



From Queasy to Easy:

A Smart Guide to
Managing Severe
Morning Sickness
and Expert Referrals

This white paper addresses the urgent need for innovative care solutions for hyperemesis gravidarum (HG) and nausea and vomiting in pregnancy (NVP). Despite affecting a significant number of pregnant women, these conditions often go underdiagnosed and poorly treated due to a lack of standardized protocols.



Harmonia Healthcare is pioneering a collaborative model that integrates cuttingedge research and state-of-the-art treatment at its New Jersey center. By working hand-in-hand with local OBGYNs, Harmonia is set to revolutionize care for those impacted by HG and NVP, ultimately enhancing health outcomes for mother and baby. This paper will explore our findings, spotlighting the necessity for specialized centers dedicated to these challenging conditions.

INTRODUCTION

Pregnancy should be a time of joy, but for many women, it also brings the challenge of nausea and vomiting. For some, symptoms are mild and fade after the first trimester. Others experience persistent nausea and vomiting with severe physical, emotional, and financial impacts. This condition, known as hyperemesis gravidarum (HG), affects up to 10% of pregnancies and poses severe risks to mother and baby, including low birth weight, postpartum depression, and autism. Yet, despite its prevalence and severity, the clinical approaches to HG are inconsistent.

Harmonia Healthcare is working to close these gaps with a unique, collaborative care model tailored to the complex needs of women suffering from HG. Drawing on ground-breaking research into the root causes of HG by Chief Scientific Officer Marlena Fejzo (who brings a deep understanding informed by her own battle with HG), Harmonia has developed researchdriven outpatient care designed to reduce emergency visits, improve patient outcomes, and support OB-GYN practices. Our state-of-the-art treatment center in New Jersey offers a seamless extension of care that integrates with local providers, providing an essential resource for effective and compassionate HG management.

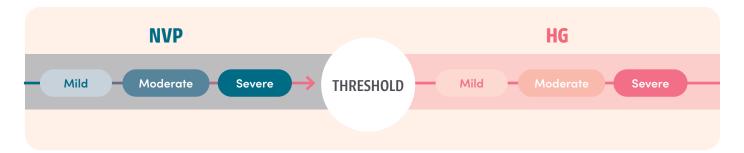


This whitepaper explores HG's causes, challenges, and management, drawing from Harmonia's latest research with OBGYNs, NPs, and PAs. It demonstrates how Harmonia's model enhances the patient experience and supports providers in delivering more effective, compassionate care.



UNDERSTANDING NAUSEA AND VOMITING IN PREGNANCY

NVP remains one of the most common complaints among pregnant patients, with cases presenting across a broad symptom range. While many experience mild "morning sickness" that typically resolves after the first trimester, others endure more severe forms that can disrupt daily life. This spectrum of symptoms reflects the complex and varied nature of NVP, where the more severe cases demand clinical attention to differentiate them from hyperemesis gravidarum (HG).



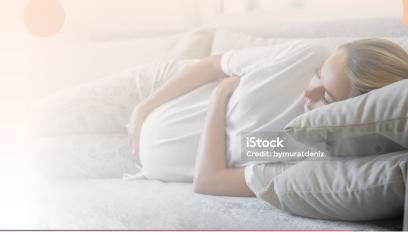
NVP and HG are usually considered to be on a continuous spectrum, with the spectrum of NVP symptoms broader and less severe than HG symptoms

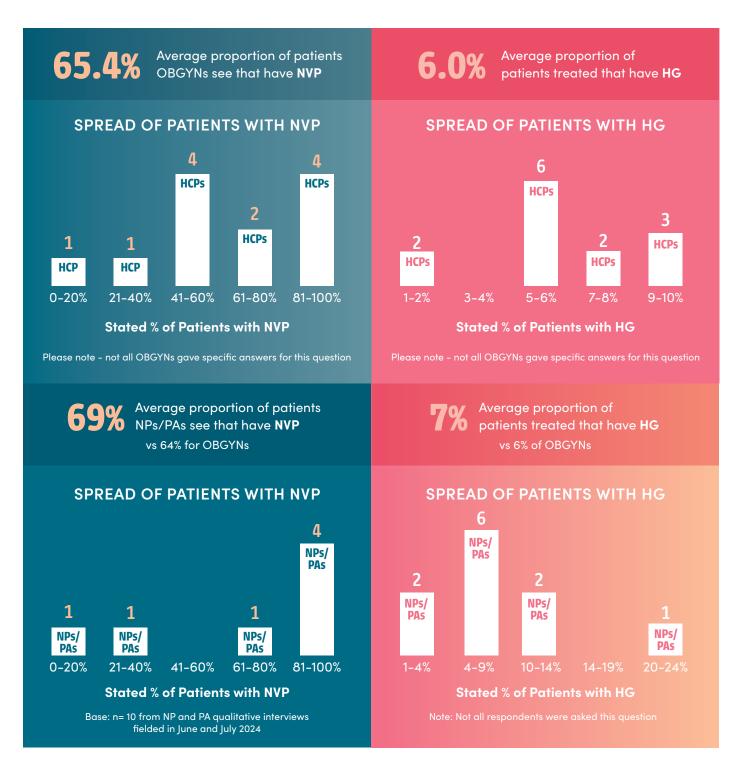
In consultation with OBGYNs we revealed that the distinction between NVP and HG is often made at a clinical threshold.

