TELEHEALTH: AN OPPORTUNITY FOR NEEDED DISRUPTION?

A COST-EFFECTIVENESS ANALYSIS OF A TELEHEALTH-SUPPLEMENTED PRENATAL CARE PROGRAM FOR LOW-RISK MEDICAID PATIENTS IN THE UNITED STATES

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JUNE 18, 2021

THESIS SUBMITTED AS A PART OF THE MASTER OF PHILOSOPHY DEGREE IN HEALTH ECONOMICS, POLICY, AND MANAGEMENT

2021

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http://www.duo.uio.no/

Universitetet i Oslo

ABSTRACT:

BACKGROUND: Standard prenatal care has not changed since World War II despite evidence that reduced-visit prenatal care programs produce equivalent maternal and fetal clinical outcomes. With the rise of the telehealth industry and the need for virtual care during the COVID-19 pandemic, a telehealth-supplemented prenatal care program may not only disrupt and update standard care but produce beneficial results.

OBJECTIVE: To investigate the claim that telehealth interventions produce clinically equivalent outcomes, increase patient satisfaction, and reduce health-system costs in prenatal care. To identify the cost-effectiveness of a reduced visit telehealth supplemented prenatal care program, Mayo Clinic OB Nest, compared to standard prenatal care.

DESIGN: Cost-effectiveness analysis using a decision tree model.

DATA SOURCES: Center for Disease Control's 2018 U.S. Natality Data; Published literature.

TARGET POPULATION: Pregnant women living in the United States, aged 13 to 36 years, and using Medicaid to finance their obstetric care and delivery. Patients must also be clinically "low-risk," without comorbidity or obstetric complication.

TIME HORIZON: 50 weeks (from enrollment prior to 13 gestational weeks until 8 weeks postpartum)

PERSPECTIVE: Health system (payer) perspective and societal perspective

INTERVENTION: OB Nest prenatal care program, comprised of 8 in-person visits supplemented with 6 virtual visits and access to a monitored online community.

OUTCOME MEASURES: Incremental cost-effectiveness ratios (2020 U.S. dollars per NICU admission avoided and 2020 U.S. dollars per Cesarean Delivery averted)

RESULTS: The Mayo Clinic OB Nest model and standard care model were assumed to produce clinically equivalent outcomes. Thus, incremental costs are more critical in understanding cost-effectiveness. In three out of four cost scenarios, 1) health system perspective traditional cost structure, 2) health system perspective innovative cost structure, and 3) societal perspective traditional cost structure, standard care is more cost-effective when compared to the OB Nest intervention. In Scenario 1, OB Nest increased costs by 16.44%; in Scenario 2, OB Nest increased costs by 3.79%, and in Scenario 3, OB Nest increased costs by 10.82%. In one cost scenario, 4) societal perspective innovative cost structure, the OB Nest model decreased costs by 0.83%. Probabilistic sensitivity analysis of 10,000 Monte Carlo simulations did not reveal a consistently optimal intervention.

LIMITATIONS: The OB Nest clinical trial, upon which the clinical event probabilities were estimated, used a patient population that was primarily white, urban, and high income—a contrast to the Medicaid population evaluated in this model. Standard and consistent reimbursement and length of stay data were missing. The model uses NICU admissions avoided as a primary outcome which is difficult to compare across different sectors of the health system. Finally, though providers may challenge the implementation of telehealth, a provider perspective was not included in this model.

CONCLUSION: The standard prenatal care program and the OB Nest program have an approximately equal probability of being cost-effective. Therefore, it cannot be concluded with certainty that either strategy outperforms the other. This conclusion is important during the COVID-19 pandemic when in-person care is not always feasible and policymakers have promoted telehealth. This foundational model can be used with future research and evolving data to make more predictive decisions on obstetric telehealth.

ACKNOWLEDGEMENTS

I am constantly amazed and humbled by the incredible people in my life that made a project such as this possible. Thank you!

To my thesis supervisor, Professor Liv Nymark. Thank you for always providing encouraging words and helpful feedback despite the time difference. To the administrative and academic staff at the Department of Health Management and Health Economics at the University of Oslo for their wealth of knowledge and flexibility during these unusual times. Coming from a background in anthropology and global health, I have learned so much about health economics, and I'm grateful for the opportunity these past two years to have explored such a necessary discipline.

To my fellow students—though we dispersed across the globe to practically every continent once COVID-19 hit in 2020, I continue to look to you all for inspiration. Knowing you all are out there makes me hopeful for the future of health care!

To my partner, Colin. Thank you for being my unofficial academic tutor, editor, and sounding board all these years. Your unfailing love and support across the Atlantic Ocean and in person has meant so much to me.

To my grandparents, Ingrid and Knut, who fed me new foods, played jazz records, and spent evenings with me by the fireplace in Drøbak. Thank you for making me feel at home in Norway. To the rest of my family in Norway, Petter, Elin, Selja, Sander, Marius, and Karen. Thank you for ensuring that my time in Oslo went beyond academics, from Friday dinners in Ullern, to Sunday brunches at Hvitsten. I will always look back on my time in Norway fondly!

To Dr. Shieva Ghofrany and my mother, Dr. Sareeta Bjerke, who have instilled their passion for equitable women's healthcare in me. Thank you both for supporting me with your compassionate mentorship and clinical expertise. To PJ Grewal, for providing me with insights into the complicated workings of Medicaid reimbursement. Without these three inspiring women, this thesis would not have been possible.

To my father, Bjørn, and my siblings, Louisa (my roommate and confidante), Lilliane (my editor-in-chief), and Oliver (my cheerleader). Thank you for always reminding me to stay curious, for "congratulating me on my failures," and for always believing in me. I am profoundly grateful to be surrounded by such a fantastic family.

Annika Bjerke

June 2021

"Communities and countries and, ultimately, the world, are only as strong as the health of their women."

-Michelle Obama

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TERMINOLOGY AND ABBREVIATIONS

Antenatal	Used interchangeably with “prenatal” to refer to the time during pregnancy
Antepartum	Used interchangeably with “prenatal” to refer to the time during pregnancy
Apgar	A 10-point score assigned to newborns at 1 minute and 5 minutes of life (measures color, heart rate, reflexes, muscle tone, and respiration)
Gestational age	measurement, in weeks from the first day of the woman’s last menstrual cycle to the current date, to describe how far along the pregnancy is
Neonate	newborn less than 28 days old
Perinatal	the period that begins at 22 weeks of gestation and ends 7 days after birth[1]
Puerperium	the period of six weeks after childbirth

ACOG	American College of Obstetrics and Gynecology
C-Section	Cesarean delivery
CDC	Center for Disease Control
CEAC	Cost-effectiveness acceptability curve
CEAF	Cost-effectiveness acceptability frontier
CMS	Center for Medicare and Medicaid Services
CPT	Current Procedural Terminology
DME	Durable Medical Equipment
FPL	Federal Poverty Level
GA	Gestational age
HCPCS	Healthcare Common procedure Coding System
HRSA	United States Federal Health Resources and Services Administration
ICER	Incremental cost-effectiveness ratio
NMB	Net monetary benefits
OB	Obstetrics
OB-GYN	Obstetrics and Gynecology (used often to refer to physicians of this field)
PSA	Probabilistic sensitivity analysis (also referred to as probabilistic analysis)
QALY	Quality-adjusted life year
WHO	World Health Organization

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1. INTRODUCTION

Telemedicine, and the telehealth industry at large, have rapidly expanded as the healthcare industry incorporates digital technologies into the delivery of its services. Now, more than ever, telemedicine has become a "hot button issue" as novel SARS-CoV-2 outbreak seizes the world. In the United States, the COVID-19 pandemic has encouraged the growth of the telehealth industry as patients, providers, and payers alike see the benefits of virtual care.

The United States Federal Health Resources and Services Administration (HRSA) defines telehealth as "the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration".[2]

"Telemedicine", a more specific category encompassed by the term, "telehealth", refers to remote health care services. As such, in its most basic sense, telemedicine is virtual care.[3] Virtual care implies that patients do not need to travel to hospitals or clinics to receive services, and providers do not need to meet their patients in person. At this moment, the nature of telemedicine implies a severe reduction in the potential transmission of the SARS-CoV-2 virus.[4] However, the purpose of this study is not to understand telemedicine's role (or lack thereof) in reducing the transmission of COVID-19 but rather to investigate the potential advantages and disadvantages of this disruptive industry within the context of prenatal care.[5,6]

This paper will evaluate a reduced-visit, telehealth-supplemented prenatal care program to investigate whether alternative prenatal programs that incorporate aspects of telehealth into their delivery can reduce costs compared to standard in-person prenatal care programs while increasing quality of care and patient satisfaction.

While evaluations of promising alternative telehealth-supplemented prenatal care programs, such as OB Nest or MultiCare, are increasingly common, they rarely, if ever, take into consideration cost.[7,8,9,10] Rather, the focus of these evaluations is typically on clinical maternal and fetal outcomes as well as patient and provider satisfaction. In contrast, the purpose of this study is to address the costs associated with a program such as OB Nest compared to standard care. The proposed model explores these two interventions and their effect on 1) costs, 2) quality of care, and 3) patient satisfaction, in line with the telehealth industry claims.[11,12]

Objectives of this paper

This paper evaluates if the OB Nest intervention, which is comprised of a reduced in-person visit schedule supplemented with telemedicine virtual visits, is preferable to standard care. In this pursuit, the paper aims :

1. To assess whether OB Nest can reduce the cost of care from the health system perspective.
2. To assess whether OB Nest improves on clinical outcomes such as reducing infant NICU admission and reducing the number of Cesarean deliveries as a proxy for quality of care.
3. To assess whether OB Nest can reduce patient costs measured in patient time saved as a proxy for patient satisfaction.

2. BACKGROUND

The term “telehealth” is often used interchangeably with the term “telemedicine” by various organizations, including the American Telemedicine Association and the World Health Organization. Though both terms refer to “remote” delivery of services, telehealth includes a broader set of objectives. Telehealth not only refers to remote clinical services but also includes “training health care providers, administrative meetings, medical education to providers and patients”.[3] Telehealth has been considered in many different medical fields, and more recently, obstetricians and gynecologists have incorporated telehealth into their services, specifically prenatal care. Since 2015, alternative prenatal care programs have been developed that reduce the number of in-person visits and supplement these interactions with telehealth services.

The following *Sections 2.1* and *2.2* present the current landscape of both the telehealth industry and prenatal care. *Section 2.2* reveals the need for prenatal care reform and the potential for telehealth to fill this need.

2.1 TELEHEALTH

Defining telehealth

The concept of telehealth may seem novel, but it has, in fact, existed in one form or another for decades, if not centuries. Telehealth disrupts the traditional delivery of healthcare which requires that both patient and physician are co-located at the same time and place. Traditional healthcare, as a result, was limited by the geographic location of its providers, consumers, and equipment, or the time necessary to relocate these factors and the speed at which information could be transferred from one location to another. Telehealth allows for the asynchronous care of patients at a distance.

Modern telehealth is categorized into four types including, 1) “store-and-forward”, 2) “real-time telemedicine” known also as “videoconferencing”, 3) “remote patient monitoring”, and 4) “Mobile Health” (mHealth). Store-and-forward refers to the acquisition of medical information through “X-rays, computerized tomography (CT) scans and video clips,” which is then transmitted to a medical specialist for later interpretation. [3,12] Videoconferencing refers to “real-time patient-provider consultations and provider-to-provider discussions”.[12] Remote patient monitoring refers to the use of “electronic devices [to] transmit patient health information to healthcare providers” and is often used for monitoring chronic diseases such as diabetes.[3,12] Finally, mHealth refers to “the application of mobile technology to provide or use health services, share clinical information and collect data”.[13]

The United States telehealth landscape

The most commonly used form of telehealth and the method which is most frequently reimbursed by insurers is synchronous videoconferencing.[14] In recent years, states like New York expanded their Medicaid reimbursement to include live coverage of videoconferencing, remote patient monitoring, and some reimbursement of store-and-forward telehealth services, depending on the clinical field.[8] While this extensive reimbursement is not common to all states in the U.S., the expected expansion of the industry “at an annualized rate of 8.3% to $4.8 billion over the five years to 2025” and more frequent evaluations of telehealth interventions likely means telemedicine reimbursement will follow in suit.

Telehealth saw a particular growth in the year 2020, which researchers claim may be attributable to the novel COVID-19 pandemic. “Industry revenue has increased at an annualized rate of 30.4%

to $3.2 billion over the five years to 2020, including an increase of 9.7% in 2020 alone".[12] With the onset of the COVID-19 pandemic, federal legislation was passed in March 2020, funding the expansion and reimbursement of telehealth services. Specifically, the Coronavirus Aid, Relief, and Economic Security Act (CARES) expanded the reimbursement of telehealth services for Medicaid patients. Following suit, the Center for Medicare and Medicaid Services (CMS) issued several briefs to assist policymakers in expanding the use of telehealth services in their respective states. In New York state, for example, the Department of Health issued guidelines calling for the expansion of "*all* Medicaid providers in *all* institutions to use a wide variety of methods to deliver services remotely during the COVID-19 State of Emergency".[15]

The objectives of telehealth

In order to investigate the telehealth industry claims, it is essential to first define what the objectives of telehealth are. These were identified by compiling the objectives and mission statements published by telehealth companies, hospital-based telehealth programs, U.S. HRSA, and other public health institutions. These objectives, which are in direct reference to traditional co-located care, include: the reduction of direct and indirect costs, the improvement of equal access to primary and specialized care, the improvement of coordination between health care units, the reduction of waiting times, the provision of at least the same level of quality clinical care, and the improvement of patient and provider satisfaction.[11]

2.2 PRENATAL CARE

Defining prenatal care

Prenatal care, also called antenatal or antepartum care, refers to the care patients receive during all stages of their pregnancy until delivery at or around week 40 of pregnancy. Obstetric physicians provide prenatal care which has historically occurred in routine in-person office visits where providers conduct physician exams, weight checks, blood or urine sample tests, ultrasounds, and other imaging tests.[16] Prenatal visits identify high-risk pregnancies and potentially risky deliveries through patient samples and tests and serve as a source of education for expectant mothers.[16] By providing these patients "with regular health evaluations and information about the course of the pregnancy, labor, birth, and parenthood, prenatal care aims to reduce the risk of unfavorable pregnancy and birth outcomes”.[17]

Prenatal care, a sub-field within obstetric care, is one of the most used preventative services in the United States, “with more than 18 million prenatal visits occurring in the United States in 2015”.[18] Additionally, “more than 98% of the nearly four million women who give birth each year will receive prenatal care”.[19]

The objectives of prenatal care

The following objectives of complete obstetric care during and following pregnancy were compiled from the American College of Obstetrics and Gynecology (ACOG) and its physician members. They include: the diagnosis of high-risk pregnancies, the provision of maternal emotional and clinical support, the education on obstetric and neonatal symptoms, development, and wellbeing, the increase in the proportion of appropriate vaginal births and full-term babies born at healthy weights, and the strong recovery of mothers and infants following delivery. [20]

