



Prioritised research areas within the fields of prevention, diagnosis and treatment of maternal birth injuries

Which research should be prioritised within the fields of prevention, diagnosis and treatment of maternal birth injuries? What are the opinions of women suffering from birth injuries or of the clinicians providing care for these women? In order to answer these questions, SBU included women with birth injuries and representatives from professions within the field of obstetric care, to discuss and prioritise research questions within the above outlined areas. As a result of this discussion, more knowledge about diagnosing birth injuries was given the highest priority (Table 1).

By highlighting the research questions prioritised by women suffering from birth injuries and clinicians caring for these women, we hope that relevant and well-designed clinical studies addressing these questions will be appropriately conducted.



Table 1 The most important areas containing evidence gaps.

1. Diagnosis of birth injuries	Specific injuries on genitally mutilated women	
2. Prevention – methods used during delivery with the potential to reduce the risk of injuries		
3. Treatment of second degree tears		Treatment of third and/or fourth degree tears
5. Treatment of the levator ani muscle injury		
6. Treatment of fistula between urinary bladder and vagina or between anus and vagina		
7. Treatment of pain associated with sexual intercourse (dyspareunia)		
8. Treatment of anal incontinence		
9. Treatment of injury caused by episiotomy (surgical incision of the perineum and the posterior vaginal wall)		

1=highest ranking. In all prioritised areas, women that had undergone genital mutilation were considered to be an important patient group to include in future research. See Appendix 1 for the description of current terms and concepts on www.sbu.se/291e

Target groups

Researchers and research funding bodies are the primary target groups of this report. Other relevant recipients of this report are women with birth injuries and their families, health care professionals and policymakers.

Background

SBU identifies evidence gaps within health and dental care, social service, as well as within the areas of functional disability and work environment. The evidence gaps that are identified are registered in a database on SBU:s website (www.sbu.se/kunskapsluckor), highlighting areas requiring further practice-based research. For areas with numerous evidence gaps, such as obstetric care, it is also necessary to prioritise these in order to better define the most relevant research questions.

Research studies are often driven by commercial or academic interests and seldomly consider the perspectives of the patient or the clinician, which is consistent with the findings by Ian Chalmer and Paul Glasziou (2009) who calculated that up to 85% of the research funding is dedicated to studies that are not practically beneficial for the patient or for the clinicians [1]. This is partly due to the fact that science does not always prioritise research questions that are of relevance for the patients or those providing care for the ones affected by the condition [1,2].

The aim of this project is to emphasise areas within prevention, diagnosis and treatment of physical injuries associated with vaginal birth that require further research (Appendix 1 www.sbu.se/291e). A working group has prioritised the evidence gaps that were identified in two previously published SBU reports about birth injuries [3,4].

Method

The method that was used to prioritise evidence gaps originates from James Lind Alliance (Figure 1). The working group that prioritised the evidence gaps was composed of 18 individuals, both women suffering from birth injuries (patient experts) and those providing care to them, such as midwives, obstetricians, physiotherapists, gynaecologist surgeons, urologists and urotherapist. When recruiting members to the working group, the aim was to include persons with different perspectives of birth injuries. Furthermore, the members should not have any personal research or commercial interests within this issue.

Figure 1 The James Lind Alliance method.

James Lind Alliance is a British organisation that strives to identify and prioritise evidence gaps [5]. Their method is based on a collaboration of patients and clinicians where they together agree on the most important evidence gaps within the field of interest. The most important area or research question is scored with the highest ranking. The aim is to highlight areas considered to be of most importance to research. The main target groups are scientists and research funding bodies.

The prioritisation was conducted in two steps. First, each group member individually chose their ten most important areas with evidence gaps among the 21 areas identified from the two SBU reports (Appendix 1 www.sbu.se/291e). Prior to this step, the group members were provided with information describing the process of prioritisation, in addition to being given a description of the 21 different areas that were to be prioritised (Appendix 1 www.sbu.se/291e). Furthermore, the group members were also provided with a modified version of the SBU ethical guide [6].

