A PROPOSED POLICY SOLUTION TO PROVIDE REMOTE PRENATAL CARE AFTER THE COVID-19 PANDEMIC†

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INTRODUCTION

The COVID-19 pandemic has imposed drastic restrictions on a local, national, and international scale, a transition that has been facilitated by an integral resource not available during the 1918 influenza outbreak: telehealth. Telehealth has likely played a considerable role in keeping morbidity and mortality rates lower than they could have been, as social gatherings and classes may be suspended indefinitely, but medical care will always be essential.

Telehealth refers to the delivery of healthcare services via electronic means of communication, such as audio and video call, that abide by the Health Insurance Portability and Accountability Act (HIPAA).[1] According to the New York State Department of Health (NYSDOH), Medicaid coverage of telehealth generally applies to services ranging

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1. New York State Department of Health. (2020). *New York State Medicaid Update.* NYSDOH website. Retrieved from https://www.health.ny.gov/health_care/medicaid/program/update/2020/no05_2020-03_covid-19_telehealth.htm.

from medical diagnosis and treatment to patient education and long-term monitoring. The NYSDOH defines telehealth according to the following categories: 1) live telemedicine, which is synchronous correspondence via audio and video call; 2) store-and-forward technology, which is asynchronous correspondence in which the patients' clinical data is recorded by photo or video to be assessed remotely by the healthcare professional at a later time; and 3) remote patient monitoring, which is the use of technology to record patients' clinical data to be routinely assessed remotely.

Primary care appointments that are limited to verbal discussion and counseling may be relatively straightforward when transitioned to remote care, such as live telemedicine. On the contrary, physical examinations and longitudinal patient monitoring are components of healthcare delivery that tend to rely more heavily on in-person communication and interaction. One particular medical specialty in which this could be an issue is obstetrics and gynecology (OB/GYN), as both the mother and baby must be examined regularly to ensure normal development. An example of the standard prenatal visit schedule can be found in the most recent Guidelines for Perinatal Care by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), published in 2017.[2] These Guidelines have recommended that a primigravida patient see her physician monthly until week twenty-eight of gestation, then biweekly until week thirty-six, then weekly until delivery; and even more frequently in cases with obstetric complications, depending on the presenting issues. Chronic conditions in pregnant women that may require closer monitoring include gestational diabetes mellitus (GDM) and preeclampsia, which are associated with sequelae that could be harmful to maternal and fetal health.

As the United States transitioned to remote operations in early 2020, the Centers for Medicare & Medicaid Services (CMS) expanded insurance coverage to telehealth, effective in early March 2020, as a temporary measure to adapt to the unprecedented circumstances.[3] Prior to the pandemic, telehealth services specific to OB/GYN were not covered by the CMS. However, the CMS policy was modified to expand

2. American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. (2017). *Guidelines for perinatal care* (8th ed.). Retrieved from https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx.

3. Centers for Medicare & Medicaid Services. (2020). *State Medicaid & CHIP Telehealth Toolkit.* CMS.gov website. Retrieved from https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit-supplement1.pdf.

coverage in 2020 with the specific modifications outlined in the State Medicaid & CHIP Telehealth Toolkit, last updated in October 2020. This was an integral decision in the field, as pregnant women comprise a particularly vulnerable patient population, and current research has found that vertical transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - though unlikely - is still possible.[4] Even before the onset of COVID-19, empirical evidence had shown that the transition from in-person care to virtual care in OB/GYN could be both feasible and effective through programs such as Mayo Clinic's OB Nest Model.[5] Not only does it now resolve the issue of safety during a pandemic, but it has previously alleviated pre-existing issues such as geographical inaccessibility and costs of transportation. It is important to acknowledge that telehealth may not suffice for all obstetric cases, but the demonstrated benefits of managing pregnancies remotely could be incorporated into a policy recommendation to extend its use beyond the duration of the pandemic.

I. WHY OB/GYN TELEHEALTH WAS NEEDED BEFORE COVID-19

Prior to the onset of the COVID-19 pandemic, telehealth had already proven useful in OB/GYN for a number of reasons. One reason that is particularly relevant to Upstate New York is geographic inaccessibility. In accordance with 42 CFR § 491.2, the City of Syracuse's Medicaid-Eligible population has been designated as a Health Professional Shortage Area (HPSA) in Primary Care by the Health Resources and Services Administration (HRSA) since April 2019.[6] In the context of HRSA classifications, primary care encompasses the fields of family medicine, internal medicine, OB/GYN, and pediatrics. On a broader scale, an Issue Brief published by the CMS in 2019 stated that almost half of the country's rural counties, home to about 18 million women of child-

4. Kotlyar, A. M., Grechukhina, O., Chen, A., Popkhadze, S., Grimshaw, A., Tal, O., Taylor, H. S., & Tal, R. (2021). Vertical transmission of coronavirus disease 2019: a systematic review and meta-analysis. *American journal of obstetrics and gynecology*, 224(1), 35–53.e3. https://doi.org/10.1016/j.ajog.2020.07.049=.

