Sundhedsstyrelsen

NATIONAL CLINICAL GUIDELINE CONCERNING

PRIMIPAROUS WOMEN WITH DYSTOCIA (LACK OF PROGRESS)

2015

National clinical guideline concerning primiparous women with dystocia (lack of progress)

Danish Health and Medicines Authority
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Contents

Quality of evidence and strength of recommendations

QUALITY OF EVIDENCE – THE FOUR LEVELS

Rating quality of evidence and grading strength of recommendations is done based on the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system. See also: http://www.gradeworkinggroup.org and Appendix 7.

High (⊕⊕⊕⊕)

We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate (⊕⊕⊕◯)

We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low (⊕⊕◯◯)

Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low (⊕◯◯◯)

We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

STRENGTH OF A RECOMMENDATION

Strong recommendation for ↑↑

The Danish Health and Medicines Authority (DHMA) makes a strong recommendation for when the desirable consequences of an intervention are judged to clearly outweigh undesirable consequences.

Weak/conditional recommendation for ↑

The DHMA makes a weak/conditional recommendation for when the desirable consequences of an intervention are judged to marginally outweigh undesirable consequences or when the available evidence cannot rule out a significant benefit of an existing practice if the adverse effects of the latter are judged to be few or absent.

Weak/conditional recommendation against ↓

The DHMA makes a weak/conditional recommendation against when the undesirable consequences of an intervention are judged to outweigh desirable consequences and this is unsupported by strong evidence. This recommendation is also

made in case of strong evidence for both beneficial and adverse effects when the balance between them is difficult to determine.

Strong recommendation against ↓↓

The DHMA makes a strong recommendation against in case of high-quality evidence showing that the undesirable consequences of an intervention clearly outweigh desirable consequences. The DHMA also makes a strong recommendation against when the review of the evidence shows with great certainty that an intervention is useless.

Good practice √

Good practice based on professional consensus among the members of the working group who prepared the clinical guideline. The recommendation may be either for or against the intervention. A good practice recommendation is made when relevant evidence is not available. Therefore, this type of recommendation is weaker than the evidence-based recommendations irrespective of whether they are strong or weak.

Key messages

Definition of dystocia

In this guideline, dystocia in primiparous women with a fetus in cephalic presentation is defined as follows:

The active phase of the first stage (the dilatation phase):

- Cervical dilatation of <2 cm assessed over 4 hours.
- In special circumstancesthe diagnosis may be arrived at earlier, in case a cervical dilatation of 2 cm in 4 hours is deemed unlikely.

The descending phase:

- When deemed unlikely that the leading part of the fetus will engage to reach the pelvic floor within 3 hours after the start of the descending phase.

The expulsive phase:

- When deemed unlikely that the child will be born within 2 hours after the start of the expulsive phase.

Recent research indicates that the active phase may not start until the cervix has dilated to 6 cm [1-4]. Therefore, evaluate the situation carefully prior to diagnosing dystocia when the cervix has only dilated to 4-6 cm. See also section 1.5.

Indication for oxytocin augmentation of labour

The active phase of the first stage

√ It is good practice to review the progress with an experienced colleague* in case of suspected dystocia in the active phase.

↑ Consider oxytocin augmentation within an hour after diagnosing dystocia in the active phase of the first stage, if the membranes have ruptured and there are <5 contractions in 10 minutes (⊕○○○).

√ In case of dystocia in the active phase, it is good practice – if the membranes have not ruptured – to perform amniotomy and await progress for another 1-2 hours before deciding whether to initiate oxytocin augmentation.

The second stage

√ It is good practice to review the progress with an experienced colleague* in case of suspected dystocia in the descending phase.

√ It is good practice to review the progress with an experienced colleague* in case of suspected dystocia in the expulsive phase – after 1 hour at the latest.

√ It is good practice to consider oxytocin augmentation in the second stage in case of dystocia and <5 contractions in 10 minutes.

√ It is good practice to consider forced delivery (caesarean section or instrumental vaginal delivery) when the expulsive phase has lasted 2 hours. Forced delivery

should be considered earlier if the parturient woman so desires or if the estimated duration of the expulsive phase exceeds 2 hours.

* Experienced colleague means, e.g., a senior staff midwife or a doctor, depending on local practice.

A review of the progress includes, among other things, assessing the following (e.g. the childbirth checklist and the labour augmentation drip package of the Danish safe childbirth ('Sikre Fødsler') project [5]):

- Fetal heart rate, including indication for CTG
- The perspective of the parturient **
- Risk factors
- Presence of mechanical mismatch
- Descent and rotation of the fetal head
- Rupture of the membranes
- Pattern of contractions
- Cervical progress (assessed, e.g., by means of a partogram)
- Micturition/bladder voiding (particularly in the second stage).

**Perspective of the parturient means preferences, need for pain relief and physical and mental condition.

Dosage regimens for oxytocin

↑ For oxytocin augmentation, consider an initial dosage level of 3.3 mU/min = 20 ml/h when using a solution of 10 IU of oxytocin in 1,000 ml of isotonic sodium chloride solution for infusion (⊕○○○).

√ In the active phase of the first stage (the dilatation phase), it is good practice to increase the dose with 3.3 mU/min = 20 ml/h every 20 minutes until reaching a maximum of 5 contractions in 10 minutes.

√ It is not good practice to let the dosage exceed 180 ml/h = 30 mU/min.[1]

Second-stage dystocia in parturients with an epidural

√ It is good practice to allow the same duration for the descending phase in parturient women with and without an epidural.

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[1] The summary of product characteristics for Syntocinon® indicates a maximum infusion rate of 120 ml/h (20 milliunits/min, 40 drops/min), but also mentions that a higher rate may be needed on rare occasions [6]. From clinical experience and the literature review, the working group finds that it may be relevant to increase the infusion rate up to 180 ml/h for special cases and based on a professional judgment, provided the fetal heart rate is normal and the frequency of contractions does not exceed 5 in 10 minutes. The indication for increasing the infusion rate must always be recorded.

Non-medicinal options

Intravenous fluid therapy

↑ Consider offering intravenous therapy using isotonic Ringer's lactate as an add-on to free oral fluid intake in case of suspected dehydration or slow progress (i.e., without waiting for 4 hours and before the criteria for dystocia have been met) (⊕○○○).

Acupuncture

↓ Acupuncture should only be used as an intervention in case of dystocia afterdue consideration. The available evidence neither demonstrates beneficial nor adverse effects (⊕○○○).

√ It is not good practice to delay relevant options such as amniotomy and oxytocin augmentation in favour of acupuncture.

√ It is good practice to inform the parturient woman about the lack of scientific documentation for beneficial as well as for adverse effects from the use of acupuncture in case of dystocia.

Rebozo

√ If rebozo is offered, it is good practice to document the use for quality follow-up.

√ When offering rebozo, it is good practice to inform the parturient woman that the effects of the treatment and potential adverse effects are undocumented**.**

Amniotomy

√ In case of dystocia in the active phase of the first stage (the dilatation phase), it is good practice to perform amniotomy and await progress for another 1-2 hours before initiating oxytocin augmentation.

√ In case of dystocia in the descending phase, it is good practice to perform amniotomy and await progress for 1 hour before initiating oxytocin augmentation.

√ In case of dystocia in the expulsive phase, it is good practice to perform amniotomy and await progress for 20 minutes before initiating oxytocin augmentation.

Duration of oxytocin augmentation of labour

√ It is good practice that the midwife responsible for the childbirth reviews progress after 4 hours of oxytocin augmentation in the active phase of the first stage (the dilatation phase).

√ In case of a cervical dilatation of <2 cm after 4 hours of oxytocin augmentation, it is good practice to review the progress with an experienced colleague*.

√ It is good practice to consider an additional 2 hours of oxytocin augmentation if a satisfactory pattern of contractions (a maximum of 5 contractions in 10 minutes) has not been reached within 4 hours.

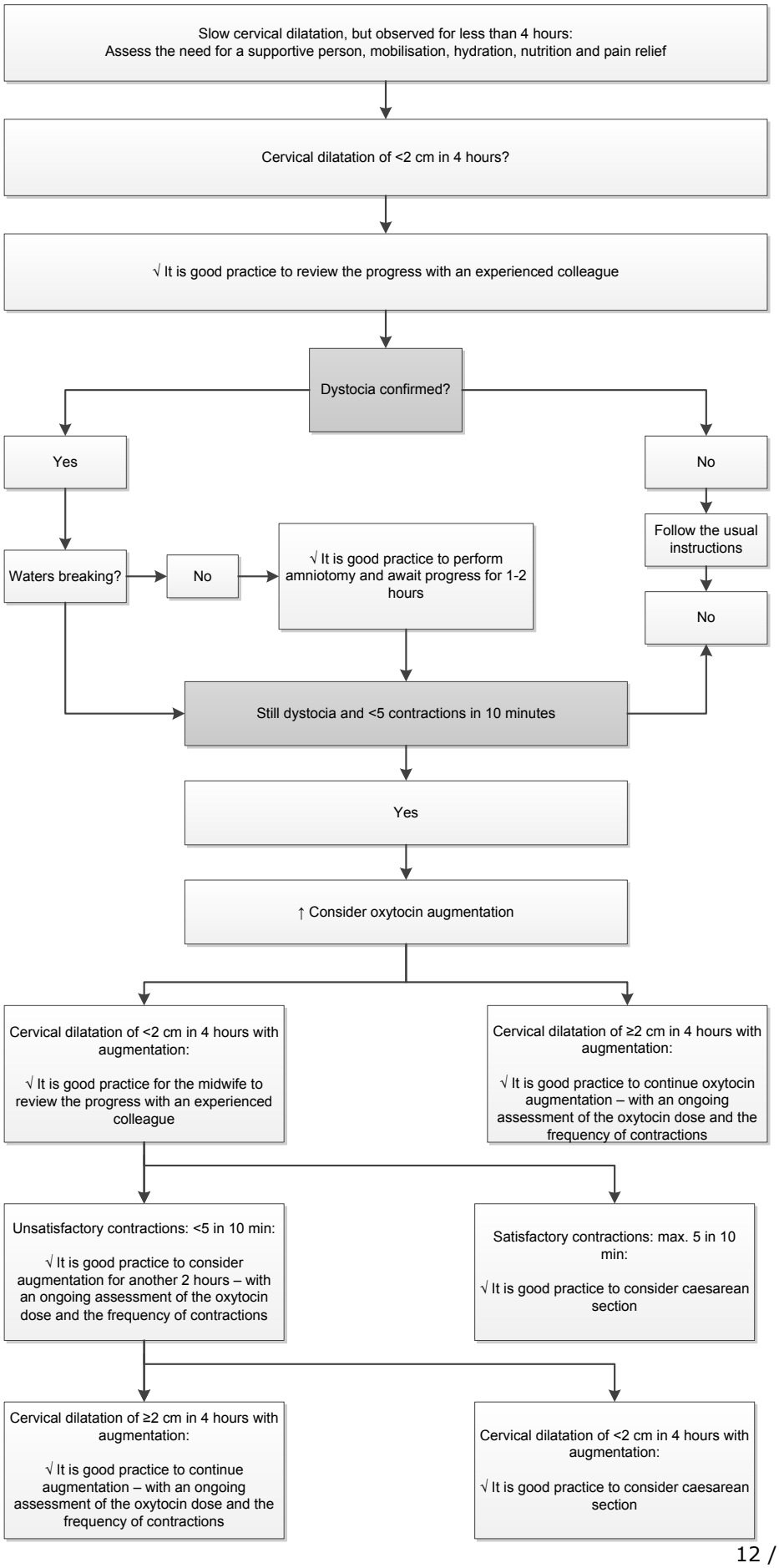
* Experienced colleague means, e.g. a senior staff midwife or a doctor, depending on local practice.

A review of the progress includes, among other items, to assess the following (e.g. the childbirth checklist and the labour augmentation drip package of the Danish safe childbirth ('Sikre Fødsler') project [5]):

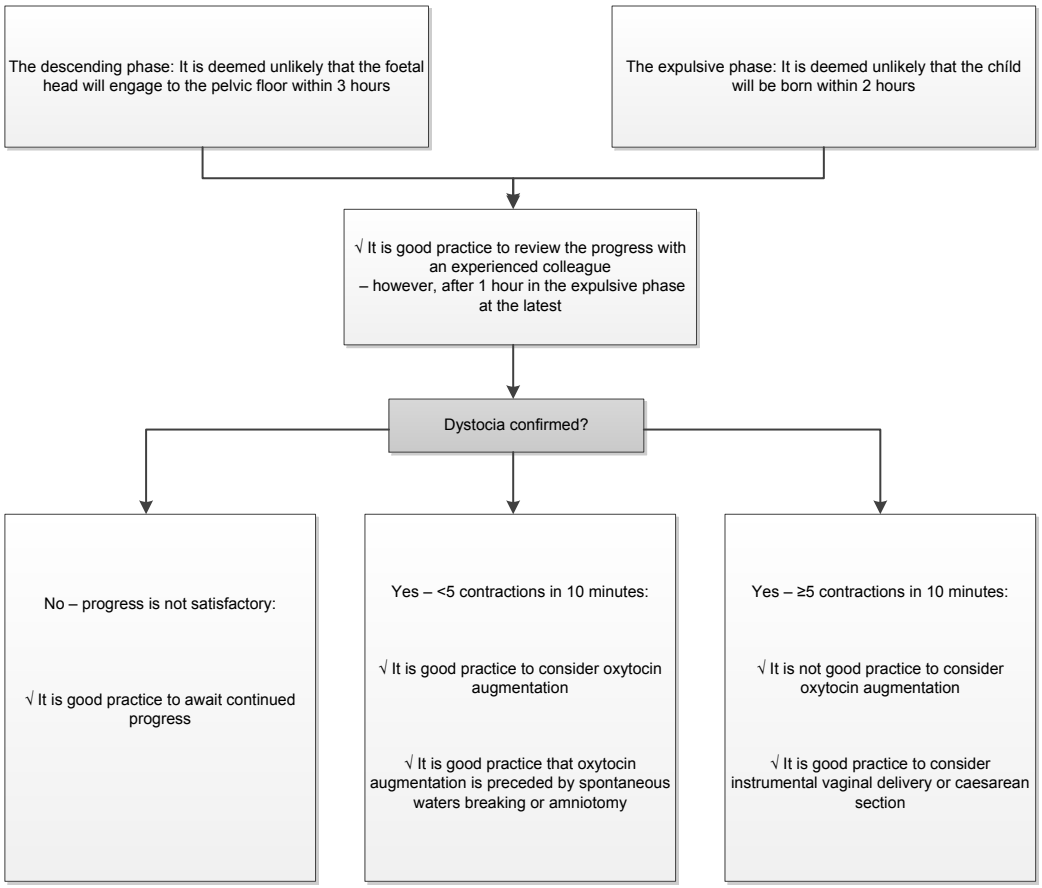
- Fetal heart rate, including indication for CTG
- The perspective of the parturient woman
- Risk factors
- Presence of mechanical mismatch (cephalopelvic disproportion)
- Descent and rotation of the fetal head
- Rupture of the membranes
- Pattern of contractions
- Cervical progress (assessed, e.g., by means of a partogram)
- Micturition/bladder emptying (particularly in the second stage).

Perspective of the parturient woman means preferences, need for pain relief and physical and mental condition.

Flowchart for dystocia in the active phase of the first stage



Flowchart for dystocia in the second stage of labour



1 Introduction

1.1 Purpose

The purpose of the national clinical guideline is to ensure the use of evidence-based procedures of a uniform high quality management across the country and to contribute to appropriate patient care, knowledge-sharing across sectors and professional groups and prioritisation in the healthcare system.

The guideline concerning dystocia in primiparous women with a fetus in cephalic presentation describes oxytocin augmentation of labour with respect to indication and administration. In addition, selected non-medicinal options with a potential use for prevention and treatment of uterine inertia are described.

1.2 Terminology

In the guideline, the stages and phases of labour are designated as follows [7]:

The **first stage** of labour starts at the onset of regular contractions and ends at a cervical dilatation of 10 cm. It consists of two phases:

- **The latent phase**: From the onset of regular contractions and until a cervical dilatation of 4 cm.
- **The active phase**: From a cervical dilatation of 4 cm, and with the presence of contractions leading to progress of cervical dilatation.

The **second stage of labour** starts at a cervical dilatation of 10 cm and ends when the child is born. It consists of two phases:

- **The descending phase**: From full dilatation of the cervix and until the parturient woman starts to push.
- **The expulsive phase**: From when the parturient woman starts to push and until the child is born.

The designation 'active labour' is used from the time the parturient enters the active phase and until the child is born.

In the first stage of labour, progress is primarily defined by the cervical dilatation. In the second stage of labour, progress is primarily defined by the fetal head´s descent through the birth canal.

1.3 Delimitation of the group of patients

The guideline concerns primiparous women in the active phase of labour, the descending phase and the expulsive phase, with a fetus in cephalic presentation and when the woman is of a gestational age of $\geq 37^{+0}$ weeks (Robson group 1) [8,9]. The guideline also applies to primiparous women in whom labour has been induced without the use of oxytocin (Robson group 2b) [8,9], whereas it does not apply to multiple pregnancies, parturients in the latent phase or parturients induced with oxytocin. This guideline does not apply in case of pathologic conditions such as suspected asphyxia (fetal oxygen deprivationfetus).

1.4 Target group/users

The primary target group for the national clinical guideline are healthcare professionals (midwives, doctors, nurses, social and healthcare assistants and students) involved in childbirth in Denmark. Therefore, the guideline is written in a language adapted to healthcare professionals.

Pregnant/parturient women and others interested in information on dystocia are also welcome to read the guideline.

1.5 Definition of dystocia

In this guideline, dystocia in primiparous women is defined as follows:

The active phase of the first stage (the dilatation phase):

- Cervical dilatation of <2 cm assessed over 4 hours.
- In special circumstances, however, the diagnosis may be arrived at earlier, in case a cervical dilatation of 2 cm in 4 hours is deemed unlikely.

The descending phase:

- When it is deemed unlikely that the leading part of the fetus will engage and descend to the pelvic floor within 3 hours.

The expulsive phase:

- When it is deemed unlikely that the child will be born within 2 hours.

Comments

The choice of definition is based on other applicable guidelines [10,11] and studies showing that the proportion of vaginal deliveries with no significant increase in the risk of complications in mother and child is high for a total duration of the second stage of up to 3 hours [12,13]. The slightly increased risk can be prevented and handled. Therefore, the possibility of vaginal delivery has been assigned a high priority.

Since recent research indicates that the active phase may not start until the cervix has dilated to 6 cm [1-4], dystocia should only be diagnosed upon careful consideration in case of cervical dilatation has reached 4-6 cm.

The selected definition of dystocia in the active phase is the most frequently used definition in Denmark and abroad [10,14-16]. In the scientific field, other definitions of dystocia are in use [2-4,17-19], but not yet examined in randomised studies. Therefore, the assessment concluded that there is currently no basis in Denmark for changing the so far most frequently used definition of dystocia in the active phase.

1.6 Delimitation of the subject matter

The national clinical guideline contains instructions on how to handle selected and well-defined clinical issues (resulting from 'probing' the patient-care process) with respect to selected critical and important outcomes that were selected prior to performing the systematic literature search. The guideline, therefore, is not intended to cover the entire field of dystocia.

Focused questions:

Questions 1-3:	Indication for oxytocin augmentation.
Question 4-5:	Dosage regimens for oxytocin.
Question 6:	Special circumstances for women with an epidural.
Questions 7-10:	Selected non-medicinal options.
Question 11:	Duration of oxytocin augmentation prior to considering instrumental vaginal delivery or caesarean section.

See also Appendix 6.

Outcomes:

- *Critical* outcomes: perinatal death, Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7.00, admission to neonatal intensive care unit, Sarnat score, Thompson score and encephalopathy.

- *Important* outcomes: caesarean section, instrumental vaginal delivery, duration of labour, hyperstimulation, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction, lactation, attachment and later caesarean section at maternal request.

1.7 Perspective of the patient

The relevant patient organisations were represented in the established reference group and had the opportunity to provide comments on the draft guideline. The names of the members of the reference group are included in Appendix 10.

1.8 Legal matters

The DHMA's national clinical guidelines are systematically prepared statements based on relevant expert knowledge.

