

# Consent and refusal of procedures during labour and birth: a survey among 11 418 women in the Netherlands

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#### ABSTRACT

Background Informed consent for medical interventions is ethically and legally required; an important aspect of quality and safety in healthcare; and essential to person-centred care. During labour and birth, respecting consent requirements, including respecting refusal, can contribute to a higher sense of choice and control for labouring women. This study examines (1) to what extent and for which procedures during labour and birth women report that consent requirements were not met and/or inadequate information was provided, (2) how frequently women consider consent requirements not being met upsetting and (3) which personal characteristics are associated with the latter. Methods A national cross-sectional survey was conducted in the Netherlands among women who gave birth up to 5 years previously. Respondents were recruited through social media with the help of influencers and organisations. The survey focused on 10 common procedures during labour and birth, investigating for each procedure if respondents were

Investigating for each procedure if respondents were offered the procedure, if they consented or refused, if the information provision was sufficient and if they underwent unconsented procedures, whether they found this upsetting. **Results** 13 359 women started the survey and 11 418 met the inclusion and exclusion criteria. Consent

418 met the inclusion and exclusion criteria. Consent not asked was most often reported by respondents who underwent postpartum oxytocin (47.5%) and episiotomy (41.7%). Refusal was most often over-ruled when performing augmentation of labour (2.2%) and episiotomy (1.9%). Information provision was reported inadequate more often when consent requirements were not met compared with when they were met. Multiparous women had decreased odds of reporting unmet consent requirements compared with primiparous (adjusted ORs 0.54-0.85). There was considerable variation across procedures in how frequently not meeting consent requirements was considered upsetting. **Conclusions** Consent for performing a procedure is frequently absent in Dutch maternity care. In some instances, procedures were performed in spite of the woman's refusal. More awareness is needed on meeting necessary consent requirements in order to achieve person-centred and high-quality care during labour and birth.

# WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Informed consent is an important aspect of person-centred care.
- ⇒ Informed consent procedures are ethically and legally required and contribute to a higher sense of choice and control for women during labour and birth.
- ⇒ Not being asked for consent for procedures during labour and birth is often mentioned as an important factor by women who had a negative or traumatic birth experience.

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### WHAT THIS STUDY ADDS

- ⇒ Women report that consent for performing a procedure is frequently absent in Dutch maternity care, and in some instances, procedures were performed in spite of the woman's explicit refusal.
- ⇒ Reporting unmet consent requirements often goes hand in hand with experiencing insufficient information provision.
- ⇒ There is considerable variation across procedures in how frequently women consider the absence of consent as upsetting.

#### INTRODUCTION

Person-centred care is receiving increasing attention in healthcare in the last decades, including in maternity care.<sup>1</sup> Personcentred care focuses on respecting and responding to the values, needs and preferences of patients, empowering them to actively provide input, participate in their healthcare and make decisions.

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#### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ More awareness is needed on the importance of obtaining genuine consent, including respecting refusal, in order to improve the quality of maternity care.
- ⇒ Challenges in meeting consent requirements during labour and birth need to be addressed.
- ⇒ It is important to secure enough time to discuss women's personal preferences by initiating the shared decision-making process in the antenatal period.

Person-centred care increases satisfaction among patients and is associated with improved health outcomes.<sup>2</sup>

Informed consent is a widely recognised ethical and legal requirement and an important expression of person-centred care.<sup>3</sup> It protects patients against infringements on their bodily integrity and interventions incongruous with their wishes.<sup>4</sup> Informed consent requires that the patient is adequately informed and understands the information given.<sup>5</sup> Consent should be voluntary: free from coercion or pressure, and the patient should have alternative options, including the possibility of declining the procedure.<sup>5</sup> Informed consent can be given in various ways, and the legal requirements for obtaining it differ among healthcare systems; in some countries written consent is recommended for most procedures,<sup>6</sup> while in others verbal consent is sufficient.<sup>7</sup>

Because in maternity care women often encounter many choices and decisions, person-centred care and informed consent are important: it contributes to a higher sense of choice and control for pregnant women. This is especially important during labour and birth, as it is associated with more positive birth outcomes, both on a psychological and a physical level.<sup>8</sup> <sup>9</sup> However, women frequently report that informed consent for procedures during labour and birth is absent, including instances where their explicit refusal is over-ruled.<sup>10–12</sup> As well as directly violating ethical and legal norms, this can result in negative consequences for the birthing process; women's labour and birth experience; and hence quality and safety of care.<sup>13</sup>

Research on how frequently consent requirements are not met during labour and birth is limited. In the Netherlands, 11.8% of women who gave birth reported not being asked for consent prior to procedures such as vaginal examinations or an episiotomy.<sup>14</sup> About half of these women reported this as upsetting. In the USA, over two-thirds of doulas and nurses reported witnessing a lack of informed consent for procedures.<sup>10</sup> Thompson and Miller<sup>11</sup> reported considerable variation in the prevalence of informed consent during labour and birth among Australian women: 26% reported unconsented episiotomy, 13% unconsented vaginal examinations and 3% unconsented emergency caesarean section.<sup>11</sup> There are also reports of women explicitly declining a procedure, after which the procedure is carried out against their wishes; in a Dutch survey, 3% of all respondents reported that an intervention was continued despite declining it, which was considered upsetting by 93%.<sup>14</sup> There is, as yet, no knowledge for which procedures this occurs most often.

Nor is there knowledge on women's evaluation of not meeting consent requirements. In Spain, women report insufficient information provision and wish to have a more active role in decision-making during labour and birth.<sup>15</sup> At the same time, a qualitative study on informed consent from Norway showed that not all women are receptive to extensive information during birth and some prefer their care provider to make decisions for them.<sup>16</sup> Thus, consent preferences during labour and birth may vary among women and need to be investigated in more depth.

