One Small Step: Eliminating Investigator Sign-offs on Individual Epic Lab Reports

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Abstract

Clinical Investigators have long been tasked with physically signing and dating study subject lab reports originating from the electronic medical record (Epic), along with indicating clinical significance for any out-of-range value. This has put an undue burden on study staff, as this is often duplicative effort, providing little value. While experiencing rapid growth and limited budgets, the MCW Cancer Center Clinical Trials Office (CTO) has had to do more with less in many areas. The MCW Cancer Center CTO needed to find a way to maintain patient safety, but reduce the burden of these lab sign-offs, which had proved problematic for research nurses, coordinators, assistants, as well as investigators. In 2017, the MCW Cancer Center CTO implemented a Standard Operating Procedure that eliminated sign-offs on individual study subject laboratory reports, citing duplicative effort. The MCW Cancer Center CTO study staff anecdotally report considerable time savings by no longer having to obtain physician signatures on labs. This SOP has been widely accepted by sponsors and auditors since the SOP's official approval in 2017. Currently, staff are still obtaining physician signatures on lab reports that come from central labs, since they are not in the medical record, but this process is being examined further.

Introduction

In an effort to show continued investigator oversight, physician investigators have long been tasked with the requirement from sponsors to physically sign and date study subject lab reports originating from the electronic medical record (Epic), along with indicating clinical significance for any out-of-range value (Figure 1). This has put an undue burden on study staff, as this is often a duplication of effort. It is standard practice for the investigators to review patient labs in Epic prior to treatment, discuss with clinical research coordinators, and review against the study dose modification section. Often, it is not feasible for study staff to obtain a physical signature on printed labs prior to treatment, so signatures are often obtained days or weeks after treatment, providing little value to this process.

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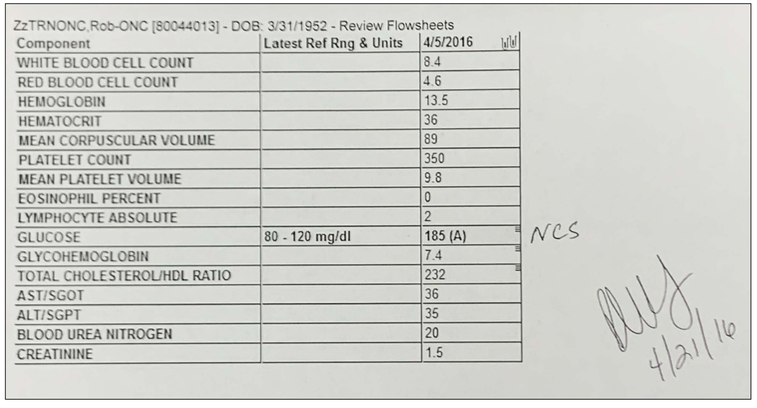
Methods and Materials

While experiencing rapid growth and limited budgets, like many U.S. cancer centers, the MCW Cancer Center Clinical Trials Office (CTO) has had to do more with less in many areas. The Cancer Center CTO needed to find a way to reduce the burden of these lab sign-offs, which had proved problematic for research nurses, coordinators, assistants, as well as investigators. The MCW Cancer Center CTO had to find a way to maximize productivity while still maintaining patient safety and proper study oversight. Signing off on laboratory reports that were days or weeks in the past was a hinderance to study staff, provided no value to the study or patients, and was taking time away from performing other meaningful safety-related tasks.

In 2017, the MCW Cancer Center CTO implemented a Standard Operating Procedure that eliminated sign-offs on individual study subject laboratory reports in Epic, citing duplicative effort. As a standard practice, the study coordinator and the subject's clinical team review patient laboratory results prior to treatment. These values are examined alongside the current protocol to check for any safety concerns, dose modifications, sponsor reporting, or other necessary actions. The investigator then approves the subject for treatment by signing the treatment orders. The study coordinator or research nurse determines clinical significance by reviewing the clinic documentation and establishing if any action resulted from the lab value (treatment held, transfusions or supplementation given, repeat lab draws, etc.). Only if a lab result is considered clinically significant, is it then reported as an adverse event on study case report forms.

If a study sponsor or auditor requests documentation that labs have been reviewed, the study staff provide documentation of the treatment plan sign offs in Epic (Figure 2).



