A Synoptic Electronic Order Set for Placental Pathology: A Framework Extensible to Nonneoplastic Pathology

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Abstract

Accurate pathologic assessment in placental pathology is mostly dependent on a complete clinical history provided by a clinical team. However, often, the necessary clinical information is lacking, and electronic order sets (EOSs), if implemented correctly, create an opportunity for entering consistent and accurate clinical data. In this viewpoint piece, we describe a framework for synoptic EOS in placental pathology. We outline the necessary data and create optional clinical data that get entered as a dropdown menu of free text. While EOSs are the best way to approach and diagnose placenta and other nonneoplastic pathologic specimens, the barriers for implementation include paper requisitions and a cultural mindset resistance. The aspiration for our synoptic EOS is to become an effective tool for communication between proceduralists and pathologists for proper diagnosis of placental specimens. Through our EOS, the appropriate and complete clinical context is conveyed from the clinical teams to the pathologist. The pathologist can easily and rapidly extract the necessary information to render an accurate and precise diagnosis. The captured data likewise become a valuable research resource.

Keywords: Electronic order set, nonneoplastic pathology, placenta, requisition, synoptic

INTRODUCTION

Generating pathologic diagnoses of biopsy and surgical resection specimens is a multiphased operation from the preanalytic phase with specimen collection/requisition in the procedure suite/operating room to the analytic phase with pathologic processing/evaluation in the laboratory and eventually to pathologic reporting. Each step in the phases contributes to an accurate diagnosis.[1] Accurate pathologic diagnoses rendered in pathology reports in turn drive downstream clinical decisions that impact patient management.

In the analytic phase, the introduction of synoptic templates has enhanced the quality of pathology reports with consistency, accuracy, and completeness. Synoptic templates such as "checklists" are intended to ensure that a minimum necessary reporting dataset is available for clinical decision-making. Prior to the introduction of synoptic templates, there existed considerable variability in consistency, accuracy, and completeness of pathology reports. Synoptic templates, currently in fact, are mandated for most cancer reports.

In the preanalytic phase, where specimens are collected from the procedure suite/operating room, paper-based requisitions are the mainstay in pathology for conveying clinical history and reasons for pathologic evaluation.

Such clinical correlative data are often necessary to rendering an accurate diagnosis for both nonneoplastic and neoplastic specimens. For instance, in neoplastic specimens, some AJCC TNM staging categories require correlative clinical data. One example is in gynecologic pathology, where capsular rupture of an ovarian tumor due to surgery is AJCC pT1c1, but if capsular rupture occurs before surgery, the pathologic stage is AJCC pT1c2. Incorrect staging therefore occurs without the clinical correlation of timing for capsular rupture.

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Despite the criticality of having clinical history and reasons for pathologic evaluation available to obtain an accurate diagnosis, such information is often lacking and, furthermore, often incorrect on paper-based requisitions. Electronic order sets (EOSs) in pathology create an opportunity to tackle this problem, through requirements for entering consistent, accurate, and complete data on clinical history data and reasons for evaluation.

EOSs are commonly deployed for the laboratory, radiology, and pharmacy, with the recent widespread adoption of electronic medical records (EMRs). EOSs have also shown enhanced care quality with Steelman *et al.*[2] recommending EOS development to decrease the number of adverse events and near misses in surgical specimen management.

In this viewpoint piece, we describe a synoptic EOS for placental specimens and detail the construction of a synoptic EOS for medical placental evaluation. We then argue the role of synoptic templates in EOSs for consistency, accuracy, and completeness toward obtaining an accurate diagnosis, particularly extended toward the setting of medical nonneoplastic pathologic assessments. Because no guidelines for standardized requirements exist for submission by the clinical team of necessary clinical history data elements for placental specimens, we show how such a standardized framework in a synoptic template can be leveraged in the EOS, just as effectively as synoptic templates are leveraged in pathology reporting. Our aspiration, through in describing this framework for a placental synoptic EOS, is to provide a blueprint extensible for future constructions of other deployable EOSs in other medical nonneoplastic pathologic assessments such as liver and kidney. Such EOS synoptic templates enable the availability of critical history and reasons for evaluation to ensure scalable, accurate, pathologic diagnoses across institutions. The captured data likewise become a valuable research resource.

