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## Evaluation and implementation of placental data collection for improved diagnostic accuracy in clinical practice: an observational study

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### ABSTRACT

**Objective.** The placenta is a crucial organ in pregnancy, yet its clinical evaluation remains limited. Inadequate data collection can lead to misinterpretations by pathologists, especially in cases of adverse outcomes. This study aimed to assess the feasibility, efficiency, and clinical utility of a standardized Placenta Documentation Form to improve placental evaluation and diagnostic accuracy.

**Patients and Methods.** This observational study enrolled 209 pregnant women delivering at the University of Pisa between February and June 2024. Inclusion criteria were singleton pregnancies, gestational age  $\geq 37$  weeks, physiological labour and delivery. A total of 123 placentas from normal pregnancies were analysed. The Placenta Documentation Form, completed post-delivery, recorded placental, membrane, and umbilical cord characteristics. The time elapsed during data collection and form completion, and staff's satisfaction (rated on a 5-point Likert scale) were assessed. Statistical analyses were performed using GraphPad Prism 10.

**Results.** The mean data collection and completion forms times were  $318.7 \pm 111.3$  and  $224.3 \pm 99.4$  seconds, respectively, with staff maximum satisfaction level reaching 81.3%. Placental clots, often associated with pathological conditions, were detected in 26.02% of cases, yet did not correlate with adverse outcomes. Membrane thickness and meconium staining were noted despite the absence of infection. Umbilical cord insertions varied, with marginal insertion in 30.08% and velamentous in 0.81% women, yet all resulted in normal deliveries.

**Conclusions.** The Placenta Documentation Form is a practical and well-accepted tool that enhances placental evaluation without disrupting clinical workflow. Its routine implementation could improve diagnostic accuracy and prevent misinterpretations in both normal and pathological pregnancies.

### INTRODUCTION

In the routine clinical setting, the placenta is often discarded immediately after its integrity has been

evaluated to exclude the presence of placental remnants as potential causes of postpartum haemorrhage. However, substantial scientific evidence emphasizes the importance of conducting a com-

prehensive morphological and anatomopathological examination of the placenta after delivery. Such an examination can provide critical insights into the causes and development (etiopathogenesis) of adverse outcomes. Additionally, this assessment can potentially provide vital information to assess any potential maternal and neonatal risk of developing health problems later in life. Despite these significant benefits, the routine practice of discarding the placenta immediately after birth persists [1].

The placenta probably plays the most important role for the development of pregnancy, yet paradoxically the least understood. It lays the foundation for all aspects of embryonic and foetal development, performing functions that later will be carried out by separate organs such as the lungs, liver, intestines, kidneys, and endocrine glands. This ultimately determines much of postnatal health [2]. Moreover, the placenta plays a pivotal role in the maternal body, functioning as a transient endocrine gland that modulates maternal physiology and metabolism. In addition, it provides a protective environment in which the foetus can develop.

Despite being an easily available specimen that, if adequately examined and reported, can provide information about antepartum and intrapartum events and possible causes of adverse pregnancy outcomes, it is often overlooked [3]. A thorough study of the placenta could also aid in the clinical management of the newborn and provide predictive information about the maternal or neonatal risk of developing specific conditions, such as diabetes, autoimmune diseases, coronary diseases, etc [4-6]. In cases of intrauterine growth restriction or preeclamptic pregnancies, the increased placental vascular resistance subjects the foetal and maternal heart to increased workload, representing a potential direct link between altered placental structure and the foetal programming of cardiovascular disease and even postpartum maternal hypertension [7]. In these cases, proper placental evaluation could also help in planning the couple's subsequent pregnancy.

Not all placentas can be subjected to a complete pathological examination due to constraints related to cost, resources, and personnel. Therefore, a postpartum macroscopic placental examination can be performed directly in the delivery room to identify abnormal placentas that should undergo a detailed macroscopic and microscopic pathological examination. The macroscopic placental examination has numerous advantages: it allows the identification of placental anomalies not detected

by prenatal tests, the documentation in the medical record of important anatomical characteristics and variations from the norm, and the distinction between normal and abnormal placentas [8].

