Evidence Based Garbage:

The Miserable Experience of Pregnant Woman

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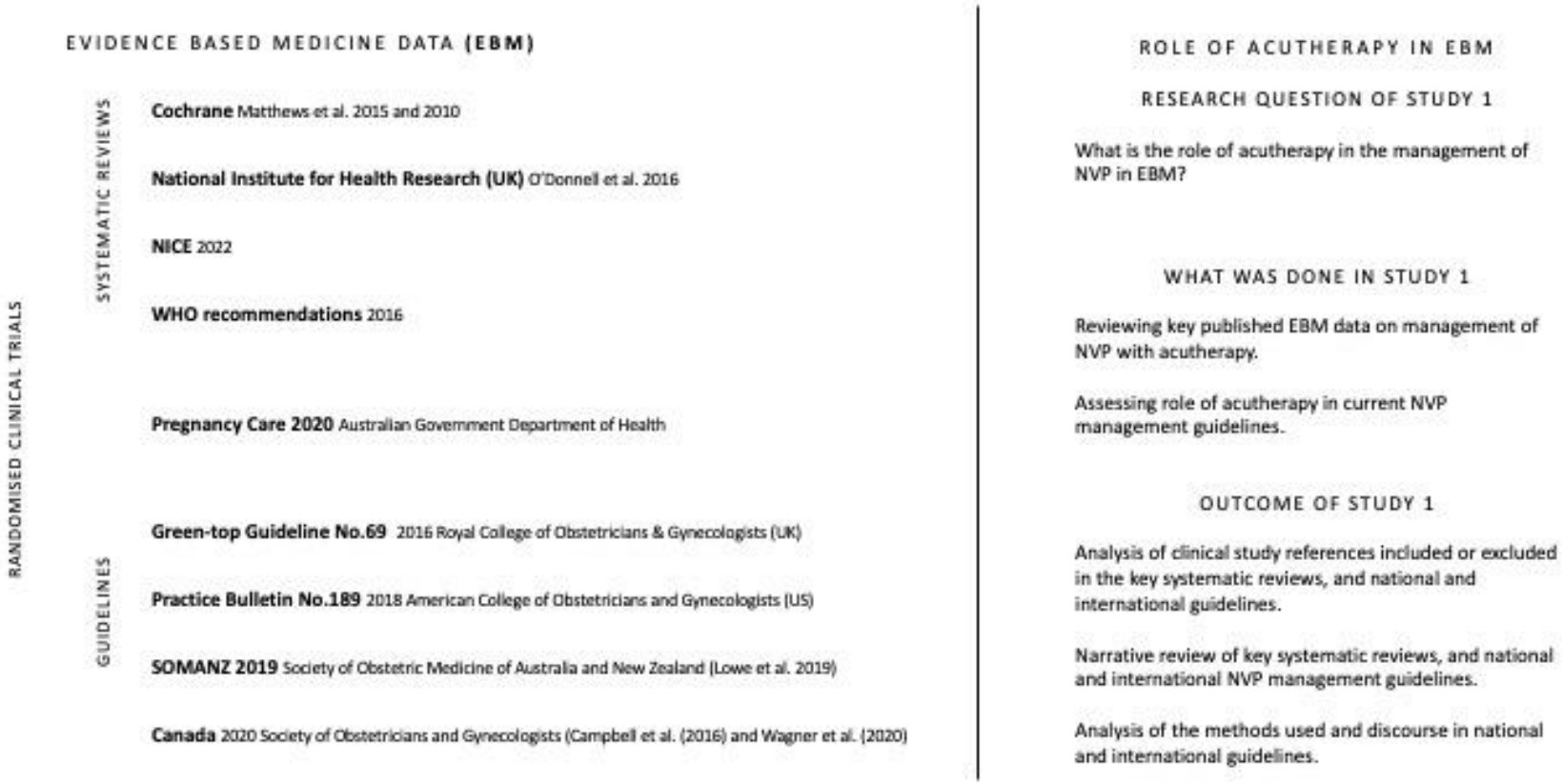
ABSTRACT

Evidence based medicine (EBM) aims to improve healthcare, quality of life and wellbeing. Good maternal care is a worldwide development priority. The majority of pregnant women experience nausea and vomiting in pregnancy (NVP). Effective care in managing NVP reduces symptoms, severity, and chances of complications. However, managing symptoms of NVP with antiemetics carries risks which many paitents, healthcare professionals, and authors may find difficult to consider. Acupuncture and acupressure may offer a safe and cost-effective alternative to managing symptoms of NVP. What is the role of acupuncture in the management of NVP? To answer this question, the present work analysed key EBM publications, namely systematic reviews, national guidelines for NVP management, and WHO recommendations. References, (randomized) clinical trial data, were analysed in a quantified manner and narratively, and compared and contrasted between systematic reviews. Guidelines on the management of NVP were similarly analysed. A role for acutherapy in EBM management of NVP is unclear

Graphical Abstract



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DISAMBIGUATION

In the present work, *acutherapy* refers to acupuncture, acupressure, and acustimulation.

Acupuncture involves puncturing the skin with a needle at a point recognized by Traditional Chinese Medicine (TCM).

Acupressure involves applying pressure by any means to a point on the body recognized by TCM.

Acustimulation involves passing an electrical current by any means through a point recognized by TCM.

(R)CT refers to a clinical trial whether deemed randomized or not.

INTRODUCTION

Evidence based medicine (EBM) aims to improve healthcare, quality of life and wellbeing. Good maternal care is a worldwide development priority. The majority of pregnant women experience nausea and vomiting in pregnancy (NVP). Effective care in managing NVP reduces symptoms, severity, and chances of complications, regardless of whether NVP frequently resolves four or five months into the pregnancy. What is the role of acutherapy in the management of NVP?

Research question, Aims, and Objectives

Research question

What is the role of acutherapy in the management of NVP in EBM?

Aims

Reviewing key published clinical trial data on management of NVP with acutherapy.

Assessing role of acutherapy in current NVP management guidelines.

Objectives

Analyse key published systematic reviews of clinical trial data.

Analyse national and international guidelines on management of NVP.

Outcomes

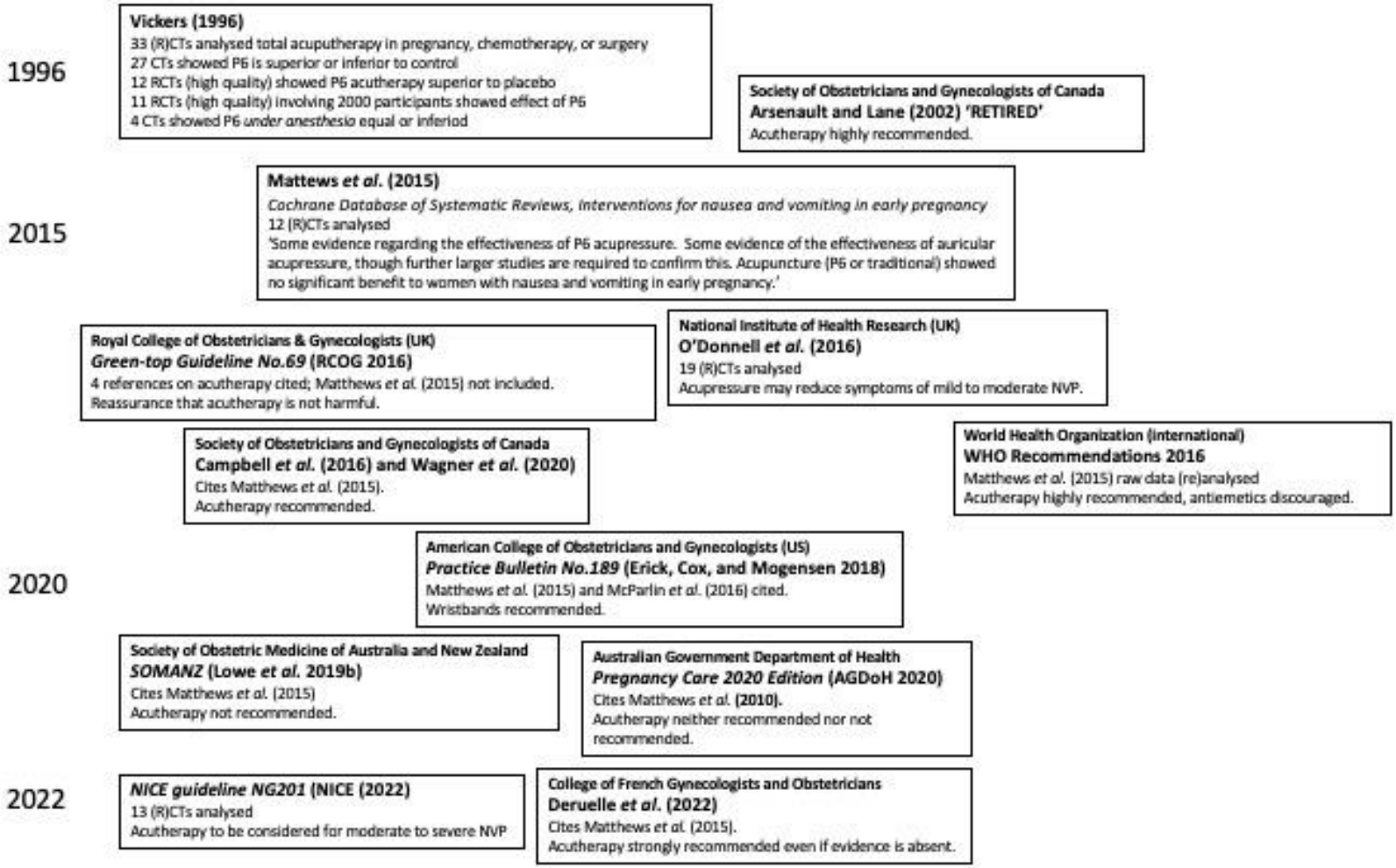
Analysis of references in the key systematic reviews, and national and international guidelines.

Review of key EBM of NVP management with acutherapy data, and national and international NVP management guidelines.

Analysis of the methods used and discourse in national and international guidelines.

Method and Results

Data analysed is summarized in the figure below.


1996
Vickers (1996)
33 (R)CTs analysed total acupuncture therapy in pregnancy, chemotherapy, or surgery
27 CTs showed P6 is superior or inferior to control
12 RCTs (high quality) showed P6 acutherapy superior to placebo
11 RCTs (high quality) involving 2000 participants showed effect of P6
4 CTs showed P6 under anesthesia equal or inferiod
Society of Obstetricians and Gynecologists of Canada
Arsenault and Lane (2002) 'RETIRED'
Acutherapy highly recommended.
2015
Mattews et al. (2015)
Cochrane Database of Systematic Reviews, Interventions for nausea and vomiting in early pregnancy
12 (R)CTs analysed
'Some evidence regarding the effectiveness of P6 acupressure. Some evidence of the effectiveness of auricular acupressure, though further larger studies are required to confirm this. Acupuncture (P6 or traditional) showed no significant benefit to women with nausea and vomiting in early pregnancy.'
Royal College of Obstetricians & Gynecologists (UK)
Green-top Guideline No.69 (RCOG 2016)
4 references on acutherapy cited; Matthews et al. (2015) not included.
Reassurance that acutherapy is not harmful.
National Institute of Health Research (UK)
O'Donnell et al. (2016)
19 (R)CTs analysed
Acupressure may reduce symptoms of mild to moderate NVP.
Society of Obstetricians and Gynecologists of Canada
Campbell et al. (2016) and Wagner et al. (2020)
Cites Matthews et al. (2015).
Acutherapy recommended.
World Health Organization (international)
WHO Recommendations 2016
Matthews et al. (2015) raw data (re)analysed
Acutherapy highly recommended, antiemetics discouraged.
2020
American College of Obstetricians and Gynecologists (US)
Practice Bulletin No.189 (Erick, Cox, and Mogensen 2018)
Matthews et al. (2015) and McParlin et al. (2016) cited.
Wristbands recommended.
Society of Obstetric Medicine of Australia and New Zealand
SOMANZ (Lowe et al. 2019b)
Cites Matthews et al. (2015)
Acutherapy not recommended.
Australian Government Department of Health
Pregnancy Care 2020 Edition (AGDoH 2020)
Cites Matthews et al. (2010).
Acutherapy neither recommended nor not recommended.
2022
NICE guideline NG201 (NICE (2022)
13 (R)CTs analysed
Acutherapy to be considered for moderate to severe NVP
College of French Gynecologists and Obstetricians
Deruelle et al. (2022)
Cites Matthews et al. (2015).
Acutherapy strongly recommended even if evidence is absent.