National clinical guidelines are aimed at facilitating decision-making for professionals concerning appropriate and good clinical healthcare services in specific situations. The national clinical guidelines are publicly available, and patients are also welcome to read the guidelines.

National clinical guidelines are classified as professional counselling, which implies that the DHMA recommends that the guidelines be followed by relevant professionals. The national clinical guidelines are not legally binding, and the professional judgment in the specific clinical situation will always take priority when deciding about appropriate and correct clinical healthcare services.

A successful treatment outcome cannot be guaranteed, even if healthcare professionals follow the recommendations. In certain situations, a treatment method with a lower strength of evidence may be preferable, because it is considered a better choice for the patient and by the patient.

Generally, healthcare professionals should involve the patient when choosing a particular treatment option. All the binding rules and guidelines from the DHMA in this field must be complied with.

2 Indication for oxytocin augmentation in primiparous women in the active phase of the first stage

2.1 Focused question 1

When should oxytocin augmentation be offered to primiparous women in case of dystocia in the active phase of the first stage (the dilatation phase)?

2.2 Recommendation

√ It is good practice to review the progress with an experienced colleague* in case of suspected dystocia in the active phase.

↑ Consider oxytocin augmentation within an hour after diagnosing dystocia in the active phase of the first stage, if the membranes have ruptured and there are <5 contractions in 10 minutes (⊕○○○).

√ In case of dystocia in the active phase, it is good practice – if the membranes have not ruptured – to perform amniotomy and await progress for another 1-2 hours before deciding whether to initiate oxytocin augmentation.

2.3 Practical advice and special patient considerations

*Experienced colleague means, e.g., a senior staff midwife or a doctor, depending on the local conditions.

A review of the progress includes, among other things, assessing the following (cf. the childbirth checklist and the labour augmentation drip package of the Danish safe childbirth ('Sikre Fødsler') project [5]):

- Fetal heart rate, including indication for CTG
- The perspective of the parturient woman**
- Risk factors
- Presence of mechanical mismatch (cephalopelvic disproportion)
- Descent and rotation of the fetal head
- Rupture of mebranes
- Pattern of contractions
- Cervical progress (assessed, e.g., by means of a partogram).

Prior to diagnosing dystocia review the situation carefully when the cervix has only dilated to 4-6 cm.

**Perspective of the parturient means: preferences, need for pain relief and physical and mental condition.

See the flowchart for the active phase of the first stage in Key messages and here (*external link to a print-friendly version*).

2.4 Background of the choice of question

Oxytocin augmentation is often used to treat dystocia and may shorten the duration of labour [20]. However, incorrect use may be associated with risk of asphyxia (oxygen deprivation in the fetus) [21-23]. In Sweden, inappropriate use of oxytocin was involved in 71% of patient insurance cases of severe asphyxia [21]. According to a recent Norwegian study, 43% of the parturients who received oxytocin did not meet the criteria for dystocia [24].

Therefore, it is important to ensure that oxytocin is only used upon careful consideration and if well-indicated.

2.5 Literature

The answer to the focused question was based in part on a systematic Cochrane review/meta-analysis [20] which amongst others included five studies of a total of 1,200 primarily primiparous women with dystocia, to whom oxytocin was administered either immediately after diagnosing dystocia or three to eight hours later. In addition, the working group included one more randomised study [25]. See the flowchart for the literature search here.

Results:

Immediate versus delayed oxytocin augmentation in primiparous women with dystocia in the active phase:

- Critical outcomes: unaffected.
- Important outcomes: 1) the duration of labour was shortened by 2.2 hours, 2) fewer caesarean sections, 3) more instrumental vaginal deliveries and 4) more interventions due to fetal heart rate changes (discontinuation of oxytocin infusion, instrumental vaginal delivery or caesarean section). There was no difference in the parturients' satisfaction or childbirth experience.

Comments:

- The two major studies in the meta-analysis used the following dissimilar definitions of dystocia:

No cervical dilatation for 2 hours or dilatation of <1 cm in 3 hours. N=630 [26].

Cervical dilatation of ≤2 cm in 4 hours. N=412 [27].

- Due to dissimilar definitions of delayed augmentation (3-8 hours) among the publications, subgroup analysis was not possible.
- The evidence for the recommendation concerning amniotomy is reviewed separately in PICO 10.

2.6 Summary of Findings table

Immediate or delayed use of intravenous oxytocin in case of dystocia

Bugg GJ, Siddiqui F, Thornton JD. Early use of intravenous oxytocin versus delayed use for slow progress in the first stage of spontaneous labour. Data only. Cochrane Database of Systematic Reviews 2013, Issue 6 [19]

Bergqvist L, Dencker A, Taft C et al. 2012 Women's experiences after early versus postponed oxytocin treatment of slow progress in first childbirth – a randomized controlled trial. Sexual & Reproductive Healthcare 2012; 3: 61–5 [25].

Population: Women in spontaneous labour with dystocia in the first stage of labour.

Intervention: Intravenous oxytocin augmentation immediately after diagnosing dystocia.

Comparison: Intravenous oxytocin augmentation delayed for 3-8 hours after diagnosing dystocia.

Outcomes	Absolute effect* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Control group Baseline risk	Intervention group Effect in the intervention group				
	Control	**Immediate oxytocin**				
Serious neonatal morbidity or perinatal death**	**4 per 1,000**	**4 per 1,000** (0 to 67)	**RR 0.98** (0.06 to 15.57)	469 (2 studies)	⊕⊕⊖⊖ **low**[2]	A relative risk of less than 1 means a **lower** risk of serious neonatal morbidity or perinatal death in the intervention group.
Apgar score <7 at 5 minutes**	**19 per 1,000**	**19 per 1,000** (9 to 43)	**RR 1.02** (0.46 to 2.28)	1,200 (5 studies)	⊕⊖⊖⊖ **very low**[2,3,4]	A relative risk of greater than 1 means a **higher** risk of Apgar 5 min <7 in the intervention group.
Admission to neonatal intensive care unit**	**61 per 1,000**	**58 per 1,000** (37 to 92)	**RR 0.95** (0.6 to 1.5)	1,140 (4 studies)	⊕⊕⊕⊖ **moderate**[2]	A relative risk of less than 1 means a **lower** risk of admission to neonatal intensive care unit in the intervention group.
Uterine hyperstimulation with fetal heart rate changes necessitating intervention	**27 per 1,000**	**67 per 1,000** (28 to 162)	**RR 2.51** (1.04 to 6.05)	472 (2 studies)	⊕⊕⊕⊕ **high**	A relative risk of greater than 1 means a **higher** risk of uterine hyperstimulation with fetal heart rate changes in the intervention group.
Instrumental vaginal delivery**	**195 per 1,000**	**228 per 1,000** (140 to 366)	**RR 1.17** (0.72 to 1.88)	1,200 (5 studies)	⊕⊕⊖⊖ **low**[2,5]	A relative risk of greater than 1 means a **higher** risk of instrumental vaginal delivery in the intervention group.
Caesarean section**	**129 per 1,000**	**113 per 1,000** (85 to 153)	**RR 0.88** (0.66 to 1.19)	1,200 (5 studies)	⊕⊕⊖⊖ **low**[2]	A relative risk of less than 1 means a **lower** risk of caesarean section in the intervention

						group.
Emergency caesarean section due to imminent asphyxia[**]	**40 per 1,000**	**43 per 1,000** (24 to 81)	**RR 1.08** (0.59 to 2.00)	909 (3 studies)	⊕⊕⊕⊖ **moderate**[2]	A relative risk of greater than 1 means a **higher** risk of emergency caesarean section due to imminent asphyxia in the intervention group.
Satisfaction with the childbirth (scale)[**]		The women in the intervention group scored **3 points higher** on average compared to the women in the control group (3.3 points lower to 9.3 higher)		281 (1 study)	⊕⊕⊕⊖ **moderate**[3]	A positive value means a **higher** level of satisfaction with the childbirth in the intervention group.
Not satisfied with the childbirth (number of women with negative memories of the childbirth)[**]	**411 per 1,000**	**428 per 1,000** (346 to 535)	**RR 1.04** (0.84 to 1.3)	442 (1 study)	⊕⊕⊖⊖ **low**[2.3]	A relative risk of greater than 1 means a **higher** risk of having negative memories of the childbirth in the intervention group.
Not satisfied with the childbirth (number of women indicating to be depressed due to the childbirth experience)[**]	**330 per 1,000**	**310 per 1,000** (234 to 406)	**RR 0.94** (0.71 to 1.23)	442 (1 study)	⊕⊕⊖⊖ **low**[2.3]	A relative risk of less than 1 means a **lower** risk of being depressed due to the childbirth experience in the intervention group.
Perceived participation/involvement during childbirth (scale)[†]		The women in the intervention group scored **0.06 points higher** on average compared to the women in the control group (0.05 points lower to 0.17 higher)		442 (1 study)	⊕⊕⊖⊖ **low**[2.3]	A positive value means a **higher** level of perceived participation in the intervention group.
Perceived safety during childbirth (scale)[†]		The women in the intervention group scored **0.03 points higher** on average compared to the women in the control group (0.08 points lower to 0.14 higher)		442 (1 study)	⊕⊕⊖⊖ **low**[2.3]	A positive value means a **higher** level of perceived safety in the intervention group.
Postpartum haemorrhage[**]	**118 per 1,000**	**98 per 1,000** (70 to 136)	**RR 0.83** (0.59 to 1.15)	1,099 (3 studies)	⊕⊕⊕⊖ **moderate**[2]	A relative risk of less than 1 means a **lower** risk of postpartum haemorrhage in the intervention group.

Time from randomisation to delivery**		The mean time from randomisation to delivery was **2.2 hours shorter** in the intervention group (3.3 to 1.1 hours shorter)	1,083 (3 studies)	⊕⊕⊕⊖ **moderate**[5]	The result means that the time from randomisation to delivery is **shorter** in the intervention group.

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

** Data from Bugg 2013 [(19)]

† Data from Bergqvist 2012 [(26)]

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group rating of quality of the evidence:

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

[1] We found no estimates of the critical outcomes of umbilical cord (artery) pH, Sarnat score, Thompson score and encephalopathy.

[2] Very wide confidence interval.

[3] Lack of blinding may have led to bias.

[4] Apgar is not a particularly good surrogate for morbidity and mortality.

[5] I^2 greater than 50%.

2.7 Working group considerations

Quality of the evidence	Of the critical outcomes, several could not be elucidated and the evidence forothers was very low to moderate. Therefore, the overall quality according to GRADE is very low.
Balance between beneficial and adverse effects	The reduced risk of caesarean section is weighted higher than the increased risk of hyperstimulation and instrumental vaginal delivery. It is assessed that the implementation of the safe childbirth ('Sikre Fødsler') project, among other initiatives, reduced the risk of hyperstimulation and that the recommendations for the focused question 11 will reduce the use of instrumental vaginal delivery.
Patient preferences	Experience shows that preferences as regards interventions during childbirth vary among parturients. Some strongly prefer the natural process and only want intervention in case it is extremely well-indicated. Others tend to let the labour and delivery team assess the indications. Since the evidence of beneficial effect of augmentation is low, the perspective of the parturient should be weighted high.
Other considerations	The studies only included women in spontaneous labour. It is assessed that the recommendations should also apply to cases of induced labour, in which there was no use of oxytocin augmentation in the latent phase.

2.8 Rationale for recommendation

Due to the very low quality of the evidence and the presumption of varying preferences among the parturients, the working group gave a weak recommendation for early oxytocin augmentation (usually within an hour) in case of dystocia as well as good practice recommendations.

3 Indication for oxytocin augmentation in the second stage

3.1 Focused question 2-3

When should oxytocin augmentation be offered to primiparous women in case of dystocia in the second stage of labour (the descending and expulsive phases)?

3.2 Recommendation

√ It is good practice to review the progress with an experienced colleague in case of suspected dystocia in the descending phase.

√ It is good practice to review the progress with an experienced colleague in case of suspected dystocia in the expulsive phase – after 1 hour at the latest.

√ It is good practice to consider oxytocin augmentation in the second stage in case of dystocia and <5 contractions in 10 minutes.

√ It is good practice to consider forced delivery (caesarean section or instrumental vaginal delivery) when the expulsive phase has lasted 2 hours. Forced delivery should be considered earlier if the parturient woman so desires or if the estimated duration of the expulsive phase exceeds 2 hours.

3.3 Practical advice and special patient considerations

Experienced colleague means, e.g., a senior staff midwife or a doctor, depending on the local conditions.

A review of the progress includes, among other items, to assess the following (cf. the childbirth checklist and the labour augmentation drip package of the Danish safe childbirth ('Sikre Fødsler') project [(5)]):

- Fetal heart rate, including indication for CTG
- The perspective of the parturient woman
- Risk factors
- Presence of mechanical mismatch (cephalopelvic disproportion)
- Descent and rotation of the fetal head
- Ruptured membranes
- Pattern of contractions
- Cervical progress (assessed, e.g., by means of a partogram)
- Micturition/bladder emptying.

Perspective of the parturient woman means preferences, need of pain relief and physical and mental condition.

See the flowchart for dystocia in the second stage of labour in Key messages and here (*external link to a print-friendly version*).

3.4 Background for the choice of the question

Please see section 2.4.

3.5 Literature

To answer the focused question, two guidelines[10,17], a systematic review [28], a randomised study [29], two secondary analyses of randomised studies [30,31] and eight observational studies [12,13,32-37] were included. The working group did not identify evidence that answered the focused question directly, and the recommendations, therefore, are based on indirect evidence and consensus among the members concerning good practice.

See flowchart for the literature search here

Guidelines for the descending phase

The NICE guideline (2007) [10] cautions against initiating oxytocin treatment during the descending phase, because the authors found no evidence of beneficial effect. Also, based on a single case report, they fear risk of uterine rupture [38]. The only exception is to consider prophylactic oxytocin in parturients who are to receive an epidural at the beginning of the second stage [10].

The Swedish guideline (2011) [17] recommends amniotomy, optionally followed by oxytocin in case of unsatisfactory progress for at least an hour and <5 contractions in 10 minutes [17].

The FIGO guideline (2012) [39] indicates that oxytocin augmentation may be considered in the second stage of labour if contractions are weak.

Guidelines for the expulsive phase

The NICE guideline (2007) cautions against initiating oxytocin for the same reasons as mentioned for the descending phase. In case of home childbirth, therefore, transfer to a maternity ward can wait until the expulsive phase has lasted 2 hours. NICE recommends amniotomy after an hour of unsatisfactory progress [10].

The Swedish guideline (2011) recommends for amniotomy, optionally followed by oxytocin in case of lack of progress for at least 30 minutes and <5 contractions in 10 minutes [17].

The FIGO guideline (2012) [39] indicates that oxytocin augmentation may be considered in the second stage of labour if contractions are weak.

Systematic review

In a systematic review (2006) of observational studies [28], it was found that duration of the second stage of labour exceeding 2-4 hours is associated with an increased risk of postpartum haemorrhage, infection and major ruptures. The descending phase and the expulsive phase are not described separately. The authors point out that the studies are associated with several questionable methodological issues.

Randomised study

Saunders (1989) [29] randomised 226 primiparous women with an epidural to prophylactic oxytocin or placebo at the beginning of the second stage. The intervention was associated with shorter duration of the second stage, reduced use of non-rotational forceps and fewer perineal ruptures, whereas there was no difference in the use of rotational forceps or neonatal outcomes.

Extended literature search

It was assessed that the review of evidence which formed the basis of the recommendations in the NICE guideline (2007) [10] was of high quality. Therefore, the literature search was only extended for the period after 2007. Hereby, two additional secondary analyses of randomised studies and nine observational studies were identified (Appendix 1c). The increased risk of prolonging the expulsive period to 1-3 hours is associated with an OR of up to 3 for a number of fetal and maternal outcomes. None of the studies render probable that this increased risk can be reduced by early intervention such as oxytocin augmentation or instrumental vaginal delivery.

3.6 Working group considerations

Quality of the evidence	**Only indirect evidence is available. Therefore, the evidence was not assessed.**
Balance between beneficial and adverse effects	Prolonged duration of the expulsive phase beyond an hour is associated with increased risks of critical outcomes, but the absolute numbers are small. It is neither documented nor rendered probable that intervention in the form of oxytocin augmentation or instrumental vaginal delivery will decrease these risks. If allowed by the condition of the fetus and the mother, the working group finds that the expulsive phase may last up to two hours if a safe, vaginal delivery is deemed likely. The umbilical cord (artery) pH decreases during the entire expulsive phase [40-42]. Therefore, it is emphasised that use of the recommendations in this guideline is conditional on absence of suspected oxygen deprivation in the fetus. It has been discussed among midwives and specialist doctors whether conservative management of prolonged descending phase and prolonged expulsive phase results in more injury to the parturient's pelvic floor than use of augmentation. The working group finds that the issue is hypothetical and notes that the experts consulted disagree on the matter [43].

Patient preferences	Experience shows that preferences as regards interventions during childbirth vary among parturients. Some strongly prefer the natural process and only want intervention in case it is extremely well-indicated. Others tend to let the labour and delivery team assess the indications. Since the evidence of beneficial effect of augmentation is low, the working group finds that the preferences of the parturient should be weighted high.
Other considerations	In Denmark, Sweden and Norway, it has been clinical practice to base the use of oxytocin in the descending and expulsive phases on judgement. The DHMA assesses that, especially in these phases, there should be room for such a judgment. Even though the scientific evidence is modest [29], many clinicians believe that the use of instrumental vaginal delivery can be reduced by use of oxytocin. Recent years have seen an increased focus on greater safety and improved fetal monitoring and CTG interpretation through the safe childbirth ('Sikre Fødsler') project and, overall, the working group finds that oxytocin augmentation may continue to be used in the management of dystocia in the second stage based on a clinical judgment.

3.7 Rationale for recommendation

When recommending for intervention with oxytocin after all, in spite of the considerations above, the main reasons are clinical experience as regards parturient preferences in the phases of labour concerned and belief in the prevention of instrumental vaginal delivery.

4 Dosage regimens for oxytocin

4.1 Focused question 4-5

Is there a preferable oxytocin regimen to treat dystocia in primiparous women in the active phase of the first stage (question 4) and the second stage of labour (question 5), respectively?

4.2 Recommendation

↑ When initiating oxytocin augmentation, consider a starting dosage of 3.3 mU/min = 20 ml/h when using a solution of 10 IU of oxytocin in 1,000 ml of isotonic sodium chloride solution for infusion (⊕○○○).

√ It is good practice to increase the dose with 3.3 mU/min = 20 ml/h every 20 minutes until reaching a maximum of 5 contractions in 10 minutes.

√ It is not good practice to let the dosage exceed 180 ml/h = 30 mU/min.[2]

4.3 Practical advice and special patient considerations

In case of satisfactory progress at <5 contractions in 10 minutes, further increase of the infusion rate is not indicated.

Prior to initiating oxytocin augmentation, the checklist in the labour augmentation drip package of the safe childbirth ('Sikre Fødsler') project should be reviewed [(5)].

4.4 Background of the choice of question

Oxytocin augmentation may shorten the duration of labour, but may also cause hyperstimulation and asphyxia (fetal oxygen deprivationfetus) [(6,20-23)].

So far, the most commonly used infusion rate in Denmark is 20 ml/h (3.3 mU/min) with a maximum dose of 120-180 ml/h (20-30 mU/min), whereas other countries are using lower as well as higher dosages.

The working group wanted to investigate whether a dosage regimen could be identified as the most advantageous one.

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[2] The assessment report for Syntocinon® indicates a maximum infusion rate of 120 ml/h (20 milliunits/min, 40 drops/min), but also mentions that a higher rate may be needed on rare occasions [(6)]. From clinical experience and the literature review, the working group finds that it may be relevant to increase the infusion rate up to 180 ml/h for special cases and based on a professional judgment, provided the foetal heart rate is normal and the frequency of contractions does not exceed 5 in 10 minutes. The indication for increasing the infusion rate must always be recorded.

4.5 Literature

To answer the focused question, two guidelines [10,17], a systematic review [44], a randomised study [29], an observational study [45] and a summary of product characteristics [6] were included. See the flowchart for the literature search here.

The active phase: guidelines concerning dosage of oxytocin in case of dystocia

Recommendations:

The NICE guideline (2007) [10] recommends for 1) no specific starting dose, 2) a dose increase every 30 minutes until a maximum of 4-5 contractions in 10 minutes, 3) no specific maximum infusion rate [10].