However, even today, looking at medical records, we know little about placentas: they are generally summarily described, ignoring that many macroscopic placental aspects are observable only after birth on a fresh specimen. There is no reference checklist, and a standardized information form for morphological placental study is lacking, which would also provide a comprehensive overview of the placenta to the pathologist [9]. In many cases, placentas are submitted to the pathologist for examination without the proper clinical information required, which can lead to inaccurate or erroneous diagnostic conclusions. Based on the "Recommendations for the anatomical-clinical diagnostics of the placenta expelled after the 14th week of gestation" [10], an electronic form was created, and its application in clinical practice was assessed. This study aimed to evaluate the feasibility, time required for completion, and level of acceptance of a new form for placental data collection by clinical staff. The objective of this evaluation was to ensure an efficient process and identify potential challenges or areas for improvement.

## MATERIALS AND METHODS

### *Patient recruitment*

This observational study enrolled 209 pregnant women at the time of delivery between February and June 2024 at the Department of Gynecology and Obstetrics, University of Pisa. The following inclusion criteria were considered: age  $\geq 18$  years, singleton pregnancy, gestational age over 37 weeks, absence of maternal diseases (like gestational diabetes mellitus, preeclampsia, risk of preterm delivery), spontaneous conception, no intrauterine growth restriction [11], physiological labour and delivery (**Table 1**). This examination aimed to document characteristics and abnormalities that might be present in normal pregnancies, providing a comprehensive baseline for a future comparison with pathological conditions.

### *Placenta documentation form*

A specific form, entitled Placenta Documentation Form, was created specifically for this study (**Table 2**) based on the "Recommendations for the Anatomical-Clinical Diagnosis of the Placenta Expelled

**Table 1.** Inclusion and exclusion criteria for the selection of the study population.

| Inclusion criteria                 | Exclusion criteria                 |
|------------------------------------|------------------------------------|
| Gestational age over 37 weeks      | Gestational age under 37 weeks     |
| Absence of maternal diseases       | Presence of maternal diseases      |
| Spontaneous conception             | Gestation by assisted reproduction |
| No intrauterine growth restriction | Intrauterine growth restriction    |
| Physiological labour               | Newborn with Apgar's score < 8     |
| Physiological delivery             | Umbilical cord Ph < 7.10           |
| Spontaneous placental delivery     | Umbilical cord base excess < -10   |
| Newborn with Apgar's score ≥ 8     |                                    |
| Umbilical cord Ph ≥ 7.10           |                                    |
| Umbilical cord base excess ≥ -10   |                                    |

After the 14<sup>th</sup> Week of Gestation" issued by Italian Scientific Societies (Italian Society of Gynecology and Obstetrics - SIGO, Association of Italian Hospital Obstetricians-Gynecologists - AOGOI, Association of Italian University Gynecologists - AGUI, Association of Territorial Gynecologists - AGITE, and the Società Italian Division of Pathological Anatomy and Diagnostic Cytology, Italian Division of the International Academy of Pathology - SIAPeC-IAP). Each woman was assigned a unique identifier. The Placenta Documentation Form was meticulously completed by the midwife after delivery for each woman regardless from the type of pregnancy. This form included an assessment of sections involving medical history, course of the pregnancy, labour and delivery outcome, neonatal evaluation, and placenta, membrane and umbilical cord assessment. The parameters included relevant placental morphological data such as placental weight, anomalies like placenta previa or placenta accreta, membrane characteristics including color, insertion, and thickness, umbilical cord length and insertion, presence of vasa previa or velamentous vessels, and the presence and location of large clots on the basal plate (Table 2).

Following the completion of the form, each operator independently and anonymously responded to three additional inquiries: 1) the duration of data collection in seconds; 2) the duration of completing the form in seconds; and 3) satisfaction, which was evaluated on a 5-point Likert scale ranging from 0 (lowest) to 5 (highest).