Reviewing key published clinical trial data on management of NVP with acutherapy

Studies analysed by Matthews et al. (2015)

and O'Donnell et al. (2016)

Clinical trials whether deemed randomized or not, or (R)CTs, found by Cochrane *Database of Systematic Reviews, Interventions for nausea and vomiting in early pregnancy*, cited in the present work as (Matthews et al. 2015) are in Table 1. Twelve (R)CTs were included for analysis of acutherapy in management of NVP by Matthews et al. (2015). Of those, no online English full text or no access was possible for seven (R)CTs. Of the remaining five, two (R)CTs showed that acupressure was no better than sham, one (R)CT showed that acupuncture is better than sham, one (R)CT showed that ginger is better than acupuncture, and the remaining 'group' of references are inconclusive.[1] Briefly, studies analysed by Matthews et al. (2015) for acutherapy management of NVP are inaccessible, inconclusive, irrelevant, or combinations thereof.

(R)CTs found by the National Institute for Health Research (UK) *Treatments for hyperemesis gravidarum and nausea and vomiting in pregnancy: a systematic review and economic assessment* (cited in the present work as (O'Donnell et al. 2016) are in Table 2. This research is published as an article (McParlin et al. 2016). A total of 19 (R)CTs were analysed.

Findings regarding acutherapy management of NVP in Matthews et al. (2015) and O'Donnell et al. (2106) are summarized in the Figure above.

[1] Matthews et al. (2015) refer to more than one publication using the same citation as shown in Table 1.

Studies not in the analysis by Matthews et al. (2015)

Eight studies all published before 2009 were missed by Matthews et al. (2015) and analysed by O'Donnell et al. (2016). One study judged by O'Donnell et al. (2016) to have a high risk of bias was included in analysis by Matthews et al. (2015), and one study judged by O'Donnell et al. (2016) to have a low risk of bias was excluded from analysis by Matthews et al. (2015). However, the reason(s) for exclusion from analysis by Matthews et al. (2015) does not appear consistent, particularly when compared and contrasted with features of studies that were included for analysis for example see footnotes 5 and 6.

NICE studies

Studies *included in analysis* in the systematic review by the National Institute for Health and Care Excellence (UK) to develop the *NICE guideline NG201* (NICE 2022) are in Table 3. All but one of these studies were *Excluded After Analysis* and so are labelled *EAA* in the Tables below. Studies that were *Excluded Before Analysis* by NICE are labelled *EBA* in the Tables below.

Studies not cited by Matthews et al. (2015), O'Donnell et al. (2016), nor NICE (2022)

These are in Table 4. The reader's attention is gently drawn to (Vickers 1996) published before 2015, and (Lu et al. 2021) published after 2015.

Table 1. (R)CTs included and excluded in the analysis by (Matthews et al. 2015)					
INCLUDED (in order of appearance in the text page 8)					
#	**Article**	**Conclusion of the article**	**Remark**	**NICE?**[2]	**Referred as**[3]
1	(Belluomini et al. 1994)	P6 acupressure reduces NVP symptoms not vomiting	No full text online?	EAA	Belluomini 1994
2	(KHAVANDIZADEH and Mahfouzi 2010)	P6 acupressure reduces severity of NVP	No full text online?	EBA	Khavandizadeh 2010
3	(Norheim et al. 2001a) (Norheim et al. 2001b)	Consider acupressure before drugs for morning sickness	Article not in English?	EBA	Norheim 2001

[2] In this column, *EBA* denotes that the article was *Excluded Before Analysis* by NICE, see Appendix K pages 204-217 of (NICE 2021a), or the online version (NICE 2021b). Links provided below. *EAA* denotes that the article was *Ecluded After Analysis,* which are all but one of the references listed in Table 3. 'No' denotes that the article was not found by NICE directly, and may have been found by NICE developers indirectly through cross-check of references excluded from the study.

[3] 'Referred as' in this column is how an article or more was referred to in (Matthews et al. 2015) References pages 25-27 or online here. Note that all these references were listed in (Matthews et al. 2015) as "…{published data only}…" (*sic, ibid*).

4	(O'Brien, Relyea, and Taerum 1996)	No benefit of P6 acupressure. No control group.	Not open access?	EBA	O'Brien 1996
5	(Werntoft and Dykes 2001)	P6 acupressure reduces NVP.	No full text online?	EAA	Werntoft 2001
6	(Jamigorn and Phupong 2007)	Acupressure therapy is not more effective than vitamin B6.	Not open access?	EBA	Jamigorn 2007
7	Saberi F. Comparison of acupressure and ginger in the treatment of nausea and vomiting of pregnancy. IRCT: Iranian Register of Clinical Trials (www.irct.ir) [accessed 20 September 2011]2011.		'Last accessed 2011'.[4] No link?	No	Saberi 2014
	(Saberi et al. 2013)	Ginger is more effective than acupressure to relieve mild to moderate NVP.			
	(Saberi et al. 2014)	Ginger was effective for the relief of mild to moderate NVP.	Irrelevant and perhaps duplicate.	EAA	

[4] 'Last accessed' data is from (Matthews et al. 2015) pages 25-27.

8	Lamyian M. Evaluation of the influence of KID 21(youmen) point acupressure on nausea and vomiting of pregnancy. IRCT: Iranian Register of Clinical Trials (www.irct.ir) [accessed 30 April 2013]2013.		‘Last accessed 2012.’ No link	No	Rad 2012
	Rad MN. Evaluation of the influence of KID 21 (youmen) point acupressure on nausea and vomiting of pregnancy. IRCT Iranian Registry of Clinical Trials (www.irct.ir) [accessed 6 December 2010]2010.				
	(Rad et al. 2012)	Acupressure on KID21 point is more effective than sham acupressure in reduction of NVP.		EAA	
9	(de Veciana et al. 2001)	Nerve stimulation does not improve symptoms and decreases vomiting bouts.	Abstract only?	No	Rosen 2003
	(Miller et al. 2001)				
	(Rosen et al. 2003)	Nerve stimulation therapy is effective in reducing nausea *and* vomiting and promoting weight gain.	No full text online or not open access?		

10	(Puangsricharern and Mahasukhon 2008)	Auricular acupressure therapy does not relieve NVP.		EAA	Puangsricharern 2008
11	(Knight et al. 2001)	Acupuncture as effective as sham in NVP treatment.		EAA	Knight 2001
12	(C Smith and Crowther 2002)	Sham acupuncture is a credible control.		No	Smith 2002
	(Caroline Smith, Crowther, and Beilby 2002b)	Consider acupuncture for NVP.		EAA	
	(Caroline Smith, Crowther, and Beilby 2002a)	No serious adverse effects with acupuncture in early pregnancy.		No	
	Smith C, Crowther C, Beilby J. Women's experiences of nausea and vomiting in early pregnancy. 2nd Annual Congress of the Perinatal Society of Australia & New Zealand; 1998 March 30-April 4; Alice Springs, Australia. 1998:142.		?	No	
13	(范永军 1995)	‘Moxibustion therapy is superior to Chinese drug in treatment of pregnant vomiting’.	Citation? Chinese?	No	Fan 1995
	(Fan, Zhu, and Fu 1995)				

EXCLUDED by (Matthews et al. 2015) pages 28-29 or click here. See also Characteristics of excluded studies page 75.					
#	**Article**	**Conclusion of the article**	**Remarks**	**NICE?**	**Referred as**
14	(Anjum et al. 2002)	Morning sickness acupressure	Citation	No	Anjum 2002
15	(Bayreuther, Pickering, and Lewith 1994)	P6 acupressure better than sham.	Included in (O'Donnell et al. 2016) study.	No	Bayreuther 1994
16	(Can Gürkan and Arslan 2008)	P6 acupressure relieves symptoms with or without placebo.		EBA	Can Gurkan 2008
17	(De Aloysio and Penacchioni 1992)	Acupressure relieves NVP	Cross-over	EBA	De Aloysio 1992
18	(Dundee et al. 1988)	P6 acupressure therapeutic in NVP	Why excluded?[5] Appears good.	EBA	Dundee 1988

[5] The reason given on page 75 is "…Not an RCT; women allocated to groups by day of the week; non-responders replaced in treatment group…"

19	(Heazell et al. 2006)	No effect of acupressure	Why excluded?[6]	EAA	Heazell 2006
20	(Hyde 1989)	Acupressure relieves depression, anxiety, and behavioral dysfunction, and nausea in NVP	Cross-over	EBA[7]	Hyde 1989
21	(Ozgoli, Shahbazzadegan, and Rassaian 2007)	Wristband with or without P6 pressure effective for NVP		No	Shahbazzadegan 2007
	Shahbazzadegan S. Investigation the trend of pregnancy nausea and vomiting treatment using acupressure wristband. IRCT: Iranian Register of Clinical Trials (http://www.irct.ir) (accessed 30 April 2013)2006.				
22	(Steele et al. 2001)	Wristband brand effective for NVP		EBA	Steele 2001

[6] "…Severe symptoms, in-patient; hyperemesis gravidarum implied (severe symptoms plus ketonuria)…" (?)

[7] NICE (2022a) also exclude studies for being cross-over. However, this was excluded for being 'duplicate' page 209-210.

Table 2. (R)CTs analysed by (O'Donnell et al. 2016) in order of appearance in the text.				
Judged 'low risk of bias' by O'Donnel *et al*. 2016				
#	**Article**	**Matthews**[8]	**NICE**[9]	**Referred as**[10]
1	(Bayreuther, Pickering, and Lewith 1994)	Yes, excluded	No	61
2	(Belluomini et al. 1994)	Yes, included	EAA	62
3	(Carlsson et al. 2000)[11]	No	No	66
4	(Jamigorn and Phupong 2007)	Yes, included	EBA	80

[8] In this column, the following question is answered: Was this article found by (Matthews et al. 2015)? If *Yes*, was it included or excluded?

[9] In this column, *No* means the article was not directly found by NICE, and may have been indirectly found through cross-check of other references. Note that on page 213 of (NICE 2021a) it states that O'Donnell et al. (2016) references were checked and no additional studies identified; *EBA* denotes that the article was *Excluded Before Analysis* by NICE, see Appendix K pages 204-217 of (NICE 2021a), or the online version (NICE 2021b). Links provided below; and *EAA* denotes that the article was *Ecluded After Analysis.*

[10] These numbers refer to the reference number in (O'Donnell et al. 2016) pages 173-182 or click here.

[11] P6 acupuncture + standard treatment faster recovery from HG compared to sham

5	(Knight et al. 2001)	Yes, included	EAA	83
6	(Rad et al. 2012)	Yes, included	EAA	91
7	(Rosen et al. 2003)	Yes, included	No	98
8	(Caroline Smith, Crowther, and Beilby 2002b)	Yes, included	EBR	101
Judged 'high risk of bias' by (O'Donnell et al. 2016)				
#	**Article**	**Matthews**	**NICE**	**Referred as**
9	(Mao and Liang 2009)	No	EBA	87
10	(Neri et al. 2005)	No	No	94
11	(Werntoft and Dykes 2001)	Yes, included	EAA	111
12	(Zhang 2005)	No	No	115
13	(Markose, Ramanathan, and Vijayakumar 2004)	No	No	124
Judged 'unclear' by O'Donnell *et al.* (2016)				
14	(Can Gürkan and Arslan 2008)	Yes, excluded	No	43

15	(A. Evans et al. 1993) and (A. T. Evans et al. 1994)[12]	No	No	73
16	(Heazell et al. 2006)	Yes, excluded, see footnote 7	Yes	78
17	(Hsu et al. 2003) Citation?	No	No	79
18	(Steele et al. 2001)	Yes, excluded	No	104
19	(de Veciana et al. 2001)	No	No	109

[12] Evans *et al.* (1993) which appears to be an abstract only is cited in O'Donnell *et al.* (2016). I found Evans *at al.* (1994) which appears not to be open access. The title of both is *Suppression of Pregnancy-Induced Nausea and Vomiting With Sensory Afferent Stimulation*. It was reported that NVP effectively improved with treatment compared to placebo device.