In the second step, the 15 evidence gaps (Appendix 1 www.sbu.se/291e) that were assigned the highest priority in the first step, were prioritised in a workshop where 15 of the 18 group members participated.

During this workshop, the participants were divided into groups where both women with birth injuries and health care personnel were represented. Each group prioritised their top 10 evidence gaps. Thereafter a discussion with all group members was held resulting in a definite prioritisation of 10 evidence gaps (Table 1).

Results

Following the discussion held in the workshop, the group agreed on prioritising primary injuries higher than their followed complications. According to the working group, reliable diagnosis and early treatment can reduce the occurrence of further complications from birth injuries such as fistula, urine or anal incontinence. With this approach, in addition to reducing the suffering of those women affected by birth injuries, this could also be beneficial from a socioeconomic point of view.

Among the prioritised areas, diagnosis of birth injuries was considered to be the most important area for further research, since a correct diagnosis is a prerequisite for an efficient treatment (Table 1). Hence, this area was given the highest rank in the prioritisation process. Due to a lack of reliable diagnostic tools, it is difficult to estimate the accurate number and magnitude of the injuries, which therefore limits the effectiveness of possible preventive methods. In addition, it is also important to develop reliable diagnostic tools that will allow for a successful diagnosis of birth injuries long after the delivery (months or even years later).

Furthermore, the working group concluded that more knowledge regarding methods preventing birth injuries during delivery is necessary. However, the group stresses out the importance of the fact that the research should not only focus on specific outcomes, but rather on the overall effects on both the mother and the child.

Knowledge regarding grade 2 to 4-degree tears was considered to be equally important and therefore given the same high-ranking position. Due to the differences in the type of degrees, the group withheld the information about the importance of studying the 2-degree tears and 3–4-degree tears separately. Two-degree tears are common, but heterogenous in their characters causing a risk that the most extensive tears go by unnoticed and are therefore not treated, which in turn can lead to future complications. Furthermore, it is unclear how to treat these injuries in a most efficient manner, both immediately after delivery and long after delivery. In relation to 3–4-degree tears, these are known to lead to severe complications,

such as anal incontinence or fistula, if not treated properly. These injuries are treated surgically, but there is still a demand for more knowledge on the treatment effects of surgery as well as additional treatment options such as physiotherapy or pain-relieving for these conditions.

Research on treatment of injuries on the levator ani muscle was also ranked high in the prioritisation process. The justification for the high scores was that it is a common injury and most often not diagnosed. Furthermore, there are no existing evidence-based treatment methods for this injury. The group brought forward the discussion that women with this injury are often neglected by the health care and therefore carry on without addressing these injuries for many years. As a result, the number of women affected by this injury is unclear.

Other areas prioritised were treatment of fistula between urinary bladder and vagina, or intestine and vagina, and treatment of pain during intercourse (dyspareunia). Fistulas often contribute to incontinence and have a negative effect on quality of life. The condition is difficult to treat, and it is an area that requires additional research. The group also brought up that dyspareunia is a neglected field. During the discussion it was withheld that although the female sexual drive is as important as that of males, it is still an underappreciated point within this area. There is a need for more research dealing with alternative treatment methods for dyspareunia, apart from using numbing cream during sexual intercourse. The group's opinion was that the different types of pain such as dyspareunia and perineal pain should be considered as one research/therapy area named "pain in the perineum".

Treatment of anal incontinence as well as treatment caused by episiotomy, were two highly ranked areas. Episiotomy is a preventive approach used in health care, and it is of great concern that proper treatment for this injury is an evidence gap. The group also believed that the number of episiotomies will increase in Swedish health care in the near future.

