Additional File 8. Intravenous paracetamol for controlling pain in labour in Liberia

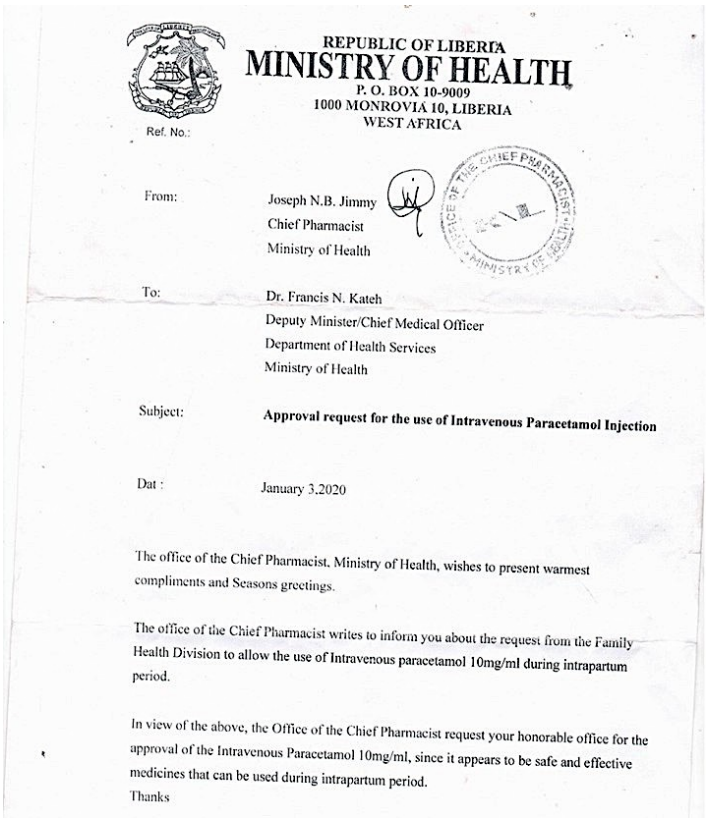
Evidence regarding the use of intravenous paracetamol during labour

No:	Journal reference	Summary of findings
1	**Intravenous infusion of paracetamol versus intravenous pethidine as an intrapartum analgesic in the first stage of labor** *International Journal of Gynecology & Obstetrics / Volume 118, Issue 1 12 April 2012* *https://doi.org/10.1016/j.ijgo.2012.01.025*	**Conclusion** The effectiveness of intravenous paracetamol was comparable to that of intravenous pethidine, but paracetamol had fewer maternal adverse effects.
2	Intravenous infusion of paracetamol for intrapartum analgesia Journal of Obstetrics and Gynaecology Research / Volume 40, Issue 11, 11 August 2014 https://doi.org/10.1111/jog.12465	**Results** Compared to controls, i.v. infusion of paracetamol was associated with significantly lower VAS score 15 and 30 min after the start of medication; also, there was a significantly lower incidence of need for rescue medication (8/57 [14%] vs 49/59 [83.1%], P < 0.001) at 60 min after the start of medication. There were no recorded maternal adverse effects in either group. There were no differences in occurrence of intrapartum fetal distress or neonatal Apgar scores between both groups. **Conclusion** Paracetamol appears to be a safe and effective medicine that can be used during the intrapartum period.
3	Intravenous paracetamol versus intramuscular pethidine in relief of labour pain in primigravid women Niger Med J. 2014 Jan-Feb; 55(1): 54–57. *doi: [10.4103/0300-1652.128167: 10.4103/0300-1652.128167]* *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4071664/*	**Conclusion**: It is concluded that intravenous paracetamol is more effective than intramuscular pethidine to relief labour pain in normal vaginal delivery.
4	Comparison of analgesic efficacy of paracetamol and tramadol for pain relief in active labor Journal of Clinical Anesthesia (2015) 27, 159–163	**Results**: Both the groups showed comparable VAS scores at all times of observation. Lower mean VAS scores were reported in both the groups till 120 minutes only. The duration of first stage of labor was shorter in group P

No:	Journal reference	Summary of findings
		(248.00 ± 98.171 vs 340.63 ± 111.592 minutes; P = .003). The duration of second stage of labor was comparable between the 2 groups. Higher incidence of maternal side effects such as nausea/vomiting and sedation was associated with the use of tramadol. Neonatal outcome was comparable. **Conclusion**: Intravenous paracetamol provides comparable analgesia as intramuscular tramadol during active labor.
5	**Intravenous paracetamol infusion versus intramuscular tramadol as an intrapartum labor analgesic** **International Journal of Reproduction, Contraception, Obstetrics and Gynecology** ***Mohan H et al. Int J Reprod Contracept Obstet Gynecol. 2015 Dec;4(6):1726-1729***	**Conclusions:** Intravenous paracetamol is more effective labor analgesic with fewer maternal adverse effects and shortens labor as compared to intramuscular tramadol.
6	Efficacy of Intravenous Infusion of Acetaminophen for Intrapartum Analgesia *Journal of Clinical and Diagnostic Research. 2016 Aug, Vol-10(8): QC18-QC21*	**Conclusion:** Intravenous acetaminophen is an efficacious non-opioid drug for relieving labour pain without any significant maternal and foetal adverse effects.
7	**I.V. paracetamol as an adjunct to patient-controlled epidural analgesia with levobupivacaine and fentanyl in labour: a randomized controlled study.** *BJA: British Journal of Anaesthesia*, Volume 117, Issue 5, November 2016, Pages 617–622, https://doi.org/10.1093/bja/aew311	**Conclusions:** Use of 1000 mg i.v. paracetamol decreases the mean hourly drug consumption through epidural route. Thus i.v. paracetamol is a safe and effective adjunct to PCEA in labour analgesia.
8	What is the evidence to support the use of IV paracetamol for the short-term treatment of moderate to severe pain in adults? Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals https://www.sps.nhs.uk/wp-content/uploads/2017/04/UKMi_QA_IV-paracetamol_Dec_2016.docx	There is a large volume of data to support the use of intravenous paracetamol for the short-term treatment of moderate to severe pain in adults. IV paracetamol has become widely used in clinical practice and incorporated into clinical guidelines including some NICE guidelines.