Table 3. Articles *Excluded After Analysis (EAA)* in NICE (2022)		
Articles in random order	**Grouped in NICE as**	**Total number of articles**
(Habek et al. 2004); (Heazell et al. 2006); (Adlan, Chooi, and Mat Adenan 2017)	Acupressure or acupuncture for moderate to severe NVP	3
(Belluomini et al. 1994); (Knight et al. 2001); (Werntoft and Dykes 2001); (Caroline Smith, Crowther, and Beilby 2002b) (Puangsricharern and Mahasukhon 2008); (Rad et al. 2012); (Saberi et al. 2014); (Galeshi et al. 2020); (Ghule and Sureshkumar 2020) (Mobarakabadi, Shahbazzadegan, and Ozgoli 2020)[13]	Acupressure or acupuncture for mild to moderate NVP	10

[13] In addition: "…One RCT reported an 8-arm unpublished trial from the 1970s that aimed to evaluate the efficacy of (Zhang 2017) pyridoxine hydrochloride and doxylamine succinate. The 8 arms of the trial were pyridoxine hydrochloride, a histamine H1-receptor antagonist (doxylamine succinate), a combination of pyridoxine hydrochloride and doxylamine succinate, and a placebo. The other arms of the trial were dicyclomine, a combination of dicyclomine and pyridoxine hydrochloride, a combination of dicyclomine and doxylamine succinate, and a combination of dicyclomine, pyridoxine hydrochloride, and doxylamine succinate, all of which were not interventions of interest for this review…" page 8 of (NICE 2021a).

Table 4. Acutherapy for NVP systematic reviews, RCTs, and clinical trials not cited by O'Donnell et al. (2016), Matthews et al. (2015), nor NICE (2022), or else found and excluded by NICE (2022) noted below					
#	**Article**	**Type**[14]	**Incl**[15]	**Conclusion of the article**	**Remarks**
PUBLISHED AFTER 2015					
1	(Yue et al. 2022)	SR	13	This systematic review reveals that the efficacy of auricular acupressure in managing NVP is insufficient and the efficacy of auricular acupressure for treating NVP remains limited.	
2	(Lu et al. 2021)	SR	16	'Our study suggested that acupuncture was effective in treating HG. However, as the potential inferior quality and underlying publication bias were found in the included studies, there is a need for more superior-quality RCTs to examine their effectiveness and safety. PROSPERO registration number: CRD42021232187.'	Chinese articles analysed largely. Includes ketonuria.

[14] *SR* denotes systematic review, *RCT* randomized clinical trial, and *CT* clinical trial.

[15] The number in this column denotes the number of studies included in an SR, or the number of participants in an RCT or CT.

7	(Mobarakabadi, Shahbazzadegan, and Ozgoli 2020)	RCT	75	P6 acupressure with or without placebo effective for NVP. Wristband brand recommended.	EAA and referred to as 2019
8	(Galeshi et al. 2020)	RCT	?	Pressure on P6 and KID21 points has no advantage over each other in the treatment of NVP, but acupressure is an effective, complication-free, inexpensive and accessible treatment for this complication	EAA
9	(Ghule and Sureshkumar 2020)	?	?	The results obtained from this study showed that the Accu TENS with Accu band can be easy to perform, least expensive, feasible and most efficient management strategy for reducing nausea, vomiting and retching, weight gain and enhancing the quality of life of individuals with early pregnancy	EAA
	(Kirca and Gul 2020)	CT	140	'Statistical results have provided that acupressure taught to women was found to be highly effective in reducing pregnancy-induced nausea and vomiting.	
10	(Tsakiridis et al. 2019)	SR	3	ASOG, SOGC, RSOG compared. Concludes: 'Evidence-based medicine may lead to the adoption of an international guideline for the management of NVP, which may lead to a more effective management of that entity.' (*sic*)	

11	(McParlin et al. 2016)	SR[16]	8[17]	This is quoted in full in footnote[18]	EBA
PUBLISHED BEFORE 2015					
12	(Vickers 1996)	SR	33	This is quoted in full in footnote[19]	

[16] This is also a guideline.

[17] These are probably articles #1 to #8 in Table 2., or those judged low risk of bias by O'Donnell et al. (2016), I did not cross-check.

[18] "…In summary for acupressure: treatment with acupressure was associated with symptom improvement for mild cases (level A, class IIa). For nerve stimulation: evidence indicates treatment may be considered, but the benefit was unclear (level B, class IIb). For acupuncture: the benefit was unclear (level A, class IIb)…"

[19] "…The effects of acupuncture on health are generally hard to assess. Stimulation of the P6 acupuncture point is used to obtain an antiemetic effect and this provides an excellent model to study the efficacy of acupuncture. Thirty-three controlled trials have been published worldwide in which the P6 acupuncture point was stimulated for treatment of nausea and/or vomiting associated with chemotherapy, pregnancy, or surgery. P6 acupuncture was equal or inferior to control in all four trials in which it was administered under anaesthesia; in 27 of the remaining 29 trials acupuncture was statistically superior. A second analysis was restricted to 12 high-quality randomized placebo-controlled trials in which P6 acupuncture point stimulation was not administered under anaesthesia. Eleven of these trials, involving nearly 2000 patients, showed an effect of P6. The reviewed papers showed consistent results across different investigators, different groups of patients, and different forms of acupuncture point stimulation. Except when administered under anaesthesia, P6 acupuncture point stimulation seems to be an effective antiemetic technique. Researchers are faced with a choice between deciding that acupuncture does have specific effects, and changing from 'Does acupuncture work?' to a set of more practical questions; or deciding that the evidence on P6 antiemesis does not provide sufficient proof, and specifying what would constitute acceptable evidence…" (Vickers 1996).

13	(Arsenault and Lane 2002)	SR[20]		RETIRED. Relevant text is quoted in footnote[21]	
14	(Duke and Don 2005)	SR	-	REMOVED	

[20] This is also a guideline.

[21] "…**Recommendations:** I. Dietary and lifestyle changes should be liberally encouraged, and women should be counselled to eat whatever appeals to them. (III-C); 2. Alternative therapies, such as ginger supplementation. acupuncture. and acupressure, may be beneficial. (I-A); 3. A doxylamine/pyridoxine combination should be the standard of care since it has the greatest evidence to support its efficacy and safety. (I-A); 4. H_1 receptor antagonists should be considered in the management of acute or breakthrough episodes of NVP. (I-A); 5. Pyridoxine monotherapy supplementation may be considered as an adjuvant measure. (I-A); 6. Phenothiazines are safe and effective for severe NVP. (I-A); 7. Metoclopramide is safe to be used for management of NVP, although evidence for efficacy is more limited. (11-2D); 8. Corticosteroids should be avoided during the first trimester because of possible increased risk of oral clefting and should be restricted to refractory cases. (I-B); 9. When NVP is refractory to initial pharmacotherapy, investigation of other potential causes should be undertaken. (III-A) … **ACUPUNCTURE AND ACUPRESSURE** Stimulation of the P6 (Neiguan) point, located three-fingers' breadth proximal to the wrist, has been used for thousands of years by acupuncturists to treat nausea and vomiting from a variety of causes. Though there are no theoretical concerns about the safety of acupressure in pregnancy, efficacy of P6 acupressure is difficult to prove because it is impossible to perform a true double-blind trial compared with no intervention. Nonetheless, non-blinded RCTs have demonstrated a decrease in "persisting nausea" by at least 50%.11 Bands worn on the wrist to apply acupressure may also be helpful (citation to: Jewell D.Young G.lnterventions for nausea and vomiting in early pregnancy (Cochrane Review). ln: The Cochrane Library. Issue 4.2000. Oxford: Update Software)…" (emphasis in the original, Arsenault and Lane 2002, pages 817, 819, and 823).

15	(Zhang 2005)	CT	150	Compares acu-p, Chinese medicine drug, and Western medicine drug. Concludes: 'Acup-moxibustion is the best method for hyperemesis gravidarum'.	Article in Chinese.
16	(Helmreich, Shiao, and Dune 2006b)	SR	22	This meta-analysis demonstrates that acupressure and ETS had greater impact than the acupuncture methods in the treatment of NVP. However, the number of acupuncture trials was limited for pregnant women, perhaps because it is impossible to self-administer the acupuncture and thus inconvenient for women experiencing NVP as chronic symptoms.	Not open access? EBA from NICE[22]
17	(Lee and Frazier 2011)	SR	?	Acupressure may be a useful strategy for the management of multiple symptoms in a variety of patient populations, but rigorous trials are needed. Inclusion of acupressure as an intervention may improve patient outcomes.	Includes chemotherapy. EBA from NICE
18	(Sinha et al. 2011)	RCT	340	In this study acupressure wristbands applied bilaterally did not reduce the incidence of nausea and vomiting during labour and delivery	

[22] Nor could I access full text for (Shiao and Dibble 2006) the first author of whom is co-author on Helmreich, Shiao, and Dune (2006), and which is published in the same volume of *Explore* journal.

Assessing role of acutherapy in current NVP management guidelines

Six current national level guidelines and one international guideline were analysed to assess the role played by acutherapy in management of NVP, discussed below and summarized in figure and graphical abstract above. To assess the role of acutherapy in a guideline, the following was done:

i. All references to acutherapy in a guideline were analysed, notably against EBM systematic reviews data presented in the preceeding section of the present work. Please note this includes all references to acutherapy in a guideline, the justification being that *acutherapy for NVP management* in a guideline is contextualized within a broader *acutherapy for NVP and other conditions* in the same guideline.

ii. Eight yes-or-no questions were asked under the heading ACURITE, these questions are listed on the next page. Briefly, the following was quantified: accurateness of a reference (was the reference used published within ten years of writing the guideline? Was the reference used about acutherapy in NVP?); usability of the guideline for acutherapy management of NVP (was there a description or treatment algorithm that includes acutherapy?); and consistency of the guideline with regards acutherapy (was acutherapy recommended? If so, is it in the treatment algorithm or is there a description?).

iii. The following question is answered: What is the guideline telling the user to do about managing NVP? This is given in a synopsis at the end of a guideline analysis.

iv. Analysis of methods used by, and discourse in the guidelines, to assess the role of acutherapy in current national and international guidelines concerned with pregnancy and NVP.

The eight yes-or-no questions that were asked under the heading *ACURITE* are (point (ii) above):

1. Was acutherapy discussed in the text of the guideline? If *Yes*, were the references used in the discussion of acutherapy:
2. …published within ten years from the date of the publication of the guideline? AND …about NVP, or about chemotherapy, surgery, motion sickness, so on, as well as NVP?[23] For example, a 1994 reference in a 2016 guideline is *ACURITE No*.
3. Was an acutherapy method described in the text?
4. Was acutherapy recommended? If *Yes*:
5. …with what grade?
6. Is acutherapy mentioned in the guideline's treatment algorithm?

Together, these questions work towards answering:

7. Can this guideline be used to manage NVP with acupuncture? For example, for a guideline with a brief acutherapy description, or for a guideline where acutherapy is mentioned in the treatment algorithm, the answer is *Yes*.
8. Is the guideline consistent regarding NVP acupuncture management? For example, for a guideline which recommends acutherapy and neither gives a description nor mentions acutherapy in the treatment algorithm, the answer is *No*. As another example, for a guideline which does not recommend acutherapy, and does not give a description nor mentions acutherapy in the treatment algorithm, the answer is *Yes*.

[23] Or something completely different. An underlying assumption here is that guideline developers would have had access to Mattews et al. (2015) at the time the guideline was published, and certainly to Matthews et al. (2010).

Green-top Guideline No.69

GUIDELINE ANALSIS #1	
Published in	UK
Published by	Royal College of Obstetricians & Gynaecologists
Publication name	*Green-top Guideline No.69*
Publication date	2016
Cited here as	(RCOG 2016)
Link to pdf	Click here.
Link to website	Click here.

ACURITE for *Green-top Guideline No.69*		
Is acupuncture discussed in the text?		Yes
	With ACURITE references?	No
	With acupuncture method description?	No
Was acupuncture recommended?		Yes
	With what grade?	B
Is acupuncture in the treatment algorithm?		No
Can this guideline be used to manage NVP with acupuncture?		No
Consistent regarding NVP acupuncture management?		No

A role for acupuncture in *Green-top Guideline No.69*?

