The Soleymani and Collins Obstetric Morbidity Score (SaCOMS): a quantitative tool for measuring maternal morbidity from complex obstetric surgery such as placenta accreta spectrum (PAS)

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Abstract

Objective: To describe a suggested version of the Clavien-Dindo morbidity classification specific to obstetrics and employ it to build a cumulative morbidity score which fully reflects the ‘patient experience’. To demonstrate the utility of this novel system in a cohort of women with Placenta Accreta Spectrum (PAS). Design: Delphi consensus and retrospective application of the resulting scores to morbidity from PAS surgery. Setting: UK Tertiary referral centre for PAS. Population: Women who had caesarean hysterectomy for PAS. Methods: The Clavien-Dindo classification was modified to reflect obstetric procedures and a quantitative morbidity measure, the Soleymani and Collins Obstetric Morbidity Score (SaCOMS), was developed based on this. Both were then validated using a Delphi consensus of experts in PAS and retrospectively applied to a cohort of 54 women with PAS. Main Outcome measures: Delphi consensus of >80%, binary outcome of adverse event or not and quantitative values from the SaCOMS. Results: Clinicians with expertise in PAS believe that the Modified Obstetric Clavien-Dindo classification system and the novel SaCOMS tool can improve assessment of maternal morbidity, and better reflect the ‘patient experience’. Application to the PAS cohort demonstrates that surgery by gynaec-oncological surgeons may be associated with decreased incidence and cumulative morbidity outcomes for women with PAS, especially those with the most severe presentation. Conclusions: This study presents a clinically useful obstetric-specific classification system for surgical morbidity. SaCOMS also provides a quantitative reflection of the full patient-journey experienced as a result of surgical complications enabling a more patient-centred representation of morbidity.

Introduction

Placenta Accreta Spectrum (PAS) is a rare condition carrying a high risk of maternal morbidity and mortality¹. Failure of the placenta to separate spontaneously can cause severe, sometimes life-threatening, haemorrhage². Morbidity can arise as a result of blood loss and the complex surgery required to treat PAS due to the neovascularity, distorted anatomy and unusually friable tissues encountered. Many different ways of managing PAS have been suggested including immediate hysterectomy³, focal resection and intentional placental retention but evidence regarding the safety of each remains limited⁴. Much of the research in obstetrics, as with most medical specialties, aims to reduce mortality and morbidity. Whilst mortality is binary outcome, accurate assessment of maternal morbidity is hindered by a lack of a unified classification system tailored to obstetrics. Obstetric procedures incorporate a unique set of combined risks, including neonatal
risks, massive haemorrhage, iatrogenic injury to pelvic structures, and risks from pregnancy-associated conditions such as eclamptic seizures\textsuperscript{5}. All of this occurs at the life-changing moment of entering parenthood with all its associated demands and expectations. Most scientific studies focus on outcomes either judged to be important by the healthcare provider, such as admission to intensive care unit (ICU) or numerically appealing such as estimated blood loss. Whilst these are undoubtedly important they do not fully represent the ‘patient experience’ at this critical moment in the mother’s life. Admission to ICU is often used as a marker of severe morbidity however, for the majority of women with PAS this is usually a short stay as a result of acute massive transfusion. Is this more ‘severe’ than a lower urinary tract injury requiring long-term catheterization, multiple investigations and repeated surgical procedures? A quantitative morbidity score which takes into account not only the severity of immediate issue, but also longer-term cumulative morbidity, is desperately needed if we are to compare novel obstetric procedures especially surgically challenging ones, such as management of placenta accreta spectrum. The Clavien-Dindo classification is a well-established functional score based on the interventions required to manage surgical complications\textsuperscript{6}. The classification focuses mainly on the therapeutic consequences of a complication attempting to match the severity of different morbidities. It is well accepted and utilised ‘as-is’ or in a modified form in several surgical specialties, including general surgery\textsuperscript{7}, urology\textsuperscript{8} and oncology\textsuperscript{9}, but is yet to be adapted for use in obstetrics. The aims of this study were twofold: Firstly, to develop both a clinically useful obstetric-specific morbidity classification system and a quantitative, patient-centred system reflecting the full journey experienced by women following any complication. The second aim was to demonstrate the potential utility of the novel quantitative scoring system by performing retrospective analyses to explore morbidity according to the type of surgeon undertaking the PAS surgery.

