

Implementation of the YEARS algorithm to optimise pulmonary embolism diagnostic workup in the emergency department

Juliana Duffy,¹ Ferco Henricus Berger^{1b},^{2,3} Ivy Cheng,^{1,4} Dominick Shelton,^{4,5} Jean-Philippe Galanaud,^{6,7} Rita Selby,^{8,9} Kristine Laing,⁴ Tali Fedorovsky,¹⁰ John Matelski,¹¹ Justin Hall^{1,4}

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For numbered affiliations see end of article.

Correspondence to

Dr Juliana Duffy;
juduffy@gmail.com

ABSTRACT

Background Excessive use of CT pulmonary angiography (CTPA) to investigate pulmonary embolism (PE) in the emergency department (ED) contributes to adverse patient outcomes. Non-invasive D-dimer testing, in the context of a clinical algorithm, may help decrease unnecessary imaging but this has not been widely implemented in Canadian EDs.

Aim To improve the diagnostic yield of CTPA for PE by 5% (absolute) within 12 months of implementing the YEARS algorithm.

Measures and design Single centre study of all ED patients >18 years investigated for PE with D-dimer and/or CTPA between February 2021 and January 2022. Primary and secondary outcomes were the diagnostic yield of CTPA and frequency of CTPA ordered compared with baseline. Process measures included the percentage of D-dimer tests ordered with CTPA and CTPAs ordered with D-dimers <500 µg/L Fibrinogen Equivalent Units (FEU). The balancing measure was the number of PEs identified on CTPA within 30 days of index visit. Multidisciplinary stakeholders developed plan-do-study-act cycles based on the YEARS algorithm.

Results Over 12 months, 2695 patients were investigated for PE, of which 942 had a CTPA. Compared with baseline, the CTPA yield increased by 2.9% (12.6% vs 15.5%, 95% CI -0.06% to 5.9%) and the proportion of patients that underwent CTPA decreased by 11.4% (46.4% vs 35%, 95% CI -14.1% to -8.8%). The percentage of CTPAs ordered with a D-dimer increased by 26.3% (30.7% vs 57%, 95% CI 22.2% to 30.3%) and there were two missed PE (2/2695, 0.07%).

Impact Implementing the YEARS criteria may safely improve the diagnostic yield of CTPAs and reduce the number of CTPAs completed without an associated increase in missed clinically significant PEs. This project provides a model for optimising the use of CTPA in the ED.

PROBLEM

The gold standard for diagnosing a pulmonary embolism (PE) in the emergency department (ED) is CT pulmonary angiography (CTPA).¹ Rates of chest imaging are rising^{2,3} and this is problematic because excessive scanning contributes to radiation

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Pulmonary embolism (PE) is often investigated in the emergency department (ED) by CT pulmonary angiography (CTPA). Excessive CTPA usage contributes to unnecessary radiation exposure, ED crowding and high costs.

WHAT THIS STUDY ADDS

⇒ Quality improvement (QI) initiatives based on implementation of the YEARS criteria can improve CTPA yield and reduce the number of CTPAs ordered to investigate PE in the ED.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This QI project provides a model for optimising the use of CTPA in the ED.

exposure,^{4,5} overdiagnosis and unnecessary treatment,^{6,7} departmental crowding^{8,9} and higher healthcare costs.^{10,11}

International guidelines^{1,12-16} endorse the use of clinical decision rules (CDRs) that combine clinical assessment with D-dimer testing to determine the pretest probability of PE. This allows clinicians to reserve CTPA for only high-risk patients. The YEARS criteria¹⁷ (online supplemental appendix 1) is a relatively new CDR shown to improve the efficiency of ruling out PE (without imaging test) without compromising safety,¹⁷⁻²² though it has not been widely implemented in Canadian EDs.

Our hospital is an academic quaternary care hospital in Toronto, Canada with regional trauma, oncology, stroke, neurosurgical and interventional cardiology programmes. The ED serves a diverse, complex population and has approximately 62 000 annual visits. Therefore, efficient processes are crucial for patient safety and departmental flow.