Conceptual Framework Design

We conceptually designed this placental EOS template in conjunction with the clinical obstetrics team input, to ensure that necessary clinical information is not omitted. There are additional benefits to having EOS templates. We outline the technical features of this placental EOS as such.

This placental EOS is constructed in a hierarchical structure with parent–child relationship, amenable for translation into an extensible markup language (XML) framework very similar to those seen with the College of American Pathologists (CAP) synoptic reports for neoplastic specimens. Included are essential clinical elements by which the absence would preclude an accurate and optimal pathologic diagnosis for placental evaluation. This EOS project created the possibility to determine necessary data fields and which of them were amenable for discrete data entry and which should be left as free text. We carefully designed the template to have discrete data fields with dropdown menus defined by data dictionaries,

where there is utility. This is to avoid the potential for less meaningful, vague, or overgeneralized data entry with free text fields. Placental pathology, in general, is difficult to report with a universal "one size fits all" EOS, especially when created for another organ system. Hence, clinical and pathologic curation for this placental EOS was performed in collaboration between the clinical teams and pathology to determine the necessary data fields and which of the data fields were amenable to discrete data entry and which should be left as free text.

Placental Electronic Order Set Wireframes

Collaboration occurred via a multidisciplinary committee consisting of two gynecologists, two pathologists, and two IT analysts (one hospital and the other pathology). The committee agreed to strive on minimizing the number of mandatory fields with hard stops. Reasons for reducing the number of mandatory fields with hard stops include usability and the significant proportion of "unfollowed" placental specimens at our center, specimens basically having no prenatal care, follow-up, or any available information. Regarding the latter, having numerous mandatory fields with hard stops for these "unfollowed" placental specimens would lock clinical teams from electronically submitting placental specimens due to missing unknown data. Our multidisciplinary committee also designed the EOS from a user perspective, keeping the number of clicks to a minimum. Certain fill-ins were judiciously left as free text, acknowledging the loss of discrete data capture, but not to encumber users with long dropdown lists.

Our placental EOS screenshots and descriptions from a test patient are shown in Figures 1 and 2. The EOS was developed in the EMR environment, which is home-built, with the granularity of the captured data housed in that system. The EOS data, housed in the EMR, are hierarchical, with seven major headings, amenable for translation into an XML framework for data interoperability. The seven major headings include maternal information, antepartum history, intrapartum history, delivery modality, neonatal information, and pathologic review indications.

The order form has mandatory fields, some autopopulated, and the remaining mandatory fields with hard and soft stops, as well as optional fields. In compliance with New York state regulations, medical record number (MRN), date of birth (DOB), specimen collection date, and specimen collection time are mandatory fields [Figure 1]. Mandatory data elements such as MRN and DOB are automatically passed through from the EMR to the AP-LIS (Sunquest Copath) through an existing interface for these specific data elements. Such a basic existing interface for these data elements is common for many health-care institutions. Specimen collection date and specimen collection time require entry and have hard stops.

Clinical history is necessary for accurate and precise diagnoses in placental pathology. We decided to further partition the clinical history into sections, and critical fields deemed mandatory but with soft stops. Partitioned mandatory fields include gestational age for every delivery or approximate

Figure 1: Mandatory fields at the beginning of the electronic order set

gestational age most likely known. Likewise, additional partitioned mandatory fields are delivery modality and neonatal information such as Apgar scores. Maternal information, antepartum, and intrapartum history are sections with optional fields and are not necessary for specimen submission, do serve as mental questions, and most likely to be completed in this EOS. Indications for pathologic review are also an optional section which proves useful when filled.