Under "…Acustimulations – acupressure and acupuncture…", it states, "…Women may be reassured that acustimulations are safe in pregnancy. Acupressure may improve NVP…" (RCOG 2016, page 4). It was given grade of recommendation B.[24] However, in the "…Treatment algorithm for NVP and HG…" (page 26), there is no mention of acupressure nor acupuncture. 'Acustimulations' is discussed in a paragraph on page 12 and four references are mentioned, discussed here in Table 5. Neither Matthews et al. (2015) nor Matthews et al. (2010) are cited in the relevant text. *Green-top Guideline No.69* developers were able to refer to (Belluomini et al. 1994) and not to (Vickers 1996). Briefly, it does not appear that effort was made to include more robust clinical trial data available to the developers of *Green-top Guideline No.69* at the time of its writing in 2016.

***Green-top Guideline No.69* treatment algorithm for NVP and HG**[25]

In this *Guideline*, 'diagnosis is by exclusion of other causes'. 'Initial assessment' includes PUQE score and for 'clinical complications (dehydration, electrolyte imbalance, weight loss)', as well as 'offer advice and support'. One of three management outcomes then becomes possible:

(i) 'antiemetics in community and lifestyle and dietary changes'; or

(ii) 'ambulatory daycare management (saline, antiemetics, and thiamine) until no ketonuria'; or

[24] Gradae recommendation B is defined as "…A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+…" (RCOG, 2016, page 23). Classification of evidence level 2++ is defined as "…High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding,bias or chance and a high probability that the relationship is causal…"; level 1++ and 1+ include meta-analyses (*ibid*).

[25] *Hyperemesis gravidarum*

(iii) ‘inpatient management’ which is ‘thromboprophylaxis, multidisciplinary team approach and consider steroids’ (RCOG 2016, page 26). A multidisciplinary team may include “…midwives, nurses, dieticians, pharmacists, endocrinologists, nutritionists and gastroenterologists, and a mental health team, including a psychiatrist…” (RCOG 2016, page 4).

Synopsis of *Green-top Guideline No.69*

Give her one of several drugs for the present classed as antiemetics. If that does not work, try a cocktail of drugs. If that does not work, give her a drug or cocktail of drugs directly into blood or rectum, and why not corticosteroid. If that does not work, admit the patient and call the cavalry. And butcher, baker, *etc*.

Table 5. Acutherapy references mentioned in *Green-top Guideline No.69,* in order of appearance on page 12 (RCOG, 2016)			
#	**Reference**	**Remarks**	**ACURITE reference?**
1	(Caroline Smith, Crowther, and Beilby 2002a)	This RCT reported safety of acupuncture in NVP management. A guideline for needling practice is outlined.	No. Not published 2006 onwards.
2	(Helmreich, Shiao, and Dune 2006a)	RCT of 14 trials acutherapy for vomiting in general. I could not access this article's full text. Nor could I access full text for (Shiao and Dibble 2006) the first author of whom is co-author on Helmreich, Shiao, and Dune (2006), and which is published in the same volume of *Explore* journal.[26]	Barely *Yes* for the date. Not specific to NVP. So *No.*
3	(Belluomini et al. 1994)	I could not access full text for this article.	No. Not published 2006 onwards.
4	(Lee and Frazier 2011)	"…Investigators in 16 of 23 studies concluded acupressure was effective, primarily for the management of nausea and vomiting in patients during pregnancy and during chemotherapy…"	No. Not specific to NVP.

[26] As mentioned elsewhere, this articles appears not to be open access and neither is (Shiao and Dibble 2006) the first author of whom is co-author on Helmreich, Shiao, and Dune (2006), and which is published in the same volume of *Explore* journal.

NICE guideline NG201

GUIDELINE ANALSIS #2	
Published in	UK
Published by	National Institute for Health and Care Excellence
Publication name	*NICE guideline NG201*
Publication date	2021
Cited here as	(NICE 2022)
Link to pdf	Click here.
Link to website	Click here.

ACURITE for *NICE guideline NG201*		
Is acutherapy discussed in the text?		Yes
	With ACURITE references?	1 Yes (acupressure + mild NVP) 3 No (acupressure + severe NVP; acupuncture + mild NVP; acupuncture + severe NVP)
	With acutherapy method description?	No
Was acutherapy recommended?		consider for moderate to severe NVP
	With what grade?	n/a
Is therapy in the treatment algorithm?		Recommendation 1.4.6
Can this guideline be used to manage NVP with acutherapy?		No
Consistent regarding NVP acutherapy management?		No

Acutherapy in *NICE guideline NG201*

Recommendation 1.4.6 states: "…For pregnant women with moderate-to-severe nausea and vomiting: consider intravenous fluids, ideally on an outpatient basis (;) consider acupressure as an adjunct treatment…" (NICE 2022).

However, in *NICE guideline NG201, [R] Management of nausea and vomiting in pregnancy, Evidence reviews underpinning recommendations 1.4.1 to 1.4.7.* it is stated that: "…The recommendation to consider acupressure as a complementary therapy represents current practice and is usually administered as a self-administered therapy…" (NICE 2021b) page 65. It may not be assumed that intravenous fluids, considered along with acupressure *per* recommendation 1.4.6, is also to be self-administered, out- or inpatient.

The ACURITE 'acupressure for moderate to severe vomiting' reference used for the *NICE guideline NG201*

The reference used to generate recommendation 1.4.6 in NICE guideline 1.4.6 is (Adlan, Chooi, and Mat Adenan 2017). References used in the systematic review on which *NICE guideline NG201* is based can be accessed through links in Table 6. Rationale for the study chosen to generate recommendation 1.4.6 can be found in *Evidence reviews underpinning recommendations 1.4.1 to 1.4.6* see (NICE 2019a) for the pdf, (NICE 2021b) for the online. Notably on page 63 it states: "…One RCT from Malaysia (2017) reported that pregnant women with severe nausea and vomiting, who had received P6 acupressure in addition to standard care (IV fluids, IV metoclopramide and thiamine supplements) showed a clinically important difference on overall relief, nausea severity, and vomiting severity than those who had taken the placebo…" (NICE 2021b) page 63. This is important because (Adlan, Chooi, and Mat Adenan 2017) do not show data on a 'more severe' HG group *vs.* a less severe *severe* NVP group; the two groups are treatment and placebo, "…As it was unethical to withhold the standard treatment for severe HG…" (Adlan, Chooi, and Mat Adenan 2017) page 665. It is also difficult to deduce which group Adlan and others are referring to: only inpatient, inpatient then outpatient, or combinations of both. See also footnote 27.

Table 6. Summary of acutherapy references used in *NICE guideline NG201,* click here to access (NICE 2021b)			
RCTs included in the NICE review	**Total**	**Of which were published 2011 onwards**	**ACURITE estimation**
For mild to moderate nausea and vomiting of pregnancy (click here for the relevant NICE data)			
Acupressure (R)CTs	7	4	Yes
Acupuncture (R)CTs	4	1	No
For moderate to severe nausea and vomiting (including hyperemesis gravidarum) (click here for NICE data)			
Acupressure (R)CTs	3	1	No
Acupuncture (R)CTs	1	nil	No

Why the ACURITE *Yes* result is not the same as the reference used to generate NICE recommendation 1.4.6

The ACURITE *Yes* estimation is for references reviewed by NICE for NVP acutherapy for 'mild to moderate NVP'. Recommendation 1.4.6 is concerned with 'moderate to severe' NVP. Please note that neither acupuncture nor acupressure were deemed to be of any benefit for 'mild to moderate NVP' (NICE 2021b) page 60. This is also clearly emphasized in the text describing 'rationale and impact section on nausea and vomiting' (click here for link): "…An exception was for acupressure combined with standard care where the evidence showed benefits in relieving symptoms in women with moderate-to-severe nausea and vomiting in pregnancy, which was not shown for women with mild and moderate nausea and vomiting…" (NICE 2022).

In addition to (Adlan, Chooi, and Mat Adenan 2017), two other references informed the 'moderate to severe NVP' section of the *NICE guideline NG201*. These were not published 2011 onwards and so were marked ACURITE *No*. These are:

(i) (Heazell et al. 2006): all participants were inpatients who received "…cyclizine as a first-line agent, prochlorperazine as second-line agent, and metoclopramide, ondansetron, or phenothiazine…" (page 816). In other words, this RCT cannot support the statement made by NICE that "…women spend fewer days in hospital when given acupressure in addition to standard treatment than a placebo and standard treatment…" since standard care is here defined as "…IV fluids, IV metoclopramide and thiamine supplements…" (NICE 2021b) page 63.[27]

(ii) (Habek et al. 2004): all participants were inpatients who may have received promethazine.

In addition to drugs not defined as 'standard care' by NICE being administered to participants of (Habek et al. 2004) and (Heazell et al. 2006), these two studies are further inapplicable within the *NICE guideline NG201* because IV fluids and drug(s) were administered to *inpatients*. Recommendation 1.4.6 states: "…consider intravenous fluids, ideally on an *outpatient* basis…" emphasis added, (NICE 2022). (Adlan, Chooi, and Mat Adenan 2017) is an ACURITE *Yes* reference and both (Habek et al. 2004) and (Heazell et al. 2006) are ACURITE *No*. ACURITE estimation for the NICE 'acupressure + moderate to severe NVP' was so an overall *No*.

In any case, (Heazell et al. 2006) and even less so (Habek et al. 2004) were *not* emphasized in the 'evidence underpinning' recommendation 1.4.6 (NICE 2021b) page 63.

[27] It is interesting to note that the definition of 'standard care' given on page 63 of (NICE 2021b) is more or less identical to that in (Adlan, Chooi, and Mat Adenan 2017); on page 665 of the latter it states: "…As it was unethical to withhold the standard treatment for severe HG, both groups were administered intravenous fluid and regular intravenous metoclopramide and thiamine supplements during inpatient admission. The total dose and amount of fluid infusion were therefore not considered as outcome parameters…". This, at least, further confuses just how much of what which participant got. When.

Exclusion of studies and selection of study for recommendation 1.4.6 'acupressure for moderate to severe NVP' in *NICE guideline NG201*

For a list of studies excluded from data underpinning the *NICE guideline NG201*, see Appendix K of (NICE 2021b). This list includes (Matthews et al. 2015) because, it is stated: "…References checked, no additional studies were identified…".

Of course, studies may have been excluded for reasons of high threshold for quality evidence, for example: "…One RCT from Croatia (2004) reported a clinically important difference favouring P6 acupuncture over placebo for pregnant women on the number of women with relief from symptoms. However, since this was the only evidence found for this intervention and it was of a low quality, the committee did not recommend acupuncture for severe nausea and vomiting…in pregnancy…" (NICE 2021a) page 63.[28]

Eligibility criteria may have already pre-excluded many studies, see Appendix A of (NICE 2021b) click here for the pdf, which, in turn, mentions other potential criteria for pre-exclusion such as *Developing NICE guidelines: the manual*.

Indeed, 43 out of a total of 184 references were selected as evidence underpinning NVP recommendations in *NICE guideline NG201*, and 141 excluded (NICE 2021a) page 79. Nevertheless, that (Adlan, Chooi, and Mat Adenan 2017) only is used to inform NICE on acutherapy in NVP did not appear commensurate.

Synopsis of *NICE guideline NG201*

Try ginger and reassurance. If that does not work, see if she had (in an earlier pregnancy) *preferred* an antiemetic, and if she chooses to take drugs, *offer* an antiemetic. If it gets worse, treat her as an outpatient with IV fluids and acupressure. If she does not respond as an outpatient, consider admission to hospital.

[28] One may argue that (Adlan, Chooi, and Mat Adenan 2017) was also the only evidence showing benefit of acupressure for moderate to severe NVP, and was also of low quality. Nevertheless, it made it through all the way up to recommendation 1.4.6 in (NICE 2022). Alone.

Practice Bulletin No.189

GUIDELINE ANALSIS #3	
Published in	US
Published by	American College of Obstetricians and Gynecologists
Publication name	*Practice Bulletin No.189*
Publication date	2018
Cited here as	(Erick, Cox, and Mogensen 2018)
Link to pdf	Not open access
Link to website	Click here.

ACURITE for *Practice Bulletin No.189*		
Is acupuncture discussed in the text?		Yes
	With ACURITE references?	Yes
	With acupuncture method description?	P6 is described, wristbands are recommended
Was acupuncture recommended?		Wristbands
	With what grade?	Emphasizes no benefit
Is acupuncture in the treatment algorithm?		Yes but not summary
Can this guideline be used to manage NVP with acutherapy?		Yes?
Consistent regarding NVP acutherapy management?		No

Acupuncture in *Practice Bulletin No.189*

The authors were inconclusive about putative efficacy of acupuncture in management of NVP on page e19 (Erick, Cox, and Mogensen 2018). Three references are mentioned namely: (Roscoe and Matteson 2002) which is a (very) brief review of acupressure and acustimulation *wristbands*; and (Matthews et al. 2015) and (McParlin et al. 2016) discussed elsewhere.