CTPA yield, defined as the proportion of imaging studies diagnostic for acute PE, is often used as a surrogate for imaging appropriateness.^{23 24} A recent audit of CTPAs performed in our ED to investigate PE (n=1301) found the yield to be 12.6% (164/1301). This was approximately 5% lower than the yield reported in a 2021 study of Canadian EDs (17.7%)²⁵ and 16% lower than in Europe (29%).²⁶ We were concerned that our hospital may be over-ordering CTPAs in the ED, possibly from inconsistent use of CDRs such as the Wells criteria or YEARS. Therefore, our aim was to improve the diagnostic yield of CTPA for PE by 5% within 12 months of implementing the YEARS criteria.

BACKGROUND

If untreated, PE has a 25% case fatality rate.²⁷ Diagnosis is challenging as PE is relatively uncommon, but its symptoms of chest pain and dyspnoea are very common and present in many benign conditions.

Multiple CDRs have been developed to standardise PE diagnosis, improve patient safety and limit resource use. Prior to this study, our ED used the Wells criteria²⁸ and the Pulmonary Embolism Rule out Criteria (PERC)²⁹ to evaluate the pretest probability of PE. For the Wells criteria, patients are stratified into 'PE likely' and 'PE unlikely' based on the presence of seven risk factors.²⁸ Among patients where a diagnosis of PE is considered unlikely, PE is ruled out with a negative D-dimer (<500 µg/L Fibrinogen Equivalent Units (FEU)), foregoing a CTPA.²⁸ For all others (PE likely or PE unlikely and D-dimer >500 µg/L FEU), a CTPA is required, accounting for 60%–70% of patients.^{17 28 30–32} For PERC, clinicians can forego D-dimer testing if none of its eight criteria are present.²⁹

Recently, a simplified decision rule called YEARS was developed.^{17 20} The YEARS criteria uses three components from the Wells criteria: haemoptysis, signs of deep vein thrombosis and PE most likely diagnosis. These criteria have the greatest predictive value for PE when the D-dimer test result is known.²⁰ The YEARS algorithm departs from traditional PE CDRs in two ways: (1) D-dimers are completed for all patients investigated for PE, not just low-risk patients and (2) the negative D-dimer threshold is increased from 500 to <1000 µg/L FEU when all risk factors are absent. Compared with prior CDRs, a greater proportion of patients have PE safely ruled out without a CTPA.¹⁷ Historically, the safety of D-dimer tests to rule out PE in moderate-risk groups was questionable,³³ but recent investigations found that the false negative rate of newer, high sensitivity D-dimer assays is similar in moderate and low-risk patients.^{20 34 35} Compared with Wells, YEARS was shown to have superior efficiency in ruling out PE,¹⁹ decreased CTPA use by 14% without an increase in clinically significant missed PEs,^{17 21 22} and was safe in pregnancy.³⁶ Additionally, YEARS decreased ED length of stay and reduced costs.¹⁰

Despite endorsement by international guidelines,^{1 12–16} EDs have had variable success in CDR implementation.^{2 37 38}

In 2007–2008, using only the Wells criteria, our ED was unsuccessful in reducing CTPAs despite high adherence.³⁷ This may have been confounded by the lower specificity of the D-dimer assay at the time, undermining provider confidence in D-dimer screening. Additionally, lack of familiarity with CDRs,^{39 40} absence of written ED diagnostic algorithms⁴⁰ or underestimation of D-dimer testing sensitivity⁴¹ have been cited as barriers to CDR uptake. Therefore, we sought to operationalise the YEARS algorithm by tailoring its implementation to the unique needs, practice patterns and clinical context of our ED. Finally, in May 2018, we switched our D-dimer assay to the INNOVANCE D-Dimer assay (Siemens Healthineers, Germany) reported in µg/L FEU, which had also been utilized in the YEARS derivation cohort study.

MEASUREMENTS

Baseline measurements were collected from medical records for 17 months (September 2019 to January 2021). Our hospital's decision support team collected patient data from electronic medical records, the Emergency Department Information System and the Laboratory Information System. We included patients >18 years with suspected PE (ie, triage complaint of chest pain, pleuritic pain, dyspnoea) who had a CTPA or D-dimer ordered. Reports were sent to a single, non-blinded chart abstractor who performed case selection. A second abstractor reviewed a sample of charts to ensure consistency and reliability of case selection. Finally, we collected demographic information (age, sex), details of visit (date of presentation, presenting complaint, disposition), as well as type of investigation (D-dimer only, CTPA only, both) and result.

