

Supplement

Development of Caesarean Section Clinical Pathway: A Lesson Learned

Pengembangan *Clinical Pathway* Sectio Caesarea: Pelajaran yang Didapat

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ABSTRACT

Although clinical pathway (CP) is aimed to ensure quality and cost, the development of CP at hospitals is primarily for administrative purposes as it is required by accreditation standards, thus causing high variations in its implementation. This study aimed to develop a clinical pathway for caesarean section and explore the problem during development and implementation test. The selection of caesarean section was based on high volume, risk, and cost. Using participatory action research, the researcher started the program by performing an implementation evaluation, literature review, and regulatory development. The evaluation identified implementation discrepancies and prolonged length of stay. Based on the evaluation and literature review results, the Professional Care Provider (PCP) in the hospital conducted discussions and made suggestions by considering available resources, current practices, and behavior. The main differences of the new clinical pathway are: 1) it is developed based on literature and current practice, and 2) it should be added with notification, explanation, inclusion and exclusion criteria, and references. Before the implementation test, the hospital provide resources, develops a standard operational procedure followed by monitoring and evaluation. Differences in the type of medication and documentation method were found, which then further discussed with all involved PCP to define the agreed solutions. Professional engagement and openness culture that embraces along the process are the main key lesson learned in addition to the understanding that CP development and implementation is a continuous learning process.

Keywords: Caesarean section, clinical pathway development, organizational learning

ABSTRAK

Clinical pathway (CP) adalah strategi krusial manajemen klinis yang bertujuan untuk kendali mutu dan biaya, namun pengembangan clinical pathway di rumah sakit lebih banyak untuk tujuan administratif sebagai persyaratan akreditasi sehingga menyebabkan variasi yang tinggi dalam implementasinya. Studi ini bertujuan untuk mengembangkan CP untuk sectio caesarea dan mengeksplorasi masalah selama pengembangan dan uji implementasi. Pemilihan kasus SC berdasarkan pada volume, risiko, dan biaya yang tinggi. Dengan menggunakan participatory action research, peneliti memulai program dengan evaluasi implementasi, tinjauan pustaka dan regulasi untuk mengusulkan revisi konsep CP SC. Evaluasi mengidentifikasi ketidaksesuaian implementasi dan pemanjangan length of stay. Berdasarkan hasil evaluasi dan kajian literatur, Profesional Pemberi Asuhan (PPA) di rumah sakit melakukan diskusi dan memberikan usulan dengan mempertimbangkan sumber daya yang tersedia, praktik terkini, dan perilaku. Perbedaan utama dari clinical pathway baru ini adalah: 1) dikembangkan berdasarkan literatur dan praktik terkini, 2) penambahan notifikasi, penjelasan, kriteria inklusi dan eksklusi, serta referensi. Sebelum uji implementasi rumah sakit menyediakan sumberdaya, mengembangkan Standar Operasional Prosedur untuk implementasi, diikuti monitoring dan evaluasi. Masih ditemukan variasi pada jenis pengobatan dan metode pengisian, yang kemudian dibahas lebih lanjut dengan semua PPA yang terlibat untuk menentukan solusi. Keterlibatan profesional dan budaya keterbukaan sepanjang proses pengembangan menjadi kunci utama pembelajaran ini. Selain itu, perlu ditekankan bahwa pengembangan dan implementasi clinical pathway adalah proses pembelajaran yang berkelanjutan.

Kata Kunci: Pembelajaran organisasi, pengembangan *clinical pathway*, *sectio caesarea*

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INTRODUCTION

A clinical pathway is a guideline used to carry out evidence-based clinical action in health care facilities. A clinical pathway is also known as critical case pathway, integrated case pathway, coordinated case pathway, or anticipated recovery pathway and is created by adopting general clinical guidelines into local protocols that can be applied in local health care facilities. A Clinical pathway is an important part of documents and tools in achieving good clinical governance in hospitals (1,2).

