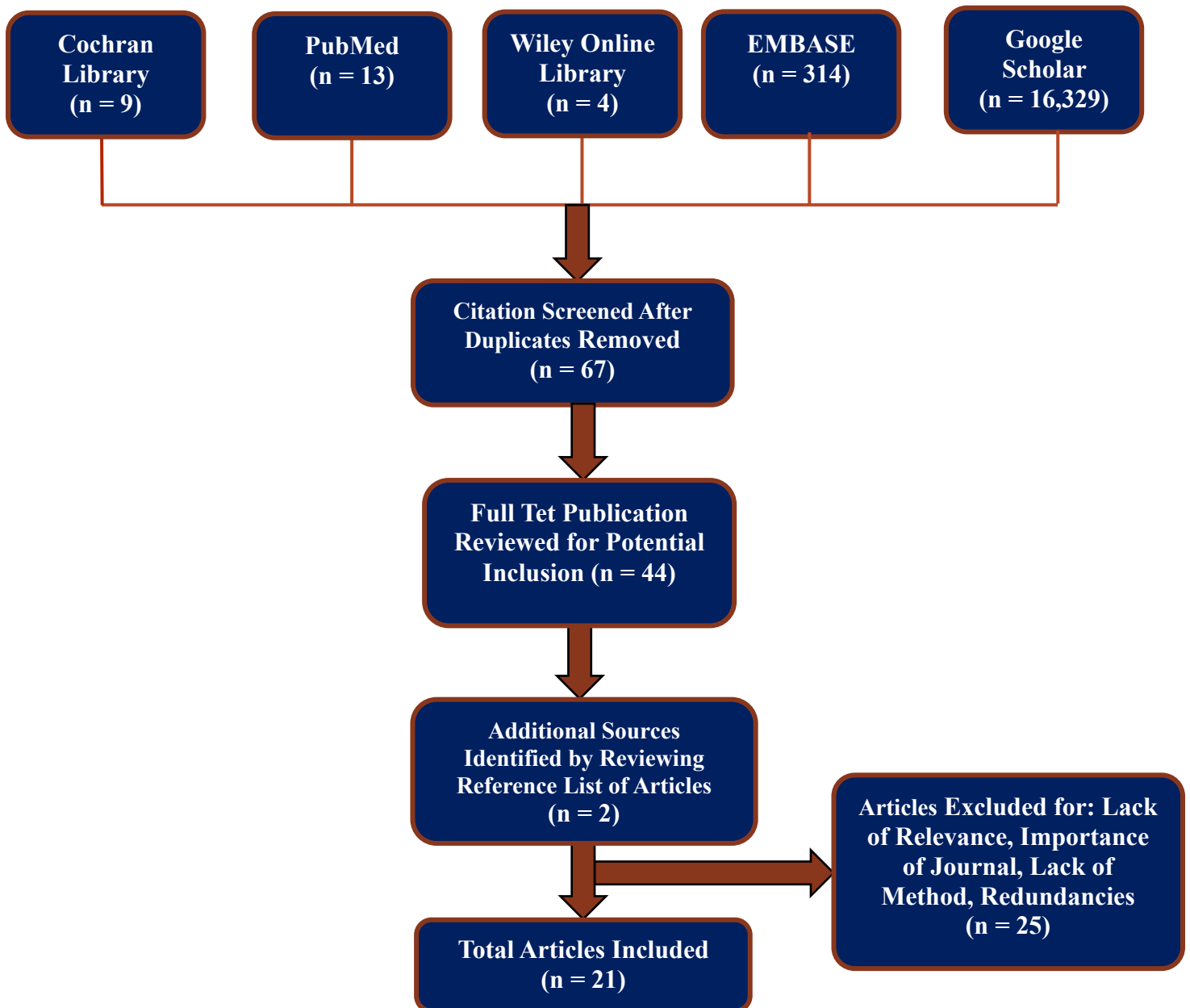
Chapter 4

Results

After reviewing the body of literature for the last two years, only a few studies have been identified regarding the use of digital interventions in the management of pregnancy-related hypertensive disorders. Even fewer reviews have been identified on the utilization of telehealth and remote device monitoring of women antepartum and postpartum for hypertensive disorders in the United States. The literature review yielded only four comprehensive reviews on the subject. Three scoping reviews and one systematic review were identified.