**Study registration and ethical approval**

This study was carried out in accordance with the recommendations of the Good Clinical practice

**Table 2.** Placenta documentation form.

| Mother data                      | Exclusion criteria  |
|----------------------------------|---|
| Actual pregnancy data            | Gestational age<br>Pathological History<br>Modality of conception<br>Intrauterine growth restriction<br>Pharmacological therapies   |
| Labor data                       | Modality of labour<br>Characteristics of labour<br>Vaginal-rectal sample<br>Membrane Rupture<br>Time of Membrane Rupture<br>Amniotic fluid<br>At the time of the rupture<br>At the time of the delivery |
| Delivery data                    | Indications for caesarean or operative delivery<br>Spontaneous placental delivery or not<br>Quantity of bleeding  |
| Placenta macroscopic examination | Placenta weight (g)<br>Anomalies of placenta<br>Placenta previa<br>Placenta accreta<br>Presence of clots on the placenta<br>Number<br>Localization<br>Size (under or over 4 cm)                         |
| Membrane exam                    | Insertion<br>Thickness<br>Colour  |
| Cord exam                        | Insertion<br>Presence of intra-velamentous vasa<br>Presence of vasa previa<br>Presence of knots<br>Total length   |
| Newborn data                     | Gender<br>Weight (gr)<br>Cranic circumference (cm)<br>Apgar's score at the first minute<br>Apgar's score at the fifth minute<br>Arterial Ph<br>Venous Ph<br>Arterial Basis<br>Venous Basis              |
| Pathologist data                 | Microbiological test<br>Clinical question   |

(ICH/GCP), Ministerial Decree of 1997. The protocol was approved by the Institutional Review Board of AOUP, Azienda Ospedaliera Universitaria Pisana, University of Pisa (reference 25772\_MANNELLA). All subjects gave written informed consent in accordance with the Declaration of Helsinki.

**Statistical analysis**

GraphPad Prism 10 (GraphPad Software Inc., San Diego, California, USA) program was used for data analysis and graphic presentations. Categorical variables, such as clinic and anthropometric aspects of women, were presented as frequency (number, n)

and relative frequency (percentage, %). Continuous variables were expressed as mean  $\pm$  standard deviation (SD), and median and interquartile range (25<sup>th</sup>-75<sup>th</sup> percentile).

Learning curves were generated using the cumulative sum (CUSUM) method to evaluate performance trends. The process comprises three phases, marked by key CUSUM inflection points. The first is the adjustment phase, characterized by high initial variability. The second is the competence-acquisition phase, marked by a steady decline in execution time. The final phase is proficiency, where performance stabilizes with minimal fluctuation. CUSUM (seconds) is calculated as:  $CUSUM_t = CUSUM_{t-1} + (Y_t - \mu)$ , where  $CUSUM_t$  is the accumulated value at time  $t$ ,  $Y_t$  is the execution time at attempt  $t$ , and  $\mu$  is the reference mean execution times.

## RESULTS

### *Macroscopic examination findings*

The initial phase of the study concentrated on the information that could be obtained from the macroscopic examination of the placentas in the immediate postpartum period. After applying the above-described exclusion criteria, 123 placentas were selected for the study from the 209 women enrolled.

One of the most notable findings was the presence of placental clots, observed in up to 26.02% of the pregnancies (32 cases). Although typically associated with adverse outcomes, these clots were unexpectedly common in otherwise normal pregnancies. A detailed analysis revealed that 90.63% (29 cases) were peripherally located, suggesting their formation resulted from minor vascular disruptions at the placental margins. Furthermore, 46.88% (15 cases) had a diameter exceeding 4 cm. The study also identified several notable characteristics of the membranes. In most cases (120, 97.56%), the membranes were thin and exhibited a shiny appearance (115 cases, 93.50%), which is typical of healthy pregnancies. Conversely, a smaller proportion of membranes were thick (3 cases, 2.44%) or meconium-stained (8 cases, 6.50%), out of a total of 123 cases. The presence of thick membranes may indicate the presence of underlying inflammatory conditions, such as chorioamnionitis; however, no clinical signs of infection were observed in this study. Although meconium-stained membranes are often associated with foetal distress, no association

with adverse neonatal outcomes was observed in our study population. Additionally, no cases of edematous membranes, which can indicate severe pathological conditions, were observed.