A clinical pathway implementation is a crucial clinical management strategy aimed at quality and cost control. Some studies show the benefits of clinical pathways, such as saving the facility usage, increasing clinical outcomes, increasing patient and clinical practitioner satisfaction, reducing treatment costs, decreasing length of stay, facilitating early discharge, increasing quality of life index and economic outcome, and reducing unnecessary actions (3).

The implementation of clinical pathways is influenced by knowledge, attitudes, competencies, cooperation, commitment, policies, and infrastructure. Knowledge significantly affects the implementation of the clinical pathway; each caregiver will fulfill the clinical pathway one another because they have different knowledge. The role of accreditation in improving the quality of services in hospitals creates a positive attitude in supporting clinical pathway implementation. Policies and Standard Operating Procedures (SOPs) for the clinical pathway implementation were established by the hospital director as a form of leadership commitment to support the fulfillment of accreditation standards at the hospital where this study was conducted (3). The observations also showed that many doctors had not attended clinical pathway training, which in turn can affect their skills to prepare and implement the clinical pathway.

Bangli General Hospital has developed five clinical pathways, and this study focused on caesarean section clinical pathway by considering its high volume, risk, and cost. The number of caesarean section cases based on the incidence rates from 2019 to 2020 was the highest with a high average claim cost of Indonesian Case Base Groups (INA-CBG's), with an equal risk among the five cases. During the period from 2019 to July 2020, there were a total of 804 deliveries. In detail, the normal delivery reached 76.4%, while the caesarean section was 23.6%. Data in 2019 showed that the most frequent indication of caesarean section was Fetal Distress, as much as 34.3%. Other indications were caesarean section scars, premature rupture of membranes, cephalopelvic disproportion (CPD), oligohydramnios, caesarean section with tubectomy (MOW), post-date, breech location, and ante partum bleeding (APB). Reports from the operating room showed that caesarean section and curettage were always the two most common procedures from 2019 to July 2020.

Preliminary studies showed that the clinical pathway document at Bangli General Hospital was made only for the accreditation requirements, and its implementation has not been aimed at quality and cost control. The process of clinical pathway document making only involved a few specialists from Obstetrics and Gynecology Functional Medical Staff. Socialization and implementation of the clinical pathway were only done in a limited way and ahead of the accreditation survey.

Therefore, it is necessary to conduct research on the development of caesarean section clinical pathway according to the rules and explore problems during the development and implementation test.

METHOD

The study was conducted using a participatory action research design that included evaluation, revision, and implementation test stages of the caesarean section clinical pathway. An evaluation was carried out by reviewing national and hospital regulations and accreditation standards, followed by a review of medical record documents. The study was carried out on 40 medical records in November 2017, December 2019, and January to June 2020. November 2017 was chosen because the caesarean section clinical pathway documents were only found in this month and were still stored at Bangli General Hospital. December 2019 was chosen because it was the month where the accreditation survey and the percentage indicator of compliance with clinical pathways reached 100%. Meanwhile, to compare services before and after the COVID-19 pandemic, the authors took data from January to June 2020. As many as five samples were taken randomly for each month.

The revision process for the caesarean section clinical pathway was carried out in several stages, namely presentation of evaluation results to all Caregiver Professionals, literature review, expert judgment, and simulation. Based on the evaluation and literature review results, a revision of the clinical pathway concept for caesarean section was prepared and adjusted to the National Guidelines for Medical Services and the Clinical Practice Guidelines for caesarean section. The revision was discussed with the Hospital Director, the Chair of the Medical Committee, Professional Care Providers, and functional staff involved in caesarean section services as many as 17 people through focus group discussion (FGD) held on October 3, 2020. Before the implementation test, FGD participants prepared the concept of Standard Operating Procedures (SOP) for filling in the clinical pathways. The implementation trial was carried out from October 19 to the end of October 2020.

RESULT

Evaluation of Caesarean Section Clinical Pathway

According to document review, the last implementation of clinical pathway for caesarean section was carried out in 2017, and due to the Covid-19 pandemic the application of clinical pathways was often ignored. The process of filling in and reporting the clinical pathway for caesarean section was held by a midwife appointed as a Person in Charge (PIC).