To "…Consider P6 acupressure with wrist bands…" is a 'first line therapy' in the treatment algorithm on page e20, along with folic acid-only supplements and ginger (Erick, Cox, and Mogensen 2018). Yet no mention of acupressure is made in the 'summary of recommendations' on page e25. Ginger is mentioned in the 'summary of recommendations' of *Practice Bulletin No.189.*

Management of NVP in the *Practice Bulletin No.189* treatment algorithm and synopsis

Non-pharmacologic options in the treatment algorithm are folic acid-only supplements, ginger, and acupressure. Subsequently, the algorithm moves onto pharmacologic options starting with pyridoxine with or without doxylamine. Protocols are described in detail and comprehensively.

Pregnancy Care 2020 Edition

GUIDELINE ANALSIS #4	
Published in	Australia
Published by	Australian Government Department of Health
Publication name	*Pregnancy Care 2020 Edition*
Publication date	2020
Cited here as	(AGDoH 2020)
Link to pdf	Click here.
Link to website	Click here.

ACURITE for *Pregnancy Care 2020 Edition*		
Is acupuncture discussed in the text?		Yes
	With ACURITE references?	No
	With acupuncture method description?	No
Was acupuncture recommended?		No
Is acupuncture in the treatment algorithm?		No
Can this guideline be used to manage NVP with acupuncture?		No
Consistent regarding NVP acupuncture management?		No

Role of acupuncture in *Pregnancy Care 2020 Edition*

In discussing a role for acutherapy in the management of NVP, the *Pregnancy Care 2020 Edition* refers to (Matthews et al. 2010) and not (Matthews et al. 2015) as the 'highest quality study' (AGDoH 2020). All references mentioned for acutherapy and NVP are discussed in Table 7. In addition to NVP, acupuncture is discussed as a therapy option for reflux in pregnancy, pelvic pain, and external cephalic version or breech presentation in the *Pregnancy Care 2020 Edition* (AGDoH 2020).

Synopsis of *Pregnancy Care 2020 Edition* NVP practice summary

The *Pregnancy Care 2020 Edition* NVP management 'practice summary' is aimed at "…midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; dietitian; pharmacist…" (AGDoH 2020) page 295. NVP is to be managed by: (i) 'informing women' that NVP is not harmful, common, not just in the morning, and likely to go away by week 16; (ii) 'advice and tips' including acknowledging that NVP can affect well-being and avoid fatty food; and (iii) 'discussing with the woman who asks' non-pharmacologic as well as pharmacologic treatment of NVP.[29]

Role of acupuncture and NVP in publications related to *Pregnancy Care 2020 Edition*

In *Pregnancy Care – Linking evidence to recommendations (revised April 2019)* and found here), under "…Nausea and vomiting (reviewed 2010)…" is the "…NICE recommendation…" informing women that NVP will go away by week 16 *or 20* and "…If a woman requests or would like to consider treatment, the following interventions appear to be effective in reducing symptoms: non-pharmacological: ginger, P6 (wrist) acupressure pharmacological: antihistamines…" (AGDoH

[29] The text reads: "…**Discuss non-pharmacological and pharmacological treatments:** If the woman asks about treatments for nausea and vomiting, suggest interventions that may help and are thought to be safe, beginning with non-pharmacological approaches. The safety and effectiveness of antiemetics should be discussed with women with more severe symptoms who choose to consider medication…" (AGDoH 2020) *sic*, emphasis in the original, page 295.

2018b) page 63.[30] It is reported that Medline, Embase, and Google Scholar were searched in 2010 to extract these data (*ibid*).[31]

In *Pregnancy Care – Short-form guideline (revised April 2019)* and found here, acupuncture is recommended for pelvic girdle pain (AGDoH 2018c) page 20. For NVP, 'informing the woman' that it will go away by 16 *to 20* weeks is recommended (NICE is not mentioned). Also reducing iron supplements.

Common Conditions During Pregnancy found here (AGDoH 2019) gives the 'practice summary' in *Pregnancy Care 2020 Edition* (AGDoH 2020) discussed above and which does not mention acutherapy.

Synopsis of NVP management in *Pregnancy Care 2020 Edition* and related publications

Tell the woman it will go away in four or five months. If the woman does not go away, you may have to tell her something else, exactly what is not clear.

[30] For contrast, see actual NICE recommendations.

[31] This is important. In *Pregnancy Care - Administrative report (revised April 2019)* found here, "…Systematic literature search and review undertaken to:…update evidence tables (where new evidence exists)…" (AGDoH 2018a) page 7. Needless to say, this administrative requirement is equally lacking in, for example, references to acupuncture used in *Pregnancy Care 2020 Edition* and summarized in Table x.

Table 7. Acupuncture references mentioned in *Pregnancy Care 2020 Edition* (AGDoH 2020) in order of appearance pages 293-4			
#	**Reference**	**Remarks**	**Is this an ACURITE reference?**
1	(Matthews et al. 2010)	Not (Matthews et al. 2015). In other words, the formerly relevant Cochrane Systematic Review.	Not unless the more recent and relevant Cochrane review is suspect.
2	(Murphy 1998)	This systematic review of alternative therapies in the management of NVP recommends acupressure namely, as well as ginger and pyridoxine.	No. Not published after 2006.
3	(Vickers 1996)	This is a systematic review of P6 stimulation for 'nausea and/or vomiting associated with chemotherapy, pregnancy, or surgery' and strongly recommends it.	No. Not published after 2006.
4	(Caroline Smith et al. 2000)	As this more general review article was referred to in the context of safety, it would be reasonable to assume that the more recent publication by those authors (Caroline Smith, Crowther, and Beilby 2002a) and which clearly discusses safety of acupuncture in pregnancy, was rather intended.	No. Probably erratic.

SOMANZ 2019

GUIDELINE ANALSIS #5	
Published in	Australia and New Zealand
Published by	Society of Obstetric Medicine of Australia and New Zealand
Publication name	*SOMANZ 2019*
Publication date	2019
Cited here as	(Lowe et al. 2019b) and (Lowe et al. 2019a)
Link to pdf(a)	Click here.
Link to pdf(b)	Click here.
Link to website	Click here.

ACURITE for *SOMANZ 2019*		
Is acutherapy discussed in the text?		Yes
	With ACURITE references?	2 Yes, 2 No
	With acupuncture method description?	No
Was acutherapy recommended?		No (strongly)
Is acupuncture in the treatment algorithm?		No
Can this guideline be used to manage NVP with acupuncture?		No
Consistent regarding NVP acupuncture management?		Yes

Acutherapy in *SOMANZ 2019*

Unlike the *NICE guideline NG201*, acutherapy in (Lowe et al. 2019b), the main text of *SOMANZ 2019* is not concerned with severe NVP.

The SOMANZ 2019 states: "…Very few studies are available in English language journals of the use of traditional acupuncture for the treatment of NVP. Only two trials compared acupuncture to sham or placebo treatment, neither found clinically significant improvement in symptoms…" and cite (Knight et al. 2001) and (C Smith and Crowther 2002). But (C Smith and Crowther 2002) "…explore[d] some aspects of the placebo response…" and sought "…to unravel and understand the benefits that women experience from being allocated to the sham acupuncture study group…" (C Smith and Crowther 2002) page 216. Surely, the authors of *SOMANZ 2019* had meant to rather cite (Caroline Smith, Crowther, and Beilby 2002a) in this context? That this is indeed so is shown in the sentence immediately following the citation of (Knight et al. 2001) and (C Smith and Crowther 2002) in *SOMANZ 2019*: "…No serious adverse outcomes from the use of acupuncture were reported…" (Lowe et al. 2019b) page 17. Clearly, the apparent must-reference for acutherapy safety in NVP, (Caroline Smith, Crowther, and Beilby 2002a), was implied. In any case, none of these references were published 2009 onwards, and so are ACURITE *No*.

After bemoaning the paucity of available studies in English on acutherapy for NVP, (Lowe et al. 2019b) later cite (Matthews et al. 2015) which is ACURITE *Yes*.

The third and final reference for acutherapy in *SOMANZ 2019* is (Adlan, Chooi, and Mat Adenan 2017), the reference used to generate recommendation 1.4.6 in *NICE guideline NG201*, and which is ACURITE *Yes*.

Apparently the authors of *SOMANZ 2019* (Lowe et al. 2019b) did not appreciate the value of (Adlan, Chooi, and Mat Adenan 2017) as much as the authors of *NICE guideline NG201*: "…Interestingly a greater percentage of the placebo group [in the (Adlan, Chooi, and Mat Adenan 2017) study] were satisfied with their treatment (85%) than the treatment group (72%, $p < 0.8$)…" (Lowe et al. 2019b) page 18.

Synopsis of acutherapy in *SOMANZ 2019*

The *SOMANZ 2019 Executive Summary* states: "…Although acupuncture, acupressure and hypnosis are safe, they have shown no clinically significant effect for NVP or HG…" (Lowe et al. 2019a) page 9 . This recommendation was graded 'EBR' or "…Where sufficient evidence was available…" (Lowe et al. 2019a) page 3.[32]

The treatment algorithm for NVP and HG is given on page 60 of the *SOMANZ 2019* main text (Lowe et al. 2019a) and acutherapy is not mentioned. The treatment algorithm is comprehensive. Briefly, antiemetics and laxatives would be administered early on in a case of mild to moderate NVP, along with diet changes, ginger, folate-only and pyridoxine regimes

[32] The other two possible recommendations are 'CBR' or "…Where there was insufficient evidence, the expert guideline development group made clinical consensus recommendations…"; and 'CPP' or "…Important implementation and other issues (such as safety, side effects or risks) arose from discussion of evidence based or clinical consensus recommendations…" (Lowe et al. 2019a) page 3.

SOG-C

GUIDELINE ANALSIS #6	
Published in	Canada
Published by	Society of Obstetricians and Gynecologists of Canada
	Public Health Agency of Canada
Name	*SOG-C*
Publication date	2016 and 2020
Cited here as	(Campbell et al. 2016) and (Wagner et al. 2020)
Link to pdf and website	(Campbell et al. 2016) is paywalled. For (Wagner et al. 2020) click here or here.

ACURITE for *SOG-C*		
Is acutherapy discussed in the text?		Yes
	With ACURITE references?	No
	With acupuncture method description?	Yes
Was acupuncture recommended?		Yes
Is acupuncture in the treatment algorithm?		No
Can this guideline be used to manage NVP with acupuncture?		Yes
Consistent regarding NVP acupuncture management?		Yes

Acutherapy in the *SOG-C*

In *Canada Public Agency of Health Care During Pregnancy (Chapter 3)*, section 5 *First Trimester Care*, section 5.2 *Nausea and Vomiting*, there is no mention of acutherapy (Wagner et al. 2020) pages 32-33. The reader is referred to (Campbell et al. 2016) for further reading and treatment algorithm. However, acupuncture is mentioned once as one of several "…complementary methods of inducing labour such as castor oil, intercourse,…or breast stimulation…" (Wagner et al. 2020) page 50.

Moving on to (Campbell et al. 2016). ACURITE analysis for acutherapy references are in Table 8. The total ACURITE score is *No.*

P6 is described and even illustrated on page 1131.

"…Acupressure may have some value in the management of nausea and vomiting of pregnancy…" and this recommendation is grade (I-B) or "…I: Evidence obtained from at least one properly randomized controlled trial…" and so "…There is fair evidence to recommend the clinical preventive action…" (Campbell et al. 2016) pages 1128 and 1130.

Treatment algorithm and synopsis

Acutherapy is not in the treatment algorithm, but neither are other non-pharmacologic treatments including ginger, psychotherapy, as well as diet and lifestyle.

The treatment algorithm is comprehensive for pharmacological treatment. Briefly, it starts with pyridoxine or doxylamine, adds dimenhydrinate, followed by metoclopramide, chlorpromazine, and so on.

