**Supplementary Files for:**

**Expert Consensus Regarding Core Outcomes for Enhanced**

**Recovery after Cesarean Delivery Studies: A Delphi study**

Sultan P, et al.

**Supplementary File 1.** Individual database search strategy (initially performed on 27th August 2019, repeated on 19th June 2020 and 7th October 2020).

**Supplementary File 2.** Reference list of the 36 included articles from which authors were identified

**Supplementary File 3.** Summary of country of practice for included stakeholders

**Supplementary Figure 1.** Summary of literature search to identify enhanced recovery after cesarean delivery studies

**Supplementary Table 1.** Summary of Round 1 results

**Supplementary Table 2.** Summary of Round 2 results

**Supplementary Table 3.** Outcomes achieving weak consensus for inclusion in core outcome set (50-69% of stakeholders voted to include)

**Supporting documents.** Letter of invitation, Participant invitation, Research information

**Supplementary File 1. Individual database search strategy (initially performed on 27th August 2019, repeated on 19th June 2020 and 7th October 2020).**

**PubMed**

(("Cesarean Section"[Mesh] OR c-section OR caesarean OR caesarian OR cesarian OR cesarean OR top up OR instrumental delivery) AND "enhanced recovery" OR “eras”)  
  
**CINAHL**

((MH "Cesarean Section" OR c-section OR caesarean OR caesarian OR cesarian OR cesarean OR top up OR instrumental delivery) AND "enhanced recovery" OR “eras”))  
  
**Web of Science**

(("Cesarean Section" OR c-section OR caesarean OR caesarian OR cesarian OR cesarean OR top up OR instrumental delivery) AND "enhanced recovery" OR “eras”))

**Embase**

(("Cesarean Section" OR c-section OR caesarean OR caesarian OR cesarian OR cesarean OR top up OR instrumental delivery) AND "enhanced recovery" OR “eras”))