The medical record document review showed that generally, the implementation of caesarean section clinical pathway had many variations, including the length of stay (LOS), supporting examinations, drugs, and pain management. The length of stay contained in the caesarean section clinical pathway was a three-day treatment, but some patients received longer treatment. It happens since some cases experienced post caesarean section complications, such as bleeding, anemia, ileus, and infection. The supporting examinations contained in the caesarean section clinical pathway were only complete blood and bleeding time/clotting time (BT/CT). However,

Table 1. Variations in the implementation of the caesarean section clinical pathway

No	Component	Clinical Pathway	Variation	Description
1	LOS	Three days	Some cases are more than three days	Patients who experience post caesarean section complications, such as bleeding, anemia, ileus, and infection
2	Supporting examination	CBC and BT/CT	Urine test, HbsAg, RDT HIV, RFT, LFT, electrolyte, USG, NST, and EKG	Patients who have not been screened in primary care and patients who have comorbidities and complications during treatment
3	Medication	Ampicillin 1 gr (injection), Ampicillin 500 mg (oral), Methylergometrine 0.125 mg (oral), and Ferrous Sulfate (oral)	Cefotaxime 1 gr (injection), Metronidazole 500 mg (flash), Oxytocin 20 IU (drip), Tranexamic Acid 500 mg (injection), Lactafit (oral), and Amoxicillin or Cefadroxil tablet (oral)	Each doctor who treats has a different pattern of therapy
4	Pain management	Pethidine 50 mg (injection), Ketorolac 30 mg (injection), and Paracetamol 500 mg (oral)	Tramadol (injection), and Mefenamic Acid tablet (oral)	Each anesthesiologist has a different combination of management patterns

Note: LOS = length of stay; CBC = complete blood; BT/CT = bleeding time/clotting time; HbsAg = Hepatitis B surface antigen; RDT HIV = Human Immunodeficiency Virus; RDT COVID-19 = rapid diagnostic test; Coronavirus Disease 2019; RFT = renal function test; LFT = liver function test; USG = ultrasonography; NST = nonstress test; ECG = electrocardiography; gr = gram; mg = milligram; IU = international unit.

data on medical records showed that there were often other supporting examinations, such as complete urine (UL), Hepatitis B Surface Antigen (HbsAg), HIV Test based on Health and Counseling Officers initiation, and Rapid Diagnostic Test (RDT) COVID-19 (since the COVID-19 Pandemic). Other tests occasionally carried out were renal function test (RFT), liver function test, electrolytes (LFT), ultrasonography (USG), nonstress test (NST), and electrocardiography (ECG).

Drug administration also had many differences compared to the existing clinical pathway for caesarean section. The checklist on the clinical pathway only mentioned Ampicillin 1 gr (injection), Ampicillin 500 mg (oral), Methylergometrine 0.125 mg (oral), and Ferrous Sulfate (oral). Meanwhile, in reality, a number of drug administration were different, such as Cefotaxime 1 gr (injection), Metronidazole 500 mg (flash), Oxytocin 20 IU (drip), Tranexamic Acid 500 mg (injection), Lactafit (oral), and Amoxicillin and Cefadroxil tablets (oral).

Variations were also found in pain management given by anesthesiologists. In the clinical pathway, pain therapies used were Pethidine 50 mg (injection), Ketorolac 30 mg (injection), and Paracetamol 500 mg. The data showed that the combination of Pethidine and Ketorolac (injection) was always used in November 2019, but since 2019 the combination of Tramadol and Ketorolac (injection) has been more frequently used. Mefenamic acid was mostly given as oral analgesics. Ondansetron (injection) was given if the patient complained about

nausea and vomiting (Table 1).

Revision of Caesarean Section Clinical Pathway

The variants found from clinical pathway studies and medical records were the length of stay, supporting examinations, drugs from the Doctor in Charge of the Patient, and pain management from anesthesiologists. After the presentation, all Caregiver Professionals agreed to revise the caesarean section clinical pathway that was adapted to the literature and expert judgment so that the caesarean section clinical pathway was adapted to the local evidence at Bangli General Hospital.

