Lothian NHS Board

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Date 10 November 2026
Your Ref
Our Ref 12063

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Dear

FREEDOM OF INFORMATION – NAUSEA AND VOMITING IN PREGNANCY

I write in response to your request for information in relation to nausea and vomiting in pregnancy,

Question:
1. A copy of your current clinical guideline or protocol for the management of nausea and vomiting in pregnancy and hyperemesis gravidarum, including its publication and review dates. If it is published online, a link is sufficient. If you do not have one, please say so.

Answer:
Please see enclosed.

Question:
2. Whether you offer ambulatory (day-case) treatment for hyperemesis gravidarum, such as IV fluids without overnight admission. A yes or no answer is sufficient.

Answer:
Yes, NHS Lothian offer SDEC (Same Day Emergency Care).

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the FOI Reviewer at the email address at the head of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI/Pages/default.aspx

Yours sincerely

ALISON MACDONALD
Executive Director, Nursing
Cc: Chief Executive

Nausea and Vomiting in Pregnancy Guideline

Maternity Services Lothian

Introduction:

Nausea and Vomiting in Pregnancy (NVP) affects 90% of pregnant women and is one of the most common indications for hospital admission among pregnant women (1).

Hyperemesis Gravidarium (HG) is a severe form of NVP which affects 0.3-3-6% of pregnant women. Reported recurrence rates vary from 15-89% in the literature. It is likely that the use of a definition that puts more emphasis on subjective patient focussed criteria will lead to an increase in reported incidence rates.

The major mechanism of NVP and HG has recently been elucidated to be related to hypersensitivity to the vomiting hormone growth differentiation factor-15 (GDF15), not related to hCG as previously suspected (1).

Aim:

To optimise the management of nausea and vomiting during pregnancy.

Diagnosis:

NVP is diagnosed when onset is prior to 16 weeks gestation and other causes of nausea and vomiting have been excluded. Typically starts between 4th and 7th weeks of gestation, peaks around 9th week and resolves by 20th week in 90% women.

HG definition (multi-stakeholder international consensus) using Windsor definition: nausea and vomiting of which one is severe, beginning in early pregnancy (before 16 weeks), inability to eat and drink normally, and strongly limiting daily living activities. Signs of dehydration are contributory to diagnosis (2).

Severity:

The Pregnancy Unique Quantification of Emesis (PUQE) score was developed by Motherisk Program (see appendix 1) (3). It is used to determine severity of NVP from mild, moderate to severe. Ketonuria is NOT an indicator of dehydration and is not associated with severity of NVP or HG.

Complications (1)**:**

Hyponatraemia, hypokalaemia, low serum urea, raised haematocrit, ketonuria with a metabolic hypochloraemic alkalosis. If severe a metabolic acidosis may develop.

Two thirds of women with HG may have abnormal thyroid function with a biochemical thyrotoxicosis and raised free thyroxine levels +/- suppressed TSH. These patients rarely have thyroid antibodies

and are euthyroid clinically. The biochemical thyrotoxicosis resolves as HG improves and treatment with antithyroid drugs is unnecessary.

Liver function tests (LFTs) are abnormal in 40% of women with HG. Most likely rise in transaminases. Bilirubin and amylase may also be mildly elevated.

A previous history of gastric reduction surgery may cause malabsorption of oral medication and increase the risk of nutrient and vitamin deficiency, particularly thiamine and vitamin K (more info in Bariatric Surgery Guideline).

Wernicke encephalopathy due to vitamin B1 (thiamine) deficiency classically presents with blurred vision, unsteadiness and confusion/memory problems and drowsiness. On examination there is usually nystagmus, ophthalmoplegia, hyporeflexia or areflexia, gait and/or finger-nose ataxia. In HG, the presentation tends to be episodic and of slow onset. Wernicke encephalopathy is a potentially fatal medical emergency and in the context of HG it is preventable. Thiamine supplementation is recommended for all women admitted with HG.

Venous thromboembolism (VTE) risk – markedly increased while persistently vomiting. Thromboprophylaxis can be discontinued at discharge or when HG resolves.

Increased risk of Preterm birth and low birth weight – if severe NVP or HG who have continued symptoms into the late second or the third trimester should be offered serial scans to monitor fetal growth.

Women who experience HG in pregnancy are at increased risk of post natal depression (PND), anxiety and PTSD post partum

Recurrence risk 15% to 81% in future pregnancies – early use of lifestyle modifications and antiemetics that were useful in the index pregnancy is advisable to reduce the risk of NVP and HG in the current pregnancy.

Management

The mainstays of management are early antiemetic therapy and rehydration therapy.

IV fluids have been shown to reduce vomiting and are therefore valuable for both outpatient and inpatient management.

