(Un)warranted variation in local hospital protocols for neonatal referral to the pediatrician: an explorative study in the Netherlands

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ORIGINAL ARTICLE

(Un)warranted variation in local hospital protocols for neonatal referral to the pediatrician: An explorative study in the Netherlands

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Abstract

Background: Studies indicate unwarranted variation in a wide range of neonatal care practices, contributing to preventable morbidity and mortality. Unwarranted variation is the result of complex interactions and multiple determinants. One of the determinants contributing to unwarranted variation in care may be variation in local hospital protocols. The purpose of this study was to examine variation in the content of obstetric and neonatal protocols for six common indications for neonatal referral to the pediatrician: large for gestational age/macrosomia, small for gestational age/fetal growth restriction, meconium-stained amniotic fluid, vacuum extraction, forceps extraction, and cesarean birth.

Methods: We conducted a nationwide cross-sectional study examining protocols for neonatal referral to the pediatrician in the obstetric and neonatal departments of all Dutch hospitals. Variation in protocols was analyzed between regions, between neonatal and obstetrics departments located in the same hospital, and within neonatal and obstetrics departments.

Results: There was considerable variation in protocols between regions, between neonatal and obstetrics departments, and within neonatal and obstetrics departments. The results of this study showed considerable variation in recommendations for type of referral, admission, screening/diagnostic tests, treatment, and discharge. Furthermore, results generally showed lower referral thresholds in neonatal departments compared with obstetric departments, and higher referral thresholds in the eastern region of the Netherlands. We also found variation in local hospital protocols, which could not be explained by population characteristics but which may be explained by varying recommendations in existing national and international guidelines and/or lack of adherence to these guidelines.

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Conclusions: To reduce unwarranted variation in local protocols, evidence-based, multidisciplinary guidelines should be developed in the Netherlands. Further research addressing knowledge gaps is needed to inform these guidelines. Attention should be paid to the implementation of evidence, and only where evidence is lacking or inconclusive should agreements be based on multidisciplinary consensus. Where protocols deviate from evidence-based guidelines because of specific local circumstances, clearer, more transparent justifications should be made. Uniformity in guidance will offer clear standards for care evaluation and provide opportunities to reduce inappropriate care.

KEYWORDS
neonatal care, neonatel referral, pediatric consultation, protocols, variation

1 | INTRODUCTION

Although it is appropriate for care to vary in response to local population characteristics, unwarranted variation in care has been identified as a key indicator of ineffective care and contributes to preventable morbidity and mortality.[1] Variation in care is warranted if, following appraisal, evidence-based recommendations are adapted to respond to individual needs. Unwarranted variation, on the other hand, refers to large variation in care not based on population needs and/or characteristics. It is associated with inappropriate use of medical services,[1–3] resulting in care that is either "too much, too soon" or "too little, too late".[4] Unwarranted variation may be caused by: (1) lack of evidence-based care; (2) differences in availability of health care resources; and/or (3) care that is provided based on providers' beliefs and interests.[1–3]

Studies indicate unwarranted variation in a broad range of neonatal care practices. This variation exists among practitioners, hospitals, regions, and countries,[5,6] and includes substantial variation in obtaining blood cultures,[7] the management of sepsis,[8] and the treatment of jaundice/hyperbilirubinemia.[9] In the Netherlands, considerable variation exists in rates of neonatal referral to the pediatrician among nulliparous women, ranging from 5% to 62% between hospitals[10] and 37% to 60% between regions.[11] Variation persists after adjustment for maternal characteristics, and maternal and neonatal outcomes have not been found to be better in regions with higher neonatal referral rates. This suggests overuse of specialist care in regions with higher neonatal referral rates.[11] Reducing such unwarranted variation and ineffective care uptake requires a more comprehensive understanding of its determinants.[3]

Unwarranted variation is the result of complex interactions among multiple determinants.[3,5,12,13] One of the determinants contributing to unwarranted variation is variation in local hospital protocols.[5,12,13] Protocols are used to reduce unwarranted practice variation through standardization.[13] Variation in protocols may exist between regions, between departments within the same hospital, and among practices within departments.[3,5,14]

The purpose of this study was to examine variation in the content of obstetric and neonatal protocols for six common indications for neonatal referral to the pediatrician: large for gestational age/macrosomia (LGA), small for gestational age/fetal growth restriction (SGA), meconium stained amniotic fluid (MSAF), vacuum extraction (VE), forceps extraction (FE), and cesarean birth (CB). We analyzed the variation in protocols between regions, between neonatal and obstetrics departments, and within neonatal and obstetrics departments.

2 | MATERIALS AND METHODS

To study variation in the content of local hospital protocols for neonatal referral to the pediatrician, we conducted a nationwide cross-sectional study of all hospitals in the Netherlands with both an obstetric and a neonatal department ($n = 74$).

2.1 | Study sample

We requested hospitals' protocols for the following six common indications for neonatal referral to the pediatrician: LGA, SGA, MSAF, VE, FE, and CB. The data were collected between September 2019 and September 2020. We contacted obstetric and neonatal departments by e-mail and asked them to send us their protocols (Supplement 1) by means of post or e-mail. The departments that did not respond received one reminder by e-mail and one reminder by telephone. The data were

anonymized by assigning numbers to the responding departments and stored in a secure, password-protected digital system at the department of Midwifery Science at the Vrije Universiteit Amsterdam.

2.2 | Data extraction

We extracted criteria for neonatal referral to the pediatrician from the protocols. The variables and categories for study were selected by the research team based on previous studies on unwarranted variation in care.[5] These included absence of, or variation in, the recommendations for care,[7–9] variation between professional groups,[14] and geographical variation.[10,11] Data were extracted by the first author and a research assistant using EXCEL software.[15]

The following characteristics were extracted for each protocol:: type of hospital, region, type of department, date of publication, type of protocol, disciplinary collaboration, patient involvement in protocol development, and use of references. Type of hospital was categorized as: "secondary-level" (providing general obstetric and neonatal care) and "tertiary-level" (with a neonatal intensive care unit). We categorized the hospitals into five regions, based on a geographical division by the Ministry of the Interior and Kingdom Relations: "north"(Drenthe, Friesland, Groningen), "east" (Flevoland, Gelderland, Overijssel), "south"(Limburg, Noord-Brabant), "southwest" (Zuid-Holland, Zeeland), and "northwest" (Noord Nederland, Utrecht).[16] Date of publication was categorized as "mentioned" (year) or "not mentioned". Type of protocol was categorized as "hospital only" (protocol applied only to the hospital), "regional" (protocol applied to the maternity care collaboration), or "not mentioned". A maternity care collaboration (MCC) is an alliance between care professionals in a hospital and the surrounding primary midwifery care practices, sometimes including other care professionals such as general practitioners and maternity care assistants.[17] Collaboration was categorized as monodisciplinary (protocol developed only by care professionals of the obstetric or neonatal department), "multidisciplinary within hospital" (protocol developed together by care professionals from the obstetric and neonatal departments), "multidisciplinary within MCC" (protocol developed by care professionals from the MCC), and "not mentioned". Patient involvement in protocol development was categorized as "mentioned" or "not mentioned". References were categorized as "scientific literature", "guidelines", "scientific literature and guidelines", "agreements between professionals", "other", and "not mentioned".