The Swedish guideline (2011) recommends for 1) a starting dose of 20 ml/h = 3.3 mU/h, 2) a dose increase every 20 minutes and 3) a maximum infusion rate of 180 ml/h [17].

Background of these two recommendations:

- The NICE guideline (2007) concluded that use of a high-dose starting infusion rate (≥4 mU/min = 24 ml/h) probably results in shorter duration of labour, fewer caesarean sections and more vaginal deliveries. However, due to the lack of evidence concerning neonatal outcomes and parturient pain, there is no direct recommendation as regards the starting dose.

The Swedish recommendations (2011) are primarily based on a systematic review of 2010 [46], which also includes studies for which the dosage regimen is comprised in the "Active Management of Labour" package [47].

The second stage: guidelines concerning dosage of oxytocin in case of dystocia

Recommendations:

- The NICE guideline (2007) cautions against initiating oxytocin in case of dystocia in the second stage of labour.

The Swedish guideline (2011) suggests 1) a starting dose of 30-50 ml/h = 5-8.3 mU/min, 2) a dose increase every 15 minutes and 3) a maximum infusion rate of >180 ml/h, provided the CTG is normal and the frequency of contractions does not exceed 5 in 10 minutes [17].

The FIGO guideline (2012) [39] suggests 1) 24 ml/h, 2) a dose increase every 30 minutes and 3) a maximum infusion rate of 360 ml/h.

Comments on these three recommendations:

- Due to the lack of evidence, the NICE guideline (2007) does not recommend oxytocin augmentation in the second stage of labour in women *without* an epidural. However, it indicates that augmentation may be considered in some cases based on a single study.

- Apparently, the Swedish recommendations (2011) are not directly supported by the literature review, but rather, at least in part, based on the opinions and experience of the working group.

The FIGO guideline refers primarily to the WHO 'Managing complications in pregnancy and childbirth. A guide for midwives and doctors'. 2000 [16,39].

Systematic review

Kenyon (2013) [44] compared high-dose regimens (starting dose of ≥4 mU/min) to low-dose regimens (starting dose of ≤4 mU/min) and found that high-dose use is associated with shorter duration of labour (3.5 hours shorter from initiating oxytocin to delivery), fewer caesarean sections, fewer children with a low Apgar score (not significant). Neither the critical outcomes of umbilical cord pH and admission to neonatal intensive care unit nor the important outcomes of instrumental vaginal delivery, postpartum haemorrhage, chorioamnionitis and hyperstimulation showed any difference.

Primary studies

Zhang et al. (2011) compared a low-dose regimen (starting dose of 1 mU/min) to a high-dose regimen (starting dose of 4 mU/min) in 15,000 women [45] who had given birth in 12 institutions with dissimilar guidelines. Neither dose increase nor maximum dose were described. The high-dose regimen was associated with shorter duration of the dilatation phase as well as of the second stage of labour,a lower proportion of neonates with Apgar score <7 at 5 minutes (only in the adjusted and not in the unadjusted analysis), whereas there was no difference in the other neonatal or maternal outcomes or in the incidence of caesarean sections.

4.6 Summary of Findings table

High versus low dose of oxytocin for augmentation in case of dystocia, meta-analysis of randomised studies

Kenyon S, Tokumasu H, Dowswell T, Pledge D, Mori R. High versus low dose of oxytocin for augmentation of delayed labour. Data only. Cochrane Database of Systematic Reviews 2013, Issue 7 [(44)]

Population: Women augmented with oxytocin due to dystocia

Intervention: High-dose infusion rate (≥4 mU/min)

Comparison: Low-dose infusion rate (<4 mU/min)

Outcomes	Absolute effect* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Control group Baseline risk	Intervention group Effect in the intervention group				
	Low dose	**High dose**				
Neonatal mortality	See comment	See comment	Cannot be estimated	604 (3 studies)		There were no neonatal deaths in any of the groups of the studies included.
Apgar score <7 at 5 minutes	**4 per 1,000**	**2 per 1,000** (0 to 38)	**RR 0.37** (0.02 to 8.5)	444 (3 studies)	⊕⊖⊖⊖ **very low**[1,2]	A relative risk of less than 1 means a **lower** risk of Apgar 5 min <7 in the intervention group.
Umbilical cord (artery) pH	The mean umbilical cord pH was **7.24-7.27** in the control groups.	The mean umbilical cord pH in the intervention group was **0 points higher** (0.03 points lower to 0.03 higher).		134 (2 studies)	⊕⊕⊕⊖ **moderate**[3]	A value of 0 means no difference in umbilical cord (artery) pH across the two groups.
Admission to neonatal intensive care unit	**79 per 1,000**	**39 per 1,000** (17 to 91)	**RR 0.5** (0.22 to 1.15)	404 (2 studies)	⊕⊕⊖⊖ **low**[4,5]	A relative risk of less than 1 means a **lower** risk of admission to neonatal intensive care unit in the intervention group.
Caesarean section	**219 per 1,000**	**136 per 1,000** (96 to 188)	**RR 0.62** (0.44 to 0.86)	644 (4 studies)	⊕⊕⊕⊖ **moderate**[4]	A relative risk of less than 1 means a **lower** risk of caesarean section in the intervention group.
Instrumental vaginal delivery	**290 per 1,000**	**241 per 1,000** (177 to 328)	**RR 0.83** (0.61 to 1.13)	444 (3 studies)	⊕⊕⊕⊖ **moderate**[5]	A relative risk of less than 1 means a **lower** risk of instrumental vaginal delivery in the intervention group.
Subgroup analysis: Caesarean section by parity (all)	**277 per 1,000**	**177 per 1,000** (122 to 252)	**RR 0.64** (0.44 to 0.91)	444 (3 studies)	⊕⊕⊕⊖ **moderate**[4,5]	A relative risk of less than 1 means a **lower** risk of caesarean section in the intervention group.

Subgroup analysis: Caesarean section by parity (primiparous women)	**296 per 1,000**	**210 per 1,000** (139 to 314)	**RR 0.71** (0.47 to 1.06)	300 (3 studies)	⊕⊕⊕⊖ **moderate**[5]	A relative risk of less than 1 means a **lower** risk of caesarean section in the intervention group.
Subgroup analysis: Caesarean section by parity (multiparous women)	**226 per 1,000**	**97 per 1,000** (43 to 219)	**RR 0.43** (0.19 to 0.97)	144 (1 study)	⊕⊕⊕⊖ **moderate**[7]	A relative risk of less than 1 means a **lower** risk of caesarean section in the intervention group.
Duration of labour from initiating oxytocin infusion to delivery (hours)	The mean duration of labour from oxytocin infusion to delivery was **11.3 hours**.	The mean duration of labour from oxytocin infusion to delivery was **3.5 hours shorter** (6.4 to 0.6 hours shorter).		40 (1 study)	⊕⊕⊕⊖ **moderate**[6]	A negative value means a **shorter** duration of labour in the intervention group.
Duration of labour from the beginning of the first stage to delivey (minutes)	The mean duration of labour from the beginning of the first stage to delivery was **943 minutes**.	The mean duration of labour from the beginning of the first stage to delivery was **26 minutes shorter** (128 minutes shorter to 76 minutes longer).		92 (1 study)	⊕⊕⊖⊖ **low**[2]	A negative value means a **shorter** duration of labour in the intervention group.
Postpartum haemorrhage	**468 per 1,000**	**445 per 1,000** (286 to 693)	**RR 0.95** (0.61 to 1.48)	94 (1 study)	⊕⊕⊕⊖ **moderate**[5]	A relative risk of less than 1 means a **lower** risk of postpartum haemorrhage in the intervention group.
Chorioamnionitis	**177 per 1,000**	**124 per 1,000** (78 to 199)	**RR 0.70** (0.44 to 1.12)	404 (2 studies)	⊕⊕⊕⊖ **moderate**[5]	A relative risk of less than 1 means a **lower** risk of chorioamnionitis in the intervention group.
Uterine hyperstimulation	**65 per 1,000**	**95 per 1,000** (47 to 191)	**RR 1.47** (0.73 to 2.94)	644 (4 studies)	⊕⊕⊕⊖ **moderate**[5]	A relative risk of greater than 1 means a **higher** risk of uterine hyperstimulation in the intervention group.

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval; **RR:** Risk ratio.

[1] Apgar is an uncertain surrogate for morbidity.

[2] Very wide confidence interval.

[3] Surrogate marker for morbidity.

[4] I^2 greater than 50%.

[5] Wide confidence interval.

[6] Bidgood [(48)] is the only study in this comparison; unblinded and no use of placebo.

[7] Imprecision (population).

High versus low dose of oxytocin for augmentation in case of dystocia, data from observational study

Zhang J, Branch DW, Ramirez MM et al. Oxytocin Regimen for Labor Augmentation, Labor Progression, and Perinatal Outcomes. Obstetrics & Gynecology. 2011; 118: 249-56 [45].

Population: Women augmented with oxytocin due to dystocia.

Intervention: High-dose infusion rate (4 mU/min).

Comparison: Low-dose infusion rate (1 mU/min)

Outcomes	Absolute effect* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Control group Baseline risk	Intervention group Effect in the intervention group				
	Low dose	**High dose**				
Newborn resuscitation			**aOR 1.0** (0.5 to 2.3)	5,392 (1 study)	⊕⊕⊖⊖ **low**	An adjusted OR (aOR) of 1 means that there is no difference in the incidence of resuscitation across the two groups.
Neonatal complications, composite index**			**aOR 0.9** (0.6 to 1.9)	5,392 (1 study)	⊕⊕⊖⊖ low	An adjusted OR (aOR) of less than 1 means fewer neonatal complications in the intervention group.
Duration of the dilatation phase (hospitalisation until fully dilated (hours))		**1.3 hours shorter** (1.7 hours shorter to 1 hour shorter)		5,392 (1 study)	⊕⊕⊖⊖ **low**	A negative value means a **shorter** duration of the dilatation phase in the intervention group.
Duration of the second stage (minutes)		**8.8 minutes shorter** (24.7 minutes shorter to 7.2 minutes shorter)		5,392 (1 study)	⊕⊕⊖⊖ **low**	A negative value means a **shorter** duration of the second stage in the intervention group
Apgar 5 minutes <7			**aOR 0.4** (0.1 to 0.9)	5,392 (1 study)	⊕⊖⊖⊖ **very low**[1]	An adjusted OR (aOR) of less than 1 means fewer cases of Apgar 5 min <7 in the intervention group.
Caesarean section			**aOR 0.9** (0.7 to 1.1)	5,392 (1 study)	⊕⊕⊖⊖ **low**	An adjusted OR (aOR) of less than 1 means fewer caesarean sections in the intervention group.
Maternal complications, composite index†**			**aOR 1.1** (0.9 to 1.4)	5,392 (1 study)	⊕⊕⊖⊖ **low**	An adjusted OR (aOR) of greater than 1 means more maternal complications in the intervention group.

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval; **RR:** Risk ratio.

**Neonatal complications, composite index: asphyxia, hypoxic-ischaemic encephalopathy, neonatal seizures, neonatal death, RDS, CPAP, artificial respiration and transient tachypnea;

†Maternal complications, composite index: placental detachment, postpartum haemorrhage, intrapartum and postpartum blood transfusion and hysterectomy.

GRADE Working Group rating of quality of the evidence:

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

[1]There was no difference in Apgar in the unadjusted analysis, but difference in the adjusted analysis.

4.7 Working group considerations

Quality of the evidence	The quality of the evidence is low to very low, and the predefined outcomes were not all elucidated.
Balance between beneficial and adverse effects	The literature review shows that a high-dose regimen is beneficial. However, it is important to stay attentive to the risks associated with oxytocin augmentation, namely hyperstimulation and intrauterine asphyxia. The working group assumes that the implementation of the safe childbirth ('Sikre Fødsler') project, among other things, improved CTG interpretation and prevention of hyperstimulation and asphyxia in Denmark.
Patient preferences	Preferences as regards handling of childbirth vary among parturients. Some women prefer a natural childbirth with as few interventions as possible, whereas other women prefer faster progress and earlier intervention. None of the studies included to answer the focused question illustrate the impact of various dosage regimens on the childbirth experience and, once again, the working group emphasises that parturient preferences should always be considered when making an informed decision concerning oxytocin augmentation.
Other considerations	In current practice, the starting dose in Danish maternity wards is 20 ml/hour = 3.3 mU/min with a dose increase every 20 minutes. Accordingly, the starting dose is a little lower than the one used in the high-dose regimens of the studies included, in which the starting dose is ≥24 ml/hour = 4 mU/min. In the literature reviewed, the dose is increased at various intervals (most often 20 or 30 minutes), and the working group found no evidence of clear benefits of dose increase every 30 minutes rather than every 20 minutes. The recommendation

	is therefore for maintaining the current dosage regimen.

4.8 Rationale for recommendation

Low to very low quality of the evidence and an assumed difference in preferences among parturients result in a weak recommendation as well as good clinical practice recommendations.

5 Second-stage dystocia in primiparous women with an epidural

5.1 Focused question 6

Should a longer descending phase be accepted prior to offering oxytocin augmentation in primiparous women, if they have an epidural?

5.2 Recommendation

√ It is good practice to allow the same duration of the descending phase in primiparous women with and without an epidural.

5.3 Practical advice and special patient considerations

In case of dystocia in parturients with an epidural, other possible reasons for slow progress should always be considered.

5.4 Background of the choice of question

It is well-established that an epidural may prolong the second stage of labour [49-52]. Against this background, guidelines specify time thresholds for diagnosing dystocia that vary according to whether or not the parturient has received an epidural (see Appendix 1b).

5.5 Literature

The working group did not identify studies that answered the focused question directly, and the recommendation, therefore, is based on a review of indirect evidence and consensus among the members.

To answer the focused question, two guidelines [10,17], a systematic review [50] and two observational studies [13,52]were included. See the flowchart for the literature search here.

Guidelines

The NICE guideline recommendations make no distinction between parturients with and without an epidural concerning duration of the second stage of labour (see Appendix 1a). However, it does recommend to prepare a plan, with each parturient with an epidural, for delivery within four hours following full dilatation of the cervix (i.e., at the beginning of the second stage) [10].

The Swedish guideline specifies the same time threshold for intervention in the second stage of labour in parturients with and without an epidural [17].

According to the US guidelines (ACOG 2003) [53], the second stage in primiparous women is prolonged when exceeding 3 hours with an epidural and 2 hours without an epidural.

The US consensus workshop (NIH, the Society for Fetal-Maternal Medicine and the American College of Obstetricians and Gynecologists) [54] suggests to increase the time threshold for dystocia in the second stage, in women with and without an epidural, to 4 and 3 hours, respectively.

Systematic review

A systematic review/meta-analysis from 2013 analysed the duration of the second stage in 4,233 women with and without an epidural. The second stage was found to be prolonged by 13 minutes from the use of an epidural, but with no distinction between the passive and active phases of the second stage [50].

Primary studies

Two recent primary studies were not included in the above-mentioned systematic review.

Cheng et al. (2014) included 22,370 primiparous women in a retrospective listing. The median duration of the second stage, with and without an epidural, was 120 and 47 minutes, respectively. The 95 percentile was 336 and 197 minutes, respectively [52]. The authors concluded that an epidural probably increases the duration of the second stage more than assumed so far, but also that a prolonged second stage is not associated with a significantly increased perinatal or maternal risk. They assessed that defining prolonged second stage to start early may result in overdiagnosing and unnecessary interventions [52].

Laughon et al. (2014) included 43,810 primiparous women in a retrospective listing [13]. The group with a second stage >3 hours and with an epidural was associated with the following increased risks, as compared with the group with a second stage >2 hours and without an epidural: 1) neonatal sepsis: 2.6% vs. 1.8%; 2) postpartum haemorrhage: 5.9% and 5.1%, 3) blood transfusion: 4.4% vs. 1.4%; and 4) chorioamnionitis: 5.6% vs. 11.1%.

For a more detailed literature review, please see Appendix 1d.

5.6 Working group considerations

Quality of the evidence	Only indirect evidence is available. Therefore, the evidence was not assessed.
Balance between beneficial and adverse effects	For a second stage >3 hours and with an epidural, the incidences of haemorrhage and infection were higher than for a second stage >2 hours without an epidural. Therefore, there is no basis for waiting longer before diagnosing dystocia in the descending phase in parturients with an epidural.
Patient preferences	Since the evidence is low, the perspective of the parturient should be weighted high when managing

	dystocia in the descending phase.
Other considerations	It was considered whether an epidural will prolong the duration of labour by other mechanisms than uterine inertia such as an increased risk of inappropriate presentation of the fetal head in the woman's pelvis. This might speak in favour of awaiting progress for an extended period of time in women with an epidural. The working group found no literature to support or reject this hypothesis.

5.7 Rationale for recommendation

Only indirect evidence is available, and since the working group assumes that preferences may vary among parturients, the group has not given any strong or weak evidence-based recommendations, but exclusively good practice recommendations.

6 Intravenous fluid therapy for the prevention of dystocia

6.1 Focused question 7

Does intravenous fluid therapy prevent the need of oxytocin augmentation in primiparous women?

6.2 Recommendation

↑ Consider offering intravenous therapy using isotonic Ringer's lactate as an add-on to free oral fluid intake in case of suspected dehydration or slow progress (i.e., without waiting for 4 hours and before the criteria for dystocia have been met) (⊕○○○).

6.3 Practical advice and special patient considerations

The parturient's fluid balance should be assessed (intake, vomiting and micturition) in case of slow progress of labour.

It is important to ensure that any intravenous fluid offered to the parturient is an isotonic electrolyte solution (such as isotonic Ringer's lactate).

Until additional documentation indicates otherwise, the working group suggests to use an infusion rate of 125-250 ml/h upon assessing the parturient woman's fluid balance.

In a woman with an epidural, special attention should be paid to bladder emptying if she is receiving intravenous fluid.

6.4 Background of the choice of question

In Denmark, there is practically no use of intravenous fluid for the prevention or treatment of dystocia. On the other hand, unlike in many other countries, parturients can eat and drink freely.

Several studies elucidate the use of fluid therapy for the prevention of treatment of dystocia [4,55-57]. The hypothesis emerged because sports physicians documented that the performance of skeletal muscle is improved by a regular fluid and nutritional intake, and because the same mechanisms might apply to the uterine muscle [55,56,58].

Against this background, the working group wanted to investigate whether intravenous fluid therapy prevents the need of oxytocin augmentation.

6.5 Literature

To answer the focused question, a systematic review [55] and two randomised studies [59,60] were included. See the flowchart for the literature search here.

A systematic review [55] included two randomised studies [59,60] comparing free oral fluid intake with intravenous isotonic fluid (60-250 ml/h) and concomitant oral fluid intake upon request. Intravenous Ringer's lactate was associated with a significantly reduced duration of labour (28 minutes). Additionally, there were fewer caesarean sections, fewer admissions to neonatal intensive care unit and a less frequent need of oxytocin augmentation in the women who received intravenous Ringer's lactate, but the findings were not statistically significant.

6.6 Summary of Findings table

Intravenous fluid therapy and oral fluid intake for reducing the duration of labour in primiparous women

Dawood F, Dowswell T, Quenby S. Intravenous fluids + oral intake for reducing the duration of labour in low risk nulliparous women. Data only. Cochrane Database of Systematic Reviews 2013, Issue 6 [55].

Subanalysis of:

Direkvand-Moghadan A, Rezaeian M. Increased intravenous hydration of nulliparous in labour. Int J Gynecol Obstet 2012; 118: 213-15.

Kavitha A, Chacko KP, Thomas E et al. A randomized controlled trial to study the effect of IV hydration on the duration of labor in nulliparous women. Arch Gynecol Obstet 2012; 285: 343-46.

Population: Primiparous women, low-risk.

Intervention: Intravenous fluid (Ringer's lactate) + free oral intake.

Comparison: Free oral fluid intake.