The aims of this study were to investigate (1) to what extent and for which procedures women report that consent requirements were not met during labour and birth and/or inadequate information was provided, (2) how frequently women consider consent requirements not being met upsetting and (3) which personal characteristics (age, ethnicity, education level and parity) are associated with consent requirements not being met.

## METHODS

### Study setting

The Dutch maternity care system is divided into primary midwife-led and secondary obstetrician-led care. Pregnant women with an uncomplicated pregnancy receive primary midwife-led care and can choose between giving birth at home, in a birth centre or in the hospital. Women with risk factors are transferred to secondary obstetrician-led care in a hospital, where hospital-based midwives and (resident) obstetricians provide care.<sup>17</sup>

Informed consent for medical procedures became a legal requirement in the Netherlands in 1995. This law, updated in 2020, states that the patient needs to be informed about the content, goal, consequences and alternative(s) of the proposed procedure, including not performing it. The law allows for the possibility of both verbal and non-verbal consent. For invasive and surgical procedures explicit consent is required, which is usually verbally obtained. However, the law does not specify which procedures are 'invasive' or 'surgical'. Although written consent is not a specific requirement in the Netherlands, for most invasive procedures the care provider often keeps record of consent—verbal or written—in the patient file.<sup>18</sup>

#### Terminology

We acknowledge that not all pregnant/birthing people identify as women. For brevity we use 'women', but this can be read as 'women and all other pregnant/ birthing people'.<sup>19</sup>

#### Study design

In this cross-sectional study, an open online survey on disrespect and abuse and informed consent was conducted between 26 October and 17 December 2020. The current study focuses on the questions on informed consent. The study is reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (guideline for reporting observational research) and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).

#### Measurement tool

The questionnaire was developed by a multidisciplinary team and was tested in multiple feedback rounds within the team. In order to establish face and content validity, the questionnaire was piloted among client representatives and adapted based on the feedback given.

The questionnaire consisted of items regarding the respondents' personal characteristics: age, ethnicity (based on the respondents' country of birth and both her parents' country of birth<sup>20</sup>), education level<sup>21</sup> and parity. Items related to pregnancy and birth were singleton or multiple pregnancy, responsible care provider at onset of pregnancy and onset of birth, actual place of birth, onset of labour and mode of birth. Additional information on the classification of the characteristics can be found in online supplemental material 1.

Informed consent was investigated through a series of questions repeated for 10 common labour procedures: induction of labour (IOL), external cardiotocography (CTG), fetal scalp electrode placement, artificial rupture of membranes (AROM), vaginal examination, augmentation of labour, episiotomy, postpartum oxytocin administration, prelabour caesarean section (prelabour CS) and caesarean section during labour (CS during labour). See online supplemental material 2 for additional information on the procedures. Respondents were asked whether the procedure was offered, whether they consented or refused, whether the information provision was sufficient and, if they underwent unconsented procedures, whether they found this upsetting. See online supplemental material 3 for a flow chart of the questions asked. After answering the questions about the 10 common procedures, respondents were given the option of filling out the same set of questions for a procedure not listed.

#### Sampling techniques

The survey was built in an online survey software program (Survalyzer, Utrecht, the Netherlands). Respondents were mostly recruited via social media with the help of social media influencers and organisations. In total, 58 social media influencers were approached, of which 16 helped to disseminate the questionnaire through Instagram on voluntary basis. Seventeen organisations representing seldom-heard groups in society were approached, of which nine voluntarily disseminated the questionnaire through their social media channels or live events. See online supplemental material 4 for additional information on sampling techniques and for examples of how respondents were recruited.

#### Analyses

The completed questionnaires were imported into SPSS V.26 (IBM). Questionnaires that were terminated early were included in the analysis if the items on 'informed consent' were filled out. The characteristics of the respondents were compared with statistics of the Dutch National Perinatal Registry (Perined) and Statistic Netherlands. Characteristics were compared by  $\chi^2$  tests for homogeneity; p levels of <0.05 were considered statistically significant.

Descriptive statistics were used to show the frequencies and percentages of consent, refusal and information provision per procedure, including the number of respondents who reported unmet consent requirements as upsetting. Descriptive statistics were also used to show how many respondents explicitly declined a proposed procedure, divided into respondents whose refusal was respected and respondents whose refusal was not respected/over-ruled.

A multivariable logistic regression analysis was used to test whether personal characteristics were associated with reported consent, dichotomised into:

- Consent requirements met: consent asked by the care provider and given by the woman, after which the procedure was performed OR consent asked by the care provider and declined by the woman, after which the refusal was respected and the procedure not performed.
- 2. Consent requirements *not* met: consent not asked and the procedure performed regardless, or consent asked and the woman declined after which the refusal was over-ruled and the procedure was still performed.

Age, ethnicity, education level and parity were included in the analyses as characteristics. Adjusted ORs (AOR) with 95% CI per category were calculated. ORs above 1 indicated increased odds of reporting unmet consent requirements.

#### Patient and public involvement

Throughout the research design and process of this study, two client representatives were involved as equal coauthors. They codefined the research aims, codesigned the questionnaire, supported the data collection and contributed to the writing of this manuscript.

#### RESULTS

In total, 13 359 respondents started the questionnaire. A total of 1941 respondents were excluded, leaving 11 418 respondents suitable for analysis. A flow chart of the respondents can be found in online supplemental material 5.