Methods

The Modified Obstetric Clavien-Dindo Classification

The original Clavien-Dindo classification classifies complications as any deviation from the normal postoperative course\textsuperscript{10}. Sequelae which are considered as ‘after-effects’ of surgery inherent to the procedure (for example infertility following hysterectomy) are excluded from this classification. Adverse events are then stratified by severity, with a focus on the corrective measures required to manage the complication. Morbidity events are graded as follows: Grade I (least severe), Grade II, Grade IIIa/b, and Grade IVa/b (most severe). Modifications from the original Clavien-Dindo classification were made to incorporate obstetric-specific considerations such as the increased circulating volume seen in pregnancy, as this affects what might reasonably considered ‘significant’ versus ‘massive’ blood transfusions. This modified classification (see Table 1) also includes examples tailored to complex obstetric procedures, including complicated lower urinary tract injuries, insertion of nephrostomies and ureteric stents, and hysterectomy +/- resection of retained products of conception. Admission to ICU is considered as an adverse event only when necessitated due to organ dysfunction, thus reducing potential confounding of data due pre-planned admission to ICU for observation being erroneously reported as an adverse outcome without significant illness or threat-to-life. This corrects for the differences in ICU admission policies seen in different units and countries. Sepsis and disseminated intravascular coagulopathy (DIC) can be assessed according to different clinical guidelines. This modified obstetric classification system uses the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)\textsuperscript{11} to occurrence of sepsis. Coagulation data including platelet count, increase in fibrin markers, PTT and fibrinogen level are used to assess for DIC as per the International Society of Thrombosis and Haemostasis (ISTH) guidelines\textsuperscript{12,13}. The Soleymani and Collins Obstetric Morbidity Score (SaCOMS) The quantitative SaCOMS simply attributes numerical values to each grade of morbidity defined by the Modified Obstetrics Clavien-Dindo (Table 2). These are used to produce a cumulative ‘overall morbidity score’ for individual women. The final total accounts for multiple morbidities and the need for delayed or long-term corrective measures, such as returns to theatre for reparative surgery. Examples of how this can be applied to demonstrate the full impact on the woman of each morbidity are shown in Table 3. Thus, the SaCOMS is
presented as a quantitative reflection of the overall ‘patient experience’ resulting from any adverse outcome.

**Modified Delphi Consensus**

Acceptability of the Modified Obstetric Clavien-Dindo classification and SaCOMS for clinical classification and quantitative assessment of morbidity was assessed using a survey-based consultation of a panel of PAS experts, all of whom were members of the International Society for Placenta Accreta Spectrum (IS-PAS). The Modified Obstetric Clavien-Dindo classification, the SaCOMS guidelines and two case examples demonstrating the calculation of the quantitative cumulative SaCOMS value (Table 3) were sent with an accompanying questionnaire. The questionnaire used Likert-scale answer values to assess opinion on the need for such an obstetrics-specific classification system, and the suitability, utility and ease-of-use of the modified obstetric Clavien-Dindo classification and SaCOMS to address such a need (Supplementary Material 1). Free-text responses were also included to facilitate an opportunity to improve either of the systems. An 80% selection of the two highest Likert-scale response options was set as the threshold for approval. If 80% was not reached, the item relating to that question would be reviewed taking into account the comments of the panel, the classification or score adapted, and the changed documents resubmitted for approval until an 80% approval score was reached.