Standard prenatal care

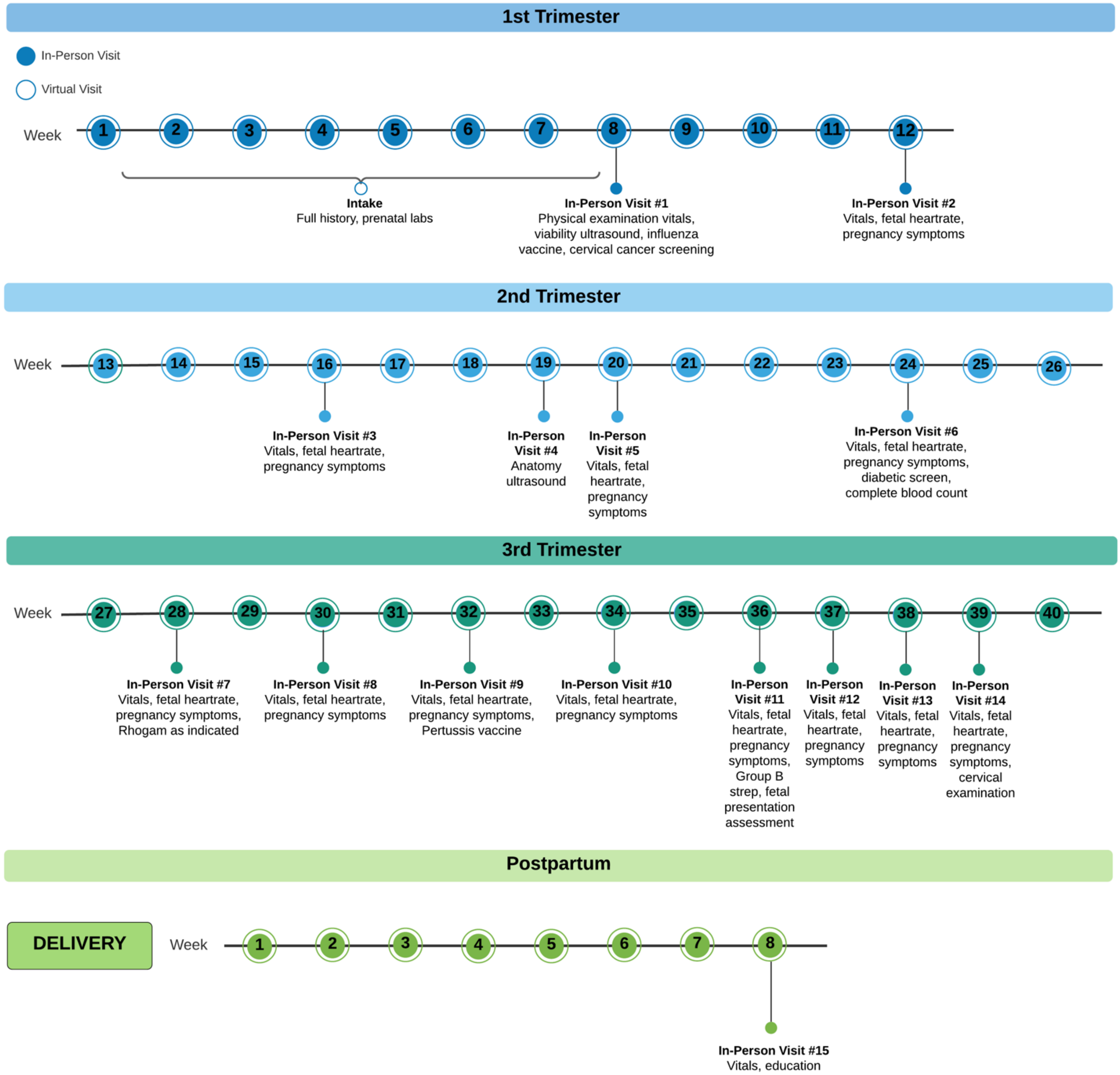
Despite its widespread use in the United States and the vast technological improvements in the medical world—including the field of telehealth—modern prenatal care looks almost as it did right after World War II.[19] The current model for prenatal care in the United States, as recommended by ACOG, calls for 14 in-person provider visits during the 40-week course of pregnancy (see *Figure 1* for the structure of traditional care and services provided at each visit).[17] This status-quo structure has been cemented in the field “despite limited supporting evidence”.[19]

The current protocol employs a “one size fits all,” “more is better” approach, which can lead to the misuse and improper distribution of patient and physician time along with health system resources.[19] This traditional prenatal care is structured around identifying high-risk pregnancies in the form of hypertensive and metabolic disorders.[21] The established timing of care assumes complete dependence on in-person consultations, or, when necessary, consultations by phone, as was available when the modern prenatal care structure was designed.

Additionally, as it is currently structured, prenatal care does not consider the productive lives of women, ignoring the time investment, productivity loss, childcare support, and potential distress of having to travel to a physician so frequently during pregnancy.[9] Studies reveal that contemporary patient preference does not match the current prenatal care structure. Many patients prefer fewer prenatal visits, and many desire contact with their care providers in-between visits.[22] While there is scientific consensus that prenatal care provides significant benefits to women and their children, there is little exploration of the potential use of contemporary technology and flexible telehealth techniques in updating and centering prenatal care on the wellbeing and satisfaction of mothers.[23,24]

In the digital era of COVID-19, there is not only a need for reform but also a unique opportunity to re-imagine prenatal care in terms of the technology with which physicians deliver services and the measures by which evaluators determine the success of prenatal programs.

Figure 1 *Standard Obstetric Weekly Rhythm of Care (based on information from Peahl[25])*



Estimating the costs associated with standard prenatal care

In order to understand the context and need for prenatal care reform, it is important to analyze some of the costs surrounding obstetrics. From 2004 to 2010, the "costs of vaginal births increased 40% to an average of $29,800 for Medicaid payers and $18,329 for commercial payers, and costs for cesarean sections increased to an average of $50,373 for Medicaid payers and $27,866 for commercial payers. With a cumulative cost exceeding $111 billion annually for approximately 4 million births, American obstetric (OB) care is the most expensive in the world".[26]

The cost of the current widely employed prenatal care program is difficult to measure as granular cost data per service is not readily available. Instead, obstetric care is reimbursed as a global lump sum covering prenatal care, delivery, and postpartum care. The services that are included in prenatal care: ultrasounds, blood and urine tests, and vaccinations are all enveloped within this package and are thus difficult to parse out. The health care space, personnel needed to run said space, and the administrative infrastructure to accommodate 12-14 in-person visits result in substantial costs. Considering then the loss of productivity pregnant women experience when taking time off to visit their physician makes the cost of prenatal care even more grievous. Butler-Tobah and colleagues estimate that the "female workforce loses (conservatively) two hours of productive time for each of those visits… The loss of productivity represented here is 84 million work hours, or roughly 10.5 million workdays per year in the United States".[9]

3. ALTERNATIVE PRENATAL CARE PROGRAMS

Overview of existing models

Obstetrics & Gynecology, the official journal for ACOG, recently published an article, "Right-Sizing Prenatal Care to Meet Patients' Needs and Improve Maternity Care Value," in May 2020. The article proposes categorizing patients into four phenotypes that take into consideration both medical and psychological support needs. The authors suggest telemedicine as an alternative avenue for delivery of care for patients categorized with low medical needs and low support needs along with patients that require high medical needs and low support needs (as access to telehealth services could provide an opportunity for increased monitoring of patients with high medical needs).[19]

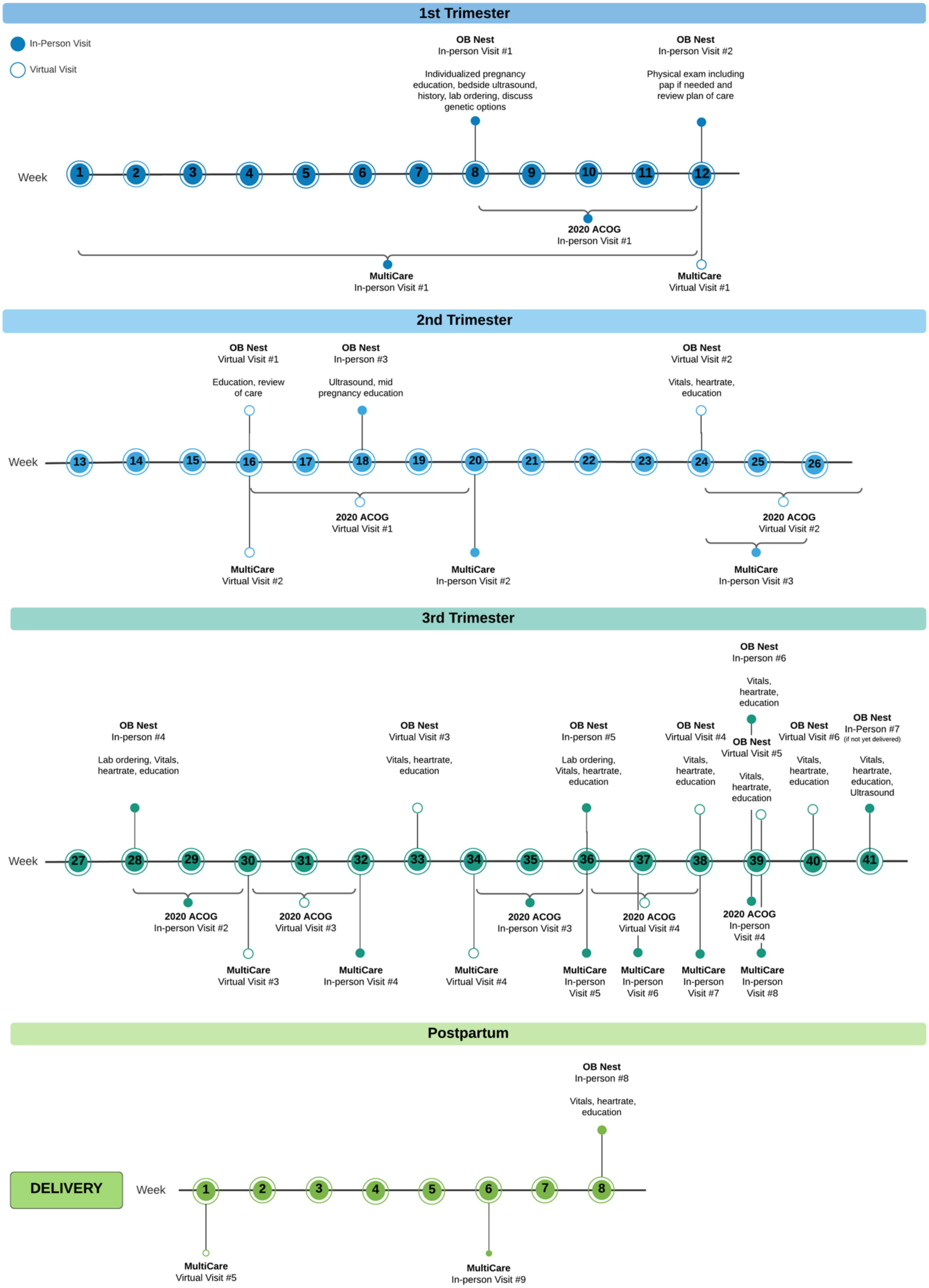
The following models, all of which are reduced-visit prenatal programs, only focus on those patients categorized as "low-risk." However, some models, like the Mayo Clinic OB Nest model and the MultiCare Virtual OB model, were also built to meet patients' support needs throughout their pregnancy. The ACOG and WHO ANC models (the WHO model is not included in the table), on the other hand, focus more on the medical needs of their patients.[27] All three models, OB Nest, MultiCare, and ACOG, replace some in-person visits with virtual visits.

While some researchers, like Butler-Tobah and colleagues, have compared the OB Nest model with the traditional standard of care through a randomized controlled trial, there have yet to be evidence-based studies comparing the OB Nest model to other alternative reduced-visit prenatal care models such as the MultiCare Virtual OB model, the 2020 ACOG model, or the 2016 WHO ANC model. It is important to note that the 2020 ACOG Model is based on the OB Nest model and was developed in response to the COVID-19 pandemic. Below, *Figure 2* compares the rhythms of the three models that include telehealth for reference. The open circle represents a virtual visit, while the closed circle represents an in-person visit.

Alternative reduced-visit models have been considered in the field of obstetrics and gynecology for many years now. In 1995, a study conducted by Binstock and colleagues compared a traditional model with 13 provider visits to a reduced model with 8 provider visits for low-risk patients. In 1997, Walker and colleagues evaluated a reduced-visit prenatal program for low-risk women in a free-standing birthing center. Both studies measured maternal and neonatal clinical outcomes and patient satisfaction. Binstock found no difference in clinical outcomes or patient satisfaction between the reduced-visit and the traditional prenatal care programs. On the other hand, Walker found that patients in the reduced-visit program had greater satisfaction compared to those enrolled in the traditional program and, just like in Binstock's study, there were no statistically significant differences in the clinical outcomes in either group.

The Mayo Clinic OB Nest model, the MultiCare Virtual OB Program, and the 2020 ACOG model all call for the supplementation of in-person provider visits with telehealth services such as the use of "self-monitoring tools, a text-based smartphone application to communicate with their care team, and moderated online communities to connect with other pregnant women." [26] Since the MultiCare Virtual OB Program and the recent ACOG model have yet to be critically evaluated with a randomized controlled trial, the model created for the purpose of this paper uses the OB Nest model as its prenatal care structure.

Figure 2 *Rhythm of Care for Three Alternative Reduced-Visit Obstetric Programs (based on information from Butler Tobah[9], Multicare[28], and ACOG[29])*



The objectives of the Mayo Clinic OB Nest model

The 2014-2015 randomized controlled trial concludes that patients enrolled in the OB Nest program experienced higher satisfaction, less maternal stress and that there was no statistical difference in the perceived quality of care measured via proxies such as clinical maternal and fetal outcomes. Additionally, the OB Nest model focuses on both the support and medical needs of low-risk patients. Consequently, the following analysis will focus on this model rather than the alternative structures visualized in *Figure 2*.

The following are a few of the most important objectives outlined by those who designed and initially investigated this model of care through a qualitative study: 1) to strengthen women's confidence, autonomy, self-awareness, and engagement, 2) to establish transparency around the rhythm of care, and 3) to enable proactive interactions throughout the entire pregnancy experience.[26]

The need for cost evaluation of alternative reduced-visit prenatal care models

As previously discussed, estimating and evaluating the cost of prenatal care is a difficult endeavor. Consequently, most critical evaluations of alternative prenatal care models which feature fewer in-person visits do not include the cost of care in favor of exclusively focusing on patient satisfaction and clinical maternal and fetal outcomes. In a paper published in 2021 by Theiler et al., the authors attempt to compare the costs associated with OB Nest and traditional care programs. The authors specifically consider "the nursing and provider staff time for all patients enrolled in the OB Nest clinical trial" and use national wage data for healthcare workers to calculate the labor cost of providing both programs.[30] "Overhead expenses and opportunity costs were not considered." [30] In other words, costs to the patients—such as traveling time to the health care clinic and time spent waiting to be seen by a provider—along with costs to the health system at large in the form of reimbursement fees for obstetric care and the costs associated with implementing a telehealth program have yet to be critically evaluated for the OB Nest model. The evaluative model outlined by this paper aims to fill this gap and consider the costs that previous analyses have excluded.

4. THE STANDARD ASSESSMENT OF TELEHEALTH

According to the 2016 systematic review conducted by AllDossary et al., the most common evaluation methods used to assess telehealth in hospital-based settings include descriptive studies, studies that evaluate from a clinical outcomes perspective, studies that undertake an economic perspective and finally, studies that analyze provider and consumer satisfaction.[31] The most frequently analyzed clinical outcomes include length of stay, morbidity, and mortality. The authors also conclude that telehealth evaluations use simple cost analyses, cost minimization analyses, and analyses that identify the break-even point at which telehealth and standard in-person care cost the same.

While AllDossary's study does not find existing cost-effectiveness analyses (or cost-benefit or cost-utility analyses) of telehealth, the 2012 systematic review conducted by Mistry exclusively focuses on the cost-effectiveness of telehealth.[32] The most common studies included in Mistry's review were cost consequence analyses, cost minimization analyses, and cost-effectiveness analyses. Mistry points out that cost-minimization analysis should only be conducted when the clinical outcomes of either alternative are assumed or proven to have no statistical difference. Most of the studies collected by the systematic review were conducted from a health system perspective, followed by a societal perspective. The outcomes measured in these evaluations ranged from QALY's gained to clinical outcomes such as mortality, cases averted, patient satisfaction, or hospitalizations avoided. 43 of the studies in this systematic review used a time horizon of less than one year and thus did not include cost discounting in its analysis.

5. THE STANDARD ASSESSMENT OF PRENATAL CARE

The recent systematic literature review conducted by Saturno-Hernandez et al. in 2019 in the *BMC Pregnancy and Childbirth Journal* categorizes indicators in the continuum of care from pregnancy, to childbirth, to puerperium, to newborn care (0 to 2 months post-delivery).[33] While this paper focuses on prenatal care, as Saturno-Hernandez points out, too often, programs and their evaluations are siloed into their subdiscipline rather than approaching obstetric and gynecological care as a larger continuum. The previously mentioned OB Nest cost analysis only considers the costs associated with prenatal care, specifically excluding the costs associated with postpartum care and newborn care. Therefore, while the focus of this study will be on prenatal care, the clinical maternal and fetal outcomes and cost inputs of the model will also consider the subsequent parts of this continuum, childbirth, puerperium, and newborn care.