For the baseline ED audit, 2804 patients were investigated for PE. The mean age of patients was 54.1 years (SD 18.9) and there were more women than men (61.4% vs 38.6%). Of these 2804 patients, 1503 (53.6%) were investigated with a D-dimer only, 902 (32.1%) received a CTPA only and 399 (14.2%) had a D-dimer and CTPA. The overall diagnostic yield of CTPA was 12.6% (164/1301). Of 399 patients that had CTPA and D-dimer, 7.5% (30) had a CTPA despite a negative D-dimer (<500 µg/L FEU). Among patients that had CTPA and a D-dimer who were diagnosed with PE on CTPA, 1/47 (2.1%) had a D-dimer <500 µg/L FEU, 5/47 (10.6%) had a D-dimer between 500 and 999 µg/L FEU and 41/47 (87.2%) had a D-dimer >1000 µg/L FEU.

Throughout the implementation period, monthly reports of all patients meeting our study criteria were reviewed. For each outcome we used a linear probability model within the generalised estimating equations framework, to estimate the % pre, % post and pre-post delta %, while accounting for repeated measures. We report a 95% CI for each estimate. The analysis was performed using the *Geepack* package in R V.4.2.1. Run charts were created in Microsoft Excel to graphically display and track our progress.⁴² The outcomes of our study were as follows.

Aim/primary outcome

- ▶ Diagnostic yield of CTPA for PE in the ED (proportion of studies diagnostic for acute PE).

Secondary outcome measures

- ▶ Rate of CTPAs ordered to rule out PE (total CTPAs ordered/total patients investigated with D-dimer).

Process measures

- ▶ Percentage of CTPAs ordered with a D-dimer.
- ▶ Percentage of CTPAs ordered with a D-dimer <500 µg/L FEU.

Balancing measure

- ▶ PE identified on CTPA within 30 days of index visit after PE excluded based on the YEARS criteria.

Design

A multidisciplinary team representing relevant specialties (emergency medicine, radiology, thromboembolism and laboratory medicine) and provider groups (staff physicians, physician assistants (PAs) and trainees) were assembled to guide the project. After reviewing the literature and ED baseline audit, we decided on two interventions: education on the YEARS criteria and development of a PE diagnostic algorithm. To mitigate challenges of implementing a new departmental diagnostic pathway,^{21 38–41 43 44} we invited feedback from colleagues during each plan-do-study-act (PDSA) cycle. Our protocol was registered with and approved by the Quality and Patient Safety Department at our institution.

PATIENT and public involvement

Patients and the public were not involved in the design, definition of measures, conduct or evaluation of this project.

STRATEGY

PDSA cycle 1: presentation of the problem and audit of practice patterns

For cycle 1, we provided the results of our baseline departmental audit. Our aim was to identify how clinicians investigated PE through group discussion and polling. We administered an anonymous survey to all physicians and PAs during a departmental meeting. Afterwards, in a follow-up email, 39/42 (92.9%) of the target audience responded. Clinicians were unaware of the low yield of CTPA, and there was agreement on overusage of CTPA in the ED. Although a high number of clinicians used a CDR (38/39, 97.4%), such as Wells, PERC or YEARS, for ordering CTPA's, several clinicians used gestalt alone (8/39, 20.5%). Only 12/39 (30.8%) of clinicians used the YEARS criteria or a D-dimer <1000 µg/L FEU to rule out PE in patients with low pretest probability (10/39, 25.6%). Therefore, we confirmed that PE investigation was heterogeneous and that there was interest in process improvement.

PDSA cycle 2: YEARS criteria education

Next, we educated the clinicians about the safety and efficacy of the YEARS criteria at a departmental meeting and through email. From the first PDSA cycle, we learnt that clinicians were concerned of the using the D-dimer to rule out PE in individuals with a moderate pretest probability^{20 34 35} and in conditions with a high false-positive rate (eg, oncology^{45 46} and COVID-19⁴⁷). This was not surprising since older CDRs discouraged D-dimer testing in higher-risk patients. Consequently, we tailored our presentations to address such concerns. Knowledge translation included links to relevant literature in our email communications and offers to meet with any clinicians who wanted to discuss the literature more fully.