**Retrospective Morbidity Analysis**

Retrospective analysis of morbidity outcomes for women with PAS used data collected for an audit examining the morbidities seen for all PAS cases delivered at a UK Tertiary referral centre, between August 2011 and May 2019. Cases were classed as emergency or elective according to the standard 1–4 categorisation stated in the National Institute for Clinical Excellence (NICE) ‘Performing caesarean section’ Guidelines. For the purposes of this cohort analysis, categories 1 and 2 were considered ‘emergency’ and categories 3 and 4 as ‘non-emergency’ or ‘elective’. This subdivision allows for the fact that delivery under non-emergency circumstances, without maternal or fetal compromise, will afford better preparation in terms of assembly of the MDT and operating theatre resources leading to potentially better outcomes. Similarly, cases were then further subdivided depending on whether PAS was ‘suspected’ antenatally (as confirmation of PAS diagnosis can only be made at delivery). Antenatal suspicion of PAS is associated with better maternal outcomes, including blood loss and need for mass transfusions. For the purpose of comparing surgeon type with respect to morbidity, only cases which were electively delivered and antenatally suspected were considered in order to account for the adequate preparation of an experienced MDT this affords. Finally, cases were grouped according to the FIGO clinical classification of PAS as either abnormally adherent (FIGO grade 1) or abnormally invasive (FIGO grades 2 and 3), to reflect clinical severity. Grades 2 and 3 result in greater neovascularity, more friable tissues and placenta involving other pelvic structures resulting in higher-risk surgical procedures, for example the need for deliberate cystotomy to facilitate hysterectomy where the posterior bladder wall cannot be detached from the anterior uterine wall. Several sources were used to collate data for each case according to a predefined audit pro-forma. The Electronic Patient Record (EPR) was used to determine patient age, gestation and BMI at time of delivery. Physical and electronic operation notes were used to determine surgical procedure, including lead surgeon, incision type, and any surgical damage documented at the time. Immediate, short-term and delayed morbidities according to the Modified Obstetric Clavien-Dindo classification and SaCOMS were recorded from both the hospital and primary practitioner’s electronic patient records, including ITU admission, long-term ureteric stents or subsequent corrective surgical procedures. Total time in theatre, estimated blood loss, and use of cell salvage were determined from anaesthetic charts and independent cell salvage records. No ethical approval was needed for the morbidity analysis as it formed part of an ongoing clinical audit and was appropriately registered and approved as such by the local NHS clinical governance team (OUH Audit Number 5544, approved 14/6/2019).
Quantification of morbidity

MORBIDITIES were identified and classified according to the Modified Obstetric Clavien-Dindo classification and SaCOMS, as previously described. Two parameters of morbidity were analysed to assess differences according to surgical speciality: presence or absence of any Adverse Event (AE) and the Soleymani and Collins Obstetric Morbidity Score (SaCOMS). The first measure (AE) describes whether a woman with PAS has experienced any adverse surgery-related outcome, regardless of severity or multiple morbidities. Calculating SaCOMS allows a broader perspective of the overall ‘patient journey’, accounting for the cumulative effect of multiple adverse complications both during and beyond delivery.

Statistical Analysis

The Shapiro-Wilk test for normality and Mann-Whitney U test were used to assess for difference in age, BMI and gestation between surgeon groups. Three parameters were tested to compare morbidity outcomes for gynaecologist vs gynae-oncologist led MDTs. Chi-squared (χ²) and Fisher’s exact tests, as appropriate, were used to compare the proportion of women experiencing any measurable morbidity (AE) according to the surgeon operating. The values for the SaCOMS were tested for normality using the Shapiro-Wilk test and compared between surgeon groups using the Mann-Whitney U test. For all tests \( p < 0.05 \) was used as the threshold for statistical significance. All statistical analysis was carried out using SPSS (SPSS 26.0; IBM Analytics).

Results

Validation of Modified Obstetric Clavien-Dindo and SaCOMS

10 completed responses to the Delphi consensus survey were recorded (Table 4). Seven respondents were obstetricians, two were gynae-oncologists and one was a specialist in maternal-fetal medicine. For all quantifiable, Likert-scale items, the 80% threshold for approval was met. 100% of respondents either ‘strongly agreed’ or ‘agreed’ that there was a need for an obstetric-specific morbidity classification system; 90% felt that the Modified Obstetric Clavien-Dindo fulfilled such a need, and 80% felt that the generation of a cumulative morbidity score (SaCOMS) value was useful. All respondents reported that they would feel comfortable using the classification system for the assessment of morbidity, with 80% reporting that they would feel comfortable using both the classification and cumulative SaCOMS value. All respondents also reported they felt the classification system was reasonable, fair and easy-to-apply, with 90% reporting they also felt this for SaCOMS.