NVP is generally identified as intermittent nausea with or without occasional vomiting, usually resolving by the second trimester. HG, on the other hand, is an erratic, non-linear progression where patients experience fluctuating severity, often unable to keep down food or liquids for extended periods. This leads to frequent hospital visits, dehydration, and considerable weight loss, with some cases continuing well into later pregnancy stages.

"Morning sickness is very common, doesn't lead to weight loss, missing work, very transient, it only occurs in the morning." – **OBGYN**

"I see it all as a spectrum. HG is the most extreme part of that spectrum, with weight loss, electrolyte abnormalities, and starvation." – OBGYN While many practitioners consider NVP and HG as part of a spectrum that meet at a threshold point, this threshold varies between providers. Our research found that both OBGYNs and NPs/PAs tend to see a higher volume of NVP cases, which is expected due to its broad prevalence. However, while HG makes up a smaller percentage, it requires a disproportionately large share of clinical resources.





This disparity underscores the need for diagnostic precision and specialized protocols, as HG patients often require more intensive support, frequent hospital visits, and interventions for complications such as dehydration and severe weight loss, and a third of HG pregnancies are not full-term. The consistent burden across both OBGYNs and NPs/PAs demonstrates the widespread need for enhanced education and support for all clinicians managing these cases.

Over 10% of all pregnancies are significantly impacted by severe nausea or hyperemesis gravidarum, with over a third of those pregnancies resulting in premature delivery, miscarriage, stillbirth, or termination.

Moreover, most OBGYNs agree that without intervention, patients may escalate from NVP to HG; however, this progression is uncommon. Some clinicians also hold that HG may be inherently distinct, with patients either predisposed to or developing HG directly, suggesting potential genetic influences.

"I think that if you manage these patients early, you can prevent them from progressing. Would use the same paradigm to treat these patients." – OBGYN

While the causes of NVP and HG are not yet fully understood, they are believed to result from genetic, hormonal, and environmental factors. Rising levels of human chorionic gonadotropin (hCG) have historically been linked to nausea and vomiting; however, recent research has identified Growth Differentiation Factor 15 (GDF15) as a potential key driver.

According to findings by Dr. Marlena Fejzo, people with HG tend to have higher blood levels of GDF15 during pregnancy, yet produce lower-than-average amounts of <u>GDF15</u> prior to pregnancy. These women then become hypersensitive to the normal rise of GDF15 during early pregnancy, impacting nausea severity by interacting with appetite-regulating pathways and intensifying symptoms beyond what is typically observed with NVP.



This insight marks a critical step in understanding HG as more than a physiological response to pregnancy, positioning it as a genetic condition with potential for targeted therapies that could lower hospital admissions. However, with currently limited treatment options, HG patients require a disproportionately high amount of care, this not only places a strain on resources due to the persistence of symptoms but without consistent, effective care, prevents positive health outcomes.

CHALLENGES OF SEVERE MORNING SICKNESS

"I'll only bring it up if they're losing weight, but I don't bring it up unless they do. Sometimes, I'll mention it in the first trimester (about 20% of the time), then as the pregnancy advances, about 5% of the time." — OBGYN

"Seeing someone prior to pregnancy, I bring it up as part of the discussion if they have had a baby before. For those already pregnant, I do ask them about their symptoms." – **OBGYN**

Despite the high prevalence, there is huge variability in how clinicians approach discussions around NVP and HG, and diagnosis remains alarmingly inconsistent. Many OBGYNs and NPs/PAs rely on subjective assessments, drawing from past experiences and general ACOG guidelines rather than standardized tools, such as the HELP Score, a validated assessment tool from the Hyperemesis Education and Research (HER) Foundation. Our research found that none of the interviewed OBGYNs was familiar with HELP Score, and only one had heard of its concept.