The following information was extracted from the protocols: recommendations for type of neonatal referral to the pediatrician, pediatrician's attendance at birth, location of admission, tests before referral, test criteria, timeframe of referral, screening/diagnostic tests after referral, tests' cutoff values, treatment, discharge criteria, and referral after discharge. Type of neonatal referral was categorized as "pediatric consultation", "neonatal admission", and "not mentioned". Pediatrician's attendance at birth and neonatal referral after discharge were categorized as "indicated", "not indicated", and "not mentioned". Location of admission was categorized as "maternity ward", "neonatal ward", and "not mentioned". Neonatal referral after discharge was categorized as "always indicated", "only if indicated", "not indicated", and "not mentioned". Information about tests before neonatal referral, test criteria, time frame of referral, screening/diagnostic tests after referral, tests" cutoff values, treatment, and discharge criteria were extracted descriptively or categorized as "not mentioned".

For all variables, the category "noncorrespondent" was used if the information within or between protocols did not correspond. The category "unclear" was used if categorization was not possible based on the description in the protocol. The category "referred to a different document" was used if we were not provided the protocol itself, but a document containing a reference to a different document.

After the data extraction, we divided the indications for neonatal referral to the pediatrician into three categories: "low threshold", "average threshold", and "high threshold". Indications that led to the most referrals were categorized as "low threshold", and indications that led to the least referrals were categorized as "high threshold".

2.3 | Analyses

Statistical analyses were conducted using STATA software 14.1.[18] We used descriptive statistics (*n*, %) to report the protocols' characteristics, content, differences between departments (interdepartment), among practices within departments (intradepartment), and between an obstetric department and a neonatal department located in the same hospital (intrahospital). We used descriptive statistics and logistic regression analyses to examine associations among referral threshold, department, and region. Univariable logistic regression analyses were conducted to calculate crude odds ratio (OR) and 95% confidence intervals (CI) for the associations between type of department and referral threshold, and region and referral threshold. Multivariable logistic regression analyses were conducted to determine adjusted ORs (aOR). The model for type of department was adjusted for region, and the model for region was adjusted for type of department as potential confounder.

We compared the three referral threshold categories "low threshold", "average threshold", and "high threshold" using dummy variables: "low threshold versus average and high threshold", "average threshold versus low and high threshold", and "high threshold versus low and average threshold". We used the obstetric department as reference category for type of department. For region, instead of using one of the regions as normative category, we used the weighted referral threshold of all regions as the reference category. This weighted referral threshold was the overall referral threshold, with the referral threshold of the region weighted for the number of responding departments in each region.

3 | RESULTS

3.1 | Characteristics of the study sample

Among the 74 hospitals that were approached, nine hospitals (12%) were tertiary-level hospitals. We received protocols from 83 departments: 39 (53%) obstetric departments and 44 (59%) neonatal departments. Of these departments, 22 (30%) were located in the same hospital. Nine (12%) hospitals did not respond to our invitation. Four obstetric departments (5%) and two neonatal departments (3%) declined participation—one obstetric department because of time constraints, and one neonatal department because their protocols were being revised at the time of this study (Figure 1, Table 1).

3.2 | Interdepartmental variation: between obstetric and neonatal departments located in different hospitals

From the 83 responding departments, we received 420 protocols, together containing 68 indications for neonatal referral to the pediatrician. We found the highest number of different indications for neonatal referral in the SGA protocols and in the protocols received from the neonatal departments (Table 2, a detailed overview of the indications for referral can be found in Supplement 2).

In most protocols, the date of publication, type of collaboration, and references were not mentioned. Of the protocols in which this information was given, the mean date of publication was 2016 and 2018 for neonatal departments and obstetric departments, respectively. Of these, most were hospital-only protocols that did not apply to the whole region, developed using a multidisciplinary approach, and based on guidelines. None of the protocols contained information about patient involvement in protocol development (Table 3).

Most of the protocols did not contain a specific recommendation about location of admission and type of referral. If type of referral was specified, this concerned a pediatric consultation. Sometimes, the recommendation was not to refer to the pediatrician. Pediatricians' attendance at birth was just as often indicated as not indicated (21%) but most often was not specified (51%) (Table 4).

In many of the protocols, the indications for referral were specified for different subindications. For

