

CASE REPORT FORM

Study Title : Impact of Advance Provision of an Evidence-Based Information Leaflet on Women's Decision Regarding Elective Induction of Labour at 39 Weeks Among Low-Risk Nulliparous Women: A Randomized Controlled Trial

VISIT 1 – Recruitment (34+0 – 36+6 weeks)

Study ID : _____

Date of recruitment: __ / __ / __ (dd/ mm/ yy)

LMP: __ / __ / __ (dd/ mm/ yy)

EDD: __ / __ / __ (dd/ mm/ yy)

Section A : Baseline Demographic

Patient characteristics

D.O.B: __ / __ / __ (dd/ mm/ yy)

Gravida: _____ Previous pregnancy losses (Abortion/Termination): _____

Planned pregnancy : ☐ Yes ☐ No

Fertility treatment :

☐ Spontaneous conception

☐ Ovulation induction

☐ IUI

☐ IVF/ICSI

Gestational age: _____

Height: _____ cm

Booking weight : _____ kg

Booking BMI : _____ kg/m²

Latest recorded Weight: _____ kg

Latest BMI : _____ kg/m²

Variable	Response
Ethnicity	☐ Malay ☐ Chinese ☐ Indian ☐ Others : _____
Marital Status	☐ Married ☐ Single ☐ Others: _____
Education Level	☐ Primary ☐ Secondary ☐ Diploma ☐ Degree ☐ Masters ☐ PHD
Occupation	☐ Employed ☐ Self-employed ☐ Homemaker ☐ Student ☐ Others : _____
Household income	☐ <3000 ☐ 3000 - 5000 ☐ 5001 - 8000 ☐ >8000

Section B : Study Allocation

Date randomised :

Study Arm : ☐ Intervention ☐ Control

Evidence-based information leaflet provided?

☐ Yes

☐ No

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VISIT 2 – Follow-up clinic (37+0 – 38+6 weeks)

Section C : Before Counselling

Date of follow up : __ / __ / __ (dd/ mm/ yy)

Gestational age: _____

Eligibility reassessment

Still eligible? ☐ Yes ☐ No

Reason if NO :

Initial thoughts BEFORE leaflet

Before today, had you already formed an opinion about whether you would accept induction of labour at 39 weeks if it were offered?

- ☐ Already decided YES
- ☐ Already decided NO
- ☐ Unsure

Section D : Counselling Documentation

(To be completed by researcher)

Evidence-based information leaflet provided before counselling? (to both groups)

☐ Yes

Standardized counselling completed?

- ☐ Yes
- ☐ No

Researcher conducting session :

- ☐ Junior Medical Officer (<2 years experience)
- ☐ Senior Medical Officer (>2 years experience)
- ☐ Specialist
- ☐ Consultant

Section E : Follow-up Questionnaire – attached below

(To assess decision quality following routine counselling regarding induction of labour at 39 weeks, including knowledge adequacy, perceived time pressure, and control over decision-making.)

Section F : Primary Outcome

Participant's decision following routine counselling:

- ☐ Accepted an appointment for induction of labour at 39 weeks
- ☐ Did not accept an appointment for induction of labour at 39 weeks

Time taken to reach decision?

- ☐ Immediately after this counselling
- ☐ Within 24 hours
- ☐ Within 2 – 3 days
- ☐ Within 1 week
- ☐ More than 1 week
- ☐ Decision deferred because further discussion requested

Reason for decision (optional):

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FOLLOW-UP QUESTIONNAIRE (Section E)

Instructions:

Please rate each of the following statements by circling a number from **0 to 10** that best represents your feelings or experience. There are **no right or wrong answers**.

Sila nilai setiap pernyataan berikut dengan membulatkan nombor dari 0 hingga 10 yang paling menggambarkan perasaan atau pengalaman anda. Tiada jawapan yang betul atau salah.

Scale

0 = Not at all / Very poor

Langsung Tidak / Sangat Lemah

5 = Moderate

Sederhana

10 = Excellent / Very high

Sangat Baik / Sangat Tinggi

Part A : Information Leaflet Use (Intervention Process Evaluation)

For participants who received advance reading of the leaflet prior to today's visit only.

1. Before today's clinic visit, did you have an opportunity to read the information leaflet?

☐ Yes

☐ No

2. If yes, how many times did you read the leaflet?

☐ Once

☐ 2–3 times

☐ More than 3 times

3. Did you discuss the leaflet with anyone before today's clinic visit?

☐ No

☐ Yes, with my partner

☐ Yes, with a family member

☐ Yes, with both partner and family

☐ Yes, with healthcare provider

☐ Yes, with someone else: _____

4. Did the leaflet help you prepare for today's discussion with your healthcare provider?

☐ Yes

☐ No

☐ Not sure

5. Did you have enough time to read and think about the information before today's clinic visit?

☐ Strongly disagree

☐ Disagree

☐ Neutral

☐ Agree

☐ Strongly agree

Part B : Decision Quality

Domain 1: Knowledge Adequacy / Kecukupan Pengetahuan

1. How well-informed do you feel about induction of labour at 39 weeks?

Sejauh manakah anda merasakan diri anda mempunyai maklumat yang mencukupi mengenai induksi kelahiran pada usia kandungan 39 minggu?