No:	Journal reference	Summary of findings
9	A Randomized controlled trial of intramuscular pentazocine compared to intravenous paracetamol for pain relief in labor at Aminu Kano Teaching Hospital, Kano https://www.ajol.info/index.php/tjog/article/view/162499 *Tropical Journal of Obstetrics and Gynaecology* *Trop J Obstet Gynaecol 2017;34:116-123*	The analgesic efficacy of IV paracetamol was similar to that of IM pentazocine in labor, with similar levels of maternal satisfaction with pain relief, but IV paracetamol was associated with significantly lower rates of adverse effects
10	**Comparison of Analgesic Efficacy of Paracetamol and Tramadol for Pain Relief in Active Labor** **Obstetrics & Gynecology: May 2017 - Volume 129 - Issue 5 - p S159-S160** **doi: 10.1097/01.AOG.0000514775.91402.3c** **Monday, May 8, 2017**	**CONCLUSION:** Due to difficulty in administering epidural analgesia to all parturients, administration of paracetamol and tramadol infusion for analgesia is simple and less invasive alternative. In the present study both paracetamol and tramadol were equally effective for labor analgesia but paracetamol has emerged as safe alternative as compared to tramadol due to low incidence of side effects.

Ethical approval for providing intravenous paracetamol to mothers in labour



REPUBLIC OF LIBERIA
MINISTRY OF HEALTH
P. O. BOX 10-9009
1000 MONROVIA 10, LIBERIA
WEST AFRICA

Ref. No.:

From: Joseph N.B. Jimmy
Chief Pharmacist
Ministry of Health

To: Dr. Francis N. Kateh
Deputy Minister/Chief Medical Officer
Department of Health Services
Ministry of Health

Subject: **Approval request for the use of Intravenous Paracetamol Injection**

Dat : January 3,2020

The office of the Chief Pharmacist, Ministry of Health, wishes to present warmest compliments and Seasons greetings.

The office of the Chief Pharmacist writes to inform you about the request from the Family Health Division to allow the use of Intravenous paracetamol 10mg/ml during intrapartum period.

In view of the above, the Office of the Chief Pharmacist request your honorable office for the approval of the Intravenous Paracetamol 10mg/ml, since it appears to be safe and effective medicines that can be used during intrapartum period.
Thanks

Pharmacology of intravenous paracetamol

Paracetamol 10 mg/ml Solution for Intravenous Infusion

1. Qualitative and quantitative composition

One ml contains 10 mg paracetamol One 100ml vial contains 1000mg paracetamol.

Excipients: Sodium 0.994mg/ml. For a full list of excipients, see secoon 5.1

2. Pharmaceutical form

Solution for infusion. **The solution must be clear.**

3. Clinical particulars

3.1 Therapeutic indications

Paracetamol 10 mg/ml Solution for Infusion is indicated for the short-term treatment of moderate to severe pain.

3.2 Posology and method of administration

Intravenous use. The 100 ml vial is restricted to adults and adolescents weighing more than 33 kg.

Posology: Dosing based on patient weight (please see the dosing table here below

Patient weight	**Dose per administration**	**Volume per administration**	**Maximum volume of paracetamol, solution for infusion (10 mg/mL) per administration based on upper weight limits of group (mL)*** **	**Maximum Daily Dose ** **
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for hepatotoxicity	1 g	100mL	100mL	4g

****Maximum daily dose:** The maximum daily dose as presented in the table above is for paoents that are not receiving other paracetamol containing products and should not be given if oral paracetamol has been taken during the previous 6 hours.

*****Patients weighing less will require smaller volumes.**

The minimum interval between each administration must be at least 4 hours.

The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours.

No more than 4 doses to be given in 24 hours.

Severe renal insufficiency: it is recommended, when giving paracetamol to patients with severe renal impairment (creatinine clearance ≤30 mL/min), to increase the minimum interval between each administration to 6 hours.

Method of administration

Take care when prescribing and administering paracetamol, solution for infusion, to avoid dosing errors due to confusion between milligram (mg) and milliliter (mL), which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. When writing prescriptions, include both the total dose in mg and the total dose in volume. Take care to

The paracetamol solution is administered as a 15-minute intravenous infusion.

Text for the 100ml vials:

To remove solution, use a 0.8 mm needle (21-gauge needle) and vertically perforate the stopper at the spot specifically indicated.

As for all solutions for infusion presented in glass vials, it should be remembered that close monitoring is needed notably at the end of the infusion, regardless of administration route. This monitoring at the end of the infusion applies particularly for central venous route infusions, to avoid air embolism.

3.3 Contraindications

• in patients with hypersensitivity to paracetamol or to propacetamol hydrochloride (prodrug of paracetamol) or to any of the excipients.

• in cases of **severe hepatocellular insufficiency.**

3.4 Special warnings and precautions for use

Warnings

RISK OF MEDICATION ERRORS
Take care to avoid dosing errors due to confusion between milligram (mg) and milliliter (mL), which could result in accidental overdose and death (see section 3.2).

To avoid the risk of overdose, check that no other medicines containing paracetamol are administered at the same time or in the previous 6 hours.

Doses higher than those recommended entail the risk of very serious liver damage. Clinical signs and symptoms of liver damage are not usually seen under two days, and up to a maximum of 4-6 days, after administration. Treatment with anecdote should be given as soon as possible (See section 3.9 Overdose).