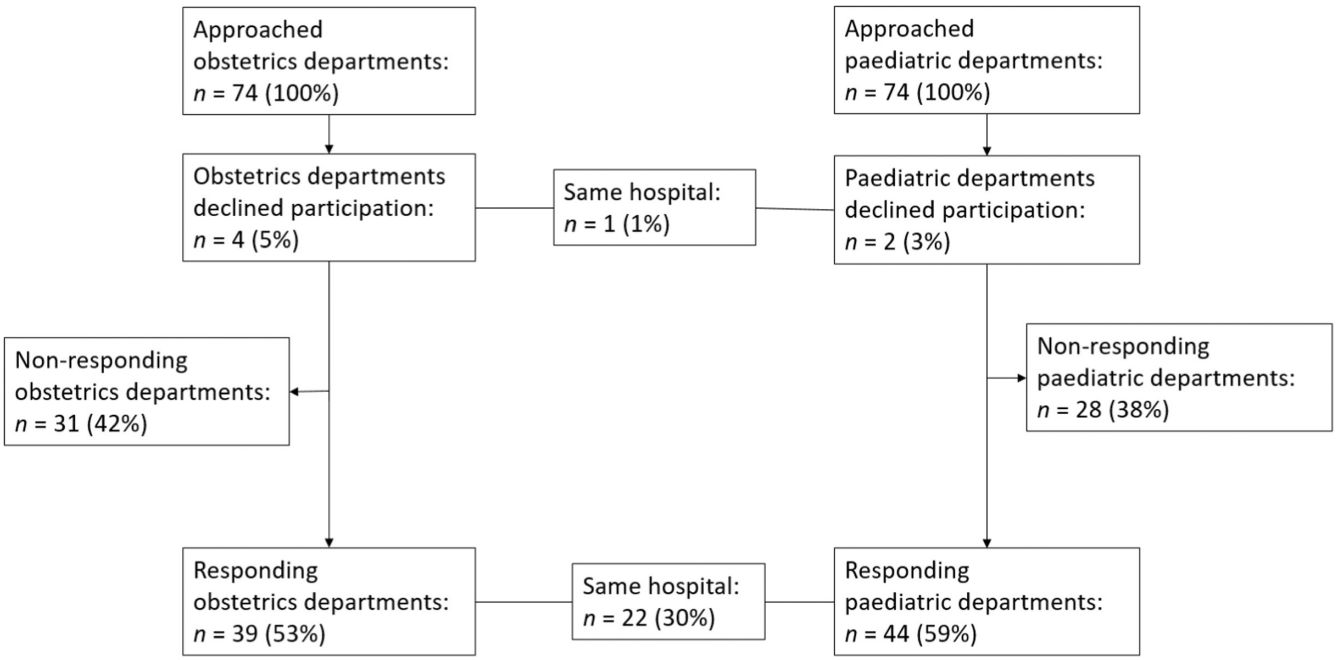

FIGURE 1 Response rate specified for type of department

TABLE 1 Department characteristics (*n*, %)

Type of department	O *n*, %	N *n*, %	O & N *n*, %
Total	39 (47)	44 (53)	22 (27)
Type of hospital			
Secondary-level	34 (45)	41 (55)	21 (29)
Tertiary-level	5 (63)	3 (38)	1 (13)
Region			
North	7 (47)	8 (53)	6 (40)
East	3 (50)	3 (50)	1 (17)
South	9 (53)	8 (47)	3 (18)
Southwest	12 (57)	9 (43)	6 (29)
Northwest	8 (33)	16 (67)	6 (25)

Abbreviations: N, neonatal department; O, obstetric department; O & N = obstetric and neonatal department part of the same hospital.

TABLE 2 Received protocols and number of different indications for neonatal referral specified for protocol and type of department (*n*)

	Protocols *n*, %	Number of different indications for neonatal referral[a] *n*, %
Total	420 (100)	68 (100)[b]
Protocol		
LGA	65 (15)	14 (21)
SGA	70 (17)	27 (40)
MSAF	74 (18)	9 (13)
VE	72 (17)	8 (12)
FE	62 (15)	7 (10)
CB	77 (18)	3 (4)
Type of department		
O	189 (45)	
N	231 (55)	

Abbreviations: CB, cesarean birth; FE, forceps extraction; LGA, large for gestational age/macrosomia; MSAF, meconium stained amniotic fluid; N, neonatal department; O & N, obstetric and neonatal department part of the same hospital; O, obstetric department; SGA, small for gestational age/fetal growth restriction; VE, vacuum extraction.

[a]Numbers obtained from the results shown in Supplement 3. Excluding the categories "noncorrespondent", "referred to a different document", "unclear", and "not mentioned".

[b]Number of unique indications.

example, indications for referral were specified for different weight categories, with different recommendations for screening/diagnostic tests, treatment, and discharge (Table 5). A detailed overview can be found in Supplement 3.

3.3 | Intrahospital variation: between obstetric and neonatal departments located in the same hospital

From 22 (30%) hospitals, we received 99 protocols from both the obstetric and the neonatal department (Table 2). Of these protocols, 18 (18%) contained noncorrespondent recommendations. Five (28%) of the noncorrespondent recommendations were about the type of neonatal referral to the pediatrician. Eleven (61%) of the noncorrespondent recommendations were about the indication for referral. For example, in one hospital, in the obstetric protocol, neonatal referral was recommended after CB when Apgar scores were ≤9/10, whereas in the neonatal department's protocol, neonatal referral was recommended after every CB. Two (11%) of the noncorrespondent recommendations were about the indication for referral and type of referral. For example, in two hospitals, the obstetric protocol

TABLE 3 Characteristics of the protocols by type of department (*n*, %)

	Total	O	N
Type of department	***n*, %**	***n*, %**	***n*, %**
Protocols	420 (100)	189 (100)	231 (100)
Date			
Mentioned	87 (21) Range: 2011–2020	49 (26) Range: 2011–2019	38 (16) Range: 2017–2020
Not mentioned	333 (79)	140 (74)	193 (84)
Type of protocol			
Hospital only	110 (26)	49 (26)	61 (26)
Regional	36 (9)	24 (13)	12 (5)
Not mentioned	274 (65)	116 (61)	158 (68)
Disciplinary collaboration			
Monodisciplinary	34 (8)	10 (5)	24 (10)
Multidisciplinary within hospital	43 (10)	16 (8)	27 (12)
Multidisciplinary within MCC	15 (4)	7 (4)	8 (3)
Not mentioned	328 (78)	156 (83)	172 (74)
References			
Scientific literature	18 (4)	10 (5)	8 (3)
Other guidelines	71 (17)	30 (16)	43 (17)
Scientific literature and other guidelines	41 (10)	14 (7)	25 (11)
Professional consensus	9 (2)	3 (2)	6 (3)
Not mentioned	281 (67)	132 (70)	149 (62)

Abbreviations: N, neonatal department; O, obstetric department.

recommended pediatric consultation after every MSAF, whereas in the neonatal protocol, consultation was only recommended in case of poor/bad neonatal vital signs in addition to MSAF.

3.4 | Intradepartmental variation: within a single obstetric or neonatal department

We found noncorresponding recommendations within the protocols of 35 departments. The most common reason for noncorrespondence (74%) concerned the indication for pediatric consultation or neonatal admission. Within eight protocols — LGA ($n = 3$), SGA ($n = 1$), MSAF ($n = 2$), VE ($n = 1$), FE ($n = 1$) — the test cutoff values did not correspond. For example, an LGA protocol from an obstetric department described within the same document referral to the pediatrician when birthweight was >4000 grams and when birthweight was >95th percentile. Type of referral and test cutoff values did not correspond in one MSAF, one VE, and one FE protocol. Type of referral and pediatrician's attendance at birth did not correspond in one VE and one FE protocol.