**Supplementary File 2. Reference list of the 36 included articles from which authors were identified**

***Enhanced recovery after cesarean delivery studies comparing control group to enhanced recovery (n=21)***

1. Bowden SJ, Dooley W, Hanrahan J, et al. Fast-track pathway for elective caesarean section: a quality improvement initiative to promote day 1 discharge. *BMJ Open Qual* 2019;**8**:e000465.
2. Deniau B, Bouhadjari N, Faitot V, et al. Evaluation of a continuous improvement programme of enhanced recovery after caesarean delivery under neuraxial anaesthesia. *Anaesth Crit Care Pain Med* 2016;**35**:405–9.
3. Baluku M, Bajunirwe F, Ngonzi J, Kiwanuka J, Ttendo S. A randomized controlled trial of enhanced recovery after surgery versus standard of care recovery for emergency cesarean deliveries at Mbarara Hospital, Uganda. *Anesth Analg* 2020;**130**:769-776.
4. Laronche A, Popescu L, Benhamou D. An enhanced recovery programme after caesarean delivery increases maternal satisfaction and improves maternal-neonatal bonding: A case control study. *Eur J Obstet Gynecol Reprod Biol* 2017;**210**:212–6.
5. Rousseau A, Sadoun M, Aimé I, et al. Comparative study about enhanced recovery after cesarean section: What benefits, what risks? *Gynecol Obstet Fertil Senol* 2017;**45**:387–92.
6. Wrench IJ, Allison A, Galimberti A, Radley S, Wilson MJ. Introduction of enhanced recovery for elective caesarean section enabling next day discharge: a tertiary centre experience. *Int J Obstet Anesth* 2015;**24**:124–30.
7. Kleiman A, Chisholm C, Dixon A, et al. Evaluation of the impact of enhanced recovery after surgery protocol implementation on maternal outcomes following elective cesarean delivery. *Int J Obstet Anesth* 2019: In Press. URL: https://www.obstetanesthesia.com/article/S0959-289X(19)30527-8/fulltext (accessed March 9th, 2020).
8. Hedderson M, Lee D, Hunt E, et al. Enhanced recovery after surgery to change process measures and reduce opioid use after cesarean delivery a quality improvement initiative. *Obstet Gynecol* 2019;**134**:511–9.
9. Cattin A, De Baene A, Achon E, et al. [Evaluation of enhanced recovery for elective cesarean section]. *Gynecol Obstet Fertil Senol* 2017;**45**:202–9.
10. Fay E, Hitti J, Delgado C, et al. An enhanced recovery after surgery pathway for cesarean delivery decreases hospital stay and cost. *Am J Obstet Gynecol* 2019;**221**:349.e1-349.e9.
11. Teigen N, Sahasrabudhe N, Doulaveris G, et al. Enhanced recovery after surgery at cesarean to reduce postoperative length of stay: A randomized controlled trial. *Am J Obstet Gynecol* 2019.In Press. URL: https://www.ajog.org/article/S0002-9378(19)31234-7/pdf (accessed March 9th, 2020).
12. *Lester S, Kim B, Tubinis M, Morgan C, Powell M.* Impact of an enhanced recovery program for cesarean delivery on postoperative opioid use. Int J Obstet Anesth 2020;43:47–55.
13. *Shinnick J, Ruhotina M, Has P et al.* Enhanced Recovery after Surgery for Cesarean Delivery Decreases Length of Hospital Stay and Opioid Consumption: A Quality Improvement Initiative. Am J Perinatol 2020:In Press. https://doi.org/10.1055/s-0040-1709456.
14. *Pan J, Hei Z, Li L et al.* The Advantage of Implementation of Enhanced Recovery After Surgery (ERAS) in Acute Pain Management During Elective Cesarean Delivery: A Prospective Randomized Controlled Trial. Ther Clin Risk Manag 2020;4:369–78.
15. *Mullman L, Hilden P, Goral J et al.* Improved Outcomes With an Enhanced Recovery Approach to Cesarean Delivery. Obstet Gynecol 2020;136:685–91.
16. Wrench IJ, Allison A, Galimberti A, Radley S, Wilson MJ. Introduction of enhanced recovery for elective caesarean section enabling next day discharge: a tertiary centre experience. Int J Obstet Anesth. 2015 May;24(2):124-30. doi: 10.1016/j.ijoa.2015.01.003. Epub 2015 Jan 14. PMID: 25794417.
17. Lester SA, Kim B, Tubinis MD, Morgan CJ, Powell MF. Impact of an enhanced recovery program for cesarean delivery on postoperative opioid use. Int J Obstet Anesth. 2020 Aug;43:47-55. doi: 10.1016/j.ijoa.2020.01.005. Epub 2020 Jan 22. PMID: 32044216.
18. Jarraya A, Zghal J, Abidi S, Smaoui M, Kolsi K. Subarachnoid morphine versus TAP blocks for enhanced recovery after caesarean section delivery: A randomized controlled trial. Anaesth Crit Care Pain Med. 2016 Dec;35(6):391-393. doi: 10.1016/j.accpm.2015.10.012. Epub 2016 Apr 11. PMID: 27080379.
19. Pirie S, Mulliner J. The introduction of an enhanced recovery pathway for elective caesarean sections. J Perioper Pract. 2018 Mar;28(3):46-50.

***ERAS Society Guidelines and SOAP consensus statement (n=4)***

1. Wilson RD, Caughey AB, Wood SL, Macones GA, Wrench IJ, Huang J, Norman M, Pettersson K, Fawcett WJ, Shalabi MM, Metcalfe A, Gramlich L, Nelson G. Guidelines for Antenatal and Preoperative care in Cesarean Delivery: Enhanced Recovery After Surgery Society Recommendations (Part 1). Am J Obstet Gynecol. 2018 Dec;219(6):523.e1-523.e15.
2. Caughey AB, Wood SL, Macones GA, Wrench IJ, Huang J, Norman M, Pettersson K, Fawcett WJ, Shalabi MM, Metcalfe A, Gramlich L, Nelson G, Wilson RD. Guidelines for intraoperative care in cesarean delivery: Enhanced Recovery After Surgery Society Recommendations (Part 2). Am J Obstet Gynecol. 2018 Dec;219(6):533-544.
3. Macones GA, Caughey AB, Wood SL, Wrench IJ, Huang J, Norman M, Pettersson K, Fawcett WJ, Shalabi MM, Metcalfe A, Gramlich L, Nelson G, Wilson RD. Guidelines for postoperative care in cesarean delivery: Enhanced Recovery After Surgery (ERAS) Society recommendations (part 3). Am J Obstet Gynecol. 2019 Sep;221(3):247.e1-247.e9.
4. Bollag L, Lim G, Sultan P, Habib AS, Landau R, Zakowski M, Tiouririne M, Bhambhani S, Carvalho B. Society for Obstetric Anesthesia and Perinatology: Consensus Statement and Recommendations for Enhanced Recovery After Cesarean. Anesth Analg. 2020 Nov 3. doi: 10.1213/ANE.0000000000005257. Epub ahead of print. PMID: 33177330.