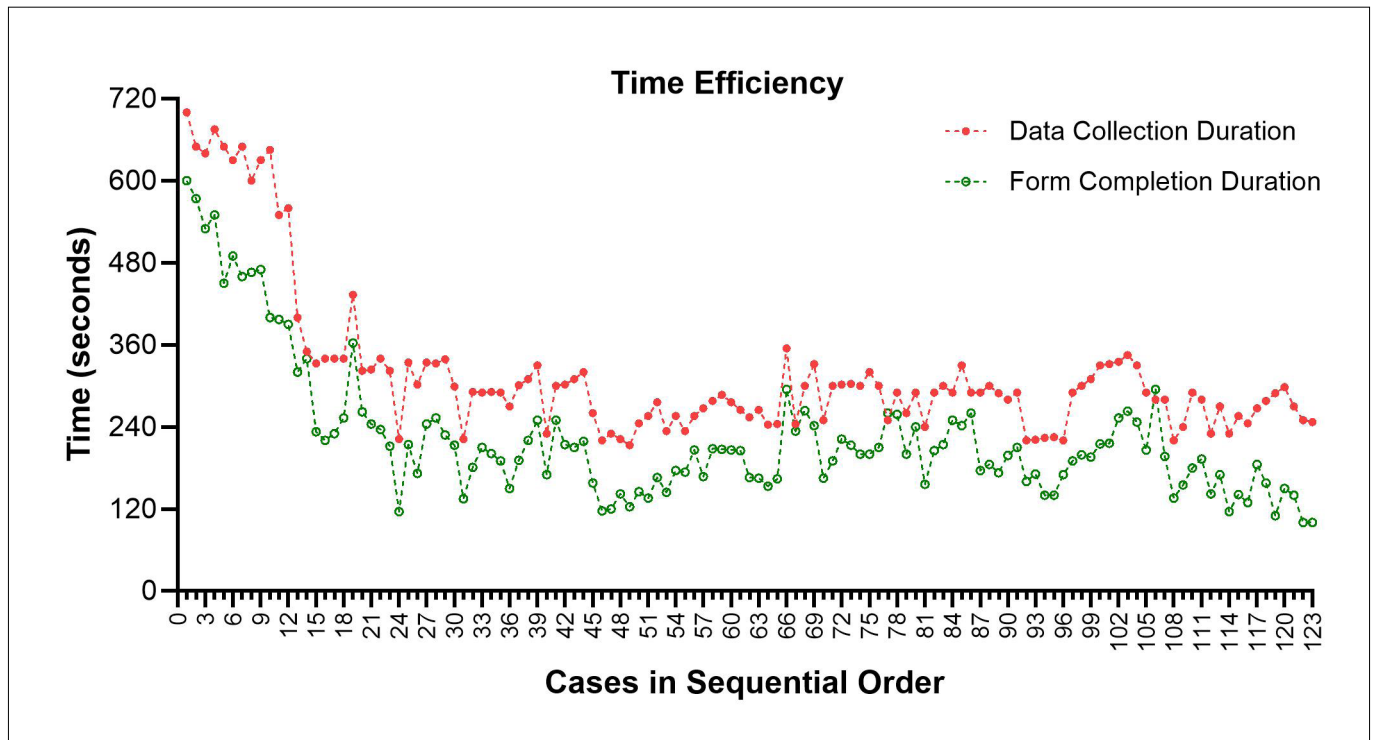
Furthermore, the examination of umbilical cord characteristics revealed significant findings. The insertion was predominantly central (85 cases, 69.11%), although marginal (37 cases, 30.08%) and velamentous (1 case, 0.81%) insertions were also observed. Despite these variations, all types of insertion were associated with normal delivery outcomes, challenging the notion that non-central insertions necessarily indicate complications.