Caesarean section clinical pathway's format was adapted to the old version and the Guidelines for Compiling Clinical Practice Guidelines and Clinical Pathways in Integrated Care according to the 2012 Hospital Accreditation Standards, while the content was adjusted to the latest knowledge. The revision of the caesarean section clinical pathway's concept was also adjusted to existing regulations, such as Laws, the Minister of Health Regulation, and internal hospital policies related to service quality. The revision of the caesarean section clinical pathway's contents was made based on the variations found in the medical record review, namely supporting examination, drug administration by the Doctor in Charge of the Patient, and pain management by anesthesiologists (Table 2).

Implementation Trial

The implementation trial has been carried out since

Table 2. The differences between the old and new version of the caesarean section clinical pathway

	Item	Old	New
1	Format		
	Font	Times New Roman	Calibri
	Format	Table	Table dan narration
	Number of Page	2	3
	Notification	No	Yes (color and description)
	Variant column	No	Yes
	Description	Column exists but without explanation	Yes, with explanations
	Inclusion and exclusion criteria	No	Yes
	Reference	No	Yes

Table 2. The differences between the old and new version of the caesarean section clinical pathway

	Item	Old	New
2	Content		
	LOS	Three days	Three days
	Supporting examination	CBC and BT/CT	Must be checked: CBC, BT/CT, and crossmatch As indicated: Urine test, RDT COVID-19, RDT HIV, RDT Syphilis, RDT HbsAg, USG, and NST or CTG
	Medication by Doctor in Charge of the Patient	Ampicillin 1 gr (injection), Ampicillin 500 mg (oral), Methylergometrine 0,125 mg (oral), and Ferrous Sulfate (oral)	Must be given: drip Oxytocin 20 IU in RL 500 ml 28 drops per minute, Cefotaxime / Ceftriaxone 3 x 1 gr IV, Cefadroxil 2 x 500 mg / Cefixime 2 x 100 mg PO, and Ferrous Sulfate 2 x 1 PO As indicated: Metronidazole 3 x 500 mg IV drip, Adrenaline / Epinephrine 1 mg IV, Ephedrine 50 mg IV, Midazolam 5 mg IV, Methylergometrine 0,2 mg IV, Tranexamic Acid 3 x 500 mg IV, Ondansetron 3 x 4 mg IV, Misoprostol tablet per rectal, Methylergometrine 0,125 mg 3 x 1 PO, and Metronidazole 3 x 500 mg PO
	Pain management by anesthesiologists	Pethidine 50 mg (injection), Ketorolac 30 mg (injection), and Paracetamol 500 mg (oral)	Day 1: Tramadol 2-3 x 50 mg IV and Ketorolac 3 x 30 mg IV Day 2-3: Mefenamic Acid / Paracetamol 3 x 500 mg PO

Note: Note: LOS = length of stay; CBC = complete blood; BT/CT = bleeding time/clotting time; HbsAg = Hepatitis B surface Antigen; HIV = Human Immunodeficiency Virus; RDT COVID-19 = rapid diagnostic test Coronavirus Disease 2019; RFT = renal function test; LFT = liver function test; USG = ultrasonography; NST = nonstress test; CTG = cardiotocography; ECG = electrocardiography; gr = gram; mg = milligram; IU = international unit; RL = ringer lactate; IV = intra vena; PO = per oral.

October 19, 2020. Until this report was compiled, four patients had undergone caesarean section. Before the initial implementation (simulation), the researcher also developed an SOP concept for implementation, logistics, as well as monitoring and evaluation. The results of the clinical pathway caesarean section simulation are presented in Table 3. Simulations on two cases still showed variations in the type of treatment and filling method, which were then discussed further with all the Caregiver Professionals involved to determine an agreed solution. Regarding the two-page form, the Verifier and the Head of the Room suggested that it should be made into three pages, and the text should be enlarged so that it could be easier to read and fill out. These improvements were made before this report was prepared. The simulation process was still being carried out until the fourth week of October 2020 to evaluate the implementation and accommodate more suggestions.