Retrospective analysis of PAS cohort

Between August 2011 and May 2019, 83 possible PAS cases were identified (Fig. 1). Seven cases (8%) were excluded initially: four because they were not delivered at the institution undertaking the audit; one because the patient’s notes could not be found; one because delivery was vaginal followed by failed removal of placenta, and one case which was a false positive PAS diagnosis (at delivery placenta was normal). Therefore, 76 cases were included in data collection: 8 (11%) were ‘emergency’ and 68 (89%) were ‘elective’. Of the 68 electively delivered cases, 56 (82%) were antenatally suspected PAS. Two of these cases (both abnormally adherent i.e. FIGO Grade 1) were delivered by an MDT led by an obstetrician and therefore excluded from the analysis. Of the remaining 54 antenatally suspected, electively delivered PAS cases, 29 (54%) were delivered by an MDT led by a gynae-oncologist and 25 (46%) were delivered by a gynaecologist-led
MDT. There was no significant difference in age ($p=0.77$, $\mu=27.5$, $SD=57.6$) or gestation at delivery ($p=0.21$, $\mu=27$, $SD=56.0$), between the surgeon groups. BMI was significantly higher in the gynaeco-oncology led cohort ($p=0.01$, $\mu=27.5$, $SD=57.6$). 19 (35%) of the 54 cases were classified as abnormally adherent (FIGO grade 1), and 35 (65%) as abnormally invasive (FIGO grades 2 and 3); 7 of the abnormally adherent cases (37%) were delivered by gynaeco-oncologists and 12 (63%) were delivered by gynaecologists. Of the 35 invasive cases, 22 (63%) were delivered by gynaeco-oncologists and 13 (37%) were delivered by gynaecologists (Fig. 1). A range of adverse outcomes were recorded (Table 5) according to the Modified Obstetric Clavien-Dindo classification. These included three cases where blood loss was sufficient to necessitate a significant transfusion ([$\geq$]5 units packed red cells) and one requiring massive blood transfusion ([$\geq$]10 units packed red cells). Other surgical morbidities included 14 women requiring 15 returns to theatre without general anaesthetic, and 9 women with a total of 17 additional procedures requiring general anaesthetic. Additional procedures included two incidences of bladder damage (one conservatively managed, one surgically managed at the time of caesarean), removal of ureteric stents (8 without and 1 with general anaesthesia), and one woman who required a nephrostomy following four unsuccessful attempts at ureteric stenting. Two women went to ITU for acute respiratory distress syndrome (ARDS), a single-organ failure. No women had multi-organ failure. No women in this study met the criteria for either sepsis or DIC, but six had post-operative infections leading to systemic inflammatory response syndrome (SIRS). Overall, of the 54 elective, antenatally suspected cases 24 experienced at least one adverse outcome as a result of the surgery. The difference in incidence of at least one adverse event between women delivered by gynaeco-oncological surgeons vs gynaecological surgeons was significant [31% (9/29) versus 60% (15/25), $p=0.033$] (Table 6). When severity of PAS according to the FIGO classification was accounted for, there was no significant difference in the proportion of women experiencing at least one adverse outcome between gynaeco-oncologists and gynaecologists for abnormally adherent (FIGO Grade 1) cases [28.6% (2/7) versus 41.7% (5/12), $p=0.656$] (Table 6). However, for abnormally invasive (FIGO Grade 2 or 3) cases significantly fewer women experienced at least one adverse outcome when operated on by gynaeco-oncologists compared to those operated on by gynaecologists [31.9% (7/22) versus 76.9% (10/13), $p=0.01$] (Table 6). Differences in SaCOMS were examined (Fig. 2). The Shapiro-Wilk test demonstrated that SaCOMS values were not normally distributed ($p<0.001$) for electively delivered, antenatally suspected PAS cases. Therefore, the Mann-Whitney-U test was used. SaCOMS was lower for women delivered by gynaeco-oncological surgeons than for women delivered by gynaecological surgeons (Mean Rank of 23.7 versus Mean Rank of 31.9, $U=252.5$, $p=0.04$) (Fig. 2a). For abnormally adherent cases, SaCOMS did not differ significantly between gynaecological surgeons and gynaeco-oncological surgeons (Mean Rank of 10.4 versus Mean Rank of 9.4, $U=71.0$, $p=0.71$) (Fig. 2b). However, for more severe cases (FIGO grades 2 and 3), women delivered by gynaecological surgeons had significantly higher SaCOMS than women delivered by gynaeco-oncological surgeons (Mean Rank of 23.5 versus Mean Rank of 14.7, $U=71.0$, $p=0.01$) (Fig. 2c).