A. Clinical Assessment

Diagnosis

- **NVP:**
  - Onset prior to 16 weeks
  - Other causes of nausea and vomiting have been excluded
- **HG:**

- Nausea and vomiting (of which one is severe)
- Onset prior to 16 weeks
- Inability to eat and drink normally
- Strongly limiting daily living activities
- Signs of dehydration (NOT ketones) are contributory to diagnosis

Clinical Features

- History:
  - Quantify severity using PUQE score (see appendix 1)
  - Ask about self-reported nutritional status or rapid weight loss
  - Co-morbidities which may be complicated by lack of oral intake of essential medications (e.g. epilepsy, diabetes, HIV, psychiatric conditions, hypoadrenalism)
  - Relevant surgical history such as gastric bypass, band or sleeve
  - Consider other causes
    - Abdominal pain
    - Urinary symptoms
    - Infection
    - Drug history (prescribed +/- recreational)
    - Cannabis use – some women continue to use cannabis in pregnancy. Symptoms of intractable, severe NVP or HG associated with cannabis consumption may be unrecognised cannabinoid hyperemesis syndrome. A hallmark diagnostic factor is that symptoms are temporarily relieved by hot showers or baths. There is no specific treatment other than stopping cannabis use and supportive treatment as for HG.
    - Chronic H. pylori infection
- Examination:
  - MEWS
  - Abdominal examination
  - Weight
  - Signs of dehydration – sunken eyes, dry lips and mouth, oliguria or anuria, tachycardia, hypotension
  - Signs of malnutrition or rapid weight loss (>5% pre pregnancy weight)
  - Neurological signs such as confusion, nystagmus or ataxia which could indicate Wernicke's encephalopathy
- Investigations:
  - Urinalysis +/- MSU – looking for signs of urinary tract infection (UTI) NOT ketones
  - FBC, U+Es, Glucose
  - If needing inpatient treatment - ultrasound scan (not urgent) – to assess viability, multiple pregnancy, or trophoblastic disease
  - Refractory cases – TFTs, LFTs, calcium and phosphate, amylase, VBG (to exclude metabolic disturbances and to monitor severity)

Place of Care (see flow charts):

- **Community Care:**
  - PUQE score 3-6 and no complications.
    Advise patient to contact GP to arrange review and prescription for antiemetics
- **Same Day Emergency Care (SDEC):** Any of the following:
  - PUQE score ≥7 with no complications
  - Unable to tolerate oral fluids
  - Community measures have failed
  - If PUQE score ≥13, invite woman in for a face-to-face review prior to deciding if suitable for SDEC.

  Advise woman to attend for SDEC – arrange next available appointment in Day Bed, ward 10 in SJH or Day Assessment in RIE.
  If referral received after 2pm, aim to give IM antiemetic in community (if pt at GP) or invite in to receive IM antiemetic. Then discharge home to return the following morning for SDEC.
  If no SDEC appts available within a suitable timeframe, arrange review in triage (RIE or SJH)

- **Inpatient Care:**

  Any PUQE score + red flag

  - 1st presentation >14/40
  - Unresponsive to outpatient management
  - Clinical dehydration
  - Weight loss >5%
  - Pre-existing diabetes
  - Confirmed or suspected co-morbidity (e.g. UTI)
  - Co-morbidity and unable to take medications (e.g. epilepsy, HIV, diabetes, psychiatric disorders)
  - Concerns regarding mental health
  - Severe abdominal pain
  - Haematemesis
  - Symptoms of meningitis/intracranial pathology
  - Confusional state (consider Wernicke's)

  Arrange review in obstetric triage in RIE. Admit directly to ward 11 in SJH.

B: Antiemetic Therapy (1)

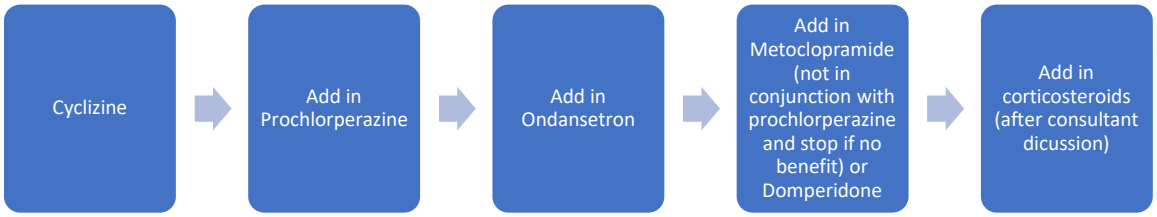
Many women will require a combination of two or more antiemetics. **When up titrating, add drugs as opposed to replacing them**. Different classes of drugs may have synergistic effects, and some women will require 3+ drugs to control their symptoms. If women have had previous HG, early use of antiemetics that were beneficial in previous pregnancy should be considered. See flow chart below for suggested up-titration. See appendix 2 for safety data of antiemetics in pregnancy.