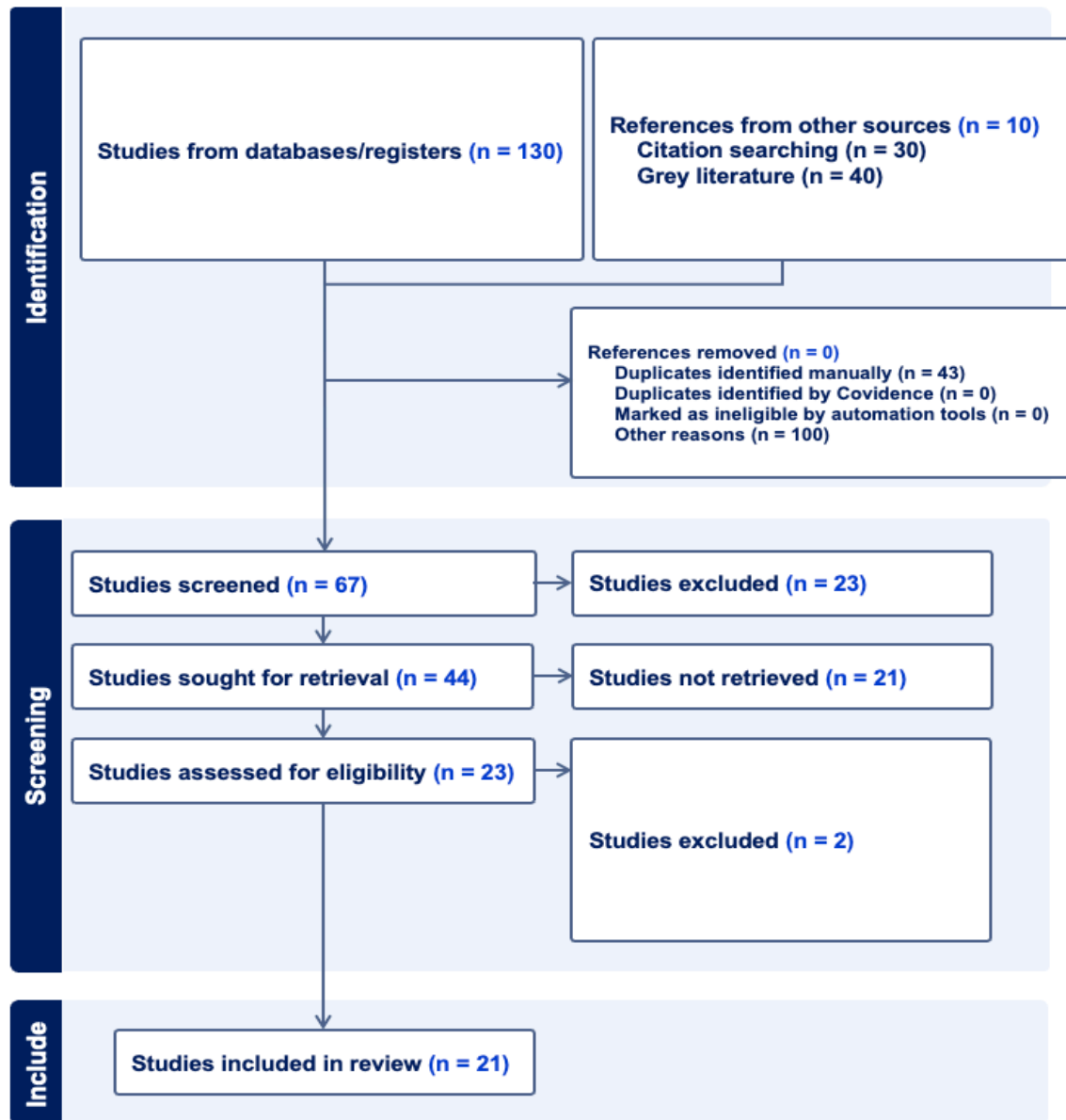
Flow Chart Utilized During the Manual Selection Articles Process

*(***PRISMA & Covidence were used to compare and Capture More Articles. Diagram on Next Page)*



PRISMA Flow Diagram for Studies, Which Includes Searches of Databases, Registers, and other Sources with Second Reviewer Input

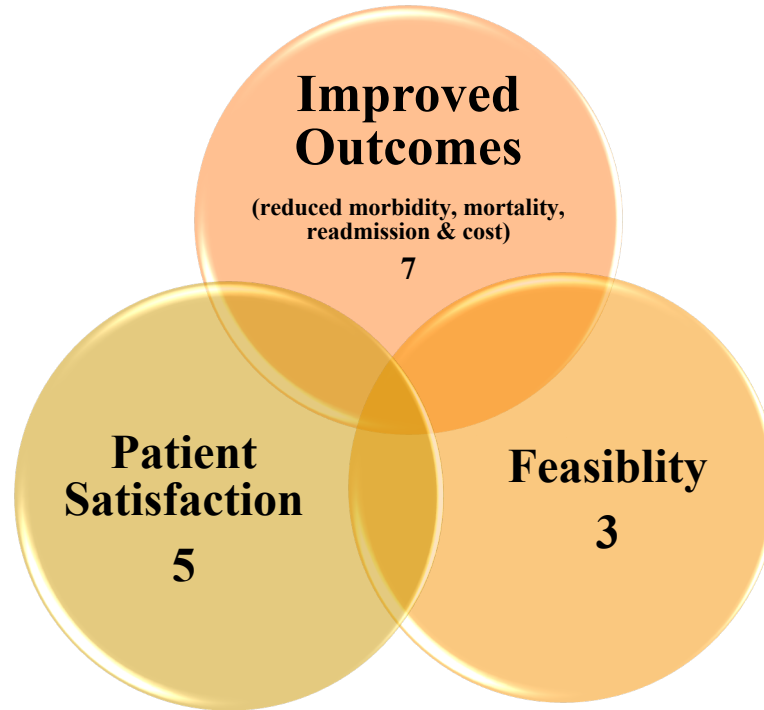
Improving Outcomes for Pregnancy-related Hypertension - PRISMA



