Final report

Safe Delivery care

Round 2, 2012-2017

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Content

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Background and aim

Löf (Landstingens Ömsesidiga Försäkringsbolag) is owned by Sweden´s 21 county councils as a mutual insurance company. The main task is to receive and investigate claims on injuries in Swedish health- and dental care – at present 16 000 per annum – and financially compensate those patients who have sustained an avoidable injury. The second task is to work for a decreased number of injuries in health- and dental care. This is done in collaboration with owners and professional organizations in multiprofessional patient safety projects.

Safe Delivery Care 2 is a continuation of Safe Delivery Care which was terminated in 2011 (for report in Swedish, see: https://lof.se/wp-content/uploads/2015/05/slutrapport_saeker_foerlossning.pdf).

At a concluding hearing in September 2011 it was unanimously decided to continue the work with multiprofessional peer-reviews and address some questions from round 1, such as risk evaluation at arrival of delivery ward, competence for fetus surveillance and the team around the asphyctic new-born baby. Two further topics were later added; management of risk pregnancies, both as regards mother and baby, and a review of how birth-related pelvic floor injuries were prevented, diagnosed and treated. The topic risk pregnancies made a smaller adjustment of the review model necessary, so that all hospitals within a region could be reviewed both individually and together.

The principal aim of Safe Delivery Care round 2 was to support Swedish delivery units in their work to decrease the frequency of preventable delivery-associated birth injuries, both for babies and for mothers, and to be able to prove that such a reduction had taken place.

Project organization

Safe Delivery Care round 2 has been based on multiprofessional cooperation between the professional organizations Svensk Förening för Obstetrik och Gynekologi (gynaecologists/obstetricians), Svenska Barnmorskeförbundet (midwives) and Svenska Neonatalföreningen (paediatrics and neonatologists). The professional organizations have been responsible for medical content, appointed peer-reviewers and expert committee members and promoted the project among their members. Löf has been responsible for financial and administrative support.

The steering committee has been composed of chairmen or board members in the respective organizations, and Löf´s chief medical officer. The committee was formed before the start of the project in February 2012, and has on average met twice yearly. The coordination has been done by project coordinators from Löf.

Projektbeskrivning

All Swedish delivery departments have, on a voluntary basis, participated in the project, which has been carried out in six stages (see table below). A total of 47 departments have been reviewed, including two that today are closed (Sollefteå and BB Sophia). All departments active in the spring of 2018 have completed all process steps.

Region	Time	Units
South-east n=7	VT 2013 – VT 2014	Eksjö, Kalmar, Linköping, Jönköping, Norrköping, Värnamo, Västervik
Northern n=9	HT 2013 – HT 2014	Sunderbyn, Skellefteå, Sollefteå, Örnsköldsvik, Östersund, Sundsvall, Umeå, Lycksele, Gällivare
Mid n=10	VT 2014 – VT 2015	Nyköping, Falun, Karlstad, Örebro, Eskilstuna, Västerås, Karlskoga, Gävle, Hudiksvall, Uppsala
Southern n=7	HT 2014 – HT 2015	Karlskrona, Ystad, Lund, Malmö, Växjö, Helsingborg, Kristianstad
Western n=6	VT 2015 – VT 2016	Varberg, Borås, Trollhättan, Göteborg, Halmstad, Skövde
Eastern n=8	HT 2015 – HT 2016	Visby, Södertälje, Södersjukhuset, KS Solna, KS Huddinge, Danderyd, BB Sophia, BB Stockholm

Safe Delivery Care round 2 was finished with three regional follow-up meetings during October 2017 (Stockholm, Hässleholm och Göteborg).

The model used has been self-assessment followed by external peer-review, improvement work and follow-up. The management at the departments has, together with staff and other departments, assessed important process steps, using a self-assessment questionnaire. This was developed by a multiprofessional expert group, tested in a pilot, and has thereafter continuously been adjusted, based on experiences. The questions have encompassed the time from arrival at the delivery ward to follow-up after birth. The answers have been reviewed by experienced colleagues from a different region.

The peer-reviewers were appointed by their professional organization. Their task has been to assist in identifying areas to increase patient safety, here specifically to decrease the risk for birth-related injuries to baby and/or mother. The minimum staffing in the review teams has been one midwife, one obstetrician and one paediatrician/neonatologist. The team visited the department during a one-day visit, mainly devoted to interviews with clinically active representatives from all professions. The combined impressions and opinions on strengths and areas for improvements were written down in a feed-back report, and together with the management, the team decided on which areas to improve.