6. DECISION MODEL

Overview

A decision model comparing standard prenatal care to the telehealth-supplemented Mayo Clinic OB Nest program was constructed in 2018 Microsoft Excel. The model covers prenatal care, delivery, and immediate neonatal care to capture the effects of the prenatal care program. A decision tree modeling approach was selected as economic evaluations in the field of obstetrics and gynecology most frequently use decision trees. Additionally, in this case, each clinical event forming the various branches of the tree is mutually exclusive at each node and occurs in close succession. The decision model was both probabilistic in nature and based on Bayesian methods of multi-parameter evidence synthesis. The decision model and its analysis sought to determine the most cost-effective strategy regarding the number of NICU admissions avoided and the number of Cesarean deliveries averted. *Figure 3* displays the decision tree's key events in chronological order and also includes the structure of each prenatal program. The in-person visits are shaded in blue, while the telehealth virtual visits remain in white. Along the left side of the figure includes the periods along the obstetric continuum as proposed by Saturno-Hernandez et al.[33]

Model structure

The structure of the decision tree model is based upon a literature review, including both ACOG standard of prenatal care guidelines, NICU admission guidelines, and studies and program evaluations of various alternative and reduced prenatal care interventions.[34,35,36] The structure is also informed by discussions with clinical experts.[21] The following sub-section provides an explanation for the inclusion of each node in the decision tree. Data inputs are reported in greater detail in *Section 8 Model Inputs and Outputs.*

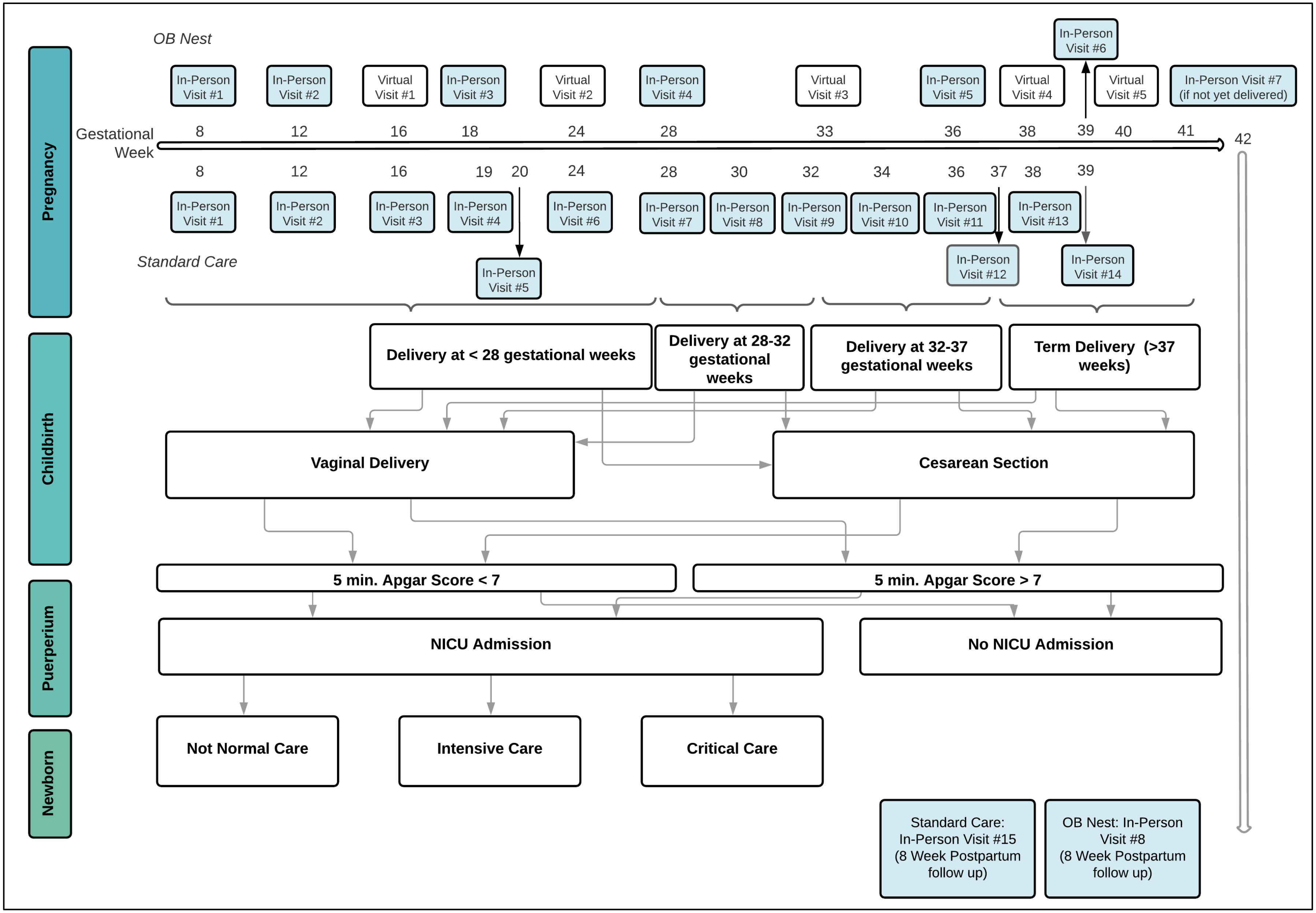


Figure 3 *Flow diagram to show OB Nest and standard prenatal care structures and the outcomes along the Continuum of Maternal and Child Care (based on information from Butler-Tobah[9], ACOG[34], and, Saturno-Hernandez[33])*

Target population

Patients enrolled in either the standard care or the telehealth-supplemented care program must meet the following eligibility criteria. First, pregnant patients must be Medicaid enrollees, using Medicaid to fund their prenatal care. Patients must speak English and must be able to provide informed consent. Additionally, patients must be clinically categorized as "low-risk" which in turn means that patients must be between the ages of 18 and 36 years, without a comorbidity or obstetric complication.[9] Consequently, patients who are diagnosed with any chronic medical conditions, including "hypertensive disorders, coagulopathies, diabetes, class 3 obesity, immunodeficiency conditions, genetic disorders, multi-fetal gestation, prior history or risk factors for preterm delivery, pulmonary disorders, unstable mental health conditions, or obstetrician judgment that determined the pregnancy was at high risk for complication" are not eligible to be included in the study population.[9] For the sake of the model, target patients must complete the full duration of the prenatal care, which means that patients must be at fewer than 13 weeks of gestation when they begin their prenatal program. Finally, this model also does not account for stillbirths or miscarriages, and thus the retrospective target population includes those patients with live births.

The 2018 Center for Disease Control Natality Public Use File included categorization of the source of payment (Medicaid; private insurance; self-pay; other), the trimester in which the patient began prenatal care (first; second; third trimester), and pregnancy risk (diabetes (pre-pregnancy or gestational); hypertension (pre-pregnancy or gestational); eclampsia; previous preterm births; pregnancy resulted from infertility treatment; mother had a previous cesarean delivery; no risk). According to this data, the number of patients in the United States in 2018 that began prenatal care in their first trimester, used Medicaid to finance their care, and were categorized as having no risk included 343,515 women. In the proposed decision tree model, 50% of these patients would receive the OB Nest prenatal care program, and the other 50% would receive standard prenatal care as usual.

Setting and location

Given the availability of national data from the Center for Disease Control (CDC), this model occurs in the United States. Medicaid reimbursement varies from state to state, and not every state's Medicaid reimbursement schedules were publicly available. Consequently, I used New

York State's Medicaid reimbursement information because, according to the most recently available 2010 census data, the state includes a representative mixture of 20 urban counties and 42 rural counties.[37] Additionally, interviewed hospital administrators were located in New York state.[38]

As the study will focus on telehealth, patients and providers may be located in off-clinic sites, in their homes, for example. In-person visits will occur at outpatient clinics, and deliveries will occur at hospitals.

Study perspective

This model will employ a United States health system and societal perspective to capture both the costs directed towards the health care payer as outlined by Medicaid reimbursement and the opportunity costs patients and society face at large in the form of travel and time costs. As mentioned in *Section 4*, these chosen perspectives are frequently used in telehealth evaluations.[32]

Comparators

This model compares standard prenatal care, 14 in-person visits with an obstetric provider, to a telehealth-supplemented reduced-visit prenatal program, OB Nest. As part of the Mayo Clinic OB Nest program, patients visit an outpatient clinic for 8 in-person visits throughout prenatal care, delivery, and postpartum care, and receive 6 virtual visits "consisting of phone or online communication with an assigned nurse, supplemented with fetal Doppler and sphygmomanometer home monitoring devices, and access to an online community of pregnant women".[9]

Time horizon

The total time horizon, 50 weeks, will include 40 weeks of gestation and 8 weeks of postpartum follow-up time. While some patients may deliver after 40 weeks, standard care is to induce delivery no later than 42 weeks.[21]

A shorter time horizon is also justifiable in terms of health care costs facing infants, especially premature infants that are admitted to the NICU following delivery. In 2010, Korvenranta et al.

conducted a cost study of preterm infants over 4 years and found that in Finland, "hospitalizations occurring during the first year of life, particularly the initial hospitalization, accounted for most of the total 4-year cost of hospital care. The later costs were low even in the lowest gestational age groups".[39] Additionally, according to the aforementioned systematic review of telehealth evaluations, the majority of studies included a time horizon of less than one year and consequently did not include a discount rate in their analysis.[32]

Discount rate

Both costs and health outcomes will be discounted at an 0% annual rate as the time horizon is less than 1 year.

Decision tree branches & outcomes

The maternal and fetal clinical events chosen and represented in the decision tree follow those outcomes recorded in the 2014-2015 randomized controlled trial comparing the OB Nest prenatal program to standard care. The order in which the outcomes appear in the decision tree was informed by ACOG clinical guidelines and interviews with OBGYNs.[21] The maternal and fetal clinical outcomes of interest represented in the decision tree include:

1) gestational age at delivery (less than 28 weeks, 28-32 weeks, 32-37 weeks, greater than 37 weeks)
2) route of delivery (vaginal or cesarean section)
3) APGAR score taken at 5 minutes of life (greater or less than 7)
4) NICU admission (admitted or not admitted)

Prematurity—a gestational age less than 37 weeks, a low APGAR score, and admission to the Neonatal Intensive Care Unit (NICU) all represent poor fetal outcomes.

While the route of delivery does not necessarily affect maternal or fetal outcomes, it does influence the cost of delivery and is thus important to report in a cost-effectiveness analysis. Route of delivery is reported as the number of Cesarean deliveries avoided and serves as a secondary outcome for this study.

Gestational age and admission to the NICU are easily measured. However, an Apgar score is a more complicated outcome, measured on a scale from 0 to 10 and assigned by a health care professional 1 minute after birth and again 5 minutes after birth for all infants. Should the infant receive an Apgar score of less than 7 at the 5-minute mark, a new Apgar score is reported every 5 minutes for 20 minutes. "The Apgar score comprises five components: 1) color, 2) heart rate, 3) reflexes, 4) muscle tone, and 5) respiration, each of which is given a score of 0, 1, or 2. The Apgar score quantitates clinical signs of neonatal depression such as cyanosis or pallor, bradycardia, depressed reflex response to stimulation, hypotonia, and apnea or gasping respirations".[40] The 2018 CDC Natality User Manual defines the Apgar score as "a measure of the need for resuscitation and a predictor of the infant's chances of surviving the first year of life".[41]

Low Apgar scores are not directly related to neonatal diagnoses; however, they can inform further tests and treatment plans. An Apgar score of 7-10 is normal, while a score of 4-6 is "moderately abnormal" and a score of 0-3 is "low".[40] Preterm births, gestational age of fewer than 37 weeks, are associated with low Apgar scores.[42] Apgar scores are not intended to predict outcomes beyond the immediate postnatal period.[43]

Low Apgar scores increase the likelihood of newborn admission to the NICU. However, admission to the NICU is not dependent on a low Apgar score.[42] The number of NICU admissions for each category was recorded using the 2018 CDC Natality Public Use File data regardless of diagnosis.

Gestational age is included as the most granular outcome in the decision tree because previous studies have shown that gestational age is correlated with NICU length of stay. [39,44] Consequently, gestational age is also correlated with costs. In fact, a study of premature infants in California conducted by Phibbs et al. reveal that "there were mean cost savings of about $35,000–39,750 for every 1-week increase in GA [gestational age] at birth as demonstrated".[45,35]

Additionally, when considering a long-term perspective, surviving preterm infants may frequently face morbidities associated with prematurity. Russell et al. report that average hospital costs for these preterm infants are four to seven times higher than those for infants of the same gestational age but without associated morbidities.[46]

The primary outcome measure for this study is the number of NICU admissions avoided. Normally, quality-adjusted life years, QALYs, serve as the primary measure included in cost-effectiveness analyses. However, studies have shown the difficulty in applying a measure that tries to value a health condition through preference-based methods to children, especially infants.[47] Despite the availability of several preference-based instruments for youth, and one instrument developed for low birth weight infants, these methods have not been widely adopted.[47,48] Thus, few studies that actually value the quality of life in infants, and none are applicable to this specific model. Therefore, QALYs will not be included in this model in favor of a more relevant measure, the number of NICU admissions avoided.

7. OVERVIEW OF REVIEW METHODS

Systematic literature reviews and analyses of 2018 United States Natality data, provided by the Center for Disease Control, were carried out in order to populate each branch of the decision tree with probability data. For other cases, conversations with experts and reviews of the published research literature were used to inform the model inputs that the national real-world data did not cover. The 2014-2015 randomized controlled trial conducted by Butler Tobah et al. was also consulted to populate the telehealth arm of the model.[9] All model probabilities were roughly confirmed by OBGYN experts.[21]

Search strategy and review methods

A search strategy was developed to provide real-world data on pregnancy, prenatal care, fetal outcomes, and NICU admissions in the United States to inform the decision model. Individual state-level health departments were investigated for potential data, including the New York State Department of Health, the Connecticut State Department of Health, and the California State Department of Health. Nationally, the Center for Medicare and Medicaid Services (CMS), the Department of Health and Human Services (HHS), and the Center for Disease Control (CDC) were also investigated. While some states did provide publicly available data, much of the data was so disaggregated and focused on a narrow fetal diagnosis that it was no longer useful in providing the information necessary for this specific decision model. CMS and HHS also did not provide publicly available relevant data.

Consequently, the model was populated using raw data from the United States CDC 2018 Natality Public Use File. 2018 was the most recently available data set, and given its pre-pandemic timing, it would not see the confounding effects of COVID-19 in its data. The telehealth arm of the decision tree was informed by two randomized controlled trials comparing the virtual supplemented OB Nest prenatal care program with standard, exclusively in-person prenatal care. Both the randomized controlled trial published in 2015 and conducted by Ridgeway et al. and the later randomized controlled trial published in 2019 and conducted by Butler-Tobah et al. measured patient-reported satisfaction, adherence to the ACOG recommended routine prenatal services, healthcare utilization, and finally, maternal and fetal outcomes. [9,17] The decision tree specifically narrows in on maternal outcomes—vaginal and cesarean delivery routes, and on fetal outcomes—gestational age at delivery, 5 minute Apgar score, and NICU admission. These outcomes were also measured in the randomized controlled trials with the exception of NICU admission. NICU admission is included in this model to demonstrate the severity of fetal outcomes and to calculate health system costs as a stay in the NICU is costly.

The raw data from the 2018 U.S. Natality data set was used to model the proportion of infants (and thus also mothers) who fell into each of the final categories represented in the decision tree. As both aforementioned randomized controlled trials found no statistically significant difference in the maternal or fetal outcomes between the OB Nest program and the standard prenatal care program, the same probabilities and proportions of patients were theorized in each arm of the decision tree—telehealth and standard care.

For information on Medicaid reimbursement fees, I investigated the national CMS website and looked into state Medicaid websites, including New York State, Washington, and North Carolina. I also discussed Medicaid reimbursement with Montefiore Hospital's Senior Director of the Revenue Cycle, Prabhjot Grewal. Grewal provided me with Montefiore's facility Medicaid reimbursement information for the study's relevant CPT codes (for specific information, see *Section 8, Tables 2, 4, and 6*).[38] While most CPT codes were clear in their applicability in the model, a conversation with OBGYN clinical expert Dr. Sareeta Agarwal Bjerke informed which neonatal intensive care CPT code was applicable for the standard care delivered for each gestational age group with a high or low 5 minute Apgar score (greater or less than 7).[21]

Data on NICU length of stay was collected by performing a literature review of 2 databases, PubMed, MEDLINE, and 2 national resources on obstetrics and infant care, ACOG and March of Dimes. The following search terms were used: (NICU length of stay OR NICU admission) AND (gestational age OR preterm). The search specifically looked at the role of gestational age in the NICU duration of stay to inform the length of stay for each gestational age group included in the decision model.