Covidence is a cloud-based tool to streamline the process of reviewing titles and abstracts for large-scale literature reviews enabling you to: Collaboratively manage an unlimited number of references and PDFs (Mayo Clinic Library 2024)

Included studies ongoing (n = 0)
Studies awaiting classification (n = 0)

Three Overarching Themes Emerged from the Studies that Were Used for Literature Review (Four Articles Had the Added Component of Equity)



The Literature Review Found:

List of Reviews of Maternal Health and the Intervention of RPM via Telehealth & IoMT in the United States

Date	Title	Author(s)	Database
03/2024	<i>Improving obstetric and perinatal outcomes with a remote patient monitoring program for hypertension in a large integrated care system</i>	Forna et. al	Elsevier
<p><u>Summary</u> A retrospective cohort study was done to evaluate differences in obstetric and perinatal outcomes using data from EMRs. Women enrolled in the study gave birth between 11/1/2019 to 10/31/2021.</p> <p><u>Results</u> 1,030 patients were enrolled in RPM HDP and 937 were matched to historical controls. 517 (50.2 %) were enrolled in the antepartum period & 513 (49.8 %) were enrolled postpartum. The study found patients in the RPM HDP cohort were more likely to have had a post-hospital discharge BP measured within the first 20 days after delivery. The number was found to be statistically significant (RR 1.56, 95 % CI: 1.47–1.65: p < 0.01). A correlation was found between a remote hypertension monitoring program for patients & improved BP monitoring, better postpartum BP control, and improved linkages to clinician care after delivery, when compared to historical controls.</p>			

1/2024	<i>Assessment of pregnancy-related telehealth interventions in the United States: A 10-year scoping review</i>	McCoy et al.	Google Scholar Search (Telemedicine and e-Health Online Publication)
<p><u>Summary</u> A scoping review of pregnancy-related telehealth studies was done to understand the current state of pregnancy-related telehealth interventions in high-risk pregnancies. The Preferred Reporting Items for Systematic Reviews (PRISMA) and Meta-Analyses framework guided the review. Seventy articles were included in the review, of which 53 (75.7%) studies included a pregnant population and 17 (24.3%) studies focused specifically on an urban and/or rural population.</p> <p><u>Results</u> Though limited, there is a growing trend in articles published on the use of telehealth to manage pregnancy-related complications. Expanding literature on pregnancy-related telehealth interventions, but more research is still needed to better understand outcomes, especially relating to patient satisfaction, health disparities, and cost-benefit</p>			
9/2023	<i>Remote Monitoring compared with in-office surveillance of blood pressure in patients w/ pregnancy-related hypertension: A randomized controlled Trial</i>	Arkerson et al.	PubMed
<p><u>Summary of Study</u> It compared the rate of BP findings within 10 days postpartum discharge among women w/ hypertensive disorders of pregnancy (HDP) via a multisite randomized-controlled trial. Women were randomly assigned to either an in-office blood pressure check or remote monitoring through a web-enabled smartphone platform. Primary outcome was the rate of any BP findings within 10 days after discharge. Secondary outcomes included rates of initiation of antihypertensive medication, additional office or triage visits for hypertension, and readmission.</p> <p><u>Results</u> Patients with remote monitoring had higher rates of postpartum blood pressure ascertainment compared with in-office surveillance. RPM can increase postpartum BP findings within 10 days of discharge for women with HDP and has the potential to promote health equity.</p>			
05/2023	<i>Validation of a Remote Monitoring Blood Pressure Device in Pregnancy</i>	Oben et al.	PubMed
<p><u>Summary of Study</u> The study focused on validating the Ideal Life Blood Pressure Manager device, which measures blood pressure (BP) in pregnant women via biosensors and automatically transmits results to the medical record of patients independent of internet access. Pregnant women were enrolled into three different subgroups as per guidelines of the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization protocol. The normotensive, aka normal blood pressure group (systolic blood pressure (SBP) < 140 and diastolic blood pressure (DBP) < 90),</p>			