5. Butler Tobah, Y. S., LeBlanc, A., Branda, M. E., Inselman, J. W., Morris, M. A., Ridgeway, J. L., Finnie, D. M., Theiler, R., Torbenson, V. E., Brodrick, E. M., Meylor de Mooij, M., Gostout, B., & Famuyide, A. (2019). Randomized comparison of a reduced-visit prenatal care model enhanced with remote monitoring. *American journal of obstetrics and gynecology*, *221*(6), 638.e1–638.e8. https://doi.org/10.1016/j.ajog.2019.06.034.

6. Health Resources & Services Administration. *Health Professional Shortage Area (HPSA) Find.* Data.HRSA.gov website. Retrieved from https://data.hrsa.gov/tools/shortage-area/hpsa-find; Legal Information Institute. *42 CFR § 491.2 - Definitions.* Cornell Law School website. Retrieved from https://www.law.cornell.edu/cfr/text/42/491.2.

bearing age, lack access to obstetric hospital care.[7] Among the rural areas with severe obstetric care shortages is Seneca County, New York, which is in proximity to Onondaga County, New York, where the City of Syracuse is located. This means that any pregnant women living in these areas of severe shortage may need to travel many miles to receive medical attention in the case of an obstetric emergency, let alone for routine care. For women without pregnancy complications, this can already be considerably difficult, especially in the third trimester during which prenatal visits are recommended every one to two weeks. But for a woman with conditions like GDM, which may cause complications and require even more frequent visits to monitor the pregnancy, the inconvenience is tremendous, in addition to the costs in terms of time, money, and material resources. A woman that is not able to afford these costs may refrain from making the appointments she needs, potentially risking the baby's life and her own.

In agreement with the Social Security Act § 1902(a)(70) and 42 CFR § 440.170, under the State Plan of New York, Medicaid is mandated to provide transportation to non-emergency services, such as primary care visits, for recipients that otherwise cannot afford the travel expenses associated with necessary appointments.[8] According to the NYSDOH, Upstate New York has accounted for about fifty-one percent of all annual trips in New York State funded by Medicaid in previous years. Furthermore, an Issue Brief published by the Medicaid and CHIP Payment and Access Commission (MACPAC) in 2019 stated that the costs of Medicaid's Non-Emergency Medical Transportation (NEMT) on a fee-for-service basis amounted to two billion dollars in fiscal year 2017.[9]

Telehealth is a potential solution not only for cost-effectiveness, but also for quality of care. For example, in the past decade, before the COVID-19 pandemic was even imaginable, Mayo Clinic developed a new model of hybrid care called the OB Nest Model, specifically for low-

7. Centers for Medicare & Medicaid Services. (2019). *Improving Access to Maternal Health Care in Rural Communities.* CMS.gov website. Retrieved from https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf.

8. New York State Department of Health. (2015). *Medicaid Transportation.* NYSDOH website. Retrieved from https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/2015-12-17_medtrans_overview.htm.

9. Medicaid and CHIP Payment and Access Commission. (2019). *Medicaid Coverage of Non-Emergency Medical Transportation.* MACPAC.gov website. Retrieved from https://www.macpac.gov/wp-content/uploads/2019/05/Medicaid-Coverage-of-Non-Emergency-Medical-Transportation.pdf

risk pregnancies.[10] As part of this Model, patients had to attend only eight in-person visits over the course of their pregnancies, along with six remote appointments in which they would receive relevant prenatal counseling from their nurses. To facilitate their remote prenatal care, the patients were provided with devices such as the fetal Doppler to monitor fetal heart sounds and sphygmomanometer to monitor blood pressure. The empirical evidence in Mayo Clinic's study demonstrated that use of the hybrid Model was associated with higher levels of patient satisfaction and lower levels of pregnancy-related stress, as well as similar levels of perceived quality of care and clinical outcomes. Theoretically, the cost savings associated with hybrid models could also alleviate some of the expenditures associated with Medicaid coverage of NEMT. Of course, not all pregnancies are low-risk and some chronic conditions, such as GDM, may require more frequent attention and tools beyond the fetal Doppler and sphygmomanometer.