8. MODEL INPUTS AND OUTPUTS

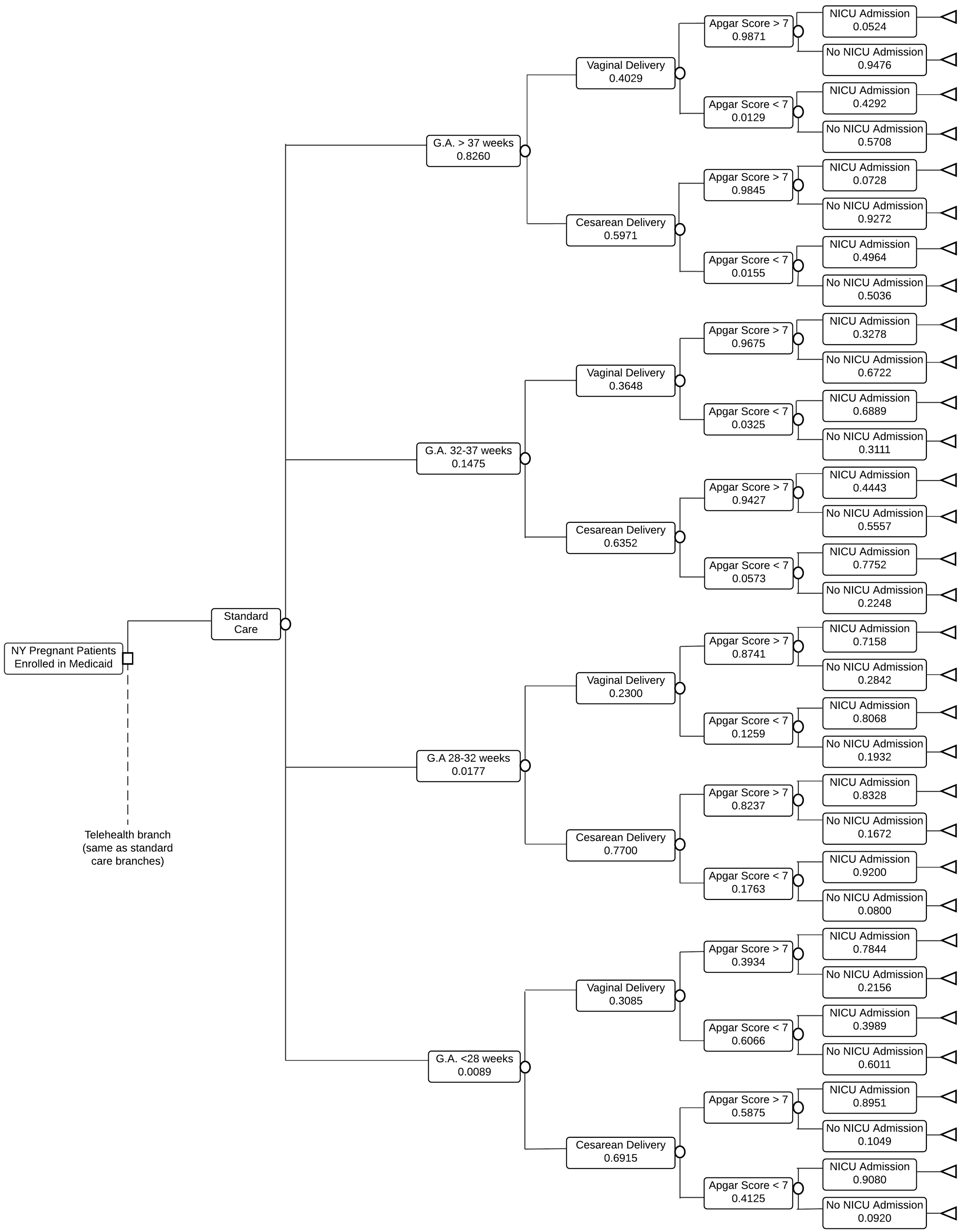
Model clinical inputs

As mentioned, the clinical event probabilities are informed by real-world data sourced from the United States CDC 2018 Natality Public Use File. The number of occurrences of each event was determined by using Stata 16 to explore the CDC data set. The complete base parameter estimates and their calculations can be found in *Appendix A*. The following *Figure 4* is an abbreviated decision tree with populated standard care probabilities used in this study.

Model outputs

As previously mentioned, the primary outcome of interest is the number of NICU admissions avoided, and the secondary outcome of interest is the number of Cesarean deliveries averted.

Figure 4 *Populated Decision Tree Reflecting Standard Care Branches*



Interventions: OB Nest Model

Table 1 reveals the estimated treatment effects of the OB Nest telehealth supplemented prenatal program, which was compared against standard care in a 2014-2015 single-center randomized controlled trial. As is evidenced by the high p-values, there are no statistical differences between the maternal (route of delivery) and fetal outcomes (preterm delivery and Apgar score). Thus, for the base case scenario, based on the outcomes from the OB Nest clinical trial, the same event probabilities are applied to both the telehealth and standard care arms of the decision tree. The Telehealth clinical event probabilities, Inputs #60-120 reflect the standard care probabilities listed as Inputs #1-60 represented in *Appendix A*.

Table 1 *Maternal and fetal outcomes, OB Nest compared to Standard Care (Source: Butler Tobah[9])*

Outcome	OB Nest (N = 134)	Standard Care (N=133)	P-value
Preterm delivery (< 37 weeks)	4 (3.0%)	3 (2.2%)	0.71
Delivery type: Cesarean	17 (12.7%)	20 (14.9%)	0.56
Apgar Score			0.66
Missing	2	3	
< 7	3 (2.2%)	2 (1.5%)	
7+	126 (94.0%)	126 (94.0%)	

Health system perspective costs and resource use

The United States uses Current Procedural Terminology (CPT) codes as a uniform method for codifying services and treatments providers offer in the health care system. The CPT system not only allows for national standardization within the medical field but also streamlines administrative duties. Private health care payers like Cigna, Aetna, or BlueCross, alongside public health care payers like Medicaid, use CPT codes as a way to process claims and set reimbursement schedules or fees.

Most payers, including Medicaid, reimburse obstetric providers in the form of a "global fee," which covers prenatal care, delivery, and postpartum care for uncomplicated pregnancies. For more complicated pregnancies, providers may bill payers using standalone CPT codes for just prenatal care. Under the global obstetric codes, 59400, 59610, 59618, and 59510, all included services must be provided by one physician, one midwife, or one physician practice under the same tax ID.

Prenatal care, referred to as antepartum care in the CPT billing guidelines, under the global obstetric codes covered by Medicaid, include the following services[49]:

- All routine prenatal visits until delivery (as depicted in *Figure 1,* standard care encompasses around 14 in-person prenatal visits)
- Recording of weight, blood pressures, and fetal heart rates
- Routine chemical urinalysis (CPT codes 81000 and 81002)
- Education on breastfeeding, lactation, and pregnancy (Medicaid patients)
- Exercise consultation or nutrition counseling during pregnancy

Table 2 records the Medicaid Facility fees associated with each relevant prenatal CPT code, while *Table 4* records the Medicaid reimbursement fees associated with each relevant neonatal CPT code. Medicaid reimbursement rates vary from county to county and from state to state, and the following fees are selected from Medicaid's reimbursement schedules at Montefiore Hospital in Bronx, NY. It is also important to note that during COVID-19, Medicaid is ensuring parity between the facility and non-facility reimbursement schedules. This means that providers will receive the same rates whether they deliver prenatal care in-person or virtually via telehealth.

As this model assumes an in-hospital delivery, subsequent neonatal care will be delivered in-person and thus does not include a non-facility fee (see *Table 2* for details). CPT codes also consider whether the patient has had a previous cesarean delivery and reimburse a greater amount for the obstetric care of patients with previous Cesarean deliveries ($1,811.21 for vaginal delivery and $2,038.10 for Cesarean delivery). For the sake of the model, costs only consider patients without previous Cesarean deliveries using CPT codes 59400 and 59510.

Table 2 *Prenatal CPT Codes and Medicaid Facility Reimbursement Fees (Source: Montefiore Hospital[50])*

Input No.	CPT Code	Input Description	Parameter Estimate ($ cost)	Data Input	Data Source
121	59400	Routine obstetric care, including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and (inpatient and outpatient) postpartum care (total, all-inclusive, "global" care)	$1,720.75	Medicaid Facility Fee: $1,720.75 Medicaid Non-Facility Fee: $1,720.75	50
122	59510	Routine obstetric care, including antepartum cesarean and (inpatient and outpatient) postpartum care (total, all-inclusive, "global" care)	$1,948.09	Medicaid Facility Fee: $1,948.09 Medicaid Non-Facility Fee: $1,948.09	50

While the above costs are all fee-for-service or bundled fees for prenatal care, delivery, and postpartum care, telehealth also has fixed infrastructure costs one must consider. "ACOG guidance indicates that blood pressure, glucose, and weight monitoring are essential components of comprehensive obstetric care, making the availability of at-home monitoring equipment essential for improving access to telehealth services for pregnant and postpartum women."[51] On account of the COVID-19 pandemic, Medicaid has expanded their coverage of "durable medical equipment" (DME), coded within the Healthcare Common Procedure Coding System (HCPCS), to include at-home monitoring devices critical to telehealth supplemented prenatal care. In the model, the input combines all the individual equipment costs into one durable medical equipment parameter, with a value of $344.92.

The HIPAA-compliant software included in *Table 3* is listed by the U.S. Department of Health and Human Services.[52] The choice of the plan included in the table are those with HIPAA-safe security and for clinics in need of 50 licenses or less (for larger health care plans, no standard pricing was readily available). $32.28 per user per month is the average of the 7 plans found in *Table 3*. Given the year-long time horizon and the limit of 50 licenses, the input is calculated as $7.75 per patient per year (See the second part of *Table 3* for the specific calculation).

Table 3 *Additional Costs and Resources applicable to both OB Nest and Standard Care interventions (data sources as specified)*

Input No.	Input Description		Data Input	Data Source
	Durable Medical Equipment			
123a	HCPCS: A4663	Blood pressure cuff	\$54.67 (Washington)	53
123b	HCPCS: E0607	Home blood glucose monitor	\$77.78 (NU), \$7.77 (RR), \$58.33 (UE) \$75.95 (Washington) \$64.99 (N. Carolina)	54 53 55
123c	HCPCS: E0445	Pulse Oximeter (Medicaid only covering during COVID-19)[56]	\$148.55 (N. Carolina)	55
123d	HCPCS: E1639	Weight scale (Medicaid only covering during COVID-19)[56]	\$76.71 (N. Carolina)	55
	HIPAA Compliant Videoconferencing Software			
124a	Doxy.me		\$42 per user, per month	57
124b	VSee		\$49 per user, per month	58
124c	Zoom for Healthcare		\$19.99 per user, per month	59
124d	GoToMeeting		\$19 per user, per month	60
124e	Microsoft Teams		\$20 per user, per month	61
124f	Cisco Webex Meetings		\$26.95 per user, per month	62
124g	Spruce Healthcare Messenger		\$49 per user, per month	63

Input No.	Input Description	Parameter Estimate (aggregate \$ cost)	Data Operation
123	Durable Medical Equipment	\$344.92	123a+123b+123c+123d
124	HIPAA Compliant Software	\$7.75/ patient/year	$\frac{\left(\frac{(124a + 124b + 124c + 124d + 124e + 124f + 124g)}{7}\right)(12)}{50}$

Neonatal intensive care for preterm infants (all infants born at a gestational age fewer than 37 weeks) "includes costs for the common admissions for respiratory problems, neonatal encephalopathy, sepsis, intrauterine growth retardation, and congenital anomalies."[45] Initial post-delivery NICU service costs were calculated regardless of the diagnosis recorded on discharge. The cost of the NICU admission was estimated by multiplying the length of stay for each final outcome group by the per diem cost reimbursed by Medicaid (see *Table 4* for reimbursement fees). The length of stay for each gestational age group was determined through reported data from March of Dimes, a national non-profit organization dedicated to maternal and pediatric health, and the appropriate CPT code and subsequent hospital service was informed by clinical expertise (see *Table 5*).[21,64]

Table 4 *Neonatal CPT Codes and Corresponding Medicaid Facility Reimbursement Fees (Source: Montefiore Hospital[50])*

Input No.	CPT Code	Treatment Description	Parameter Estimate ($ cost)	Data Input	Data Source
125	99221-99223	Initial hospital evaluation and management of care for newborns who are not normal but do not require intensive services.	$51.20	Medicaid Facility Fee: $34.90; $48.07; $70.62	50
126	99231-99233	Subsequent hospital care for newborns who are not normal but do not require intensive services.	$25.29	Medicaid Facility Fee: $14.57; $26.01; $37.28	50
127	99477	Initial hospital care of the newborn *who is not critically ill* but requires intensive observation, frequent interventions, and other intensive care services…including intensive cardiac and respiratory monitoring, continuous and/or frequent vital sign monitoring, heat maintenance, enteral and/or parenteral nutritional adjustments, laboratory and oxygen monitoring, and constant observation by the health care team under direct physician supervision. This code may be reported only once per day and by only one physician.[65]	$132.44	Medicaid Facility Fee: $132.44	50
128	99478-99480	Subsequent intensive care, per day, for the evaluation and management of the recovering low or very low birth weight infant (<1,500 g; 1500-2500g; 2,501-5,000g).[65]	$63.96	Medicaid Facility Fee: $70.48, $61.88, $59.51	50
129	99468	Initial day of critical care for the evaluation and management of a critically ill neonate, 28-days of age or less.[65]	$354.03	Medicaid Facility Fee: $354.03	50
130	99469	Subsequent days of critical care to the critically ill neonate are reported per day.[65]	$155.02	Medicaid Facility Fee: $155.02	50

Table 5 *Neonatal Intensive Care Unit Length of Stay Parameters (Source: March of Dimes[64])*

Input No.	Input Description	Parameter Estimate (# days)	Data Input	Data Source
131	Length of stay in the NICU for infants born at a gestational age < 28 weeks (not including initial admission day)	116.73	117.731-1	64
132	Length of stay in the NICU for infants born at a gestational age 28-32 weeks (not including initial admission day)	56.75	57.75-1	64
133	Length of stay in the NICU for infants born at a gestational age 32-37 weeks (not including initial admission day)	42.60	43.60-1	64
134	Length of stay in the NICU for infants born at a gestational age > 37 weeks (not including initial admission day)	2.50	3.50-1	64

Innovative cost structuring

Table 6 includes the CPT codes that record separated obstetric services, as opposed to the standard bundled care structure. By breaking up the obstetric services—specifically detaching prenatal visits from delivery and postpartum care—the cost for reduced-visit prenatal care programs becomes significantly less than standard care programs that include 12-14 in-person provider visits. While Medicaid currently ensures payment parity between telehealth and in-person prenatal programs, an innovative cost structure may result in cost savings. Standard care would refer to CPT code 59426, reimbursed at $817.52, while OB nest would include 6 antepartum in-person visits, CPT code 59425, reimbursed at $326.92. OB Nest also includes 6 virtual visits, billed for CPT code 99442, which would be reimbursed for a total of $140.88. Thus, the OB Nest prenatal program, in a base case scenario would result in a savings of $349.72 per patient ($817.52 - $326.92 - $140.88). The cost comparison excludes postpartum care as the separated cost, listed below in *Table 6*, is equivalent for the OB Nest program and for standard care.

Table 6 *CPT Codes and Corresponding Medicaid Reimbursement Fees for Obstetric Services that can be Separated (Source: Montefiore Hospital[50])*

Input	CPT Code	Input Description	Parameter Estimate ($ cost)	Data Input	Data Source
135	59426	7 or more antepartum visits	$817.52	Medicaid non-facility fee: $817.52	50
136	59425	4-6 visits, antepartum care only	$326.92	Medicaid non-facility fee: $326.92	50
137	99442	Online digital evaluation and management amounting to 11-20 minutes	$23.48	Medicaid non-facility fee: $23.48	50
138	59410	Vaginal delivery only	$763.98	Medicaid non-facility fee: $763.98	50
139	59612	Vaginal delivery following previous Cesarean section	$856.17	Medicaid non-facility fee: $856.17	50
140	59514	Cesarean section only	$903.11	Medicaid non-facility fee: $903.11	50
141	59620	Cesarean section following previous Cesarean section	$985.48	Medicaid non-facility fee: $985.48	50
142	59510	Postpartum care only	$156.29	Medicaid non-facility fee: $156.29	50

Societal perspective costs

In order to convert the patient time costs into dollar amounts, the 2018 Federal Poverty Level (FPL), upon which Medicaid eligibility rests, was calculated. The year 2018 was chosen because the study on the distance to hospitals across the U.S. was conducted in 2018, and the available CDC data upon which the event probabilities are based was also from 2018. Pregnant women eligible for Medicaid coverage must be within 200% of the FPL. Individual states have the discretion to increase or decrease the eligibility threshold as a percentage of the FPL. For example, states like Idaho, Louisiana, Oklahoma, and South Dakota all mandate that Medicaid eligibility is determined by 138% of the FPL, while other states like Iowa have mandated that Medicaid eligibility is determined by 380% of the FPL.[66]

According to the U.S. Department of Health and Human Resources, the poverty level depends on the size of the household—a 1-person household must earn $12,140 or less, while a 4-person household must earn $25,100 or less in 2018.[67] Thus, Medicaid pregnant patients must earn $24,280 or less for a 1-person household and $50,200 or less for a 4-person household. To simplify the calculation, an average Medicaid pregnant enrollee's income level was determined by averaging 200% of the FPL for 1 to 4-person household annual incomes. The resulting average annual income for a Medicaid enrollee was $37,240. Federal full-time employees work a compensable 2080 hours a year.[68] An hourly wage was thus calculated by dividing $37,240 by 2080 hours, resulting in an average Medicaid enrollee wage of $18 per hour.

The calculation of patient costs also weighs their rural, urban, and suburban residence status. Generally, 24% of Medicaid enrollees live in rural areas, 22% live in urban areas, and 21% live in "other" regions, including suburban counties.[69] *Table 7* provides additional detail about these calculations and the overall patient-facing parameter estimates for telehealth appointments, in-person appointments, and travel time.