Currently, OBGYNs are not using protocols or procedures to diagnose NVP or HG, preferring to rely on previous experiences and ACOG guidelines.



Inconsistent treatment protocols compound the absence of diagnostic standards. The current "wait-and-escalate" model begins with lifestyle changes and only progresses to medical intervention when symptoms become severe. This approach often leads to significant delays in care, leaving patients to endure debilitating symptoms for extended periods.

NVP

HG

Lifestyle Mod. & Dietary Changes:

Most OBGYNs initiate lifestyle & dietary changes for women experiencing NVP, including ginger tablets, "bland" diet, cracckers before rising, reduced water intake, increased electrolyte intake, and pressure point wristbands.

Over the Counter Options:

Most OBGYNs will mention NVP patients try a combination of vitamin B6 + Unisom to combat NVP.

Some also recommend Benadryl.

First Line:

Most perscribe Diclegis (or it's generic form).

Some will also prefer Benadryl.

Minority will immediately prescribe Oral

Minority will immediately prescribe Oral Zofran or Reglan.

Second Line:

Most OBGYNs will also prescribe oral Zofran and Reglan.

Some OBGYNs will send to ER for fluids (if severe enough).

Minority may recommend Phenergan suppositories

Third Line:

Most will presribe IV fluids (through ER), Oral or Fluid Zofran or Reglan

Some will recommend antihistamines in the ER **Minority** will refer sever NVP patients to at home infusion companies

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Most OBGYNs intiate lifestyle & dietary changes for women experiencing NVP, including ginger tablets, "bland" diet, crackers before rising, reduced water intake, increased electrolyte intake, and pressure point wristbands.

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Zofran or Reglan or Phenergan and if hospitalized, IV fluids.

Second Line:

If patient is still experiencing NVP, **majority** OBGYNs will send the HG patient to the hospital (ER) for IV fluids.

Some will also prescribe a suppository Zofran, Reglan or Phenergan.

Third Line:

Once discharged, **majority** of HG patients will receive follow up care consisting of oral Zofran or Realan.

Most will continue with the IV (+Zofran or Reglan) if symptoms do not improve.

Fragmented care is also prevalent: in our research, while almost half (49%) of NVP cases receive no medical intervention, 100% of diagnosed HG cases eventually involve prescribed medication or hospital treatment. However, by the time HG patients reach this level of care, they're often already at breaking point. Without an effective care setting to deliver established protocols, combined with a lack of physician training, patient's needs are not met.

"I would tell her to eat crackers first thing in the morning, to start her to B6 and doxylamine. When she gets to the office, I would ask her to drink cups of water and see how she is reacting. If worsening, I'd ask her to go to ER, and she might end up getting Zofran." – OBGYN

For patients, the consequences of poor diagnosis and care are life-altering. HG is far more than just "morning sickness" and is physically, emotionally, and financially overwhelming.

Survey data from a study of 1,220 respondents who experienced HG revealed that many women suffer from extreme weight loss, with over 15% of their pre-pregnancy body weight lost. While those who took medication as prescribed made fewer visits to providers, no medication combination or dose was found significantly more effective in preventing weight loss or repeat hospital visits. This weight loss causes severe health complications for mother and baby and increases financial burdens.



Impact on the Mother

Physical Health Complications: Women with HG are at risk for serious health complications, including preeclampsia, organ damage, esophageal rupture, Wernicke's encephalopathy, and electrolyte imbalances, which can require multiple ER visits or inpatient hospitalizations over one or more trimesters.

Mental and Brain Health: Depression and anxiety are common among patients, with some considering <u>suicide</u>. Over 18% of those who experience HG also meet the full criteria for PTSD, with more than half reporting some level of post-traumatic stress after their pregnancy.

Frequent Hospital Visits: With serious complications, HG is the <u>leading cause of hospitalization</u> in early pregnancy and the second most common cause during pregnancy overall, after preterm labor. Up to <u>60% of patients</u> require multiple hospital visits, highlighting the need for better outpatient solutions.

Disproportionate Impact on Vulnerable Groups:Survey data also highlighted that certain groups face a more severe experience with HG. Of the 1,200 respondents, those who were people of color (POC), unable to work, had no children, and lost significant weight were more likely to require repeated hospital visits.