The caesarean section clinical pathway that Functional Medical Staff and management have agreed will then be socialized before being implemented.

DISCUSSION

This study identifies discrepancies in the clinical pathway implementation both in the development process and the service practices compared to the guidelines contained in the clinical pathway. Variations were found in the therapy administration, pain management, supporting examination, and the outcome (prolonged LOS). Based on the data and references, a revision of the clinical pathway was developed in terms of format and content. The clinical pathway caesarean section format was adjusted to the old version and the Guidelines for Compiling Clinical Practice Guidelines and Clinical Pathways in Integrated Care According to Hospital Accreditation Standards 2012; and,

Table 3. Simulation results of the caesarean section clinical pathway

Case	Indication	Difficulty	Variant	Description
1	Anencephaly	None	None	Treatment according to the new format clinical pathway
2	LMR	None	Pain management day 1: a combination of Pethidine 175 mg and Tramadol 150 mg drip in D5% 28 drops per minute and Ketorolac 3 x 30 mg IV	The drug administration considers the patient's low pain threshold and pain assessment with a visual analog scale reaching 7 out of a maximum of 10.
3	Grande Multipara	Tubectomy		Not managed with clinical pathways because there are additional actions (tubectomy) that are in the exclusion criteria
4	Grande Multipara	Tubectomy		Not managed with clinical pathways because there are additional actions (tubectomy) that are in the exclusion criteria

Note: LMR= Locus Menorus Resisten

the content was adjusted to the latest science. The revision of the clinical pathway caesarean section concept was also adjusted to existing regulations, namely the Laws, the Minister of Health, and hospital internal policies related to service quality. The revision of the content of the caesarean section clinical pathway was made based on the variations found in the medical record review, namely supporting examinations, drug administration by the Doctor in Charge of the Patient, and pain management by anesthesiologists (3).

The implementation discrepancy in this study was also found in previous studies because, in general, only 30% of patients are treated with clinical pathways in general hospitals. The rest of the patients were treated with the usual procedures. Clinical pathways are only effective and efficient if carried out for diseases or health conditions whose progression is predictable, especially if they require multi-disciplinary care. (3) The clinical course and outcome of the disease made in the clinical pathway may not match the expectations because the nature of the disease is varied in certain individuals, therapy is not given as prescribed, the patient does not tolerate the drug, or there are comorbidities. Therefore, on the clinical pathway form, there is a recording mechanism in the variant along with the reasons. Based on the variance records, an evaluation of the suitability of the clinical pathway was carried out.

Recommendations for the revision of the caesarean section clinical pathway in this study classify the mandatory investigations, and the options according to the indications are detection of HIV infection, syphilis, and hepatitis B because more than 90% of infections in children occur due to transmission from the mother. This mechanism should be carried out at the antenatal visit of pregnant women as an effort to eliminate the transmission of HIV, syphilis, and hepatitis B using the RDT examination. Early detection of this pregnancy can be repeated for pregnant women and their sexual partners at least after three months or before delivery, or if there are indications or suspicions (4).

Another screening applied to the revised caesarean section clinical pathway is screening for suspected Covid-19 infection. Patients who will undergo elective and cito caesarean section and inpartum must be screened according to the flow for obstetric patients (5). However, with the limited facilities and infrastructure at Bangli General Hospital and in Indonesia, adjustments are made by combining the flow with the Indonesian Ministry of Health guidelines and recommendations from the COVID-19 Accelerated Handling Task Force (7,8). In accordance with the recommendations of the COVID-19 Accelerated Handling Task Force, rapid tests must be carried out on pregnant women before giving birth, except for referral cases where rapid tests have been carried out or pregnant women who have confirmed COVID-19. Inpartum pregnant women with positive rapid test screening results are still subjected to specimen collection and PCR examination, as well as determination of their status (9). However, the use of the rapid test has to be evaluated since the positive predictive value (PPV) widely varies, ranging from 60% to 100% at 5% prevalence depending on the brand and methods used, such as immunoassays (10,11). Therefore, the rapid test results cannot be used for Covid-19 diagnostics but help in making care plan decisions and increasing awareness.