The respondent characteristics are shown in table 1. The largest group of respondents were between 30 and 34 years old at the time of giving birth (44.8%). In the study population 101 nationalities were represented; however, the majority of respondents were of Dutch origin (87.7%). In the national data, this is 71.5%. More than half of the respondents were nulliparous (57.4%). Most respondents gave birth in the hospital in obstetrician-led care (63.6%), which is less than the national percentage (72.7%). In terms of mode of birth, 74.9% had a spontaneous vaginal birth, similar to 76.5% nationally. 9.2% of the respondents had an assisted vaginal birth and 15.0% had a caesarean section. The  $\chi^2$  tests revealed that all characteristics statistically differed from the Dutch population.

Table 2 includes the results of all included respondents, showing the reported consent and refusal per procedure, including the number of respondents who reported consent not asked and refusal over-ruled as upsetting. The most performed procedure was vaginal examination (93.1%); prelabour CS was the least performed (4.8%). Among all procedures that took place, not being asked for consent was most often reported for postpartum oxytocin administration (47.5%) and episiotomy (41.7%) and least often for prelabour CS (2.6%) and vaginal examination (6.8%).

When consent was not asked, the proportion of respondents reporting this as upsetting ranged from 6.9% (external CTG) and 15.9% (AROM) to 30.7% (augmentation of labour), with a higher proportion for a small number of respondents who had a prelabour CS (33.3%, n=5). Over-ruling a respondent's refusal was reported most often for augmentation of labour (2.2%) and episiotomy (1.9%). When refusal was over-ruled, the proportion of respondents reporting this upsetting ranged from 67.4% for episiotomy to 92.7% for vaginal examination, not counting prelabour CS (100%, n=1).

When respondents did not know if the procedure was performed, this was classified as missing value. This was 0.2% (n=25) for IOL, 2.8% for external CTG (n=239), 5% for fetal scalp electrode (n=414), 2% for vaginal examination (n=213), 1.7% for AROM (n=179), 0.8% for augmentation of labour (n=53), 0.3% for episiotomy (n=37), 15.7% for post-partum oxytocin administration (n=1669) and 0% for caesarean section.

Table 3 shows the total number of respondents who refused a procedure, and whether the refusal was respected or over-ruled. IOL and CS during labour were most often declined by respondents (both 8.7%). Of all respondents who declined IOL, 92.6% had their refusal respected: the procedure was not performed (n=277). For CS during labour, this was 88.5% (n=100). Among respondents who declined vaginal

examinations, 56.9% had their refusal over-ruled (n=41). For external CTG this was 53.2% (n=25).

Table 4 summarises consent per procedure, presented as 'consent requirements met' and 'consent requirements not met'. Consent requirements not being met was reported most often for postpartum oxytocin administration (46.9%) and episiotomy (41.3%) and least often for prelabour CS (2.7%) and vaginal examination (7.2%). Information provision was reported as inadequate more often when consent requirements were not met compared with when they were.

The respondents also had the opportunity to fill out the questions for a procedure that was not listed. The procedures mentioned most often were manual placental removal (n=95), of which 26.3% reported unmet consent requirements, suturing (n=60), of which 18.6% reported unmet consent requirements, fetal scalp blood sampling (n=44), of which 43.1% reported not meeting consent requirements, and catheterisation (n=42), of which 39.0% reported unmet consent requirements.

Significant associations between the respondents' characteristics and unmet consent requirements are presented as AORs per procedure in table 5. Respondents who themselves and one or both their parents were born abroad had increased odds of reporting unmet consent requirements for IOL (AOR 1.96) and vaginal examination (AOR 1.48) compared with respondents of whom both parents were born in the Netherlands. For oxytocin post partum, these respondents had decreased odds of reporting unmet consent requirements (AOR 0.65). Respondents with upper secondary school or higher vocational training and respondents with a bachelor's, master's or doctoral degree had increased odds for reporting unmet consent requirements for external CTG (AOR 1.45 and 1.86) and augmentation of labour (AOR 1.98 and 2.18), compared with respondents who either had primary school, first 3 years of secondary school or lower level of vocational training. Multiparous respondents had decreased odds of reporting unmet consent requirements compared with primiparous for all procedures (AOR ranging from 0.54 to 0.85), except CS during labour.

#### DISCUSSION

In this study, we aimed to investigate to what extent and for which procedures women report that consent requirements were not met and/or inadequate information was provided during labour and birth; how frequently women consider unmet consent requirements upsetting; and which personal characteristics are associated with reporting unmet consent requirements.

Although the majority of women reported that consent requirements were met, unconsented procedures were common, ranging from 2.7% (prelabour CS) to 46.9% (postpartum oxytocin). Most