	<p>hypertensive without proteinuria (no protein in urine) (SBP \geq 140 or DBP \geq 90), and preeclampsia (SBP \geq 140 or DBP \geq 90 with proteinuria). Two specially trained research staff used a mercury sphygmomanometer to validate the Ideal Life Blood Pressure Manager device, alternating sphygmomanometer, and device readings for a total of 9 measurements.</p> <p>Results: The study found that the BP device tended to overestimate BP, but most readings had a difference of less than 10 mm Hg. The Ideal Life BP Manager met the validity criteria recognized globally. Most of the paired readings had < 10 mm Hg differences across the averaged paired readings. The study found that the Ideal Life BP Manager met the internationally recognized validity criteria</p>		
04/2023	<p><i>Effectiveness of extended postpartum inpatient monitoring for hypertensive disorders of pregnancy to reduce the risk of readmission for preeclampsia with severe features</i></p>	Bronner et al.	Google Scholar Search (NIH Library of Medicine)
	<p>Summary Bronner et al. conducted a retrospective cohort study to analyze the impact of extended inpatient monitoring of postpartum hypertension on singleton pregnancies with hypertensive disorders. The participants included women who delivered one year before and after the monitoring implementation.</p> <p>Results A multivariable analysis involving 567 patients with a previous diagnosis of an HDP was done. The study aimed to determine if extended monitoring with a strict blood pressure goal could decrease readmissions for preeclampsia with severe features in these patients. However, the results showed that extended monitoring did not significantly reduce readmissions for preeclampsia with severe features. Patients in the study group were more likely to be readmitted for this condition than patients in the preintervention group. This study adds to our understanding of the challenges in managing hypertensive disorders of pregnancy and highlights the need for further research to identify effective interventions for preventing readmissions in these patients.</p>		
02/2023	<p><i>Use of cellular-enabled remote patient monitoring device for hypertension management in pregnant women: A feasibility study</i></p>	Jones et al.	Google Scholar Search (Springer)
	<p>Summary Jones et al. conducted a mixed-method pilot study et al. to gauge the satisfaction and feasibility of using an integrated model of cellular-enabled RPM devices for tracking blood pressure in managing HDP supported by a 24/7 nurse call center.</p> <p>Results The study explored participants perceived benefits from using the IoMT device. The women experienced increased peace of mind because monitoring was being done by health professionals, increased self-awareness, and they experienced fewer clinic visits. Patients also reported the convenience of use of the device. The disadvantages included higher readings when compared to clinical readings.</p>		

01/2023	<i>How wearable sensors can support the research on foetal and pregnancy outcomes: A scoping review</i>	Mugeri et al.	Google Scholar Search (Journal of Personalized Medicine (MDPI))
<p><u>Summary</u> Mugeri et al. conducted a study using the PRISMA-ScR checklist to ensure a systematic approach. The review sought to identify all potentially relevant articles on the topic under investigation. To achieve this, several relevant medical databases, including but not limited to MEDLINE, EMBASE, and Web of Science, were searched from 2000 to October 2022. By conducting this comprehensive search, the review provided an in-depth overview of the existing body of research on the topic.</p> <p><u>Results</u> A scoping review was done to identify gaps in the literature and deep dive into wearable devices as a possible intervention to guide future research. The technologies are feasible but only partly address the needs of antenatal care. There was insufficient evidence to fully contextualize the participants' experiences to design effective interventions. More high-quality research is needed to determine which and how wearable devices could support antenatal care.</p>			
12/2022	Virtual clinic in pregnancy and postpartum healthcare: A systematic review	Shamsabadi et al.	Wiley
<p><u>Summary</u> A systematic review search was conducted via PubMed, Scopus, and Web of Science from February 2013 through February 2022. Additionally, a manual search in Google Scholar was done, and a search of the articles' reference lists of included studies was done as well. The systematic review included six articles that reported experiences in virtual clinics in pregnancy and postpartum healthcare. The studies in the articles ranged from experimental, cohort, and cross-sectional.</p> <p><u>Results</u> The reviewed studies illustrated promising results in terms of patient and provider satisfaction. It was predicted that telehealth would become a growingly significant part of gynecological care.</p>			
12/2022	<i>Economic evaluation of prenatal and postpartum care in women with gestational diabetes and hypertensive disorders of pregnancy: A systematic review</i>	Li et al.	Elsevier
<p><u>Summary</u> Electronic databases, including Embase, the Cochrane Library, MEDLINE, and PubMed, were searched from January 1, 2000, to October 1, 2021. Researchers followed the Preferred Reporting rules for Meta-Analyses & Systematic Reviews</p> <p><u>Results</u> The systematic review identified twenty-two studies, and nine of the reviews reported favorable interventions based on cost-effectiveness. For prenatal management of HDP, home blood pressure monitoring was found to be cost-effective compared with in-person visits in improving maternal and neonatal outcomes</p>			