Table 8. Analysis of references cited in (Campbell et al. 2016)			
Reference	**Context in which reference is used in (Campbell et al. 2016), quoted below *verbatim* from page 1130**	**What the reference is actually about**	**ACURITE reference?**
(Streitberger, Ezzo, and Schneider 2006)	"…There is good evidence to support the use of acupuncture for nausea and vomiting…"	This article 'overviews' acutherapy for nausea and vomiting in general including motion sickness. And it states: "…For pregnancy-related nausea and vomiting, results were mixed…"	Barely *Yes* for the date and *No* for the topic. So *No*
(Neutel and Johansen 2000)	"…However, there is insufficient data for this intervention in pregnant women…"	This reference is titled *Variation in rates of hospitalization for excessive vomiting in pregnancy by Bendectin/Diclectin use in Canada*. It is very strange.	*No* for the date and *No* again for the topic.
(Matthews et al. 2015)	"…Acupressure is affordable, is easy to self-administer, appears safe, and may be beneficial in reducing NVP for some women…"	There might be a typo in the (Wagner et al. 2020) references (reference number 14) for this authoritative piece, the date there is 2014.	Yes

Reference	Context in which reference is used in (Campbell et al. 2016), quoted below *verbatim* from page 1130	What the reference is actually about	ACURITE reference?
(Lee and Frazier 2011)	"…Acupressure applied to P6 has been demonstrated to reduce nausea and episodes of vomiting for women with NVP, although there are limitations to these findings…"	This is concerned with chemotherapy induced nausea and vomiting as well as NVP.	No
(Roscoe and Matteson 2002)		This is concerned with NVP as well as other nausea and vomiting.	*No* for the date and *No* again for the topic.
(Shin, Song, and Seo 2007)		This reports that P6 acupressure is useful in HG.	Yes
TOTAL ACURITE ESTIMATE: 4 *No* and 2 *Yes*. So *No*			

WHO Recommendations

GUIDELINE ANALSIS #7	
Published in	International
Published by	United Nations World Health Organization
Name	*WHO Recommendations*
Publication date	2016
Cited here as	(WHO 2016)
Link to pdf	Click here.

ACURITE for *WHO RECOMMENDATIONS*		
Is acutherapy discussed in the text?		Yes
	With ACURITE reference?	Yes
	With acupuncture method description?	No
Was acupuncture recommended?		Yes
Is acupuncture in the treatment algorithm?		Yes
Can this guideline be used to manage NVP with acutherapy?		Yes
Consistent regarding NVP acutherapy management?		No

Acutherapy reference for NVP in the *WHO Recommendations*

On page 75 of *WHO recommendations on antenatal care for a positive pregnancy experience*, under 'effects for interventions for NVP', it is stated: "…The evidence on the effects of various interventions for nausea and vomiting in pregnancy was derived from a Cochrane systematic review…" and Matthews et al. (2015) is cited (WHO 2016). It goes on to say: "…Alternative therapies and non-pharmacological agents evaluated included acupuncture, acupressure, vitamin B6, ginger, chamomile, mint oil and lemon oil. Pharmacological agents included antihistamines, phenothiazines, dopamine-receptor antagonists and serotonin 5-HT3 receptor antagonists. Due to heterogeneity among the types of interventions and reporting of outcomes, reviewers were seldom able to pool data. The primary outcome of all interventions was maternal relief from symptoms (usually measured using the Rhodes Index), and perinatal outcomes relevant to this guideline were rarely reported…" (WHO 2016, page 75).

***WHO Recommendations* did not pool data**

Under 'Acupuncture and acupressure versus placebo or no treatment', the authors briefly describe the features of eight of the (R)CTs analysed by Matthews et al. (2016), see Table 1. And then conclude: "…Low-certainty evidence suggests that P6 acupressure may reduce nausea symptom scores…and reduce the number of vomiting episodes…Low-certainty evidence…suggests that auricular acupressure may also reduce nausea symptom scores…as may traditional Chinese acupuncture…Low-certainty evidence suggests that P6 acupuncture may make little or no difference to mean nausea scores compared with P6 placebo acupuncture…" (WHO 2016, pages 75 and 76).

Under 'Additional considerations', the authors summarise "…Low-certainty evidence [from studies analysed by Matthews et al. 2015 see Table 1.] from single studies comparing different non-pharmacological interventions with each other – namely acupuncture plus vitamin B6 versus P6 acupuncture plus placebo traditional acupuncture and P6 acupuncture…ginger…vitamin B6…" *etc.* and conclude: "…suggests

there may be little or no difference in effects on relief of nausea symptoms….".

Acutherapy for NVP in *WHO Recommendations*

Under "Resources…Acupuncture requires professional training and skills and is probably associated with higher costs…" and under "Feasibility… A lack of suitably trained staff may limit feasibility of certain interventions (high confidence in the evidence)…" (WHO 2016 pages 74 to 77), and (Downe et al. 2016a) is cited.[33]

Under "Acceptability…Qualitative evidence…suggests that women may be more likely to turn to traditional healers, herbal remedies or traditional birth attendants (TBAs) to treat these symptoms (moderate confidence in the evidence) [(Downe et al. 2016a) citation]…In addition, evidence from a diverse range of settings indicates that while women generally appreciate the interventions and information provided during antenatal visits, they are less likely to engage with services if their beliefs, traditions and socioeconomic circumstances are ignored or overlooked by health-care providers and/or policy-makers (high

[33] Reference 13 in WHO (2016): "…Downe S, Finlayson K, Tunçalp Ö, Gülmezoglu AM. What matters to women: a scoping review to identify the processes and outcomes of antenatal care provision that are important to healthy pregnant women. BJOG. 2016;123(4):529–39. doi:10.1111/1471-0528.13819…". This is cited in the present work as (Downe et al. 2016b). Reference 22 in WHO (2016): "…Downe S, Finlayson K, Tunçalp Ö, Gülmezoglu AM. Factors that influence the use of routine antenatal services by pregnant women: qualitative evidence synthesis. Cochrane Database Syst Rev. 2016;(10):CD012392…". This is cited in the present work as (Downe et al. 2016a). Reference 45 in WHO (2016): "…Downe S, Finlayson K, Tunçalp Ö, Gülmezoglu AM. Factors that influence the provision of good quality routine antenatal care services by health staff: a qualitative evidence synthesis. Cochrane Database Syst Rev. 2016 (in press)…". This is also cited in the present work as (Downe et al. 2016a) because references 22 and 45 in WHO (2016) appear to be the same. The most recent relevant publication by those authors is (Downe et al. 2019)

confidence in the evidence). This may be particularly pertinent for acupuncture or acupressure, which may be culturally alien and/or poorly understood in certain contexts…" (WHO 2016, pages 76 and 77).

Under "…Women's Values…A scoping review of what women want from ANC and what outcomes they value informed the ANC guideline [(Downe et al. 2016b) is cited]…Evidence showed that women from high-, medium- and low-resource settings valued having a positive pregnancy experience. This included woman-centred advice and treatment for common physiological symptoms (high confidence in the evidence)…this also included support and respect for women's use of alternative or traditional approaches to the diagnosis and treatment of common pregnancy-related symptoms (moderate confidence in the evidence)…".

Nevertheless "…RECOMMENDATION D.1 [Interventions for NVP]: Ginger, chamomile, vitamin B6 and/or acupuncture are recommended for the relief of nausea in early pregnancy, based on a woman's preferences and available options. (Recommended)…In the absence of stronger evidence…these non-pharmacological options are unlikely to have harmful effects on mother and baby…Women should be informed that symptoms of nausea and vomiting usually resolve in the second half of pregnancy…Pharmacological treatments for nausea and vomiting, such as doxylamine and metoclopramide, should be reserved for those pregnant women experiencing distressing symptoms that are not relieved by non-pharmacological options, under the supervision of a medical doctor…" (WHO 2016, page 74).

And under 'Executive summary – interventions for common physiological symptoms – nausea and vomiting': "…Ginger, chamomile, vitamin B6 and/or acupuncture are recommended for the relief of nausea in early pregnancy, based on a woman's preferences and available options…." (WHO 2016, page xv).

Acutherapy for other conditions in *WHO Recommendations*

Acutherapy is discussed for low back and pelvic pain, and heart burn. More or less the same text quoted above for NVP acutherapy under 'resources', 'feasibility', and 'acceptability' is repeated for heart burn. For low back and pelvic pain it is emphasized: "…Physiotherapy and

acupuncture require specialist training and are therefore likely to be more resource intensive…In addition, where there are likely to be additional costs associated with treatment or where the treatment may be unavailable (because of resource constraints), women are less likely to engage with health services (high confidence in the evidence)…A lack of resources may limit the offer of treatment for this condition (high confidence in the evidence) [(Downe et al. 2016a) citation]…." (WHO 2016, page 81).

Synopsis of acutherapy for NVP in *WHO Recommendations*

DO NOT prescribe antiemetics UNLESS you've tried ginger, chamomile, pyridoxine, and acutherapy, AND you are a medical doctor. But acupuncture is expensive and rare, and so not feasible, and acupuncture is also alien and poorly understood, and so not acceptable.

***Green-top guideline No.69* 2016**

In *Green-top Guideline No.69*, NVP is to be diagnosed by exclusion of other causes. Such a gate keeping function (Lewin 1947) may exclude many health care professionals from using the Guideline.[34] The treatment algorithm given is less of a practical-guideline and more of a thought-guideline for the highly qualified and experienced. However, if the Royal College of Obstetricians & Gynaecologists (UK) is addressing experienced fellow(es) and colleagues in the Guideline, would it not be safe to assume that the most authoritative (and hopefully recent) references are cited? So that said experienced fellow(es) and colleagues will have immediate (and hopefully open) access to the most up-to-date and definitive references on a topic, say acutherapy for the management of NVP. Instead, Matthews et al. (2015) is not cited. Not even Matthews et al. (2010) is cited in the relevant text. Not even the older relevant Cochrane review (Jewell and Young 2003) is cited. A reason why any one of the four references mentioned by the *Green-top guideline NG201* were cited at all by the developers when discussing acutherapy management of NVP appears mysterious (see Table 5.). It is tedious to go into details one by one, even if there are only four of them. In any case, we can only speculate why the developers at the Royal College of Obstetricians & Gynaecologists (UK) chose to cite those four references, and absurdly.[35]

[34] A gate here is "…the constellation of the forces before and after the gate region is decisively different in such a way that the passing or not passing of the unit through the whole channel depends to a high degree upon what happens in the gate region…This holds…for the travelling of a news item through certain communication channels in a group…"; a gate keeper is: "…Gate sections are governed either by impartial rulers or by 'gate keepers'…" (Lewin 1947, page 145).

[35] Absurdly here refers to a speculation, not the reason(s) the developers had for citing those four references listed in Table 5. though it may appear otherwise.

And none of these four references is Matthews et al. (2015). None of these four references is even Matthews et al. (2010), or the earlier Cochrane review (Jewell and Young 2003). One should rather consult with a 2011 article in *Journal of Pain and Symptom Management*.

If the Cochrane reviews are not OK, we need to be told. Did the Royal College of Obstetricians & Gynaecologists (UK) *shun* Matthews *et al.* (2015)? Or even Matthews et al. (2010)? And (Jewell and Young 2003)?

NICE guideline NG201 2022

Exclusion of all studies but one

Perhaps the Royal College of Obstetricians & Gynaecologists (UK) *did* indeed shun Matthews et al. (2015) as well as Matthews et al. (2010). It might be safe to assume that even O'Donnell et al. (2016) was also shunned by the developers of the *NICE guideline NG201* and which, needless to say, rely on guidelines from the Royal College of Obstetricians & Gynaecologists (UK). This is odd because if data from Matthews and others at Cochrane is not OK, surely data from O'Donnell and others at the National Institute for Health Research (UK) *is* OK?

In any case, the developers at NICE set out to do what Matthews and O'Donnell and many others had done (albeit differently): systematically review all (R)CTs they could find for acutherapy and NVP management. And to be thorough, NICE developers did take a look at everything else they found on the way, including other systematic reviews and books of the same. They were transparent about how they did the systematic review and this is commendable.

What is not commendable is that the developers of *NICE guideline NG201* proceeded to exclude *all* studies until only *one* was left. Some of these studies *Excluded Before Analysis* and all those *Excluded After Analysis* are labelled in the present work as *EBA and EAA*, respectively. In fact, the developers excluded about thirty (R)CTs, fifteen or more systematic reviews including Matthews et al. (2015) *and* (2010), O'Donnell (2016), and several books discussing acutherapy in NVP management. Always, the developers, in the NICE Appendix K, told us that references were cross-checked with this particular review or book, and if they had found any additional references, the developers tell us

the number. A total of thirteen (R)CTs made it through for analysis by NICE, see Table 6.