Implementing an additional interface or expanding on the existing basic interface from the EMR to our AP-LIS to pass the entirety of EOS data at high fidelity is a significant undertaking and determined better as second stage of this EOS initiative as more EOSs come online. Hence, to exchange the EOS data not part of the existing interface automating MRN and DOB, the output from the EOS is a printout; the ramifications of which are addressed later. EOS data, not part of the existing interface, get re-entered manually into the AP-LIS by specimen accessioners from the printout. These data, now accessible in the AP-LIS and in addition to the printout, are available to pathologists during sign-out. Our EOS data get linked on the specimen level and not part level because parts are later assigned in the AP-LIS, after the EOS data are entered. For placental specimens, the majority have only one part and hence EOS data are mostly tied one to one to the placental specimen.

DISCUSSION

Rationale and intent for synoptic electronic order sets implementation

Synoptic templates are universally adopted for neoplastic specimens to enhance care through comprehensive pathology reporting. Synoptic reports are further mandated on all neoplastic resection specimens by the CAP with CAP guidelines for synoptic reporting aiding to create standardized, high-quality cancer reports across institutions.

To generate a quality report, often critically overlooked, is the precise communication between proceduralists and pathologists at the beginning of this complex process in rendering pathologic diagnoses. Such communication conveys the appropriate clinical context required to render an accurate diagnosis, thus reducing the risk of adverse events.[2,3] Unlike in generating pathology reports which occurs in the analytic phase of laboratory specimen handling, most adverse events occur earlier in the preanalytical phase. Such adverse events are largely attributable to incorrect ordering, poor specimen description, or mislabeling, with failures in communication or handoffs.[1]

Despite the most adverse events occurring in the preanalytical phase, scalable mechanisms to mitigate such events are underdeveloped. Many times, the incorrect ordering, poor specimen description or mislabeling, and failures in communication or handoffs, are the by-products of paper hand-written requisitions submitted with the specimens from procedure suites/operating rooms. Highly overlooked is how pathology reporting suffers, with the omission of appropriate clinical information prior to the pathologic evaluation. This is especially true for medical nonneoplastic specimens such as liver, kidney, dermatologic, and placental specimens.

Paper requisitions allow for unstructured narrative clinical histories, prone to omissions and variability in completeness. Often, the paper requisitions are submitted in a rush, half-illegible,

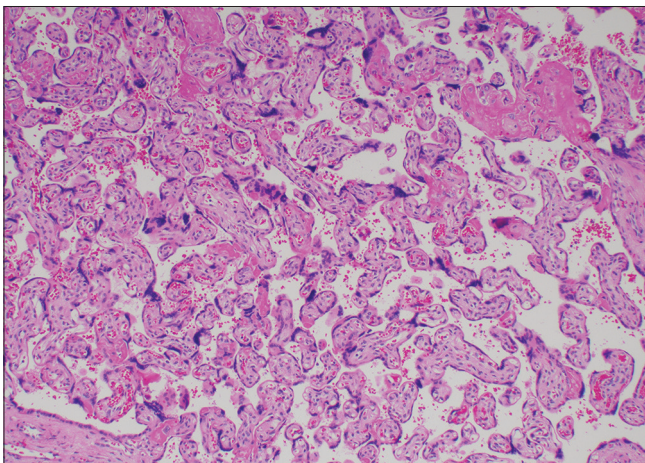**Figure 2:** Optional fields with easy check boxes for indications

Figure 3: Mature appearing placenta and completely normal findings at 40 weeks gestational age. At 34 weeks similar findings can be interpreted as accelerated villous maturation

or even worse with incorrect clinical information. The inability to enforce hard and soft stops to enter key information such as clinical histories creates opportunities for omission or filling of nonmeaningful, vague overgeneralized histories.

In nonneoplastic specimens from liver, renal, dermatologic, and placenta, a precise and accurate diagnosis cannot be rendered without the appropriate clinical context provided by the submitted clinical team. Contrast nonneoplastic specimens with neoplastic specimens where most times clinical history plays less of a role in determining the final diagnosis of cancer or not. In addition to clinical histories for nonneoplastic specimens, other clinical data elements prove necessary to render the most accurate diagnosis.