Additionally, the umbilical cord length typically ranged between 30 and 80 cm (108 cases, 87.80%), while 12 cases (9.76%) measured less than 30 cm and 3 cases (2.44%) exceeded 80 cm. Notably, both shorter and longer cords were still associated with physiological deliveries. This finding suggests that umbilical cord length, within certain limits, may not be as critical a factor in delivery outcomes as previously thought.

### *Efficiency of the placenta documentation form*

In the second phase of the study, we evaluated the efficacy of the Placenta Documentation Form as a data collection tool. The implementation of this form required minimal time for both data collection and form completion. Over time, a progressive decline in data collection and completion times was observed, reflecting improved efficiency (**Figure 1**). The mean time required for data collection was  $318.7 \pm 111.3$  seconds, with a median of 290 seconds (range: 256-330), demonstrating a minimal impact on the overall workflow in the delivery room. Similarly, the mean completion time was  $224.3 \pm 99.4$  seconds, with a median of 205 seconds (range: 165-244), reinforcing the practicality of this tool in routine clinical practice. Both data collection and form completion times showed a progressive reduction across cases, reflecting an overall gain in efficiency during the study period.

A clear learning curve emerged as staff members became more familiar with the form and data collection process (**Figure 2a,b**). The CUSUM learning curves for data collection and form completion durations were clearly characterized by three phases – initial adjustment, rapid learning, and performance stabilization – which were indicative of effective and rapid staff adaptation to the new form's structure. This led to a significant reduction in completion time and confirmed the feasibility



**Figure 1.** Time efficiency in data collection and form completion.

The figure shows the time required for data collection (red) and form completion (green) over a sequential series of cases ( $n = 123$ ). Dots represent individual cases, with dashed lines indicating temporal patterns. Both processes exhibit an initial decline, reflecting improved efficiency, followed by stabilization with fluctuations.

of integrating this data collection tool into routine clinical practice without imposing an excessive burden on healthcare personnel.

### Staff satisfaction

At the end of this pilot study, the participating staff members were requested to assess their experience with completing the 5-point Likert Scale, with the options ranging from 0 (minimum) to 5 (maximum). It is noteworthy that the highest level of satisfaction was recorded at 81.3% following the initial assessment, reflecting broad acceptance among the clinical. This positive response serves to reinforce the perceived value of the data collection form in facilitating comprehensive placental evaluation and enhancing diagnostic accuracy.

## DISCUSSION

### Main findings

In this study, we demonstrated the feasibility of applying a data collection form suggested by the main international scientific societies, as previously documented [12-14]. Data collection was very rapid, taking only a few minutes, and it allowed for the collection of a series of useful information not