PDSA cycle 3: development and dissemination of departmental algorithm

Our learnings from the first two PDSA cycles revealed ordering heterogeneity and a knowledge gap that was subsequently addressed. Our resulting change idea was the creation of a PE-ordering algorithm based on the YEARS criteria (online supplemental appendix 1).¹⁷ To foster engagement and test pathway usability, we collaborated with several ED clinicians. Multiple iterative phases were carried out prior to implementation of the final algorithm (figure 1). We incorporated feedback which included a separate pathway for pregnant or unstable patients, major exclusion criteria and a prompt on when to use PERC. The final algorithm was posted in clinician workspaces and circulated electronically.

We answered questions as they arose and delivered an orientation to new clinicians onboarding to our hospital's ED. We regularly shared results and sent electronic reminders for the first 9 months of the project. Afterwards, we discontinued reminders to assess for a sustained use of the algorithm.

Since we could not directly monitor clinician uptake of the algorithm, we measured the percentage of CTPAs ordered with a D-dimer and percentage of CTPAs ordered with a D-dimer <500 µg/L FEU as a surrogate for algorithm usage.

RESULTS

During the 12-month study, 2695 patients were investigated for PE (compared with 2804 during the 17-month baseline period). The mean age was 55 with more women than men (62.7% vs 37.3%). There was no difference in the mean age or sex preintervention and postintervention.

Compared with baseline, we found a 2.1% and 3.8% increase in CTPA yield at 2 months and 5 months, respectively. To assess for sustainability, we assessed CTPA yield at 12 months postintervention and found the CTPA yield still increased by 2.9% compared with baseline (15.5% vs 12.6%, 95% CI -0.06% to 5.9%) (figure 2).

There was an 11.4% decrease in the rate of CTPAs ordered (35.0% vs 46.4%, 95% CI -14.1% to -8.8%),