Table 1 Char	acteristics of the respondents (n=11 418) compared with nation	al data		
		n (%) or mean	[SD]	X <sup>2</sup>
Characteristics		Respondents	National Perinatal Registry* or Statistics Netherlands †	P value
Maternal age at	Moon [SD]	20 57 [2 07]		<0.001
time of birth	25	616 (5 6)	12 /00 /2 /)*	<0.001
	25 20	2770 (24 2)	13 499 (0.4)	
	30.34	1024 (11 8)	64 200 (20 8)*	
	35_30	1505 (13.7)	30 / 20 (18 8)*	
	×10	178 (1.6)	5811 (3.6)*	
	Missing	/25	5044 (5.0)	
Maternal	Roth parents horn in the Netherlands	9517 (87 7)	3 158 000 (71 5)+	~0.001
ethnicity	Recondent and one or both her parents born abroad	384 (3.5)	762 000 (17 3)+	<0.001
	Respondent and one of both her parents both abroad	055 (2 2)	/02 000 (17.3)1	
	abroad	900 (0.0)	495 000 (11.2)1	
	Missing	565		
Maternal education level at	Primary school, first 3 years of secondary school or lower level of vocational training	673 (6.1)	975 000 (22.6)†	<0.001
time of birth	Upper secondary school or higher vocational training	2659 (24.3)	1 710 000 (39.6)†	
	Bachelor's, master's or doctoral degree programmes	7617 (69.6)	1 633 000 (37.8)†	
	Missing	469		
Parity	Nulliparous	6556 (57.4)	71 950 (44.5)*	< 0.001
	Multiparous	4862 (42.6)	89 589 (55.5)*	
Singleton	Singleton pregnancy	11 198 (98.1)	159 213 (98.5)*	0.001
or multiple pregnancy	Multiple pregnancy	220 (1.9)	2477 (1.5)*	
Responsible care	Midwife-led care	9691 (84.9)	143 312 (88.0)*	< 0.001
provider at onset	Obstetrician-led care	1692 (14.8)	21 975 (11.7)*	
of pregnancy	General practitioner	25 (0.2)		
	Other	10 (0.1)		
Responsible care	Midwife-led care	6915 (60.6)	77 623 (47.7)*	< 0.001
provider at onset	Obstetrician-led care	4487 (39.3)	78 204 (48.0)*	
of labour	General practitioner	15 (0.1)		
	No care provider	1 (0.0)		
Onset of labour	Spontaneous	7692 (67.3)	104 906 (67.0)*	< 0.001
	Spontaneous rupture of membranes, followed by an induction with tablets or oxytocin	398 (3.5)	39 050 (25.0)*	
	Rupture of membranes to induce labour	681 (6.0)		
	Induction of labour with tablets/Foley catheter/oxytocin	2004 (17.6)		
	Prelabour caesarean section	643 (5.6)	12 460 (8.0)*	
Mode of birth	Spontaneous vaginal birth	7195 (63.0)	118 823 (76.5)	< 0.001
	Spontaneous vaginal birth with episiotomy	1356 (11.9)	11 240 (7.2)*	
	Vacuum or forceps delivery	1053 (9.2)		
	Attempted vacuum or forceps, followed by caesarean section	101 (0.9)	12 962 (8.3)*	
	Caesarean section during labour	1130 (9.9)		
	Prelabour caesarean section	583 (5.1)	12 460 (8.0)*	
Pharmacological	No pain relief	7014 (64.8)	93 334 (57.7)*	< 0.001
pain relief‡	Epidural	2417 (22.3)	68 386 (42.3)*	
	Remifentanil	1026 (9.5)		
	Epidural and remifentanil	154 (1.4)		
	Other	179 (1.7)		
	Epidural and 'other'	29 (0.3)		
	Remifentanil and 'other'	5 (0.0)		
	Epidural, remifentanil and 'other'	4 (0.0)		

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	Tab	le 1	Continued
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		n (%) or mean	[SD]	X <sup>2</sup>
Characteristics		Respondents	National Perinatal Registry* or Statistics Netherlands †	P value
Actual place of	Midwife-led care at home	2329 (20.4)	20 487 (12.7)*	<0.001
birth	Midwife-led care at birth centre	452 (4.0)	4241 (2.6)*	
	Midwife-led care at the hospital	1330 (11.6)	19 309 (11.9)*	
	Obstetrician-led care at the hospital	7260 (63.6)	117 516 (72.7)*	
	Other	47 (0.4)	155 (0.1)*	

\*Based on women in the Netherlands who gave birth in 2019 registered by Perined (n=162 832). Not all add up to 100% due to unknown data. †Based on women aged 15–55 in the Netherlands in 2019 registered by Statistics Netherlands (n=4 414 000).

‡Respondents who had a prelabour caesarean section were excluded from this question.

unconsented procedures were those where consent was not asked, most often reported for postpartum oxytocin (47.5%) and episiotomy (41.7%). In other countries, episiotomy is also identified as procedure for which consent is often not asked: in 39% of the cases in Italy and 34.5% in Australia.<sup>11 22</sup> Over-ruled refusal occurred less frequent; most often reported for augmentation of labour (2.2%) and episiotomy (1.9%). Vaginal examination was the most often performed procedure (93.1%) and mostly performed with consent: in 92.8% of the cases. For all procedures, information provision was reported as inadequate more often when consent requirements were not met, compared with when they were met, which is consistent with previous findings.<sup>11 15</sup>

When a procedure was performed without asking consent, the proportion of respondents reporting this as upsetting ranged from 6.9% (external CTG) to 30.7% (augmentation of labour). This indicates that while not all women consider unmet consent requirements upsetting, a proportion is clearly affected by it. The results from the current study provide insight into procedures for which the meeting of consent requirements is most important for women. Even so, the aim should be that all procedures are performed with consent, both on ethical and legal grounds, and because it is important for quality and safety: not meeting consent requirements increases the chance of negative and traumatic birth experiences.<sup>23 24</sup> Every woman should have the opportunity to make an informed and autonomous decision regarding procedures she may receive during labour and birth. To secure enough time for information provision and discussion of women's personal preferences, it is recommended to initiate the shared decision-making process in the antenatal period.<sup>25 26</sup> This lays the ground for informed decision-making during labour and birth, where consent will still be required. Sometimes, women may want to make a decision about some procedures antenatally. The woman's preference is guiding here, and antenatal decisions are always reversible.<sup>27</sup>

Women do not often refuse procedures, ranging from 0.7% for external CTG and vaginal examination

to 8.7% for IOL and CS during labour. However, if women decline a procedure, the frequency of them being over-ruled is high, in some cases even more than 50%. In the case of vaginal examination, 56.9% of the refusals were over-ruled. A study from the UK shows that over 40% of the women did not feel as they could refuse a vaginal examination.<sup>28</sup> Over-ruling a woman's refusal directly contravenes widely accepted ethical and legal requirements: it violates the woman's bodily integrity and fundamental rights; can affect the birthing process negatively, thus negatively impacting quality of care; and negatively impacts a woman's experiences.<sup>29 30</sup> This negative impact was also found in the current study: when women's refusal was overruled, the proportion of respondents considering this as upsetting was uniformly high: ranging from 67.4% (episiotomy) to 92.7% (vaginal examination).