Outcomes	Absolute effect* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Control group Baseline risk	Intervention group The effect in the intervention group				
	Free oral fluid intake	**Intravenous fluid + free oral fluid intake**				
Mean duration of labour (minutes)	The mean duration of labour in the control group was **264 minutes**	The mean duration of labour in the intervention group was **28.9 minutes shorter** (47.4 minutes shorter to 10.3 shorter)		241 (2 studies)	⊕⊕⊕⊖ **moderate**[2,5]	
Caesarean section	**295 per 1,000**	**215 per 1,000** (144 to 318)	**RR 0.73** (0.49 to 1.08)	315 (2 studies)	⊕⊕⊖⊖ **low**[2,5]	A relative risk of less than 1 means a **lower** risk of caesarean section in the intervention group.
Admission to neonatal intensive care unit	**20 per 1,000**	**11 per 1,000** (1 to 113)	**RR 0.52** (0.05 to 5.59)	195 (1 study)	⊕⊖⊖⊖ **very low**[2,3,5]	A relative risk of less than 1 means a **lower** risk of admission to neonatal intensive care unit in the intervention group.

Oxytocin augmentation	**411 per 1,000**	**283 per 1,000** (173 to 468)	**RR 0.69** (0.42 to 1.14)	413 (2 studies)	⊕⊖⊖⊖ **very low**[2,4,5]	A relative risk of less than 1 means a **lower** risk of oxytocin augmentation in the intervention group.

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group rating of quality of the evidence:

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

[1] The critical outcomes of neonatal death, Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score and encephalopathy were not reported.

[2] Wide confidence interval.

[3] Admission to neonatal intensive care unit is a surrogate for neonatal morbidity and mortality.

[4] An attempt was made to handle I^2 >50% with a random effects model.

[5] Lack of blinding.

6.7 Working group considerations

Quality of the evidence	The quality of the evidence was moderate to very low.
Balance between beneficial and adverse effects	The literature review shows that an intravenously administered isotonic electrolyte solution has the effect to reduce the duration of labour without reported adverse effects. However, not all relevant and important outcomes were critically evaluated in the litterature.
Patient preferences	The parturient women's views on prophylactic intravenous fluid therapy were not investigated in any of the studies. Placement of an intravenous access may inhibit the mobility, be associated with discomfort and contributes to medicalising healthy, normal delivery. The opinions about this may vary among parturients.
Other considerations	The two studies were carried out in countries (India and Iran) with a warmer climate than in Denmark, which may be of importance to hydration and the

	effect of intravenous fluid therapy. It is important to assess the parturient's fluid balance and offer appropriate type(s) of fluid to her. It has been shown that a very high intake of hypotonic fluid during labour may result in hyponatraemia, instrumental vaginal delivery, caesarean section indicated for dystocia, dystocia in the second stage of labour [58,61] and, in extreme cases, brain edema in newborns [60]. In the study of Moen et al. [58,61], the parturients mainly received hypotonic fluid, and two-thirds of the fluid intake was oral, while the studies in the meta-analysis used isotonic Ringer's lactate. Additionally, it could be considered whether the same effect as found in the DHMA's meta-analysis could have been obtained by offering a fluid with an optimised level of electrolytes to the parturients. According to the experience of the working group, parturients are often offered hypotonic fluid (tap water or juice) which is hardly optimal. However, answering these questions was outside the terms of reference for the working group.

6.8 Rationale for recommendation

Based on the moderate to very low quality of the evidence and an assumed difference in preferences among parturients, the working group gave a weak recommendation for the use of intravenous isotonic electrolyte solution to prevent dystocia.

7 Acupuncture in case of dystocia

7.1 Focused question 8

Does the use of acupuncture in case of dystocia prevent the need of oxytocin augmentation in primiparous women?

7.2 Recommendation

↓ Acupuncture should only be used as an intervention in case of dystocia upon due consideration. The available evidence neither demonstrates beneficial nor adverse effects (⊕○○○).

√ It is not good practice to delay relevant options such as amniotomy and oxytocin augmentation in favour of acupuncture.

√ It is good practice to inform the parturient about the lack of scientific documentation for beneficial as well as for adverse effects from the use of acupuncture in case of dystocia.

7.3 Practical advice and special patient considerations

Use of acupuncture in case of dystocia should be documented for quality follow-up describing group of patients and beneficial and adverse effects.

The diagnosis code for acupuncture used in case of uterine inertia is BKXA31.

7.4 Background of the choice of question

Acupuncture is the stimulation of specific points on the body using thin needles and originates from traditional Chinese medicine, but has spread throughout the world today. A US study of 2000 showed that acupuncture was used for pregnant women by 20% of midwives [(62)]. Danish figures have not been determined. In the opinion of the working group, however, use of acupuncture is widespread in Danish maternity wards. In general, acupuncture is considered to cause few adverse reactions [(63,64)]. Therefore, it may be a non-medicinal alternative treatment in various contexts in pregnant and parturient women.

In Denmark, acupuncture is primarily offered in case of nausea during pregnancy and for pain relief during labour [(63)], and the effects of acupuncture on cervical maturing and in the induction of labour have also been studied [(65,66)].

Furthermore, acupuncture is used for augmentation in case of slow progress during active labour, and the working group wanted to investigate the evidence behind this use.

7.5 Literature

To answer the focused question, one randomised, controlled study was identified [(67)]. See the flowchart for the literature search here.

Lyngsø et al. (2010) included 84 primiparous and multiparous women with dystocia in a single-blind, randomised study. The women were randomised to acupuncture in five points and acupressure in one point or the usual treatment. The findings included shorter duration of labour from the beginning of active labour to childbirth in the acupuncture group, but longer time from inclusion to childbirth. The need of oxytocin augmentation, the proportion of instrumental vaginal deliveries and the number of newborns with umbilical cord pH <7.10 were lower in the acupuncture group, while the proportions of caesarean sections and children with an Apgar score <7 at 5 minutes were higher [67]. The evidence is assessed to be of low to very low quality due to wide confidence intervals and risk of bias. The authors provide a power calculation which shows that 150 parturients should have been included to demonstrate a difference, but they only managed to include 84, which implies a risk of type II errors in the study.

Therefore, the study demonstrates no clear beneficial or adverse effect.

7.6 Summary of Findings table

Acupuncture in case of dystocia

Lyngsø CE, Lorentzen IP, Lauszuz F. Akupunktur til vestimulation under fødslen. Ugeskrift for Læger. 2010; 172:289-93 (Acupuncture for augmentation of labour. Ugeskrift for Læger. 2010; 172:289-93) [67]

Population: Parturients with dystocia.

Intervention: Acupuncture.

Comparison: No acupuncture.

Outcomes	Absolute effect* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Control group Baseline risk **No acupuncture**	Intervention group The effect in the intervention group **Acupuncture**				
Duration of labour from active labour to childbirth (minutes)		The mean duration of labour was **32 minutes shorter in the intervention group** (146 minutes shorter to 82 minutes longer).		84 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	A negative value means a **shorter** duration of labour in the intervention group.
Duration of labour from the time of inclusion to childbirth (minutes)		The mean duration of labour from inclusion to childbirth was **20 minutes longer in the intervention group** (48 minutes shorter to 88 minutes longer).		84 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	A positive value means a **longer** duration of labour in the intervention group.
Use of oxytocin augmentation	**762 per 1,000**	**716 per 1,000** (283 to 945)	**RR 0.94** (0.72 to 1.24)	84 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	A relative risk of less than 1 means a **lower** risk of oxytocin augmentation in the intervention group.
Caesarean section	**119 per 1,000**	**143 per 1,000**	**RR 1.2**	84	⊕⊖⊖⊖	A relative risk of greater than 1 means

		(41 to 513)	(0.34 to 4.31)*	(1 study)	**very low**[1,2,4]	a **higher** risk of caesarean section in the intervention group.
Instrumental vaginal delivery	**262 per 1,000**	**215 per 1,000** (9 to 506)	**RR 0.82** (0.34 to 1.93)	84 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	A relative risk of less than 1 means a **lower** risk of instrumental vaginal delivery in the intervention group.
Apgar score <7 at 5 minutes	**0 per 42**	**1 per 42**	Not calculated due to 0 in the control group.	84 (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]	There were no cases of Apgar <7 at 5 minutes in the control group.
Umbilical cord pH <7.10	**161 per 1,000**	**100 per 1,000** (31 to 446)	**RR 0.62** (0.1 to 2.77)	61 (1 study)	⊕⊖⊖⊖ **very low**[1,2,3, 4]	A relative risk of less than 1 means a **lower** risk of umbilical cord pH <7.10 in the intervention group.

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval; **RR:** Risk ratio.

**Neonatal complications, composite index: asphyxia, hypoxic-ischaemic encephalopathy, neonatal seizures, neonatal death, RDS, CPAP, artificial respiration and transient tachypnoea;

†Maternal complications, composite index: placental detachment, postpartum haemorrhage, intrapartum and postpartum blood transfusion and hysterectomy.

GRADE Working Group rating of quality of the evidence:

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

[1] Wide confidence interval.

[2] Lack of blinding of patient and midwife may lead to bias.

[3] Umbilical cord pH only reported for 61 in 84 women which entails a risk of selective reporting bias.

[4] According to the power calculation provided, the study did not include a sufficient number of parturients.

7.7 Working group considerations

Quality of the evidence	The quality of the evidence was very low.

Balance between beneficial and adverse effects	The study demonstrates no clear beneficial or adverse effect of acupuncture in case of dystocia. In general, acupuncture is considered to be harmless, and the working group finds no reason for recommending against it, as long as the use does not delay documented treatments and as long as the use of acupuncture is documented for future listings of the frequency of use and the effect.
Patient preferences	The working group assumes that values and preferences as regards types of interventions vary among parturients.
Other considerations	The midwives who performed the acupuncture in the study concerned had been trained in acupuncture for 23-30 hours [65,67], which is a low level of training. It is well-documented that acupuncture used during induction of labour by staff trained at this level has no positive or negative effect [66]. Induction of labour and augmentation of labour in case of dystocia are likely to share many elements, thereby supporting the observation of lack of effect of acupuncture in case of dystocia. However, the working group found no literature to support this hypothesis.

7.8 Rationale for recommendation

Due to the very low quality of the evidence and the presumption of varying preferences among the parturients, the working group gave a weak recommendation against use of acupuncture in case of dystocia as well as good practice recommendations.

8 Rebozo in case of dystocia

8.1 Focused question 9

Does rebozo prevent the need of oxytocin augmentation in primiparous women?

8.2 Recommendation

Due to the lack of evidence of the beneficial and/or adverse effects of the intervention, the DHMA gives neither a recommendsationfor or against rebozo.

√ If rebozo is offered, it is good practice to document the use for quality follow-up.

√ When offering rebozo, it is good practice to inform the parturient woman that the effects of the treatment and potential adverse effects are undocumented**.**

8.3 Practical advice and special patient considerations

The diagnosis code for rebozo is BKXA9A.

8.4 Background of the choice of question

Rebozo is a wide and long piece of fabric, a kind of shawl or scarf, used before and during labour for relaxation, alleviation and to help in obtaining the appropriate presentation of the fetal head in the woman's pelvis. For the latter, the rebozo is placed under the parturient's pelvis, which is then lifted, rocked and/or shaken by the labour and delivery team member. This is meant to help the parturient relax and to promote correct positioning of the head in the pelvis. Reportedly, therefore, rebozo may also relieve dystocia caused by inappropriate presentation of the head.

The method originates from Mexico, but has spread increasingly in Denmark in recent years [68,69].

The working group is aware that studies of the effect of rebozo are being organised, but has no advance knowledge of scientific literature on rebozo and therefore wants to shed light on it.

8.5 Literature

The working group did not identify scientific literature investigating the effect of rebozo.

8.6 Working group considerations

Quality of the evidence	There is no available evidence.
Balance between beneficial and adverse effects	The working group finds no reason to believe that rebozo is harmful, but there is no available documentation on neither beneficial nor adverse effects.

Patient preferences	Based on clinical experience, the working group assumes that preferences and opinions as regards the use of rebozo in case of dystocia vary among parturients.

8.7 Rationale for recommendation

The working group is only able to give good practice recommendations, because it identified no literature that documents beneficial or adverse effects from the use of rebozo.

9 Order for use of amniotomy and oxytocin augmentation

9.1 Focused question 10

Should amniotomy be performed prior to offering oxytocin augmentation in case of dystocia in primiparous women, or should oxytocin augmentation be offered prior to performing amniotomy?

9.2 Recommendation

√ In case of dystocia in the active phase of the first stage (the dilatation phase), it is good practice to perform amniotomy and await progress for another 1-2 hours before initiating oxytocin augmentation.

√ In case of dystocia in the descending phase, it is good practice to perform amniotomy and await progress for 1 hour before initiating oxytocin augmentation.

√ In case of dystocia in the expulsive phase, it is good practice to perform amniotomy and await progress for 20 minutes before initiating oxytocin augmentation.

9.3 Practical advice and special patient considerations

An individual assessment of risk factors for umbilical cord prolapse (unengaged or high fetal head, polyhydramnios) should be carried out prior to performing amniotomy.

In case of prolonged rupture of membranesg, the parturient should be observed for signs of infection according to applicable local guidelines.

9.4 Background of the choice of question

It is the current practice in Denmark to perform amniotomy prior to offering oxytocin augmentation. Amniotomy is thought to shorten labour [10], and, additionally, the practice is justified by a preference for performing the intervention deemed to be mildest (amniotomy) prior to a more extensive intervention associated with more risks (oxytocin augmentation). However, amniotomy is associated with the risk of umbilical cord prolapse, especially in case of unengaged or high fetal head and polyhydramnios, and the risk of infection in case of prolongedrupture of membranes. The working group is also aware of the hypothesis that the fetal head will engage more easily in an optimal way before the membranes have ruptured. Against this background, the working group wanted to investigate whether a documented, ideal priority of use of amniotomy and oxytocin augmentation, in case of dystocia, could be identified.

9.5 Literature

To answer the focused question, two guidelines [10,17], a systematic review [70] and a randomised study [71] were included. The randomised study was designed to answer the focused question. Still, the working group assessed that additional literature

was needed as an indirect contribution to answering the question. Therefore, the recommendation is based on consensus among the members of the working group. See the flowchart for the literature search here.

Guidelines

In case of dystocia, the NICE guideline (2007) [10] and the Swedish guideline (2011) [17] both recommend to perform amniotomy prior to offering oxytocin augmentation.

Comments on the guidelines:

- The guidelines both refer to meta-analyses, according to which amniotomy results in shorter duration of labour as compared to waiting without amniotomy.

Randomised study

Rouse et al. (1994) randomised 118 women with dystocia and intact membranes to oxytocin augmentation without amniotomy or oxytocin augmentation preceded by amniotomy [71]. Amniotomy was associated with shorter duration of labour (0.7 hours, not statistically significant) and several cases of infection. The authors do not describe use of prophylactic antibiotics during prolonged rupture of membranes or internal fetal monitoring.

Comment on the randomised study:

Internal CTG recording, which may increase the risk of infection, was used in the amniotomy group [72]. This may explain the increased risk of infection associated with amniotomy prior to oxytocin augmentation.

Systematic review

A recent systematic Cochrane review/meta-analysis by Smyth et al. assessed the effect of routine amniotomy in 5,513 parturients without dystocia [70].

In the amniotomy group, the second stage was 5 minutes shorter and the use of oxytocin augmentation less frequent (RR 0.72 (0.54 to 0.96)) [70]. Overall, in all parturients, there was no significant difference in the duration of the active phase, the incidence of caesarean sections, the parturient's satisfaction, Apgar score <7 at 5 minutes, maternal infection, admission to neonatal intensive care unit, perinatal death, neonatal seizures or duration of the second stage.

A subgroup analysis of parturients with dystocia (n=39) showed a higher level of satisfaction among women in the amniotomy group [73].

Some of the predefined critical and important outcomes were not elucidated in the meta-analysis.

9.6 Summary of Findings table

Amniotomy or preservation of intact membranes in case of dystocia

Rouse DJ, McCullough C, Wren AL, Owen J and Hauth JC. Active-Phase Labour Arrest: A Randomized Trial of Chorioamnion Management. Obstetetrics and Gynecology. 1994; 83: 937-40 [(71)].

Population: Women in spontaneous labour, gestational age ≥36 completed weeks, singleton fetus in cephalic presentation, cervical dilatation of at least 4 cm, intact membranes and dystocia defined as a dilatation of ≤1 cm assessed over 2 hours.

Intervention: Oxytocin augmentation without previous amniotomy (oxytocin first).

Comparison: Oxytocin augmentation preceded by amniotomy (amniotomy first).

Outcomes	Absolute effect* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Control group Baseline risk	Intervention group The effect in the intervention group				
	Amniotomy first	**Oxytocin first**				
Duration of labour from randomisation to childbirth (hours)		The mean duration of labour was **0.7 hours longer in the intervention group** (1.5 hours longer to 0.5 hours shorter).		109 (1 study)	⊕⊕⊖⊖ **low**[1,2]	A positive value means a **longer** duration of labour in the intervention group.
Caesarean section	**69 per 1,000**	**57 per 1,000** (13 to 236)	**RR 0.83** (0.19 to 3.42)	118 (1 study)	⊕⊕⊖⊖ **low**[1,2]	A relative risk of less than 1 means a **lower** risk of caesarean section in the intervention group.
Chorioamnionitis	**3 per 60**	**0 per 58**		118 (1 study)	⊕⊖⊖⊖ **very low**[2,3,4]	There were no cases of chorioamnionitis in the intervention group.
Endometritis	**3 per 60**	**0 per 58**		118 (1 study)	⊕⊖⊖⊖ **very low**[2,3,4]	There were no cases of endometritis in the intervention group.
Verified neonatal infection	**1 per 60**	**0 per 58**		118 (1 study)	⊕⊖⊖⊖ **very low**[2,3,4]	There were no cases of verified neonatal infection in the intervention group.

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group rating of quality of the evidence:

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be

close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

[1] Wide confidence interval.

[2] Lack of blinding of the intervention may lead to bias.

[3] No information on use of prophylactic antibiotics during prolonged waters breaking/amniotomy.

[4] In addition to amniotomy, the intervention included internal monitoring, which in some studies is associated with an increased risk of infection.

Amniotomy or preservation of intact membranes in case of normal progress of labour

Smyth RMD, Marham C, Dowsell T. Amniotomy versus no amniotomy for shortening spontaneous labour. Data only. Cochrane Database of Systematic Reviews 2013, Issue 6 [(70)]

Population: Singleton pregnant women in spontaneous labour, both primiparous and multiparous women.

Intervention: Amniotomy.

Comparison: Preservation of membranes.

Outcomes	Absolute effect* (95% CI)		Relative effect (95% CI)	No. of participants (studies) refer to references	Quality of the evidence (GRADE) refer to footnotes	Comments
	Control group Baseline risk	Intervention group The effect in the intervention group				
	Preservation of membranes	**Amniotomy**				
Apgar score <7 at 5 minutes, primiparous women	**18 per 1,000**	**8 per 1,000** (4 to 16)	**RR 0.42** (0.2 to 0.88)	2,542 (4 studies)	⊕⊕⊖⊖ **low**[3.4]	A relative risk of less than 1 means a **lower** risk of Apgar 5 min <7 in the intervention group.
Perinatal death, primiparous women	0	0	Cannot be estimated	2733 (7 studies)		There were no cases of perinatal death in the control or intervention group.
Admission to neonatal intensive care unit, primiparous women	**55 per 1,000**	**61 per 1,000** (43 to 85)	**RR 1.1** (0.78 to 1.54)	2,153 (5 studies)	⊕⊕⊕⊖ **moderate**[2]	A relative risk of greater than 1 means a **higher** risk of admission to neonatal intensive care unit in the intervention group.
Neonatal seizures, primiparous women	**2 per 1,000**	**1 per 1,000** (0 to 9)	**RR 0.88** (0.15 to 5.35)	2,545 (4 studies)	⊕⊕⊖⊖ **low**[2]	A relative risk of less than 1 means a **lower** risk of neonatal seizures in the intervention group.
Oxytocin augmentation, primiparous wom-	**428 per 1,000**	**338 per 1,000**	**RR 0.79**	1,179	⊕⊖⊖⊖	A relative risk of less than 1 means a **lower** risk of oxytocin aug-

en		(240 to 475)	(0.56 to 1.11)	(3 studies)	**very low**[2,3,5]	mentation in the intervention group.
Caesarean section, primiparous women	**70 per 1,000**	**80 per 1,000**	**RR 1.15**	2,674	⊕⊕⊖⊖	A relative risk of greater than 1 means a **higher** risk of caesarean section in the intervention group.
		(61 to 105)	(0.88 to 1.51)	(6 studies)	**low**[2,3]	
Duration of the first stage, primiparous women (minutes)	The mean duration of the first stage was **359 minutes**.	The mean duration of the first stage was **57.9 minutes shorter** (152.7 minutes shorter to 36.8 minutes longer).		379 (4 studies)	⊕⊖⊖⊖ **very low**[1,2]	A negative value means a **shorter** duration of the first stage in the intervention group.
Duration of the second stage, primiparous women (minutes)	The mean duration of the second stage was **39-83 minutes**.	The mean duration of the second stage was **5.4 minutes shorter** (10.0 minutes shorter to 0.9 minutes shorter).		653 (7 studies)	⊕⊕⊕⊖ **moderate**[2]	A negative value means a **shorter** duration of the second stage in the intervention group.
Maternal satisfaction with the childbirth experience, all parturients (scale)	The mean satisfaction was **213**.	The mean satisfaction was **1.1 points lower** (7.2 points lower to 5.0 higher).		84 (1 study)	⊕⊕⊖⊖ **low**[2,3]	A negative value means a **lower** maternal satisfaction with the childbirth experience in the intervention group.
Maternal infection, primiparous women	**18 per 1,000**	**15 per 1,000**	**RR 0.81**	1,617	⊕⊕⊕⊖	A relative risk of less than 1 means a **lower** risk of maternal infection in the intervention group.
		(7 to 32)	(0.38 to 1.72)	(3 studies)	**moderate**[2]	

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group rating of quality of the evidence:

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

[1] I^2 greater than 80%.