***Review articles (n=5)***

1. Sultan P, Sharawi N, Blake L, Carvalho B. Enhanced recovery after caesarean delivery versus standard care studies: a systematic review of interventions and outcomes. Int J Obstet Anesth. 2020 Aug;43:72-86.
2. Corso E, Hind D, Beever D, Fuller G, Wilson MJ, Wrench IJ, Chambers D. Enhanced recovery after elective caesarean: a rapid review of clinical protocols, and an umbrella review of systematic reviews. BMC Pregnancy Childbirth. 2017 Mar 20;17(1):91.
3. Suharwardy S, Carvalho B. Enhanced recovery after surgery for cesarean delivery. Curr Opin Obstet Gynecol. 2020 Apr;32(2):113-120.
4. Liu ZQ, Du WJ, Yao SL. Enhanced recovery after cesarean delivery: a challenge for anesthesiologists. Chin Med J (Engl). 2020 Mar 5;133(5):590-596.
5. Ituk U, Habib AS. Enhanced recovery after cesarean delivery. F1000Res. 2018 Apr 27;7:F1000 Faculty Rev-513. doi: 10.12688/f1000research.13895.1. PMID: 29770203

***Editorial (n=2)***

1. Lucas DN, Gough KL. Enhanced recovery in obstetrics--a new frontier? Int J Obstet Anesth. 2013 Apr;22(2):92-5.
2. Peahl AF, Smith R, Johnson TRB, Morgan DM, Pearlman MD. Better late than never: why obstetricians must implement enhanced recovery after cesarean. Am J Obstet Gynecol. 2019 Aug;221(2):117.e1-117.e7.

***National Surveys (n=4)***

1. Aluri S, Wrench IJ. Enhanced recovery from obstetric surgery: a U.K. survey of practice. Int J Obstet Anesth. 2014 May;23(2):157-60.
2. Jacques V, Vial F, Lerintiu M, Thilly N, Mc Nelis U, Raft J, Bouaziz H. Réhabilitation périopératoire des césariennes programmées non compliquées en France : enquête de pratique nationale [Enhanced recovery following uncomplicated elective caesarean section in France: a survey of national practice]. Ann Fr Anesth Reanim. 2013 Mar;32(3):142-8.
3. Wyniecki A, Raucoules-Aimé M, de Montblanc J, Benhamou D. Réhabilitation précoce après césarienne programmée : enquête de pratique auprès des maternités des régions Provence - Alpes - Côte d'Azur et Île-de-France [Enhanced recovery after Caesarean delivery: a practice survey in two French regions]. Ann Fr Anesth Reanim. 2013 Mar;32(3):149-56.
4. Pujic B, Kendrisic M, Shotwell M, Shi Y, Baysinger CL. A Survey of Enhanced Recovery After Surgery Protocols for Cesarean Delivery in Serbia. Front Med (Lausanne). 2018 Apr 17;5:100.

**Supplementary File 3. Summary of country of practice for included stakeholders**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Anesthesiologists (18)** | **Obstetrics**  **(8)** | **Patients\***  **(4)** | **Nurse / Midwife**  **(1)** |
| **USA** | 12 | 3 | 3 | 1 |
| **UK** | 2 | 3 | 1 |  |
| **Canada** | 0 | 2 |  |  |
| **France** | 1 |  |  |  |
| **Israel** | 1 |  |  |  |
| **Serbia** | 1 |  |  |  |
| **Uganda** | 1 |  |  |  |

\*Place of birthing experience reported for patients; 3 patients underwent previous cesarean delivery and the remaining patient had 1 operative vaginal delivery and 1 normal vaginal delivery.

**Supplementary Figure 1. Summary of literature search to identify ERAC studies**

Exclusions (103):

* Not ERAC (48)
* Non-national survey (14)
* Repeat data published elsewhere (2)
* Duplicates (3)
* Letters / newsletters (2)
* Abstract (34)

139 studies retrieved for review

71 excluded based on title and abstract

TOTAL = 210 studies

ERAC studies and ERAC related publications (n=36):

* ERAC studies comparing control group to ERAC (n=21)
* ERAS Society Guidelines (Parts 1-3; n=3)
* SOAP consensus statement (n=1)
* Review articles (n=5)
* Editorial (n=2)
* National Surveys about ERAC (n=4)