	Medication	**Dose/Route**	**Additional Information**
First Line	Cyclizine	50mg Oral, IM or IV, 8 hourly	No increased risk of congenital malformations or adverse pregnancy outcomes
	Prochlorperazine	5-10mg 6-8hrly oral or 3mg 6-8hrly buccal or 12.5mg IM/IV 8hrly	No increased risk of congenital malformations or adverse pregnancy outcomes
	Xonvea© (pyridoxine-doxylamine)*	n/a	Not currently available in NHS Scotland
Second Line	Ondansetron	4mg 8 hourly or 8mg 12 hourly Oral/IM;	Possible increased risk of orofacial clefting from 11/10000 births to 14/10000 births if used in 1st trimester – see appendix 2 for more info. No increased risk if started >11/40. Risk of QT prolongation **Highly constipating**
	Metoclopramide	5-10mg 8 hourly, Oral, IV/IM If <60kg, 500micrograms/kg daily in 3 divided doses. If prescribed IV should be a slow bolus injection over at least 3 minutes	Extrapyramidal risks – can be used for >5 days if getting symptomatic benefit, otherwise discontinue. Do not use in conjunction with prochlorperazine as increases risk of extrapyramidal side effects
	Domperidone	10mg 8 hourly oral	

Third Line	Corticosteroids	Hydrocortisone 100mg 12hrly IV, once clinical improvement, then convert to oral prednisolone 40-50mg daily, gradually taper (by 5-10mg/week) until lowest maintenance dose where symptoms controlled	Reserved for cases where standard treatment ineffective. Consultant obstetrician decision. Require BP monitoring and GDM screening Avoid steroid doses after 6pm due to insomnia

* A slow-release combination of doxylamine and pyridoxine (vitamin B6) called Xonvea© is the only licensed treatment of NVP in the UK. It is not currently approved for use in NHS Scotland so cannot currently be prescribed for women in NHS Lothian. If felt to be indicated on an individual patient basis, a PACS2 application would be needed.

Flow chart to guide titration of antiemetics:



C: Other Pharmaceutical Therapies

Medication	Indication	Dose	Caution/Other Info
Omeprazole	GORD, oesophagitis, gastritis	20mg OD	Could consider Peptac first
Folic Acid	Prevention of neural tube defects	5mg OD	
Thiamine	For all women admitted with HG for prevention of Wernicke's. Consider if community management and severely reduced oral intake.	100mg TDS oral; Pabrinex IV (one pair of ampoules diluted in 100ml 0.9% NaCl, infused over 30-60min; weekly, if unable to tolerate oral intake. Can be increased to daily for 10 days if risk of re-feeding syndrome, severe malnourishment or Wernicke's – see refeeding guidance (4))	Potentially serious allergic reactions may rarely occur during or shortly after IV Pabrinex. Check serum Mg level as response to thiamine is poor if magnesium is low.
Dalteparin	All women admitted. If OP management – conduct VTE risk assessment	As per VTE risk guideline	TEDS should be used when LMWH is contra-indicated Can be discontinued at discharge if no other indication
Laxatives	Particularly if ondansetron prescribed	Choice as per formulary/patient preference	
Avoid Iron	Avoid iron-containing preparations **IF** these exacerbate symptoms.		Consider alternative preparations, dosing or IV iron if required – see Anaemia guideline

D: Intravenous Fluid Management

IV fluids have been shown to reduce vomiting and are therefore valuable for both outpatient and inpatient management.

The IV fluid should be sodium chloride 0.9% with additional potassium chloride in each bag, with administration guided by daily monitoring of electrolytes. The use of glucose infusions for fluid replacement in NVP and HG is not recommended.

A suggested initial IV prescription schedule: 2 x500ml bags of Sodium Chloride 0.9% with 10mmol KCl running at 500ml/hr. Further fluid prescription should then be guided by electrolyte review. Most women will require at least one further litre of fluid resuscitation.

All women should be on a fluid balance chart.

E: Nutrition Support

Consider referral to the dietician service (inpatients only) if meet any of the following criteria:

- Weight loss >5%
- No oral intake despite maximum anti-emetics
- 3rd inpatient stay with HG
- Fetal growth concerns in context of HG and reduced oral intake
- Complex patients, including those with previous bariatric surgery who are at risk of nutrient deficiencies.

If requiring parenteral nutritional support, women will need transferred to RIE.

F: Mental Health/Wellbeing

A woman's quality of life can be adversely affected by NVP and HG

Practitioners should carry out a full assessment of both physical and mental health status during the pregnancy and refer for psychological support if necessary.

Pre-existing mental health conditions may be exacerbated by HG particularly where prescribed oral medications are not being taken or kept down because of vomiting. Therefore, consideration to alternative routes of administration, proactive use of antiemetics and appropriate referrals should be considered.

Information about patient support groups should be provided to all women admitted with nausea and vomiting in pregnancy. QR code for pregnancy sickness support website:

G: Antenatal Care

Women with severe NVP or HG who have continued symptoms into the late second or third trimester should be referred to their locality consultant for review and offered serial scans to monitor fetal growth.