The delivery unit has had the final word on which areas to improve, and also full responsibility for that agreed measures has been taken. Completed areas of improvement was presented and discussed at a follow-up visit 6 months after the initial visit.

All material produced is stored in digital format on a server owned by Löf. The material is classified as company secret material, and only the steering committee can decide on access to the material. The material is owned by the professional organizations, who collectively decide on use of the material within the promises of secrecy given to departments and peer-reviewers.

The steering committee decided to keep the model used in round 1 of Safe Delivery Care, thereby creating a possibility for a larger number of professionals to participate in the peer-review teams, and thus maximize the opportunities for exchange of experiences and diffusion of good examples. The alternative, with a small number of ”professional peer-reviewers”, who

could have resulted in more coherent reviews, but also in a more limited diffusion of good examples, was not judged as productive.

The questions in the self-assessment questionnaire concerned the following topics: risk assessment before and during delivery, fetal surveillance competence, team competence for an asphyctic baby including neonatal CPR, treatment with labor-stimulating drugs, routines for risk pregnancies, prevention of urinary bladder distention, and prevention, diagnosis and follow-up of pelvic floor injuries.

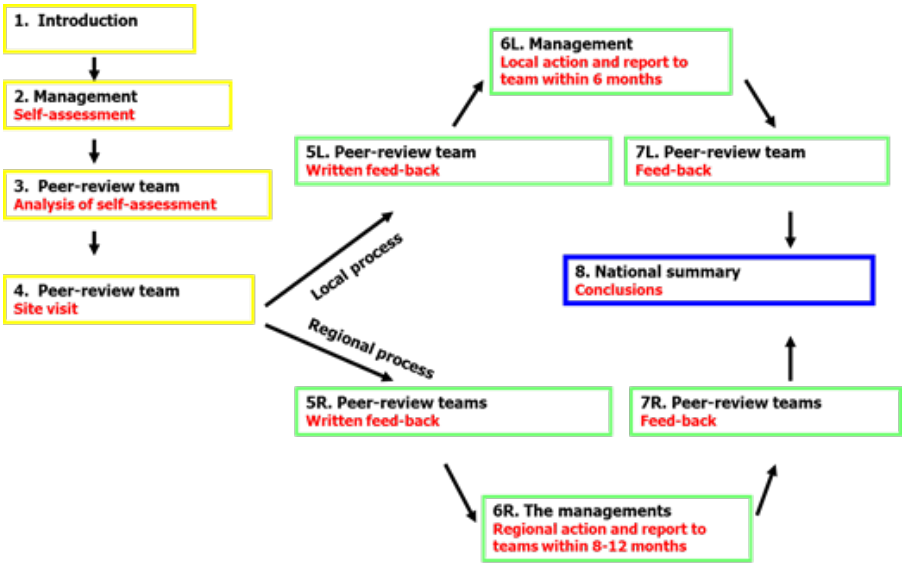
Questions have been open-ended and have been posed as ”How do you ensure…?” and with sub questions: a) Which routines/guidelines do you have? b) How do you create conditions for compliance? c) How do you measure adherence to your guidelines? d) How do you give feed-back (on c) to staff, and e) What ideas for improvement do you have (a-d)?.

The alternative of a norming design was also in this round dismissed. National detailed guidelines are to a large extent not at hand, Swedish departments by tradition have a large degree of freedom to decide for themselves, and, most importantly, neither the professional organizations nor Löf have any supervisory authority. Positive experiences from round 1 and similar projects (PRISS and Safe Abdominal Surgery) supported this decision.

Other important principles were that areas of improvement should be achievable within the resources of the respective department, and to not provide any specific method of intervention.

Not all individual departments handle risk pregnancies. Therefore, there was a need for an assessment on how this is done in a region as a whole. The review model was adapted so that a region was reviewed as a whole, both separate departments but also the cooperation between them. Separate agreements of improvement were signed for the departments and the region as a whole.

The figure shows a schematic picture of how a review stage was done. The time from introduction to completed follow-up was up to 18 months.