3.5 | Regional and interdepartmental variation in referral threshold

We found variation in threshold for neonatal referral to the pediatrician between departments and between regions (Table 6). The categories for referral threshold are presented in Supplement 4. Overall, the obstetric departments' protocols and the protocols from hospitals located in the northern and southern region contained the highest number of recommendations with a low threshold, leading to a higher referral rate. The neonatal department's protocols and the protocols from hospitals in the eastern region contained most of the recommendations with a high threshold, leading to a lower referral rate.

TABLE 4 Recommendations by protocol about type of neonatal referral, pediatrician's attendance at birth, location of admission, and referral after discharge (*n*, %)

Protocol	Total			LGA			SGA		
	Total	O	N	Total	O	N	Total	O	N
Type of department	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)
Type of neonatal referral									
Total	514 (100)	226 (100)	288 (100)	67 (100)	26 (100)	41 (100)	122 (100)	50 (100)	72 (100)
Pediatric consultation	222 (43)	99 (37)	123 (43)	37 (55)	16 (62)	21 (51)	52 (43)	22 (44)	30 (42)
Neonatal admission	90 (18)	43 (16)	47 (16)	12 (18)	5 (19)	7 (17)	44 (36)	19 (38)	25 (35)
Neonatal referral not indicated	13 (3)	6 (3)	7 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Unclear whether pediatric consultations or neonatal admissions is indicated	92 (18)	31 (14)	61 (21)	12 (18)	2 (8)	10 (24)	14 (11)	3 (6)	11 (15)
Unclear if neonatal referral is indicated	64 (12)	28 (12)	36 (13)	4 (6)	1 (4)	3 (7)	7 (6)	3 (6)	4 (6)
Noncorrespondent within protocol	31 (6)	18 (8)	13 (5)	2 (3)	2 (8)	0 (0)	5 (4)	3 (6)	2 (3)
Pediatrician's attendance at birth									
Total	437 (100)	192 (100)	245 (100)	63 (100)	25 (100)	38 (100)	115 (100)	47 (100)	68 (100)
Indicated	93 (21)	39 (20)	54 (22)	9 (14)	1 (4)	8 (21)	8 (7)	2 (4)	6 (9)
Not indicated	92 (21)	56 (29)	36 (15)	39 (62)	10 (40)	29 (94)	20 (17)	15 (9)	5 (7)
Noncorrespondent	2 (0)	2 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Unclear	26 (6)	14 (7)	12 (5)	1 (2)	0 (0)	1 (3)	9 (8)	3 (6)	6 (9)
Not mentioned	224 (51)	81 (42)	143 (58)	14 (22)	14 (56)	0 (0)	78 (68)	27 (57)	51 (75)
Location of admission									
Total	437 (100)	192 (100)	245 (100)	63 (100)	25 (100)	38 (100)	115 (100)	47 (100)	68 (100)
Maternity ward	174 (40)	75 (39)	99 (40)	27 (43)	10 (40)	17 (45)	29 (25)	12 (26)	17 (25)
Neonatal ward	38 (9)	11 (6)	27 (11)	2 (3)	0 (0)	2 (5)	33 (29)	11 (23)	22 (32)
Depending on clinical assessment	1 (0)	0 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Decided together by obstetrician and pediatrician	2 (0)	1 (1)	1 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
Unclear	3 (1)	0 (0)	3 (1)	2 (3)	0 (0)	2 (5)	1 (1)	0 (0)	1 (1)
Not mentioned	219 (50)	105 (55)	114 (47)	32 (51)	15 (60)	17 (45)	51 (44)	24 (51)	27 (40)
Referral after discharge									
Total	437 (100)	192 (100)	245 (100)	63 (100)	25 (100)	38 (100)	115 (100)	47 (100)	68 (100)
Routine	19 (4)	7 (4)	12 (5)	0	0 (0)	0 (0)	19 (17)	7 (15)	12 (18)
If indicated	1 (0)	0 (0)	1 (0)	0	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
Not indicated	32 (7)	8 (4)	24 (10)	6 (10)	2 (8)	4 (11)	5 (4)	2 (4)	3 (4)
Unclear	8 (2)	1 (1)	7 (3)	0	0 (0)	0 (0)	8 (7)	1 (2)	7 (10)
Not mentioned	377 (86)	176 (92)	201 (82)	57 (90)	23 (92)	34 (89)	82 (71)	37 (79)	45 (66)

Protocol	MSAF			VE			FE			CB		
	Total	O	N	Total	O	N	Total	O	N	Total	O	N
Type of department	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)
Type of neonatal referral												
Total	93 (100)	42 (100)	51 (100)	76(100)	36 (100)	40 (100)	67 (100)	29 (100)	38 (100)	88 (100)	43 (100)	45 (100)
Pediatric consultation	36 (39)	15 (36)	21 (41)	36 (47)	16 (44)	20 (50)	32 (48)	14 (48)	18 (47)	29 (33)	16 (37)	13 (29)

(Continues)

TABLE 4 (Continued)