Women with low pregnancy weight gain are at increased risk of preterm birth and low birth weight.

Women who experience HG in pregnancy are at increased risk of PND, anxiety and PTSD post partum.

Women with previous HG should be advised that there is a risk of recurrence in future pregnancies (reported rates vary from 15% to 81%). Early use of lifestyle/dietary modifications and antiemetics that were useful in the index pregnancy is advisable to reduce the risk of NVP and HG in the current pregnancy.

In the last 24 hours….	1	2	3	4	5
How long have you felt nauseated or sick to your stomach?	Not at all (1)	1 hour or less (2)	2-3 hours (3)	4-6 hours (4)	More than 6 hours (5)
How many times have you vomited or thrown up?	I did not throw up (1)	1-2 times (2)	3-4 times (3)	5-6 times (4)	7 or more times (5)
How many times have you had retching or dry heaves without bringing anything up?	No times (1)	1-2 times (2)	3-4 times (3)	5-6 times (4)	7 or more times (5)

Initial Assessment

Confirm Diagnosis:

NVP:

- Onset of nausea and/or vomiting in early pregnancy with no other cause.

HG:

- Nausea and vomiting (one of which is severe)

A. Onset<16 weeks' gestation
B. Inability to eat and drink normally
C. Symptoms limit daily activity

History

- Previous history of NVP/HG
- Ptyalism (hypersalivation)
- Weight loss
- Poor oral intake
- Effect on quality of life
- Effect on mental health/mood
- Urine Volume

Consider other causes in those with:

- Abdominal pain
- Urinary symptoms
- Infective symptoms
- Possible drug cause
- Chronic H. pylori infection

Examination:

Observations
- MEWS score

Physical examination

- Signs of dehydration (skin, turgor, muscles, membranes)
- Signs of malnutrition*
- Abdominal examination
- Neurological signs (presence of confusion, nystagmus or ataxia should raise suspicion of Wernicke's)
- Weight