Löf:s expenses for Safe Delivery Care round 2, from 2012 to 2017, has been around 11 million Swedish kronor, mainly in forms of wages, travel and lodging, and production of web-educations.

Evaluation and results

Local actions taken

Several hundreds of improvement actions have been performed. When compared to those in round 1, these have been of a minor character, such as updating rather than producing clinical guidelines and routines. The most common areas have been:

- Implementation of SBAR communication
- Team training of neonatal CPR in a simulated milieu
- Structured record review
- Improved documentation of neonatal CPR

Regional actions taken

Several improvement actions have been taken. These have mainly been production, or harmonizing, of guidelines, but also development of education activities. As a whole, the regional collaboration has increased.

Examples of improvement areas are:

All six regions:

- Improved routines for transport of pregnant women/neonatal transports
- Pelvic floor injuries (shared routines, education, follow-up routines)
- Common routines for risk assessment, labour stimulation, vacuum extraction, urinary retention, pelvic floor injuries
- Methods to measure adherence to routines and guidelines through record review or Rutinkollen

Some regions:

- Rotation of staff, mainly for educational purposes
- Routines for neonatal CPR-education
- Routines for CTG-education
- Routines for documentation concerning the new-born baby

Web-educations

The two existing web-educations on CTG and neonatal CPR have been updated and supplemented. All material has been updated in accordance with clinical definitions, mainly those of FIGO (Federation Internationale de Gynecologie et d´Obstetrique) definitions from 2015, and current best practice. A third web-education has been produced with a focus on how to prevent, diagnose, treat and follow-up pelvic floor injuries. The three educations and supplementary material (pocket cards and posters) are distributed free-of-charge via Löf, and are, except for a minor part of the pelvic floor education, open for all to use. User statistics show between 2 500 and 4 000 individual site-visits per month. The educations are also used by universities and nursing schools.

The educations can be found at:

- ctgutbildning.se
- neohlrutbildning.se
- backenbottenutbildning.se

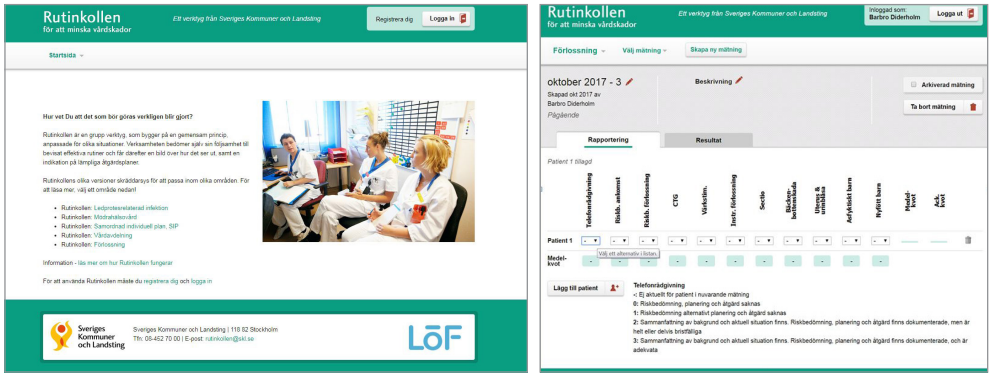
ctgutbildning.se

neohlrutbildning.se

backenbottenutbildning.se

Rutinkollen

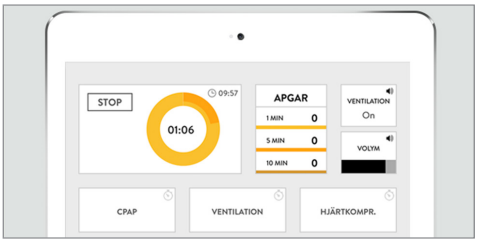
Two versions of Rutinkollen (a web-based tool for self-assessment of adherence to best practice) has been produced, one for maternity care and the other for delivery care. These give the opportunity for a department to self-assess adherence to own routines, and to improve. Also these tools are open to all and free-of-charge at: www.rutinkollen.se.



rutinkollen.se

NeoTap

Even though this tool has not been a formal part of Safe Delivery Care round 2, Löf has during the project contributed financially to the development of NeoTap, an app which both gives support during resuscitation of new-borns, but also a possibility to document measures taken and drugs delivered. The app can be found, free-of-charge, at: http://tap4life.org.



tap4life.org

Expert group documents

All documents produced in round 1 have been updated. New ones have been produced, for example on prevention of Sudden Unexpected Postnatal Collapse (SUPC). All documents can be found at: https://lof.se/patientsakerhet/vara-projekt/rekommendationer-och-rad.

