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Complexity in Obstetrics: An Inter-observer Reproducibility Evaluation Using CORA (Complexity of Obstetric Care Scale) Experimental Tool

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Abstract

Background: *The theme of complexity in Obstetrics represents a crucial concept through pregnancy, childbirth and the postpartum period. Defining and quantifying this abstract concept and applying it to the organizational care model in use, can help to deliver a comprehensive and personalized care while appropriately responding to the diverse needs of women and their newborns. Assessing different complexity levels allows to organize human resources, accordingly, based on the criteria of appropriateness and flexibility.*

Materials and Methods: *This is an inter-observer reproducibility study, which revealed the internal consistency of the CORA tool which was tested in real world organizational care delivery model, by cross-referencing daily attendance data.*

Results: *CORA successfully guided personnel and staffing policies in realizing tailored assistance to pregnant and post pregnant women.*

Conclusion: *Complexity is recognized, acknowledging that not all obstetric cases are equal, and women's need vary, based on multiple factors. This goes beyond just physical health and considers psychosocial factors, support networks, and caregiver presence and compliance.*

Keywords: *Complexity in obstetrics, inter-observer methodology, staffing modulation, Professionalizing Assistance Method.*

1. INTRODUCTION

The theme of complexity in obstetrics represents a crucial concept in the providing care of women during pregnancy, childbirth, and the postpartum period. As Neuhaus pointed out[1], it "is the result of a balancing act in which multiple goal conflicts are continuously negotiated and managed right at the boundary of acceptable performance in a complex adaptive system". A maternity and newborn care ward is a complex adaptive system, as the impulse to harmonize complexity with innovation is a constant factor[2], with the ultimate goal of providing the best care possible to every mother and child. Midwives have to deal with a number of challenges and difficulties, and they can provided a tailored assistance to meet people's need if they can accurately assess the complexity level of the patient so as to scale their staffing appropriately and address different patient's health literacy levels.[3] Timely, appropriate, and respectful assistance is a part of World Health Organization (WHO) framework for quality of maternal and newborn health care (World Health Organization, 2016). One of the tools used to measure assistive complexity in obstetrics is based on the Professionalizing Assistance Method (MAP)[5]. This tool considers different dimensions, including the clinical one that reflects physiological and pathological aspects related to pregnancy, the responsiveness dimension that evaluates the woman's ability to define her own needs, the independence dimension that explores the woman's ability to act autonomously, and the contextual element that considers external factors that may influence care. MAP was chosen to be the framework and inspiration for the tool we created -CORA (Complessità Ostetrica Relativa all'Assistenza, Complexity of Obstetric Care

Scale)- because it also considers two aspects that we deem particularly important, namely the assessment of the care complexity for each patient and the staffing needed to implement the best possible care. It is essential to offer a more detailed description of the MAP to better understand why it was chosen as the foundational framework for our tool. MAP relies on four dimensions: (i) the clinical stability or instability of the patient, (ii) their ability to define their own needs and choose the most suitable behaviours to adopt, (iii) the ability to be autonomous or not, (iv) and the socio-economic context in which they live. For each of the four dimensions, sixty equally important modalities are identified within which an equal number of specific variables are defined to help the assessor describe in detail the possible observable states. This results in an assessment process that guides care performance. This tool allows the assessor to adapt the assistance interventions according to the complexity level of the individual being assisted, the activities to be assigned to personnel in obstetric care. The structure of the MAP has been adopted to create the new tool, CORA, that is currently used to assess complexity in Obstetrics.

In summary, the assessment of assistive complexity in obstetrics represents a comprehensive and personalized approach to ensure quality care during the pregnancy-childbirth-postpartum cycle, responding appropriately to the diverse needs of women and their newborns.

This study has two objectives: (i) the first is to illustrate how the new tool, CORA, has internal consistency that enables its effective use, as its inter-operator reproducibility has been tested in real-life scenarios; (ii) the second is to describe the process that led to its construction and how this tool has successfully guided personnel and staffing policies within a particular organizational context.