*Weight loss >5%, muscle wasting as measured by arm circumference

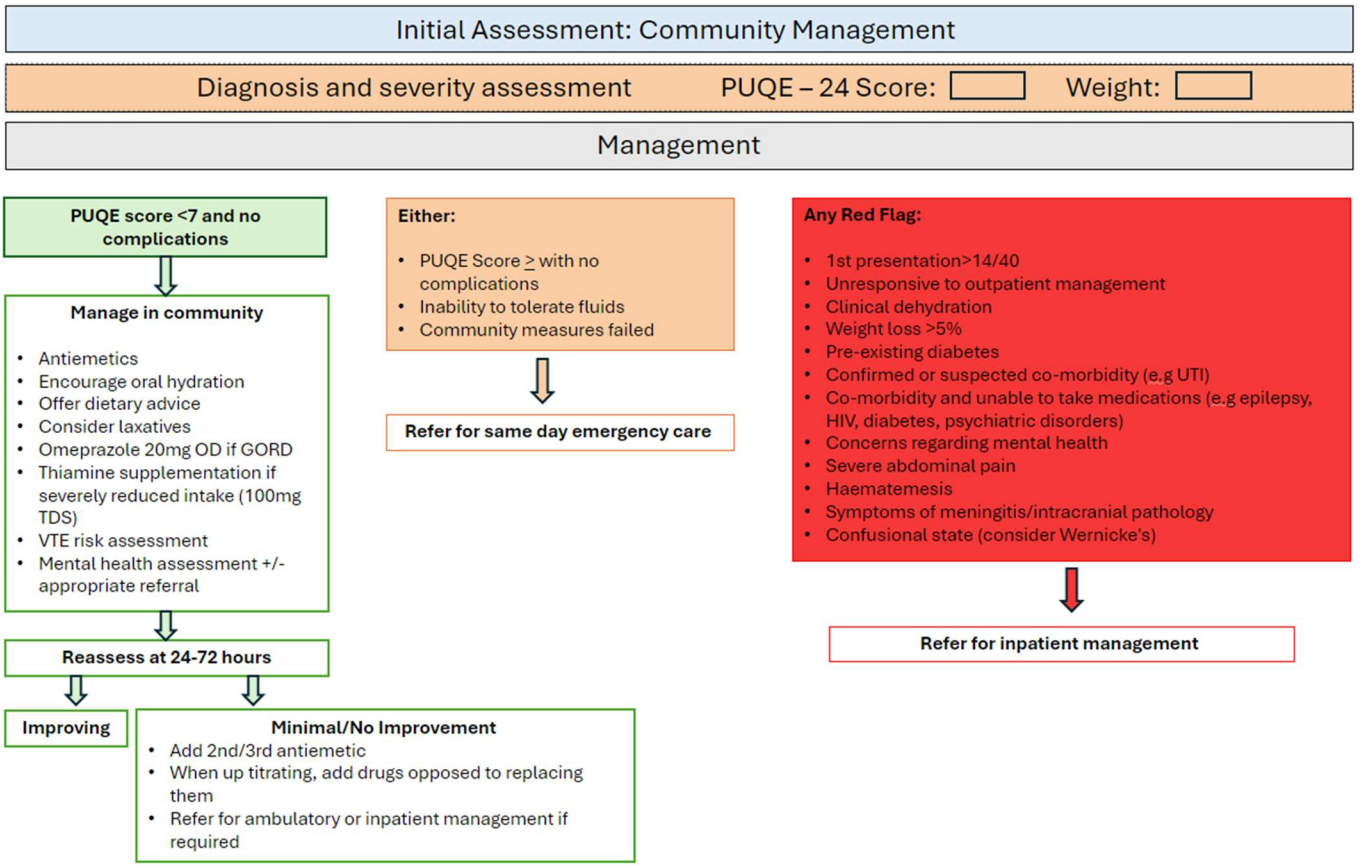
Investigations

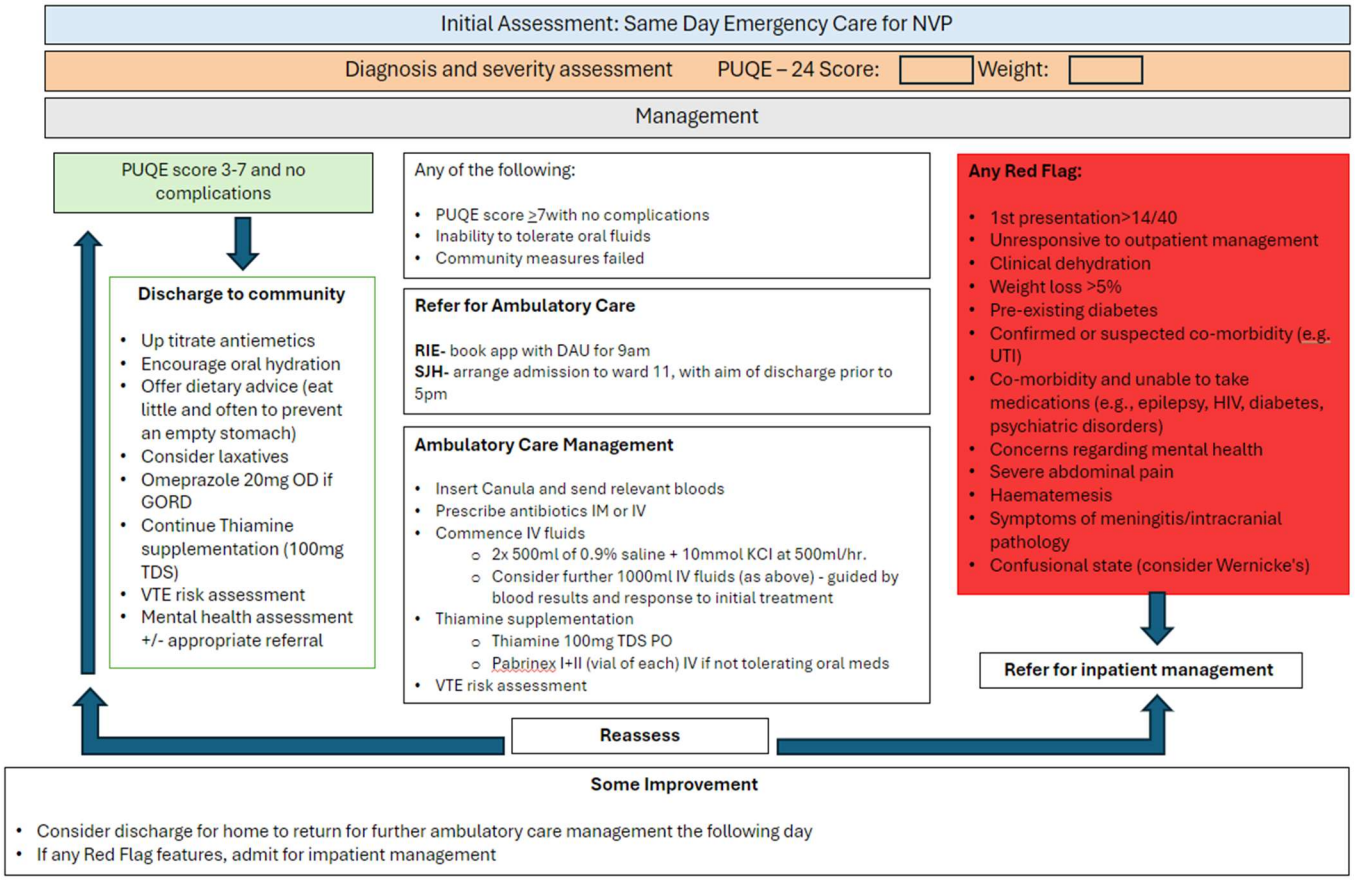
- Urine dipstick +/- MSU (looking for UTI NOT ketones)
- U+Es – electrolyte status, AKI
- FBC – infection, raised Hb or Hct may indicate dehydration.
- LFTs
- Glucose – to assess for diabetes.