Updating of CTG-material according to FIGO 2015

During round 2, FIGO updated their classification and guidelines on interpretation of CTG. All documents in the project are now updated according to this classification.

Cooperation with national quality registers on pregnancy and pelvic floor injuries

During round 2, the possibilities to evaluate the development of Swedish maternity and delivery care have significantly increased with the creation of Graviditetsregistret och Bristningsregistret. The possibilities to in real time follow results and development now exist, and Safe Delivery Care has established a fruitful collaboration with these quality registers.

Public opinion

During "Almedalsveckan 2017" Löf arranged a public symposium entitled "How is it really with Swedish maternity and delivery care?", with participants from Svenska Barnmorskeförbundet, Svenska Neonatalföreningen, Svensk Förening för Obstetrik och Gynekologi, Graviditetsregistret and Stockholm County Council. This symposium was followed up with a debating article in Svenska Dagbladet in November 2017.

International attention

Representatives of delivery care in Åland (formally part of Finland) have asked for permission to use all material, and now use the web-educations in clinical care and education.

Members of Safe Delivery Care have in various ways acted as advisors to NHS England in their improvement work of English delivery care and redress system for injured babies. A proposal is now undergoing a political consensus process. Read more at: https://www.gov.uk/government/consultations/rapid-resolution-and-redress-scheme-for-severe-birth-injury.

Scientific evaluation

Parts of Safe Delivery Care, mainly round 1, have undergone scientific evaluation. Charlotte Millde Luthander presented her PhD-thesis focusing on the project 2016 (https://openarchive.ki.se/xmlui/handle/10616/45151). The thesis concludes that extensive improvement efforts have been made, but

there are still gaps in knowledge that need to be filled. Evaluation of large-scale projects is challenging, due to a diversity of interests and factors in a constantly changing environment. The chance to succeed is larger if evidence-based process and outcome measures are at hand when a project starts, and if they are followed.

An early collaboration with CPUP (Cerebral Pares UppföljningsProgram, a Swedish national quality register for children and adolescents with cerebral paresis) to, if possible, detect a change in pattern of CP has resulted in a study, which will be published in 2018. The total prevalence of CP has decreased since the year 2000. Initially, this was seen in prematurely born babies, but can now be seen also in full-term babies. This decrease coincides with both Safe Delivery Care and with the development and spread of cooling treatment as everyday care. (Personal communication, Gunnar Hägglund, CPUP, February 2018).

In the Western region, where the prevalence of cerebral paresis has been followed since the 1950s, a reduction has been seen of those types of CP that are assumed to be caused by asphyxia at birth. (Himmelmann et al. Acta Pediatrica. 2018; 107: 462–468).

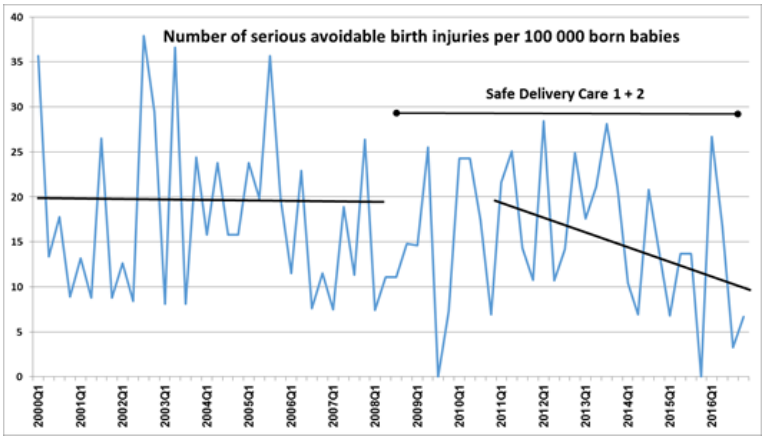
Regional follow-up meetings

During October 2017, three regional follow-up meetings were arranged with a total of close to 100 participants in Stockholm, Hässleholm and Göteborg. At the meetings, results were shown, but more importantly also the participants' opinions on the continuation of Safe Delivery Care. These opinions have been addressed by the steering committee in their planning of future areas of improvement.