In placental pathology, a vague history of "intrauterine pregnancy" is the most commonly written data element on paper requisitions in our experience. Such clinical history of "intrauterine pregnancy" is useless information to establish a precise and accurate diagnosis. By contrast, clinical data elements about gestational age and intrauterine growth retardation (IUGR) are critical in obviating a sentinel error in reporting. In fact, gestational age is the most critical clinical data element for further pathologic examination, with the interpretation greatly changing according to subtle differences in gestational age. For instance, if the gestational age is 40 weeks, a histologic appearance for villi is small size and nondilated shape. At 30–34 weeks gestational age, similar histologic appearance for villi is considered accelerated villous maturation, due to severe ischemia or uteroplacental insufficiency. Maternal and antepartum information of preeclampsia with IUGR would trigger additional sampling of fetal membranes, where decidual vasculopathy findings are likely found. The clinical finding of acute abruption may not be followed by the histologic findings of abruption, and a statement should then be added in the report that acute abruption cannot be excluded for accuracy.

Because gestational age is so critical for diagnosis, for instance, gestational age is designed as mandatory data element in our synoptic EOS [Figure 3]. Optional data elements such as maternal and antepartum information and indications for placental examination are also useful for both gross and microscopic examination and thus are included in the synoptic EOS.

An unfortunate reality is that hand-written paper requisitions are the mainstay for collecting critical preanalytic information

and specimen metadata for most of the anatomic pathology labs. Paper hand-written requisitions have reinforced the issues of omission and incorrectly conveyed clinical information. With advances in information technology, EOSs enhance patient care for pathology specimens by mitigating adverse risk through the transfer of complete necessary information and appropriate clinical context to assure for accuracy and completeness of pathologic diagnoses.[4]

Barriers to optimal electronic order sets implementation

EOSs are widely implemented for the laboratory, radiology, and pharmacy. In anatomic pathology, however, EOS implementation across institutions is surprisingly few. There are many reasons for this and include a cultural mindset showing resistance to change from paper requisitions. Even for those groups which accept change toward EOS, usability of EOS then becomes the largest issue with staff acquiring the specimen, requiring data entry workflows that are the least disruptive and time-consuming to their practice. This creates the need for a balance between the necessity of including critical information with the usability and time needed to enter the specimen metadata accurately and completely. The design of this placental synoptic EOS embraces clinical team input for value-added factors to ensure easy to use and optimization.

Because most of our EOS output is not interfaced from the EMR to the AP-LIS, but rather a printout with only few EOS elements (i.e., MRN and DOB) exchanged automatically through an existing basic interface, manual re-entry was not avertable. One consolation was that testing was rapid and more straightforward than with a new interface or expansion of the existing interface. Going live with our EOS involved using both the EOS and physical requisitions to transition the clinical teams to the workflow and converting later only through EOS.

In general, for change management, clinicians are unaccustomed to using practical templates for ordering surgical specimens. Moreover, where the pathologic diagnosis is reliant on knowing such information, particularly for nonneoplastic pathology specimens such as placental, liver, and renal, clinicians are unaccustomed at being nudged to provide clinical data elements crucial for rendering the most accurate diagnosis. There are no guidelines or available standardized EOS sets for groups wanting to build EOS templates specific to capture critical data elements meant for accurate and precise diagnoses, unlike the CAP guidelines provided for cancer synoptic reporting. The absence of prior EOS implementation efforts for anatomic pathology specimen requisitions, especially for nonneoplastic pathology specimens, further justifies the importance of this viewpoint piece in emphasizing the need for more published work in EOS development.

Unlike EOSs for the laboratory, radiology, and pharmacy, EOS construction is more nuanced for anatomic pathology laboratories. Generic "one size fits all" umbrella EOS templates, though easier builds, quickly turn ineffective and irrelevant. With our placental EOS, the numerous data elements needed for a diagnosis are specific only to placenta and not generalizable to other pathologic specimens.