In refractory cases:

- TFTs
- Calcium/Phosphate
- Amylase to assess for pancreatitis
- VBG – sever cases to exclude metabolic disturbance.

Severity Assessment using PUQE-24 scoring system


Initial Assessment: Community Management
Diagnosis and severity assessment
PUQE – 24 Score:
Weight:
Management
PUQE score <7 and no complications
Manage in community
Antiemetics
Encourage oral hydration
Offer dietary advice
Consider laxatives
Omeprazole 20mg OD if GORD
Thiamine supplementation if severely reduced intake (100mg TDS)
VTE risk assessment
Mental health assessment +/- appropriate referral
Reassess at 24-72 hours
Improving
Minimal/No Improvement
Add 2nd/3rd antiemetic
When up titrating, add drugs opposed to replacing them
Refer for ambulatory or inpatient management if required
Either:
PUQE Score ≥ with no complications
Inability to tolerate fluids
Community measures failed
Refer for same day emergency care
Any Red Flag:
1st presentation>14/40
Unresponsive to outpatient management
Clinical dehydration
Weight loss >5%
Pre-existing diabetes
Confirmed or suspected co-morbidity (e.g UTI)
Co-morbidity and unable to take medications (e.g epilepsy, HIV, diabetes, psychiatric disorders)
Concerns regarding mental health
Severe abdominal pain
Haematemesis
Symptoms of meningitis/intracranial pathology
Confusional state (consider Wernicke's)
Refer for inpatient management


Initial Assessment: Same Day Emergency Care for NVP
Diagnosis and severity assessment PUQE – 24 Score: Weight:
Management
PUQE score 3-7 and no complications
Discharge to community
Up titrate antiemetics
Encourage oral hydration
Offer dietary advice (eat little and often to prevent an empty stomach)
Consider laxatives
Omeprazole 20mg OD if GORD
Continue Thiamine supplementation (100mg TDS)
VTE risk assessment
Mental health assessment +/- appropriate referral
Any of the following:
PUQE score ≥7with no complications
Inability to tolerate oral fluids
Community measures failed
Refer for Ambulatory Care
RIE- book app with DAU for 9am
SJH- arrange admission to ward 11, with aim of discharge prior to 5pm
Ambulatory Care Management
Insert Canula and send relevant bloods
Prescribe antibiotics IM or IV
Commence IV fluids
2x 500ml of 0.9% saline + 10mmol KCl at 500ml/hr.
Consider further 1000ml IV fluids (as above) - guided by blood results and response to initial treatment
Thiamine supplementation
Thiamine 100mg TDS PO
Pabrinex I+II (vial of each) IV if not tolerating oral meds
VTE risk assessment
Any Red Flag:
1st presentation>14/40
Unresponsive to outpatient management
Clinical dehydration
Weight loss >5%
Pre-existing diabetes
Confirmed or suspected co-morbidity (e.g. UTI)
Co-morbidity and unable to take medications (e.g., epilepsy, HIV, diabetes, psychiatric disorders)
Concerns regarding mental health
Severe abdominal pain
Haematemesis
Symptoms of meningitis/intracranial pathology
Confusional state (consider Wernicke's)
Refer for inpatient management
Reassess
Some Improvement
Consider discharge for home to return for further ambulatory care management the following day
If any Red Flag features, admit for impatient management

Initial Assessment: Inpatient Management

Diagnosis and severity assessment **PUQE – 24 Score:** ☐ **Weight:** ☐

Management

Admission criteria and management

Admit if any of the following:

- 1st presentation>14/40
- Unresponsive to outpatient management
- Clinical dehydration
- Weight loss >5%
- Pre-existing diabetes
- Confirmed or suspected co-morbidity (e.g UTI)
- Co-morbidity and unable to take medications (e.g epilepsy, HIV, diabetes, psychiatric disorders)
- Concerns regarding mental health
- Severe abdominal pain
- Haematemesis
- Symptoms of meningitis/intracranial pathology
- Confusional state (consider Wernicke's)

On Discharge to Community

- Up titrate antiemetics
- Encourage oral hydration
- Offer dietary advice (eat little and often to prevent an empty stomach
- Consider Laxatives
- Omeprazole 20mg OD if GORD
- Continue Thiamine supplementation (100mg TDS)
- VTE risk assessment
- Mental health assessment +/- appropriate referral
- Ensure has contact numbers for triage / day assessment

Inpatient Mangement:

- Insert cannula and send relevant bloods
- Prescribe antiemetics (IM or IV)
- Prescribe IV fluids
  - 2x 500ml of 0.9% saline + 10mmol KCl at 500ml/hr.
  - Consider further 1000ml IV fluids (as above) - guided by blood results and response to initial treatment
  - Guided by daily monitoring of electrolytes
- Prescribe Thiamine supplementation
  - Thiamine 100mg TDS PO
  - Pabrinex I+II (vial of each) IV if not tolerating oral intake or sever prolonged vomiting. Usually given weekly but can be increased to alternative days in sever, refractory cases.
- TEDS and Dalteparin
- Omeprazole 20mg OD if GORD
- Laxatives (especially if on ondansetron)
- Mental health assessment +/- appropriate referral
- Schedule ultrasound to confirm viability, gestational age, and to assess for trophoblastic disease or multiple pregnancy
- Consider dietician referral +/- enteral/paternal nutrition cases where medical therapies have failed to sufficiently manage symptoms (see section E in main guideline)
- If ongoing symptoms into late 2nd/3rd trimester, ensure referral to locality consultants to consider antenatal care, including serial growth scans.

References

1. *The Management of Nausea and Vomiting in Pregnancy and Hyperemesis Gravidarum (Green-top Guideline No. 69).* **Nelson-Piercy C, Dean C, Shehmar M, Gadsby R, O'Hara M, Hodson K, et al.** 2024, BJOG, pp. 1-30.

2. *The windsore definition for hyperemesis gravidarum: A multistakeholder international consensus definition.* **Jansen LAW, Koot MH, Van't Hooft J, et al.** Nov 2021, Eur J Obstet Gynecol Reprod Biol., Vol. 266, pp. 15-22.

3. *Motherisk-PUQE (pregnancy-unique quantification of emesis and nausea) scoring system for nausea and vomiting of pregnancy.* **Koren G, Boskovic R, Hard M, Maltepe C, Navioz Y, Einarson A.** 5 Suppl Understanding, May 2002, Am J Obstet Gynecol, Vol. 186, pp. S228-31.

4. **Guideline for the Prevention and Management of Re-feeding Syndrome in Adult Acute Hospital Inpatients. [Online] http://intranet.lothian.scot.nhs.uk/Directory/dietetics/TubeFeeding/Documents/NHSL%20Prevention%20and%20Management%20of%20Refeeding%20Syndrome%20February%202024.pdf.**

Appendix 1: Pregnancy-Unique Quantification of Emesis (PUQE) index (3)

Total score is sum of replies to each of the three questions.

PUQE-24 Score: Mild ≤6; Moderate 7-12; Severe 13-15

Motherisk PUQE-24 scoring system					
In the last 24hours, for how long have you felt nauseated or sick to your stomach?	**Not at all (1)**	**1 hour or less (2)**	**2-3 hours (3)**	**4-6 hours (4)**	**More than 6 hours (5)**
In the last 24hours have you vomited or thrown up?	**I did not throw up (1)**	**1-2 times (2)**	**3-4 times (3)**	**5-6 times (4)**	**7 or more times (5)**
In the last 24hours how many times have you retching or dry heaves without bringing anything up?	**No times (1)**	**1-2 times (2)**	**3-4 times (3)**	**5-6 times (4)**	**7 or more times (5)**

How many hours have you slept out of 24 hours? Why?

On a scale of 0 to 10, how would you rate your wellbeing? (0=worst possible; 10=best you felt before pregnancy)

Can you tell me what causes you to feel that way?

Appendix 2: Safety Data for Antiemetics (1)

First line – There are safety data for antiemetics such as anti (H1) histamines, pheonthiazines and pyridoxine-doxylamine (Xonvea) and they should be prescribed when required for NVP and HG. Cochrane review reports no increased risk of congenital malformations or other adverse pregnancy outcomes.

Ondansetron – There is evidence that ondansetron is safe. Its use should **not** be discouraged if first line antiemetics are ineffective. Women can be reassured regarding a very small increase in the absolute risk of orofacial clefting with ondansetron use *in the first trimester* (no increased risk if started after 11 weeks), which should be balanced with the risks of poorly managed HG. The body of literature to support **no** overall increased risk of congenital malformations is increasing. UKTIS have published a systematic review of the literature that concludes "currently available data do not provide evidence that ondansetron use in the first trimester of pregnancy is associated with an increase in the overall malformation rate". A cohort study noticed a small increased risk of orofacial clefting. The main limitation of this study is that they compared women with severe NVP and HG taking ondansetron to women who did not have severe NVP or HG. This leaves open the possibility that any effects are compounded by indication, nor do they consider the competing risks to women with severe NVP and HG of leaving their illness poorly controlled. Absolute risk of orofacial clefting

increases from a background risk of 11 cases per 10000 births, to 14 cases per 10000 births with ondansetron.