Overall judgement of effects – conclusions

During 2016 and 2017, Swedish maternity and delivery care has been subject to intense public debate. Available medical outcomes have not always been the topic of this debate.

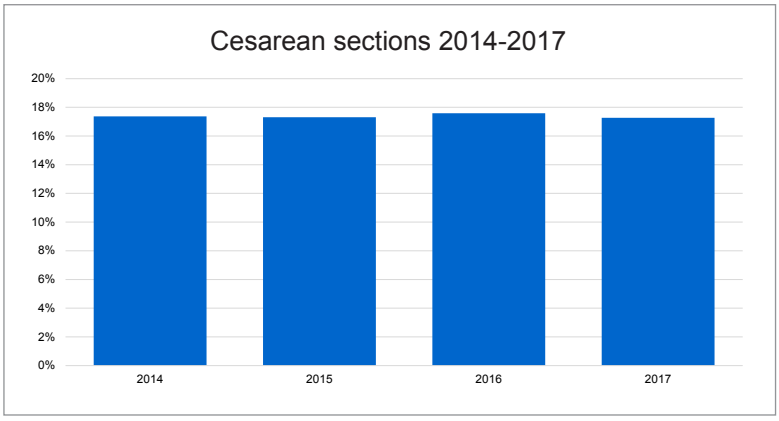
From a medical perspective, it can be stated that the development in large is positive. Löf is observing a trend towards a lower frequency of settled claims concerning birth injuries, even though this trend should be regarded with caution, mainly due to a lag in when claims are filed.



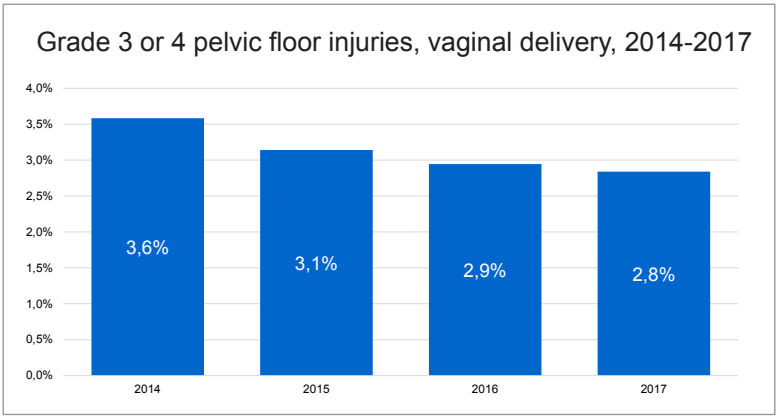
Number of settled serious (= minimum 30 % medical invalidity or death) birth injuries per 100 000 born babies during 2000 – 2016. Graph based on internal statistics at Löf.

As regards the second aim for Safe Delivery Care round 2 (fewer maternal birth injuries, especially pelvic floor injuries) a very positive trend can be noted, in that with a constant rate of cesarean sections, a decreasing trend of pelvic floor injuries grade 3 or 4 can be seen, even if the range between different county councils is large. Grade 3 or 4-injuries are becoming less frequent with constant frequency of cesarean sections.

Several departments show frequencies of around 1 % as regards grade 3 or 4-injuries. This is a dramatic improvement, and in particular, it shows that it is possible to decrease the frequency of pelvic floor injuries without compromising other parameters.

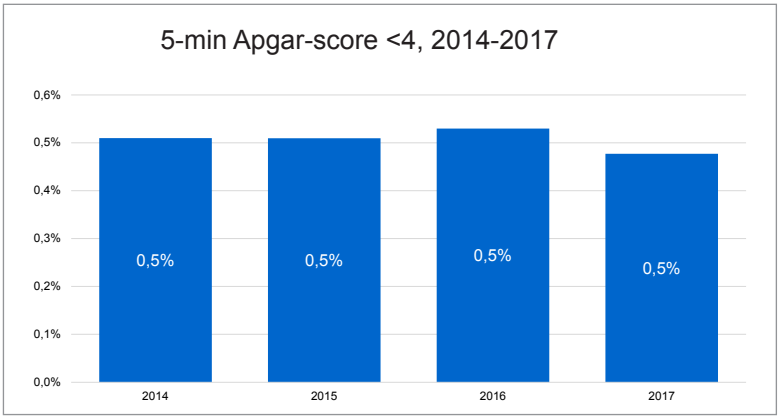


Frequency of cesarean sections in percent of all deliveries, 2014-2017. Data from Graviditetsregistret, January 2018.