**Supplementary Table 1. Summary of Round 1 results**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Outcome** | **Median**  **[Interquartile range]** | **Include**  **(7-9)** | **Maybe**  **(4-6)** | **Exclude**  **(1-3)** |
| **Duration of hospital stay** | | | | |
| Length of hospital stay\* | 9 [8,9] | 29 | 1 | 2 |
| Proportion of women discharged on Day 1 postoperatively | 6 [3,8] | 11 | 14 | 7 |
| Proportion of women discharged on Day 2 postoperatively | 6 [5,8] | 15 | 11 | 6 |
| Proportion of women discharged on Day 3 postoperatively | 6 [5,8] | 13 | 15 | 4 |
| Proportion of women discharged after Day 3 postoperatively | 6 [4.5,8.25] | 14 | 12 | 6 |
| Mean day of discharge\* (pre vs post ERAC) | 8 [7.5,9] | 26 | 5 | 1 |
| Mean day of discharge\*  (reported monthly pre and post ERAC) | 8 [6,8] | 22 | 7 | 3 |
| Time woman feels ready for discharge | 5 [4.5,9] | 16 | 11 | 5 |
| **General Measures** | | | | |
| Pathway or bundle compliance (% items)\* | 8 [6,9] | 23 | 9 | 0 |
| Pathway or bundle compliance (100 %) | 8 [6,8.75] | 19 | 12 | 1 |
| Projected cost savings (per cesarean) | 6 [6,8] | 18 | 12 | 2 |
| Projected cost savings (annual savings) | 6 [6,8] | 17 | 13 | 2 |
| **Readmissions** | | | | |
| Maternal re-admission rate after discharge\* | 8 [8,9] | 27 | 5 | 0 |
| Maternal re-attendance rate (unplanned out-patient visit)\* | 8 [6,8] | 22 | 10 | 0 |
| Neonatal re-admission rate | 6 [6,9] | 20 | 9 | 3 |
| **Obstetric Outcomes** | | | | |
| Uterine atony | 5 [3,5] | 7 | 17 | 8 |
| Postpartum Hemorrhage | 6 [5,7.5] | 16 | 14 | 2 |
| Blood transfusion requirement within 30 days of delivery | 5 [5,6] | 11 | 16 | 5 |
| Prophylactic antibiotic administration compliance | 6 [5,8] | 16 | 11 | 5 |
| **Complications** | | | | |
| Post-dural puncture headache (PDPH) within 7 days of delivery | 5 [3,6.5] | 13 | 12 | 7 |
| Sepsis within 30 days | 6 [5,8] | 15 | 13 | 4 |
| Wound infection or surgical site infection within 30 days | 6 [5,8] | 20 | 9 | 3 |
| Pyrexia within 30 days | 6 [5,6] | 9 | 17 | 6 |
| 30-day morbidity | 8 [5.75,9] | 18 | 11 | 3 |
| Foul smelling lochia within 30 days of delivery | 5 [3,5] | 4 | 14 | 12 |
| **Maternal Satisfaction** | | | | |
| Maternal Satisfaction: cesarean delivery\* | 8 [6,9] | 22 | 10 | 0 |
| Maternal Satisfaction: hospital stay | 8 [6,9] | 20 | 11 | 1 |
| Maternal Satisfaction: ERAC protocol | 8 [6,9] | 18 | 11 | 3 |
| Maternal Satisfaction re: timing of discharge | 8 [5,9] | 20 | 10 | 2 |
| Maternal Satisfaction re: analgesia\* | 8 [7,9] | 26 | 6 | 0 |
| Maternal satisfaction compared to previous cesarean delivery | 6 [5,8] | 16 | 11 | 6 |
| Maternal satisfaction with timing of cannula removal | 4 [3,6] | 8 | 11 | 13 |
| Maternal satisfaction with timing of urinary catheter removal | 6 [3,8] | 13 | 12 | 7 |
| Friends or family test | 6 [5,8] | 14 | 12 | 6 |
| Were your expectations met with your delivery experience? | 6 [6,8] | 17 | 15 | 0 |
| Were your expectations met during your hospital stay? | 6 [6,8] | 15 | 16 | 1 |
| **Pain** | | | | |
| Maximum pain scores at rest | 8 [6,9] | 19 | 13 | 0 |
| Maximum pain scores on movement | 8 [6,9] | 20 | 12 | 0 |
| Average pain scores (rest and movement) | 8 [6,9] | 21 | 11 | 0 |
| AUC pain scores | 6 [5,8] | 15 | 16 | 1 |
| Pain score change before and after analgesia | 5 [5,6] | 8 | 17 | 5 |
| Intraoperative opioid consumption | 5.5 [5,8] | 12 | 14 | 6 |
| Postpartum opioid use (MME)\* | 9 [8,9] | 28 | 4 | 0 |
| Postpartum opioid use (%)\* | 8 [6,9] | 24 | 7 | 1 |
| Need for opioid beyond 24 hours (%)\* | 8 [6,8.25] | 23 | 7 | 2 |
| Limited activity due to pain (%) | 7 [6,8.75] | 19 | 12 | 1 |
| Compliance rate of multimodal analgesia usage\* | 8 [6,9] | 25 | 7 | 0 |