[2] Wide confidence interval.

[3] Lack of blinding.

[4] Apgar is not a good surrogate for perinatal morbidity and mortality.

[5] I^2 greater than 50%.

Routine amniotomy or preservation of intact membranes in case of dystocia

Amniotomy versus no amniotomy for shortening spontaneous labour. Data only. Smyth RMD, Marham C, Dowsell T. Cochrane Database of Systematic Reviews 2013, Issue 6 [70,73].

Subgroup analysis of data from Blanch G, Lavender T, Walkinshaw S, Alfiveric Z. Dysfunctional labour: a randomised trial. BJOG 1998; 105:117-20 [73].

Population: Singleton pregnant women in spontaneous, active labour (cervical dilatation of ≥3 cm) on term, with dystocia (no progress for 2 hours or <1 cm / 3 hours), both primiparous and multiparous women.

Intervention: Amniotomy.

Comparison: Preservation of membranes.

Outcomes	Absolute effect* (95 % CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Control group Baseline risk	Intervention group The effect in the intervention group				
	Preservation of membranes	**Amniotomy**				
Apgar score <7 at 5 minutes	**0**	**0**	**Cannot be estimated**	39 (1 study)		No cases of Apgar <7 at 5 minutes in the intervention or control group.
Admission to neonatal intensive care unit	**0**	**0**	**Cannot be estimated**	39 (1 study)		No cases of admission to neonatal intensive care unit in the intervention or control group.
Caesarean section due to imminent asphyxia	**0**	**0**	**Cannot be estimated**	39 (1 study)		No cases of caesarean section due to imminent asphyxia in the intervention or control group.
Caesarean section due to dystocia	**105 per 1,000**	**49 per 1,000** (5 to 507)	**RR 0.47** (0.05 to 4.82)	39 (1 study)	⊕⊖⊖⊖ **very low**[1,2]	A positive value means a **lower** severity of hallmark symptoms in the intervention group.
Oxytocin augmentation	**632 per 1,000**	**549 per 1,000** (328 to 928)	**RR 0.87** (0.52 to 1.47)	39 (1 study)	⊕⊕⊖⊖ **low**[1,2]	A positive value means a **lower** severity of hallmark symptoms in the intervention group.
Maternal satisfaction with the childbirth experience (scale)		The mean satisfaction was **22 points higher** (2.7 to 41.3 points higher)		39 (1 study)	⊕⊕⊕⊖ **moderate**[1]	A positive value means a **higher** satisfaction with the childbirth experience in the intervention group.

*The baseline risk is based on the median control group risk across the studies included. The effect in the intervention group is based on the baseline risk and the relative effect of intervention.

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group rating of quality of the evidence:

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be

close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

[1] No blinding.

[2] Wide confidence interval.

9.7 Working group considerations

Quality of the evidence	Overall, the evidence is of low or very low quality.
Balance between beneficial and adverse effects	The effect of amniotomy to shorten labour is probably lower than assumed so far. A potentially increased risk of infection in association with amniotomy does not seem substantiated and can be handled with appropriate monitoring of the parturient and prophylactic antibiotics in case of prolonged waters breaking according to applicable local instructions.
Patient preferences	The parturients most likely prefer a less extensive intervention (amniotomy) to a more extensive intervention (oxytocin augmentation), and the subgroup analysis supports this [(73)].
Other considerations	In case of an unengaged foetal head and a risk of umbilical cord prolapse, it may be appropriate to prioritise differently. The studies only included women in spontaneous labour. The working group has assessed, however, that the recommendations should also apply to cases of induced labour, in which there was no use of oxytocin augmentation in the latent phase.

9.8 Rationale for recommendation

Based on the above-mentioned literature review and the quality of the evidence, the working group finds that there are still good reasons for recommending for amniotomy prior to offering oxytocin augmentation. In formulating the recommendation, the principle of performing the least extensive intervention first was weighted high.

Since the evidence is indirect, the working group only gave good practice recommendations.

10 Duration of oxytocin augmentation of labour

10.1 Focused question 11

For how long, after initiating oxytocin augmentation, should progress be awaited in the active phase of the first stage prior to performing another intervention (caesarean section)?

10.2 Recommendation

√ It is good practice that the midwife responsible for the childbirth reviews the progress after 4 hours of oxytocin augmentation in the active phase of the first stage (the dilatation phase).

√ In case of a cervical dilatation of <2 cm after 4 hours of oxytocin augmentation, it is good practice to review the progress with an experienced colleague.

√ It is good practice to consider an additional 2 hours of oxytocin augmentation if a satisfactory pattern of contractions (a maximum of 5 contractions in 10 minutes) has not been reached within 4 hours.

10.3 Practical advice and special patient considerations

Experienced colleague means, e.g., a senior staff midwife or a doctor, depending on the local conditions.

A review of the progress includes, among other things, assessing the following (cf. the childbirth checklist and the labour augmentation drip package of the Danish safe childbirth ('Sikre Fødsler') project [5]):

- Fetal heart rate, including indication for CTG
- The perspective of the parturient woman
- Risk factors
- Presence of mechanical mismatch (cephalopelvic disproportion)
- Descent and rotation of the fetal head
- Rupture of membranes
- Pattern of contractions
- Cervical progress (assessed, e.g., by means of a partogram)
-

Perspective of the parturient means preferences, need of pain relief and physical and mental condition.

See the flowchart for dystocia in the active phase of the first stage (the dilatation phase) in Key messages and here (*external link to a print-friendly version*).

10.4 Background of the choice of question

Oxytocin augmentation may increase the labour frequency and intensity, but will not necessarily cause the desired progress of the cervical dilatation. The working group wanted to investigate for how long, after initiating oxytocin augmentation, progress in labour may be awaited prior to considering another method of delivery (caesarean section):

10.5 Literature

To answer the focused question, two guidelines [10,17] and two observational studies [74,75] were included. See the flowchart for the literature search here.

The active phase: guidelines for duration of oxytocin augmentation in primiparous women

The NICE guideline (2007) recommends a review of the progress every 4 hours following initiation of oxytocin augmentation in the active phase. In case of cervical dilatation of ≥2 cm in 4 hours, the augmentation may continue. In case of cervical dilatation of <2 cm in 4 hours, caesarean section should be considered [10].

The Swedish guideline (2011) recommends for delaying assessment of progress until after at least 4 hours of optimal augmentation (defined as 4-5 contractions in 10 minutes) [17].

Comments on the two recommendations:

The recommendations both seem to be based on two prospective cohort studies from the 1990s with, respectively, 442 [74] and 501 [75] parturient women with dystocia and oxytocin augmentation. The studies show that even among primiparous women with a cervical dilatation of ≤1 cm in 2 hours 74% delivered vaginally. After 4 hours of oxytocin augmentation and lack of progress, the vaginal delivery rate was 56% for primiparous women. The risk of infections (endometritis and chorioamnionitis) was correlated to slow progress (7% vs. 13%). This was not the case for the risk of blood transfusion. The authors conclude that the neonatal outcomes were good and not related to the pattern of progress [74].

The working group extended the literature search for the period following 2007, but did not find any further primary or secondary literature to be used in answering the focused question.

10.6 Working group considerations

Quality of the evidence	Generally, evidence based on observational studies, as is the case here, is assessed to be of low quality. The working group found no reason to upgrade the evidence.
Balance between beneficial and adverse effects	A continued high likelihood of vaginal delivery following 4 hours of oxytocin augmentation should be weighed against a potentially increased risk of infection. The working group finds, however, that this risk can be handled with appropriate monitor-

	ing of the parturient and antibiotics according to applicable local instructions.
Patient preferences	The childbirth experience was not investigated in the studies included in answering the focused question. However, the opinions among parturients as regards duration of augmentation most likely vary, and therefore the parturient's values and preferences should be considered when deciding whether to continue augmentation.
Other considerations	The possibility of vaginal delivery has been assigned a high priority by the working group – in consideration of the current process as well as potential future pregnancies in which earlier caesarean section will constitute a risk factor.

10.7 Rationale for recommendation

Since the evidence is indirect, and because values and preferences most likely vary among parturients, the working group gave good practice recommendations.

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12 Appendixes

Appendix 1a: Background

Appendix 1b: Definitions of dystocia in other guidelines

Appendix 1c: Tables concerning focused questions 1-3

Appendix 1d: Literature review

Appendix 2: Implementation

Appendix 3: Monitoring

Appendix 4: Update and further research

Appendix 5: Description of the method used

Appendix 6: Focused questions in PICO form

Appendix 7: Description of the strength and implications of recommendations

Appendix 8: Search strategy incl. flowchart

Appendix 9: Assessment of evidence

Appendix 10: Working group and reference group

Appendix 11: Abbreviations and concepts

Appendix 1a: Background

Lack of progress of labour (dystocia) is common. According to a Danish listing from 2009, the incidence of dystocia was 37% in a group of healthy primiparous women [76]. Dystocia is associated with an increased risk of instrumental vaginal delivery and caesarean section. In the USA, dystocia (*labour arrest*) is the indication for up to 50% of all first-time caesarean sections [54].

Dystocia may be caused by several factors: abnormal fetal presentation (*passenger*), mechanical mismatch between the fetus and the pelvis (*passageway*) and uterine inertia (*power*) [77], and various conditions may predispose to dystocia. Epidural, increasing maternal age, low maternal height, genetic predisposition, overweight and emotional stress are all associated with an increased risk of dystocia [76-78] and, most recently, de- or dyshydration in the parturient has been suggested as a factor which may impact on contractions of the uterine muscle [55].

The incidence of dystocia is closely associated with the definition applied to normal progress. This definition has been the object of research and discussion, and agreement has still not been reached as to which definition is the correct or most appropriate one. Various current definitions appear from Appendix 1b.

In 1973, as part of the *Active Management of Labour*, O'Driscoll suggested intervention at a progress of less than 1 cm/h in primiparous women during active labour [47]. Since then, WHO [16] and the NICE 'Clinical Guideline: Intrapartum Care' (2007) [10], suggesting a dilatation rate of less than 0.5 cm/h assessed over 4 hours during the dilatation phase as the threshold for normal progress, among others, have moved in the direction of handling progress of labour in a more awaiting manner.

Most often, active labour has been defined as regular contractions and a cervical dilatation of 3-4 cm [10,14,16]. However, these definitions are challenged by observational studies. In a large US cohort study including more than 60,000 parturients, Zhang 2010 [3] described slower progression until a cervical dilatation of 6 cm and suggested that the transition from the latent phase to active labour with accelerating progression does not occur until a cervical dilatation of 6 cm is reached. This definition was adopted in a recent US guideline [4].

Other studies also describe slower progress than that considered normal, traditionnally, in primiparous women [1-3].

A potential future relaxation of the criteria for active labour and dystocia may result in diagnosing dystocia less often and, therefore, less frequent initiation of treatment. However, this issue should be dealt with in future research.

Treatments in case of dystocia range from non-medicinal, simple options such as mobilisation, change of position, rest, pain relief and fluid and food to more extensive interventions such as oxytocin augmentation, instrumental vaginal delivery or caesarean section [77-79]. Also, it is well-documented that assignment of one labour and delivery team member throughout the process will promote the normal progress of labour [80]. Other options, which are considered alternative treatments in Denmark, comprise acupuncture, acupressure and rebozo.

Oxytocin augmentation is widely used in Denmark, in that use in up to 30% of all primiparous women has been reported [76,81]. Unpublished listings of the use following the implementation of the Danish national safe childbirth ('Sikre Fødsler') initiative, however, indicate that the use is decreasing.

Oxytocin infusion may increase the contraction frequency and intensity, shorten the duration of labour and promote a vaginal delivery [6,20]. However, as any other medicine, it is associated with risk of adverse reactions. The well-described ones are the acute adverse reactions caused by excessive dosage, namely hyperstimulation characterised by frequent contractions, short intervals between contractions and the risk of intrauterine asphyxia [6]. Incorrect use of oxytocin has been shown to be implicated in up to 77% of the Scandinavian patient insurance cases, in which medical error lead to serious fetal asphyxia resulting in death or serious injury [21,23].

Additionally, in recent years, attention has been on investigating whether intrauterine exposure to synthetic oxytocin may have other adverse effects. In both humans and animals, oxytocin plays a key role in relation to breast-feeding and attachment, and experimental animal studies have shown that synthetic oxytocin given in connection with or immediately after childbirth may interfere with the attachment process. A study investigating behaviour in newborns exposed to synthetic oxytocin during birth showed signs of deviant neurological behaviour in these newborns, and the authors concluded that the long-term effects on the children's social and neurological development should be investigated [82]. The hypotheses on potential adverse effects of synthetic oxytocin are mainly based on small exploratory studies and experimental animal studies which do not provide sufficient basis for recommendations against the use of synthetic oxytocin during labour. However, they may contribute to considering the use of a precautionary principle.

The working group wishes to promote safe, vaginal delivery, avoid potential adverse effects of unnecessary use or incorrect dosing of oxytocin and to give the new families a good and safe start. It is their hope that this guideline will provide a practical and evidence-based basis for the clinical management of dystocia.

Appendix 1b: Definitions of dystocia in other guidelines

Guideline	Active labour	Dystocia in the dilatation phase	Dystocia in the passive second stage	Dystocia in the active second stage
DSOG Dystoci (DSOG Dystocia, in Danish only) (draft). Denmark 2011[14].	Regular contractions and cervical dilatation of 4 cm.	Cervical dilatation of <2 cm in 4 hours.	No progress in descent of the head assessed over 1 hour (2 hours in case of epidural).	Duration >1 hour.
Nationella Medicinska Indikationer: Indikation för värkstimulering med oxytocin under aktiv förlossning (National Medical Indications: Indication for oxytocin augmentation during the active phase of labour, in Swedish only). Sweden 2011[17].	At least two of the following three: • Cervical dilatation of 3-4 cm. • Waters breaking. • Regular, painful contractions.	No dilatation in 3 hours.	No progress for at least 1 hour.	No progress for at least 30 minutes.
The Norwegian Society of Gynaecology, Veileder i Fødselshjelp (Guideline concerning childbirth aid, in Nowegian only). Norway 2014[15].	Regular contractions and cervical dilatation of 4 cm.	Cervical dilatation of <2 cm in 4 hours (WHO partogram).	Not described.	Instrumental vaginal delivery at a duration >1 hour, with or without an epidural.

NICE Clinical Guideline 55: Intra-partum Care. UK 2007[10] *	Painful contractions and cervical dilatation of 4 cm.	Cervical dilatation of <2 cm in 4 hours.	Not described.	Duration of ≥ 2 hours and delivery not approaching.

*Unchanged in the draft updated 2014 version (9 March 2014).

Guideline	Active labour	Dystocia in the dilatation phase	Dystocia in the passive second stage	Dystocia in the active second stage
ACOG Practice Bulletin: Dystocia. USA 2003[53].	Cervical dilatation of 3-4 cm.	'An adequate trial of labor'. 'slower-than-normal or complete cessation of progress'. <3 contractions in 10 minutes.	Total duration of the descending and expulsive phases ('second stage') of >2 hours in women without an epidural. OR Total duration of the descending and expulsive phases ('second stage') of >3 hours in women with an epidural.	
ICSI Institute for Clinical Systems Improvement. Health Care Guideline: Management of Labor. USA 2013[4].	Cervical dilatation of 6 cm or more.	Cervical dilatation of <1 cm in 2 hours.	Descent of the head of <1 cm in 1 time.	
Managing complications in pregnancy and childbirth: a guide for midwives and doctors. WHO 2007[16].	Cervical dilatation of 4 cm or more.	Dilatation of <2 cm in 4 hours (actually at least 1 cm/h, but the partogram with the action line is displaced 4 hours).	No descent of the head.	No progress during the expulsive phase.

Appendix 1c: Tables concerning focused questions 1-3

The results of the two secondary analyses of randomised studies and nine observational studies identified for focused question 2-3 appear from the tables below.

Le Ray 2009 [30]	The expulsive phase 1-2 hours	The expulsive phase 2-3 hours	The expulsive phase >3 hours
	$OR_{adjusted}$ (95% CI)	$OR_{adjusted}$ (95% CI)	$OR_{adjusted}$ (95% CI)
Apgar <7 at 5 min	1.1 (0.3 to 3.6)	0.4 (0.1 to 2.1)	0.7 (0.7 to 3.5)
Arterial pH <7.10	1.1 (0.8 to 3.0)	0.4 (0.1 to 1.3)	0.2 (0.1 to 1.1)
Admission to neonatal intensive care unit	1.1 (0.6 to 2.0)	1.5 (0.8 to 3.0)	1.5 (0.7 to 3.3)
Significance of the duration of the expulsive phase in a secondary analysis of 1,862 primiparous women. The reference was an expulsive phase of <1 hour.			

Yli 2012 [31]	The expulsive phase 15-30 min	The expulsive phase 1½-2 hours	The expulsive phase >2 hours
	$OR_{adjusted}$ (95% CI)	$OR_{adjusted}$ (95% CI)	$OR_{adjusted}$ (95% CI)
Apgar <7 at 5 min	1.3 (0.8 to 2.1)	2.3 (1.1 to 5.0)	2.3 (0.8 to 6.4)
pH <7.00	3.2 (1.7 to 6.0)	7.3[3] (3.1 to 17.5)	5.1 (1.5 to 17.9)
The significance of the duration of the expulsive phase in a secondary analysis of 36,432 primiparous and multiparous women, wherein the adjustment includes parity. The reference was an expulsive phase of <15 min.			

Laughon 2014 [13]	2nd stage ≤2 hours	2nd stage >2 hours	$OR_{unadjusted}$ (95% CI)
Apgar <4 at 5 min	0.4%	0.4%	0.83 (0.3 to 2.4)
Asphyxia (not defined)	0.1%	0.4%	3.1 (0.9 to 10)

[3] If the reference is an expulsive phase of 15-30 minutes, the risk of an Apgar score <7 at 5 min and pH <7.00, respectively, for an expulsive phase of 1½-2 hours is 1.8 and 2.3, respectively (the DHMA's own calculations based on data from the original publication Yli 2012).

Admission to neonatal intensive care unit	5.1%	8.6%	1.8 (1.4 to 2.2)
The significance of the duration of the 2nd stage in a registry study including 8,153 primiparous women without an epidural.			

Allen 2009 [83]	2nd stage 2-3 hours	2nd stage 3-4 hours	2nd stage 4-5 hours
	$OR_{adjusted}$ (95% CI)	$OR_{adjusted}$ (95% CI)	$OR_{adjusted}$ (95% CI)
Apgar <7 at 5 min	1.3 (1.1 to 1.6)	1.4 (1.0 to 1.8)	1.0 (0.7 to 1.5)
Admission to neonatal intensive care unit	1.4 (1.3 to 1.6)	1.9 (1.7 to 2.2)	2.1 (1.8 to 2.4)
The significance of the duration of the 2nd stage in a registry study including 63,404 primiparous women. The reference was a 2nd stage of <2 hours.			