It is unknown what happened in the situations where women report a refusal of a procedure. Some respondents may have explicitly said no prior to or during the procedure. Others may have said no or expressed their ideas against the procedure, but felt pressured, experiencing limited opportunity to discuss their wishes and finally complied with the procedure under duress.<sup>31 32</sup> A study from Switzerland showed that 27% of women experience some form of informal coercion during birth.<sup>30</sup> Similar numbers were found in the USA, where 30% of the women felt pressured.<sup>33</sup> This suggests significant discrepancy between care providers and patients' perception of whether consent requirements were met; care providers may have misinterpreted silence or reluctant compliance or coerced agreement as consent.<sup>34 35</sup> Since consent must be voluntary and needs to be given before it can be received, priority must be given to women's perceptions. This underlines the need for continuous careful attention for and communication with women throughout labour and birth to prevent miscommunication and procedures being done without women's genuine and voluntary informed consent.

Having a migrant background is a risk factor for unconsented IOL and vaginal examination. Other studies confirm that the burden of unconsented

	Procedure perfo	rmed, n (%)					Procedure not p	oerformed, n (%		
Procedure Consent ↓ →	Total performed	Consent asked and given*	Consent not asked*	Considered upsetting	Refusal over- ruled*	Considered upsetting	Total not performed	Refusal respected*	Not applicable anymore†	Not discussed‡
Induction of labour	3145 (27.6)	2862 (91.0)	261 (8.3)C	54 (20.7)	22 (0.7)	15 (68.2)	8248 (72.4)	277 (6.2)	1306 (15.8)	6665 (80.8)
External cardiotocography	6329 (77.6)	3948 (62.4)	2356 (37.2)	163 (6.9)	25 (0.4)	23 (92.0)	1828 (22.4)	22 (1.2)	61 (3.3)	1745 (95.5)
Fetal scalp electrode	4275 (53.8)	2696 (63.1)	1527 (35.7)	291 (19.1)	52 (1.2)	40 (76.9)	3673 (46.2)	98 (2.7)	92 (2.5)	3483 (94.8)
Vaginal examination	9770 (93.1)	9064 (92.8)	665 (6.8)	176 (26.5)	41 (0.4)	38 (92.7)	719 (6.9)	31 (4.3)	45 (6.3)	643 (89.4)
Artificial rupture of membranes	5778 (54.7)	4856 (84.0)	901 (15.6)	143 (15.9)	21 (0.4)	15 (71.4)	4778 (45.3)	82 (1.7)	360 (7.5)	4336 (90.7)
Augmentation of labour	2786 (44.4)	2064 (74.1)	662 (23.8)	203 (30.7)	60 (2.2)	49 (81.7)	3495 (55.6)	60 (1.7)	202 (5.8)	3233 (92.5)
Episiotomy	2308 (21.7)	1303 (56.5)	962 (41.7)	255 (26.5)	43 (1.9)	29 (67.4)	8322 (78.3)	125 (1.5)	454 (5.5)	7743 (93.0)
Postpartum oxytocin administration	4788 (53.4)	2473 (51.6)	2274 (47.5)	561 (24.7)	41 (0.9)	34 (82.9)	4181 (46.6)	152 (3.6)	112 (2.7)	3917 (93.7)
Caesarean section during labour	1201 (14.5)	974 (81.1)	214 (17.8)	48 (22.4)	13 (1.1)	10 (76.9)	7061 (85.5)	100 (6.2)	524 (7.4)	6437 (91.2)
Prelabour caesarean section§	587 (4.8)	571 (97.3)	15 (2.6)	5 (33.3)	1 (0.2)	1 (100.0)	Missing	Missing	Missing	
*The colours used in the t'not applicable anymou #'Not discussed' encom §Informed consent ques	ese columns align wit re' encompasses situs passes situations in w tions for prelabour ca	h the coloured categ ations in which the pr which there was no q aesarean section wer	ories shown in online ocedure was conside uestion of the procec e only asked to respo	e supplemental ma ered, but before co dure at all. ondents who had a	aterial 3. Insent could be a	sked and/or the rean section.	procedure could be	performed it was	not needed anymor	ai

Table 3	Respondents who reported de	clining a procedure amo	ong all respondents w	ho were offered the p	rocedure, divided into refusal
respected,	after which procedure was not	performed, and refusal	over-ruled, after whi	ch the procedure was	performed