2. Material And Methods

This is an Inter-Observer Reproducibility Study, that is a comprehensive investigation aimed at assessing the level of agreement among multiple observers when evaluating the same patient within a defined timeframe, thus establishing the reliability and consistency of the assessments. The process that led us to the construction of CORA involved the commitment of multiple obstetric experts who meticulously undertook an analysis of the existing literature on tools used for calculating complexity in obstetrics. The results of the analysis were presented to an extended expert group that was engaged in a and subsequent focus group. This gathering collected ideas and insights from the experts, ultimately leading to the selection and development of the type of tool intended for development, which will be discussed in this paper. The same experts were then involved in a series of Delphi rounds to build a strong consensus on obstetric variables identified for two distinct types of patients - namely, the pregnant woman and the postpartum woman - and on the assignment of a level of care commitment expressed on a progressive numerical scale from 0 to 4. The tools that have been derived are illustrated in table 1 and table 2.

How to read and interpret complexity scores from 0 to 4:

Level 0

It indicates the norm, the baseline, the standard. The professional's commitment is predominantly educational and is realized through health promotion interventions. (Low care commitment; medium educational commitment)

Level 1

It is a modest difference from the baseline, from the standard way of working. The expression of the variable indicates a condition of average attention. In addition to the educational aspect, there is a medium-intensity care commitment. (Medium care commitment; medium educational commitment)

Level 2

The distance from the baseline is profound. The care commitment is prevalent and requires planning integrated care with other professional figures. (High care commitment; medium educational commitment)

Level 3

This level identifies high commitment situations both in care and education. The commitment may involve the cultural and emotional dimensions, thus requiring the professional to tailor the educational interventions underlying care, also by activating specific tools or

integrating health and non-health specialists. (High care commitment; high educational commitment)

Level 4

This level is linked to the occurrence of an emergency, and it indicates a situation that requires the immediate activation of professionals on duty and integrated multi-professional interventions.

Building on the MAP, a new assessment tool has been developed for pregnant women, as well as one for postpartum women (respectively reported in table 2 and 3).

CORA tool considers three intrinsic dimensions (clinical, responsiveness, independence) and one extrinsic element (context). In particular: (i) "Clinical dimension": indicates a clinical relevance, whether related to the pregnancy condition or not; it reflects the degree and numerosity of altered physiological parameters, determining the level of clinical stability/instability. (ii) "Responsiveness dimension": indicates the person's ability to define their own needs and choose behaviours most suitable for them. (iii) "Independence dimension": indicates the person's ability to act autonomously to satisfy their own needs, and conversely, the degree and number of problems for which they require assistance and support. (iv) "Contextual element": describes extrinsic factors to the individual that can act as facilitators or barriers both in the person's health project and in the delivery of care by professional.

Table 1. *Pregnant woman data collection form*

Pregnant woman data collection form	
	Score
Obstetric Factors I	
Single pregnancy	0
Twin pregnancy	2
Obstetric Factors II	
Gestational age <24 weeks	0
Gestational age >=24 weeks	1
Isolation	
No indication	0
Patient in isolation	3
Parity	
Multiparous	0
Nulliparous	1
Status of Membranes	
Intact membranes	0
Ruptured membranes with clear amniotic fluid	1
Ruptured membranes with tinted amniotic fluid	2
Contractile Activity	
Absent	0
Prodromal, non-painful	1
Prodromal, painful	2
Blood Pressure	
BP <=140/90 mmHg	0
BP systolic 141-159 mmHg and/or diastolic 91-99 mmHg	1
BP >160/100 mmHg	2
Body Temperature	
Temp <37.5°C	0
Temp 37.5-38.5 °C	1
Temp >38.5°C	2
Pain Unrelated to Uterine Activity	
Absent or mild pain VAS 0-2	0
Moderate or severe pain VAS >=3	2
Therapy	
Absence of therapy IV/transfusion	0
IV therapy up to 3 times a day	1
IV therapy more than 3 times a day or continuous infusion	2

