Electronic Source Documentation in EPIC Reduces Key Audit Findings and Aids in Remote Coordinating and Auditing

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Introduction

In 2018, space for paper charts became increasingly limited. Auditing revealed source was not being created or reviewed in a timely manner. Additionally, the clinical trials office (CTO) and cancer clinics are in separate buildings making obtaining PI signatures difficult. Moreover, research logs were not standardized, and current protocols were hard to access through VPN in clinic. A solution for these documentation shortcomings beyond increased staffing and space was needed.

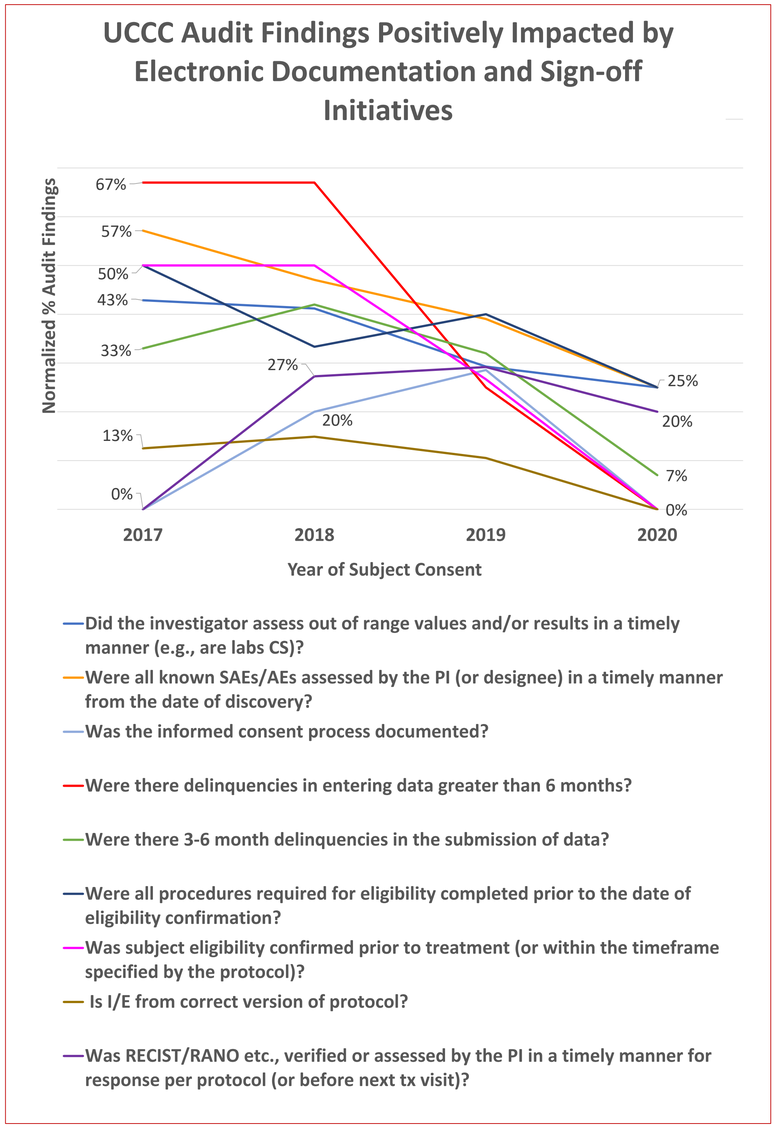
The use of standardized electronic logs and smart phrases in our electronic medical record system EPIC was intended to: increase timely creation of source documentation, reduce delays in maintaining source and PI reviews, and reduce the number of internal audit findings attributable to paper source usage. This was also intended to allow for remote auditing and monitoring.

Methods

In 2019, the CTO implemented the use of electronic source documentation in EPIC. The CTO developed EPIC smart phrases to standardize source documentation & visit notes. Electronic logs were developed within EPIC for lab/EKG clinical significance (CS), AEs, medical history, con-meds and RECIST to enable PI review and sign-off. In 2019, protocols were transitioned to an online eRegulatory system (Complion).

Results

Comparing normalized internal audit data from subjects consented in 2017-2020, our standardized metrics have quantified the benefits of documenting primarily within electronic systems. The accompanying graph details the most significant percentage changes in key audit findings during this time-period. Below the change in frequency of each is summarized, and a brief description of which electronic documentation tool or abandoned paper source-based practice impacted each.



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Results (cont.)

- **100%** decrease in:
  - Not documenting the consent process (smartphrase for consent discussion)
  - 6+ month delinquencies in data entry (no printing and wet-ink signature delays)
  - Eligibility documentation occurring after treatment (education, visit smartphrases, and allowing confirmations via email)
  - Eligibility criteria from incorrect protocol version (use of eRegulatory)
- **32%** decrease in AEs not being assessed by PIs/Sub-Is in a timely manner (electronic AE logs)
- **26%** decrease in 3–6-month data entry delinquencies (no printing and wet-ink signature delays)
- **25%** decrease in documentation of eligibility procedures after eligibility was confirmed (electronic CS, medical history, and RECIST logs; and visit smartphrases)
- **18%** decrease in PIs not documenting CS in a timely manner (electronic CS logs and visit smartphrases)
- **7%** decrease in RECIST not being assessed in a timely manner (electronic RECIST logs)

Discussion

While a change from paper to electronic source improved key audit findings other contributing factors were increased staffing, detailed workflows and an educator position. Each electronic tool was developed gradually allowing early adopters to test and champion use with peers. Having electronic documentation by 2020, the CTO easily continued auditing, monitoring and data entry activities remotely during the COVID-19 restrictions.

In the future we hope to implement electronic consenting and to find solutions to allow our EPIC records to interface directly with electronic data capture systems to reduce transcription errors and free up additional staff time to focus on clinical duties.

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