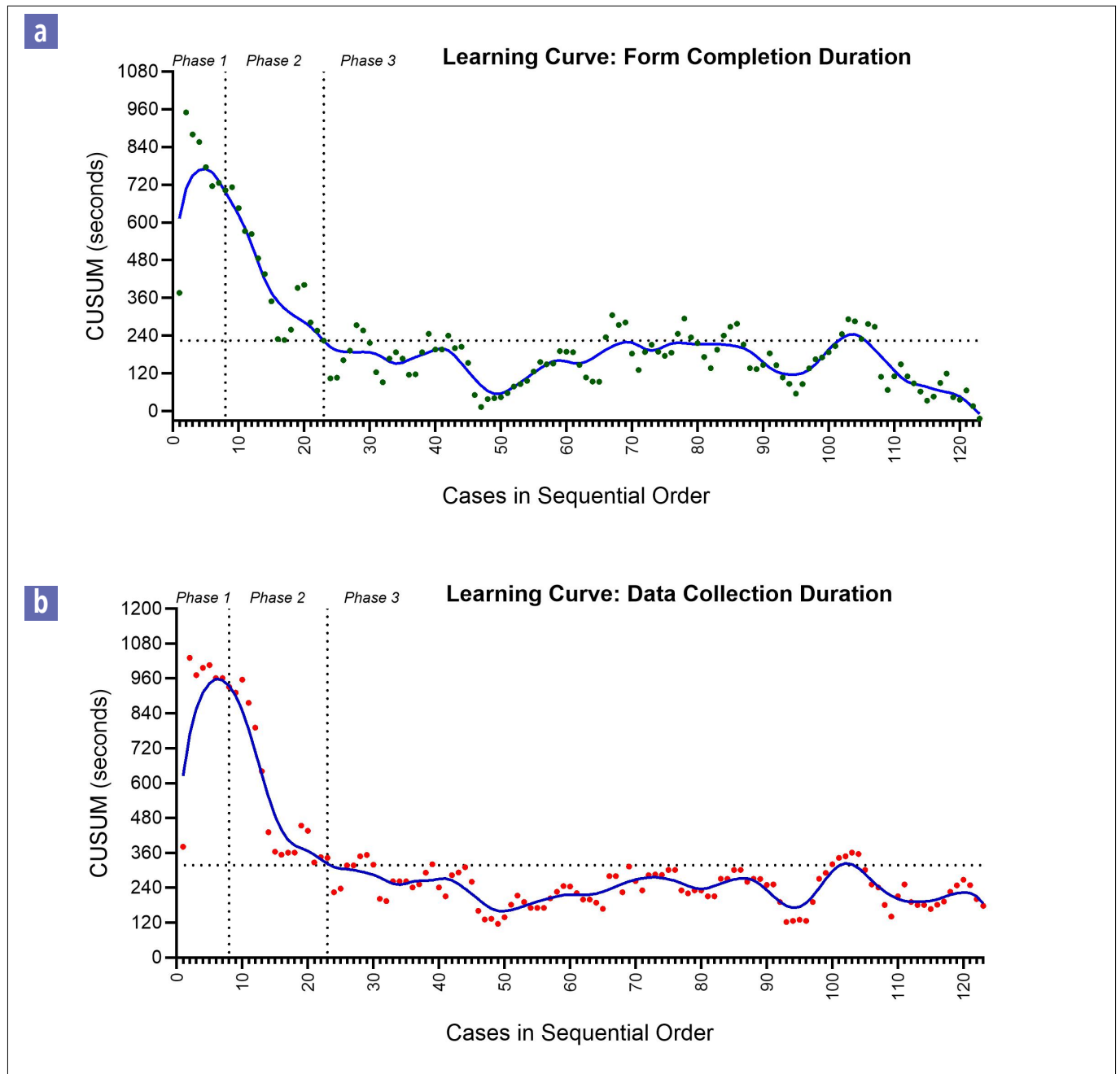
only for the pathologist's evaluation but also for avoiding gross interpretation errors.

In constructing the form, we aimed to include significant morphological parameters that are easy to evaluate, allowing for quick and effortless completion, thus minimizing the impact on the busy clinical activity in the delivery room. As a result, satisfaction levels were consistently high, with 81.3% of clinical staff reporting the maximum level of satisfaction using the form, highlighting its feasibility and acceptance in routine obstetric practice.

Our study also showed that many placental characteristics that are usually considered as risk factors for neonatal adverse outcomes were present in placentas of mothers with physiological pregnancy and childbirth. For instance, placental clots, marginal cord insertion, and meconium-stained membranes, often considered markers of pathological conditions, were frequently observed in our study population, albeit not related to adverse neonatal outcomes. This suggests the need for a more nuanced interpretation of these features.

### Strengths and limitations

A key strength of this study is its prospective design, which allowed for the systematic evaluation of placental characteristics using a standardized



**Figure 2.** Learning curve in data collection and form completion.

The figure shows the CUSUM (Cumulative Sum Control Chart) learning curve for data collection duration (a) and form completion duration (b). Dots represent data points, while the blue line represents the trend. Three phases are observed: an initial increase (adjustment period), a steep decline (learning phase), and stabilization with fluctuations (consistent performance). The CUSUM method highlights efficiency trends over time.