Protocol	MSAF			VE			FE			CB		
	Total	O	N	Total	O	N	Total	O	N	Total	O	N
Type of department	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)	(*n*, %)
Neonatal admission	7 (8)	3 (7)	4 (8)	5 (7)	3 (8)	2 (5)	5 (7)	3 (10)	2 (5)	17 (19)	10 (93)	7 (16)
Neonatal referral not indicated	8 (9)	3 (7)	5 (10)	3 (4)	2 (6)	1 (3)	2 (3)	1 (3)	1 (3)	0 (0)	0 (0)	0 (0)
Unclear whether pediatric consultations or neonatal admissions is indicated	20 (22)	11 (26)	9 (18)	10 (13)	4 (11)	6 (15)	10 (15)	3 (10)	7 (18)	27 (31)	9 (21)	18 (40)
Unclear if neonatal referral is indicated	15 (16)	6 (14)	9 (18)	17 (22)	8 (22)	9 (23)	14 (21)	6 (21)	8 (21)	7 (8)	4 (9)	3 (7)
Noncorrespondent within protocol	7 (8)	4 (10)	3 (6)	5 (7)	3 (8)	2 (5)	4 (6)	2 (7)	2 (5)	8 (9)	4 (9)	4 (9)
Pediatrician's attendance at birth												
Total	70 (100)	33 (100)	37 (100)	57 (100)	26 (100)	31 (100)	51 (100)	22 (100)	29 (100)	81 (100)	39 (100)	42 (100)
Indicated	14 (20)	5 (15)	9 (24)	8 (14)	2 (8)	6 (19)	9 (18)	3 (14)	6 (21)	55 (68)	27 (69)	28 (67)
Not indicated	21 (30)	14 (42)	7 (19)	14 (25)	7 (19)	7 (23)	12 (24)	6 (27)	6 (21)	5 (6)	3 (8)	2 (5)
Noncorrespondent	1 (1)	1 (3)	0 (0)	1 (2)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Unclear	7 (10)	4 (12)	3 (8)	4 (7)	3 (12)	1 (3)	2 (4)	1 (5)	1 (3)	2 (2)	2 (5)	0 (0)
Not mentioned	27 (39)	9 (27)	18 (49)	30 (53)	13 (50)	17 (55)	28 (55)	12 (55)	16 (55)	19 (23)	7 (18)	12 (29)
Location of admission												
Total	70 (100)	33 (100)	37 (100)	57 (100)	26 (100)	31 (100)	51 (100)	22 (100)	29 (100)	81(100)	39 (100)	42 (100)
Maternity ward	31 (44)	15 (45)	16 (43)	29 (51)	12 (46)	17 (54)	1 (2)	0 (0)	1 (3)	35 (43)	18 (46)	17 (40)
Neonatal ward	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	1 (3)	23 (45)	8 (36)	15 (52)	1 (1)	0 (0)	1 (2)
Depending on clinical assessment	1 (1)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Decided together by obstetrician and pediatrician	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Unclear	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Not mentioned	38 (54)	18 (55)	20 (54)	27 (47)	14 (54)	13 (42)	26 (51)	13 (59)	13 (45)	45 (56)	21 (54)	24 (57)
Referral after discharge												
Total	70 (100)	33 (100)	37 (100)	57 (100)	26 (100)	31 (100)	51 (100)	22 (100)	29 (100)	81 (100)	39 (100)	42 (100)
Routine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
If indicated	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Not indicated	6 (9)	2 (6)	4 (11)	4 (7)	0 (0)	4 (13)	3 (6)	0 (0)	3 (10)	8 (10)	2 (5)	6 (14)
Unclear	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Not mentioned	64 (91)	31 (94)	33 (89)	53 (93)	26 (100)	27 (87)	48 (94)	22 (100)	26 (90)	73 (90)	37 (95)	36 (86)

Abbreviations: CB, cesarean birth; FE, forceps extraction; LGA, large for gestational age/macrosomia; MSAF, meconium stained amniotic fluid; N, neonatal department; O, obstetric department; SGA, small for gestational age/fetal growth restriction; VE, vacuum extraction.

Compared with obstetric departments, neonatal departments had low threshold for referral in their protocols (aOR 0.56 [95% CI 0.34–0.93]) significantly less often, and significantly more often a high threshold for referral in their protocols (aOR 2.31 [95% CI 1.16–4.60]). The eastern region had significantly more often a high threshold for referral in their protocols compared with the other regions (aOR 2.52 [95% CI 1.05–6.09]) (Table 7).

TABLE 5 Recommendations for the tests, treatment and discharge by protocol and specified for type of department (*n*)[b]

Type of department	Tests before neonatal referral	O	N	Test criteria	O	N	Time frame of neonatal referral	O	N
		n	*n*		*n*	*n*		*n*	*n*
Protocol									
LGA	Total[a]	25	38	Total[a]	25	38	Total[a]	25	38
	Observation	0	1	Physical appearance	0	1	Directly pp	1	2
	Birth weight	23	30	Birth weight *p*-value	17	25	Decided by obstetrician and/or pediatrician	2	1
	Birth weight and observation feeding	0	1	Birth weight grams	1	0	During the pediatricians' rounds	1	3
	Birthweight and glucose assessment	0	5	Birth weight *p*-value and grams	3	5	Within a certain time frame	3	4
	Referred to different document	0	1	Birth weight *p*-value and food intake	0	1	Depending on the part of the day	4	6
	Noncorrespondent	1	0	Birth weight *p*-value and physical appearance	1	1	Other	0	1
	Not mentioned	1	0	Birth weight grams and physical appearance	0	1	Unclear	1	3
				Birth weight *p*-value and glucose assessment	0	3	Not mentioned	13	18
				Referred to different document	0	1			
				Unclear	1	1			
				Not mentioned	2	0			
SGA	Total[a]	47	68	Total[a]	47	68	Total[a]	47	68
	Observation	0	1	Physical appearance			Before birth	0	1
	Birth weight	45	63	Birth weight *p*-value	20	31	Directly pp	5	8
	Birthweight and glucose assessment	1	3	Birth weight grams	16	30	Decided by obstetrician and/or pediatrician	3	2
	Referred to different document	0	1	Birth weight *p*-value and grams	6	0	During the pediatricians' rounds	1	2
	Unclear	1	0	Birth weight *p*-value and CMV test	0	1	Within a certain time frame	4	5
				Birth weight *p*-value and physical appearance	1	1	Depending on the part of the day	5	7
				Birth weight grams and physical appearance	1	0	Unclear	1	4
				Birth weight *p*-value and glucose assessment	0	2	Not mentioned	28	38
				Birth weight, *p*-value, grams and glucose assessment	0	1			
				Referred to different document	0	1			
				Noncorrespondent	0	1			
				Unclear	1	0			

(Continues)

TABLE 5 (Continued)

Type of department	Tests before neonatal referral	O	N	Test criteria	O	N	Time frame of neonatal referral	O	N
		n	*n*		*n*	*n*		*n*	*n*
MSAF	Total[a]	33	37	Total[a]	33	37	Total[a]	33	37
	Observation color amniotic fluid	23	23	MSAF	24	17	Directly pp	1	6
	Observation color amniotic fluid and assessment fetal condition during birth	1	2	MSAF consistency	0	6	Decided by obstetrician and/or pediatrician	2	1
	Observation color amniotic fluid and assessment neonatal condition pp	7	11	MSAF and risk factors during birth	1	4	During the pediatricians' rounds	0	2
	Other	0	1	MSAF and risk factors pp	6	9	Within a certain time frame	2	4
	Noncorrespondent	2	0	MSAF and risk factors during birth or pp	1	1	Depending on the part of the day	5	4
				Noncorrespondent	1	0	Other	1	0
							Unclear	1	3
							Noncorrespondent	1	0
							Not mentioned	20	17
VE	Total[a]	26	31	Total[a]	26	31	Total[a]	26	31
	Always after VE	20	19	Conducting VE	20	19	Directly pp	0	1
	Assessment fetal/neonatal condition	0	2	Progress expulsion stage	2	2	During the pediatricians' rounds	0	2
	Assessment fetal condition	2	3	Fetal/neonatal condition	1	2	Within a certain time frame	4	2
	Assessment expulsion stage	0	2	Fetal condition	1	2	Depending on the part of the day	5	5
	Assessment fetal condition and assessment expulsion stage	3	1	Fetal condition and progress expulsion stage	1	3	Unclear	1	1
	Assessment neonatal condition and assessment expulsion stage	0	3	Neonatal condition	1	1	Not mentioned	16	20
	Assessment neonatal	1	0	Neonatal condition and progress expulsion stage	0	1			
	Unclear	0	1	Unclear	0	1			