Procedure	Total number of offered procedures	Refused a procedure, n (%)	Refusal was respected, n (%)	Refusal was over- ruled, n (%)
Induction of labour	3422	299 (8.7)	277 (92.6)	22 (7.4)
External cardiotocography	6351	47 (0.7)	22 (46.8)	25 (53.2)
Fetal scalp electrode	4373	150 (3.4)	98 (65.3)	52 (34.7)
Vaginal examination	9801	72 (0.7)	31 (43.1)	41 (56.9)
Artificial rupture of membranes	5860	103 (1.8)	82 (79.6)	21 (20.4)
Augmentation of labour	2846	120 (4.2)	60 (50.0)	60 (50.0)
Episiotomy	2433	168 (6.9)	125 (74.4)	43 (25.6)
Postpartum oxytocin administration	4940	193 (3.9)	152 (78.8)	41 (21.2)
Caesarean section during labour	1301	113 (8.7)	100 (88.5)	13 (11.5)
Prelabour caesarean section	587	1 (0.2)	0	1 (100.0)

procedures is not evenly distributed over groups.<sup>30 36</sup> In Switzerland, migrant women experience more informal coercion during birth compared with native women.<sup>30</sup> In the USA, women with black racial identity experience more unconsented procedures compared with white women.<sup>33</sup> These findings match the evidence on existing ethnic and racial disparities in maternity care and need to be taken into account in addressing the issue.<sup>37</sup> In the current study, having a migrant background was found to be a protective factor for unconsented oxytocin post partum. Oxytocin post partum had the highest number of respondents who did not know or remember if they received the procedure (15.7%). This may undermine the reliability of the findings on this procedure.

Having at least a bachelor's degree is a risk factor for reporting unconsented external CTG and augmentation of labour. Being primiparous was a risk factor for absence of consent for almost all procedures. Research by O'Cathain *et al* showed similar results: multiparous

women and women who left full-time education before 18 years old were more likely to experience informed choices during antenatal care.<sup>38</sup> Women who had more extended education in their lives may be more aware of their rights, making them less easily satisfied with decision-making procedures in which they are insufficiently involved. In line with these findings, as multiparous women have previous experiences with giving birth, it might be easier for them to be proactive in the decision-making process.<sup>39</sup> Furthermore, multiparous women often need fewer procedures during labour and birth. Chalmers and Dzakpasu<sup>40</sup> found that, as the number of interventions during a woman's labour and birth increased, her involvement in decision-making declined.<sup>40</sup> An increase in age decreases the chance of unconsented procedures. These results are similar to previous findings; women with higher age have less chance of experiencing lack of choices and lack of communication during birth.<sup>14</sup>

 Table 4
 Consent requirements met and consent requirements not met per procedure among all respondents who were offered the procedure

	Total number	Consent requirements met, n (%)		Consent requirements not met, n (%)	
Procedure	of offered procedures	Total	Received sufficient information*	Total	Received sufficient information†
Induction of labour	3422	3139 (91.7)	2626 (83.7)	283 (8.3)	144 (50.9)
External cardiotocography	6351	3970 (62.5)	3640 (91.7)	2381 (37.5)	1472 (61.8)
Fetal scalp electrode	4373	2794 (63.9)	2357 (84.4)	1579 (36.1)	676 (42.8)
Vaginal examination	9801	9095 (92.8)	8757 (96.3)	706 (7.2)	386 (54.7)
Artificial rupture of membranes	5860	4938 (84.3)	4521 (91.6)	922 (15.7)	513 (55.6)
Augmentation of labour	2846	2124 (74.6)	1772 (83.4)	722 (25.4)	282 (39.1)
Episiotomy	2433	1428 (58.7)	1194 (83.6)	1005 (41.3)	468 (46.6)
Postpartum oxytocin administration	4940	2625 (53.1)	2249 (85.7)	2315 (46.9)	895 (38.7)
Caesarean section during labour	1301	1074 (82.6)	870 (81)	227 (17.4)	122 (53.7)
Prelabour caesarean section	587	571 (97.3)	522 (91.4)	16 (2.7)	8 (50)

\*The proportion of respondents who indicated they had received sufficient information regarding the procedure of the number of respondents by whom the consent requirements were met.

†The proportion of respondents who indicated they had received sufficient information regarding the procedure of the number of respondents by whom the consent requirements were not met.

Table 5The ass	sociation between respondent characteristics and reported 'consent requirements $\mathbf{n}$	ot met'
Respondent characte	ristics	Adjusted OR (95% CI)*
Induction of labour		
Ethnicity	Both parents born in the Netherlands	Ref
	Respondent and one or both her parents born abroad	1.96 (1.15 to 3.34)
	Respondent born in the Netherlands, one or both her parents born abroad	1.46 (0.99 to 2.17)
Parity	Nulliparous	Ref
	Multiparous	0.65 (0.49 to 0.87)
External cardiotocog	raphy	
Increasing age		0.97 (0.96 to 0.99)
Education level	Primary school, first 3 years of secondary school or lower level of vocational training	Ref
	Upper secondary school or higher vocational training	1.45 (1.14 to 1.84)
	Bachelor's, master's or doctoral degree programmes	1.86 (1.48 to 2.35)
Parity	Nulliparous	Ref
	Multiparous	0.85 (0.75 to 0.96)
Fetal scalp electrode		
Increasing age		0.97 (0.96 to 0.99)
Parity	Nulliparous	Ref
	Multiparous	0.77 (0.66 to 0.89)
Vaginal examination		
Ethnicity	Both parents born in the Netherlands	Ref
	Respondent and one or both her parents born abroad	1.48 (1.00 to 2.18)
	Respondent born in the Netherlands, one or both her parents born abroad	1.02 (0.77 to 1.35)
Parity	Nulliparous	Ref
	Multiparous	0.65 (0.55 to 0.78)
Artificial rupture of n	nembranes	
Parity	Nulliparous	Ref
	Multiparous	0.54 (0.46 to 0.64)
Augmentation of lab	our	
Increasing age		0.94 (0.92 to 0.96)
Education level	Primary school, first 3 years of secondary school or lower level of vocational training	Ref
	Upper secondary school or higher vocational training	1.98 (1.25 to 3.13)
	Bachelor's, master's or doctoral degree programmes	2.18 (1.40 to 3.39)
Parity	Nulliparous	Ref
	Multiparous	0.68 (0.54 to 0.87)
Episiotomy		
Parity	Nulliparous	Ref
	Multiparous	0.75 (0.60 to 0.94)
Postpartum oxytocin		
Increasing age		0.96 (0.94 to 0.98)
Ethnicity	Both parents born in the Netherlands	Ref
	Respondent and one or both her parents born abroad	0.65 (0.45 to 0.95)
	Respondent born in the Netherlands, one or both her parents born abroad	0.88 (0.71 to 1.08)
Parity	Nulliparous	Ref
	Multiparous	0.73 (0.65 to 0.83)
Caesarean section du	rring labour†	
Increasing age		0.94 (0.91 to 0.98)
*Variables with at least on tPrelabour caesarean sect	ie statistically significant result are presented in this table. Significant adjusted ORs are shown in bold.	