Table 7 *Patient facing costs included in the societal perspective (data sources as specified)*

Input	Input Description	Parameter Estimate ($ cost)	Data Input	Data Source
143	Telehealth appointment cost (wait time and length of appointment	$2.98	$\left(\frac{\$18}{60\text{ min.}}\right)(10\text{ min.})$	21 67 68
144	In-person appointment cost (wait time and length of appointment)	$8.95	$\left(\frac{\$18}{60\text{ min.}}\right)(40\text{ min.})$	21 67 68
145	Average two-way travel cost to health care center (weighted by rural, suburban, urban status)	$5.29	$\left(\left(\frac{\$18}{60\text{ min}}\right)(17.0\text{ min})\right)(0.24)$ =Rural: $2.44 $\left(\left(\frac{\$18}{60\text{ min}}\right)(11.9\text{ min})\right)(0.21)$ =Suburban: $1.49 $\left(\left(\frac{\$18}{60\text{ min}}\right)(10.4\text{ min})\right)(0.22)$ =Urban: $1.37	67 68 70

Patient cost-sharing

Normally, in cost-effectiveness analyses that consider a societal perspective, patient cost-sharing is an important factor in understanding which costs land on the payer and which costs land on the patient. Though the OB Nest clinical trial provides little information on patient cost-sharing for its programs, Medicaid law prohibits states from charge patients deductibles, copayments, or other similar charges for pregnancy-related services.[71]

Additionally, a child born to a woman enrolled in Medicaid at the time of the birth is eligible for Medicaid newborn coverage that lasts for one year regardless of any income changes that may occur in that year. This implies that NICU costs, which are the most expensive inputs in this model, would be covered by Medicaid, ensuring that the infants' mothers would not be burdened with outrageous costs.[71]

9. COST-EFFECTIVENESS: METHODS AND RESULTS

Overview

The purpose of this cost-effectiveness analysis is to inform decision-making about which method, a standard care program or a reduced-visit, telehealth-supplemented program is best and should be considered following the COVID-19 pandemic for low-risk Medicaid patients in the United States. To that end, the evaluation addressed the following questions: 1) which intervention, standard care, or OB Nest, appears to be the most cost-effective within each cost context for this particular patient population; and 2) what is the uncertainty surrounding these choices? While *Section 9* addresses the first of these questions, *Section 10* addresses the second question.

To address the first question, we need to estimate the costs and the chosen clinical effects, NICU admissions avoided and Cesarean deliveries averted, for both the standard care and the Mayo Clinic OB Nest intervention. Following this, we can then determine which intervention is cost-effective in terms of these clinical outcomes. Typically, standard decision rules are applied whereby dominated and extendedly dominated interventions are removed from consideration and the incremental cost-effectiveness ratio (ICER)—in this case using NICU admissions avoided or Cesarean deliveries averted as the incremental effect—is calculated for the remaining strategies.[72] In this case, however, both interventions have clinically equivalent outcomes, resulting in an indeterminate ICER with zero in the denominator. The difference of interest, at least in a deterministic model, is thus incremental costs.

I argue that while standard practice might not continue to conduct a cost-effectiveness analysis on clinically equivalent strategies, it is of particular importance to do so at this moment. During the current national health emergency, health care in general, and obstetric care in particular, have shifted towards telehealth delivery to reduce viral transmission. It is thus especially important to investigate the costs and effects surrounding the telehealth intervention to inform future policy decisions on whether or not to continue a telehealth-supplemented care program following the end of the pandemic. Additionally, there is some precedence within the field of health economics for continuing with evaluation even after no statistically significant difference is found in clinical outcomes.[73,74]

Given the clinical equivalence and the fact that both the incremental NICU admissions avoided and the incremental Cesarean deliveries averted are both 0, the most reductive and rigid decision is determined by which strategy is less costly. Depending on the willingness to pay threshold for a policy decision, the optimal intervention can be identified. However, a standard willingness to pay threshold has not yet been determined for NICU admissions avoided or Cesarean deliveries averted for the United States.

Several cost outputs were produced considering various evaluation perspectives and cost inputs. First, health system costs were considered. These include costs facing the payer—reimbursement fees for obstetric and neonatal intensive care. Second, patient costs were considered from a societal perspective. These included both the costs facing the payer and costs facing the patients, such as time spent waiting and seeing the physician in an office visit and time traveling to health care centers. Within each perspective, traditional costs and "innovative" costs were considered. Traditional costs include the global sums Medicaid is currently reimbursing, while "innovative" costs include CPT reimbursement that differs for reduced-visit prenatal care programs (See *Section 8, Table 6*).

Results

Table 8 *Results (costs and clinical effects) of the deterministic analysis*

	Health System Perspective		Societal Perspective		Clinical Effect	
Structure	Traditional Costs	Innovative Costs	Traditional Costs	Innovative Costs	C-Sections Averted	NICU Admissions Avoided
Standard Care	$2,144.73	$2,108.25	$2,344.13	$2,307.66	76024.7662	128781.8204
OB Nest	$2,497.39	$2,188.22	$2,597.75	$2,288.58	76024.7662	128781.8204
Increment:	**$352.67**	**$79.97**	**$253.62**	**-$19.08**	**0.000**	**0.000**

	Health System Perspective	Societal Perspective
ICER (traditional costs, NICU admissions)	$\frac{\$352.67}{0}$	$\frac{\$253.62}{0}$
ICER (traditional costs, C-sections)	$\frac{\$352.67}{0}$	$\frac{\$253.62}{0}$
ICER (innovative costs, NICU admissions)	$\frac{\$79.97}{0}$	$\frac{-\$19.08}{0}$
ICER (innovative costs, C-sections)	$\frac{\$79.97}{0}$	$\frac{-\$19.08}{0}$

Table 8 reveals that under the current assumptions and model parameter values, three out of the four cost contexts find that the standard care program is more costly compared to the telehealth-supplemented OB Nest intervention. In cost scenario 1, a health system perspective that considers traditional costs, the OB Nest program increased costs by 16.44%. In cost scenario 2, a health system perspective considering innovative costs, the OB Nest program increased costs by 3.79%. Finally, in cost scenario 3, a societal perspective considering traditional costs, the OB Nest program increased costs by 10.82%. The innovative cost structure considered within a societal perspective is the only case where the OB Nest program is actually cost-saving with an incremental cost difference of -$19.08—a 0.83% decrease in costs.

10. DECISION UNCERTAINTY AND VALUE OF INFORMATION ANALYSIS

Section 9 discussed the expected deterministic cost results, considering a variety of contexts and expected deterministic clinical outcomes of both interventions. The analysis shows that standard care is the most cost-effective intervention in all cost contexts, save one, given the currently available data and information. The decision on whether to continue with standard care following the pandemic is one that must also consider whether the existing evidence is sufficient enough to be confident in this decision or whether more information is necessary to come to a more informed conclusion.

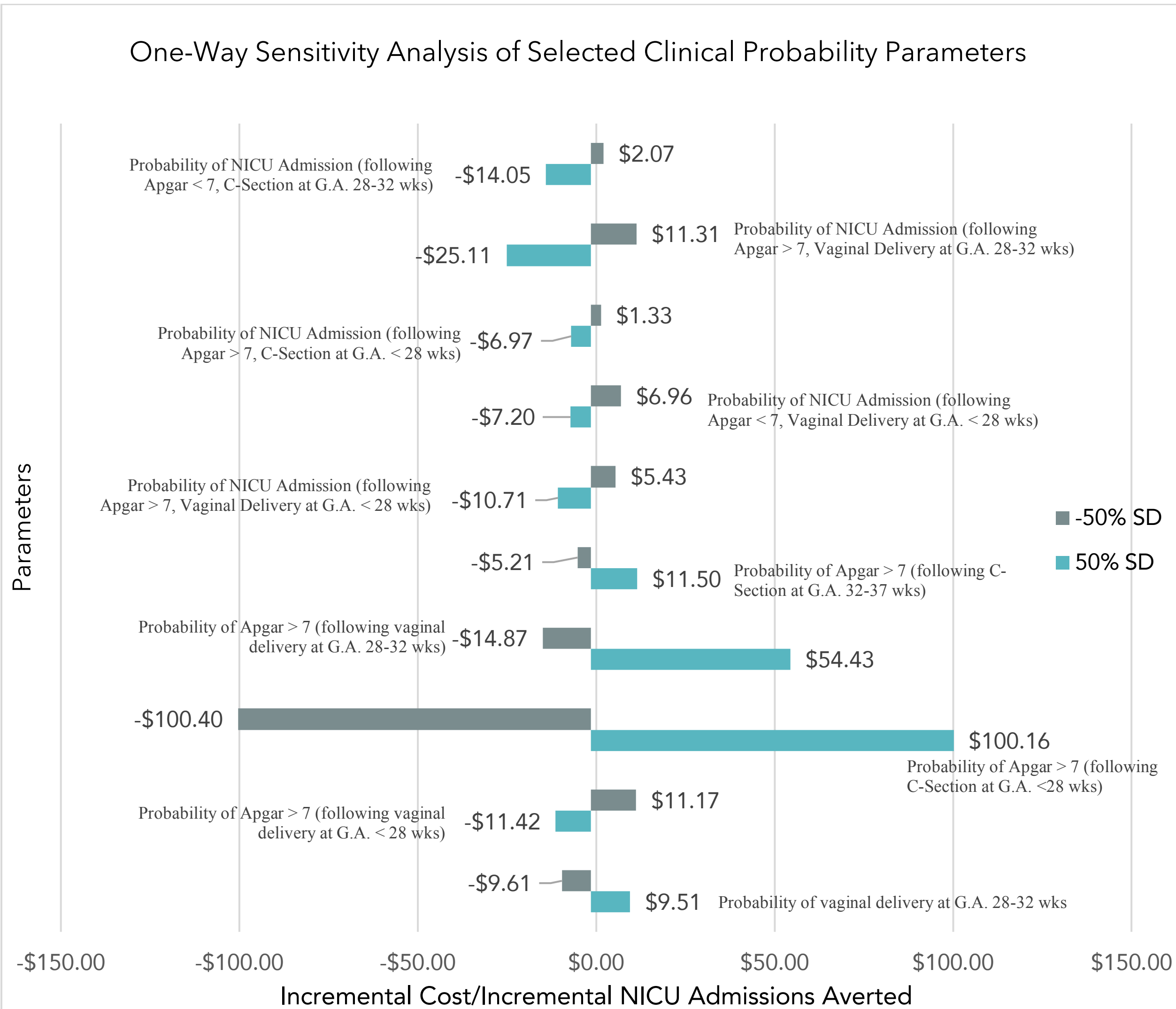
Section 8 shows that there is extensive uncertainty surrounding the model inputs—Medicaid eligibility and reimbursement is not consistent across the United States, there are only two randomized controlled trials available for the OB Nest intervention with a different patient population than the one included in this model, and patient travel costs may vary significantly across the country dependent on rural, suburban, or urban residence status. *Section 9* shows that the cost-effectiveness decision is subject to variation depending on the cost structure and perspective considered.

Deterministic sensitivity analysis

Consequently, extensive sensitivity analysis was conducted to shed further light on the uncertainty surrounding this model and its conclusions. First, a one-way deterministic sensitivity analysis of each parameter considered in the telehealth intervention was conducted in order to explore the extent to which the ICER results changed under a range of parameter values. The analysis varied the parameter by +/-50% or up to 0.99 for probability parameters (if +50% was greater than 1.0). The complete results can be found in *Appendix B*. The tornado diagram in *Figure 5* displays the 10 clinical event probability parameters whose variation had the greatest effect on the incremental traditional cost-incremental NICU admission avoided ratio from a health system perspective. As *Figure 5* reveals, the parameter with the greatest change in ICER is the probability of a 5-minute Apgar score > 7 following a Cesarean delivery at a gestational age of fewer than 28 weeks.

As to be expected, varying the cost parameter values only affected incremental costs. The greatest variation from the base estimate came from the Medicaid global sum reimbursement for obstetric services during pregnancy, delivery, and postpartum care. The complete results can be found in *Appendix B*.

Figure 5 *One-way sensitivity analysis of the 10 clinical event parameters that had the greatest influence on the ICER (incremental traditional costs/incremental NICU admissions avoided), presented as a tornado diagram*



Probabilistic sensitivity analysis

A probabilistic sensitivity analysis was conducted to provide a broader picture of the joint uncertainty present in the model. In this analysis, gestational probabilities were sampled from Dirichlet distributions, while the rest of the clinical event probabilities were sampled from beta distributions. Cost, length of stay, and the number of prenatal visit parameters were sampled from gamma distributions. Gestational probabilities were not binomial but were still bound within the interval 0 to 1, which is why the Dirichlet distribution was chosen. The beta distribution, assigned to the other clinical event probabilities that were binomial, is also consistent with these boundaries. On the other hand, costs have the potential to be large following expensive, lengthy NICU stays, and thus a gamma distribution, where values are positive and only bound 0 on one end, is appropriate. The sampling distributions were derived from point estimates provided by the 2018 CDC Natality data file and by a 25% standard error for each variable. 25% was chosen to reflect the pervasive uncertainty present in this model.

A second-order Monte Carlo simulation was run using 2018 Microsoft Excel with 10,000 iterations to test the uncertainty surrounding the ICER. In each of the 10,000 iterations, the simulation randomly selected input parameters from the aforementioned statistical probability distributions and produced new costs and clinical effects, used to then calculate ICERs. *Table 9* records the average results from both the health system and societal perspectives. Unlike in the deterministic case where the incremental NICU admissions avoided and incremental Cesarean deliveries averted were both 0, the probabilistic results record an average difference across the 10,000 iterations, which results in an incremental difference of 2 Cesarean deliveries averted and -1 NICU admission avoided. The difference in clinical effect allows for the calculation of average probabilistic ICERs, as shown in the second part of *Table 9*. The smallest positive average probabilistic ICER, at $14.20, is the one that considers the societal perspective and uses the innovative cost structure. The health system traditional cost ICER, the health system innovative cost ICER, and the societal traditional cost ICER—three of the four different ICERs that use the incremental NICU admissions avoided were negative. While this may make it seem like the OB Nest intervention is the most cost-effective when considering these perspectives, it is important to note that drawing conclusions on the sign of the ICER may be faulty. Negative ICERs can be located in either the Northwest or Southeast quadrants of the cost-effectiveness plane.

Table 9: *Average probabilistic analysis results (costs and clinical effects) from 10,000 Monte Carlo simulations*

	Health System Perspective		**Societal Perspective**		**Clinical Effect**	
Structure:	Traditional Costs	Innovative Costs	Traditional Costs	Innovative Costs	C-Sections Averted	NICU Admissions Avoided
Standard Care	$2,144.47	$2,104.17	$2,343.84	$2,303.55	76,023	128,782
OB Nest	$2,503.99	$2,187.88	$2,604.03	$2,287.92	76,025	128,781
Increment:	**$359.52**	**$83.71**	**$260.18**	**-$15.63**	**2**	**-1**

	Health System Perspective	**Societal Perspective**
ICER (traditional costs, NICU admissions)	-$326.69	-$236.42
ICER (traditional costs, C-sections)	$189.35	$137.03
ICER (innovative costs, NICU admissions)	-$76.07	$14.20
ICER (innovative costs, C-sections)	-$44.09	-$8.23

Table 10 depicts the location on the cost-effectiveness plane of the 10,000 PSA simulated ICERs that consider traditional and innovative costs in either the health system or societal perspective, and the incremental NICU admissions avoided. Those iterations located in the Northwest quadrant represent the simulations where the standard care program dominates. In other words, the OB Nest program is more costly and less effective. The iterations located in the Southeast quadrant represent the cases where the OB Nest program dominates and where it should be adopted as it is less costly and more effective. The Northeast and Southwest quadrant represent cases where a tradeoff occurs, depending on a willingness to pay per NICU admission avoided threshold.

Using the health system traditional cost perspective, we can see that concluding that the OB Nest program is cost-effective on account of its negative ICER is not necessarily correct since 38.88% of its iterations are located in the Northwest quadrant compared to 11.40% located in the Southeast quadrant. The spread of all iterations in each cost scenario makes it difficult to conclude whether the OB Nest intervention is cost-effective in terms of incremental NICU admissions avoided. Similar results were found when exploring the secondary outcome of interest, Cesarean deliveries averted (please see *Appendix C* for specific details).

Table 10: *Cost-effectiveness plane locations for 10,000 probabilistic ICERs (incremental cost/incremental NICU admission averted)*

	Health System Perspective		Societal Perspective	
C.E. Quadrant:	Traditional Costs	Innovative Costs	Traditional Costs	Innovative Costs
Northeast	3808 (38.08%)	3203 (32.03%)	3445 (34.45%)	2452 (24.52%)
Northwest	3888 (38.88%)	3233 (32.33%)	3586 (35.86%)	2476 (24.76%)
Southeast	1140 (11.40%)	1745 (17.45%)	1503 (15.03%)	2496 (24.96%)
Southwest	1164 (11.64%)	1819(18.19%)	1466 (14.66%)	2576 (25.76%)

A cost-effectiveness acceptability curve (CEAC) and a cost-effectiveness acceptability frontier (CEAF) were also considered for each cost perspective to provide additional information on the likelihood of cost-effectiveness and optimal intervention. To create the CEAC and CEAF, Net Monetary Benefits (NMB) were also considered. A baseline willingness to pay threshold for a NICU admission avoided was determined by averaging the NICU length of stay (54.65 days) and the NICU reimbursement values ($179.22 for the initial day and $81.64 for subsequent days), which came to $4,599. For simplicity, a $5,000 threshold was used. As noted in *Table 11*, at a $5,000 per NICU admission avoided, the OB Nest has a slightly greater than 50% (50.52-50.54%) probability of being cost-effective for all four cost structures and perspectives.