This medicinal product contains 4.32mmol sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Precautions for use Paracetamol should be used with caution in cases of:

1. hepatocellular insufficiency,
2. severe renal insufficiency (creatinine clearance ≤30 mL/min) (see sections 4.2 Posology and method of administration and 5.2 Pharmacokinetic properties),
3. chronic alcoholism,
4. chronic malnutrition (low reserves of hepatic glutathione),
5. dehydration.

3.5 Interaction with other medicinal products and other forms of interaction

• Probenecid causes an almost 2-fold reduction in clearance of paracetamol by inhibiting its conjugation with glucuronic acid. A reduction in the paracetamol dose should be considered if it is to be used concomitantly with probenecid.

• Salicylamide may prolong the elimination t½ of paracetamol.

• Caution should be taken with the concomitant intake of enzyme-inducing substances (see section 3.9 Overdose).

3.6 Fertility, pregnancy and lactation
Pregnancy:

Clinical experience of the intravenous administration of paracetamol is limited. However, epidemiological data from the use of oral therapeutic doses of paracetamol indicate no undesirable effects in pregnancy or on the health of the fetus / newborn infant. Nevertheless, Paracetamol 10 mg/ml Solution for Infusion should only be used during pregnancy after a careful benefit-risk assessment. In this case, the recommended posology and duration must be strictly observed.

LactaYon

After oral administration, paracetamol is excreted into breast milk in small quantities. No undesirable effects on nursing infants have been reported. Consequently, Paracetamol 10 mg/ml Solution for Infusion may be used in breast-feeding women.

3.8 Undesirable effects
The frequency of adverse events listed below is defined using the following convention:

very common (≥ 1/10); common (≥ 1/100 to 1/10); uncommon (≥ 1/1,000 to 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).

Organ System	**Rare**	**Very rare**
General	Malaise	Hypersensitivity reaction
Cardiovascular	Hypotension	
Liver	Increased levels of liver transaminases	
Skin and subcutaneous tissue disorders		Very rare cases of serious skin reactions have been reported.
Platelet/blood		Thrombocytopenia Leucopenia, Neutropenia

Very rare cases of hypersensitivity reactions ranging from simple skin rash or urticaria to anaphylactic shock have been reported and require discontinuation of treatment.

Always have Adrenaline available in case of anaphylaxis (as with any drug that the patient **has not previously been exposed to)**

Reporting of suspected adverse reactions

Reporting suspected adverse reactions atter authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

3.9 Overdose
There is a risk of poisoning, particularly in patients with liver disease, in cases of chronic alcoholism, in patients with chronic malnutrition. Overdosing may be fatal in these cases.

Symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor and abdominal pain.

Overdose, 7.5 g or more of paracetamol in a single administration in adults or 140 mg/kg of body weight in a single administration in children (under 18 years), causes hepatic cytolysis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic

transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with decreased prothrombin levels that may appear 12 to 48 hours after administration. Clinical symptoms of liver damage are usually evident initially after two days and reach a maximum after 4 to 6 days.

Emergency measures

Before beginning treatment, take a blood sample for plasma paracetamol assay, as soon as possible after the overdose.

The treatment includes administration of the antidote, N-acetylcysteine (NAC) by the intravenous or oral route, if possible before the 10th hour. NAC can, however, give some degree of protection even after 10 hours, but in these cases prolonged treatment is given. (see MCAI International Maternal and Child Healthcare Book for more information on Paracetamol poisoning).

4. Pharmacological properties

4.1 Pharmacodynamic properties

Pharmacotherapeutic group: other analgesics and antipyretics ATC Code: N02BE01

The precise mechanism of the analgesic and antipyretic properties of paracetamol has yet to be established; it may involve central and peripheral actions.

Paracetamol 10 mg/ml Solution for intravenous Infusion provides onset of pain relief within 5 to 10 minutes after the start of administration. The peak analgesic effect is obtained in 1 hour and the duration of this effect is usually 4 to 6 hours.

4.2 Pharmacokinetic properties

Adults

Absorption: Paracetamol pharmacokinetics is linear up to 2 g after single administration and after repeated administration during 24 hours.

The maximal plasma concentration (Cmax) of paracetamol observed at the end of 15-minutes intravenous infusion of 500mg and 1 g of Paracetamol 10 mg/ml Solution for Infusion is about 15µg/ml and 30 µg/ml respectively.

Distribution: The volume of distribution of paracetamol is approximately 1 L/kg. Paracetamol is not extensively bound to plasma proteins. Following infusion of 1 g paracetamol, significant concentrations of paracetamol (about 1.5 µg/mL) were observed in the cerebrospinal fluid at and after the 20th minute following infusion.

Metabolism: Paracetamol is metabolised mainly in the liver following two major hepatic pathways: glucuronic acid conjugation and sulphuric acid conjugation. The la}er route is rapidly saturable at doses that exceed the therapeutic doses. A small fraction (less than 4%) is metabolised by cytochrome P450 to a reactive intermediate (N-acetyl benzoquinone imine) which, under normal conditions of use, is rapidly detoxified by reduced glutathione and eliminated in the urine after conjugation with cysteine and mercapturic acid. However, during massive overdosing, the quantity of this toxic metabolite is increased.

Elimination: The metabolites of paracetamol are mainly excreted in the urine. 90% of the dose administered is excreted within 24 hours, mainly as glucuronide (60-80%) and sulphate (20-30%) conjugates. Less than 5% is eliminated unchanged. Plasma half-life is 2.7 hours and total body clearance is 18 L/h.

Neonates, infants and children: The pharmacokinetic parameters of paracetamol in children are similar to those observed in adults, except for the plasma half-life that is slightly shorter (1.5 to 2 h) than in adults.