**Discussion**

**Main findings**

We propose adoption of a modified approach to the widely-used Clavien-Dindo classification, adapted to reflect the portfolio of risks associated with complex obstetric cases and extended to develop the Soleymani and Collins Obstetric Morbidity Score (SaCOMS) - a novel morbidity assessment tool which has the additional benefit of accounting for the cumulative impact of multiple adverse outcomes on the overall patient journey. We have validated this classification methodology by Delphi consensus consultation of expert clinicians, and have demonstrated its utility via consideration of two case studies and a retrospective analysis of a cohort of patients with PAS.
**Interpretation**

Evaluation of two case studies indicates the additional patient-focused insight this provides; the additive detriment of six follow-up procedures despite a low-grade of clinical disease for patient 1 compared to well-managed blood loss and a one-night inpatient stay in ICU for patient 2 (with a high-grade of clinical disease) is reflected in a notably higher SaCOMS value. A survey-based modified Delphi consensus shows that relevant clinicians believe this system to provide value in assessing morbidity for individual patients and analysis of data. In addition to qualitative consideration of the Modified Obstetric Clavien-Dindo classification and SaCOMS by considering individual case studies, its utility as a tool for quantitative analysis to draw meaningful clinical conclusions is demonstrated by retrospective analysis of morbidity outcomes for surgical delivery women with PAS by type of surgeon leading the MDT. The major finding of the retrospective PAS cohort analysis was that, according to both measures of morbidity - presence of any adverse event, and SaCOMS - gynaec-oncologist led MDTs had significantly better outcomes than gynaecologist-led MDTs for electively delivered, anetnata tally suspected PAS cases. These data suggest that women delivered by gynaec-oncological surgeons are less likely to experience any measurable morbidity, irrespective of severity or multiple morbidities. Furthermore, for women who experienced adverse outcomes, delivery by gynaec-oncological surgeon was associated with a lower cumulative experience of morbidity. As both parameters of morbidity concur this provides evidence that gynaec-oncological surgeons provided the safest management of PAS, particularly for clinically severe cases, probably due to their extended training in open laparotomy and experience with friable, hyper-vascularised tissue and distorted anatomy. Adequate clinical and academic assessment of maternal morbidity from obstetric procedures has previously been hindered by a lack of consensus in classification and reporting of adverse events. In turn, this limits evidence-based evaluation of the benefit of novel techniques and intervention for complex obstetric disorders, such as PAS. Studies examining morbidity from complex obstetric cases tend to put the emphasis on the amount of blood lost, blood products given and admission to intensive care unit (ICU). Whilst these are undoubtedly important markers, they are fraught with difficulties. Blood loss is always an estimate and the blood products given are often dependent on the practice of the anaesthetist and local guidelines. ICU admission may also be impacted by the availability of ICU beds or presence of a specific obstetric high dependency unit (HDU) as well as local practice and guidelines. Other morbidities recorded often include accidental visceral trauma or post-operative infection. Again, these can result in significantly different experiences for the woman herself; a cystotomy repaired at the time of surgery is likely to have a lower impact on her quality of life than ureteric trauma requiring multiple surgical interventions over the months or years to come. This is particularly important as the patient is a new mother and any ongoing morbidity may affect her ability to bond with, and care for, her new baby. This can also have significant impacts on her partner and other children.