	(***)Canada-Study only referenced to show other countries are exploring this intervention more than the U.S.).		
10/2022	<i>Telemedicine may increase visit completion rates in postpartum patients with preeclampsia</i>	Sanghavi et al.	Google Scholar Search (PLOS ONE)
	<p><u>Summary</u> The goal of this comparative study was to compare the cardiovascular risk The main objective of this comparative study was to compare the effectiveness of telemedicine appointments versus in-person office visits for new patients with preeclampsia who were referred for postpartum hypertension management at a healthcare center. The study analyzed data from electronic medical records, including demographic information, visit type, and visit completion status for patients with preeclampsia who had postpartum visits between March 1, 2020, and August 30, 2020. The focus of the study was on cardiovascular risk assessment and the completion rate of the visits.</p> <p><u>Results</u> The proportion of telemedicine visits vs. office visits decreased after July 2020, while the show rate remained consistently higher for telemedicine visits.</p>		
09/2021	<i>Cost-effectiveness of telehealth with remote patient monitoring for postpartum hypertension</i>	Niu et al.	Google Scholar Search (Taylor & Francis)
	<p><u>Summary</u> Researchers utilized data from a non-randomized controlled trial to develop a decision tree, which was applied to assess the cost-effectiveness of telehealth with RPM for postpartum hypertension disorder in Wisconsin.</p> <p><u>Results</u> The study found that the postpartum re-admission rate was reduced by 3%, at an average cost of \$309 per RPM patient, compared with \$420 per non-RPM patient. Overall, there was a reported \$93 per RPM patient saving. There was also a better QALY for RPM patients compared with no-RPM patients (41.70 vs. 41.76). ICER was less than 0.</p>		
05/2022	<i>Pre-eclampsia: A scoping review of risk factors and suggestions for future research direction</i>	Lee & Brayboy	Google Scholar Search (Springer)
	<p><u>Summary</u> A scoping review was conducted to identify risk factors and research directions for pre-eclampsia, including input from men.</p> <p><u>Results</u> According to the author, screening for pre-eclampsia should take place before individuals who are at risk of the condition become pregnant. Additionally, the current practice of assessing patient risk solely based on patient characteristics should be reevaluated, and low-cost technologies should be developed to increase access to prenatal screening. This technological development should include more affordable wearables. The study found that the completion rate was visited and 70% for telemedicine visits vs. 32% for in-person clinics, and the findings were statistically significant ($p < 0.001$).</p>		

05/2022	<i>Elimination of racial disparities in postpartum hypertension follow-up after incorporation of telehealth into a quality bundle</i>	Khosla et al.	Elsevier
<p><u>Summary</u> A retrospective cohort study was done at an urban tertiary care center, including all patients with HDP who delivered between December 2019 and June 2020. The institution had implemented a preexisting postpartum hypertension quality improvement initiative and a follow-up adherence program. At the 6-week follow-up visit, vitals were compared to those taken before February 15, 2020.</p> <p><u>Results</u> Researchers focused on the transition to audio-based telehealth visits at the start of COVID-19 to improve attendance to postpartum hypertension visits among non-Hispanic Black women, thereby reducing racial disparities in follow-up rates. Telehealth visits were found to be helpful.</p>			
05/2022	<i>Implementation of a universal postpartum blood pressure monitoring program: feasibility and outcomes</i>	Hacker et al.	PubMed
<p><u>Summary of Study</u> A recent prospective observational study by Hacker et al. delved into the possibility of implementing a patient-driven universal postpartum remote patient monitoring (RPM) program for women who have not been previously diagnosed with hypertensive disorders of pregnancy (HDP). The study observed women who were discharged from July 2020 to June 2021 to assess the feasibility of such a program.</p> <p><u>Results</u> The study suggests a patient-driven postpartum remote patient monitoring (RPM) program can be effectively implemented using the existing resources and infrastructure. Furthermore, it highlights that the incidence of new-onset postpartum hypertensive disorders of pregnancy (HDP) may be higher than previously thought in retrospective cohorts. Therefore, it is essential to closely monitor all women with patient-driven home blood pressure monitoring, especially those with risk factors or those living in maternity deserts or with limited resources, which can help identify, treat, and manage any potential health issues promptly, ultimately improving the outcomes for both the mother and infant.</p>			
04/2022	<i>A Systematic review of the role of telemedicine in blood pressure control: Focus on patient engagement.</i>	Khanijahani et al.	Google Scholar Search (Springer)
<p><u>Summary</u> PubMed, Wiley Online Library, Scopus, and Embase were searched for relevant studies from 2012 to 2020. Search terms were limited to include different variations of telemedicine, patient engagement, and hypertension. The initial search yielded 775 results. Only six studies were found about the U.S.</p> <p><u>Results</u> The study found that customizing telemedicine interventions based on socioeconomic characteristics and patient demographics is essential for optimal patient engagement.</p>			