Special populations:

Renal insufficiency: In cases of severe renal impairment (creatinine clearance 10-30 mL/min), the elimination of paracetamol is slightly delayed, the elimination half-life ranging from 2 to 5.3 hours. For the glucuronide and sulphate conjugates, the elimination rate is 3 times slower in subjects with severe renal impairment than in healthy subjects. Therefore, when giving paracetamol to patients with severe renal impairment (creatinine clearance ≤30 mL/min), the minimum interval between each administration should be increased to 6 hours (see section 3.2. Posology and method of administration).

4.3 Preclinical safety data
Preclinical data reveal no special hazard for humans beyond the information included in other sections of the SmPC. Studies on local tolerance of Paracetamol 10 mg/ml Solution for Infusion in rats and rabbits showed good tolerability. Absence of delayed contact hypersensitivity has been tested in guinea pigs.

5. Pharmaceutical particulars

5.1 List of excipients
Cysteine hydrochloride monohydrate
Disodium phosphate dihydrate
Hydrochloric acid 1M (for pH-adjustment)
Mannitol
Sodium hydroxide 1M (for pH-adjustment)
Water for Injections

5.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products except for dilution with 0.9% sodium chloride or 5% glucose solution

5.3 Shelf life 24 months.

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, **the product should be used immediately**. If not used immediately, in-use storage times and conditions are the responsibility of the user.

5.4 Special precautions for storage
Store below 30°C. Protect from light. Store in the original package. Do not refrigerate or freeze.

5.5 Nature and contents of container
50ml and 100 ml Type II colorless glass vial with bromobutyl stopper and an aluminium cap.

5.6 Special precautions for disposal and other handling
Before administration, the product should be visually inspected for any particulate ma}er and discoloration. For single use only. Any unused solution should be discarded.

McGills pain intensity scale

0	No pain
1	Mild pain
2	Discomfort
3	Distressing
4	Horrible
5	Excruciating

1000mg IV OVER 15 minutes

Measurement of pain relief was done with McGills' pain intensity scale after 1, 2, 3, 4 and 5 hours of drug administration.

Mode of delivery, neonatal outcome, duration of labor, drug delivery interval, and side effects

One gram of intravenous paracetamol should only be given when weight is more than 33 kg, and hepatic disorders are ruled out. It should not be repeated within 4 h and must not exceed four grams in 24 h [13].

Peak analgesic effect of paracetamol is seen at 1 h, and effect lasts for 4 to 6 h,

Controlling the pain of labour in mothers attending CB Dunbar Hospital in Liberia.

STATEMENT TO BE READOUT AND DISCUSSED WITH MOTHERS DURING LABOUR

Acting on feedback from women in labour who have told us that they are in pain and want us to do something to help them we are trying to reduce the severity of pain suffered by mothers during labour.

However, providing pain control in labour is not straightforward. We must be sure that it does not harm either you or your unborn baby. One drug which may be helpful is called Paracetamol. This is widely used as an oral medicine both within and outside pregnancy to control common causes of pain such as headaches or muscular aches following minor injuries. Provided the dose taken does not exceed 4 grams per 24 hours in an adult there are no significant side effects.

The pain resulting from the contractions that occur during labour can be extremely severe and most of the techniques and drugs used in well-resourced countries are not easy to control or even safe in situations where medical resources are limited, as in Liberia.

In the last few years, a form of Paracetamol has been developed that can reduce severe pain. It has to be given into a vein and, if an intravenous cannula is not already in place, a cannula will need to be placed in one of your veins in order for it to be administered. Previous studies in other countries, during labour, have shown that this intravenous preparation of Paracetamol can reduce severe pain. With permission of the Ministry of Health and yourself we would like to offer you this form of treatment during your labour.

Pain can be described in the following 5 ways
Level 1. Mild,
Level 2. Causing you significant discomfort,
Level 3. Causing you significant distress
Level 4. Is so severe that it can be described as horrible
Level 5. Is so very severe that it can be described as excruciaong or the worst possible pain that you could imagine.
Intravenous paracetamol will only be offered if you describe your labour pain as causing major distress; that is level 4 or 5.

In any 6-hour period, only one intravenous injection of Paracetamol can be given. It is likely, and we hope, that the severity of pain will be reduced within the first 10 to 15 minutes and the benefit last for at least 5 more hours. You will be asked for your views on the level of pain you are suffering every 1 hour following the injection and this will be recorded onto a chart.

If labour is continuing for more than 6 hours after the injection of paracetamol and is causing severe pain a second dose **could be given at this time**, provided that you consider it is helping you. Again, measurements of labour pains every hour after this second injection will continue until your labour has ended or until another 6 hours have passed. If labour has not ended 12 hours after the first injection has been given and you remain in severe distress/pain an additional third dose could be given.

Very many thanks for reading/listening to this explanation.

I CONFIRM THAT I HAVE READ TO THE MOTHER THE ABOVE STATEMENT ON THE USE OF INTRAVENOUS PARACETAMOL IN THE CONTROL OF SEVERE PAIN DURING LABOUR AND, WHEN APPROPRIATE, THE MOTHER HAS ALSO READ THIS DOCUMENT.

NAME …….
SIGNATURE……Date…….

Essential information to be recorded for each patient treated

Woman's Name..... Body weight..... Kg

Age of mother: ..... Gravida and Parity of mother.....

PLEASE CONFIRM HERE THE FOLLOWING INFORMATION regarding the mother's health. If any answer is **YES then the intravenous paracetamol cannot be given**

1. The mother is taking any other drug at this time: YES/NO
2. The mother has taken any paracetamol by mouth in the last 6 hours YES/NO
3. The mother has taken any traditional medicines or herbs YES/NO
4. The mother has a history of liver or kidney disease YES/NO
5. The mother is suffering any medical complication of pregnancy such as pre-eclampsia YES/NO

Type of birth: Normal vaginal / Caesarean / Vacuum
If Caesarean or vacuum what was the reason? .....