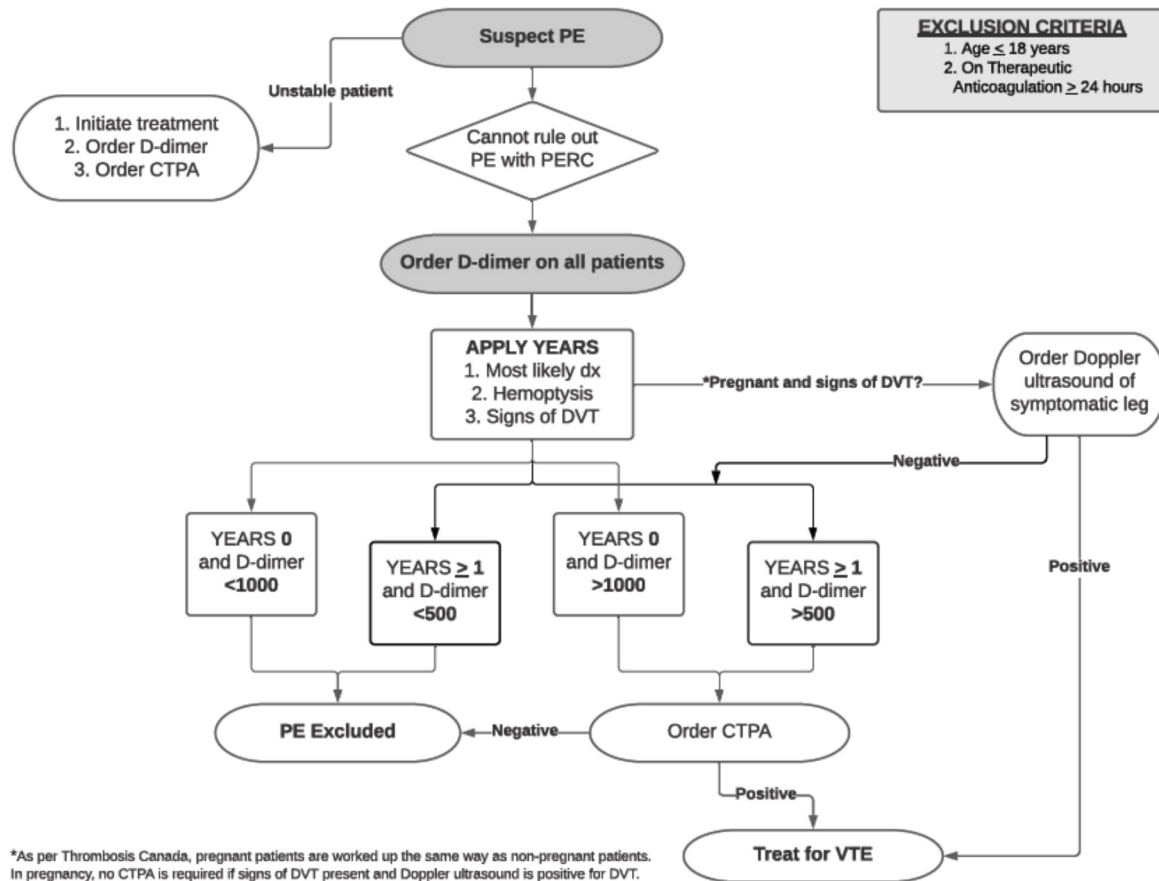


Figure 1 Departmental algorithm. CTPA, CT pulmonary angiography; DVT, deep vein thrombosis; PE, pulmonary embolism; PERC, Pulmonary Embolism Rule out Criteria; VTE, venous thromboembolism.

in the postintervention period compared with the pre intervention period (figure 3). Additionally, there was a 26.3% increase in the rate of patients with a D-dimer prior to CTPA (57.0% vs 30.7%, 95% CI 22.2% to 30.3%) (figure 3). At 12 months postintervention, there was no

significant reduction in the rate of CTPAs ordered with D-dimer <500 $\mu\text{g/L}$ FEU (7.1% vs 7.5%, 95% CI -3.8% to 3.0%) (figure 3).

During the study period, there were two 'missed PEs' (PE ruled out with YEARS criteria then diagnosed on

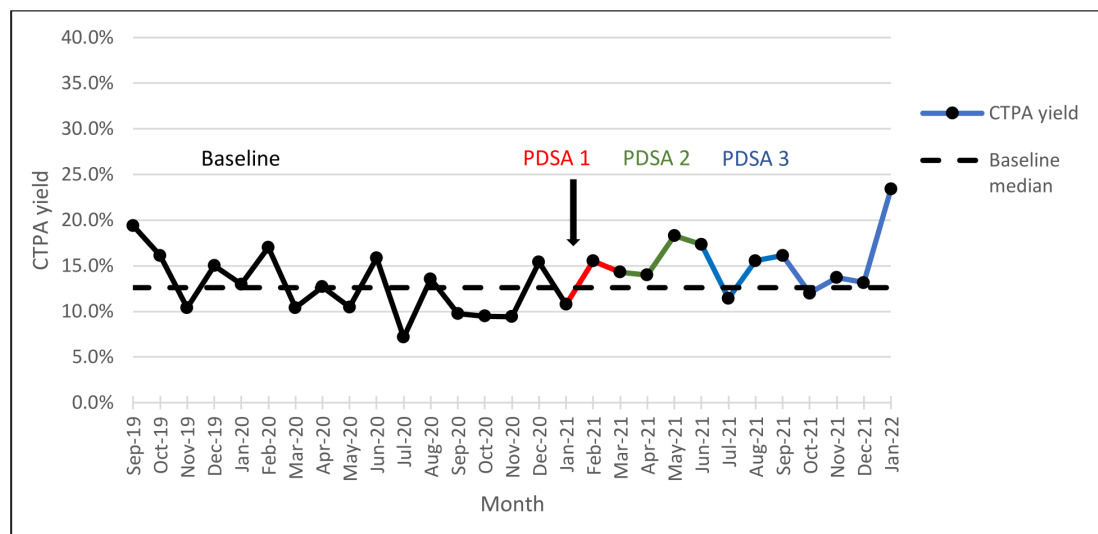


Figure 2 Run chart of CTPA yield at baseline and by PDSA cycle. Run chart depicting the CTPA yield (positive CTPAs/all CTPAs performed) in the preintervention and postintervention period. The arrow indicates when the first PDSA cycle began. The dotted line indicates the baseline median CTPA yield of 12.6% in the preintervention period. CTPA, CT pulmonary angiography; PDSA, plan-do-study-act.