According to the Centers for Disease Control and Prevention (CDC), GDM can be found in up to ten percent of pregnant women in the United States as of 2019.[11] Therefore, this prenatal condition may affect a substantial fraction of pregnant women that live in HPSAs and depend on Medicaid services, including NEMT. Thus, we will examine the following question with implications for policy change: 1) Can GDM be effectively monitored via telemedicine; and 2) Do the benefits suggest that Medicaid should extend coverage for remote monitoring after the pandemic?

II. HOW OBSTETRIC OUTCOMES HAVE FARED WITH TELEHEALTH

Telemedicine (TM) applications in OB/GYN for low-risk pregnant women have been integrated into the traditional prenatal care model to allow for efficiency, convenience, and potentially lower costs of care. In the Virtual Visit program, TM services were provided by a nurse practitioner between face-to-face visits that included the first OB visit with a physician, twenty-week fetal anatomy ultrasound, and twenty-

10. Butler Tobah, Y. S., LeBlanc, A., Branda, M. E., Inselman, J. W., Morris, M. A., Ridgeway, J. L., Finnie, D. M., Theiler, R., Torbenson, V. E., Brodrick, E. M., Meylor de Mooij, M., Gostout, B., & Famuyide, A. (2019). Randomized comparison of a reduced-visit prenatal care model enhanced with remote monitoring. *American journal of obstetrics and gynecology*, *221*(6), 638.e1–638.e8. https://doi.org/10.1016/j.ajog.2019.06.034.

11. Centers for Disease Control and Prevention. (2019). *Gestational Diabetes.* CDC.gov website. Retrieved from https://www.cdc.gov/diabetes/basics/gestational.html.

eight-week GDM screening.[12] Like Mayo Clinic's model, the Virtual Visit program's results demonstrated similar maternal and fetal outcomes between traditional and TM-integrated care models. Patients may benefit from this integrated model by minimizing lengthy and costly travel to see a provider, while also missing fewer days of work or not having to arrange for childcare. Providers, who are also relevant stakeholders in the use of TM, may benefit from more flexible hours of practice and higher patient retention.[13]

TM has also been shown to be effective in the management of chronic conditions such as GDM, or maternal high blood sugar associated with fetal macrosomia, cesarean birth, and neonatal hypoglycemia.[14] One GDM-focused study compared a standard care model, which involved recording blood glucose values in a paper diary and visiting the clinic every two to four weeks, with a TM model, which involved recording values on a mobile phone application and visiting the clinic only every four to eight weeks.[15] If the patients' electronic values exceeded predefined thresholds, the mobile system alerted the patient with educational resources, adjusted medication dosages, and messages of encouragement. Another study's cost-effectiveness analysis showed that remote GDM-care was associated with savings of about sixteen percent in Canadian dollars per patient, as well as sustained quality of care and patient satisfaction.[16] Both studies demonstrated that TM offers patients a convenient way to communicate with their healthcare team, bypassing certain barriers that might discourage them from contacting their provider beyond standard visit encounters. Moreover, TM may provide a more cost-effective way to manage chronic conditions like GDM, and to

12. Pflugeisen, B.M., McCarren, C., Poore, S., Carlile, M., Schroeder, R. (2016). Virtual Visits: Managing prenatal care with modern technology. *MCN Am J Matern Child Nurs, 41*(1):24-30. https://doi.org/10.1097/NMC.0000000000000199.

13. Greiner, A.L. (2017). Telemedicine Applications in Obstetrics and Gynecology. *Clin Obstet Gynecol, 60*(4):853-866. https://doi.org/10.1097/GRF.0000000000000328.

14. American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. (2017). *Guidelines for perinatal care* (8th ed.). Retrieved from https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx.

15. Mackillop, L., Hirst, J. E., Bartlett, K. J., Birks, J. S., Clifton, L., Farmer, A. J., Gibson, O., Kenworthy, Y., Levy, J. C., Loerup, L., Rivero-Arias, O., Ming, W. K., Velardo, C., & Tarassenko, L. (2018). Comparing the Efficacy of a Mobile Phone-Based Blood Glucose Management System With Standard Clinic Care in Women With Gestational Diabetes: Randomized Controlled Trial. *JMIR mHealth and uHealth*, *6*(3), e71. https://doi.org/10.2196/mhealth.9512

16. Lemelin, A., Paré, G., Bernard, S., & Godbout, A. (2020). Demonstrated Cost-Effectiveness of a Telehomecare Program for Gestational Diabetes Mellitus Management. *Diabetes Technology & Therapeutics, 22*(3), 195-202. http://doi.org/10.1089/dia.2019.0259.

evaluate whether or not a patient requires additional on-site interventions in the clinic or hospital.