documentation form. This approach enhances reproducibility and ensures that critical placental features are consistently recorded, minimizing the risk of misinterpretation. Additionally, the study's inclusion criteria, which focused exclusively on physiological pregnancies, provided a robust reference for distinguishing normal placental variations from pathological findings. The high level of staff satisfaction and the minimal time required for form completion further support the feasibility of

integrating this tool into routine clinical practice. Not enrolling women with pathological pregnancy or childbirth, despite appearing as a limitation of the study, was intentional since our goal was to show how some features that are normally ascribed pathological significance are actually present in fully physiological women. However, the study also presents some limitations. First, its observational design inherently limits the ability to establish causal relationships between

placental characteristics and clinical outcomes. Secondly, while efforts were made to ensure standardized data collection, the study may still be subject to interobserver variability, as placental assessments were performed by different personnel with varying levels of experience. Another potential limitation is the presence of unmeasured confounding factors, such as maternal lifestyle, genetic predispositions, or undiagnosed subclinical conditions. Furthermore, while the form was well accepted, its implementation relied on the active participation of clinical staff, and its effectiveness in settings with different resource availability remains to be tested. Additionally, the study does not have a comparator (*e.g.*, a historical cohort or standard of care documentation) to assess the actual improvement in diagnostic performance compared with a baseline situation. Finally, histopathological correlation was not systematically performed, which may have provided further validation of the macroscopic findings. Future studies should focus on expanding the use of this tool to high-risk pregnancies and assessing the role of anatomo-pathological alterations on neonatal outcomes.

### **Interpretation**

Placental evaluation is often “forgotten” and is usually only performed in cases of adverse outcomes [15]. This leads to two major issues: 1) the inability of the staff to perform an adequate macroscopic evaluation that highlights useful elements for the pathologist that are not always detectable later in the laboratory (*e.g.*, clots); 2) pathologists are generally “accustomed” to observing placentas with adverse outcomes and thus have little experience with placentas from physiological pregnancies and deliveries. Additionally, pathologists often receive very little clinical information, such as the date of membrane rupture or the characteristics of the amniotic fluid. This results in diagnostic difficulties and easy misinterpretations of the histological findings [16].

For this reason, the decision to evaluate only pregnancies and deliveries with a completely physiological course was not random. Our aim was to observe and document “normal” placentas by using a standardized form [17]. We observed that certain aspects – such as the presence of placental clots, even larger than 4 cm – can be found in physiological pregnancies and deliveries without any adverse outcomes. This evidence contrasts with previous studies that hypothesized that the

presence of intrauterine hematomas is strongly associated with adverse pregnancy events, including gestational hypertension, preeclampsia, placental abruption, preterm birth, small for gestational age (SGA) infants, and low Apgar scores at 5 minutes [18, 19]. Intrauterine hematomas are blood clots that accumulate between the placenta or chorionic tissue and the inner lining of the uterus; the most common ones are retroplacental hematomas that form between the placenta and the endometrium. Most of these studies analysed the presence of such hematomas via ultrasound during pregnancy, assessing prenatal and postnatal outcomes. In our study, despite their presence, pregnancy and childbirth proceeded regularly.

Additionally, the presence of thick or meconium-stained membranes was not indicative of a pathological condition. Normally, these membranes are thin, whereas, in the presence of inflammatory conditions such as chorioamnionitis, their thickness can vary. Chorioamnionitis is an acute inflammation of the membranes and chorion of the placenta, typically due to an ascending polymicrobial bacterial infection in the context of membrane rupture. It is associated with significant adverse maternal, perinatal, and long-term outcomes. Adverse maternal outcomes include postpartum infections and sepsis, while adverse infant outcomes include stillbirths, preterm births, neonatal sepsis, chronic lung disease, and brain injuries leading to cerebral palsy and other neurodevelopmental disabilities [20, 21]. In our sample, three cases of thickened membranes were found, none of which showed symptoms or signs of an ongoing infection during labour, nor were there any adverse neonatal events. Physiologically, the colour of the membranes is shiny, while when they come in contact with meconium, they take on its colour. Meconium is the initial substance present in the developing foetus’s intestines and constitutes the first bowel movement of the newborn. Healthy term infants expel meconium 24 to 48 hours after birth. The presence of meconium-stained amniotic fluid may indicate normal gastrointestinal maturation or, more concerning, may be a sign of acute or chronic foetal hypoxia. Babies born with meconium-stained amniotic fluid are at a higher risk of adverse events such as perinatal asphyxia and respiratory distress [22]. In our case, this did not affect maternal-neonatal outcome. Similar considerations can be made for the macroscopic analysis of the umbilical cord, for which we considered the insertion and length. Normally,