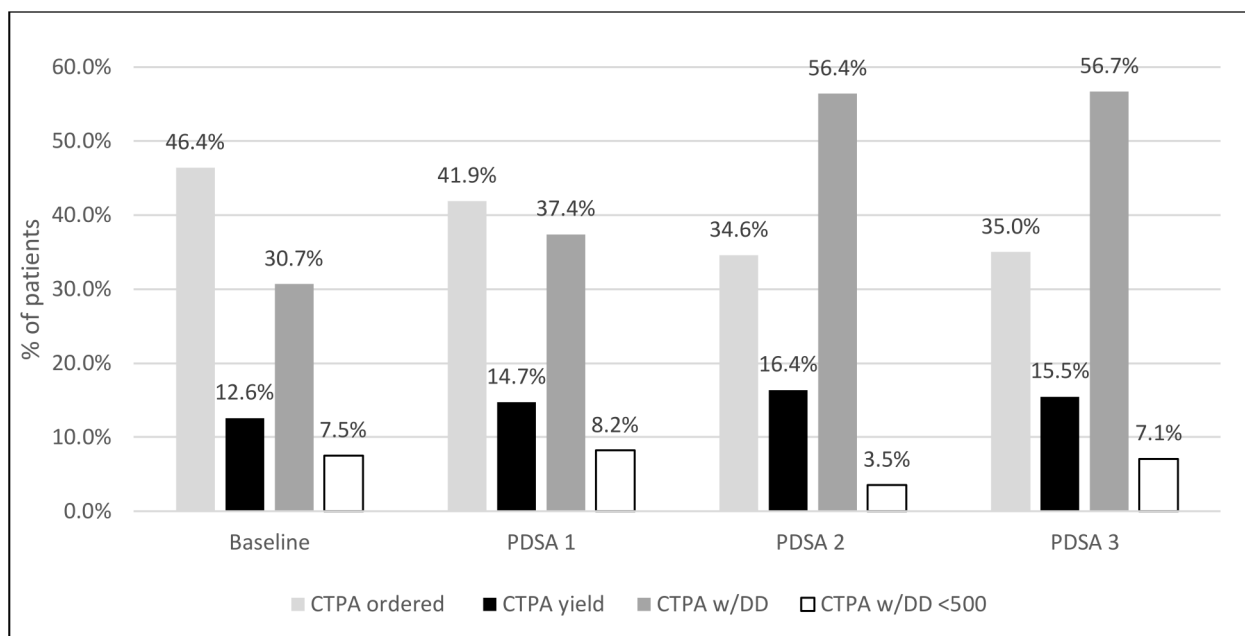


Figure 3 Primary/secondary outcomes and process measures by PDSA cycle. CTPA ordered=number of CTPA/all patients investigated for PE; CTPA yield=positive CTPA/all CTPAs performed; CTPA w/DD=CTPAs with D-dimer/all CTPAs performed; and CTPA w/DD <500=CTPAs ordered with D-dimer <500/CTPAs with D-dimer. CTPA, CT pulmonary angiography; PDSA, plan-do-study-act.

CTPA within 30 days of index visit). There were two additional cases where a PE was found with a D-dimer <500 µg/L FEU.

Lessons and limitations

Our primary goal was to improve the diagnostic yield of CTPAs when investigating for PE by using the YEARS criteria. Based on challenges previously described in the literature,^{21 38–41 43 44} we sought feedback from clinicians during the project's design, implementation and analysis to maximise its suitability in our ED. Additionally, we sent regular electronic communication to clinicians with project updates and links to relevant literature. Although we did not meet our target of a 5% absolute improvement in CTPA yield, our intervention showed a 2.9% increase from the baseline of 12.6%–15.5%. Further, we achieved a significant reduction in the number of CTPAs ordered to rule out PE in our ED. We acknowledge that further work towards reaching the 5% target is warranted and will be addressed in our next PDSA cycle (detailed below). We also noted a plateau in both measures at the end of the third PDSA cycle which coincided with cessation of project updates. This underscores the importance of continued engagement to maximise sustainable change and the need to onboard new clinicians.