TABLE 5 (Continued)

Type of department	Tests before neonatal referral	O	N	Test criteria	O	N	Time frame of neonatal referral	O	N
		n	*n*		*n*	*n*		*n*	*n*
FE	Total[a]	22	29	Total [a]	22	29	Total[a]	22	29
	Always after FE	17	17	Conducting FE	17	17	Directly	0	1
	Assessment of fetal/neonatal condition	0	2	Progress expulsion stage	2	2	Within a certain time frame	2	2
	Assessment fetal condition	2	3	Fetal/neonatal condition	1	3	Depending on the part of the day	4	5
	Assessment fetal condition and assessment expulsion stage	2	3	Fetal condition	1	2	During the pediatricians' rounds	1	2
	Assessment expulsion stage	1	2	Fetal condition and progress expulsion stage	1	3	Not mentioned	13	19
	Assessment of the neonatal condition and assessment expulsion stage	0	1	Neonatal condition and progress expulsion stage	0	1	Unclear	1	0
	Unclear	0	1	Unclear	0	1	Noncorrespondent	1	0
CB	Total[a]	39	42	Total[a]	39	42	Total[a]	39	42
	Always after CB	33	37	Conducting CB	26	34	Directly	4	4
	Assessment of indication for primary or secondary CB	1	0	Level of urgency CB	6	0	Within a certain time frame	2	3
	Assessment neonatal condition after CB	4	4	Indication for CB	2	3	Depending on the part of the day	2	2
	Unclear	1	1	Neonatal condition	4	4	During daily rounds	0	2
				Unclear	1	1	Other	0	1
							Not mentioned	28	28
							Unclear	3	2
Type of department	**Screening/diagnostic tests**	**O**	**N**	**Tests' cutoff values**	**O**	**N**	**Treatment**	**O**	**N**
		n	*n*		*n*	*n*		*n*	*n*
Protocol									
LGA	Total[a]	25	38	Total[a]	25	38	Total[a]	25	38
	Glucose assessment	5	12	Glucose <1.1 mmol/L	0	2	No supplementary feeding	0	2
	Glucose assessment and other tests	1	5	Glucose <2.0 mmol/L	3	3	Supplementary feeding	4	5
	Referred to a different document	8	0	Glucose <2.6 mmol/L	2	12	Supplementary feeding and glucose gel/infusion	4	10
	Unclear	3	10	Unclear	3	10	Other	1	0
	Not mentioned	8	11	Not mentioned	17	11	Unclear	1	1
							Not mentioned	15	20

(Continues)

TABLE 5 (Continued)

Type of department	Screening/diagnostic tests	O	N	Tests' cutoff values	O	N	Treatment	O	N
		n	*n*		*n*	*n*		*n*	*n*
SGA	Total[a]	47	68	Total[a]	47	68	Total[a]	47	68
	Glucose assessment	13	18	Glucose <2.0 mmol/L	4	5	Supplementary feeding only if necessary	0	3
	Clinical assessment	0	2	Glucose <2.6 mmol/L	2	14	Routine supplementary feeding	6	8
	Glucose assessment and other tests	7	15	Unclear	4	0	Routine supplementary feeding and upscaling with glucose	8	13
	Unclear	1	0	Not mentioned	37	49	Not mentioned	33	44
	Not mentioned	26	33						
MSAF	Total[a]	33	37		33	37		33	37
	Assessment neonatal condition postpartum	4	4	Assessment ≥3 parameters	1	3	Observation	3	4
	Assessment neonatal condition and observation ≥8 h postpartum	16	24	Assessment >3 parameters	1	2	Referred to a different document	2	1
	Assessment neonatal condition and observation 9–12 h postpartum	2	0	Referred to a different document	2	1	Not mentioned	28	32
	Assessment neonatal condition and observation 13–24 h postpartum	2	1	Unclear	1	0			
	Referred to a different document	2	1	Not mentioned	28	31			
	Unclear	1	0						
	Not mentioned	6	7						
VE	Total[a]	26	31		26	31		26	31
	Assessment neonatal condition postpartum	3	2	Assessment ≥3 parameters	3	3	Pain medication	10	10
	Assessment neonatal condition and observation ≥8 h postpartum	6	7	Assessment >3 parameters	1	1	Pain medication and other treatment	2	0
	Assessment neonatal condition and observation 9–12 h postpartum	2	4	Referred to a different document	1	0	Not mentioned	14	21
	Assessment neonatal condition and observation 13–24 h postpartum	3	2	Not mentioned	21	27			
	Not mentioned	12	16						

TABLE 5 (Continued)

Type of department	Screening/diagnostic tests	O	N	Tests' cutoff values	O	N	Treatment	O	N
		n	*n*		*n*	*n*		*n*	*n*
FE	Total[a]	22	29		22	29		22	29
	Assessment neonatal condition postpartum	4	2	Assessment ≥3 parameters	1	3	Pain medication	6	8
	Assessment neonatal condition and observation up to 8 h postpartum	2	5	Assessment >3 parameters	1	1	Pain medication and other treatment	2	0
	Assessment neonatal condition and observation up to 12 h postpartum	1	4	Referred to a different document	1	0	Not mentioned	14	21
	Assessment neonatal condition and observation 24 h postpartum	2	2	Not mentioned	19	25			
	Not mentioned	13	16						
CB	Total[a]	39	42		39	42		39	42
	Assessment neonatal condition postpartum	14	13	Assessment vital parameters	2	2	Not mentioned	39	42
	Assessment neonatal condition and observation 3 h postpartum	1	0	Assessment feeding	0	1			
	Assessment neonatal condition and observation 12 h postpartum	1	2	Assessment lung function	0	1			
	Assessment neonatal condition and observation 24 h postpartum	2	4	Not mentioned	37	38			
	Not mentioned	21	23						