Table 11: *Cost-effectiveness acceptability curve results for each cost scenario at a $5,000 per NICU admission avoided threshold*

	Health System Perspective		Patient Perspective	
Structure:	Traditional Costs	Innovative Costs	Traditional Costs	Innovative Costs
Standard Care	49.46%	49.48%	49.48%	49.48%
OB Nest	50.54%	50.52%	50.52%	50.52%

11. DISCUSSION/ APPLICATION OF THE TELEHEALTH PRENATAL PROGRAM EVALUATION

Analytical approach

One strength of this study is the use of real-world data and randomized controlled trial data in informing the parameter estimates. The fact that the data comes from 2018 and the fact that the randomized control trial occurred in 2014-2015 ensures that the current pandemic did not influence the data and thus the model. The presence of the COVID-19 pandemic might otherwise have had an underlying confounding influence as virtual care displaced in-person care across the country when emergency policies were implemented. Additionally, as mentioned earlier, this study begins to fill the void in the literature around evaluating the costs associated with telehealth prenatal care programs. The fact that this study includes both payer reimbursement costs and patient-facing costs in four differently constructed cost scenarios is a strength.

Nevertheless, many assumptions were made creating and running this model, resulting in potential limitations.

Limitations

First, it was assumed that the clinical event probabilities were the same for those receiving the telehealth intervention as for those receiving standard care, as was the case in the 2014-2015 OB Nest clinical trial (See *Section 8*). It is important to note, however, that 81% of women enrolled in the OB Nest trial earned an annual household income of greater than $80,000, 90% had private insurance, and 91.3% were white.[9] While this population might be representative of Rochester, Minnesota, the location in which the clinical trial took place, it is not representative of the United States at large. The clinical trial population is especially not representative of U.S. women enrolled in Medicaid, the nation's public insurance for people with low income.[75] As discussed in *Section 8*, pregnant Medicaid enrollees must be within 200% of the federal poverty level and even less so in some U.S. states. This means that, on average, 1-4-person households earn a total of $37,240 or less annually—less than half of what the enrollees in the clinical trial earned.

Second, while the 2018 CDC Natality data file provides information for all clinical event probabilities, it does not include any NICU length of stay data. Consequently, the NICU length of stay is estimated based on gestational age—information provided by other studies.[64] While studies show that gestational age is correlated with length of stay, it does not cause or determine precisely how long infants stay in the intensive care unit. Thus, predicting NICU length of stay based on gestational age is not ideal. Additionally, since the data file does not include the specific services the NICU provided to each infant, it is not certain that the CPT code applied to the various infants in each decision tree group represents the services that were actually provided.

Another limitation is the lack of standard quality of life information for newborns. For reasons mentioned in *Section* 6, it is not possible to use QALYs in this model without collecting additional data that uses parents or caregivers as proxies for newborns. With QALY estimates, a standard willingness to pay threshold could have been applied, helping decision-makers understand the tradeoffs implicit in funding these interventions. ICERs that use NICU admissions avoided may be less meaningful to health service administrators as they do not allow for comparison across differing diagnoses, treatments, or patient groups. Consequently, the ICERs calculated in this study do not necessarily inform whether the programs would result in net costs or savings to the health care system at large as would be the case if it were possible to use a more universal and health-system comprehensive measure, such as QALY.[32]

Fourth, as mentioned in *Section 8*, Medicaid reimbursement is determined on a state-level, implying that while CMS may provide regulations and recommendations, it cannot determine whether state Medicaid covers certain services—such as telehealth-supplemented prenatal care—and it cannot determine the reimbursement amount. Therefore, significant variation between the states can be expected, implying that estimates from the state Medicaid services that make their cost information accessible—such as New York State are not necessarily representative of all states. This model assumes one set of Medicaid reimbursement values as its cost inputs for the U.S. population. The standard error included in the probabilistic sensitivity analysis is large at 25% to account for this tenuous assumption.

Lastly, the cost scenarios only capture reimbursement to practitioners and leaves for a future study one of the potentially largest hurdles to implementing an efficient telehealth program, namely provider involvement. Unless a physician or other provider can make up any reduced reimbursement rates by time and cost savings that allow them to recapture the lost revenue, they are not likely to voluntarily embrace telehealth.

Generalizability of findings

This model is based on data inputs that represent the best publicly available evidence at the time of this review. In an ideal world, data would be available for the year 2019 to serve as a base case against the year 2020 when virtual care became more prevalent. If 2020 data were available, it might have been possible to tease out additional cost information, such as a change in demand for telehealth, which might have been of great relevance for current policymakers considering continuing telehealth after the pandemic.

The need for reform of prenatal care programs

According to 2010 U.S. Census data, "there are 2.65 [OB-GYN doctors] for every 10,000 women and 5.39 OB-GYN doctors per 10,000 reproductive-aged women. It is noteworthy that approximately 49% of all the US counties did not have a single OB-GYN doctor, and 8.2% of all U.S. women lived in those predominantly rural areas."[3] This is equivalent to over ten million women that may not have access to obstetric physicians at all or may have to travel significant distances to access obstetric care.[76] Consequently, the need for remote care is significant as co-located and in-person prenatal care is not always possible.

Additionally, despite the enormous amount of money dedicated towards obstetric services, the United States is the only so-called developed country where the rate of maternal mortality has been increasing over the last few decades.[77] The U.S. "has one of the highest rates of both infant and maternal deaths among industrialized nations, and with a 1 in 1800 risk of maternal death, maternal mortality is on the rise. Moreover, 52,000 women each year experience severe maternal morbidity, which may lead to health problems that last a lifetime".[26] Poor obstetric outcomes are often attributed to "poor access to prenatal care, high rates of chronic disease, and the highest rate of skipping necessary health care due to cost barriers".[76]

There is also a significant disparity in who faces these outcomes. In particular, Black women, Native American women, and women living in rural areas are at increased statistical risk of poor maternal outcomes. In fact, women in rural regions "have a 9% greater likelihood of severe maternal morbidity/mortality than their urban counterparts because of factors including workforce shortages, transportation barriers, the opioid epidemic and limited access to specialty care".[76]

Medicaid financed 43% of all births in the United States in 2018, which in itself is reason enough to narrow in on its population.[78] A focus on Medicaid is even more called for since "Medicaid paid for a larger share of births in rural areas that other payers".[78] Additionally, in 2018, 59.3% of all Medicaid recipients across the United States are people of color, with 19.7% Black enrollees 1.1% American Indian/Alaska Native enrollees.[79]

Given the inadequate access to obstetric physicians and prenatal care in rural areas in the United States and the rise in severe obstetric outcomes such as maternal mortality and morbidity in communities of color, there is a clear need for reform in an industry that has been stagnant since World War II.

Addressing access barriers for the Medicaid population

Telehealth presents a particular opportunity for patients enrolled in Medicaid. Not only do patients save time traveling back and forth to obstetric clinics with fewer in-person visits in a program like OB Nest, as shown by this model, but a greater number of patients may potentially gain access to care that they might otherwise not have received. Though this model does not consider an increase in the demand for telehealth, it is a consideration that should not be overlooked.

Recent U.S. trends show that rural hospitals are shutting down at alarming rates. As of December 2018, "95 rural hospitals have closed since 2010".[80] In fact, the rates of closure are worsening since "twice the number of hospitals have closed between 2013 and 2017 than in the previous five-year period".[80] This trend may mean a particular barrier to access for the large portion of Medicaid patients living in rural areas.

Additionally, March of Dimes, a national non-profited dedicated to maternal and pediatric health, recently conducted a study that analyzed the existence of "maternity care deserts," counties where access to obstetric care is limited or unavailable altogether due to a lack of these services or barriers to access care. The study found that more than 5 million women in 1,085 counties across the United States live in these care deserts where there is neither an available hospital providing obstetric services nor any obstetric providers.[81]

These two concerning U.S. trends reveal that telehealth can potentially remove some of the access barriers Medicaid patients face. By providing care at a distance, patients living in maternity care deserts and other rural areas may save time and have additional access to obstetric care proven to improve maternal and neonatal outcomes compared to those with access to no prenatal care.[23,24]

Additional demand may drive the cost of telehealth even lower since more providers may share HIPAA compliant software subscriptions, more clinics may overcome high infrastructure costs, and durable medical equipment may become less costly as patients return the equipment following the course of pregnancy.

The potential advantages of telehealth during the COVID-19 pandemic

The United States is at a particularly unique moment in its history where the implications of the novel COVID-19 pandemic have spread beyond the confines of the health industry and have permeated the political, legal, and policy arena. Historically, "telemedicine is not utilized and developed actively due to lack of legal and policy support for [the] responsibility of services, absence of effective evidence, instability of information and communication technology, and insufficient infrastructure for education and training systems." [82] In particular, Medicaid—the single largest source of health care coverage in the United States, insuring over 72.5 million Americans—only reimbursed telehealth services delivered to patients in their homes in 19 out of the 50 states. [76,83]

However, the interest, funding, and policy support of telemedicine have all risen to the occasion to meet the need of patients and providers who cannot leave their homes to receive or deliver care in-person during the COVID-19 pandemic.

At the beginning of the SARS CoV-2 outbreak in March, the United States declared a national state of emergency on account of the pandemic. Following this declaration, the Coronavirus Aid, Relief, and Economic Security Act (CARES) was passed to provide support to the American people in their time of crisis. This large policy not only injected billions in funding into the health care sector, called for paid sick leave, and required the reimbursement of COVID-tests, the CARES Act also highlighted and encouraged the growth of the telehealth industry.[84]

The potential disadvantages of telehealth

While the advantages of telehealth, especially at this moment, appear great, concerns over the potential disadvantages of this disruptive industry must not be overlooked. For example, some patients may have limited access to computer or broadband internet access, while others may receive different providers with each health care interaction.[85] Studies that interview telehealth patients and providers have shown that this may reduce comfort, stress, or trust in the services provided.[86]

Sometimes, long-distance diagnosis may be difficult or even impossible as additional tests may require equipment not available at the patients' location. If misdiagnosis does occur, malpractice lawsuits provide additional burden and risk to providers. Additionally, despite the recent policy expanding telehealth reimbursement, cross-state and cross-payer reimbursement is tedious and poses an additional administrative burden.[3]

Finally, though there is currently payment equality between the reimbursement amounts for services delivered via telehealth and those delivered in-person, there is a potential disparity between the two routes of care delivery, as evidenced by the difference in reimbursement between the "traditional cost" and "innovative cost" structure in this model. While payers like Medicaid might find the cost-saving aspect of the innovative cost structure beneficial, it may serve as a point of friction with providers who face a loss in income. Providers may therefore be disincentivized to provide telehealth services to their patients.

Recommendations for future studies

Given the lack of available data and the other limitations present in this study, there are opportunities for fruitful future research. First, by collecting information and using health-related quality of life measures specifically designed for infants in the NICU, rather than just using a NICU admission avoided measure, net costs and benefits to the health system as a whole can be more readily identified. A threshold value might also be available for this type of quality of life measure. There are several promising measures, including the Infant Quality of Life Instrument (IQI), that might be worthwhile introducing into future studies that include NICU admissions in their decision tree models.[47]

Additionally, collecting data through expert interviews, using the Delphi technique, for example, might inform the probabilities in varying patient populations.[87,88] This model uses the same probabilities for Medicaid patients located across the United States, as patients enrolled in the 2014-2015 Mayo Clinic OB Nest clinical trial, who, as previously discussed, have different demographic characteristics. By interviewing obstetric physicians and nurses in areas that are dependent upon Medicaid to finance the majority of prenatal care, delivery, and postpartum care, these social determinants of health might be teased out, and the decision tree probabilities might become more representative of the specific patient population.

This paper does not directly undertake a provider perspective. Some studies have shown that physicians and other providers actually present one of the greatest challenges to the implementation of telehealth services.[89] Some providers may not want to change their way of care delivery because of the advantages associated with in-person care or, more importantly, due to concerns over reimbursement.[88] While payers like Medicaid would be interested in a cost-saving structure such as the "innovative costs" structure presented in this paper, physicians might see it as a loss of income. Therefore, future studies might find it beneficial to explore reimbursement structures that do not decrease physician reimbursement but rather delegate costs differently. For example, by considering the type of skilled worker involved in delivering each aspect of obstetric care, Medicaid might reimburse less for telehealth monitoring conducted by nurses rather than physicians.[30] If it were shown that physicians then saved time by not monitoring the telehealth aspect of prenatal care and were able to see additional patients for the in-person aspect of their care, the physician might not see a loss in income.

This paper also does not directly address COVID-19 and instead uses 2018 data to inform its probabilities. The paper does consider Medicaid reimbursement in 2020 and payment parity between telehealth and in-person care through the "traditional cost" structure, included in both the health system perspective and the societal perspective. A prenatal care study that retrospectively begins in 2019 and continues through the COVID-19 pandemic might be useful in understanding the demand for obstetric telehealth services and whether it has changed during COVID-19. Since virtual care became increasingly normalized and promoted by the CDC and CMS in early 2020 to curb viral transmission in health care settings, it would be interesting to study whether those who had not previously had access to in-person prenatal care had novel access to virtual care. If the United States saw an increase in demand for obstetric telehealth in these areas, the demand might be sustainable following the end of the pandemic. If this were the case, telehealth might prove even more cost-effective. Therefore, it is important to understand the telehealth trends under COVID-19 and their potential for continuity following the end of the national emergency and emergency policies.

12. CONCLUSION

The purpose of this study is to evaluate the cost-effectiveness of the Mayo Clinic OB Nest program compared to standard prenatal care for U.S. low-risk Medicaid patients. More specifically, the three main objectives of this thesis are to 1) assess whether the OB Nest program can reduce the cost of care from a health system perspective, 2) assess whether the OB Nest program improves on clinical outcomes, including reducing NICU Admission and Cesarean deliveries, as a proxy for quality of care and 3) to assess whether OB Nest can reduce patient costs measured in patient time saved as a proxy for patient satisfaction.

To my knowledge, this is the first study that compares the costs associated with OB Nest and standard prenatal care beyond health care personnel time.[30] Additionally, this is the first study, to my knowledge, that investigates the cost-effectiveness of a reduced-visit, telehealth-supplemented prenatal care program in a United States-wide Medicaid population. While many assumptions are made, and publicly available data is limited, the results of this study provide initial insight into what obstetric telehealth might look like in a population that may have difficulty accessing care and one that is facing increasing maternal mortality. Additionally, the logic behind this model can be used to consider the cost-effectiveness of prenatal telehealth following the end of the COVID-19 pandemic when reimbursement policies are at the precipice of change.

Under the assumptions and parameters included in this model, the considered perspectives (health system and societal) and the considered cost structures ("traditional" and "innovative") both the standard prenatal care and the OB Nest program are equally cost-effective. While the deterministic results find no incremental clinical difference between the observed clinical outcomes for each program in terms of Cesarean deliveries averted and NICU admissions avoided, the results show differences in the incremental costs associated with each program. However, these cost differences must be taken with a grain of salt in light of the probabilistic sensitivity analysis, which finds hardly any difference in terms of incremental clinical effects and incremental costs. This small observed difference (less than 1%) in the probability of cost-effectiveness of each intervention, assuming a threshold of $5,000 per NICU admission avoided, is likely a result of random sampling noise. Thus, both interventions appear equally cost-effective.

While a model that concludes that there is no difference in cost-effectiveness between two interventions may sound disappointing, it is, in fact, an important conclusion in this current moment. In a time where COVID-19 makes it difficult and dangerous to visit physicians in person, it is essential to know that telehealth-supplemented prenatal care is an equally good option compared to standard in-person care.

Following the end of the pandemic, this model can be used with U.S. data collected retrospectively during the pandemic. By incorporating the low-risk Medicaid population in the sample that is used to inform decision-makers on whether to continue reimbursing reduced-visit, telehealth-supplemented prenatal care, we can gain insight into the benefits such care offers to a large and representative portion of all pregnant women in the United States. Ultimately, there is a need for reform within prenatal care to meet contemporary patient preferences, curb shameful maternal mortality statistics, and provide access to obstetric care to the most vulnerable women in the United States. This study can serve as the starting point to investigate whether telehealth is the optimal method for achieving this reform.