Caesarean section is a surgery to give birth through an incision in the abdominal wall and uterus, which can cause complications of Surgical Site Infection (SSI). Prophylactic antibiotics are highly recommended before surgery to reduce and prevent the occurrence of SSI by 30-65%. The recommended prophylactic antibiotic is Cefazolin 1 gr (1st generation Cephalosporin) (9,10). The duration of prophylactic antibiotics in cesarean section is recommended no more than 24 hours. One of the Cephalosporin class drugs given orally is Cefadroxil, which is well absorbed in the gastrointestinal tract and can be given after 24 hours (9).

Research at Prof. Dr. R. D. Kandou General Hospital Manado found that 58.9% of cesarean section patients were given Ceftriaxone (3rd generation Cephalosporin). According to guidelines published by IMOH7, Cefazolin is used to prevent surgical wound infection. At Bangli General Hospital, the selection of prophylactic antibiotics for caesarean section is more often than using 3rd generation of Cephalosporins, either Cefotaxime or Ceftriaxone. The choice is related to the Obstetrics and Gynecology Department agreement and considering the supply of drugs in the pharmacy installation according to the Indonesian National Formulary (Fornas). In general, the number of drugs used in private hospitals in Indonesia will be higher than those in public hospitals. There are no regulations that can restrict the use. Patients in public hospitals are protected by government insurance; therefore, doctors are only allowed to choose antibiotics from the Indonesian National Formulary (11).

Pain management in caesarean section patients is necessary because caesarean section causes tissue damage and causes pain ranging from mild to severe. The pain can be relieved by oral, injection, and other routes of analgesics administration. Research at Tanjung Pura General Hospital shows that the analgesics given to post caesarean section patients are non-opioid analgesics, namely Mefenamic Acid, Ibuprofen, Ketorolac injection, Paracetamol infusion, Paracetamol tablets, and Profenid suppositories. One study stated that the analgesic in caesarean section patients with a lower cost was the combination Tramadol-Ketorolac (12). This was also confirmed by the Head of Anesthesia Department of Bangli General Hospital that the combination of Tramadol-Ketorolac was chosen because the price is lower than the combination of Pethidine-Ketorolac.

Determining the priority for making clinical pathways considers cases that are high in number (high volume), have a high risk, have a tendency to spend high costs, and have a risk to diseases or clinical conditions that require a multi-disciplinary approach and a predictable clinical course (in at least 70% of cases). The focus of these priority areas can be taken based on monthly data reports from the medical record section in the form of the ten largest outpatient diseases for each polyclinic, the ten largest inpatient diseases, ten causes of death for each department, surgery data reports, and INA-CBG's tariff data (3).

The implementation trial still identified variations in the treatment type and filling method. Lessons were taken to improve the format for easy implementation and the need for verifiers to ensure the implementation. Verifiers are officers appointed either the Case Manager or the Head of the Room. The clinical pathway form is filled out by the Verifier and not by the Doctor in Charge of the Patient. The

clinical pathway form is not a part of the medical record, but it is a quality control tool by the quality team of the Medical Committee, Nursing, and other Health Professions in the hospital. The Case Manager can be a general practitioner or senior nurse who is in charge of monitoring the compliance process in each case in the room and will consult with all Professional Care Providers if problems are found during handling cases. The Case Manager performs monitoring by filling in the checklist in the clinical pathway from the beginning until the patient is discharged from the hospital. The clinical pathway form that has been completed is collected at the Medical

Committee for periodic review (3).

This study confirms that CP development is an organizational learning process that must be supported by data to produce the best choice of action according to capabilities and evidence at the hospital level by considering policies and references. Professional involvement and a culture of openness throughout the development process are the keys. Variations in implementation tests illustrate the importance of continuous monitoring and evaluation mechanisms to achieve the ultimate goals of clinical pathways: quality and efficiency.

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