0	1	2	3	4	5	6	7	8	9	10
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2. How clear and understandable was the information you received?

Sejauh manakah maklumat yang anda terima jelas dan mudah difahami?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

3. How confident are you that you understand the benefits and risks of both induction of labour at 39 weeks and expectant management?

Sejauh manakah anda yakin bahawa anda memahami manfaat dan risiko kedua-dua pilihan, iaitu induksi kelahiran pada usia kandungan 39 minggu dan menunggu kelahiran secara spontan?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

4. How well do you understand both management options available to you (elective induction of labour at 39 weeks and expectant management)?

Sejauh manakah anda memahami kedua-dua pilihan pengurusan yang tersedia untuk anda, iaitu induksi kelahiran elektif pada usia kandungan 39 minggu dan menunggu kelahiran secara spontan?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Scoring : Mean of Questions 1–4

Higher score = better knowledge adequacy

Skor lebih tinggi = kecukupan pengetahuan yang lebih baik

Domain 2: Perceived Time Pressure / Tekanan Masa Yang Dirasai

5. Do you feel that you were given sufficient time to decide on whether to have a labour induction at 39 weeks or not?

Adakah anda merasakan bahawa anda telah diberikan masa yang mencukupi untuk membuat keputusan sama ada ingin menjalani induksi kelahiran pada usia kandungan 39 minggu atau tidak?

(0 = Not enough time at all / Masa langsung tidak mencukupi, 10 = All the time I need/ Masa yang sangat mencukupi)

0	1	2	3	4	5	6	7	8	9	10
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Higher score = less perceived pressure

Skor lebih tinggi = tekanan masa yang lebih rendah

Domain 3: Control Over Decision-Making / Kawalan Dalam Membuat Keputusan

6. How much control do you feel you have over the decision regarding induction of labour at 39 weeks?

Sejauh manakah anda merasakan anda mempunyai kawalan terhadap keputusan berkaitan induksi kelahiran?

0	1	2	3	4	5	6	7	8	9	10
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7. How involved do you feel in making decisions about induction of labour at 39 weeks?

Sejauh manakah anda merasakan diri anda terlibat dalam membuat keputusan berkaitan induksi kelahiran pada usia kandungan 39 minggu?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

8. How much do healthcare staff respect your preferences and choices?

Sejauh manakah kakitangan kesihatan menghormati pilihan dan kehendak anda?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

9. How confident are you that your decision today on whether to induce at 39 weeks or not reflects your personal values and preferences?

Sejauh manakah anda yakin bahawa keputusan anda hari ini sama ada untuk menjalani induksi kelahiran pada usia kandungan 39 minggu atau tidak adalah selaras dengan nilai dan keutamaan peribadi anda?

(0 = Not confident at all / *Langsung tidak yakin*, 10 = Very confident / *Sangat yakin*)

0	1	2	3	4	5	6	7	8	9	10
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Scoring : Mean of Questions 6 - 9

Higher score = greater perceived autonomy and control

Skor lebih tinggi = autonomi dan kawalan yang lebih tinggi dalam membuat Keputusan

Calculated Scores (For Research Team Only)

Knowledge Adequacy Score = _____

Perceived Time Pressure Score = _____

Control Over Decision-Making Score = _____

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DELIVERY ADMISSION

Section F : Delivery and Maternal Outcomes

Date of admission for delivery	
Date of delivery	
Gestational age at delivery	
Actual labour management received	☐ Elective induction at 39 weeks ☐ Expectant management with spontaneous labour ☐ Medically indicated induction ☐ Caesarean delivery before onset of labour ☐ Others : _____
If actual labour management differed from preferred decision, specify reason	☐ Obstetric indication : _____ ☐ Fetal indication : _____ ☐ Maternal request ☐ Caesarean delivery before onset of labour ☐ Others : _____
Induction of Labour Performed	☐ Yes ☐ No If induction performed, Initial method of induction: ☐ Foley's catheter ☐ Prostaglandin ☐ Artificial rupture of membrane ☐ Others : _____ Additional method of induction (if applicable): ☐ Foley's catheter ☐ Prostaglandin ☐ Artificial rupture of membrane ☐ Others : _____
Duration of Labour (hours) (Labour onset defined as commencement of active labour (≥6 cm cervical dilatation))	Time start : _____ Time end : _____
Duration of oxytocin	Time start : _____ Time end : _____
Analgesia in labour	☐ No analgesia ☐ Entonox ☐ Opiates (IM) ☐ Neuraxial analgesia (eg : Epidural) ☐ Others : _____
Presence of birth companion	☐ Yes ☐ No
Mode of delivery	☐ Spontaneous Vaginal Delivery ☐ Operative Vaginal Delivery (Vacuum) ☐ Operative Vaginal Delivery (Forceps) ☐ Caesarean Delivery
Indication for operative/caesarean delivery	
Maximum temperature from IOL to delivery	
Antibiotics given?	☐ No ☐ Yes, Indication : _____