Rouse 2009 [12]	2nd stage 2-3 hours	2nd stage 3-4 hours	2nd stage ≥ 5 hours
Apgar <4 at 5 min	0.2%	0%	0%

pH <7.0	0.8%	1.2%	0%
Endometritis	2.4%	6.0%	4.5%
The significance of the duration of the 2nd stage in a secondary analysis of a registry study including 4,126 primiparous and multiparous women.			

Le Ray 2011 [33]	Control	Postpartum haemorrhage	$OR_{adjusted}$
Active phase (1st stage)	5.6%	12%	2.8 (1.2 to 6.8)
Descending phase of >2 hours	8.0%	9.1%	1.2 (0.5 to 2.9)
Expulsive phase of >250 min	1.1%	8.8%	13 (4.1 to 43)
Case-control secondary analysis of postpartum haemorrhage (>1,000 ml) in primiparous women (N = 3,330) vs. duration of the descending and expulsive phases.			

Lu 2009 [34]	Control	Postpartum haemorrhage	$OR_{unadjusted}$ (95% CI)
Fraction with a 2nd stage of >3 hours	5%	18%	4.7 (2.0 to 11)
Case-control study of postpartum haemorrhage.			

Bleich 2012 [35]	<3 hours (control)	3-4 hours	≥ 4 hours
Apgar <3 at 5 min	0.1%	0.3%	0.5%
pH <7.0	0.4%	0.8%	1.0%
Neonatal intensive care unit	0.7%	2.0%	2.0%
Fever of ≥ 38.0° (maternal)	3.0%	7.0%	13%
Retrospective study including primiparous women with a prolonged 2nd stage.			

Brown 2011 [36]	2nd stage ≤2 hours (3 hours, if with an epidural)	2nd stage >2 hours (3 hours, if with an epidural)	$OR_{adjusted}$ (95% CI)
Urinary incontinence	29%	37%	2.2 (1.1 to 3.4)
Questionnaire concerning the risk of urinary incontinence 3 months after childbirth with answers from 1,507 primiparous women.			

Badiou [37]	2nd stage <30 min	2nd stage >90 min	P Fisher's exact test
Flatus incontinence	16%	9%	0.18
Faecal incontinence	5%	2%	0.45
Questionnaire concerning flatus and faecal incontinence 15 months after childbirth with answers from 184 primiparous women.			

Appendix 1d: Literature review focused question 6

Literature review for focused question 6: Second-stage dystocia in primiparous women with an epidural

Guidelines

The British 'NICE Clinical Guideline: Intrapartum Care' of 2007 [6] and the Swedish guideline 'Indikation för värkstimulering med oxytocin under aktiv förlossning (Indication for oxytocin augmentation during the active phase of labour, in Swedish only)' from 2011 [17] both make no distinction between women with and without an epidural in their recommendations for intervention in case of dystocia during the first stage of labour (see Appendix 1a).

The NICE guideline recommendations make no direct distinction between parturients with and without an epidural concerning duration of the second stage of labour (see Appendix 1a). However, in the section concerning duration of normal labour, they mention that the delivery should be expected within 3 hours following the beginning of the expulsive phase in most primiparous women. In the section concerning use of an epidural, they recommend to prepare a plan, with each parturient with an epidural, for delivery within four hours following full dilatation of the cervix (i.e., at the beginning of the second stage). Thus, a time window is provided for the second stage in women with an epidural. However, not in women without an epidural, in that the guideline does not specify a recommended maximum duration of the descending phase in this group [10].

The Swedish guideline refers to three systematic reviews which show that the second stage of labour is prolonged and that the risk of instrumental vaginal delivery, but not of caesarean section, seems to be increased from the use of an epidural. This guideline specifies one time threshold for intervention in the second stage of labour, whether or not the parturient has received an epidural [17].

Systematic review

A systematic review/meta-analysis from 2013 analysed the duration of the second stage in 4,233 women with and without an epidural. The second stage was found to be prolonged by 13 minutes from the use of an epidural, but with no distinction between the passive and active phases of the second stage [50].

Primary studies

Cheng 2014 analysed the duration of the second stage of labour in a US retrospective cohort study including 22,370 primiparous women with and without an epidural. The duration of the second stage was found to be prolonged by the use of an epidural, given that the 50 percentile for the duration of the second stage was 120 and 47 minutes in primiparous women with and without an epidural, respectively. Likewise, the 95 percentile is 336 and 197 minutes for primiparous women with and without an epidural, respectively [52].

This was compared to the current US definition (ACOG 2003) [53] of prolonged second stage in primiparous women which is 3 and 2 hours in woman with and without an epidural, respectively. There was no difference in the neonatal outcomes of Apgar score <7 at 5 minutes, arterial pH <7.0, meconium aspiration syndrome, sepsis, admission to neonatal intensive care unit or the composite outcome of *birth trauma* (cephalhaematoma, laceration, fractured clavicle, skull fracture, paresis of the facial nerve and Erb's paresis) between women with normal vs. prolonged second stage according to the ACOG 2003 definition. The authors repeated the same analysis, but grouped the childbirths using a time threshold for a prolonged second stage corresponding to the ACOG definition plus 1 hour, i.e. 4 and 3 hours in women with and without an epidural, respectively. In a second repetition, the childbirths were grouped using the above-mentioned 95 percentile as the time threshold. In the second and third analyses, there was a significant difference in the composite outcome of 'birth trauma' (the adjusted odds ratio was 2.08 (1.38 to 3.15) and 2.73 (1.62 to 4.61), respectively), but not in the other neonatal outcomes. The analyses were not stratified based on use of epidural or not in the women.

When, in the same three analyses, looking at the maternal outcomes of caesarean section, instrumental vaginal delivery, 3rd and 4th degree perineal ruptures, postpartum haemorrhage, chorioamnionitis and endomyometritis, a prolonged second stage was associated with an increased risk – regardless of the definition chosen. The adjusted odds ratios for the individual maternal outcomes were almost identical across the various definitions of prolonged second stage.

On this basis, Cheng 2014 concluded that an epidural probably increases the duration of the second stage more than assumed so far, but also that a prolonged second stage is not associated with a significantly increased perinatal or maternal risk. Defining prolonged second stage to start too early may result in overdiagnosing and unnecessary interventions which may have consequences for, e.g., future pregnancies (such as caesarean section) [52].

Additionally, the authors relied on the consensus from a US workshop in which representatives from the NIH, the Society for Fetal-Maternal Medicine and the American College of Obstetricians and Gynecologists [54] suggest to increase the time threshold for dystocia in the second stage, in women with and without an epidural, to 4 and 3 hours, respectively. Furthermore, they wrote that the data also support to move the threshold for women without an epidural, but did not clearly state how. Also, any differences in the outcomes for women with and without an epidural were not stated. Therefore, the study supports that the second stage is prolonged from the use of an epidural and that a prolonged second stage is not necessarily associated with poor neonatal and maternal outcomes [52]. However, it doesn't show why intervention should take place earlier in women without an epidural.

In another large US cohort study including 43,810 primiparous women [13], a number of neonatal and maternal outcomes were analysed in primiparous and multiparous women with and without an epidural, in whom the second stage was prolonged according to the ACOG 2003 definition. In a comparison of the incidence of a number of neonatal and maternal outcomes in women with and without an epidural and with prolongation defined as >3 hours and >2 hours, respectively, almost no differences were found in the neonatal outcomes. For example, the incidence of the critical outcome of 'admission to neonatal intensive care unit' was 8.2% and 8.6%, respectively, in the group with an epidural/3 hours and the group without an epidural/2 hours. Likewise, the incidence of Apgar score <4 at 5 minutes was 0.4%

and 0.5%, respectively, and the incidence of asphyxia was 0.3% and 0.4%, respectively. There was no difference in the incidence of neonatal seizures either, whereas the incidence of sepsis was 1.8% in the group without an epidural/2 hours vs. 2.6% in the group with an epidural/3 hours. For the maternal outcomes, a difference was found in the percentage of episiotomies in that 33.8% in the group with an epidural/3 hours had had an episiotomy vs. 40.6% in the group without an epidural/2 hours threshold. The authors also found a small difference in the incidence of postpartum haemorrhage, namely 5.9 and 5.1%, respectively, in women with and without an epidural, and in the percentage of parturients receiving blood transfusion which was 4.4% and 1.4%, respectively. The incidence of chorioamnionitis was higher in the group with an epidural/3 hours, in which 11.1% were diagnosed, and 5.6% in the group without an epidural/2 hours. The slightly increased incidence of infections and haemorrhage in women with an epidural may be explained by the longer duration of the childbirth. The difference in episiotomies may give rise to considerations as to whether the lower time threshold for prolonged second stage may lead to more interventions because of the temporal definition alone.

Appendix 2: Implementation

This section decribes the stakeholders (organisations, professional groups, authorities) co-responsible for ensuring the dissemination of knowledge and application of the guideline recommendations among healthcare professionals who meet the parturients in clinical practice and will decide on diagnostics and treatment for this group of patients. Additionally, the section includes the working group's suggested specific activities which may be initiated by the stakeholders to support the implementation.

The regions and the regional hospitals play an important role in facilitating the implementation of the national clinical guideline through communicating the content of the guideline and supporting the practical application of the guideline. To support application of the national clinical guideline locally, it should preferably be attuned with or integrated into process descriptions, instructions and guidelines which are already in use. Therefore, each region should ensure that the recommendations of relevance to specialised departments at hospital level are incorporated into instructions and guidelines in that region.

The professional organisations are important stakeholders as regards disseminating knowledge of the guideline. The DHMA, therefore, suggests to mention the national clinical guideline on the websites of the relevant professional organisations, possibly including a description of the implications of it for the speciality in question and with a link to the full version of the guideline. Also, the DHMA suggests to present the guideline at annual meetings in the professional organisations. A presentation is planned at the Danish Society of Obstetrics and Gynaecology's annual obstetric guideline meeting, the Sandbjerg meeting, in January 2015.

Information may also be communicated via members' magazines and electronic newsletters.

Furthermore, the DHMA suggests to communicate the content of the guideline to the patients and to involve relevant patient organisations in the communication process.

As a starting point, implementation of the national clinical guideline on dystocia is a regional responsibility. However, the DHMA wishes to support the implementation. To this end, the DHMA published a toolbox with tools for the implementation in the spring of 2014. It is available as an electronic work of reference on the DHMA's website (in Danish only). The toolbox is based on the evidence of the effect of interventions and is meant to assist the manager or project manager who is to work on implementing change of a certain extent locally.

At the time of publishing the guideline, it has been decided to publish a quick guide in addition to the full guideline. The quick guide is a short version of 1-2 A4 pages. It only contains the guideline recommendations and key messages, if any, with specification of evidence rating and strength of the recommendations. Also, the guideline on dystocia will be supplemented with two flowcharts for the management of dystocia in the dilatation phase and the second stage of labour, respectively. Additionally, an application for smartphones and tablets, from which the national clinical guidelines can be accessed, is under development.

Appendix 3: Monitoring

Process and impact indicators

The working group suggests to survey all the maternity wards in Denmark when publishing the guideline and again two years later to investigate whether the recommendations in the national clinical guideline on dystocia are being followed.

The working group recommends to always code for the use of rebozo and acupuncture in the treatment of dystocia. In future, this coding may serve as a process indicator and lead to increased knowledge of the frequency of use and the effect of rebozo and acupuncture.

Additionally, the data sources below may be used for shedding light on, e.g., changed incidence of diagnosing dystocia, use of oxytocin augmentation and birth of children with asphyxia. However, the working group finds that it will be difficult to ascribe any changes to the national clinical guideline on dystocia alone, because the safe childbirth ('Sikre Fødsler') project has had a partially overlapping focus in the form of optimisation of monitoring and diagnostics during childbirth since 2013.

Furthermore, the working group suggests to supplement the obstetric code for dystocia (DO62) with an additional code to enable recording of the cervical dilatation at the time of dystocia.

Data sources

The Danish National Patient Registry, the Danish Medical Birth Registry and clinical, obstetric databases are useful for assessing and monitoring dystocia.

Appendix 4: Update and further research

Update

As a starting point, the guideline should be updated 3 years from the date of publication, unless new evidence or the technological development in this field justifies otherwise.

In the opinion of the working group, special attention should be paid to the development in the definition of normal and abnormal progress of labour when updating.

Further research

The literature search for this guideline revealed areas with absence of evidence and areas in which the evidence has several methodical weaknesses. The working group suggests to investigate the following areas further in new studies:

- Consequences of changed definitions of active labour (such as at a cervical dilatation of 6 cm), normal progress and dystocia.
- Effect and safety of oxytocin in the second stage of labour.
- Long-term effects in children who were exposed to oxytocin augmentation during birth.
- Frequency of use, effect and safety of acupuncture indicated for dystocia in the active phase of the first stage of labour and in the second stage.
- Frequency of use, effect and safety of rebozo indicated for dystocia in the active phase of the first stage of labour and in the second stage.
- Effect and safety associated with the use of isotonic intravenous fluid in case of dystocia or slow progress of labour. Should be compared to optimal oral intake of fluid.

Appendix 5: Description of the method used

For a detailed description of the method, please see the DHMA's NCG methods guide (in Danish only).

Appendix 6: Focused questions

Focused question 1

Population: Primiparous women in the **dilatation phase** of spontaneous and induced labour, with dystocia, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Oxytocin augmentation delayed for some hours after diagnosing dystocia.

Comparison: Oxytocin augmentation immediately after diagnosing dystocia.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 2

Population: Primiparous women in the **descending phase** of spontaneous and induced labour, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Oxytocin augmentation delayed for some time after diagnosing dystocia.

Comparison: Oxytocin augmentation immediately after diagnosing dystocia.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 3

Population: Primiparous women in the **expulsive phase** of spontaneous and induced labour, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Oxytocin augmentation delayed for some time after diagnosing dystocia.

Comparison: Oxytocin augmentation immediately after diagnosing dystocia.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 4

Population: Primiparous women in the **dilatation phase** of spontaneous and induced labour, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Oxytocin dosage regimen 1.

Comparison: Oxytocin dosage regimen 2.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 5

Population: Primiparous women in the **second stage (descending and expulsive phases)** of spontaneous and induced labour, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Oxytocin dosage regimen 1.

Comparison: Oxytocin dosage regimen 2.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 6

Population: Primiparous women in the descending phase of spontaneous and induced labour, with an epidural, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Intervention after the same time period with slow progress as in parturients without an epidural.

Comparison: Intervention after a longer time period with slow progress than in parturients without an epidural.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 7

Population: Primiparous women in spontaneous and induced active labour, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Intravenous fluid and free oral fluid intake

Comparison: Free oral fluid intake

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, need of oxytocin augmentation, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 8

Population: Primiparous women in spontaneous and induced active labour, with dystocia, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Acupuncture

Comparison: No acupuncture

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, need of oxytocin augmentation, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 9

Population: Primiparous women in spontaneous and induced active labour, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Rebozo

Comparison: No rebozo

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, need of oxytocin augmentation, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 10

Population: Primiparous women in the active phase of the first stage (the dilatation phase) of spontaneous and induced labour, with dystocia, on term (gestational age ≥37+0), with a fetus in cephalic presentation and with intact membranes.

Intervention: Oxytocin augmentation prior to amniotomy.

Comparison: Amniotomy prior to oxytocin augmentation.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Focused question 11

Population: Primiparous women in the active phase of the first stage (the dilatation phase) of spontaneous and induced labour receiving treatment with oxytocin, on term (gestational age ≥37+0) and with a fetus in cephalic presentation.

Intervention: Oxytocin augmentation for X hours (long-time treatment) prior to caesarean section.

Comparison: Oxytocin augmentation for Y hours (short-time treatment) prior to caesarean section.

Outcomes:

Critical: Perinatal death. Apgar score <7 at 5 minutes, umbilical cord (artery) pH <7, Sarnat score, Thompson score, encephalopathy.

Important: Caesarean section, instrumental vaginal delivery, duration of labour, anal sphincter rupture, incontinence, haemorrhage >1,000 ml, infection, satisfaction/childbirth experience, breast-feeding, attachment and later caesarean section at maternal request.

Appendix 7: Description of the strength and implications of recommendations

Presented below are, firstly, the four types of recommendations to be used in case of evidence and, afterwards, the recommendations which may be given for questions for which the systematic search showed that there was no evidence.

The four types of evidence-based recommendations

A recommendation can be either for or against a given intervention. A recommendation can be either strong or weak/conditional. Therefore, the following four types of recommendations are available:

Strong recommendation for ↑↑

Give/use …

The DHMA makes a strong recommendation for in case of high-quality evidence showing that the desirable consequences of an intervention clearly outweigh its undesirable consequences.

The following will point in the direction of a strong recommendation for:

- High-quality evidence
- High intended effect and few, if any, unintended adverse effects of the intervention
- The patients' values and preferences are well-known and consistent in favour of the intervention

Implications:

- Most patients would want the intervention.
- The vast majority of clinicians would prescribe the intervention.

Weak/conditional recommendation for ↑

Consider …

The DHMA makes a weak/conditional recommendation for when the desirable consequences of an intervention are judged to marginally outweigh its undesirable consequences or when the available evidence cannot rule out a significant benefit of an existing practice if the adverse effects of the latter are judged to be few or absent.

The following will point in the direction of a weak recommendation for:

- Low-quality evidence

- The intended effect of the intervention is assessed to marginally outweigh the unintended adverse effects
- Preferences and values vary significantly among patients or are unknown

Implications:

- Most patients would want the intervention, but a substantial number would not
- The clinicians will need to help the patient make a decision that matches the patient's values and preferences.

Weak/conditional recommendation against ↓

Use only … upon due consideration, since the beneficial effect is uncertain and/or low and there are documented adverse effects such as …

The DHMA makes a weak/conditional recommendation against when the undesirable consequences of an intervention are judged to outweigh its desirable consequences and this is unsupported by strong evidence. This recommendation is also made in case of strong evidence of both beneficial and adverse effects when the balance between them is difficult to determine.

The following will point in the direction of a weak recommendation against:

- Low-quality evidence
- Uncertain effect of the intervention
- Uncertain adverse effects of the intervention
- The unintended adverse effects of the intervention are assessed to marginally outweigh the intended effect
- Preferences and values vary significantly among patients or are unknown

Implications:

- Most patients would not want the intervention, but a certain number would
- The clinicians will need to help the patient make a decision that matches the patient's values and preferences.

Strong recommendation against ↓↓

Do not give/do not use/avoid …

The DHMA makes a strong recommendation against in case of high-quality evidence showing that the undesirable consequences of an intervention clearly outweigh its desirable consequences. The DHMA also makes a strong recommendation against when the review of the evidence shows with great certainty that an intervention is useless.

The following will point in the direction of a strong recommendation against:

- High-quality evidence
- The intended effect of the intervention is low
- Some or significant unintended adverse effects of the intervention
- The patients' values and preferences are well-known and consistent against the intervention

Implications:

- Most patients would not want the intervention.
- Clinicians would typically not prescribe the intervention.

The two types of good practice recommendations

Good practice √

For:

It is good practice to …

Against:

It is not good practice to …

It is not good practice, on a routine basis, to …

It is good practice to avoid …

It is good practice to avoid, on a routine basis, …

Good practice based on professional consensus among the members of the working group that prepared the clinical guideline. The recommendation may be either for or against the intervention. A good practice recommendation is made when relevant evidence is not available. Therefore, this type of recommendation is weaker than the evidence-based recommendations irrespective of whether they are strong or weak.

Appendix 8: Search strategy and flowcharts

For this clinical guideline, the searches were performed in a predefined group of databases selected for search for clinical guidelines. For a detailed description, please see the DHMA's NCG method guide (in Danish only). The searches were performed by Hanne Caspersen, AU Library, Health Sciences, in Aarhus, in collaboration with special subject adviser Anne Ersbøll.

Three searches were performed: 1. a systematic background search for clinical guidelines, 2. a follow-up search for secondary literature (systematic reviews and meta-analyses) and primary literature for each of the focused questions alone or grouped, when relevant, and 3. a follow-up search for supplementary literature for the focused questions 2 and 3 for the period 2006 through 6 May 2014.

The searches were performed during the period 13 January through 6 May 2014.

The search protocols with the search strategies are available on the DHMA's website (in Danish only).