| Need for opioids within 24 hours of hospital discharge\* | 8 [6,9] | 23 | 7 | 1 |
| Number of opioid tablets at discharge | 7 [5.25,9] | 17 | 10 | 4 |
| Opioid prescription refills at 6-week follow-up | 8 [6,9] | 19 | 8 | 4 |
| **Nausea and Vomiting** | | | | |
| Prophylactic anti-emetic rate (%) | 8 [6,9] | 21 | 11 | 0 |
| Postoperative Nausea\* (%) | 8 [6,9] | 25 | 7 | 0 |
| Postoperative Nausea (nausea score) | 6 [5,8] | 11 | 19 | 2 |
| Postoperative Vomiting (%) | 6 [5,8] | 18 | 12 | 2 |
| Postoperative Nausea or Vomiting (PONV)\* | 8 [5.25,8.75] | 23 | 8 | 1 |
| **Pruritis** | | | | |
| Pruritis (patient-reported) | 6 [5,6] | 10 | 19 | 3 |
| Pruritis\* (requiring treatment) | 6 [5,6.5] | 15 | 13 | 4 |
| **Breastfeeding** | | | | |
| Lactation success | 8 [5,9] | 18 | 12 | 2 |
| Breastfeeding success | 8 [6,9] | 20 | 10 | 2 |
| Breastfeeding by time of discharge\* | 8 [7,9] | 24 | 6 | 2 |
| Type of feeding (breast/formula) | 8 [7,9] | 24 | 6 | 2 |
| Breastfeeding / bottle feeding / both | 6 [5,6] | 11 | 15 | 6 |
| Breastfeeding at time of discharge | 8 [6,9] | 21 | 8 | 2 |
| Maternal perception of breastfeeding experience | 6 [5,8] | 15 | 14 | 2 |
| Difficulty with feeding / nursing | 6 [5,8] | 12 | 15 | 3 |
| **Mobilization** | | | | |
| Time to first mobilization\* | 8 [6,9] | 23 | 8 | 1 |
| % mobilizing <12 hours\* | 8 [6,9] | 23 | 9 | 0 |
| % Day 0 mobilization | 7 [6,8.75] | 18 | 12 | 2 |
| **Oral Intake of food and drink** | | | | |
| Duration of preoperative fasting (solids) | 7 [5.25,9] | 19 | 10 | 2 |
| Duration of preoperative fasting (liquids)\* | 8.5 [5.75,9] | 22 | 8 | 1 |
| Timing to first fluid intake postoperatively\* | 8 [6,9] | 23 | 7 | 2 |
| Timing of first postoperative soft food | 6 [5,9] | 16 | 12 | 4 |
| Timing of first postoperative solid food | 6 [5.25,8.75] | 16 | 13 | 3 |
| First oral fluid intake in PACU | 6 [5,8] | 16 | 11 | 5 |
| Eating and drinking in PACU | 6 [3.5,7.5] | 8 | 17 | 7 |
| First postoperative food intake <4 hours following PACU admission | 6 [5,8] | 14 | 14 | 4 |
| First postoperative food intake <6 hours following PACU admission | 6 [5,8] | 13 | 15 | 4 |
| First postoperative oral liquid intake <2 hours following PACU admission | 5[3.5,8] | 14 | 12 | 5 |
| First postoperative oral liquid intake <4 hours following PACU admission | 5.5 [3,7.5] | 10 | 16 | 6 |
| **IV and fluid therapy** | | | | |
| IV cannula removal timing | 6 [4.75,8.25] | 16 | 12 | 4 |
| Timing IV fluids stopped | 6 [5.25,9] | 13 | 18 | 1 |
| IV volume administered | 6 [5,9] | 14 | 15 | 3 |
| IV cannula removal within 6 hours of PACU admission | 5 [5,6] | 6 | 21 | 5 |
| Time to urinary catheter removal\* | 9 [6,9] | 26 | 6 | 0 |
| % urinary catheter removal (PACU to 24 hours) | 6 [6,8.5] | 13 | 18 | 1 |
| % urinary catheter removal (PACU to 6 hours) | 6 [5,7.5] | 14 | 15 | 3 |
| Day 0 urinary catheter removal rate | 6 [5,8.25] | 18 | 11 | 3 |
| Urinary re-catheterization rate | 8 [6,9] | 20 | 11 | 1 |
| Able to walk independently to the toilet (hours) | 6 [5,9] | 18 | 13 | 1 |
| Time to void after catheter removal (hours) | 6 [5,8] | 12 | 19 | 1 |
| **Staff Follow-up** | | | | |
| Time till postoperative physician review | 5 [3,8] | 13 | 10 | 8 |
| Review by midwife within 48 hours after discharge | 5 [3,8.5] | 11 | 13 | 7 |
| Discharge medication ready by 6 hours | 5 [3,8] | 11 | 9 | 12 |
| **Neonatal Outcomes** | | | | |
| Early skin-to-skin contact (OR)\* | 8 [8,9] | 24 | 6 | 2 |
| Maternal-neonatal bonding assessment | 6 [5,8] | 16 | 13 | 3 |
| Frequency of mother carrying baby | 5 [3,6] | 5 | 19 | 8 |
| Number of breastfeeds within 24 hours postpartum | 6 [5.25,7.5] | 13 | 15 | 4 |
| Maternal mood | 6 [6,9] | 20 | 10 | 2 |