Maternal outcome: list any complications of labour, delivery or after birth:
.....
.....
Baby outcome
Survival: Live birth / still birth Gender Male / Female
Apgar score at 1-minute _____ Apgar score at 5 minutes _____
Was the baby resuscitated? Yes/No
If **yes**, please give details

Was baby admitted to neonatal ward? Yes/No
If **yes**, what was the reason?

PLEASE ASK THE MOTHER THE FOLLOWING QUESTIONS USING THESE EXACT WORDS:
"HOW DID YOU FIND THE INTRAVENOUS DRUG GIVEN TO HELP CONTROL THE PAIN OF LABOUR ? DID IT HELP WITH YOUR LABOUR? IF SO, IN WHAT WAYS?
DID IT CAUSE YOU ANY PROBLEMS? IF SO, IN WHAT WAYS?"
PLEASE ALLOW THE MOTHER TO WRITE HER ANSWER BELOW OR WRITE DOWN HER ANSWER **USING HER OWN WORDS**.
.....
.....

THE CONTROL OF LABOUR PAIN WITH INTRAVENOUS PARACETAMOL FORM TO BE COMPLETED

Time Record approx. every 1 hour following the FIRST intravenous injection of paracetamol	**Dose of IV paracetamol given over 15 minutes (see dose below based on body weight) by intravenous infusion (maximum 1 dose every 6 hours)**	**Pain score** **Level1. Pain is mild** **Level 2. Causing you significant discomfort,** **Level 3. Causing you significant distress** **Level 4. Is so severe that it can be described as horrible** **Level 5. Is so very severe that it can be described as excruciating or the worst possible pain that you could imagine**
Immediately before paracetamol:	First dose given in ml =	

Time Record approx. every 1 hour following the FIRST intravenous injection of paracetamol	**Dose of IV paracetamol given over 15 minutes (see dose below based on body weight) by intravenous infusion (maximum 1 dose every 6 hours)**	**Pain score** **Level1. Pain is mild** **Level 2. Causing you significant discomfort,** **Level 3. Causing you significant distress** **Level 4. Is so severe that it can be described as horrible** **Level 5. Is so very severe that it can be described as excruciating or the worst possible pain that you could imagine**
Immediately before paracetamol:	First dose given in ml =	
	2nd dose if needed in ml =	
	3rd dose if needed in ml =	
	4th dose if needed in ml =	

Each 6 hourly dose given based on body weight: **Do not give more than 4 doses in a 24-hour period**
Mother's weight 50 Kg or more give 1-gram (1000mg) doses (100ml by slow IV infusion over 15 minutes)
Mother's weight 44 to 49 Kg give 750 mg doses (75ml by slow IV infusion over 15 minutes)*
Mother's weight 33 to 43Kg give 500 mg doses (50ml by slow IV infusion over 15 minutes)*

*1. For the 500mg dose 'before starting the paracetamol infusion the midwife should withdraw and discard 50ml of the solution from the 100ml (1000mg) bottle of paracetamol'.

*2. For the 750mg dose 'before starting the paracetamol infusion the midwife should withdraw and discard 25ml of the solution from the 100ml (1000mg) bottle of paracetamol'.

3. For the 1000mg dose 'the midwife should infuse the whole bottle (100ml) of paracetamol'

Summary of results of first year of intravenous paracetamol given during labour at CB Dunbar Maternity Hospital Table 1

No.	Age yrs	Gravida	Delivery	Reason C-section or other problems	Live Birth/ Still Birth	M/F	Apgar Score	Resuscitation	Neonatal Ward	Sc 1st taken	Sc 1st hour	Sc 2nd hour	Sc 3rd hour	Sc 4th hour	Sc 5th hour	Did pain reduce?	Mothers Comments
1	19	G1, P0	NV		LB	F	9-10	No	No	4	3	2				Yes	It good. I feel fine it help me to bring my pain down and I was not having problem with it
2	20	G1, P0	NV		LB	M	8-10	No	No	5	4	4	3	3		Yes	The medicine was helpful to me as it helps to cool down my pain. I want to say thank you very much. It did not cause me any problems.
3	20	G1, P0	NV		LB	F		No	No	4	3	3	4			Yes	
4	25	G6, P2	NV		LB	M	8-10	No	No	4	3	3	3			Yes	I want to say thanks very much for this new idea. The pain medicine helps to reduce my pain.
5	19	G1, P0	NV		LB	F	8-10	No	No	5	4	3	3			Yes	I want to say thank you and the hospital for the paracetamol help me good in my pain.
6	26	G4, P3	NV		LB	F	8-10	No	No	4	3	2				Yes	The medicine is fine. It reduced my pain and no problem using it. I hope to use it next time.
7	21	G1, P0	NV		LB	F	6-10	Yes	No	4	3	3	3	2		Yes	The medicine fine it helps me by reducing my stomach pain. I don't have problem using it. I want other people to try it too.
8	20	G2, P1	CS	Previous CS x 1 Prolonged labour Twin	LB	F	8-10 9-10	No	No	4	3	3	3	4	4	Yes	She said the medicine help her greatly because the pain was too much but the medicine helps to cool it down. 2nd dose 4,3,3
9	34	G6, P5	NV	IUFD	SB	F	0-0			4	4	3	3	3		Yes	I felt very good about the medicine. It helps reduce my pain.
10	16	G1, P0	CS	Failure to progress	LB	F	8-10	No	No	4	4	3	3	3	4	Yes	The pain medicine was good. The pain was too much but the medicine helps to reduce it.
11	31	G8, P1	NV		LB	M	8-10	No	No	4	3	3	2			Yes	I like the medicine is good. The pain was very hard on me but it reduced the pain and don't know the baby started coming. It really helpful. Thank you.
12	30	G4, P3, L3	NV		LB	F	8-10	No	No	4	3	2				Yes	Thank you so much. My pain was too much but when you give me the medicine it brings my pain small.
13	29	G4, P3, L3	NV	Twin	LB	F	9-10 10-10	No	No	4	3	3	3			Yes	My stomach was hurting when you gave me the medicine. It reduce my pain small but it started back again
14	14	G1, P0	NV		LB	M		No	No	5	4	3	4			Yes	
15	23	G4, P2,	NV		LB	F		No	No	4	3	3	3			Yes	
16	23	G2, P1, L1	Vac	prolonged 2nd stage	LB	F	6-10	Yes	Yes	4	3	2	1			Yes	The medicine good it can help reduce pain so I hope you will give it when people come to born their baby