Frequency of grade 3 or 4 pelvic floor injuries, vaginal delivery, 2014-2017. Data from Graviditetsregistret, January 2018.

Also for the frequency of babies born with an Apgar-score under 4, a positive trend can be noted, albeit not large. There are no signs that the decreasing frequency of serious pelvic floor injuries has resulted in more babies born with low Apgar-scores.



Rate of born babies with Apgar-score <4 at 5 minutes, 2014-2017. Exact numbers are 0.51 %, 0.51 %, 0.53 % and 0.48 %. Data from Graviditetsregistret January 2018.

Of course, it cannot be scientifically stated that Safe Delivery Care has contributed to this positive development. Safe Delivery Care was never intended to be a scientific study, and neither can nor should be evaluated as such. The project has coincided with a massively increased education and team training in neonatal CPR all over Sweden, and with the implementation of controlled hypothermia treatment of babies born with asphyxia. It is very reasonable to state that all these factors together have contributed to the

positive development we now are observing.

A subjective view, which never can be measured, is that the project, despite its non-normative design, has become normative in several areas. Examples of this are how neonatal CPR should be done, but also that midwives, obstetricians and paediatricians/neonatologists now work together on improvements. This type of collaboration can now be considered as established.

Continued development

Safe Delivery Care will continue. At present (March 2018), there are no plans to start new reviews, as this, as judged by the steering committee, is not where the best effects can be expected. The Swedish government will in coming years spend large sums of money on maternity and delivery care, and already today it is of importance to avoid double work.

Safe Delivery Care will in the coming years:

- Manage and develop existing web-educations and other programs. An organisation for this has been set up.
- Develop existing guidelines and recommendations. We plan to develop these into more formal expert group documents on best practice. New documents will also be produced in areas such as: induction of delivery, use of oxytocin, obstetric haemorrhage, sectio, vaginal delivery after sectio and others.
- Keep and develop the arena/platform for multiprofessional development that has been built. This will mainly be done via regular meetings with representatives from all professions.
- Disseminate knowledge on practices and outcomes at professional meetings and other fora.
- Monitor how Swedish maternity and delivery care develop.

The massive investment on maternity and delivery care that the Swedish government has initiated will hopefully address staffing and competence problems. Also as regards a development towards better follow-up, and larger influence from women and relatives in these areas, there are reasons to assume a positive trend.

Concluding remarks

It is very encouraging to be part of today's development of Swedish delivery and neonatal care. The risks for mother and baby to experience an avoidable injury are small, and have further decreased over the eleven years that Safe Delivery Care has been going. We shall be collectively proud of this.

When concluding the second round of reviews, it is both timely and adequate to sum up what has been achieved. Most likely, the most important result is that the cooperation between our organizations has become a successful model for how to improve delivery and neonatal care, locally as well as regionally and nationally.

The members of our organizations – midwives, obstetricians and neonatologists – work together daily in the delivery units around Sweden. Good team-work is a key factor in being able to offer mothers and babies a safe care. We hope and believe that Safe Delivery Care has inspired all involved to a continued good cooperation in all departments around our country. We see abundant opportunities for a continued collaborative improvement work, and a need to create conditions for a good working environment.

Our experience of working together in Safe Delivery Care, and under the auspice of Löf, is that it has been stimulating, and that we together can achieve a whole lot! The fact that our organizations together stand behind education programs and guidelines has contributed to the solid reputation they have, and that they have been so positively received.

We want to extend a warm thank you to all of you who with enthusiasm and hours have contributed in the national work, as well at your own departments! From the professional organizations, we also want to thank Löf for administrating the project. It has been very much appreciated!

During the follow-up meetings in October 2017, it became obvious that several units and staff have not yet had the time and resources to use all the education programs and quality and safety material that has been produced within Safe Delivery Care. It is now our wish, as well as our hope, that everything that has been produced will be used, for education as well as for further improvement work locally, regionally and nationally. We will be back!

Andreas Herbst	Mia Ahlberg	Béatrice Skiöld
ordförande SFOG	ordförande SBF	ordförande SNF