Metoclopramide - Due to the risk of extrapyramidal effects with metoclopramide, it should be used as second-line therapy. Metoclopramide is safe and can be used alone or in combination with other antiemetics. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use, has recommended that metoclopramide is only prescribed for short term use. If prescribed IV, it shoulder be administered by slow bolus injection over at least 3 minutes to reduce the risk of extrapyramidal effects. The RCOG guidance recommend that it can be prescribed for more than five days in those women who gain symptomatic relief from it.

Corticosteroids – Corticosteroids (hydrocortisone and prednisolone) should be reserved for cases where standard therapies have been ineffective and used in combination with antiemetics. Their use in the first trimester is not associated with an increase in risk of congenital malformations overall. There is less data available and therefore their use is less well studied in comparison to other anti-emetic medications.

Visual risk summary

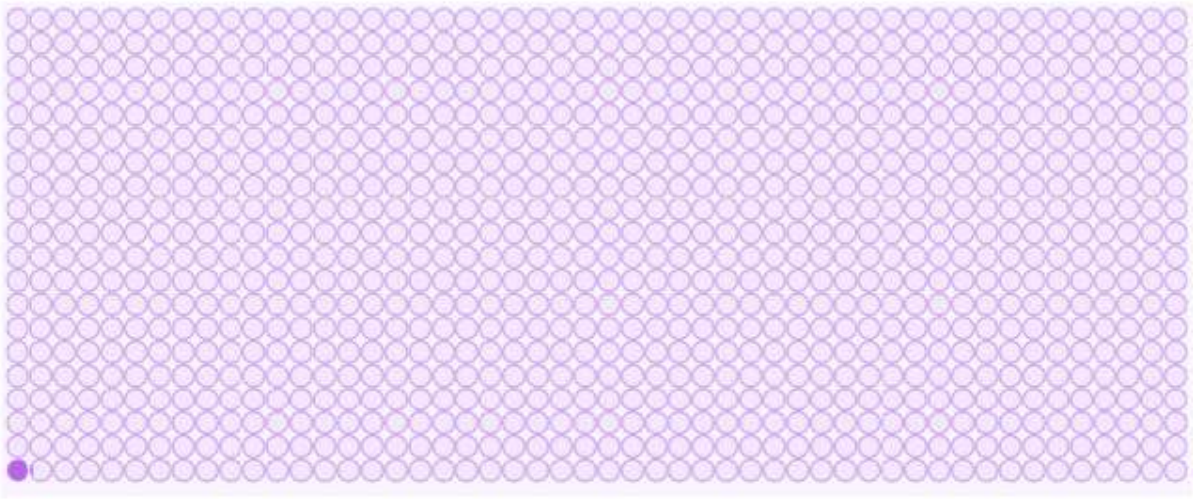


Figure 1. Rate of orofacial clefts in non-exposed pregnancies- 11 per 10,000

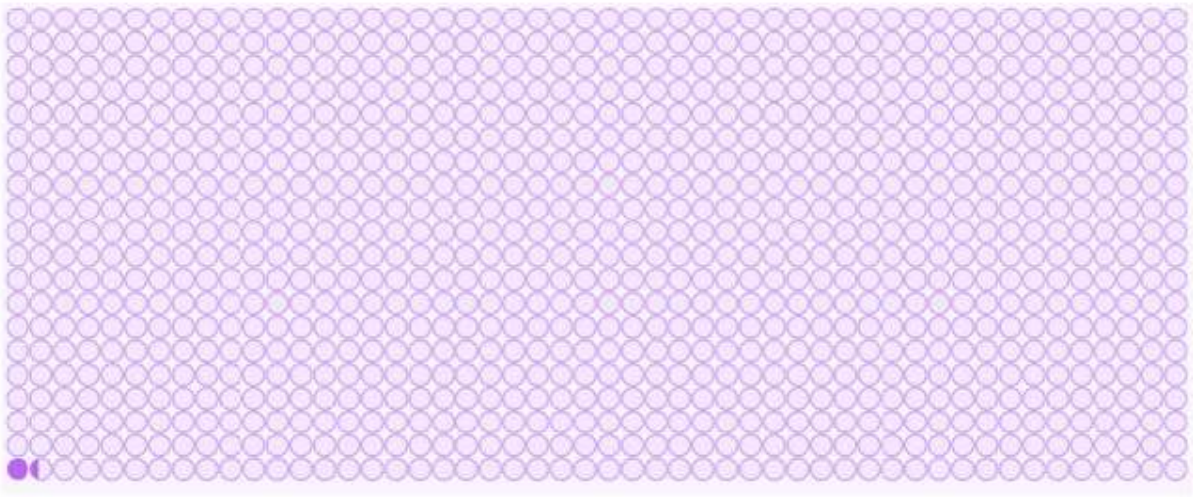


Figure 2. Rate of orofacial clefts in ondansetron-exposed pregnancies- 14 per 10,000

Irish Medicines in Pregnancy Service: Position Statement on Ondansetron Use in Pregnancy. 23 October 2019, 2019. Rotunda IMPS Ondansetron Response statement 231019.pdf