Ref, reference category.

This study reports a concerning number of unconsented procedures and situations with insufficient information provision, including the over-ruling of refusals by care providers. This indicates a mismatch between legal and ethical informed consent requirements and daily practice.<sup>34 41 42</sup> Care providers often demonstrate poor understanding of the rights of women and their babies.<sup>43</sup> Care providers also cite women's competence, their vulnerability and emergency situations as barriers for meeting consent requirements during childbirth. Although these are challenges that should be acknowledged, this does not take away women's explicit right to consent to or refuse any procedure.<sup>27 44</sup> At minimum, even a short or simple interaction could establish (at least some form of) consent and could make a big difference in a woman's experience and hence the quality of her care. It is important that care providers receive specific training in how to meet consent requirements in any situation, even in vulnerable or time-constrained ones.  $^{\rm 27}$ 

Underlying factors of unmet consent requirements also stem from institutional and societal structures. The medicalisation of childbirth involved an increasing trust in scientific and factual knowledge, at the expense of empathy, caring and attention for women's personal experience.<sup>45</sup> Furthermore, strict protocols and evidence-based guidelines make it difficult for care providers to deviate from standards, explaining the high proportions of refusals over-ruled.<sup>43</sup> A lack of respect for women's autonomy may also stem from structural gender inequality in society.<sup>46</sup> Women in general, and in the maternity setting in particular, are held to exacting standards of maternal sacrifice and are expected to take on a passive role.47 48 Subsequently, care providers have control.<sup>49</sup> This also shapes women's expectations and could also explain why respondents did not consider unmet consent requirements upsetting. This suggests there are deeper dynamics in healthcare and society that limit women's autonomy during labour and birth. This substantiates that a broad approach is needed to improve this issue.

#### Strengths and limitations

To our knowledge, this is the first study focusing on the incidence of unmet consent requirements in maternity care and the extent to which women consider this upsetting. We distinguished between two forms of unmet consent requirements: 'consent not being asked' and 'refusal overruled'. We also included situations in which procedures were not performed due to refusals being respected. Information provision was evaluated, which is an essential element for validly consenting to or declining a procedure. Our study had a large number of responses with over 13 000 women filling out the questionnaire.

The questionnaire focused on women's perceptions of being informed and being asked for consent; we did not observe what happened in practice or get care providers' perspectives. Women's subjective perceptions are important because consent is theirs to give or withhold. Further study is required to understand how care providers understand and experience these situations; what challenges they face in meeting consent requirements; and what training may be necessary to improve the better meeting of consent requirements during labour and birth.

Our study only asked women whether they consented to or declined a proposed procedure, and in case of unmet consent requirements, whether they found this upsetting. We did not ask how consent took place (verbally, nonverbally, in writing; once or after repeated asking, etc). We recommend further research to gain in-depth information on which types of consent are most common during labour and birth, which women prefer most and how the process of information provision and decisionmaking, culminating in consent and refusal, unfolds. Furthermore, we recommend qualitative methods to further study the impact of unmet consent requirements on labouring women.

Some respondents indicated they did not remember if a certain procedure took place. It is possible women underwent procedures unnoticed, which suggests that consent requirements are more frequently unmet than reported. It is also possible that at the time, women were aware the procedure took place but do not remember any more, for example, due to the intense experience of labour and birth or the time elapsed. This recall bias could have influenced the overall results of the study. Currently, there is insufficient evidence on what the most effective timing is of assessment of childbirth satisfaction.<sup>50</sup>

In addition to consenting to or declining procedures proposed by care providers, it is also possible that women may have wished or requested that a certain procedure would be performed, but that these wishes were ignored. Maternal requests for procedures were not included in our study. As literature on maternal request often focuses on caesarean section,<sup>51</sup> we recommend to study maternal requests for other procedures as well.

Although this study included 101 nationalities, overall, women with a migrant background were underrepresented, as were women who either had primary school, first 3 years of secondary school or lower level of vocational training as their main education. Previous research shows that seldom-heard groups more often experience a lower quality of care and less optimal communication during labour and birth. As this could be relevant to informed consent, it is possible the real incidence of unconsented procedures is higher.<sup>37</sup>

The study consisted of more women who gave birth at home, and more nulliparous women compared with the national average. Women who give birth at home often experience more autonomy,<sup>52</sup> which may have led to an underestimation of the number of unconsented procedures in the current study. Nulliparous women report unmet consent requirements more often, which could indicate an over-representation of the unconsented procedures.

#### CONCLUSION

Although ethically and legally required, consent for performing a procedure is frequently absent in Dutch maternity care. In some instances, procedures were performed against the women's explicit refusal. Information provision is also often experienced as inadequate, especially when consent requirements reportedly were not met. This lack of person-centred care negatively affects the quality of maternity care and can have negative consequences for labouring women. More awareness is needed on meeting necessary consent requirements during labour and birth. As there is considerable variation in how frequently unconsented procedures were considered upsetting, person-centred care requires that enough time is secured to discuss women's personal preferences by initiating the shared decision-making process in the antenatal period. Further research is needed to understand the impact of unmet consent requirements on labouring women, what challenges care providers face in obtaining consent and what is needed to improve this.