\*Met the inclusion criteria for inclusion in Round 2; MME= morphine mg equivalents; ERAC=enhanced recovery after cesarean; OR=operating room; PACU=post anesthesia care unit

**Supplementary Table 2. Summary of Round 2 results**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Outcome** | **Median**  **[Interquartile range]** | **Include**  **(7-9)** | **Maybe**  **(4-6)** | **Exclude**  **(1-3)** |
| **Duration of hospital stay** | | | | |
| Length of hospital stay\* | 9 [8,9] | 30 | 1 | 0 |
| Mean day of discharge (pre vs post ERAC) | 8 [6,8] | 21 | 9 | 1 |
| Mean day of discharge (reported monthly pre and post ERAC) | 6 [5.5,8] | 14 | 14 | 3 |
| **Compliance** | | | | |
| Pathway or bundle compliance (% items)\* | 8 [7,9] | 26 | 5 | 0 |
| **Readmissions** | | | | |
| Maternal re-admission rate after discharge\* | 8 [7,9] | 26 | 5 | 0 |
| Maternal re-attendance rate (unplanned out-patient visit)\* | 8 [7,9] | 26 | 4 | 1 |
| **Maternal Satisfaction** | | | | |
| Maternal Satisfaction: cesarean delivery\* | 8 [7,9] | 26 | 5 | 0 |
| Maternal Satisfaction re: analgesia\* | 8 [7,9] | 26 | 5 | 0 |
| **Maternal Pain** | | | | |
| Postpartum opioid use (MME)\* | 9 [8,9] | 29 | 2 | 0 |
| Postpartum opioid use (%)\* | 8 [7,9] | 26 | 5 | 0 |
| Need for opioids beyond 24 hours (%) | 7 [6,8] | 20 | 9 | 2 |
| Compliance rate of multimodal analgesia usage\* | 8 [6,8] | 22 | 9 | 0 |
| Need for opioids within 24 hours of hospital discharge | 8 [6,8.5] | 18 | 12 | 1 |
| **Nausea and Vomiting** | | | | |
| Postoperative Nausea (%) | 6 [5,7.5] | 17 | 10 | 4 |
| Postoperative Nausea and Vomiting (PONV; %) | 7 [6,8] | 21 | 10 | 0 |
| **Breastfeeding** | | | | |
| Breastfeeding by time of discharge\* (%) | 7 [7,9] | 24 | 6 | 1 |
| **Mobilization** | | | | |
| Time to first mobilization\* | 8 [7,9] | 24 | 7 | 0 |
| % mobilizing <12 hours | 8 [6,8] | 20 | 11 | 0 |
| **Oral Intake of Food and Drinks** | | | | |
| Duration of preoperative fasting (liquids)\* | 8 [7,9] | 23 | 7 | 1 |
| Time to first fluid intake postoperatively\* | 8 [7.5,9] | 27 | 4 | 0 |
| Time to urinary catheter removal\* | 8 [7,9] | 25 | 6 | 0 |
| **Maternal-Neonatal** | | | | |
| Early skin-to-skin contact (OR) | 7 [6,9] | 21 | 10 | 0 |