Blood transfusion or blood products at least once a day	3
Laboratory Diagnostic Procedures	
No execution or simple sample collection	0
Complex or repeated sample collection in the shift	1
Diagnostic, Instrumental, or Radiological Procedures	
No procedures or simple procedures	0
Execution of procedures involving preparation or patient movement	1
Activation of Specialized Consultations	
No activation	0
Activation of one specialist during the work shift	1
Activation of multiple specialists or repeated activation of the same	2
Detection of Fetal Heart Rate or CTG Execution	
1-2 times a day	0
3-4 times a day	1
>4 times a day	2
Blood pressure, heart rate, body temperature monitoring	
Up to three times a day measurement	0
More than three measurement a day	1
Occurrence of obstetric emergency	
None	0
Prolonged fetal bradycardia	4
Placental abruption	4
Cord prolapse or descent	4
Anaphylactic shock	4
Other emergency causing severe compromise of maternal/fetal parameters	4
Communication	
Able to communicate	0
Communicates partially or is unable to communicate	3
Deficit	
No deficits or deficits present without consequences	0
Uncompensated hearing deficit	1
Uncompensated ambulation deficit	1
Uncompensated visual deficit	1
Uncompensated cognitive deficit	2
Emotivity	
Absence of emotional distress	0
Reported worry or agitation	1
Emotional distress treated with medication, current or past	2
Psycho-affective factors	
Nothing relevant	0
Activation of psychological support	2
Activation of social services, foster home, or other local social networks	2
Documented substance dependence	2
Pregnancy obtained through egg donation	1
Depression treated with medication in the previous postpartum period	1
Single parent	2
Anonymous birth	2
Previous negative obstetric history	2
Intrauterine fetal death	3
Mobility	
Independent in mobility	0
Bedridden for clinical reasons	1
Not autonomous, needs to be mobilized	2
Hygiene care	
Independent in personal hygiene care	0
Poor self-care	1
Bed hygiene care by staff	2
Caregiver and support network	

Not present and not necessary or present and cooperative	0
Not present but necessary	1
Present and obstructive	2
Discharge	
Absence of discharge planning	0
Planned transfer to another hospital facility	1
Discharge planning through social services	2

Table 2. *Postpartum woman data collection form*

Postpartum woman data collection form	
	Score
Obstetric Factors	
Single pregnancy	0
Twin pregnancy	2
Mode of delivery	
Spontaneous or operative delivery without tears or with first or second-degree tears	0
Scheduled Cesarean Section	0
Spontaneous or operative delivery with third-degree tears/episiotomy/both	1
Emergency Cesarean Section	2
Spontaneous or operative delivery with fourth-degree tears/complicated episiotomy	2
Blood loss during childbirth	
<1000 cc	0
>=1000 cc	1
Characteristics of the newborn in rooming-in	
Newborn in rooming in, nothing relevant	0
Newborn admitted to another setting	0
Late preterm newborn (34 weeks ≤ g.a. < 37 weeks)	1
Low birth weight newborn (2000 g < gr ≦ < 2500)	1
Weight loss to be monitored (8%-10%)	1
Breastfeeding difficulties detected through feeding observation	2
Newborn at risk of hypoglycemia	2
Newborn at risk of infection	2
Isolation	
No indication	0
Patient in isolation	3
Parity	
Multiparous	0
Nulliparous	1
Maternal characteristics	
Nothing to report	0
Previous negative breastfeeding experience reported	2
Previous breast surgery	2
Flat, inverted, or very large nipples compared to the baby's mouth	2
Blood Pressure	
BP <=140/90 mmHg	0
BP systolic 141-159 mmHg and/or diastolic 91-99 mmHg	1
BP >160/100 mmHg	2
Body Temperature	
Temp <37.5°C	0
Temp 37.5-38.5 °C	1
Temp >38.5°C	2
Pain	
Absent or mild pain VAS 0-2	0
Moderate or severe pain VAS >=3	1
Therapy	
Absence of therapy IV/transfusion	0
IV therapy up to 3 times a day	1
IV therapy more than 3 times a day or continuous infusion	2