Since one study was selected for generation of recommendation 1.4.6 (*i.e.* after analysis, and that reference is (Adlan, Chooi, and Mat Adenan 2017), the exclusion process is meaningless.

Meaning of recommendation 1.4.6

NICE developers recommend acupressure for moderate to severe NVP and not for mild to moderate NVP as recently noted by (Savona-Ventura and Mahmood 2022). A reasonable physiological view may hold that this benign, almost certainly harmless, and mechanistically complex intervention would be more appropriate for management early in the presentation of NVP, in other words with mild to moderate NVP. But NICE recommend acupressure for moderate to severe NVP. Of course, this is something the patient should do on her own, it is 'self-administered', we are told, in case there was any doubt.

But the recommendation for acutherapy comes along with IV fluids, preferably as an outpatient, both are recommendation 1.4.6. Do we poke the patient with our finger in the same arm in which we poke the cannula, for the IV fluids? Or the contralateral arm? No, wait, she will poke her own arm when she goes home. Anyways, acupressure for moderate to severe NVP is an *adjunct* therapy, to be considered, along with IV fluid standard care à la (Adlan, Chooi, and Mat Adenan 2017) see fotnote 27. As an outpatient please; consideration to admit mum as an inpatient is to be done only if she is very poorly, and outpatient management ('IV fluid standard care') + self-administered acupressure has failed to improve nausea and vomiting, perhaps several times.

This meaninglessness results from the following: that the authors of the reference used for generation of NICE recommendation 1.4.6 (Adlan, Chooi, and Mat Adenan 2017) thought it was *ethical* to treat patients suffering from mild NVP the same way they treated patients with severe NVP. In other words, that participation in a clinical trial (of sorts), as opposed to diagnosis, is an indication for treatment.

(Adlan, Chooi, and Mat Adenan 2017) mixed the inpatient with the outpatient, with the inpatient who became an outpatient, with the

inpatient who stayed as an inpatient. NICE developers were more sure about this: treat her as an outpatient please.

Let her choose to take antiemetics

A user of the *NICE guideline NG201* is to check if the multigravida had previously *preferred* antiemetics. And for mutli- and primigravida *who choose a pharmacological treatment*, the user is to *offer* an antiemetic. A link to a table informs user of the advantages and disadvantages of stuff which acts on histamine, dopamine, serotonin, all kinds of stuff, to discuss with mum. Another link takes the user to *shared decision making*. May it be safe to extrapolate that the user, the health professional for whose benefit *NICE guideline NG201* was developed, as well as all those outside the UK who look to this definitive source for guidance, would have liked to have a decision made for them, and so for mum? Because mum feels bad, she may have tried this or that, and nothing seems to be working, and it would be great if someone who's done a lot of work excluding evidence could guide us.

NICE's answer is clear and firm and not so nice: the decision to take drugs lies with *the woman.*

Pregnancy Care 2020 Edition

The Australian Government Department of Health told us that *Pregnancy Care 2020 Edition* has to be updated regularly, and told us that the references were checked to be the most up-to-date. And then told us that the *highest* reference of a grand total of four to consider with regards acutherapy for management of NVP is Matthews et al. 2010. Not 2015. Note this is the *2020 Edition*.

The health professional or guideline user is told to wait until the woman *asks* if there is anything to help with NVP. And then to tell the woman to choose to take drugs.

Under 'Resources' for NVP in *Pregnancy Care 2020 Edition*, there is only one reference cited click here. This one reference, or resource despite allegations of plurality, is (Arsenault and Lane 2002) - which, the publisher is very quick to inform us, is RETIRED and should *not* be consulted for any reason other than historical. Fortunately, the user of *Pregnancy Care 2020 Edition*, is *not* taken to Arsenault and Lane (2002) by the link provided in the online *Pregnancy Care 2020 Edition*. The user is taken to (Campbell et al. 2016), which is the more recent

guideline from Society of Obstetricians and Gynecologists of Canada, analysed above along with (Wagner et al. 2020). Well anyways, Campbell *et al.* (2016) and Arsenault and Lane (2002) read identically in parts (the text is more or less identical in parts), but of course there are important differences, obviously, or the publisher would not make us declare never to use Arsenault and Lane (2002) for any purpose other than historical. And anyways neither Campbell et al. (2016) nor Arsenault and Lane (2002 RETIRED) are open access. So the user is kind of told to find resource(s) for him- or herself. The various handouts for various users that come along and around the *Pregnancy Care* as well as the *2020 Edition* address mum (through the user) in what I thought was a most rude manner. And basically the management of NVP is to tell mum to bugger off, so we should not be surprised that user, in addition to mum, may also check the resource (in the single plurality, and assuming user literacy, of course) and also bugger off.

And it told the user to withhold information from mum which may help until asked for it – what is the confidence level in that recommendation? The point to make here before moving on is that confidence was lost in what one was told by *Pregnancy Care 2020 Edition* quickly and thoroughly.

Active science and methods *vs.* retired science and methods

The resource furnished by the Australian Government Department of Health so the user may not check because it is RETIRED, Arsenault and Lane (2002) write: "…Though there are no theoretical concerns about the safety of acupressure in pregnancy, efficacy of P6 acupressure is difficult to prove because it is impossible to perform a true double-blind trial compared with no intervention. *Nonetheless*, non-blinded RCTs have demonstrated a decrease in 'persisting nausea' by at least 50%... [and cite Jewell and Young (2003)]…" (emphasis added, Aresenault and Lane 2002, page 819).

A feeling of disbelief which may be communicated from reading this paragraph is well reflected in the text from Vickers (1996), quoted in the present work in footnote 19. What, authors have been asking, is it exactly that you want to see?

WHO – circling back to Matthews (2015) and O'Donnell (2016)

There is only one source of evidence for acutherapy management of NVP in (WHO 2016) and that is Matthews et al. (2015). Which is fine, it is what Cochrane are there for, to do that EBM work. What the authors of (WHO 2016) appeared to find *not* fine is throwing in numbers from studies together.

So the authors of (WHO 2016) took the references from Matthews et al. (2015) one by one, described the findings, and stated how confident or not they were regarding this reference, this piece of evidence.

Kind of like what O'Donnell et al. (2016) eventually ended up doing.[36] WHO (2016) tell us the evidence on acutherapy management of NVP from (R)CTs is what it is. But acutherapy is expensive and needs trained specialists and it's not feasible. And acutherapy is *alien.* And poorly understood.

Alien acutherapy

The least flattering reference to acutherapy in all the guidelines analysed has to be the one in (Wagner et al. 2020), the one about alternative methods for inducing labour. How does a healthcare professional suggest to mum to have a shag, some castor oil, breasts fondled, and acupuncture? Can those methods be combined? In series or perhaps even in parallel?

The discourse on acutherapy in (WHO 2016) is concerning. The authors appear to definitely not want to hand out pills. So we must do everything we can to help without pills, and the evidence about acutherapy for NVP is what it is. And what about acutherapy for heartburn and low back and pelvic pain? Not terribly enthusiastic about heartburn. For low back and pelvic pain, the authors seem to appreciate the therapeutic potential of acutherapy.

[36] "… Data were therefore summarized narratively and prioritized to emphasize the highest quality of evidence, defined as randomized clinical trials with a low risk of bias…" under Methods in (McParlin et al. 2016) page 1393. It is interesting to note the NICE developers excluded narrative reviews offhand, see Appendix K of the NICE Guideline.

But for all of NVP, heartburn, and low back and pelvic pain: acutherapy requires trained specialists and rare resources which are expensive and so it is not feasible; and it may be perceived as alien and so it is unacceptable. The references used to support these arguments are in footnote 32 of the present work. Briefly, (Downe et al. 2016a) is the relevant Cochrane protocol, and so is an irrelevant reference, because there are no findings, unless you want to make sure that the findings, which would come in 2019, will be solid. (Downe et al. 2016b) finds that "…A positive pregnancy experience matters across all cultural and sociodemographic contexts…". Later (Downe et al. 2019) finds that "…women use antenatal care if they find it is a positive experience that fits with their beliefs and values, is easy for them to access, affordable, and treats them as an individual. …".

Of course, WHO (2016) did not have access to Downe et al. (2019). Nevertheless, the difficulty in fitting earlier work by Downe and others into the *WHO Recommendations* specific to acutherapy is further compounded by the following: Are the authors of *WHO Recommendations* aware that some of the majority of people in the world, in say China, Malaysia, Indonesia, Japan, and California, may perceive acutherapy as ineffectual or even quackery, but certainly not *alien*?

SOMANZ 2019

The Society of Obstetric Medicine of Australia and New Zealand, represented by Lowe et al. (2019a/b), did not like acutherapy. One cannot blame them. Look at what they wrote about (Adlan, Chooi, and Mat Adenan 2017). Maybe they thought it was alien.

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Matthews et al. (2015) and McParlin et al 2016 (which is the O'Donnell et al. (2016) study) are cited, and another one for wrist bands, check with your local pharmacy.

DISCUSSION

A role for NVP management with acutherapy in EBM is overall unclear. In my opinion, an adjective which may more or less describe acutherapy management of NVP in EBM is ‘miserable’.

Some national guidelines tell us to try acutherapy or wristbands for NVP, some say don’t bother, some tell us we *must* try acutherapy for NVP, and let us leave NICE to one side for the moment.

Well, obviously. The relevant EBM is in Matthews et al. (2010) and (2015), O’Donnell et al. (2016), and the evidence in there comes from (R)CTs . Which we simply cannot see, mostly, because the (R)CT in question is obsolete, or behind a paywall, or just an abstract. And when we *can* see the full text (R)CT cited by Matthews et al. (2015) and/or O’Donnell et al. (2016) it much more often than not looks like…well.

Vomit really.[37]

[37] This has word has regrettable connotations in general and in particular, so garbage will be used.

So garbage in garbage out? The garbage is nuanced. Do you put the garbage in the blender? Or do you process the garbage one by one? Or do you take the items of garbage that someone else chose to put in a blender, and then process it one by one?

The prize for collecting the most items of garbage goes to NICE, hands down. And then they threw all that garbage out except thirteen pieces. And then they threw ten of those away (mild to moderate NVP). And then kind of smuggled two of the remaining three pieces of garbage, and looked at only one. Clearly this is absurd, in like evidence based anything.[38] Here is novel evidence of whimsy-based medicine by definition (Upshur and Tracy 2004).[39]

It becomes more absurd when we look at the recommendation that came out of looking at this one piece of garbage: consider IV fluids standard care and acupressure for moderate to severe NVP. Why? Because NICE only saw one piece of very odious garbage.[40]

So one has seen (or not seen) the (R)CTs, or garbage, based upon which is the systematic reviews, guidelines, and guidline/reviews that is EBM. Garbage in the plural of course, but in the case of NICE the garbage was singular. Some items of garbage can be traced with or without difficulty

[38] For a truly excellent totally evidence based example of the absurd in EBM to do with guidelines, see (Messerli, Rimoldi, and Bangalore 2018): changing the definition of hypertension changed the status of millions in the US from hypertensive to normal overnight. And then changed the status of tens of millions in the US from normal to hypertensive another night.

[39] Upshur and Tracey (2004) could not have known of course that the *NICE guideline NG201* and *Green-top Guideline No.69* are, by definition, whimsy-based. In other words, Upshur and Tracey (2004) were using 'whimsy-based medicine' in abstract and not concrete terms on page 203.

[40] To place this in the medicine-in-literature tradition: The whole thing is Orwellian of course, but this particular absurdity of NICE outpatient self-administered *ad nauseaum*? I would say it is less Franz Kafka and more Italo Calvino.

and money, most items of garbage are invisible, they cannot actually be seen (as a discrete item of garbage, and not as an item in a garbage catalogue). In some cases the garbage was blenderdised. In other cases garbage was left as pieces of garbage, and with some dressing. It does not really matter because what me mostly see (hopefully without difficulty nor money) is either blenderdised garbage or reduced garbage plus dressing.

May one look at something else please? May one, for example, look at the experiences of health professionals in Western countries with acutherapy for NVP? No. Why not? Because. That's the way it is.

Since when, one may ask? Since when are experiences of Western physicians and more recently midwives, nurses, and maternity school professionals, since when is this body of knowledge labelled as experience of no importance as evidence for making guidelines, arguably for the whole world? The answer is: round about the same time Cochrane came into being (Greenhalgh, Howick, and Maskrey 2014).[41] And what Cochrane say, goes. No? No.