\*Met the criteria for inclusion in Round 3; MME=morphine mg equivalents

**Supplementary Table 3. Outcomes achieving weak consensus for inclusion in core outcome set (50-69% of stakeholders voted to include)**

|  |  |
| --- | --- |
| **Outcome** | **Definition and**  **units of measurement (where applicable)** |
| Maternal satisfaction:  cesarean delivery | Response to the proposed question:  How satisfied were you with your cesarean delivery experience?  Proposed Likert response options:  Very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, very dissatisfied |
| Requirement for NICU admission | Number and percentage of neonates born requiring NICU admission (n/N and %) |

NICU=neonatal intensive care unit;outcomes achieving weak consensus can be considered in future ERAC implementation studies

**Expert Consensus Regarding core outcomes for enhAnced recovery after cesarean DeLivery studiEs: a delphi study**

**(CRADLE delphi study)**

**Investigators: Pervez Sultan, MBChB, FRCA, MD (Res)**

**Brendan Carvalho MBBCh, FRCA**

**Carolyn Weiniger, MD**

**Kariem El-Boghdadly, MBBS, BSc, FRCA, EDRA, MSc**

**Ronald B. George, MD, FRCPC**

Dear Enhanced recovery expert,

There has been recent interest in other areas of medicine to standardize the endpoints used across research with the purpose of enabling improved comparison and combination of the results from diverse studies. There have been numerous studies evaluating the efficacy of enhanced recovery protocols, however inconsistencies in outcomes make them difficult to compare and limit the value of available published research.

The Delphi methodology has become a well-established method to collect expert opinion surrounding a topic in order to achieve consensus within the group being asked. Our study will use the Delphi methodology with the goal of achieving expert consensus on outcomes that should be included in future enhanced recovery after cesarean delivery studies and achieve expert consensus on how each of these outcomes may most effectively be studied.

We intend to distribute the questionnaire to members of the following committees:

* Corresponding authors of published studies assessing the impact of enhanced recovery after cesarean delivery
* Society for Obstetric Anesthesia and Perinatology (SOAP) enhanced recovery consensus statement authors
* Corresponding authors of Parts 1-3 of the Enhanced Recovery After Surgery Society published in American Journal of Obstetrics and Gynecology.

We are aiming for a sample size of approximately 30 participants. Individuals who are part of more than one of these named organizations will only receive a single invitation.

We will use 2 rounds of questionnaires and an e-discussion. During each round we will summarize the results and present them back to the group. You will be able to revise your responses, if you wish, based on the responses of your colleagues. This following questionnaire is the first of 2 questionnaires.

**Participants who complete the 2 questionnaires, participate in e-discussion and manuscript editing, will be authors on the manuscript publication. Please review the attached authorship agreement.**

On behalf of the core investigator group, thank you for your participation,

Pervez, Brendan, Carolyn, Kariem and Ron

Text, letter

Description automatically generated

Dr. Pervez Sultan

Associate Professor

Department of Anesthesiology, Perioperative and Pain Medicine

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CA 94305

**Participant Information**

**Study Title: expert Consensus Regarding core outcomes for enhAnced recovery after cesarean DeLivery studiEs: a delphi study**

**(CRADLE delphi study)**

**Investigators:** **Pervez Sultan, MBChB, FRCA, MD (Res)**

**Brendan Carvalho MBBCh, FRCA**

**Carolyn Weiniger, MD**

**Kariem El-Boghdadly, MBBS, BSc, FRCA, EDRA, MSc**

**Ronald B. George, MD, FRCPC**

Dear Enhanced Recovery after cesarean expert,

Thank you for taking the time to consider participating in our research project. There has been a recent push in various areas of medicine to standardize the endpoints used across research with the purpose of improving the comparison and combination of results from diverse studies. There is no consensus regarding the specific mandatory clinical outcomes for reporting in studies evaluating the efficacy of enhanced recovery after cesarean delivery protocols.

Upon review of the published clinical trials and abstracts comparing enhanced recovery after cesarean delivery to a control group, 47 studies and abstracts were identified. Among included studies and abstracts 90 different outcomes were used to evaluate impact of ERAC introduction, and two-thirds of these outcomes were utilized in singe studies. The outcomes measure aspects of:

* compliance to protocol implementation (e.g. bundle compliance, percentage of women achieving catheter removal or mobilizing within the desired time period stated in the protocol),
* maternal outcomes (e.g. readmission rates and opioid consumption) and
* neonatal outcomes (e.g. neonatal readmission) following delivery resulting from ERAC protocol implementation.