No.	Age yrs	Gravida	Delivery	Reason C-section or other problems	Live Birth/ Still Birth	M/F	Apgar Score	Resuscitation	Neonatal Ward	Sc 1st taken	Sc 1st hour	Sc 2nd hour	Sc 3rd hour	Sc 4th hour	Sc 5th hour	Did pain reduce?	Mothers Comments
17	25	G5, P2	CS	Arrest of Descent	LB	M	7-10	No	No	4	4	4	4	4		Remained at high	No comment left
18	15	G1, P0	NV		LB	M		No	No	5	3	3	4			Yes	
19	24	G4, P3, A	NV		LB	M	8-10	No	No	4	3	2				Yes	I find it really reduced my pain. I hope to use it next time and other people to use it. Thank you for it.
20	22	G2, P1	NV		LB	M	8-10	No	No	4	3	3				Yes	The medicine was good because it helps to reduce my pain. It did not cause me any problem.
21	20	G1, P0	NV	Twin	LB	M	8-10 10-10	No	No	4	3	3				Yes	The paracetamol drip was alright. It help to reduce the pain. It did not cause any problem for me.
22	17	G1, P0	NV		LB	M	8-10	No	No	5	4	4				Yes	I fine this medicine very good because it help me plenty. My pain was strong but it help to cool it down. It did not cause me any problem.
23	28	G3, P2	NV	Abruption	SB		0-0			4	4	3				Yes	I want to say thank you very much for the
24	27	G5, P2	NV		LB	M	8-10	No	N	4	3					Yes	The medicine good it bring my pain down. I don't have problem with using it. Thank you
25	33	G4, P3	CS	Fetal distress & deep transverse arrest	LB	-	7-10	No	No	5	4	4	3	3		Yes	This new thing (pain medication) is a very good thing. The pain was too much for me but the medicine help me a lot. I want to say thanks to all the doctors of CB Dunbar hospital.
26	30	G2, P1	CS	Deep transverse arrest	LB	F	7-10	No	No	5	4	3				Yes	I am very happy for this new medicine. The pain was too much for me but the medicine help to reduce my pain. So I was able to monitor my baby heart beat
27	18	G1, P0	NV		LB	M	7-10	No	No	4	4	3	3	4		Yes	I want to say a big thank you to everybody for giving me medicine to cool down my pain. The medicine help me. It did not cause me any problem
28	19	G1, P0	NV		LB	F	9-10	No	No	5	4	3	3			Yes	The medicine makes me not feel much pain
29	35	G2, P1	CS	Fetal distress FHT	LB	F	7-10	No	No	4	4	3	3			Yes	I want to tell God thank you and also the hospital for the two new programs. If it was not because the pain medicine I was not going to be able to monitor my baby heart beat and this is what saved my babies life.
30	35	G2, P1	CS	Fetal distress	LB	F	7-10	No	No	4	3	3	3	2	2	Yes	This pain medicine help me very much with my pain. I want to say thank you very much for this new program.

No.	Age yrs	Gravida	Delivery	Reason C-section or other problems	Live Birth/ Still Birth	M/F	Apgar Score	Resuscitation	Neonatal Ward	Sc 1st taken	Sc 1st hour	Sc 2nd hour	Sc 3rd hour	Sc 4th hour	Sc 5th hour	Did pain reduce?	Mothers Comments
31	23	G4, P3	NV	Twin	LB		8-10 10-10	No	No	4	3	3	2			Yes	According to mom the medicine given was a great one. It help the pain and she enjoy using this medication during labour again. She told me that she hopes to see me again in her labour.
32	18	G1, P0	CS	Twin	LB	M	9-10 10-10	No	No	5	4	4	3	3		Yes	The medicine is good. It reduced the pain small. It did not cause any problem.
33	20	G1, P0	NV		LB	F	7-10	No	Yes	4	3	3	3			Yes	I feel good the pain was very strong but after taking the medicine the pain go down. It help me good and don't cause problem for me.
34	18	G1, P0	NV		LB	F	8-10	No	No	4	4	3	3	4		Yes	I want to tell you people thank you very much for the pain medicine. Even though it did not stop my pain but it cool it down small. It did not cause me any problem.
35	20	G1, P0	NV		LB	-	8-10	No	No	4	3	2				Yes	The medicine find it help me reduced my stomach pain. The pain was very hard on me but after taking the medicine the pain reduced and I born my baby at least small pain. Thank you for the medicine.
36	26	G2, P1	Vac		LB	F	7-10	No	No	4	3	2				Yes	The medicine is good it bring my pain down it make it easy for me to born my baby. Thank you very much. I hope that other people will use it.
37	21	G3, P1, L4	CS	Obstructed labour Twin	LB	M	6-10 8/10	Yes/No	Yes/No	4	3					Yes	The medicine (PCM injection) you give me is very good. It can help my pain to go down small.