In an updated meta-analysis of 32 randomized controlled trials with 5,108 patients, patients with GDM in the TM groups had lower values of GDM indicators such as glycated hemoglobin (HbA1c), fasting blood glucose (FBG), and 2-hour postprandial blood glucose (2hBG) compared to patients with GDM in the standard or traditional care group.[17] All of these measures reached statistical significance. There were also further favorable secondary outcomes in the TM groups, including lower incidences of macrosomia, cesarean section, and neonatal hypoglycemia. These data show that pregnant patients with GDM can be monitored through the integration of TM services without sacrificing effectiveness or quality of care. In fact, this meta-analysis shows more beneficial outcomes using this TM care model.

It is important to note that TM is not a complete replacement for in-person clinical visits in the management of GDM. It is an option for hybrid or integrated maternal care rather than a stand-alone source of care. TM groups in the meta-analysis still had in-person visits, though fewer than those in the standard care groups.[18] Additionally, utilization of TM presumes that pregnant patients have access to technological devices, internet, and knowledge of how to navigate virtual systems. In some of the studies included in the meta-analysis, participants used their personal computer, tablet, or phone to access TM services, while other studies provided a mobile phone with a preinstalled health app.[19] Some patients may not have access to these devices to use TM, particularly those of lower socioeconomic status.

However, among patients who were able to access TM in the management of their GDM, satisfaction with such services was high

17. Xie, W., Dai, P., Qin, Y., Wu, M., Yang, B., & Yu, X. (2020). Effectiveness of telemedicine for pregnant women with gestational diabetes mellitus: an updated meta-analysis of 32 randomized controlled trials with trial sequential analysis. *BMC pregnancy and childbirth*, *20*(1), 198. https://doi.org/10.1186/s12884-020-02892-1.

18. *Id.*

19. Mackillop, L., Hirst, J. E., Bartlett, K. J., Birks, J. S., Clifton, L., Farmer, A. J., Gibson, O., Kenworthy, Y., Levy, J. C., Loerup, L., Rivero-Arias, O., Ming, W. K., Velardo, C., & Tarassenko, L. (2018). Comparing the Efficacy of a Mobile Phone-Based Blood Glucose Management System With Standard Clinic Care in Women With Gestational Diabetes: Randomized Controlled Trial. *JMIR mHealth and uHealth*, *6*(3), e71. https://doi.org/10.2196/mhealth.9512; Lemelin, A., Paré, G., Bernard, S., & Godbout, A. (2020). Demonstrated Cost-Effectiveness of a Telehomecare Program for Gestational Diabetes Mellitus Management. *Diabetes Technology & Therapeutics*, *22*(3), 195-202. http://doi.org/10.1089/dia.2019.0259; Xie, W. et al, *supra note* 17, at 198.

based on validated rating scales. In one study, Likert scales yielded similar results among both groups, while another study actually revealed higher satisfaction-of-care scores in the TM group.[20] In the latter study, these scores were attributed to patients' feelings toward the support, monitoring, and perceived cost savings.[21] Patients felt they were provided ample guidance and reassurance through convenient usage of TM services. Patients from other studies also noted that they felt they were receiving primary care in the privacy of their own home, in addition to accessing subspecialists who were not in their geographic region.[22] The combination of prompt communication, adequate educational resources, and convenience of use may improve compliance with blood glucose measurements and medication usage, as well as alleviate the anxiety of pregnant patients, further improving clinical outcomes.[23]

III. RECOMMENDATIONS FOR OB/GYN TELEHEALTH SINCE COVID-19

Given the highly infectious nature of SARS-CoV-2, most medical specialties had to quickly adapt to delivering care via TM platforms. OB/GYN was no exception, especially because pregnant women comprise a higher-risk population. The latest issue of the CDC's Morbidity and Mortality Weekly Report (MMWR) showed that among over 400,000 symptomatic women with a confirmed diagnosis of COVID-19, pregnant women were 3 times more likely to have been admitted to an ICU, 2.9 times more likely to have received invasive ventilation, 2.4 times more likely to have received extracorporeal membrane oxygenation (ECMO), and 1.7 times more likely to die from complications of COVID-19.[24] These data emphasize the need for social distancing, along with mask-wearing, and diligent handwashing.