Impact on the Baby

Preterm Birth and Pregnancy Loss: The severe symptoms and mental health challenges of HG can make it challenging to sustain a full-term pregnancy. More than <u>a third of pregnancies</u> impacted by HG result in preterm birth, miscarriage, stillbirth, or termination.

Neurodevelopmental Challenges:

Children exposed to HG in utero face a higher likelihood of low birth weight and neurodevelopmental challenges. Recent research on adolescents prenatally exposed to HG found elevated rates of neurodevelopmental delays, attention deficit disorder, sensory processing disorder, and autism.

HG is not the "morning sickness" of healthy, normal pregnancies. It is a distinct diagnosis marked by severe and relentless symptoms that pose significant risks to the health of both mom and baby.



Economic Burden of HG

National Economic Burden: The economic burden of NVP in the US exceeds \$2.2 billion annually, driven largely by repeat hospitalizations. This "ER-centered" model often fails to meet patient needs, underscoring the need for specialized, more effective care.

High Cost of Care: The economic burden of NVP in the US exceeds \$2.2 billion annually, driven largely by repeat hospitalizations. The high cost of care is overwhelming for many patients, with women in our case studies paying up to \$69,000 for care that provides no lasting relief. Across case studies, the economic savings with our outpatient care model average 94%, offering substantial financial relief and lasting support for patients.



Impact on Healthcare Systems

Strained Resources: The economic impact of managing HG is equally significant for healthcare systems. Frequent hospital visits, interventions, medication management, and potential complications can strain budgets and burden healthcare facilities and staff.

Logistical Challenges: The need for hospitalization may create logistical challenges in coordinating care. Managing HG may involve various healthcare professionals, including obstetricians, nutritionists, and mental health specialists. Effective communication and collaboration among these providers are crucial but difficult to achieve.

HARMONIA HEALTHCARE'S COLLABORATIVE MODEL

At Harmonia Healthcare, we believe early intervention and continuity of care are key to effectively managing HG. Through our collaborative care model, we partner with healthcare providers to deliver targeted support for women experiencing severe NVP and HG.

Harmonia can assist healthcare professionals in delivering more effective treatment solutions for NVP and HG, ensuring healthier pregnancies and improved quality of life.

By focusing on early, tailored outpatient care, we can provide treatment plans customized to each patient's unique symptoms.

Our specialized solutions include:



IV Fluids



Vitamin Infusions



Electrolyte Replacement



Antiemetics



Lab and Prescription Management



With these targeted interventions, we can minimize unnecessary hospital visits, ensuring patients receive the right care at the right time. Our model has improved health outcomes for over 500 women and can support other healthcare professionals in offering timely, effective treatments that promote healthier pregnancies and enhance patients' quality of life.







OUR LATEST CASE STUDIES HAVE SHOWN:

95% reduction in emergency room visits: Harmonia's model has near eliminated the need for ER visits for women with severe NVP and HG. By managing symptoms in an outpatient setting and providing reliable, continuous support, we prevent the escalations that typically lead to hospitalization.

90% reduction in overall care costs: Our focus on outpatient care, guided by healthcare providers, allows us to streamline expenses, saving healthcare systems and patients substantial amounts in care costs while enhancing the quality of treatment.

94% reduction in economic impact related to HG:

Our outpatient model eases the financial strain of HG, allowing patients to resume work and daily activities more consistently. This reduction in economic impact provides patients and their families with greater financial stability during pregnancy, reducing the stress of repeated hospital bills.

Proven Model to Improve Health and Economic Outcomes

	Patient Case	1st Pregnancy	2nd Pregnancy	1st Pregnancy	
	Studies	Past Standard of Care	Post Harmonia Care	Pre Harmonia Care	Post Harmonia Care
Health Outcomes	Ages	33	37	32	
	Symptom Onset	5 weeks	6 weeks	5 weeks	
	Treatment Initiation	20 weeks	16 weeks	5 weeks	16 weeks
	Treatment Plan	Zofran Pump, PICC Line Home Infusion	Weekly Infusion, Oral Medication, Granisetron Patches, Transitioned off Zofran W29	Home IV Infusion	2-3 x Weekly Infusion
	Weight Change	-12lbs	+17lbs	-29lbs	+9lbs (at 27 weeks)
	Symptom Improvement	None	19 weeks	None	22 weeks
	Outcomes	Induced* 37wks	Healthy delivery	Currently Pregnant / Healthy at 27 weeks	
	ER Visits / Hospital Admission	3/1	0**/0	2/0	0/0
Economic Outcomes	Total Cost of Care	>\$100,000	\$5,500	>\$12,000	\$10,000
	Impact to Payer	Total Cost of Care Decreased by 95%		Saving >\$3,500 per ER Visit	
	Economic Impact to Patient	Paid/Vacation leaves at 10wks	Quit job prior to pregnancy to prepare	4-20 Weeks Paid Disability	20 Weeks Ended Disability
	Lost Income	Lost ~\$44,000 in wages	Lost >\$100,000 wages	Lost \$17,000 in wages	Working Remotely