General search terms

English: labor, labour, delivery, birth, oxytocin, syntocinon, dystocia, obstructed, delayed, prolonged, slow progress, duration, intervention, obstetric complications, high dose, low dose, epidural, acupuncture, fluid, rebozo, amniotomy, augmentation.

Danish: dystoci, fødsel, oxytocin, syntocinon.

Norwegian: dystoci, fødsel, oxytocin, syntocinon.

Swedish: dystoci, förlossning, oxytocin, syntocinon.

The follow-up searches for the focused questions were performed by searching with individual search terms for each PICO question (see the search protocol for the follow-up search).

General inclusion criteria

Years of publication: 2004 through May 2014

Languages: English, Danish, Norwegian and Swedish.

Document types: Guidelines, systematic reviews, meta-analyses, randomised controlled studies, cohort studies.

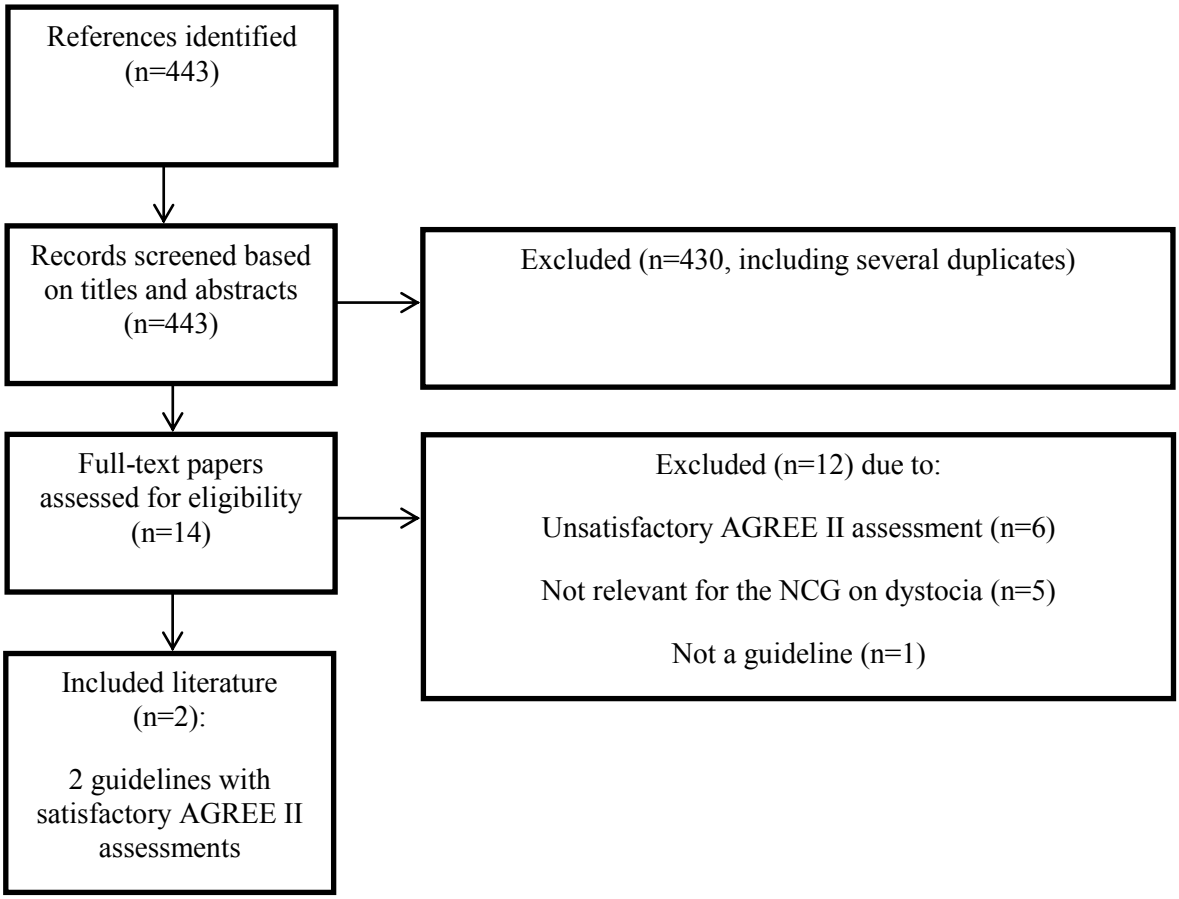
Background search

The search for clinical guidelines was performed in the following sources of information: the Guidelines International Network – G-I-N, NICE (UK), the National

guideline Clearinghouse, the Scottish Intercollegiate Guidelines Network – SIGN, the HTA database, the Cochrane Library, the SBU (Sweden), the Swedish National Board of Health and Welfare, the Norwegian Directorate of Health, the Norwegian Knowledge Centre for the Health Services, Medline and Embase.

The background search also involved searching on the websites of the Danish Society of Obstetrics and Gynaecology, the Norwegian Society of Gynaecology, the Swedish Society of Obstetrics and Gynaecology, the International Federation of Gynecology and Obstetrics, the American Congress of Obstetricians and Gynecologists and the Royal College of Obstetricians and Gynaecologists.

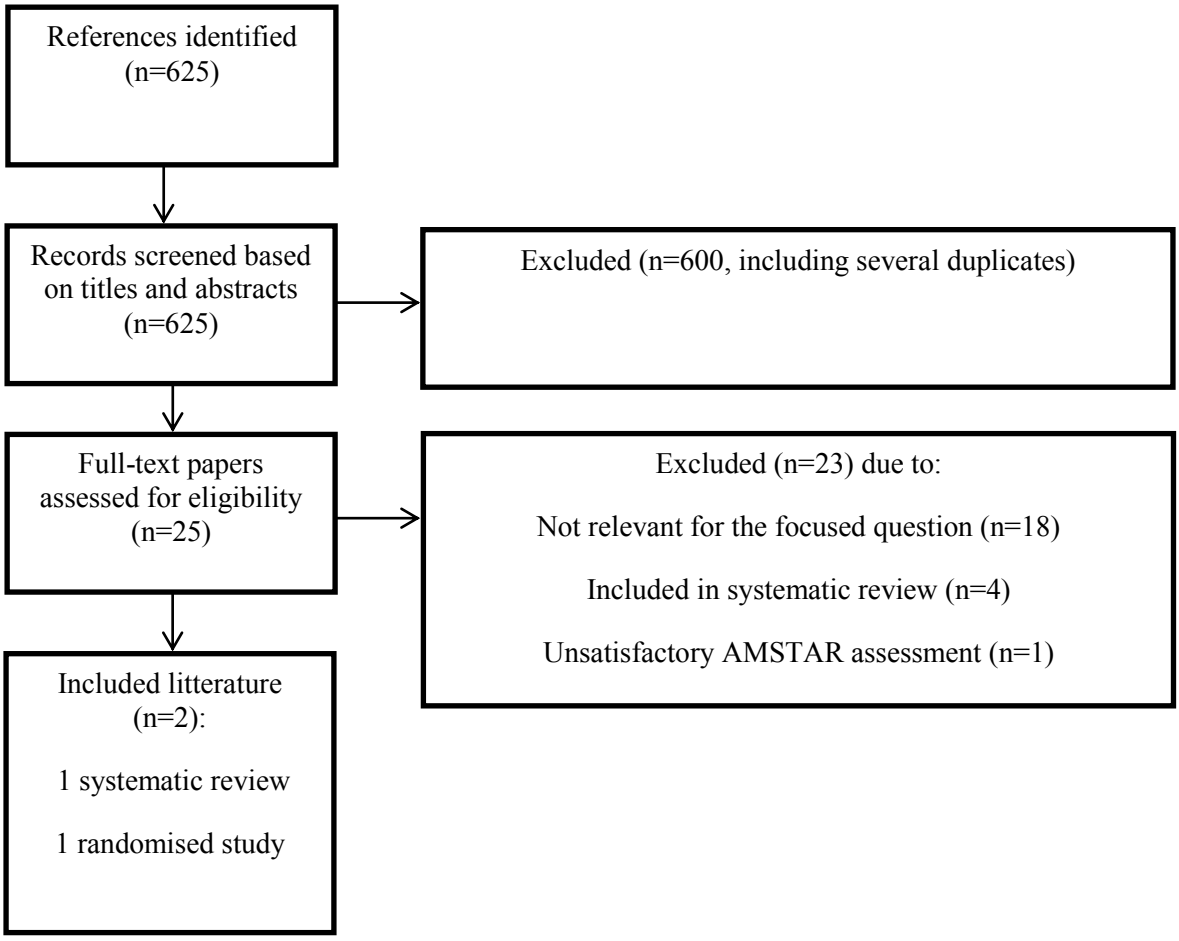
Background search for guidelines



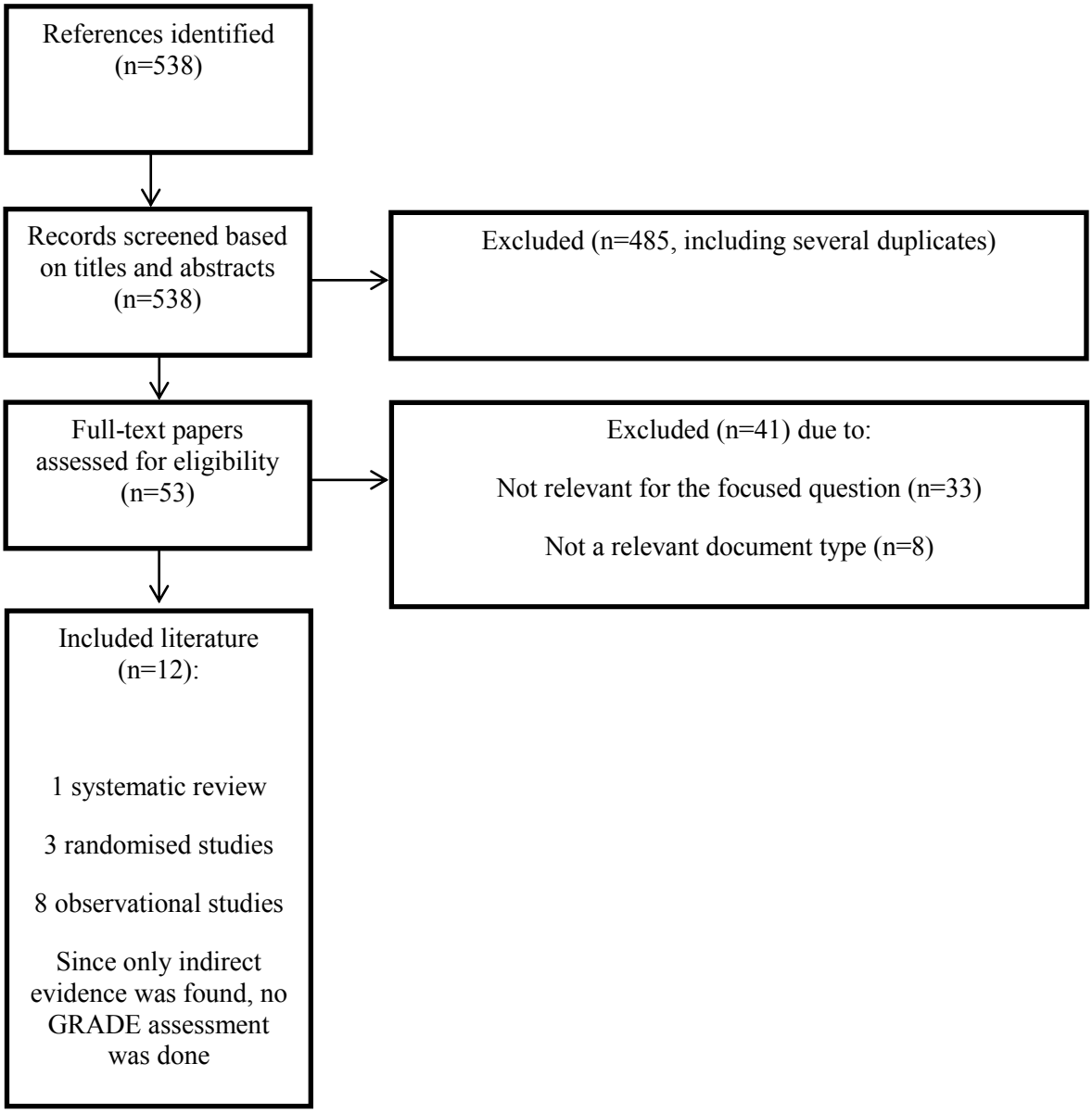
Follow-up searches for secondary and primary literature

Searches for systematic reviews, meta-analyses, randomised controlled studies and observational studies were performed in the Cochrane Library, Medline and Embase via Ovid. These searches were based on the focused questions in PICO form.