04/2021	<i>Long-term IoT-Based maternal monitoring: system design and evaluation</i>	Sarhaddi et al,	Google Scholar Search (NIH Library of Medicine)
<p><u>Summary</u> The study delved into the topic of maternal health monitoring and how it can enhance the health of both mothers and their babies. The study introduced an IoT-based maternal monitoring system that delivers services like stress monitoring during pregnancy and postpartum, physical activity monitoring, sleep tracking, and more. The system was tested with end-users to evaluate its effectiveness.</p> <p><u>Results</u> The study found the feasibility for the implementation of the system in terms of interacting with mobile application usage and smartwatch. The device can integrate with current system.</p>			
12/2020	<i>Racial differences in postpartum blood pressure trajectories among women after a hypertensive disorder of pregnancy</i>	Hauspurg et al.	PubMed
<p><u>Summary</u> A prospective cohort study of women with a clinical diagnosis of an HDP who gave birth between 1/1/2018 to 12/31/2019 was done. Women were followed from delivery to 6 weeks postpartum. Mixed-effects regression models displayed blood pressure trajectories in the first six weeks postpartum.</p> <p><u>Results</u> After the program was completed, 126 out of 185 Black women (68.1%) met the Stage 1 or Stage 2 hypertension criteria, while 393 out of 764 Caucasian women (51.4%) did the same. This number difference was statistically significant with a p-value of less than .001. The study also revealed that blood pressure during the postpartum period decreased rapidly in the first three weeks and then stabilized. It further showed that black women had a less rapid decline in BP, which resulted in higher BP levels at the end of a 6-week program, compared to white women. Due to the significant number of women with hypertension even after the program, it is crucial to provide ongoing postpartum care beyond the first six weeks following delivery.</p>			
06/2020	<i>Using mHealth in postpartum women with pre-eclampsia: Lessons learned from a qualitative study</i>	Payakachat et al.	PubMed
<p><u>Summary</u> A non-randomized cohort study was conducted postpartum to explore perceptions and attitudes of postpartum women with pre-eclampsia towards remote monitoring (mHealth) and communication with the call center.</p> <p><u>Results</u> Twenty-one individuals who used mHealth and 16 who did not use it participated in the interview. Both groups agreed that mHealth helped manage their health condition. However, non-users were concerned about the difficulty of integrating mHealth into their daily routine. On the other hand, users appreciated using mHealth daily and communicating with the call center. They found it to be beneficial. Some of the challenges encountered by users included poor wireless connectivity, the size of</p>			

	the equipment, and the stress associated with mHealth monitoring. Users stated that they would have preferred to use mHealth during pregnancy. These findings provide valuable insights for implementing a remote monitoring program among perinatal and postpartum women.		
05/2020	<i>Exploring the use of telemonitoring for patients at high risk for hypertensive disorders of pregnancy in the antepartum and postpartum periods: Scoping review</i>	Aquino et al.	PubMed
	<p><u>Summary</u> A scoping review explored the use of telemonitoring in patients at high risk for HDP antepartum and postpartum. The literature review tried to answer the question: “<i>What is the current knowledge base related to the use of telemonitoring interventions for the management of patients at high risk for HDP?</i>”</p> <p><u>Results</u> Of the 3,904 articles initially identified, only 20 published between 2017 and 2018 met the inclusion criteria. These 20 articles described 16 unique interventions, all of which provided clinical decision support, and 12 also facilitated the self-management of HDP. Two studies reported significant findings for the telemonitoring group. However, more research is needed to establish the safety and effectiveness of telemonitoring for managing patients at high risk for HDP. Recommendations for future research include implementing extensive prospective studies to establish best practices for the effectiveness and safety of telemonitoring interventions, additional research to determine patient suitability and context-specific requirements for remote regions and underserved populations.</p>		
2/2020	Telehealth interventions to improve obstetric and gynecologic health outcomes: a systematic review.	DeNicola, N	NIH Library of Medicine
	<p><u>Summary</u> The article presented a systematic review to evaluate the effectiveness of telehealth interventions for improving OB/GYN health outcomes. The study identified 3,926 published abstracts, of which only 47 met the inclusion criteria. The review included 31,967 participants, and the researchers assessed whether telehealth interventions could reduce the need for high-risk obstetric monitoring office visits while maintaining maternal and fetal outcomes. The study found that one telehealth intervention resulted in a reduction in diagnosed preeclampsia among women with gestational hypertension.</p> <p><u>Results</u> The study found that the interventions of telehealth were associated with improved OB outcomes & allowed for optimizing high-risk OB care. More studies needed</p>		
10/2019	A Postpartum Remote Hypertension Monitoring Protocol Implemented at the Hospital Level	Hauspurg et al.	PubMed
	<p><u>Summary</u> The study evaluated the feasibility, acceptability, and compliance of an RPM protocol for managing hypertension in 6-week postpartum women after tertiary hospital discharge. Women enrolled in the study had a diagnosis of chronic</p>		