Furthermore, the endpoint for similar outcomes are reported inconsistently. For example length of hospital stay can be reported as number of hours or days and proportion of patients discharged on either day 1, 2 or 3 etc. following delivery.

Inconsistent clinical outcomes used to define successful ERAC protocol implementation and inconsistent methods and timing of measurement of these outcomes make them difficult to compare and limits the value of the research**.** Therefore given the huge heterogeneity that currently exists among studies evaluating ERAC efficacy, there is an urgent need to gain consensus regarding which outcomes are most important to be assessed in future research studies.

The Delphi methodology has become a well-established way to collect expert opinion on a topic in order to achieve consensus. This study will use the Delphi methodology to conduct three questionnaires. The core investigator group will summarize the results and present them back to the participants who can then revise their response based on that of their colleagues. In these questionnaires you will be asked to score each of the items listed using a scale of 1-9 (1-3 indicating the outcome is ‘of limited importance or invalid,’ 4-6 indicating the outcome is ‘important but not critical for inclusion or requires revision’ and 7-9 indicating the outcome is ‘critical for inclusion’). Outcomes with ≥70% of votes for scores of ≥ 7 or 4-6 will be retained for consideration in the next round. There will be space available for your comments on individual outcomes. Following the 2nd questionnaire, a round table e-discussion will allow us to determine the outcomes to be included in the final core outcome set (≥70% agreement will be considered strong consensus for inclusion; 50-69% will be considered weak consensus for inclusion). You will have three weeks to complete each round, with a reminder sent at 7 days and 14 days after the initial questionnaire email to those who have not completed it. If you do not complete all three questionnaires, your response will still be included in the rounds you have completed.

We request your participation in this study by answering and returning this questionnaire regarding enhanced recovery outcomes. Your participation is voluntary and consent to participate in the study is implied by completing the questionnaire and returning your responses via email. Only the Research Assistant will have access to the return emails at psultan@stanford.edu. Responses will be de-identified and provided to the core investigator group for analysis to prepare the next phase of the Delphi questionnaire. To minimize any risk of breech of personal information and data, all electronic data will be securely stored on the secure H-drive in a locked office in the Department of Anesthesiology, Perioperative and Pain Medicine, accessible only by research staff.

On behalf of the core investigator group, thank you for your participation,

Pervez, Brendan, Carolyn, Kariem and Ron

Dr. Pervez Sultan

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**Stanford Research Information Sheet (IRB 54128; May 27th, 2020)**

**Protocol Director: Dr. Pervez Sultan**

**DESCRIPTION:** You are invited to participate in a Delphi research study to determine the outcome measures that should be utilized by researchers in studies evaluating the efficacy of enhanced recovery after cesarean delivery protocols. This will be a Delphi study involving completion of 2 rounds of questionnaires and e-discussion with experts in this field. Results of each round of questionnaires will be anonymously summarized and fed back to participants in order to gain consensus regarding optimal recovery outcome measures. The list of outcome measures selected in this Delphi study will guide future researchers in this field when designing and executing enhanced recovery efficacy studies.

**TIME INVOLVEMENT:** Your participation will take approximately 3 months.

**RISKS AND BENEFITS:** There are no risks associated with participation in this study.The benefits which may reasonably be expected to result from this study are to facilitate researhers designing enhanced recovery efficacy studies and clinicians aiming to evaluate efficacy of their adopted protocols.. Completion of this study will result in authorship on the published consensus that results from this study.

**PAYMENTS:** You will receive no payment for your participation.

**PARTICIPANT'S RIGHTS:** If you have read this form and have decided to participate in this project, please understand your participation is voluntaryand you have the right to withdraw your consent or discontinue participation at any time without penalty.The alternative is not to participate. You have the right to refuse to answer particular questions. The results of this research study may be presented at scientific or professional meetings and will be published in scientific journals. Your individual privacy will be maintained in all published and written data resulting from the study.

Your private information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**CONTACT INFORMATION:**

Questions:If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Protocol Director,(Dr Pervez Sultan, 669-800-9929).

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244, or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

If you agree to participate in this research, please complete the attached questionnaire / survey

Kind regards,

Dr. Pervez Sultan