Genitally mutilated women were considered an important patient group that should be included in all the above discussed prioritised areas (Table 1). This group of women may have substantial difficulties communicating their issues due to a social and cultural stigma within this subject, and therefore it is of great importance that their problems are recognised. The work group stressed that increased knowledge

regarding interventions for women with birth injuries in general also favors genitally mutilated women. However, this group may still have unique problems and therefore studies should address prevention, diagnosis and treatment separately for this population.

Overall for birth injuries in women, the working group stressed out the need for more knowledge regarding physiotherapy and moreover focusing on the specific role of the physiotherapist. The group also pointed out that it is important that the research similarly focuses on how new research findings can be implemented in practice so that interventions within prevention, diagnosis and treatment, which hold some evidence, can be appropriately introduced. For example, the methods that hold evidence regarding diagnosis of anal sphincter injuries (3–4-degree tears) should be efficiently introduced. Another question that was raised was the importance of research regarding the psychological effects that are caused by birth injuries.

Discussion

Today there is a gap between the ongoing research and the actual science that is requested by patients and clinicians. In the present project, a group consisting of individuals with personal or clinical experience of birth injuries, has prioritised the areas that they believe are of most importance to research.

The James Lind Alliance method enables patients and clinicians to work together on equal terms to identify and agree on a prioritisation of evidence gaps regarding the effects of treatments that could be addressed by research.

When SBU recruited the participants for the working group, the aim was to include individuals with as many perspectives in the field as possible. However, it is impossible to ensure that the result this group found would also be established by another set of group members. A possible weakness regarding the representativeness of this working group could be that the patient experts were homogenous in age and ethnicity. Nevertheless, the clinical experiences of the group members are broad regarding treatments and complications of primary birth injuries, including birth injuries of genitally mutilated women.

How broad is the knowledge within this field?

Two SBU reports [3,4] show that there are some published peer-reviewed studies within the areas of prevention, diagnosis and treatment of birth injuries, foremost anal sphincter injuries.

Regarding preventive and diagnostic tools, there is some knowledge regarding protective preventive effects in those cases where delivery ward staff are trained to promote slow delivery and to manually protect the perineal region with different handholds [4]. Furthermore, an episiotomy can prevent anal sphincter injuries when a woman, who is giving birth for the first time, requires vacuum extraction. Even warm compresses applied to the perineum during the pushing stage of childbirth can provide some protection against anal sphincter injury. In addition, more injuries to the anal sphincter can be detected and treated if an ultrasound examination is added to the visual and manual routine examinations currently performed on women immediately after the delivery.

Regarding treatment of 2-degree tears and injuries caused by episiotomy, there is some knowledge covering the effects of different suturing techniques on perineal pain and dyspareunia [3].

It should be considered that new studies, primary studies or systematic reviews, might have been published after the publication of the two SBU reports, which the prioritisation in this report is based on [3,4].

What specifies an evidence gap?

A method or practice is an evidence gap if:

- Systematic literature reviews find that there is no conclusive evidence of benefits and risks.
- No systematic literature reviews of good quality can be identified.

By evaluating and compiling research results in a systematic review, it is possible to identify both measurements and methods that hold a scientific support and where evidence gaps exist. Common reasons for a method to be considered an evidence gap is that the method is investigated in a limited number of studies consisting of a small number of participants, that the studies hold high risk of bias or that the studies show conflicting results. As a result of this, more practice-based research regarding the positive and negative effects of a method is needed.

What is needed to fill evidence gaps?

For the areas where there is no systematic review of good quality, a systematic review that clarifies whether new research is needed, should be performed. For areas where a systematic review of good quality specifies evidence gaps, new primary studies with adequate design and relevant outcomes should be performed.

Conflict of interest

In accordance with SBU's requirements, the participants in the working group in this project have submitted statements about conflicts of interest. These documents are available at SBU's secretariat. SBU has determined that the conditions described in the submissions are compatible with SBU's requirements for objectivity and impartiality.

Working group

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