Blood transfusion or blood products at least once a day	3
Laboratory Diagnostic Procedures	
No execution or simple sample collection	0
Complex or repeated sample collection in the shift	1
Diagnostic, Instrumental, or Radiological Procedures	
No procedures or simple procedures	0
Execution of procedures involving preparation or patient movement	1
Activation of Specialized Consultations	
No activation	0
Activation of one specialist during the work shift	1
Activation of multiple specialists or repeated activation of the same	2
Dressings and monitoring of surgical wound/episiotomy	
Absence of checks or simple dressing	0
Dressing for a complicated wound (edema, suppuration, bleeding...) / drains	1
Central Venous Catheter (CVC)	
Present	0
No CVC	1
Application/Replacement	2
Vital Signs Monitoring	
Monitoring up to 3 times a day	0
Monitoring more than 3 times a day	1
Maternal or neonatal emergency	
No emergency	0
Late postpartum hemorrhage	4
Maternal eclamptic crisis	4
Neonatal cardiorespiratory arrest	4
Other emergency with severe compromise of maternal/neonatal parameters	4
Communication	
Able to communicate	0
Communicates with difficulty/unable to communicate	4
Deficit	
Absence of deficits or deficits present without consequences	0
Uncompensated hearing deficit	1
Uncompensated walking deficit	1
Uncompensated visual deficit	1
Uncompensated cognitive deficit	2
Emotivity	
Absence of emotional distress	0
Reported worry or agitation	1
Emotional distress treated with medication, current or past	2
Psycho-affective factors	
Nothing relevant	0
Activation of psychological support	2
Activation of social services, foster home, or other local social networks	2
Documented substance dependence	2
Pregnancy obtained through egg donation	2
Depression treated with medication in the previous postpartum period	2
Single parent	3
Anonymous birth	2
Previous negative obstetric history	2
Intrauterine fetal death	3
Mobility	
Independent in mobility	0
Bedridden for clinical reasons	1
Not autonomous, needs to be mobilized	2
Hygiene care	
Independent in personal hygiene care	0
Poor self-care	1

Bed hygiene care by staff	1
Caregiver and support network	
Not present and not necessary or present and cooperative	0
Not present but necessary	1
Present and obstructive	2
Discharge	
Absence of discharge planning	0
Planned transfer to another hospital facility	1
Discharge planning through social services	2

In the context of obstetric care, CORA was conceived to gauge the complexity of the assistance to be provided. Therefore, this study involves multiple operators, who independently conducted patients' assessments using CORA tool within a specified time frame. The study was conducted in a second-level birth point for fifteen days of data collection by different assessors. According to the Italian Regional Law (DRG 804/2019), a Level II centre provides care for high-risk pregnancies and deliveries. It is equipped with a Neonatal Pathology Unit capable of assisting preterm infants who could require intensive neonatal care (NICU).

Training sessions for assessors were implemented to familiarize the involved staff with the tool and with the overall methodology used in the study. The sample that was assessed during the data collection days, was found to be composed of eighty-two hospitalized women (forty pregnant women and forty-two postpartum women) who provided informed consent for anonymous use and publication of health data (sample characteristics are reported in table 3). During each observation day, a maximum of 6 patients (three pregnant patients and 3 postpartum women) were identified.

Table 3. *Sample's characteristics*

Characteristics of the study sample	
Nationality	
Nationality of the sample: Italian	70,73%
Nationality of the sample: not Italian	29,27%
Educational level	
Elementary/ Lower Secondary School	37%
High school diploma	40%
Bachelor's degree	23%
Age	
Average maternal age	32,17 yrs.
Average age at first childbirth for the entire sample	32,5 yrs.
Average age at first childbirth for Italian patients	33,6 yrs.
Average age at first childbirth for foreign patients	28,6 yrs.
Parity	
Nulliparous	75,61%
Multipara	24,39%

Study Design: Inter-Observer Reproducibility Study

Study Location: This was a second level hospital-based study done in the Department of Obstetrics, at Santo Stefano Hospital, Prato, Italy.

Study Duration: June 2023 to January 2024.

Sample Size: 82 patients.

Sample Size Calculation: A convenience sample was chosen, based on their availability to the researchers.

Subjects & Selection Method: The study population, a convenience sample of pregnant and postpartum women was drawn from consecutive patients who presented to the Hospital and were hospitalized during the study days. The two groups were independently studied.

Inclusion Criteria

1. Pregnant and Postpartum women,
2. Aged ≥ 18 years,
3. Patients hospitalized during study days in the ward, who expressed informed consent.

Exclusion Criteria

1. Patients temporarily accommodated in the department, meaning non-obstetric patients who, due to temporary space constraints in the appropriate settings, have been admitted to the obstetrics unit in the meantime.
2. Patients who did not gave their informed consent.

While the CORA tool was undergoing its real-world data validation, a study of administrative data took place. Data related to the simple presence of pregnant versus postpartum women in the ward for the years 2022 and 2023 have been analyzed. The historical records of daily attendance revealed that the same bed has a 69% chance of being occupied by a postpartum woman, as opposed to a 31% chance of being occupied by a pregnant woman.