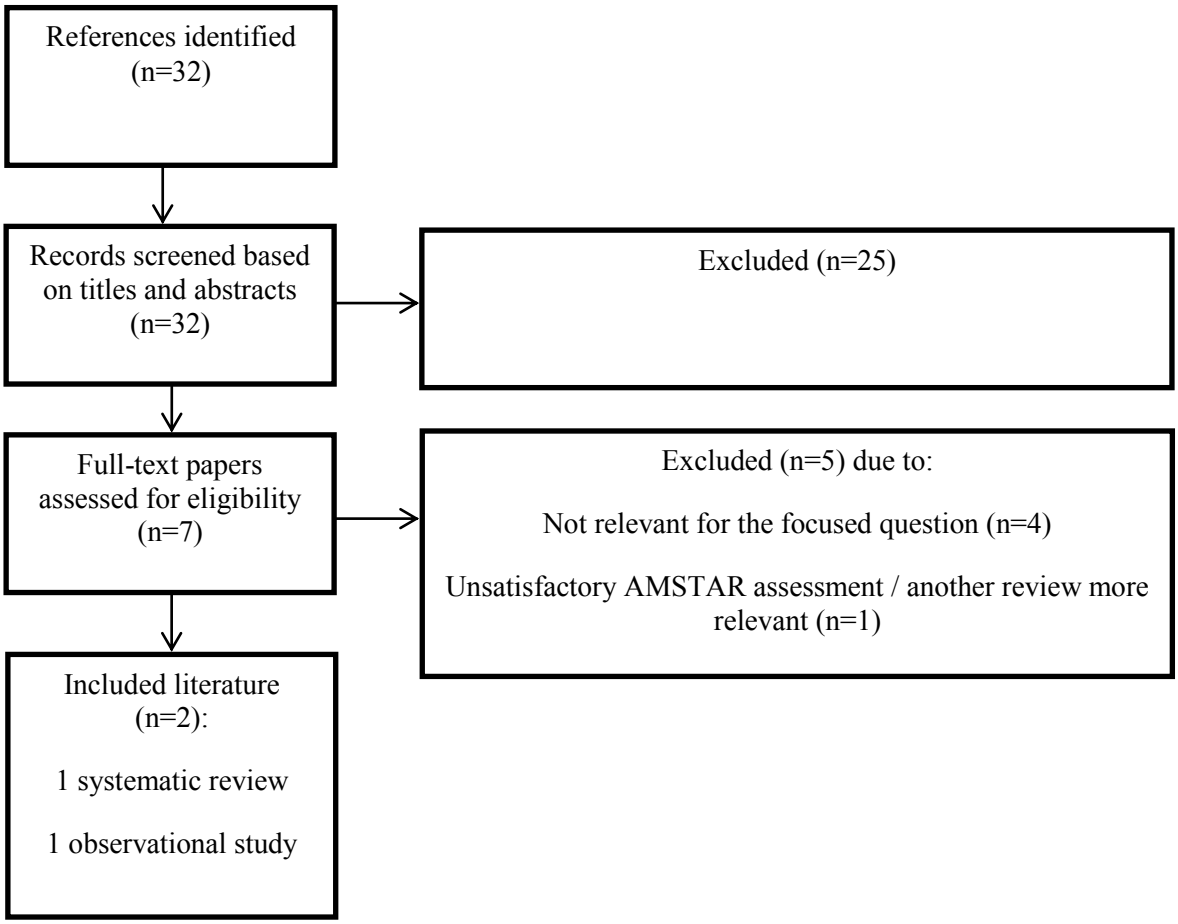
Focused question 1



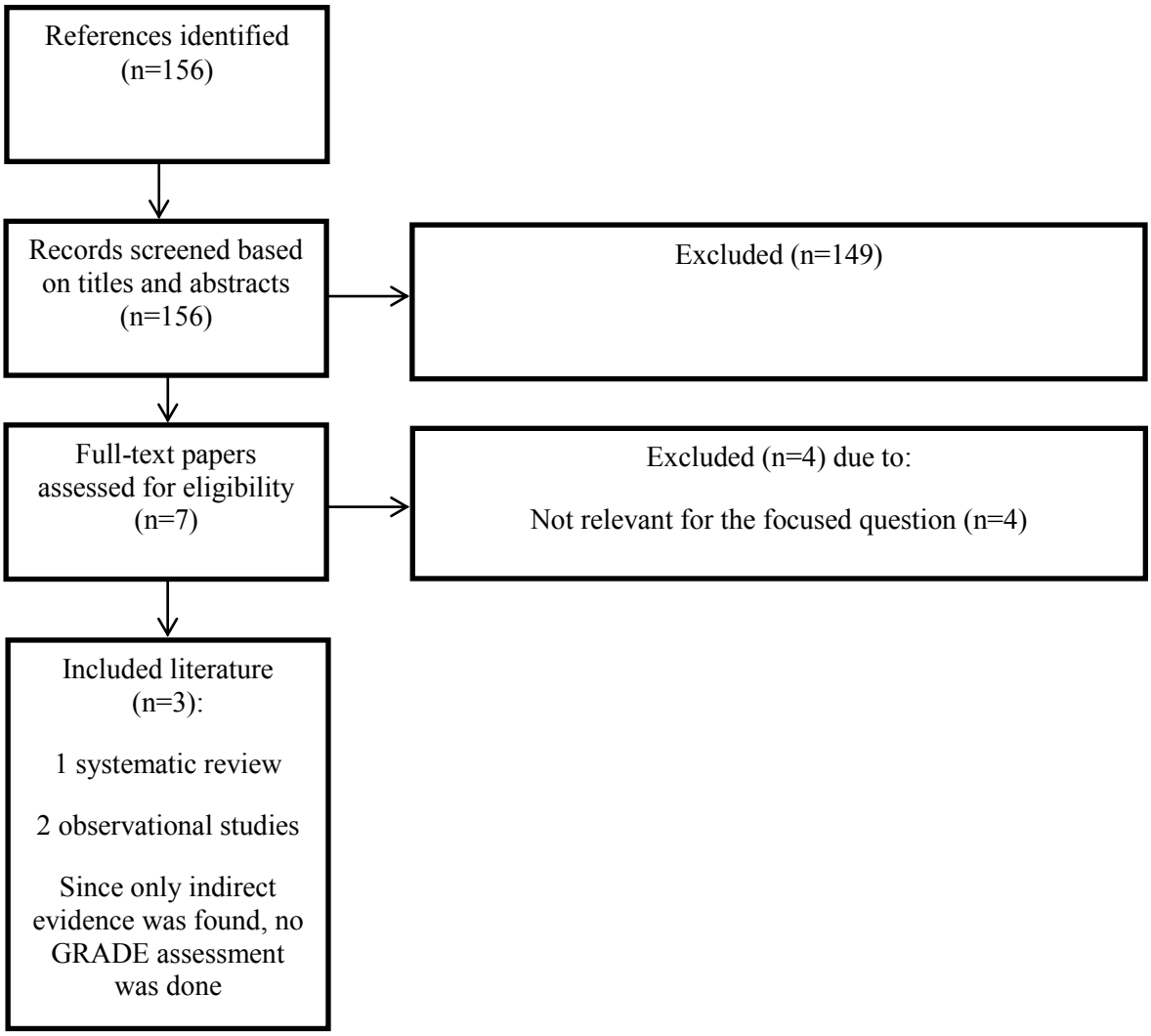
Focused questions 2-3



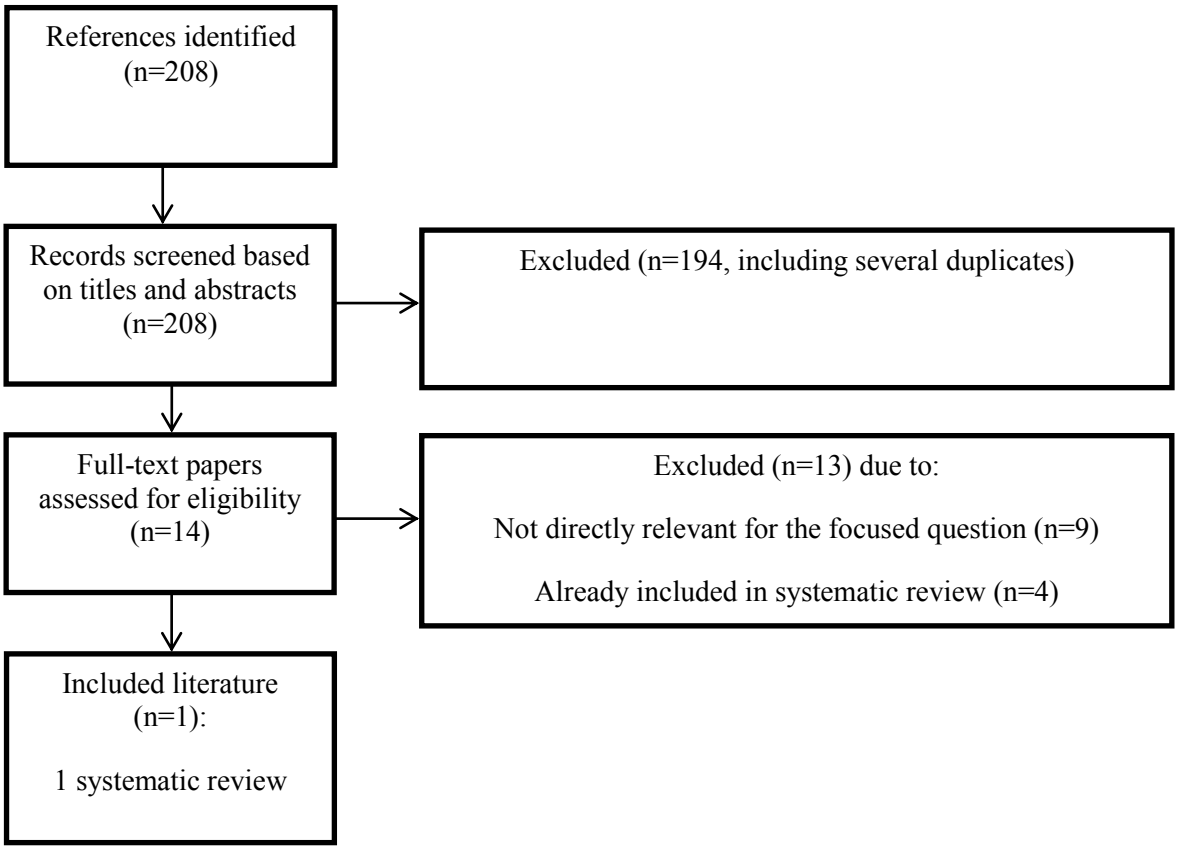
Focused questions 4-5



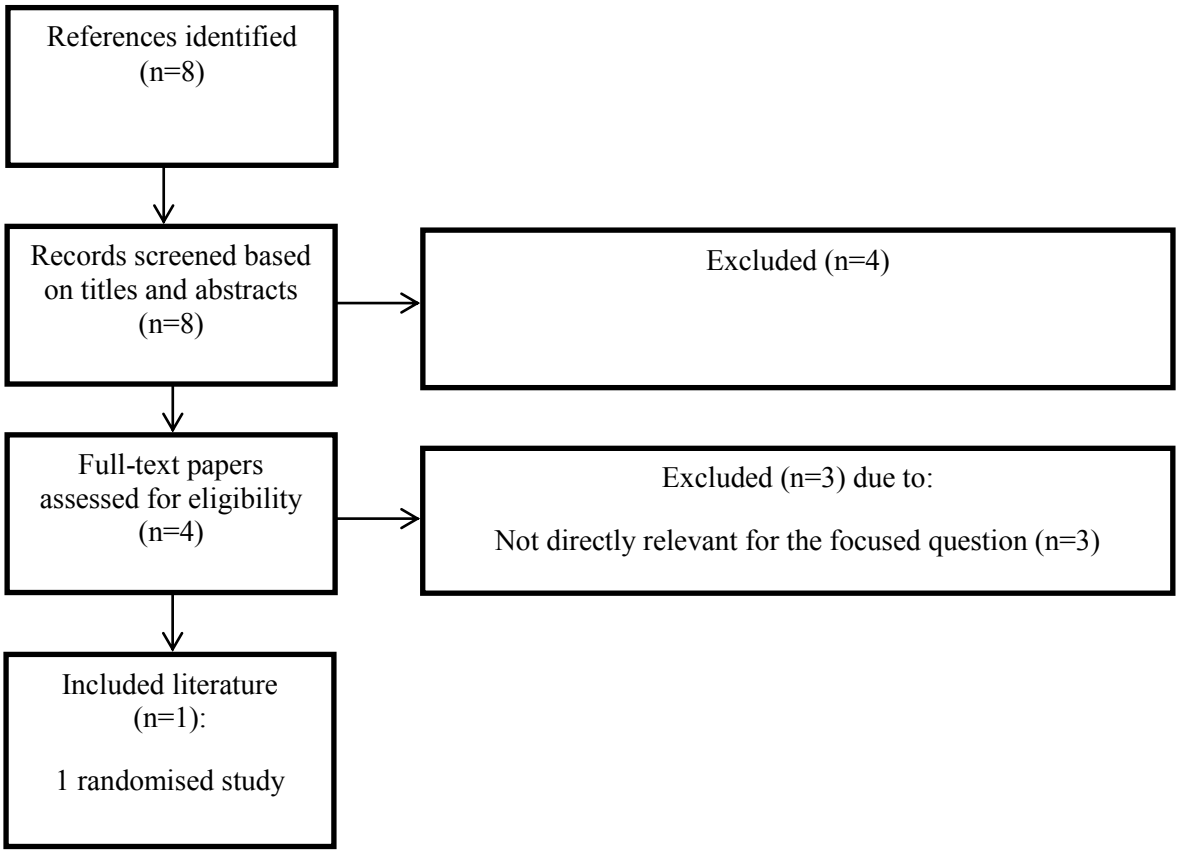
Focused question 6



Focused question 7



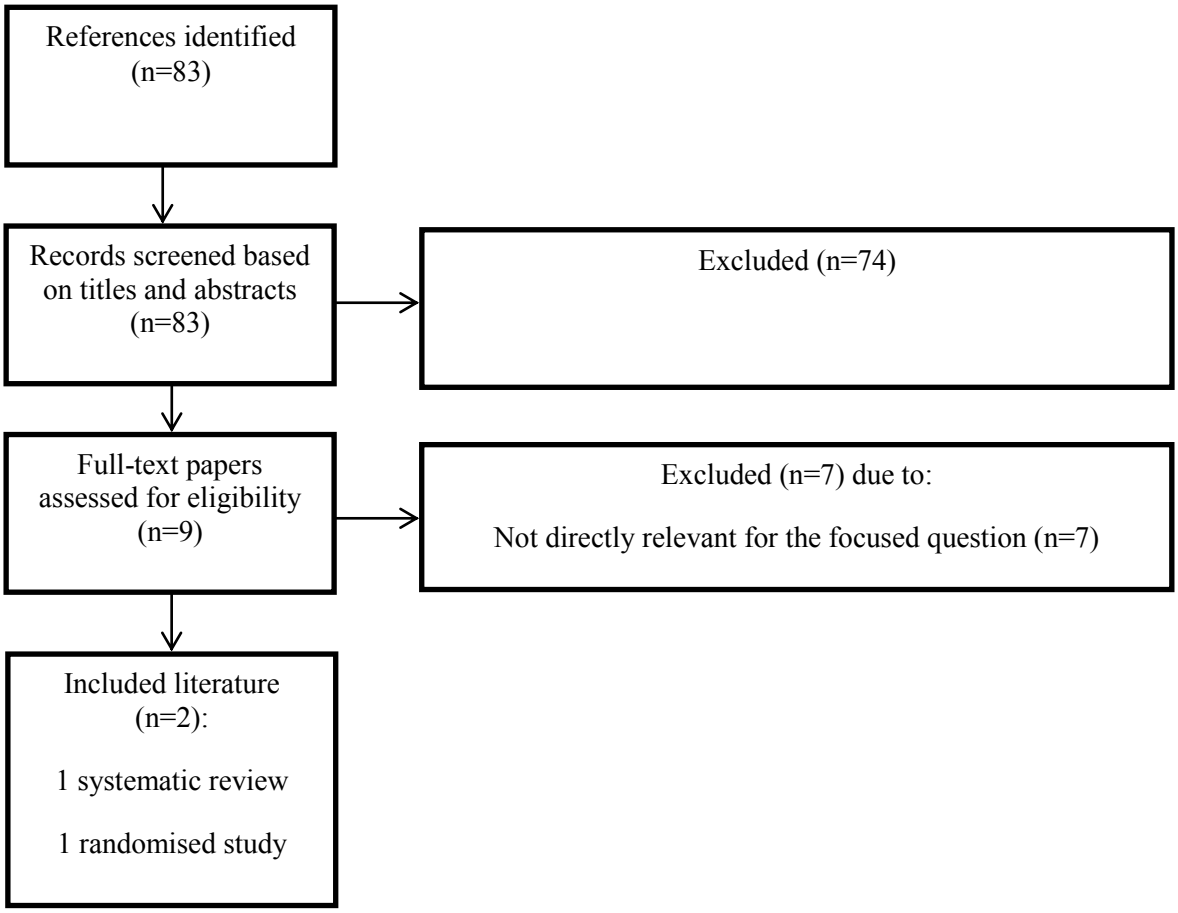
Focused question 8



Focused question 9

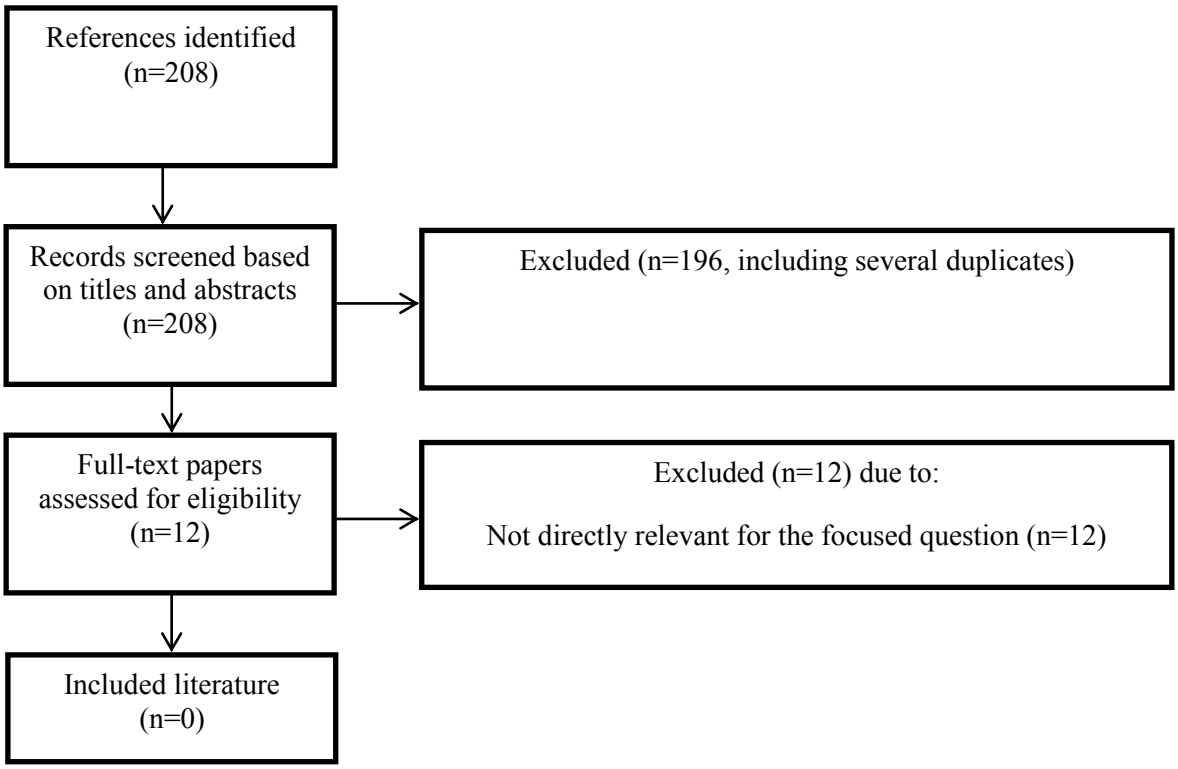
References identified
(n=0)

Focused question 10



Focused question 11

The two observational studies included in answering the focused question were identified via the two guidelines identified during the primary search. These guidelines were also included in answering the question. The studies are more than 10 years old and therefore were not identified in the secondary literature search.



Appendix 9: Assessment of evidence

AGREE II assessments

Six guidelines were selected for use in an AGREE II assessment of the quality of the evidence. Two guidelines were included in the final preparation of this NCG, and the others are mentioned in the background literature. Every guideline was assessed by at least one working group member and by the special subject adviser. This means that every guideline was assessed by at least two persons.

Guideline	Overall assessment	Conclusion
DSOG Dystoci (DSOG Dystocia, in Danish only). Denmark 2011[14].	3 2	Excluded
Nationella Medicinska Indikationer: Indikation för värkstimulering med oxytocin under aktiv förlossning (National Medical Indications: Indication for oxytocin augmentation during the active phase of labour, in Swedish only). Sweden 2011[17].	6 3 5	Included
NICE Clinical Guideline 55: Intrapartum Care. United Kingdom 2007[10].	7 6 6	Included
ACOG Practice Bulletin: Dystocia and augmentation of labour. USA 2003[53].	4 3	Excluded
ICSI Institute for Clinical Systems Improvement. Health Care Guideline: Management of Labor. USA 2013[4].	5 3	Excluded
The Ottawa Hospital's Clinical Practice Guideline for The Second Stage of Labour. Canada 2006.	4 4 3	Excluded

The working group's AMSTAR assessments of systematic reviews are available here (in Danish only).

Evidence profiles and meta-analyses are available here (partially in English).

Appendix 10: Working group and reference group

The working group

The working group that prepared the national clinical guideline on dystocia consists of the following persons:

- Niels Uldbjerg (chairman), appointed by the DHMA, professor and consultant doctor, Department of Obstetrics and Gynaecology, Aarhus University Hospital, Skejby.
- Lena Mariann Eriksen, appointed by the Danish Association of Midwives, midwife, Metropolitan University College, Copenhagen.
- Morten Hedegaard, appointed by the DSOG, Head of Department and consultant doctor, Department of Obstetrics, Copenhagen University Hospital.
- Lone Krebs, appointed by the DSOG, consultant doctor, Department of Gynaecology and Obstetrics, Holbæk Hospital.
- Christina Rørbye, appointed by the DSOG, consultant doctor, Department of Gynaecology and Obstetrics, Hvidovre Hospital.
- Anne-Mette Schroll, appointed by the Danish Association of Midwives, development consultant and midwife, Danish Association of Midwives, Copenhagen.
- Misan Anne Cathrine Stehouwer, appointed by the Danish Association of Midwives, senior staff midwife, maternity ward 1, Aarhus University Hospital, Skejby.

Conflicts of interest

Any person who works within public administration and has a personal interest in the outcome of a specific case may not participate in any processing of that case. If a person has conflicting interests, there is a risk that he or she may not provide an independent assessment of a given case. Declaration of interest forms for all the working group members are available here (in Danish only).

The reference group

The reference group was appointed by regions, municipalities, patient organisations and other relevant stakeholders in this field, and its assignment has been to comment on the delimitation of and the professional content of the guideline.

The reference group in connection with the national clinical guideline on dystocia consists of the following persons:

- Marianne Dahl, appointed by the Danish Paediatric Society, consultant doctor, Department H, Odense University Hospital

- Mia Francis Ferneborg, appointed by the Danish Ministry of Health, Head of Section, Danish Ministry of Health
- Anette Frederiksen, appointed by the Region of Southern Denmark, Head of Midwifery, Department of Gynaecology and Obstetrics, Odense University Hospital
- Margrethe Møller, appointed by the North Denmark Region, consultant doctor, Family Outpatient Clinic for North Denmark Region, Aalborg University Hospital
- Jannie Dalby Salvig, appointed by the Central Denmark Region, chief consultant doctor, Department of Obstetrics and Gynaecology, Aarhus University Hospital, Skejby
- Mathilde Schousboe, appointed by the Danish organisation Parenting and Childbirth
- Charlotte Wilken-Jensen, appointed by the Capital Region of Denmark, chief consultant doctor, Department of Gynaecology and Obstetrics, Hvidovre Hospital

Secretariat

The secretariat for both groups:

- Hanne Caspersen, search consultant, the DHMA.
- Anne Schjødt Ersbøll, special subject adviser, the DHMA
- Christina Debes Helm, project worker, the DHMA
- Stine Ulendorf Jacobsen, project manager, the DHMA
- Birgitte Holm Petersen, search specialist, the DHMA
- Jeppe Schroll, method consultant, the DHMA

Peer review and public consultation

Prior to publication, the national clinical guideline on dystocia was submitted for consultation among the following parties:

- the Danish Paediatric Society
- the Danish Society of Obstetrics and Gynaecology
- the Danish Regions
- the Danish organisation Parenting and Childbirth
- the Local Government Denmark
- the Danish Association of Midwives

- the Danish Ministry of Health

During the same period of time, the guideline was peer reviewed by:

- Marie Berg, professor, midwife, University of Gothenburg, Sweden
- Tom Weber, consultant doctor, Department of Gynaecology and Obstetrics, Hvidovre Hospital

Appendix 11: Abbreviations and concepts

ACOG	The American College of Obstestricians and Gynecologists.
Active Management of Labour	Approach for the management of labour; developed in Ireland. Comprises many components and involves early intervention in case of slow progress, among other things (O'Driscoll 1973).
Amniotomy	Artificial rupturing of the foetal membranes.
Apgar score	Scoring system for the assessment of newborns. Reflexes, muscle tone, breathing, skin colour and pulse are assessed and assigned 0, 1 or 2 points. The total maximum score is 10 points.
Asphyxia	Oxygen deprivation in the fetus.
Bias	Bias is defined as systematic errors in a study which lead to over- or underestimation of the effect.
CI	Confidence interval. An expression of the accuracy of a point estimate. A confidence interval of 95% around an estimated effect means that the true estimated effect will be included in the confidence interval in 95 out of 100 studies conducted the same way. This limit was chosen by convention, not based on a natural law. Therefore, it is not a scientific evidence of an effect, if a result is statistically significant – what it means is that the effect is rendered probable.

CTG	Cardiotocography.
DSOG	The Danish Society of Obstetrics and Gynaecology.
FIGO	The International Federation of Gynecology and Obstetrics.
GRADE	A standardised system for assessing the strength of the evidence for individual outcomes of healthcare interventions. The assessment of the strength of the evidence varies as to whether it is based on randomised studies or observational studies. Additionally, it is based on an assessment of the presence or not of a number of systematic errors (bias) in the studies, whether the results from the individual studies are consistent, the accuracy of the overall aim of the effect of the intervention and whether the studies were conducted in a representative group of persons who were given a treatment similar to the treatment to be investigated. GRADE is an abbreviation for 'The Grading of Recommendations Assessment, Development and Evaluation'.
ICSI	The Institute for Clinical Systems Improvements.
NICE	The National Institute for Health and Care Excellence.

NIH	The National Institute of Health.
Ringer's lactate	Isotonic solution for infusion. The content of 1 litre is 0.2 g calcium chloride dihydrate, 0.3 g potassium chloride, 6.0 g sodium chloride and 3.1 g sodium lactate.
Risk of bias (RoB)	An assessment of the magnitude of the risk of bias in a study or across a number of studies.
RR	Risk ratio or relative risk. An estimate of how many times higher the disease risk is in the exposed group as compared to the non-exposed group.
Sarnat score	A classification scale for the assessment of hypoxic-ischaemic encephalopathy in newborns.
SFOG	The Swedish Society of Obstetrics and Gynaecology
Syntocinon®	The trade name for synthetic oxytocin, which is used for augmentation of labour in Denmark.

Thompson score	A classification scale for the assessment of hypoxic-ischaemic encephalopathy in newborns.
WHO	World Health Organization.