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Type of perineal tear sustained	☐ Intact perineum ☐ Episiotomy ☐ First degree tear ☐ Second degree tear ☐ Third degree tear ☐ Fourth degree tear
Estimated Blood Loss (ml)	
Any complications to mother?	☐ None ☐ Specify :
Date of discharge	
HDU/ICU Admission?	☐ Yes ☐ No
Reason for admission	

Section G : Neonatal Outcomes

Birth Weight (g)	
Baby Outcome	☐ Live ☐ Stillbirth
Sex of baby	☐ Boy ☐ Girl
Apgar score (1min/5min)	
Cord blood gas	pH : BE:
Any complications to baby?	☐ None ☐ Specify :
Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia	☐ No ☐ Yes
Birth trauma?	☐ None ☐ Cephalohematoma ☐ Clavicle fracture ☐ Brachial plexus injury ☐ Others, specify :
Admission required?	☐ Yes ☐ No If yes, specify : SCN / NICU / PICU
Indication for admission	
Requires antibiotics?	☐ No ☐ Yes, Indication : _____
Date of discharge	

Section H : Questionnaire (Post-delivery; prior to discharge) – as attached

(To assess maternal satisfaction with the labour and birth experience prior to hospital discharge.)

POSTPARTUM (PRIOR DISCHARGE)

SECTION H: POST-DELIVERY QUESTIONNAIRE

Instructions:

Please rate each of the following statements by circling a number from **0 to 10** that best represents your feelings or experience. There are **no right or wrong answers**.

Sila nilai setiap pernyataan berikut dengan membulatkan nombor dari 0 hingga 10 yang paling menggambarkan perasaan atau pengalaman anda. Tiada jawapan yang betul atau salah.

Scale

0 = Not at all / Very poor

Langsung Tidak / Sangat Lemah

5 = Moderate

Sederhana

10 = Excellent / Very high

Sangat Baik / Sangat Tinggi

Maternal Satisfaction with Labour and Birth Experience / Kepuasan Ibu Terhadap Pengalaman Bersalin dan Kelahiran

1. Overall, how satisfied were you with your labour and birth experience?

Secara keseluruhan, sejauh manakah anda berpuas hati dengan pengalaman bersalin dan kelahiran anda?

0	1	2	3	4	5	6	7	8	9	10
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2. How well did your birth experience meet your expectations?

Sejauh manakah pengalaman kelahiran anda memenuhi jangkaan anda?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

3. How supported did you feel by healthcare staff during labour and birth?

Sejauh manakah anda merasakan sokongan yang diberikan oleh kakitangan kesihatan semasa proses bersalin dan kelahiran?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Maternal Satisfaction Score = Mean of Questions 1-3

Higher score = greater maternal satisfaction

Skor yang lebih tinggi menunjukkan tahap kepuasan ibu yang lebih tinggi.

**For those induced,*

Optional Exploratory Questions

1. What information was most helpful when making your decision about labour?

Maklumat apakah yang paling membantu anda semasa membuat keputusan berkaitan kelahiran?

-
2. Was there any information you wished you had received earlier?

Adakah terdapat maklumat lain yang anda berharap dapat diterima dengan lebih awal?

-
3. What was the most positive part of your labour and birth experience?

Apakah bahagian yang paling positif dalam pengalaman bersalin dan kelahiran anda?

-
4. What could have been improved?

Apakah yang boleh diperbaiki untuk menjadikan pengalaman anda lebih baik?

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Calculated Score (For Research Team Only)

Maternal Satisfaction Score = _____

Overall, how useful was the information leaflet in helping you understand your options regarding induction of labour at 39 weeks?

Secara keseluruhan, sejauh manakah risalah maklumat ini membantu anda memahami pilihan yang ada berkaitan induksi kelahiran pada usia kandungan 39 minggu?

Circle your score below (higher score, greater satisfaction)

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

I would recommend receiving this type of information during pregnancy to a friend in a similar situation.

Saya akan mengesyorkan maklumat seperti ini diberikan kepada rakan yang sedang hamil dan berada dalam situasi yang sama.

- a) Strongly disagree / *Sangat Tidak Setuju*
- b) Disagree / *Tidak Setuju*
- c) Neither agree nor disagree / *Neutral*
- d) Agree / *Setuju*
- e) Strongly agree / *Sangat Setuju*