Summary of results of first year of intravenous paracetamol given during labour at CB Dunbar Maternity Hospital Table 2

No.	Age yrs	Gravida	Delivery Type	Reason for C- section or other problems	Live Birth/ Still birth	M/F	Apgar Score 1 and 5 mins	Resuscitation	Neonatal Ward	1st taken	1st hour	2nd hour	3rd hour	4th hour	5th hour	Did pain reduce?	Mothers Comments
38	27	G3, P1, A, L1	NV		LB	F	9-10	No	No	4	3	2				Yes	I really happy for this medicine. I find it help reduce my pain and borning the baby was not too hard for me.
39	22	G1, P0	C	Obstructed labour	LB	M	7-10	No	Yes	4	3	3	3			Yes	The medicine good it reduce my stomach pain. No problem using it.
40	19	G1, P0	NV	IUFD	SB		0-0			4	4	3	3	3		Yes	I say thank you for the pain medicine. It help me with my pain. Even though my baby die but the medicine help me with my pain.
41	28	G3, P2	NV		LB	F	8-10	No	No	4	3	2				Yes	Its fine to use the medicine. It bring my stomach pain down it help good because the pain was too hard for me. Thank you. Not problem to use the medicine.
42	17	G, P0	NV		LB	F	8-10	No	No	4	3	3				Yes	I find the pain medicine very good because when my pain was very strong it help to cool it down. I want to say thank to the doctor very much. It did not cause me any problem.
43	18	G1, P0	NV		LB	F	8-10	No	No	5	4	3	2	3		Yes	The medicine help me good with my pain
44	23	G2, P1	NV		LB	F	8-10	No	No	4	4	3	2	3		Yes	The medicine help me to cool my pain. I say thank you. It did not cause me any problem.
45	**27**	G2, P1	NV		LB	M	8-10	No	No	4	3	3				Yes	
46	**16**	G1, P0	NV	IUFD Preeclampsia	SB		0-0			4	3	3				Yes	It good. It help me to baring my stomach pain down. It caused no problems.
47	27	G2, P1	NV		LB	F	8-10	No	No	4	3	2				Yes	The drug is good. It helps me with my stomach pain. It bring down and I was able to breath good and push the baby. It did not cause me any problem . My baby and myself and OK. Thank you.
48	33	G3, P2	C	Previous c/section x 2.	LB	M	8-10	No	No	4	3					Yes	The medicine help me to bring my pain down but I was confused because of the operation business.. The way the pain was very strong and after taking the medicine it was reduced. Thank you for my baby and myself.

49	21	G2, P0	NV		LB	F	8-10	No	No	4	3	2	2			Yes	I enjoyed the medicine it help to bring my stomach and back pain down. It really help me because the pain was very strong. Thank you. My baby is alright and I alright too.
50	22	G1, P0	NV		LB	F	9-10	No	No	4	3	3				Yes	I find the medicine good. The pain was very hard on me but after taking it my stomach pain come down and I born my baby without too much pain. It not cause any problem.
51	18	G1	NV		-	-	-	-	-	4	4	3	3	4		Yes	I want to say thank you to everybody for helping me to reduce my pain by giving me pain medicine. Even though the medicine help but later the pain become strong again
52	23	G3, P1, L4	C	Prolonged latent phase Fetal distress Twin	LB	M	7-10 10-10	No	No	4	4	3	3	3	2	Yes	Thank you for the medicine it help reduce my pain
53	26	G1, P0	NV		LB	F	9-10	No	No	4	3	2				Yes	The medicine help me with my pain by bringing it down. Pain was very hard on me but when I took it the pain came down. I hope to use it net time. I don't get any trouble using it.
54	17	G1, P0	NV		LB	M	8-10	No	No	5	5	4	3	3		Yes	I want to say thank you very much for the pain medicine. My pain was too much but the medicine help me and I am happy.
55	28	G3, P1	NV		LB	F	9-10	No	No	4	3					Yes	It fine. It reduce my pain. I don't have any problem.
56	25	G3, P, A, L	NV		LB	F	8-10	No	No	4	3	3				Yes	I find it good. It carried my stomach pain down and I born my baby without hard pain. It don't cause me any problem in taking it.
57	17	G1, P0	NV		LB	F	9-10	No	No	5	4	3	3			Yes	I want to tell you people thank you very much. The pain was too much but the medicine help to reduce it small.
58	19	G1, P0	C	Obstructed labour	LB	M	4-7	Yes	Yes	4	3	2				Yes	The medicine fine. It help bring my pain down. I was not feeling the pain too much again but the baby was not coming down. Thank God I fine and my trying.
59	17	G1, P0	NV	Twin	LB	M	8-10 10-10	No	No	5	3	3	4			Yes	The medicine is helpful. It help reduce the labour pain. It not cause any problem.
60	28	G8, P5, +2, L5	NV		LB	F	8-10	No	No	4	3					Yes	The medicine is very good At least it can help reduce pain a bit but my stomach still hurting.
61	16	G1, P0	NV		LB	F	7-10	No	No	4	4	3	3	2		Yes	I say thank you for the medicine. It helps to slow my pain. Thank you very much. The pain was heavy.