^{*}oligohydramnios (low amniotic fluid) **Pre-Harmonia



Our model is billed outside of standard global reimbursement for childbirth so patients can access necessary treatments without affecting their overall obstetrical expenses. This reduces the financial strain on families while ensuring comprehensive HG management.

Our care has zero impact on global obstetrical reimbursement, as it is billed outside the standard global reimbursement for childbirth.

Through our collaborative approach, we also keep healthcare providers informed every step of the way, ensuring patient progress, treatment, and adjustments are communicated directly. OBGYNs are removed from the burden of providing infusions, which is not a service offered in their clinics. This seamless information-sharing allows OBGYNs to focus on broader prenatal care needs while trusting that our team expertly manages HG symptoms.

> "Send them to whoever can do this. It's a distraction for my office to have patients come in. As long as it's covered by insurance, that's great." - OBGYN



OVERVIEW PROVIDER CONFIDENCE IN HARMONIA'S MODEL

During our discussions with OBGYNs, responses to our model were overwhelmingly positive:

100%

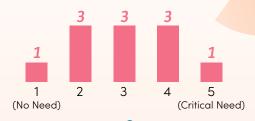
of participants agreed on the need for a specialized center for treating **NVP** and HG



indicated they would likely refer patients to a facility like Harmonia

Need for a specialized treatment center for NVP and HG

(Before Stimuli)



Seeing Harmonia Healthcare Stimuli

Likelihood to refer relevant patients to Harmonia Healthcare

(After Stimuli)



(Not At All Likely



Leading Expertise:

OBGYNs highlighted Harmonia's commitment to staying on the cutting edge of research and treatment. With the latest findings, including insights from genetic studies on HG, our nurses can offer patients care based on current scientific evidence.



Dedicated Team:

At Harmonia, every patient benefits from a dedicated team of providers specializing in NVP and HG. This was frequently noted as an advantage for OBGYNs, as our team becomes an extension of their practice, delivering continuous, patient-centered support.

"I think this is amazing. Not just for early pregnancy, can be good even postpartum." – **OBGYN**



Beyond "Piece-Meal" Treatment:

OBGYNs also appreciated our ability to reduce the fragmentation often associated with HG treatment. Our all-in-one approach minimizes the patchwork of visits, appointments, and referrals, creating a seamless care experience.



Improved Patient Experience:

Unlike the often overwhelming setting of ER rooms, our centers offer a calming atmosphere. This focus on patient comfort creates a positive environment, which OBGYNs noted as essential for encouraging patient compliance.

"It would be so much nicer than going to an ER when you are vomiting everywhere. Patients would be much more compliant with going to somewhere like this." — OBGYN



Relief for OBGYN Practices:

The majority of OBGYNs recognized the alleviation of strain on their own practices as a major advantage. Our approach relieves the administrative and clinical burden on OBGYNs, allowing for more efficient management of clinic resources.



Enhanced Outcomes:

Our model has led to a 95% reduction in ER visits, allowing patients to avoid repeated, stressful hospitalizations. Combined with a 90% drop in care costs and a 94% reduced economic burden, this shows the value of our model for patients and providers.

Harmonia Healthcare's collaborative model supports improved health outcomes, reduces costs, and enhances the experience for both patients and providers. This integrated approach ensures a higher standard of care for women with HG, creating a reliable, sustainable solution that OBGYNs and their patients can depend on.

We invite healthcare providers to contact us for more information or to explore collaboration opportunities with Harmonia Healthcare. Together, we can improve the lives of women experiencing hyperemesis gravidarum and ensure they receive the compassionate, effective care they deserve.



For more information on Harmonia, hyperemesis gravidarum, and our latest research, visit www.harmoniahealthcare.com or connect with us on Instagram at @harmoniahealthcare.





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