Over the course of 12 months, where PE was suspected in 2695 patients, there were two 'missed PEs'. This corresponds to a miss rate of 0.07% which is less than the accepted threshold of 1.8% for low-risk patients,^{18 19} below which, the risk of testing may outweigh the benefits.⁴⁸ However, this may be an underestimation as we could not account for ED visits to other hospitals or death out of hospital. In the first case, as per the physician note,

PE was ruled out based on low clinical probability with a YEARS score of zero and a D-dimer (698 µg/L FEU). However, a small subsegmental PE (not clinically significant) was diagnosed on CTPA at a subsequent visit, highlighting the importance of clear discharge instructions from the ED. In the second patient, CTPA was ordered despite a D-dimer <500 µg/L FEU and a segmental PE was found. This individual had a history of massive PE and Crohn's disease but was not anticoagulated. The false negative D-dimer may be explained by a delay in presentation as caution is advised when interpreting D-dimers in those with symptoms >14 days.⁴⁹ This PE was also noted by a staff radiologist to be tiny, which may explain the low D-dimer. According to the Clinical and Laboratory Standards Institute, a D-dimer value may be below threshold if a clot is small and of insufficient size to raise D-dimer values above the threshold.⁵⁰ Finally, there were two other cases in which PE was diagnosed with a D-dimer <500 µg/L FEU. However, these individuals were on therapeutic anticoagulation and therefore met the exclusion criteria for the algorithm.

The total number of patients investigated for PE may be over-estimated as documentation specifically stating concern for PE was inconsistent. For example, an alternative pathology (ie, aortic dissection) may have been under consideration among those investigated with D-dimer only. To ensure homogeneity between groups, we applied consistent inclusion rules during chart abstraction. Further, while we do not have convincing reasons from our data to believe diagnostic performance of CTPA over the course of this investigation has significantly changed, we cannot entirely exclude that a CT scanner

replacement during the last 9 months of the study had any influence on detection of pulmonary emboli. Additionally, it is worth noting that our ED saw higher volumes of patients with COVID-19 in the study phase compared with the baseline data collection phase. Since COVID-19 is known to be a prothrombotic state, it is possible that the incidence of PE was higher in our study population, and this may have contributed to the higher diagnostic yield. It was outside the scope of this project to collect epidemiological data on which patients also had a diagnosis of COVID-19.

Another limitation of the project was relying on indirect measurement for adherence to the YEARS criteria (see Process measures). The increased frequency of patients that had D-dimer testing with CTPA suggests high uptake of the algorithm. However, we did not see a significant change in the rate of CTPAs with a D-dimer <500 µg/L FEU, indicating that not all providers were following the algorithm. Alternatively, it may have been that CTPA was ordered before a D-dimer result was available based on high pretest probability (suggests uptake), exclusion criteria were not appropriately applied (suggests improper application), or the utility of the D-dimer among COVID-19 positive patients early in the pandemic was unknown (suggests knowledge gap).

Finally, complete patient level data to assess pretest probability and to ensure exclusion criteria were properly applied when using the algorithm was not available. Therefore, it was impossible to determine what percentage of CTPAs were potentially avoidable from the 163/175 patients with negative CTPA and a D-dimer between 500 and <1000 µg/L FEU. To address this limitation, we plan to embed the algorithm in our electronic ordering system as an additional intervention. Previous work has shown implementation of electronic clinical decision support can increase the CTPA yield.² This would also support ongoing algorithm engagement through frequent prompting to use the YEARS criteria. We have already collaborated with our development team to create a drop-down style menu based on the YEARS items that will appear when ordering chest imaging.

CONCLUSION

Using quality improvement methodology, we may have been able to safely increase the diagnostic yield of CTPA by 2.9% using the YEARS criteria. Although this was below our project's aim of 5%, we also successfully decreased the frequency of CTPAs ordered to investigate PE by 11.4%. Importantly, this was not associated with an increase in clinically significant missed PE.

Our study highlights the importance of engaging clinicians during each PDSA cycle and providing ongoing communication of project outcomes to facilitate sustained change. We intend to further improve our outcomes through implementation of electronic ordering assistance to facilitate ongoing application of the YEARS algorithm. By sharing these interventions, we aim to provide

a model for other Canadian EDs interested in optimising PE investigation.

Author affiliations

- ¹Division of Emergency Medicine, Department of Medicine, Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
- ²Department of Medical Imaging, Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
- ³Department of Medical Imaging, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada
- ⁴Department of Emergency Services, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada
- ⁵Department of Family & Community Medicine, Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
- ⁶Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada
- ⁷Department of Medicine, Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
- ⁸Department of Laboratory Medicine & Pathobiology, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada
- ⁹Department of Laboratory Medicine & Pathobiology, Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
- ¹⁰Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
- ¹¹BioStatistics Research Unit, University Health Network, Toronto, Ontario, Canada

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ORCID iD

Ferco Henricus Berger <http://orcid.org/0000-0003-3696-2554>

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