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# SUPPLEMENTAL MATERIAL 1. ADDITIONAL INFORMATION ON THE CLASSIFICATION OF THE PERSONAL CHARACTERISTICS AND PREGNANCY AND BIRTH CHARACTERISTICS

#### Personal characteristics:

- Maternal age at time of birth: <25/25-29/30-34/35-39/>40.
- Maternal ethnicity: Both parents are born in the Netherlands/Respondent and one or both her parents born abroad/Respondent born in the Netherlands, one or both her parents born abroad.
- Educational level at time of birth: Primary school, first three years of secondary school, or lower level
  of vocational training/Upper secondary school or higher vocational training/Bachelor, master or
  doctoral degree programs.
- Parity: nulliparous/multiparous.

#### Pregnancy and birth characteristics:

- Singleton/multiple pregnancy.
- Responsible care provider at onset of pregnancy: midwife-led care/obstetrician-led care/general practitioner/other.
- Responsible care provider at onset of labour: midwife-led care/obstetrician-led care/general practitioner/no care provider.
- Onset of labour: spontaneous/spontaneous rupture of membranes, followed by an induction with tablets or oxytocin/rupture of membranes to induce labour/induction of labour with tablets, foley catheter or oxytocin/prelabour caesarean section.
- Mode of birth: spontaneous vaginal birth/spontaneous vaginal birth with episiotomy/vacuum or forceps/attempted vacuum or forceps, followed by caesarean section/caesarean section during labour/prelabour caesarean section.
- Pharmacological pain relief: no pain relief/epidural/remifentanil/epidural an remifentanil/other/epidural and 'other'/remifentanil and 'other'/epidural, remifentanil and 'other'.
- Actual place of birth: midwife-led care at home/midwife-led care at birth centre/midwife-led care at the hospital/obstetrician-led care at the hospital/other.

# SUPPLEMENTAL MATERIAL 2. ADDITIONAL INFORMATION ON THE TEN INVESTIGATED PROCEDURES AS PROVIDED TO SURVEY RESPONDENTS

Procedure	Description
Induction of labour (IOL)	Induction means that the labour did not start by itself, and had to be
	started with an infusion, medication, a balloon or tablets.
External cardiotocography	CTG stands for 'cardiotocography', which is a method used to monitor
(CTG)	the baby's heart rate, and involves placing a belt around the abdomen of
	the mother.
Fetal scalp electrode placement	Fetal scalp electrode placement is a method used to monitor the baby's
	heart rate, and involves placing an electrode on the baby's head. This
	procedure is used during labour after the membranes have ruptured.
Artificial rupture of the	Artificial rupture of the membranes is when the care provider punctures
membranes (AROM)	the membranes during an vaginal examination. It's also known as
	breaking the waters. It may be done before labour (to induce labour) or
	during labour (accelerate labour).
Vaginal examination	During a vaginal examination the care provider inserts his or her fingers
	into your vagina, for example to see how labour is progressing.
Augmentation of labour	When labour starts spontaneously but does not progress, contractions can
	be stimulated by administering medication.
Episiotomy	An episiotomy is performed when the care provider makes a cut in the
	skin between the vagina and the anus with the aim to help the baby to be
	born faster in the second stage of labour.
Postpartum oxytocin	Oxytocin can be given after childbirth to make the uterus contract, with
administration	the aim to accelerate the birth of the placenta and prevent excessive
	bleeding.
Prelabour caesarean section	A caesarean section is the surgical delivery of a baby through the
(prelabour CS)	mother's abdomen, by making a cut (incision) in the abdomen and
	uterus. A Prelabour caesarean section is most often planned, and is
	performed when the labour has not started yet, for example when the
	baby is breech.
Caesarean section during labour	A caesarean section during labour is performed after the onset of labour.
(CS during labour)	

# SUPPLEMENTAL MATERIAL 3. FLOWCHART OF THE QUESTIONS REGARDING INFORMED CONSENT



# SUPPLEMENTAL MATERIAL 4. ADDITIONAL INFORMATION ON SAMPLING TECHNIQUES

Through the website https://baringervaring.nl/, respondents could access the survey. On the website, respondents were informed about the purpose of the study, the organisation and the investigators linked to the study, the length of time of the survey, data storage and privacy.

When participating in the survey, respondents could win a gift card of 50 euros of a skincare brand. If respondents wanted to have a chance of winning, they had to leave their e-mail address at the end of the survey. To secure the respondents' privacy, collected email addresses were stored separately from the filled out questionnaires.

Data was collected between between October 26 and December 17, 2020. The answers given by the respondents were automatically stored in an online database.

In order to reach respondents, 58 social media influencers active on the platform Instagram were approached, of which 16 helped to disseminate the questionnaire on voluntary basis. The influencers were selected based on the relevance concerning the topic: most influencers recently gave birth themselves. Furthermore, they were also chosen based on variance in personal characteristics, such as age, ethnicity and religion. We also sought variance in parity, type and location of birth with their last child, and their personal birth experiences. Below, an example is given of an Instagram Story post that promoted the study (in Dutch).



Seventeen organisations representing hard-to-reach groups in society were approached, of which nine organisations voluntarily assisted in disseminating the questionnaire through their social media channels or live events. Below, an example of a recruitment flyer is given.



# SUPPLEMENTAL MATERIAL 5. FLOWCHART OF THE RESPONDENTS INCLUDED IN ANALYSIS (N=11,418)