Type of department	Discharge	O	P
		n, %	*n*, %
Protocol			
LGA	Total[a]	25	38
	After a certain time frame	2	4
	Glucose values	2	6
	After a certain time frame and glucose values	0	3
	Unclear	3	2
	Not mentioned	18	23
SGA	Total[a]	47	68
	After a certain time frame	3	6
	Glucose values	2	3
	After a certain time frame and glucose values	0	4
	Weight	0	4
	Unclear	2	6
	Not mentioned	40	45

(Continues)

TABLE 5 (Continued)

	Discharge		
		O	P
Type of department		*n*, %	*n*, %
MSAF	Total[a]	33	37
	Neonatal condition	2	2
	After ≥8 h postpartum	17	22
	After 9–12 h postpartum	5	0
	After 13–48 h postpartum	1	1
	Referred to a different document	6	2
	Not mentioned	2	10
VE	Total[a]	26	31
	Neonatal condition	0	1
	After ≥8 h postpartum	4	5
	After 9–12 h postpartum	5	6
	After 13–48 h postpartum	3	2
	Not mentioned	14	17
FE	Total[a]	22	29
	Neonatal condition	0	1
	After ≥8 h postpartum	2	3
	After 9–12 h postpartum	5	6
	After 13–28 h postpartum	1	2
	Not mentioned	14	17
CB	Total[a]	39	42
	Food intake	0	1
	After ≥12 h postpartum	1	2
	After 13–24 h postpartum	3	9
	Not mentioned	35	30

Abbreviations: CB, cesarean birth; FE, forceps extraction; LGA, large for gestational age/macrosomia; MSAF, meconium stained amniotic fluid; N, neonatal department; O, obstetric department; SGA, small for gestational age/fetal growth restriction; VE, vacuum extraction.

[a]Excluding the categories "referral not indicated" and "unclear if referral is indicated" (Table 4).

[b]Numbers obtained from the results shown in Supplement 2.

4 | DISCUSSION

This study provides insight into variation in local hospital protocols for neonatal referral to the pediatrician in the Netherlands as a possible determinant contributing to unwarranted practice variation.[5,12,13] Analysis of the protocols for LGA, SGA, MSAF, VE, FE, and CB showed interhospital, interdepartmental, and intradepartmental variation in recommendations for type of neonatal referral, admission, screening/diagnostic tests, treatment, and discharge. Furthermore, we found lower referral thresholds in neonatal departments compared with obstetric departments, and a higher referral threshold in the eastern region compared with the weighted referral threshold of all regions.

4.1 | Explaining unwarranted variation: the role of evidence-based guidelines, health care resources, and providers' beliefs and interests

In this study, we did not examine the association between variation in local hospital protocols and care outcomes. Further study is needed to determine whether the variation in local hospital protocols for neonatal referral to the pediatrician results in unwarranted variation in neonatal care outcomes. The protocols analyzed in this study did not contain descriptions of local population characteristics as explanations for specific recommendations. Reflecting on the study findings using definitions of warranted and unwarranted variation suggests that the variation in hospital

TABLE 6 The referral threshold[a] specified for type of department and region (*n*, %)

	Total		Low		Average		High	
Threshold for referral	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
Type of department								
Obstetric	152	100	120	79	19	13	13	9
Neonatal	190	100	126	66	28	15	36	19
Region								
North	65	100	50	77	9	14	6	9
East	25	100	17	68	1	4	7	28
South	79	100	60	76	9	11	10	13
Southwest	88	100	65	74	14	16	9	10
Northwest	85	100	54	63	14	17	17	20

[a]Low threshold = indications that led to the most pediatric consultations or neonatal admissions; High threshold = indications led to the least pediatric consultations or neonatal admissions.

TABLE 7 Association between referral threshold, type of department and region (OR, aOR)

	Low		Average		High	
Referral threshold	**OR [95% CI]**	**aOR [95% CI][a]**	**OR [95% CI]**	**aOR [95% CI][a]**	**OR [95% CI]**	**aOR [95% CI][a]**
Type of department						
Obstetric (reference category)	1.0	1.0	1.0	1.0	1.0	1.0
Neonatal	0.53 [0.32–0.86]*	0.56 [0.34–0.93]*	1.21 [0.65–2.26]	1.18 [0.63–2.35]	2.50 [1.27–4.91]*	2.31 [1.16–4.60]*
Region[b]						
North	1.28 [0.77–2.14]	1.24 [0.74–2.09]	1.06 [0.56–2.02]	1.07 [0.56–2.65]	0.65 [0.31–1.35]	0.68 [0.32–1.42]
East	0.82 [0.36–1.84]	0.82 [0.36–1.86]	0.27 [0.04–1.79]	0.27 [0.42–1.66]	2.48 [1.04–5.91]*	2.52 [1.05–6.09]*
South	1.22 [0.78–1.90]	1.19 [0.76–1.87]	0.85 [0.46–1.55]	1.85 [0.04–2.10]	0.92 [0.52–1.65]	0.95 [0.53–1.71]
Southwest	1.09 [0.72–1.64]	1.05 [0.69–1.58]	1.25 [0.74–2.09]	1.26 [0.47–2.90]	0.73 [0.41–1.29]	0.76 [0.43–1.36]
Northwest	0.67 [0.45–0.99]*	0.73 [0.49–1.08]	1.29 [0.77–2.19]	1.27 [0.75–2.94]	1.59 [0.97–2.61]	1.43 [0.86–2.34]

Abbreviations: N, neonatal department; O, obstetric department.

[a]The model for type of department was adjusted for region and the model for region was adjusted for type of department potential confounders.

[b]The reference category (OR of 1.0) is the weighted referral threshold of all regions.