	<p>hypertension, gestational hypertension, superimposed preeclampsia, preeclampsia, or postpartum hypertension. Nurse Call Center used in conjunction with RPM via BP device (Wearable IoMT) & Smart Phone (Wearable and Nearable IoMT)</p> <p><u>Results</u> The study found high retention, compliance, and patient satisfaction with the program, which supports the feasibility & scalability of a RPM program connected to the electronic medical record under the 24/7 watchful eye of an RN. 235 out of 250 women who completed a post-program survey reported high satisfaction.</p>		
01/2019	<i>Telehealth with remote blood pressure monitoring for postpartum hypertension: A prospective single-cohort feasibility study</i>	Hoppe et al.	Elsevier
	<p><u>Summary</u> A single-center, prospective single-cohort feasibility study was done that focused on women with gestational hypertension participated in a postpartum telehealth intervention for blood pressure management after discharge. The study assessed recruitment and retention after discharge through 6 weeks postpartum. Other interested outcomes included the 6-week hospital readmission rate, incidences of severe postpartum hypertension and need for blood pressure treatment after discharge, and participant satisfaction. Women received a tablet and BP equipment to transmit vital signs daily to a central monitoring site. The women participated in telehealth or telephone visits with a nurse at 48 hours intervals and as needed.</p> <p><u>Results</u> There were no hospital readmissions. Eighty-six percent of the participants were satisfied with the remote monitoring—feasibility illustrated by the reported patient satisfaction and high retention rate. The incidence of severe hypertension and the need for blood pressure treatment after discharge and for six weeks postpartum was 16% and 53%. Results indicated that telehealth is a promising tool for the management of postpartum hypertension to decrease maternal morbidity and hospital readmission</p>		
5/2017	<i>Exploring implementation of m-Health monitoring in postpartum women with hypertension</i>	Rhoads et al.	PubMed
	<p><u>Summary</u> The study examined the use of mobile health technologies to manage the care of women with preeclampsia during the postpartum period. Fifty women were enrolled and monitored by a call center nurse to identify factors influencing adherence to symptom monitoring.</p> <p><u>Results</u> The study found that women participating in it had lower technology barriers and higher benefits. RPM technology can be beneficial for antepartum and postpartum care for women with preeclampsia by allowing close management of their BP and early detection of warning signs, mitigating disease development or progression.</p>		

Chapter 5

Discussion

XII. Implications

The Demand for Health Capital was published in 1972, and it is the seminal work of Michael Grossman (Grossman, 2022). The Grossman Model of Health was introduced in this seminal publication. It postulates that health can be viewed as a robust capital stock that produces a utility of healthy time (Shafrin, 2019). It is the interpretation of the author of this scoping review that at the national level, health capital in terms of maternal health involves the collective and individual policies that affect the health of pregnant and recently pregnant women. These policies then trickle down to shape state laws. At the local and community level, health capital in relation to maternal health refers to the umbrella of local programs that provide direct outreach and support for women antepartum and postpartum.

The field can benefit from more reviews being conducted on the topic, considering hypertensive disorders of pregnancy (preeclampsia, eclampsia, eclampsia, postpartum eclampsia, and hypertension) are the sixth leading cause of pregnancy-related deaths in the United States (CDC, 2023). After a deep dive into the breadth of literature, it seems that the intervention of telehealth and the accompanying IoMT have been mixed (Gajarawala & Pelkowski, 2021). More significant questions have been raised about the well-documented barriers to telemedicine, including access to stable internet, access to computers, and understanding how to use IT, encompassing the issues surrounding disparities and social determinants of health (Bailey et al., 2021). Problems have arisen about using telehealth in pregnancy in general because of privacy concerns for both at-risk and not-at-risk pregnancies. More research needs to be done.

XIII. Conclusion

IoMT and RPM can help women invest more in their health stock and provide for more utilization of health stock (illness-free days). As more women from socio-disadvantaged communities demand more access and better treatment by maternity healthcare professionals,

perhaps then we can implement better tools such as wearables/nearables and other IoMTs to assist in the management of remote maternal monitoring for hypertensive disorders for at-risk pregnancies. The touchpoint of the first trimester is a vital period during care to identify women who are experiencing hypertension or predisposed to hypertension due to underlying or comorbid diagnoses. Using the Grossman Model of buying shares in health capital will result in better health and non-health outcomes for women when we provide an investment in developing and building out the telehealth infrastructure that facilitates RPMs via IoMT's nearables and wearables to mitigate complications because of hypertension antepartum and postpartum.

The groundwork for the mitigation of complications starts with addressing the SDOH and DDoH that result in disparities in healthcare. The Grossman Model takes a lifespan view of health. As a prerequisite, it is necessary to understand the link between health-related decisions on both the part of the healthcare provider and patients, as both significantly impact outcomes on the individual and aggregate state and national level (Laporte, 2020). Further exploration of health inequity through the lens of the Grossman Model of health stock can be used to drive the utilization of IoMT to improve maternal health outcomes.

A productivity cost is associated with the loss of health stock associated with pregnancy-associated hypertension (MacLeod et al., 2022). High blood pressure has been attributed to premature births as a direct result of placental abruption (Mayo Clinic, 2024). High blood pressure and preeclampsia increase the risk for placental abruption, which then contributes to the increased risk of hemorrhaging and other life-threatening complications (Mayo Clinic, 2024). In January 2024, Vanessa Perez Patel et al. published the study "*Workplace Productivity Loss and Indirect Costs Associated with Preterm Birth in the United States.*" Patel et al. found that premature births were correlated with disability claims and medical-related absenteeism in the year after birth compared with full-term births. The study found statistical significance that premature births

resulted in 4.2 more workdays lost and \$1,045 more costs attributable to medical-related absenteeism than nonpremature births (Patel et al., 2024, p. 26). It was also reported that there were 2.8 more workdays lost and a cost of \$422 attributable to disability as compared with nonpremature births (Patel et al., 2024, p. 26).