CORA has been designed to guide staffing decisions for 8-bed and 10-bed care modules. By cross-referencing the data, we obtained a score beyond which a single midwife cannot remain alone on duty due to the complexity of patients, risking the inability to provide effective assistance.

Procedure Methodology

1. Development of a tool for the assessment of care complexity in Obstetrics (CORA)
2. Administrative data analysis for the years 2022 and 2023 on records of daily attendance in the Obstetric ward
3. Inter-observer validation of the CORA tool
4. Data cross-referencing to determine the limits of complexity, expressed in CORA score, that a single midwife can manage on order to give the hospitalized women a safe and effective assistance.

3. Results

With respect to the two stated objectives of the study, it can be affirmed as follows:

(i) Illustrate how the new tool, CORA, has internal consistency that enables its effective use, as its inter-operator reproducibility has been tested in real-life scenarios: different operators assessed the same patients. This allowed for an evaluation of whether there were differences in the way patients were assessed depending on the observer. There were no significant differences in the assessment of patients (both pregnant and postpartum women) by different evaluators using the forms listed in tables 1 and 2. Observers received the same training. This demonstrates a strong internal consistency of the instrument, which empirically proves to be suitable and structured in a way that aligns with reality.

(ii) The process that led to its construction and how this tool has successfully guided personnel and staffing policies within a particular organizational context: the greatest challenge was to structure a tool that could measure the complexity of the group of hospitalized women at a given moment in a ward and based on complexity scores, allocate the necessary staff to ensure effective and quality care for them. The results obtained from cross-referencing administrative data on the presence of women in the ward for two years of activity have led to the determination that one unit of midwifery staff can effectively and safely manage a total of 29 CORA score points on a ward with 8 or 10 hospitalized women. This is considering that, with 100% of the beds occupied, the average complexity of an 8-bed ward is 25.67 CORA score, and a 10-bed ward averages a CORA score of 32.09.

4. Discussion

Complexity in obstetrics directly influences the quality of care and outcomes for both mother and newborn[7]. Obstetric cases vary widely in complexity, ranging from routine pregnancies to high-risk cases with multiple complications. Accurately assessing this complexity is crucial for tailoring care to each patient's specific needs. We deemed it necessary to embark on the path of objectifying complexity because we wanted to ensure personalized care to for all patients: by identifying individual complexities, midwifes can create a care plan that is specific to each patient's situation. This ensures that mothers and newborn receive the most appropriate and effective care possible.

By addressing individual complexities promptly and effectively, midwifes can reduce the risk of complications and improve overall health outcomes for both mothers and newborns while reducing costs by optimizing care delivery.

The complexity of care in obstetrics should be considered as a new parameter to enhance the appropriateness of human resource utilization in a mono-disciplinary organizational model such as an obstetric ward. Sizing the staff not based on the number of beds but on the complexity of

the hospitalized women at a given moment is equivalent to not treating all cases as if they were equal. It is particularly noteworthy that not only physical factors such as vital signs were considered but also aspects beyond the sole health assessment, such as the presence and compliance of the caregiver and support network, and the evaluation of psychosocial factors. Recognizing complexity means to acknowledge the fact that the needs of women vary based on multiple factors.

5. Conclusion

The approach described so far for determining the level of complexity in an obstetric setting has undeniable strengths but also limitations. It also raises new questions and the need for further reflections.

The main strengths are represented by the fact that complexity is recognized, acknowledging that not all obstetric cases are equal, and the needs of women vary based on multiple factors. This goes beyond just physical health and considers psychosocial factors, support networks, and caregiver presence. In addition, the efficiency potential that could be enhanced from the staff, optimizing their utilization. Such an approach could ultimately promote a holistic approach to people's health. As illustrated, this approach considers the woman's overall well-being, not just immediate medical needs, potentially leading to better patient experience and satisfaction.

Challenges are to be considered as well. The first resides in the difficulty of defining complexity, and often it remains nothing more than an abstract concept. Our efforts converged towards its objectification creating CORA, a structured measurement tool for complexity, that must be adapted to be scalable. Overall, the idea of utilizing complexity of care in obstetrics to improve human resource utilization holds promise, but carefully considering the challenges of its implications. Further investigations are needed to determine exploring how this approach can complement existing staffing models and healthcare systems.

Ethics: Ethical committee approval is not required for the type of data collected in this study. Informed consent was signed for every patient. Moreover, the research has a public utility purpose and does not pursue commercial aims.

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