Well-designed customized templates configured to specific specimens add contextual value in quality clinical diagnoses and data reuse for research. Work for well-designed customized templates takes work and collaboration with clinical input. The lack of guidance and available standardized EOSs often results in poor design with omission of crucial clinical information or the submission of meaningless information for EOSs. Moreover, the absence of guidelines means the lack of standardized definable dictionaries which serve as the appropriate dropdown menus for EOS sets in nonneoplastic specimens. This leads to the same narrative problem for EOSs seen with traditional paper requisition submissions, where unstructured narrative texts make extraction and repurposing of data elements for future data use for research impossible. This unfortunate reality stemming from lack of standardized frameworks leads to implementations of EOSs for pathologic specimens that do not live up to their optimal potential.[4] As CAP embarked on cancer synoptic reporting, designing customized EOS templates configured to specific specimens is a valuable effort for organizations like CAP to partake.

Our EOS implementation is early stage, and there is yet enough accrual of follow-up data and results of the implementation. Systematic collection of such data and results can serve as the basis of a detailed follow-up article. Preliminarily substantial value-added impacts from our synoptic EOS performance are as follows. First, the typing time is minimized using checkboxes, and the possibility of typographical errors is drastically reduced. The time for text editing is also reduced with the usage of checkboxes. Much of the data entries in this placental synoptic EOS are as discrete data fields, enabling data specific research queries for clinical information. Thus, our synoptic EOS serves as a workspace, learning environment, and powerful research tool for residents, fellows, and motivated pathologists for future projects. Responses are chosen from the list in our synoptic EOS, and free texts are typed only when a pertinent response is not available. Simultaneously, the synoptic EOS avoids the appearance of a massive checklist and includes only data elements necessary for diagnostic purposes. Second, a uniform order set reduces significant variation in terminologies and the presentation of data by the clinical team and hence. The reduction of variation avoids misunderstanding by the pathologists.[5] Third, having the availability of necessary data elements provided in synoptic EOS shortens the time to sign-out reports because it saves pathologists time by not having to sift through potentially multiple EMR sources, which commonly occurs in placental specimens that require extensive searching for information on the mother and the baby.

CONCLUSIONS

Our synoptic EOS for placental specimens is intended to provide a conceptual template for future designs of synoptic

EOSs for medical evaluation of other nonneoplastic specimens in anatomic pathology. The rationale and intent for mandating entry of critically necessary data elements is to optimize pathologic assessment and avert catastrophic sentinel errors of omission, particularly for nonneoplastic specimens where medical pathologic evaluation is highly dependent on such critical necessary information.

The aspiration for our synoptic EOS is to become an effective tool for effective communication between proceduralists and pathologists for proper diagnosis of placental specimens. Through our EOS, the appropriate and complete clinical context is conveyed from the clinical teams to the pathologist and where the pathologist can easily and rapidly extract the necessary information to render an accurate and precise diagnosis.

Building our synoptic EOS for placental specimens establishes an effective standardized/complete data framework available to others. The concept of standardizing complete EOS data framework should be extended to other nonneoplastic specimens such as liver, renal, and dermatologic, where critically necessary data elements are needed for optimal pathologic assessment. Moreover, our approach to EOS implementation is extensible to neoplastic pathology like gynecologic pathology and any other neoplastic subspecialty area. For an EOS customized to gynecologic pathology, data elements such as last menstrual period, history of hyperplasia, history of breast cancer such as lobular carcinoma, contraceptive/IUD use, and patient weight enable a quality endometrial biopsy diagnosis. Like the momentum for CAP efforts in implementing cancer synoptic reporting, we aspire for our efforts to initiate impetus for widespread demand and adoption of synoptic EOS tools in the preanalytic phase to enable quality pathologic reporting.

Overall EOSs are achievable with clinical input and buy-in, and the effort for developing EOSs has rewards for better patient care and beyond from a data perspective. There are no guidelines available and not enough publications for EOS implementation. Underleveraged is the potential for EOSs to capture cleanly data upstream, so data are passed downstream and repurposed for crucial clinical and research use cases. Our hope is for this viewpoint piece to serve as a useful summary of the untapped benefits and considerations behind an EOS and one center's experiences in implementing them.

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Conflicts of interest

There are no conflicts of interest.

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