the umbilical cord has a central/paracentral insertion (central or middle third of the placental disc). However, two main types of abnormal insertion have been identified: velamentous and marginal insertion. Velamentous cord insertion is diagnosed when the umbilical vessels insert into the membranes before reaching the placental margin, leaving the umbilical vessels unprotected by Wharton's jelly for the tract between the insertion and the placental margin. In marginal cord insertions, this distance is minimized, but the insertion site is supported by a minimal amount of placental tissue [23]. Abnormal cord insertions are associated with adverse maternal-foetal outcomes, including increased incidence of preterm birth, low birth weight, perinatal mortality, low Apgar scores, and emergency caesarean sections due to pathological labour progression. Additionally, velamentous insertion sometimes combines with vasa previa, a rare but serious condition where unprotected umbilical vessels are near the internal cervical orifice, associated with high perinatal mortality when not diagnosed prenatally [24]. In our completely physiological study population, marginal cord insertion cases accounted for 30.08% of the total, and there was one case of velamentous insertion. The length of the umbilical cord is also an important factor to consider. At birth, a cord typically ranges from 30 cm to 80 cm. A cord is considered short when it is less than 30 cm and excessively long when it exceeds 80 cm. Excessively short cords are associated with delayed second-stage labour, irregular foetal heart rate, placental abruption, umbilical cord rupture, uterine inversion, birth asphyxia, and cord hernia. Excessively long umbilical cords are associated with cord prolapse, torsion, true knots around the foetus, and delivery complications. Length abnormalities correlate with foetal distress, foetal anomalies, and respiratory distress [25]. In our study, the placental samples with abnormal cord length came from women having physiological labour and delivery, and none of the complications associated with these conditions were reported. These discrepancies should be highlighted and carefully considered. In such cases, inadequate information to the pathologist could lead to incorrect pathological conclusions in entirely normal conditions [26, 27]. It is conceivable that such evaluations may be even more misinterpreted in case of pathological pregnancies or adverse birth outcomes.

## CONCLUSIONS

In this study, we developed and implemented a standardized Placenta Documentation Form to enhance the collection of clinical and macroscopic data. We assessed its feasibility, time efficiency, and acceptance among clinical staff, while also analysing key placental characteristics in physiological pregnancies to distinguish normal variations from pathological findings. We believe that completing a standardized and recommended form on the placental clinical and macroscopic data should be highly recommended. The form requires little time and is well accepted by the staff, not being perceived as an additional burden. Moreover, it provides very important data as some macroscopic elements may escape subsequent evaluation by the pathologist. Lastly, but perhaps most importantly, this form provides fundamental information to the pathologist to guide them to a correct diagnosis of the placenta. For these reasons, we believe it should be adopted in all delivery rooms as a routine tool for placental evaluation.

## COMPLIANCE WITH ETHICAL STANDARDS

### *Authors' contribution*

F.P.: Conceptualization, investigation, validation, writing – original draft, project administration. D.B., G.B., M.C.: Data curation, validation, writing – original draft. E.P., A.F., G.Q.: Validation, writing – review & editing. M.M.M.G.: Formal analysis, writing – review & editing, project administration. P.M.: Conceptualization, writing – review & editing, project administration.

### *Funding*

None.

### *Study registration*

N/A.

### *Disclosure of interests*

The authors declare no competing interests.

### *Ethical approval*

The study was approved by the Institutional Review Board of AOUP, Azienda Ospedaliera Universitaria Pisana, University of Pisa (reference 25772\_MANNELLA), in accordance with the Good Clinical Practice (ICH/GCP) guidelines and the Ministerial Decree of 1997.

**Informed consent**

All participants provided written informed consent in accordance with the Declaration of Helsinki.

**Data sharing**

Data are available under reasonable request to the corresponding author.

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