Obviously not. The National Institute for Health Research (UK) found the garbage Cochrane had blenderdised in addition to other garbage, did not blenderise, summarized or reduced those items of garbage, and put dressing (high bias, low confidence, *etc.*).

NICE totally ignored all garbage but one. Well, they found the (un)blenderdised garbage from Cochrane, the discretely dressed garbage from The National Institute for Health Research (UK), and much much more, and *then* ignored it.

The Royal College of Obstetricians & Gynaecologists (UK) had their own four items of garbage, visibility mixed.

So clearly what Cochrane say does not have to go. Cochrane is there for EBM but you can ignore it for the purpose of EBM.

[41] The references on distortion of evidence and vested interest are noteworthy. The discussion of other causes and effects of a 'crisis' in EBM appears reasonable. The remainder and majority on what we can do about all that is bombastic and tedious if endearing.

Never mind for now *since when*, it is what it is. Why? Why is the body of knowledge labelled as experience in acutherapy management of NVP not admissible in EBM?

….

Oh dear. It gets complicated very quickly. All we want to know is why there is no role in EBM for the experiences of Western health professionals with acutherapy for NVP.

One easy answer is the nature of the knowledge itself:

> …The appeal to the authority of evidence that characterizes evidence-based practices does not increase objectivity but rather obscures the subjective elements that inescapably enter all forms of human inquiry…
>
> …Against feminist misgivings about so-called objectivity, rationality, and value-neutrality, EBM proposes to introduce rational order into the deliberative processes of healthcare decision-making. The epistemic concerns of feminist scientists and philosophers are accompanied by a feminist commitment to improving the lives of women. Feminist critiques of science are driven by a deep concern that the abstractions made in the names of scientific objectivity, generalisability, and predictability harm women. These tendencies appear to resurface in the practice of EBM…

(Goldenberg 2006) pages 2621 and 2627

But that is too easy. 'Nature of knowledge' discussions are easily scoffed away, should anyone dare bring them forward, say in an EBM conference, with some variant of 'bitches be crazy' rule-of-thumb.[42]

Let us feign sanity. Let us ask EBM for evidence of experience of health professionals in the management of NVP on EBM's own terms, its own garbage, what is defined as evidence in EBM.

[42] The author here is referring to himself, though his wife may disagree.

Well, we *did* agree to look at garbage which is absurd (us looking at garbage that is). So we might as well look only at some garbage, which is even more absurd (us deciding to look at some garbage but not other garbage, not us looking at garbage all). So let us just look at EBM garbage only. Why is there no garbage, discrete, reduced, blenderdised, why is there no garbage of any kind about experience in the EBM of NVP management?

We find that the nature of experience is not amenable to garbage-ification. EBM places experience and studies about experience very low in terms of legitimacy, hierarchy, and authority (Upshur and Tracy 2004).[43]

One gets the feeling we've been through this before. Way back in 1996 when Vickers huffed, 'What is it exactly that you want to see (and I'll show it you)!' and in 2002 when the Society of Obstetricians and Gynecologists of Canada (EBM or no?) said there is no such thing as a randomized acutherapy clinical trial, but that article is RETIRED and one is obliged not to use it for any purpose other than historical. Not to mention the tens of articles one may cite belabouring the placebo in acutherapy trials, the reviews of those, models, commentaries, and briefs alleging to have fatally debunked all the above.

Oh dear. I say again, it got complicated very quickly. All we wanted to know is why there is no role in EBM for the experiences of, for example, Western health professionals with acutherapy for NVP.

[43] The study by Upshur and Tracy (2004) abstract: "…This paper examines four challenges that proponents of evidence-based medicine (EBM) must address to establish its claims to universality and legitimacy. It is argued that the failures to meet the evidence-of-effectiveness challenge, the authority challenge, the conflicting hierarchy challenge, and the definition-of-evidence challenge diminish arguments for the superiority of EBM. In the second part of the essay, recent developments in the theory of EBM are discussed with specific reference to what is termed the Oslerian turn, and a relationship between EBM and rationality is entertained…"

Let us not throw this question into GoogleScholar. Let us ask the producers of the key systematic reviews, and national and international guidelines themselves. That's narrowing it down. Let us ask these key producers of EBM: Why is there no role for the experiences of Western health professionals in EBM of acutherapy for NVP please?

Cochrane (Matthews and others) and the National Institute for Health Research (UK, O'Donnell and others) would reply that they use only (R)CTs for analysis (blenderdised, or reduced and dressed, items of garbage, respectively). One does not come across double-blind randomized placebo-controlled clinical trials of experience in general, cross-over or no, let alone Western health professionals acutherapy *etc.* One would wonder about the validity of such a trial, should one ever come across such a thing. In any case, for the present, there are not any.

NICE may reply that, 'Pfff, everything was looked at, all the garbage out there anyone ever found, good luck seeing it'.

All that garbage was thrown out. 'We took the one piece of garbage'. Which one? 'The one that was not thrown out.' It exists as a discrete item of garbage without blenderification, nor reduction and dressing. It can be seen in its form as a discrete item of garbage without difficulty nor money so one may see it.

Wonderful, one has seen (Adlan, Chooi, and Mat Adenan 2017). One may allow for 'experience of health professionals' room in this item of garbage (an (R)CT, of course, that goes without saying) only in the most loose terms, imagination not recommended. It was said to be from Malaysia. That's a bit of a problem because it has to be relevant to the UK. So the other two studies NICE kinda looked at (for moderate to severe NVP only, mind you) and yeah there's an item of garbage or two from the UK…so…yeah. Experience.

Well and good. Experience is in the NICE EBM. The recommendation please, which of course includes evidence from the experiences of health professionals from around the world and of course from the UK. The recommendation is: IV fluids and acupressure for moderate to severe NVP. Is this recommendation in line with experience? Physiology even? Perhaps the answer is no.

The Royal College of Obstetricians and Gynaecologists (UK) would reply: *'Only* experience was considered!' Theirs, of course, and which leads one to the four items of garbage catalogued in Table 5. Which happens to be what we expect to see in that same truck of EBM garbage (acutherapy NVP), no experience except with the most loose imagination *etc*.

'A ha!' one may shout. So *in the experience of The Royal College of Obstetricians and Gynaecologists (UK)*, Cochrane is not to be trusted? The garbage from (Matthews et al. 2015) was not taken into consideration while developing *Green-top guideline No.69* in 2016.

Oh, that's embarrassing. But Matthews et al. (2010) was cited! It was? It is not in Table 5. So it was not cited in any context related to acutherapy for the management of NVP. In fact, Matthews et al. (2010) was first cited in the *Green-top guideline No.69* 2016 after the statement that "…HG is the severe form of NVP, which affects about 0.3–3.6% of pregnant women…", along with three other references on page 5.[44]

Well, it does not matter because the Guideline was based on Fellows' experience, which does not have to include Cochrane, in fact Cochrane was brazenly ignored. Fair enough. But then this experience of the Royal College of Obstetricians and Gynaecologists (UK) is not EBM. And is petulant.

The answer from *Practice Bulletin No.189* is that in the experience of Erick, Cox, and Mogensen (2018), wristbands are recommended. The answer from *Pregnancy Care 2020 Edition* is probably rude, and anyways withheld until we actually do ask, in which case Matthews et al. (2010) was checked again in 2020 at least once, and nothing new was found, including Matthews et al. (2015). The answer from SOMANZ 2019 is that in the experience of Lowe et al. (2019a&b) acutherapy for

[44] Interestingly one of those articles is 'Miller F. Nausea and vomiting in pregnancy: the problem of perception—is it really a disease? *Am J Obstet Gynecol* 2002;186 Suppl 2:S182–3'. One would hope that HG is not perceived to be a perceptual problem?

management of NVP is not recommended and it is best not to look too closely at an article from Malaysia.

The answer from Society of Obstetricians and Gynecologists of Canada is that in the experience of Campbell et al. (2016), acutherapy is recommended but not worth putting in the treatment algorithm and ginger, psychotherapy, as well as diet and lifestyle are also not worth including in the treatment algorithm.

The *WHO 2016 Recommendations* are EBM, of course. So the garbage from Cochrane was taken as is? Not exactly. Developers at WHO did not like Cochrane's blenderization process, so took a little bit of all the hard work in Matthews et al. (2015), how Cochrane chooses the items of garbage that will go into the blender.[45] It is a little bit of the whole work, which includes searching for garbage, sorting it, finding out which items of garbage fit into your blender, and so on, and that is still a lot of work. So WHO took that little bit of a lot a lot of work and worked it again, one by one. Anyways, there is no knowledge of experience in the Cochrane garbage, so *WHO Recommendations* did not consider evidence of experience in acutherapy management of NVP.

Wait. What? WHO ignored experience? Of course not! Who could say such a thing. *WHO 2016 Recommendations* has whole *repeating* sections, sometimes *verbatim*, on Values, Acceptability, Preferences, and what not. And the reference is Downe and others, who said a lot of common sense things about being nice to mum and caring for her and making sure there's ethanol and cotton balls in the primary maternal clinic, anything we might really need to help these women anyway we can, heck some information would be *great*, like a guideline or something…wait…what? There *is* a guideline?

So once more, how does that guideline, how does *WHO Recommendations 2016* consider the experience of Western health practitioners with acutherapy for the management of NVP? The answer

[45] The items of garbage, as we know by now, are mostly invisible, not seen in discrete form as opposed to abstracts or items in a garbage catalogue. What some may find invisible however could potentially be seen by WHO developers.

might look like ‘it does not’ because Cochrane sorted out experience from the garbage it selected, arguably by definition, so right at the very start, before the mega-search for (R)CTs was even launched. And there is no doubt that there is no health practitioner experience of acutherapy for the management of NVP in Cochrane EBM after experience was in any way defined. The fact that WHO reduced and dressed the items of garbage selected by Cochrane does not alter the fact that experience does not feature in said items of garbage.

Experience based evidence (not EBM) in *WHO Recommendations* comes from Downe and others. And somehow this is: acutherapy is alien, expensive, not very feasible, and not readily acceptable. One may not see how the work of Downe and others relates to the language in *WHO Recommendations*, let alone EBM.

Has the world gone mad? Is there no role for practitioner experience in EBM of acutherapy for the management of NVP?

‘Of course NOT!’ shouts the Expert Consensus from the College of French Gynecologists and Obstetricians (Deruelle et al. 2022). ‘OUR national guideline states’: “…If the PUQE score is < 6, even in the absence of proof of their benefit, ginger, pyridoxine (B6 vitamin), acupuncture or electrostimulation can be used, even in the absence of proof of benefit…”. ‘We obviously based OUR recommendations on our experience as well as that of professionals from maternity schools across France!’

Por le cul dieu. Why did you not speak out earlier?

One more question please. Why did you have to say ‘in the absence of proof of benefit’ – TWICE? Is your experience, the experience of professionals from across maternity schools, and numerous other colleagues from around the world, not *evidence (presence) of proof*? In other words, experience is absent by your own admission.

The role played by acutherapy for the management of NVP in key clinical publications and national and international guidelines is miserable because it is disconnected from experience.

This study ends here.

AFTERWORD

The abstract of the ‘confession’ by (Ioannidis 2016) is dense with shocking allegations about EBM.

(Cairney and Oliver 2017) was serious about the gap in EBM policy making, but one gets lost somewhere. How can one be pragmatic about the absurd ‘beliefs’ of others? Well one can, perhaps, but it does not help EBM of NVP. See also (Haynes 2002).

(Ernst 2009) discusses absurdity in EBM. However the main arguments (how data moves from quackery to evidence) may work by replacing, for example, ‘alternative therapies’ with ‘EBM’. Arguments that work the same way from left to right as right to left are interesting.

(Lundeberg et al. 2008) has a title that tried to be funny.

Shared decision making in EBM is celebrated in (Djulbegovic and Guyatt 2017).

An app to care for mum in (Ngo et al. 2022). More data needed.

(Wong et al. 2022) appeared to have analysed mostly Australian guidelines and a sense of frustration is mixed with what appears to be admirable restraint.

Nottinghamshire Area Prescribing Committee guideline click here.

The Royal Women’s Hospital, Victoria Australia click here.

Royal College of Physicians of Ireland, Institute of Obstetrics and Gynecology guideline here.

News celebrating SOGC click here and here.

News celebrating NICE click here.

Paywalled guideline platform https://g-i-n.net/

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