*p value <0.05.

protocols found in this study might may be explained by: (1) variation in existing guidelines, (2) availability of health care resources, and/or (3) care based on providers' beliefs and interests.[1–3]

International guidelines are the foundation for national guidelines, providing professionals with evidence-based guidance in care. National guidelines form the basis for local protocols, describing the procedures of care.[19] Protocols can deviate from guidelines and differ because of population characteristics or local organization of care. Unexplained differences between protocols in recommendations for care may result from gaps in guidelines because of unaddressed questions and/or lack of evidence. Indeed, for SGA and LGA, international evidence-based guidelines contain varying glucose and birth weight *p*-value cutoff points, which is consistent with our findings.[20–24] According to Thornton and Adamkin (2016), this variation is unsurprising, considering the paucity of evidence about clinically significant levels of neonatal hypoglycemia and the lack of consensus about a specific level or range to define hypoglycemia.[22] Recently, the Dutch association of pediatricians developed a national multidisciplinary guideline on hypoglycemia. This guideline was consensus-based because of incomplete and inconclusive evidence.[23]

Another explanation for the variation in protocols found in this study may be professionals' lack of adherence to national or international guidelines because they are unaware of them or do not agree with them.[25–28] Indeed, in contrast with the majority of the MSAF, VE, FE, and CB protocols

included in this study, international guidelines do not recommend routine neonatal referral to the pediatrician.[29–31] For MSAF, Dutch national guidelines differ. The guideline of the professional association of obstetricians (2011) recommends 8 h of observation, based on a Dutch study.[32] The guidelines of the professional association of midwives (2015)[33] are based on the guideline of the United Kingdom's National Institute for Health Care and Excellence (NICE),[31] which differentiates between nonsignificant and significant MSAF, and recommends an observation period of 2 and 12 h, respectively. Neither the obstetricians' nor the midwives' guidelines explicitly recommend pediatric involvement.

Variation in guidelines leaves room for recommendations in protocols based on professionals' beliefs and interests.[4,5,26,28,34,35] Interprofessional differences in attitudes, beliefs, and interests may explain the differences in neonatal referral thresholds between obstetric and neonatal departments. Most studies on interprofessional differences in maternal and newborn care focus on differences between obstetricians and midwives, indicating differences in provider attitudes, beliefs, and interests.[36–40] Little is known about the differences in attitudes, beliefs, and interests between obstetricians and pediatricians. Geurtzen and colleagues (2016) studied Dutch obstetricians' and neonatologists' treatment decisions for the extremely premature neonate. They found disagreement in preferred treatment decisions between obstetricians and neonatologists, contributing to considerable variation within one hospital.[28]

The differences in the threshold for neonatal referral to the pediatrician between regions found in this study may also be explained by local availability of resources.[2,3] For example, Offerhaus and colleagues (2013) found no association between referral rates for people with healthy pregnancies and perinatal outcomes in the Netherlands in the years 2000–2008. However, they did find a small rise in NICU admissions. According to these researchers, this may be associated with the improved NICU availability in the Netherlands since 2006.[41]

4.2 | Enhancing effective health care: toward the implementation of multidisciplinary, evidence-based guidelines

To reduce unwarranted variation in local protocols, we recommend evidence-based, international, multidisciplinary guidelines to support national guideline and local protocol development. Research on unanswered questions and gaps in evidence is necessary to inform these guidelines. Where evidence is lacking, guidelines should include consensus-based recommendations to reduce local provider preference and supply-based care. These guidelines should also include recommendations against the use of specific practices where these are contraindicated.[35] For example, for MSAF, the international[31,42] and national[32,33] guidelines, and many protocols included in our study, contained a recommendation against routine intrapartum and postpartum nasal or oral suction. If international guidelines differ or cannot easily be applied because of differences in population characteristics, we recommend multidisciplinary national guidelines. Attention should be paid to guideline implementation. If local protocols deviate from guidelines because of specific local circumstances, this should be well described. Uniformity in guidelines and protocols will offer clear standards for care evaluations, which can lead to a reduction of underuse or overuse of care and reduce care disparity because of unwarranted variation in care.

4.3 | Strengths and limitations

To our knowledge, this is the first nationwide study exploring variation in local hospital protocols for neonatal referral to the pediatrician within and between obstetric and neonatal departments as a possible determinant contributing to unwarranted variation in neonatal referral. More than half of the obstetric and neonatology departments in the Netherlands participated in this study, providing us with 420 protocols. This enabled detailed examination of a large variety of protocols in neonatal care.

Our study has some limitations. We were unable to study differences between smaller geographical areas because of the limited number of departments per province that provided information. More research is necessary to better understand regional variation in protocols. The missing protocols from departments that did not respond or declined participation may have biased the study's outcomes. Also, not all participating departments sent us all six requested protocols. This may have biased our sample. Eleven obstetric and eleven neonatology departments were located in the same hospital, enabling us to study intrahospital variation. However, these departments cannot be considered independent of one other, which may have affected the multivariable analyses.

4.4 | Conclusions

This study provides insight into variation in local hospital protocols for neonatal referral to the pediatrician as a determinant of unwarranted variation in care. Comparison of these protocols showed unexplained large variation in recommendations for care. We found differences in recommendations for type of referral, admission, screening/

diagnostic tests, treatment, and discharge. Furthermore, the results showed lower referral thresholds in neonatal departments compared with obstetric departments, and higher referral thresholds in the eastern region compared with the weighted referral thresholds of all regions. These results suggest unwarranted variation in hospitals protocols, which may contribute to unwarranted variation in care. The recommendations in local protocols were not always consistent with existing evidence-based guidelines. This may be explained by variation and gaps in guidelines and/or a lack of adherence to guidelines, leaving room for provider preference and resource-driven recommendations. To reduce unwarranted variation in local protocols, we recommend the development of evidence-based, multidisciplinary guidelines to support local protocols. Only where evidence is lacking or inconclusive should agreements be based on multidisciplinary consensus. Moreover, attention should be paid to the implementation of evidence. If local protocols deviate from evidence-based guidance because of specific local circumstances, this should be well described. Uniformity in guidance will offer clear standards for care evaluation, including opportunities to reduce inappropriate care.

AUTHOR CONTRIBUTIONS

BG is the main author of the manuscript, organizing all aspects of the article including data collection, data extraction, data analyses, and drafting of the initial manuscript. ASS, DC, HL, TA, AK, and AJ provided guidance and critically reviewed the manuscript. ASS checked the syntax for the analyses. All authors contributed to the manuscript revisions, and read and approved the submitted version. AJ supervised the study.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

DATA AVAILABILITY STATEMENT

The protocols collected for this study are not readily available because of respondent's privacy. The data set developed for this study is accessible. Requests to access the data sets should be directed to corresponding author.

ETHICS STATEMENT

Ethical approval was requested from the Medical Ethics Review Committee of VU University Medical Centre. The committee confirmed that ethical approval was not required because the Medical Research involving Human Subjects Act did not apply to this study (nr. 2019.549).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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