In the context of the COVID-19 pandemic, TM allows pregnant patients to limit their use of NEMT and thereby limit potential SARS-CoV-2 transmission, while maintaining adequate prenatal care, including

20. Mackillop, L. et al., *supra note* 19 at e71; Lemelin, A. et al, *supra note* 19 at 195-202.

21. Mackillop, L. et al., *supra note* 19 at e71.

22. Given, J.E., Bunting, B.P., O'Kane, M.J., Dunne, F., Coates, V.E. (2015). Tele-Mum: A Feasibility Study for a Randomized Controlled Trial Exploring the Potential for Telemedicine in the Diabetes Care of Those with Gestational Diabetes. *Diabetes Technol Ther, 17*(12):880-8. https://doi.org/10.1089/dia.2015.0147.

23. Xie, W. et al, *supra* note 17, at 198.

24. Zambrano, L.D., Ellington, S., Strid, P., et al. (2020). Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep, 69*:1641–1647. http://dx.doi.org/10.15585/mmwr.mm6944e3.

monitoring and counseling in high-risk cases.[25] However, in the case of high-risk pregnancies, the physician and patient will need to weigh the risks and benefits of in-person care to determine the need for and frequency of in-person services. GDM is one such condition discussed above that is associated with risks and complications, yet has been shown to be effectively and possibly better managed with the integration of TM.

At the time of this writing, both the Pfizer-BioNTech and Moderna COVID-19 mRNA vaccines are being administered internationally. No data currently exists to identify the safety of mRNA vaccines in pregnant women specifically, but the ACOG expects the safety outcomes to resemble those in non-pregnant women, and Moderna's mRNA toxicology studies in pregnant rats demonstrated no major adverse outcomes in prenatal development.[26] Given that empirical evidence has demonstrated the potential risks to pregnant women who contract COVID-19, pregnancy is considered a high-risk medical condition in this context, and the ACOG recommends access to the vaccines for pregnant women that fulfill the criteria set by the Advisory Committee on Immunization Practices (ACIP). Patients should have the autonomy to make informed decisions regarding the vaccine after thorough discussion with their healthcare providers about individualized risks and benefits. While awaiting official safety data, pregnant women must also continue to be vigilant about proper hand-washing, mask-wearing, and social distancing.

CONCLUSION

TM in OB/GYN has been a new normal during the COVID-19 pandemic and is expected to remain supplemental to healthcare delivery to continue mitigating risks, as we learn about the long-term safety and efficacy of the COVID-19 vaccines in pregnant women. Therefore, the prolonged extension of Medicaid coverage to TM services could prove to be beneficial both at the community level and at the policy level. As the existing literature has demonstrated, the provision of TM was already

25. Aziz, A., Zork, N., Aubey, J. J., Baptiste, C. D., D'Alton, M. E., Emeruwa, U. N., Fuchs, K. M., Goffman, D., Gyamfi-Bannerman, C., Haythe, J. H., LaSala, A. P., Madden, N., Miller, E. C., Miller, R. S., Monk, C., Moroz, L., Ona, S., Ring, L. E., Sheen, J. J., Spiegel, E. S., … Friedman, A. M. (2020). Telehealth for High-Risk Pregnancies in the Setting of the COVID-19 Pandemic. *American journal of perinatology*, *37*(8), 800–808. https://doi.org/10.1055/s-0040-1712121.

26. American College of Obstetricians and Gynecologists. (2020). *Practice Advisory: Vaccinating Pregnant and Lactating Patients Against COVID-19.* ACOG. Retrieved from https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19.

advantageous to patients in rural areas, where geographical accessibility to healthcare facilities has been a longstanding issue. It is even more advantageous now when a pandemic warrants social distancing measures to prevent transmission of a deadly virus. Furthermore, as previous research has shown, allowing patients to monitor chronic conditions remotely has had positive impacts on patient satisfaction and effectiveness of care. The additional advantage that should be taken into consideration is that the government already pays a hefty price to provide NEMT to patients in rural areas. Meanwhile, remote monitoring of a chronic prenatal condition like GDM, which would normally require frequent in-person visits, instead can allow for considerable cost savings per patient. Thus, provisions of TM covered by Medicaid would not only account for the patients' wellbeing, but it may also ameliorate some of the financial burden on CMS, some of which could be redirected toward providing tools for remote care, like mobile phones and blood glucose monitors. As long as TM is offered, CMS should work toward maintaining insurance coverage of remote services, given the numerous benefits to multiple stakeholders described above.