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14. APPENDICES

Appendix A: Model Inputs—Clinical Event Probabilities

Table 12 *Clinical Event Probability Inputs (Source: CDC 2018 Natality File[41])*

Input No.	Input Description	Parameter Estimate (probability)	Data Input	Data Source
	Gestational Age at Delivery			
1	Proportion of women that deliver at a gestational age < 28 weeks	0.0089	3,057/ 343,515	41
2	Proportion of women that deliver at a gestational age 28-32 weeks	0.0177	6,077/ 343,515	41
3	Proportion of women that deliver at a gestational age 32-37 weeks	0.1475	50,654/ 343,515	41
4	Proportion of women that deliver at a gestational age > 37weeks	0.8260	283,727/ 343,515	41
	Route of Delivery			
	Gestational Age (G.A.) < 28 weeks			41
5	Proportion of women who delivery vaginally	0.3085	943/3,057	
6	Proportion of women who deliver via c-section	0.6915	2,114/3,057	
	Gestational Age (G.A.) 28-32 weeks			41
7	Proportion of women who delivery vaginally	0.2300	1,398/6,077	
8	Proportion of women who deliver via c-section	0.7700	4,679/6,077	
	Gestational Age (G.A) 32-37 weeks			41
9	Proportion of women who delivery vaginally	0.3648	18,477/50,647	
10	Proportion of women who deliver via c-section	0.6352	32,170/50,647	
	Gestational Age (G.A.) > 37 weeks			41
11	Proportion of women who delivery vaginally	0.4029	114,290/283,698	
12	Proportion of women who deliver via c-section	0.5971	169,408/283,698	
	5 minute Apgar Score			
	G.A. < 28 wks, Vaginal Delivery			41
13	Proportion of infants with an Apgar Score ≥ 7	0.3934	371/943	
14	Proportion of infants with an Apgar Score < 7	0.6066	572/943	
	G.A. < 28 wks, C-Section			41
15	Proportion of infants with an Apgar Score ≥ 7	0.5875	1,242/2,114	
16	Proportion of infants with an Apgar Score < 7	0.4125	872/2,114	
	G.A. 28-32 wks,Vaginal Delivery			41
17	Proportion of infants with an Apgar Score ≥ 7	0.8741	1,222/1,398	
18	Proportion of infants with an Apgar Score < 7	0.1259	176/1,398	
	G.A. 28-32 wks, C-Section			41
19	Proportion of infants with an Apgar Score ≥ 7	0.8237	3,854/4,679	
20	Proportion of infants with an Apgar Score < 7	0.1763	825/4,679	
	G.A. 32-37 wks, Vaginal Delivery			41
21	Proportion of infants with an Apgar Score ≥ 7	0.9675	17,876/18,477	
22	Proportion of infants with an Apgar Score < 7	0.0325	601/18,477	
	G.A. 32-37 wks, C-Section			41
23	Proportion of infants with an Apgar Score ≥ 7	0.9427	30,327/32,170	
24	Proportion of infants with an Apgar Score < 7	0.0573	1,843/32,170	

	G.A. > 37 wks, Vaginal Delivery			41
25	Proportion of infants with an Apgar Score ≥ 7	0.9871	112,811/114,290	
26	Proportion of infants with an Apgar Score < 7	0.0129	1,479/114,290	
	G.A. > 37 wks, C-Section			41
27	Proportion of infants with an Apgar Score ≥ 7	0.9845	166,781/169,408	
28	Proportion of infants with an Apgar Score < 7	0.0155	2,627/169,408	
	NICU Admission			
	G.A. < 28 wks, Vaginal Delivery, Apgar ≥ 7			41
29	Proportion of infants admitted to the NICU	0.7844	291/371	
30	Proportion of infants not admitted to the NICU	0.2156	80/371	
	G.A. < 28 wks, Vaginal Delivery, Apgar < 7			41
31	Proportion of infants admitted to the NICU	0.3989	225/564	
32	Proportion of infants not admitted to the NICU	0.6011	339/564	
	G.A. < 28 wks, C-Section, Apgar ≥ 7			41
33	Proportion of infants admitted to the NICU	0.8951	1,109/1,239	
34	Proportion of infants not admitted to the NICU	0.1049	130/1,239	
	G.A. < 28 wks, C-Section, Apgar <7			41
35	Proportion of infants admitted to the NICU	0.9080	790/870	
36	Proportion of infants not admitted to the NICU	0.0920	80/870	
	G.A. 28-32 wks,Vaginal Delivery, Apgar ≥ 7			41
37	Proportion of infants admitted to the NICU	0.7158	874/1,221	
38	Proportion of infants not admitted to the NICU	0.2842	347/1,221	
	G.A. 28-32 wks,Vaginal Delivery, Apgar < 7			41
39	Proportion of infants admitted to the NICU	0.8068	142/176	
40	Proportion of infants not admitted to the NICU	0.1932	34/176	
	G.A. 28-32 wks, C-Section, Apgar ≥ 7			41
41	Proportion of infants admitted to the NICU	0.8328	3,208/3,852	
42	Proportion of infants not admitted to the NICU	0.1672	644/3,852	
	G.A. 28-32 wks, C-Section, Apgar < 7			41
43	Proportion of infants admitted to the NICU	0.9200	759/825	
44	Proportion of infants not admitted to the NICU	0.0800	66/825	
	G.A. 32-37 wks, Vaginal Delivery, Apgar ≥ 7			41
45	Proportion of infants admitted to the NICU	0.3278	5,857/17,865	
46	Proportion of infants not admitted to the NICU	0.6722	12,008/17,865	
	G.A. 32-37 wks, Vaginal Delivery, Apgar < 7			41
47	Proportion of infants admitted to the NICU	0.6889	414/601	
48	Proportion of infants not admitted to the NICU	0.3111	187/601	
	G.A. 32-37 wks, C-Section, Apgar ≥ 7			41
49	Proportion of infants admitted to the NICU	0.4443	13,464/30,304	
50	Proportion of infants not admitted to the NICU	0.5557	16,840/30,304	
	G.A. 32-37 wks, C-Section, Apgar < 7			41
51	Proportion of infants admitted to the NICU	0.7752	1,428/1,842	
52	Proportion of infants not admitted to the NICU	0.2248	414/1,842	
	G.A. > 37 wks, Vaginal Delivery, Apgar ≥ 7			41
53	Proportion of infants admitted to the NICU	0.0524	5,909/112,740	
54	Proportion of infants not admitted to the NICU 7	0.9476	106,831/112,740	
	G.A. > 37 wks, Vaginal Delivery, Apgar < 7			41
55	Proportion of infants admitted to the NICU	0.4292	633/1,475	
56	Proportion of infants not admitted to the NICU 7	0.5708	842/1,475	
	G.A. > 37 wks, C-Section, Apgar ≥ 7			41
57	Proportion of infants admitted to the NICU	0.0728	12,141/166,662	
58	Proportion of infants not admitted to the NICU	0.9272	154,521/166,662	
	G.A. > 37 wks, C-Section, Apgar < 7			41
59	Proportion of infants admitted to the NICU	0.4964	1,304/2,627	
60	Proportion of infants not admitted to the NICU	0.5036	1,323/2,627	

Appendix B: One-Way Deterministic Sensitivity Analysis Results

Table 13 *One-way sensitivity analysis: clinical event parameters (from a health system perspective considering "traditional costs")*

Clinical Event Parameter Description (Health System Perspective)	Base Estimate	Values Explored	Incremental Costs (Traditional)	Variation from Base Incr. Cost (Traditional)	ICER (Incr. Traditional Costs/Incr. NICU)
Probability of delivery at a gestational age 28-32 weeks	0.018	0.027 0.009	$257.71 $447.42	-$94.86 $94.86	$257.71/0 $447.42/0
Probability of delivery at a gestational age 32-37 weeks	0.148	0.221 0.074	-$686.97 $1,391.12	-$1,039.04 $1,039.04	-$686.97/0 $1,391.12/0
Probability of delivery at a gestational age > 37 weeks	0.826	0.990 0.413	-$2,048.13 $6,297.08	-$2,400.10 $6,044.16	-$0.12 -$0.14
Probability of vaginal delivery following G.A. < 28 weeks	0.309	0.463 0.154	$343.49 $361.84	-$9.17 $9.17	$4.77 -$5.02
Probability of vaginal delivery following G.A. 28-32 weeks	0.230	0.345 0.115	$350.62 $354.72	-$2.05 $2.05	$9.51 -$9.61
Probability of vaginal delivery following G.A. 32-37 weeks	0.365	0.547 0.182	$341.70 $363.64	-$10.97 $10.97	$0.68 -$0.73
Probability of vaginal delivery following G.A. > 37 weeks	0.403	0.604 0.201	$314.41 $390.91	-$38.25 $38.25	$0.56 -$0.71
Probability of Apgar > 7 (vaginal delivery at G.A. < 28 weeks)	0.393	0.590 0.197	$356.51 $348.83	$3.84 -$3.84	-$11.42 $11.17
Probability of Apgar > 7 (Cesarean delivery at G.A. < 28 weeks)	0.588	0.881 0.294	$352.23 $353.10	-$0.43 $0.43	$100.16 -$100.40
Probability of Apgar > 7 (vaginal delivery at G.A. 28-32 weeks)	0.874	0.990 0.437	$350.45 $361.01	-$2.21 $8.34	$54.42 -$14.87
Probability of Apgar > 7 (Cesarean delivery at G.A. 28-32 weeks)	0.824	0.990 0.412	$340.69 $382.32	-$11.97 $29.65	$11.50 -$5.21
Probability of Apgar > 7 (vaginal delivery at G.A. 32-37 weeks)	0.968	0.990 0.484	$350.74 $394.01	-$1.92 $41.35	$5.34 -$0.28
Probability of Apgar > 7 (Cesarean delivery at G.A. 32-37 weeks)	0.943	0.990 0.471	$345.13 $427.76	-$7.54 $75.09	$1.57 -$0.20
Probability of Apgar > 7 (vaginal delivery at G.A. > 37 weeks)	0.987	0.990 0.494	$352.62 $359.85	-$0.04 $7.18	$6.37 -$0.04
Probability of Apgar > 7 (Cesarean delivery at G.A. > 37 weeks)	0.985	0.990 0.492	$352.53 $364.60	-$0.13 $11.94	$2.04 -$0.02
Probability of NICU Admission (Apgar > 7, vaginal delivery at G.A. < 28 weeks)	0.784	0.990 0.392	$356.76 $344.85	$4.10 -$7.81	-$10.71 $5.43
Probability of NICU Admission (Apgar < 7, vaginal delivery at G.A. < 28 weeks)	0.399	0.598 0.199	$358.79 $346.54	$6.13 -$6.13	-$7.20 $6.96
Probability of NICU Admission (Apgar > 7, Cesarean delivery at G.A. < 28 weeks)	0.895	0.990 0.448	$359.00 $322.81	$6.33 -$29.85	-$6.97 $1.33
Probability of NICU Admission (Apgar < 7, Cesarean delivery at G.A. < 28 weeks)	0.908	0.990 0.454	$356.51 $331.40	$3.84 -$21.26	-$1.42 $1.92
Probability of NICU Admission (Apgar > 7, vaginal delivery at G.A. 28-32 weeks)	0.716	0.990 0.358	$356.34 $347.88	$3.67 -$4.79	-$2.44 $1.82
Probability of NICU Admission (Apgar < 7, vaginal delivery at G.A. 28-32 weeks)	0.807	0.990 0.403	$353.53 $350.78	$0.86 -$1.89	-$25.11 $11.31
Probability of NICU Admission (Apgar > 7, Cesarean delivery at G.A. 28-32 weeks)	0.833	0.990 0.416	$359.30 $335.09	$6.63 -$17.57	-$1.36 $0.48
Probability of NICU Admission (Apgar < 7, Cesarean delivery at G.A. 28-32 weeks)	0.920	0.990 0.460	$354.21 $342.56	$1.54 -$10.11	-$14.05 $2.07

Probability of NICU Admission (Apgar > 7, vaginal delivery at G.A. 32-37 weeks)	0.328	0.492 0.164	$362.53 $342.80	$9.87 -$9.87	-$0.28 $0.27
Probability of NICU Admission (Apgar < 7, vaginal delivery at G.A. 32-37 weeks)	0.689	0.990 0.344	$354.17 $350.95	$1.51 -$1.72	-$4.48 $3.88
Probability of NICU Admission (Apgar > 7, Cesarean delivery at G.A. 32-37 weeks)	0.444	0.666 0.222	$375.36 $322.66	$22.69 -$22.69	-$0.13 $0.11
Probability of NICU Admission (Apgar < 7, Cesarean delivery at G.A. 32-37 weeks)	0.775	0.990 0.388	$355.96 $346.72	$3.29 -$5.94	-$2.05 $1.11
Probability of NICU Admission (Apgar > 7, vaginal delivery at G.A. >37 weeks)	0.052	0.079 0.026	$353.67 $351.67	$1.00 -$1.00	-$0.27 $0.27
Probability of NICU Admission (Apgar < 7, vaginal delivery at G.A. >37 weeks)	0.429	0.644 0.215	$352.77 $352.56	$0.11 -$0.11	-$2.54 $2.54
Probability of NICU Admission (Apgar > 7, Cesarean delivery at G.A. >37 weeks)	0.073	0.109 0.036	$354.72 $350.61	$2.05 -$2.05	-$0.13 $0.13
Probability of NICU Admission (Apgar < 7, Cesarean delivery at G.A. >37 weeks)	0.496	0.745 0.248	$35.89 $352.45	$0.22 -$0.22	-$1.24 $1.24

Table 14 *On- way sensitivity analysis: Neonatal Intensive Care Unit length of stay parameters (from a health system perspective considering "traditional costs")*

NICU Length of Stay Parameter Description	Base Estimate	Values Explored	Incremental Costs (Traditional)	Variation from Base Incr. Cost (Traditional)
Length of NICU Stay (following initial admission day) for infants delivered at a G.A. < 28 weeks	116.731	175.097 58.366	$352.67 $352.67	$0.00 $0.00
Length of NICU Stay (following initial admission day) for infants delivered at a G.A. 28-32 weeks	56.750	85.125 28.375	$352.67 $352.67	$0.00 $0.00
Length of NICU Stay (following initial admission day) for infants delivered at a G.A. 32-37 weeks	42.600	63.900 21.300	$352.67 $352.67	$0.00 $0.00
Length of NICU Stay (following initial admission day) for infants delivered at a G.A. > 37 weeks	2.500	3.750 1.250	$352.67 $352.67	$0.00 $0.00

Table 15 *One-way sensitivity analysis: Medicaid reimbursement parameters (from a health system perspective considering "traditional costs")*

Medicaid Reimbursement Parameter Description	Base Estimate	Values Explored	Incremental Costs (Traditional)	Variation from Base Incr. Cost (Traditional)
Cost (global sum) of obstetric care, including vaginal delivery	$1,720.75	$2,581.13 $860.38	$691.10 $14.24	$338.43 $338.43
Cost (global sum) of obstetric care, including Cesarean delivery	$1,948.09	$2,922.14 $974.05	$943.57 -$238.24	$590.90 -$590.90
Cost of initial day in the NICU for "not normal" patients	$51.20	$76.80 $25.60	$352.67 $352.67	$0.00 $0.00
Cost of each subsequent day in the NICU for "not normal patients"	$25.95	$38.93 $12.98	$352.67 $352.67	$0.00 $0.00
Cost of initial day in the NICU for patients needing "intensive care"	$132.44	$198.66 $66.22	$352.67 $352.67	$0.00 $0.00
Cost of each subsequent day in the NICU for patients needing "intensive care"	$63.96	$95.94 $31.98	$352.67 $352.67	$0.00 $0.00
Cost of initial day in the NICU for patients needing "critical care"	$354.03	$351.05 $177.02	$352.67 $352.67	$0.00 $0.00

Cost of each subsequent day in the NICU for patients needing “critical care”	$155.02	$232.53 $77.51	$352.67 $352.67	$0.00 $0.00
Cost of Durable Medical Equipment (DME)	$344.92	$517.38 $172.46	$525.13 $180.21	$172.46 -$172.46
Cost of HIPAA compliant videoconferencing software	$7.75	$11.62 $3.87	$356.54 $348.79	$3.87 -$3.87

Table 16 *One-way sensitivity analysis: time cost parameters (from a societal perspective considering "traditional costs")*

Societal Parameter Description	Base Estimate	Values Explored	Incremental Costs (Traditional)	Variation from Base Incr. Cost (Traditional)
Cost of In-Person Visit Length (waiting time and consultation)	$8.95	$13.43 $4.48	$217.82 $289.42	-$35.80 $35.80
Cost of Telehealth Visit Length (waiting time and consultation)	$2.98	$4.47 $1.49	$261.07 $246.17	$7.45 -$7.45
Cost of Travel to In-Person Visits	$5.29	$7.94 $2.65	$232.49 $274.81	-$21.16 $21.16

Appendix C: PSA Scatterplots

Figure C-1 *Probabilistic Sensitivity Analysis—Scatterplot of 10,000 Monte Carlo simulations from a health system perspective considering "traditional" costs*