**Strengths and Limitations**

A cohesive and consistent system for classifying surgical morbidity in obstetrics which is reflective of the burden of cumulative morbidity events, has the potential to improve the accuracy and utility of academic research into surgical morbidity in obstetrics. Clinically, this has the knock-on effect of bolstering efforts to develop and optimising the surgical approach to complex obstetric surgery, guided by enhanced research methodology. A potential confounding factor could be clinical severity of PAS for the cases managed by each surgeon type. For example, if gynaec-oncologists had been undertaking most of the less invasive, less clinically severe cases (and/or gynaecologists undertook disproportionately more high-grade cases) this could obfuscate any true relationship between surgeon type and morbidity outcomes. Sub-group analysis by severity demonstrated that this was not the case; gynaecologists performed most of the deliveries for abnormally adherent (FIGO Grade 1) cases (12/19, 63%), and gynaec-oncologists performed the majority of caesareans for the more technically challenging abnormally invasive (FIGO Grade 2 or 3) cases (22/35, 63%). Furthermore, gynaec-oncology-led MDTs had better morbidity outcomes despite the women having higher BMI scores, which increases surgical risk. The difference in morbidity outcomes between the two surgeon types varied between abnormally adherent (FIGO Grade 1) and abnormally invasive (FIGO Grade 2 and 3) cohorts. Analysing the less surgically complex abnormally adherent cases separately demonstrated that there was no
significant difference in incidence of any adverse event and SaCOMS between the surgeon types for clinically less severe cases. For abnormally invasive cases however, both morbidity parameters were significantly lower when the MDT was led by gynaec-oncological surgeons. This suggests that gynaec-oncological surgeons are better equipped to tackle the surgical complexity required to manage more severe, invasive cases of PAS (which inherently carry a higher surgical risk18). Surgical experience is another potential confounding factor to consider; if gynaec-oncologists performed more PAS surgeries overall, this could allow for increased experience of MDTs and of individual surgeons. Surgical experience is well correlated with improved surgical outcomes for several types of surgery24–26 (known as the volume-outcome relationship), including in the management of PAS27. This was not the case however, as both surgeon types performed a similar number of surgeries in the study period. Gynaecologists performed caesarean hysterectomies for 46.3% (25) of all elective antenatally suspected PAS cases within the study period, whilst gynaec-oncologists performed the remaining 53.7% (29). Although the learning curve of individual surgeons and MDTs cannot be controlled for, the specialist PAS service at the JRH was led by gynaecologists for four years (2011-2014) and by gynaec-oncologists for four and a half years (2015-mid 2019), allowing for a similar timeframe to develop familiarity with operating on women with PAS. An important strength of the morbidity analysis is the robustness of the diagnostic criteria for PAS. All cases included were confirmed by experts in PAS diagnosis according to strict clinical criteria and histopathological diagnosis. This enabled the sub-division into the less severe abnormally adherent and more surgically complex abnormally invasive cases. A notable limitation to the retrospective morbidity analysis is the small sample size, with data from only one NHS trust. It would be difficult to scale-up this study to include multiple NHS trusts, owing to the highly specialist nature of the surgery requiring referral to specialist tertiary-level obstetric units28. PAS is a very rare placental disorder, with an estimated incidence of 0.07% (IQR 0.05-0.16)29, meaning the sample size was unavoidably very small and the study had low power to detect mild to moderate effects. However, statistical significance across both measures of morbidity is testament to the effect size of using gynaec-oncological surgeons. A prospective study or rolling audit over a period of several years might reveal additional statistically significant results and rule out type II statistical errors. For example, a difference in morbidity outcomes between gynaec-oncologists and gynaecologists for abnormally adherent cases might be revealed with higher-powered analysis afforded by a greater sample size. It would also allow accurate data collection at the time of surgery, according to a pre-defined pro forma and tailored to the research aims. This could facilitate investigation of additional morbidities for which there was not sufficient data available for the present study; for example psychological sequelae such as PTSD, which has been associated with PAS30. A larger cohort would also allow investigation of morbidity outcomes in emergency cases, for which the sample size was too small to analyse in the present study.

Conclusion

Clinicians with expertise in PAS believe that the Modified Obstetric Clavien-Dindo classification system and the novel SaCOMS tool can aid in drawing meaningful clinical conclusions regarding maternal morbidity, including representing the detrimental impact of cumulative morbidity outcomes. Analysis of two morbidity parameters including the novel SaCOMS, demonstrated that for women electively delivered with antenatally suspected PAS, surgery by gynaec-oncological surgeons was associated with better morbidity outcomes compared to delivery by gynaecological surgeons, especially for more clinically severe cases. This is probably due to greater experience with handling the distorted anatomy, neovascularity and friable tissue encountered with abnormal placentation. These data suggest a potential benefit to using gynaec-oncology-led MDTs as standard for PAS caesarean deliveries.

Conflicts of Interests: The authors have nothing to disclose.

Contribution to Authorship: EW: methods, data collection, data analysis, manuscript preparation and approval. SC/HS: Concept, methods, data analysis, manuscript preparation and approval. SA/AC: Methods, data analysis, manuscript preparation and approval.

Ethical Approval: The data was collected as part of a locally approved audit (OUH Audit 5544).

References

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