Summary of results of first year of intravenous paracetamol given during labour at CB Dunbar Maternity Hospital Table 3

No.	Age yrs	Gravida etc.	Delivery Type	Reason for C- section or other problems	Live Birth/ Still birth	M/F	Apgar Score 1 and 5 mins	Resuscitation	Neonatal Ward	Sc1st taken	Sc1st hour	Sc 2nd hour	Sc 3rd hour	Sc 4th hour	Sc 5th hour	Did pain reduce ?	Mothers Comments
62	17	G1, P0	NV	Preterm	LB	M	5-7	Yes	Yes BA	4	3					Yes	The medicine is very good and help me reduce the pain and I slept small.
63	19	G1, P0	CS	Non-reassuring FHT	LB	M	8-10	No	No	4	4	3				Yes	This medicine help me plenty. The pain was too much but the medicine help to reduce it so I was able to monitor my baby heart beat and this help save my baby life. I am happy for my baby.
64	26	G4, P1	NV	Twin	LB	F	8-10 10-10	-	No	5	3	3				Yes	The medicine is good. Yes it help to reduce the pain. No it did not cause any problem for me.
65	38	G4, P1	NV		LB	F	9-10	No	No	5	4	4	3	3	4	Yes	The pain was too much for me. I have never felt pain like this before. Thank God for the pain medicine. It help cool my pain down a little.
66	23	G2, P1	NV		LB	F	8-10	No	No	4	3	3	2	2		Yes	I like the medicine, it is good. It reduced my stomach pan and it made it easy to born my baby. I'm happy now.. Thank you very much.
67	17	G1, P0	NV		LB		8-10		No	4	3	3	3			Yes	I feel good. It help reduce my pain. Thank you for giving me the medicine. I don't have any problem using it.
68	19	G2, P1	NV		LB	F	9-10	No	No	5	4	4				Yes	The pain medicine was very good. The pain was too much for me but the medicine help to reduce my pain. I am very happy about this new programme. I hope you will help many other women.
69	35	G9, P8, D4, L4	NV		LB	F	9-10	No	No	4	3	2				Yes	Thank to you. I hope you will continue it because the medicine cane replace people pain small.
70	30	G3, P2	NV		LB	F	8-10	No	No	4	3					Yes	The medicine find it bring the pain down and I was able to born my baby. Thank you
71	29	G5, P4	NV		LB	M	3-6	Yes	Yes BA	4	3	2				Yes	The medicine help me to reduce my pain but my baby not born good. I hope he will come on good. I don't think the medicine cause the baby to born like that. I pray the next time I will use it.

72	33	G1, P0	CS	Obstructed labour	LB	F		No	No	5	5	4	4	4	3	Yes	I want to tell the CB Dunbar people thank you very much for the pain medicine. It help me small with my pain. 2nd dose given 4,3
73	33	G2, P1	CS	Obstructed labour	LB	F	8-10	No	No	5	5	4	4	4	4	Yes	
74	19	G1, P0	NV	Multiple gestation with one live fetus and one IUFD	LB/SB	F	8-10	No	No	4	3	3	2			Yes	I want to say thanks to the midwives for the care and for the pain medicine. The medicine helps to reduce my pain.
75	17	G1, P0	NV	vaginal laceration	LB	F	9-10	No	No	4	3	3	4			Yes	The medicine was good because it helps to reduce my pain. I want to tell the doctor thank you. It did not cause me any problem.
76	29	G3, P2, L2	CS	Failure to progress, Previous C/S x 1 Twin	LB	M	7/10 9/10	No	No	4	3	2				Yes	The medicine good. It can help people pain to reduce small.
77	35	G2, P1	NV		LB	F	9-10	No	No	4	4	3	3	3	4	Yes	Thanks very much for the medication. My pain was very strong but the medicine help reduce it. 2nd dose 4, 3
78	23	G1, P0	NV	Twin	LB	M	7-10 10-10	No	No	5	2	2				Yes	I am feeling fine about the medicine. It calm the pain and cool down small. No, it did not cause any problem for me.
79		G2, P1	NV	Twin	LB	M/F	9/10 7/10	No/Yes	No/yes	4	3					Yes	The medicine was good. It help reduce my stomach pain. I did not have any problems using the medicine and I hope to use it again and other people will use it too.
80	36	G2, P1	NV	Previous C/S x 1	LB	M	8-10	No	No	4	2					Yes	I like the medicine. It fine. It help reduce my pain. It not cause me problem. Now my baby and myself alright. Thank you for the medicine.
81	17	G1, P0	NV		LB	F	8-10	No	No	4	3	2				Yes	I want to say thank you very much. The medicine help to reduce my pain. It did not cause me any problem.
82	20	G1, P0	NV		LB	M	8-10	No	No	5	4	3	3			Yes	The medicine help reduce my pain
83	25	G1, P0	NV		LB	M		No	No	5	4	3	3			Yes	
84	16	G1, P0	NV		LB	F	3-4	Yes BA CC	Yes	4	3	2				Yes	The medicine is fine. It help me to bring my pain down and help me to born my baby quick my baby was going to die because it was not breathing good. I am happy.

85	20	G2, P1	CS	Fetal distress Face presenting mento posterior	LB	F	9-10	No	Yes Swollen eyes	4	3	3				Yes	The medicine was good. The pain was hard to bear but after taking the medicine the pain reduced. It helped reduce my pain
86	19	G1, P0	NV	Vaginal laceration	LB	M	9-10	No	No	4	3	2	3	3		Yes	The medicine was helpful to me. It helps to reduce my pain. I want to say thank you very much.
87	20	G2, P0, A1	NV		LB	F	9-10	No	No	4	3	3	2			Yes	I find it help reducing the pain
88	35	G6, P5	NV		LB	F	6-10	Yes	No	4	3	2	2			Yes	The drug is very helpful. It reduced my labour pain. I hope I will use it next time. Thank you very much.
89	23	G1, P0	NV	Arrived with IUFD	SB	M	0-0			4	4	3	3			Yes	
90	16	G1, P0	CS		LB	F	8-10	No	No	4	3	2				Yes	It help to bring the pain down. I was not feeling the pain too much again but I was not able to born the baby.

Abbreviations

Sc = Score of pain control
NV = Unassisted vaginal delivery
Vac= Vacuum assisted delivery
CS = Caesarean section
LB = Live birth
SB = Stillbirth
IUFD = Intrauterine fetal death
M = Male
F = Female
BA = Birth asphyxia
CC = Chest compressions