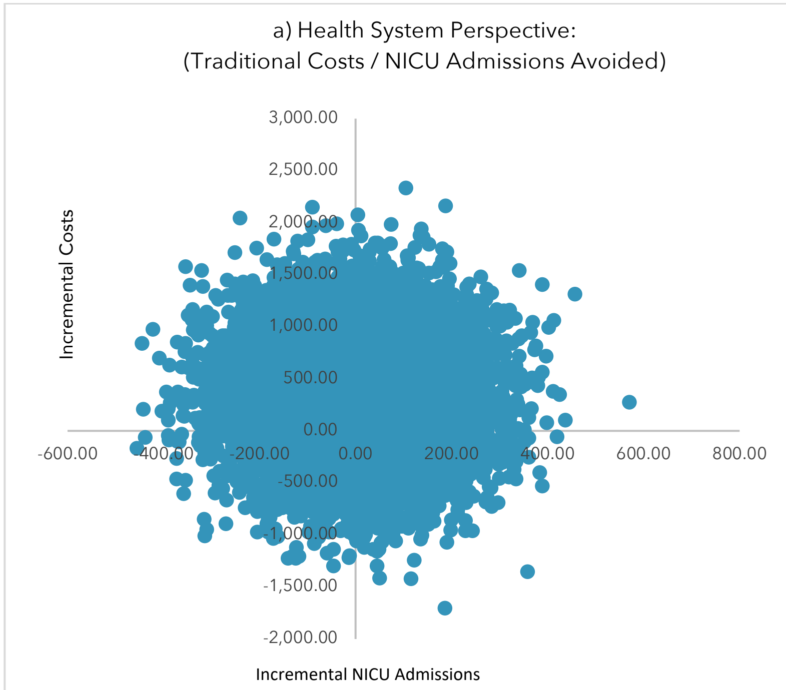


Figure C-2 *Probabilistic Sensitivity Analysis—Scatterplot of 10,000 Monte Carlo simulations from a health system perspective considering "innovative" costs*

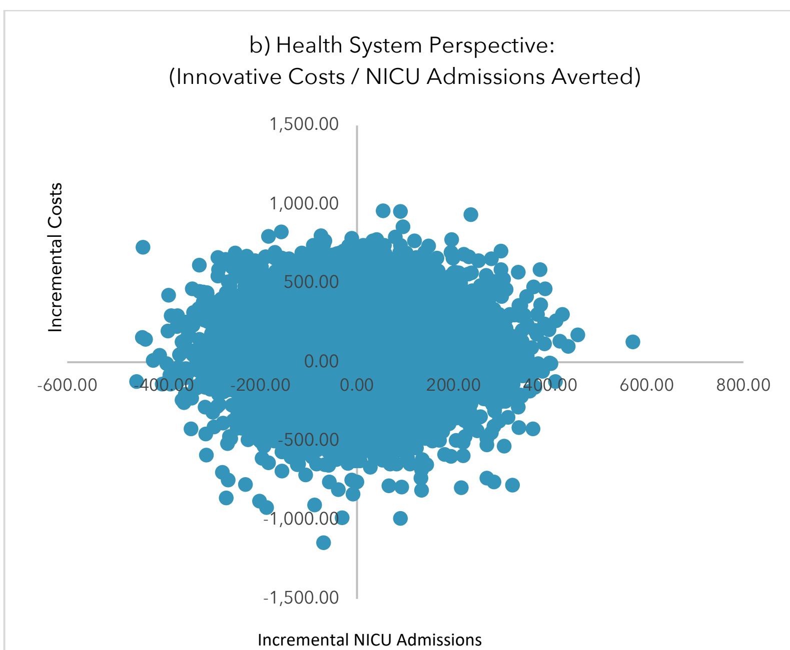


Figure C-3 *Probabilistic Sensitivity Analysis—Scatterplot of 10,000 Monte Carlo simulations from a societal perspective considering "traditional" costs*

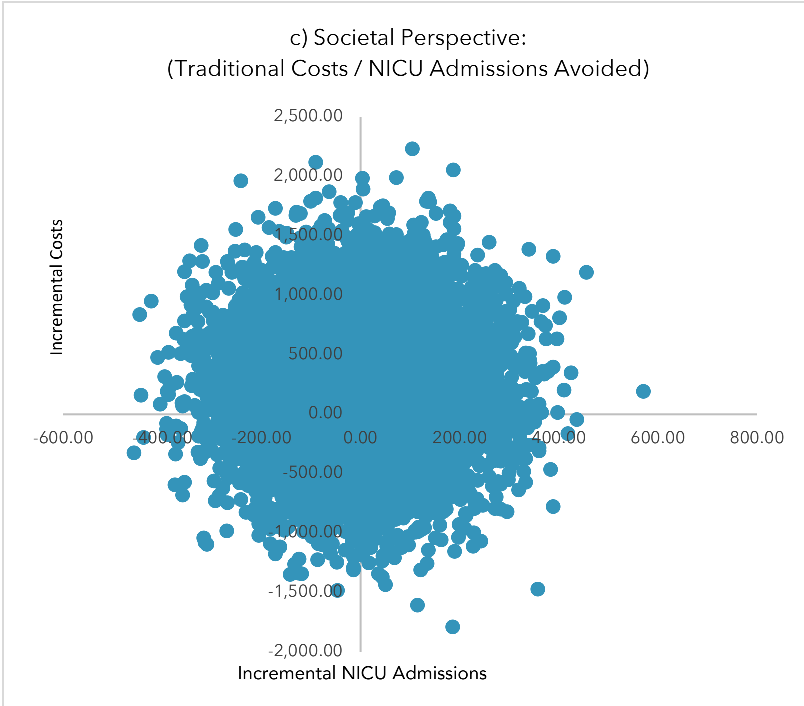
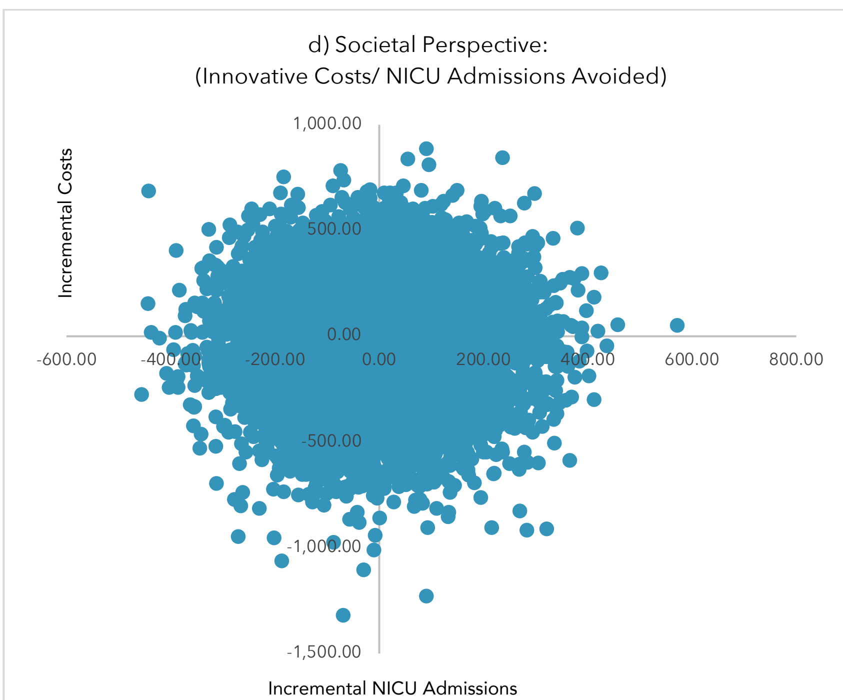


Figure C-2 *Probabilistic Sensitivity Analysis—Scatterplot of 10,000 Monte Carlo simulations from a societal perspective considering "innovative" costs*



Appendix D: Distribution of PSA C-Section Results in Each C.E. Quadrant

Table D-1 *Cost-effectiveness plane locations for 10,000 probabilistic ICERs (incremental cost/incremental Cesarean delivery averted)*

	Health System Perspective		Societal Perspective	
Strategy:	Traditional Costs	Innovative Costs	Traditional Costs	Innovative Costs
Northeast	3834 (38.34%)	3208 (32.08%)	3493(34.93%)	2448 (24.48%)
Northwest	3826 (38.26%)	3228 (32.28%)	3538 (34.84%)	2480 (24.80%)
Southeast	1160 (11.60%)	1786 (17.86%)	1501 (15.01%)	2546 (25.46%)
Southwest	1144 (11.44%)	1778 (17.78%)	1468 (14.68%)	2526 (25.26%)

Appendix E: CEAC (Incremental NICU Admissions Avoided)

Figure E-1 *Cost Effectiveness Acceptability Curve from a health system perspective considering "traditional" costs*

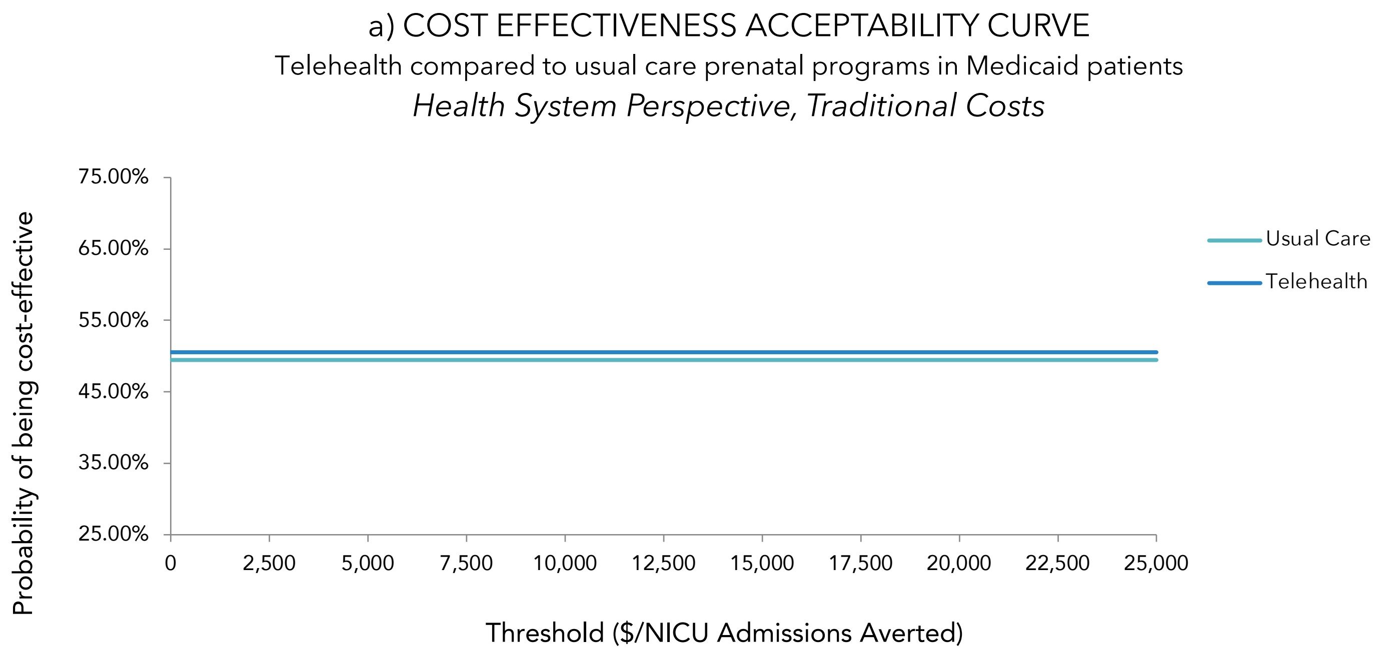


Figure E-2 *Cost Effectiveness Acceptability Curve from a health system perspective considering "innovative" costs*

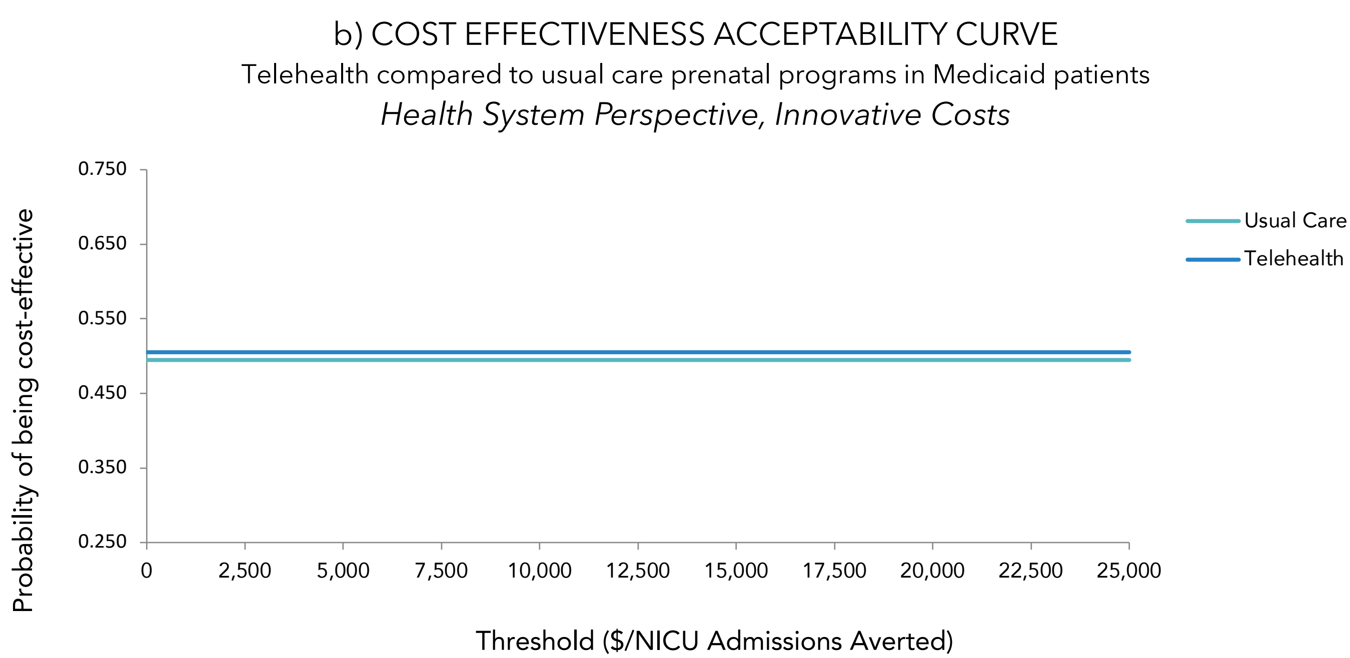


Figure E-3 *Cost Effectiveness Acceptability Curve from a societal perspective considering "traditional" costs*

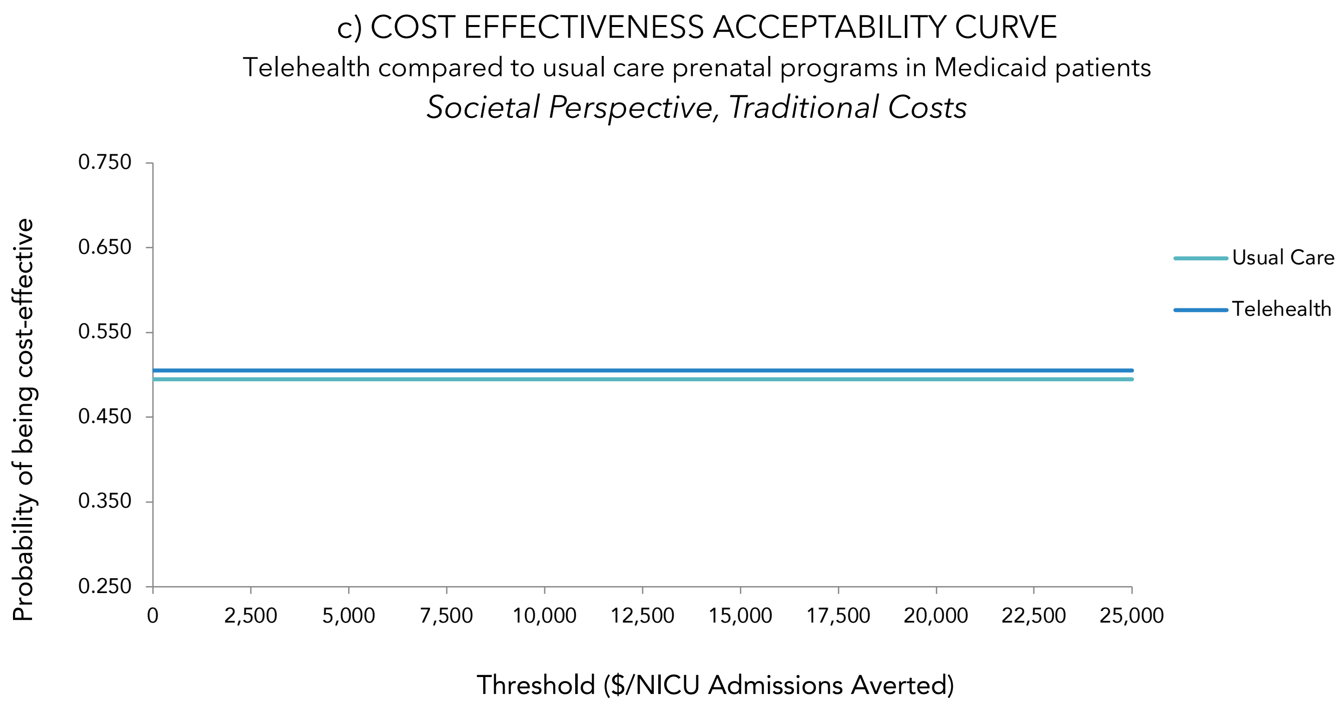


Figure E-3 *Cost Effectiveness Acceptability Curve from a societal perspective considering "traditional" costs*