ZzTRNONC,Rob-ONC [80044013] - DOB: 3/31/1952 - Review Flowsheets

Component	Latest Ref Rng & Units	4/5/2016
WHITE BLOOD CELL COUNT		8.4
RED BLOOD CELL COUNT		4.6
HEMOGLOBIN		13.5
HEMATOCRIT		36
MEAN CORPUSCULAR VOLUME		89
PLATELET COUNT		350
MEAN PLATELET VOLUME		9.8
EOSINOPHIL PERCENT		0
LYMPHOCYTE ABSOLUTE		2
GLUCOSE	80 - 120 mg/dl	185 (A)
GLYCOHEMOGLOBIN		7.4
TOTAL CHOLESTEROL/HDL RATIO		232
AST/SGOT		36
ALT/SGPT		35
BLOOD UREA NITROGEN		20
CREATININE		1.5

NCS

4/21/16

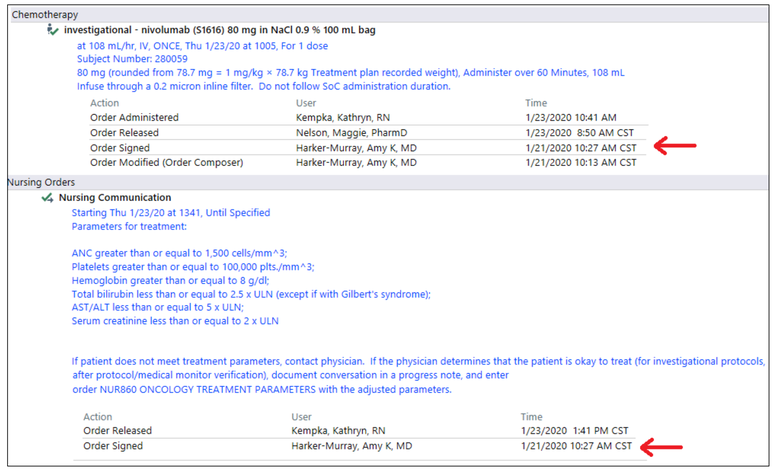
Figure 1: Lab report signed by investigator with clinical significance indicated (test patient)

Results

The MCW Cancer Center CTO has not collected and analyzed formal time saving data around this issue. However, MCW Cancer Center CTO study staff anecdotally report considerable time savings by no longer having to obtain physician signatures on labs. This SOP has also saved considerable time for staff since they are no longer recording labs as Adverse Events that are considered not clinically significant. This has been widely accepted by sponsors and auditors since the SOP's official approval in 2017. Investigators have not been burdened with signing these lab reports.

Conclusions & Discussion

Currently, study staff are still obtaining physician signatures on lab reports that come from central labs, since they are not in the medical record. MCW Cancer Center CTO is exploring the need for these signatures, since they are often received by sites in the days following treatment, and therefore, not being used for clinical and treatment-related decisions. These reports also typically ask for clinical significance to be recorded as well, another duplication of effort.



Chemotherapy

investigational - nivolumab (S1616) 80 mg in NaCl 0.9 % 100 mL bag
at 108 mL/hr, IV, ONCE, Thu 1/23/20 at 1005, For 1 dose
Subject Number: 280059
80 mg (rounded from 78.7 mg = 1 mg/kg × 78.7 kg Treatment plan recorded weight), Administer over 60 Minutes, 108 mL
Infuse through a 0.2 micron inline filter. Do not follow SoC administration duration.

Action	User	Time
Order Administered	Kempka, Kathryn, RN	1/23/2020 10:41 AM
Order Released	Nelson, Maggie, PharmD	1/23/2020 8:50 AM CST
Order Signed	Harker-Murray, Amy K, MD	1/21/2020 10:27 AM CST
Order Modified (Order Composer)	Harker-Murray, Amy K, MD	1/21/2020 10:13 AM CST

Nursing Orders

Nursing Communication
Starting Thu 1/23/20 at 1341, Until Specified
Parameters for treatment:

ANC greater than or equal to 1,500 cells/mm^3;
Platelets greater than or equal to 100,000 plts./mm^3;
Hemoglobin greater than or equal to 8 g/dl;
Total bilirubin less than or equal to 2.5 x ULN (except if with Gilbert's syndrome);
AST/ALT less than or equal to 5 x ULN;
Serum creatinine less than or equal to 2 x ULN

If patient does not meet treatment parameters, contact physician. If the physician determines that the patient is okay to treat (for investigational protocols, after protocol/medical monitor verification), document conversation in a progress note, and enter
order NUR860 ONCOLOGY TREATMENT PARAMETERS with the adjusted parameters.

Action	User	Time
Order Released	Kempka, Kathryn, RN	1/23/2020 1:41 PM CST
Order Signed	Harker-Murray, Amy K, MD	1/21/2020 10:27 AM CST

Figure 2: Investigator signing off on treatment plan in Epic

Acknowledgements

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