This study, in part, quantifies some of the productivity costs and loss of health stock associated with preeclampsia, eclampsia, and other hypertensive disorders of pregnancy. When considering Grossman's Model, the loss of health utility is even more significant when considering the factors of more severe health complications such as death or the development of cardiovascular disease and other debilitating health conditions. During the pandemic, the use of RPM to provide a patient-centered continuum of care has been well documented. After working on this scoping review for the last two years, there is a gap in studies being conducted on the use of IoMT to manage hypertensive complications during pregnancy. It is essential to conduct pilots and to assess and quantify the potential benefits of RPM during pregnancy to improve maternal mortality rate and decrease morbidity and death. The former first lady, Michelle Obama, once stated that "communities and countries and ultimately the world are only as strong as the health of their women," nothing can be more accurate. More needs to be done and can be done to manage the blood pressure of women antepartum and postpartum.

Chapter 6

Next Steps

This paper highlights a strong need for more robust studies and the development of pilot programs focused on applying technological interventions that facilitate remote patient monitoring through the Internet of Medical Things (IoMT), a dimension of telehealth (Manickam, 2022). This intervention can be used to help fill a gap in healthcare. IoMT is emerging as the next-generation personalized bio-analytical tool that can be used for the management of pregnancy-associated hypertension. HDP, such as preeclampsia and eclampsia, have a significant impact on healthcare expenditures, maternal health, and non-health outcomes, especially in poor, underserved communities or rural populations. Remote patient monitoring can be used to decrease this number.

XIV. Writing of Grant Proposal

This researcher hopes that the next step is to use this scoping review to provide the framework for working with clinical healthcare professionals to draft a proposal for an R01 or RM1 Grant to secure NIH funding.

XV. Pilot

The funds secured from the grant proposal will be used to conduct a mixed method non-randomized pilot to illustrate the benefits of implementing an integrated model of a cellular-enabled RPM device supported by, ideally, a 24/7 nurse call center for blood pressure monitoring for women with pregnancy-associated hypertension. After much research, it has been determined that the best IoMT to use is the Omron HeartGuide wearable blood pressure monitor. Omron is a clinically validated Class III medical device that received FDA clearance in 2019 (Smith et al., 2023). Other devices can also be explored, such as BodyTrace or the Ideal Life Blood Pressure Manager device used in the Oben et al. study (Oben et al., 2023). The main benefit of this device is that it does not require internet access. The pilot will focus on the dimensions of patient outcomes (compare non-RPM patient outcomes with RPM outcomes via reviewing medical records in EPIC), cost (readmission, compare non-RPM cost per/ patient outcomes with RPM outcomes via

reviewing medical records), adherence to appointments (compare non-RPM patient outcomes with RPM outcomes via reviewing medical records (shows and no-show in EPIC), and perceived benefits to patients (captured via semi-structured interviews & a brief 5-question survey). The duration and scope of the project require further development and input from subject matter experts and study design experts that extend beyond a novice researcher, such as the individual writing this review.

XVI. Next Phase of Dissertation

The author of this dissertation entered the AUPHA doctoral student essay competition to explore another dimension of the issue. Another next step on a smaller scale will be to contribute more to the body of literature. The essay is entitled “*The Three-pronged Approach of Internet of Medical Things (IoMT), Remote Patient Monitoring (RPM), and Didactics in the Management of Hypertensive Disorders of Pregnancy (HDP) to Mitigate Complications Antepartum and Postpartum*”, and it focused on the importance of teaching healthcare professionals about the benefits of using emerging technology to manage maternal health conditions. The author of this dissertation will also explore the perceptions of frontline healthcare workers through semi-structured interviews and a survey working with antepartum and postpartum women via taking a class at MUSC to write a publishable manuscript on a related topic. This will bring the issue from a macro to a meso and micro level to add another dimension and depth.

APPENDICES

Appendix 1: HeartGuide Blood Pressure Monitoring Smart Watch

HeartGuide™

**BLOOD PRESSURE ANYTIME,
ANYWHERE.**

★★★★★ 3.7 [Write a review](#)

Designed to fit your lifestyle, HeartGuide is a clinically accurate, wearable blood pressure monitor available in the U.S. Now, track your heart data and learn how your behaviors impact your heart health.



The premiere wearable blood pressure monitor and much more.

Engineered to keep you informed, HeartGuide is the first clinically-accurate, wearable blood pressure monitor designed in the innovative form of a wristwatch, and is registered with the FDA as a medical device. In tandem with its companion app, OMRON connect US/CAN, HeartGuide delivers powerful new technology that makes tracking and managing your blood pressure easier than ever before.

With HeartGuide wherever you go,
you're in the know.

Source: Omron Health, 2023

Appendix 2: PRISMA Checklist



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
Reporting bias assessment	14	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Certainty assessment	15	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71
For more information, visit: <http://www.prisma-statement.org/>

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