

Computer-Aided Detection, Triage and Notification Software for Computed Tomography Pulmonary Angiography (CTPA)

Submitted by Aidoc

ICD-10 Coordination and Maintenance Committee

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CODING ISSUE

- Today, there are no unique ICD-10-PCS codes to describe CT pulmonary angiography (CTPA) with computer-assisted triage and notification
- A unique ICD-10-PCS code is needed to identify CTPA with computer-assisted triage and notification
- Aidoc has applied for New Technology Add-on Payment (NTAP) for Briefcase for PE, a radiological computer-assisted triage and notification software
 - Briefcase for PE is used in patients with suspected PE to identify, prioritize, and notify radiologists of time sensitive images for review

PULMONARY EMBOLISM

Pulmonary embolism is the third most common cause of death from cardiovascular disease

In the United States, in 2017, the age-standardized annual mortality rate with PE as the underlying cause was 4.3 per 100,000¹

- Since 2006 the CDC Multiple Cause of Death database, shows an increase in PE-related age-standardized mortality rates in adults aged 65–79 years¹
- Treatment strategies vary from anticoagulation therapy to advanced treatment including catheter-directed thrombolysis, thrombectomy, etc²⁻⁴

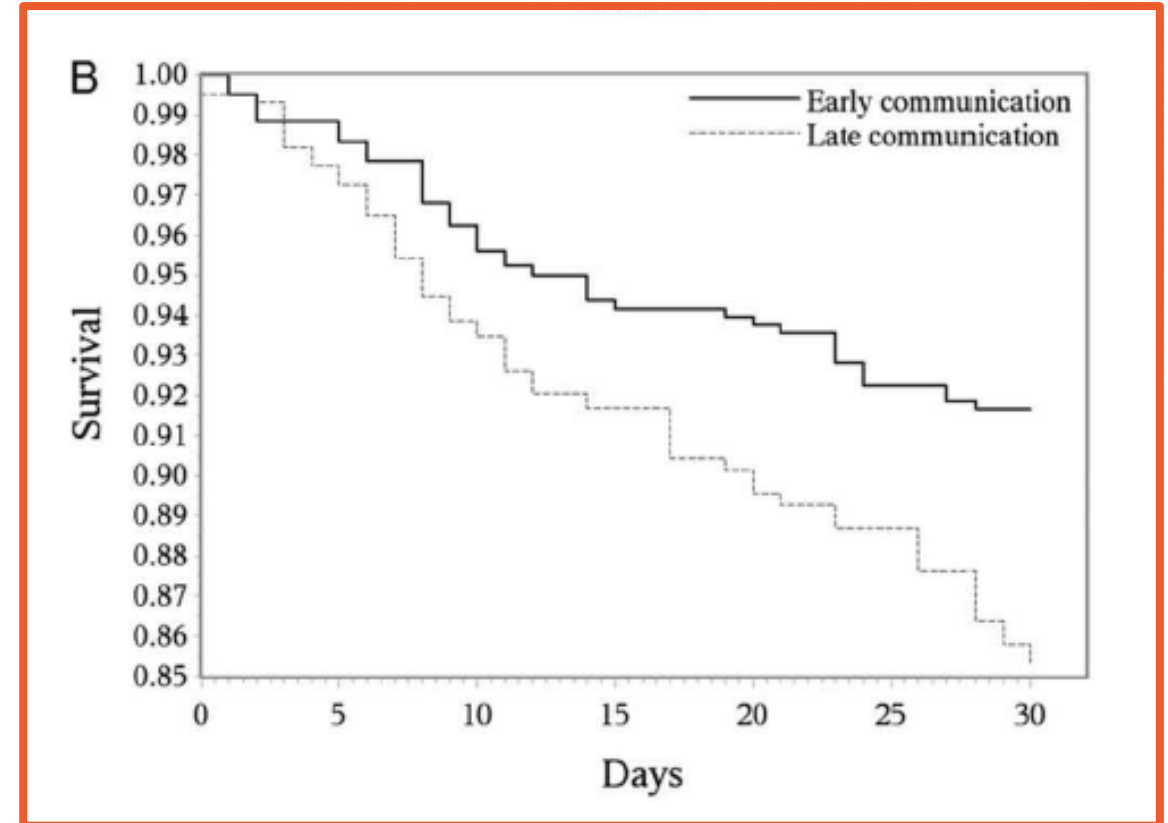
Clinical studies have demonstrated a strong correlation between time to communication of PE findings, treatment and clinical outcomes⁵⁻⁷

Pulmonary embolism is a life-threatening medical emergency that demands urgent intervention

- Acute, symptomatic PE can cause death within 1 hour of onset in up to 10% of cases⁸

TIME TO COMMUNICATION OF PE IS LINKED TO TIME TO TREATMENT AND CLINICAL OUTCOMES

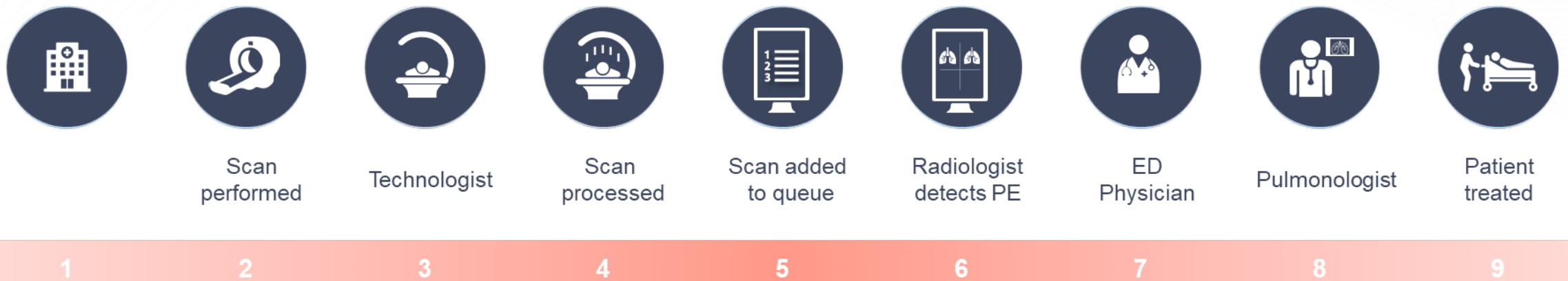
- Studies have demonstrated a strong correlation between time to communication of PE findings, treatment and clinical outcomes¹¹⁻¹⁵
- A retrospective study of 796 patients showed that early communication (<1.5h) of imaging findings was associated with shorter time to anticoagulation treatment initiation and lower all-cause and PE-related 30-day mortality¹¹



Cumulative all-cause mortality rate stratified by the early (<1.5h) and late (>1.5h) communications Weighted Kaplan-Meier curves¹¹

STANDARD OF CARE

- Clinical management of patients with PE is based on the radiologist interpretation of CTPA images and diagnosis⁹



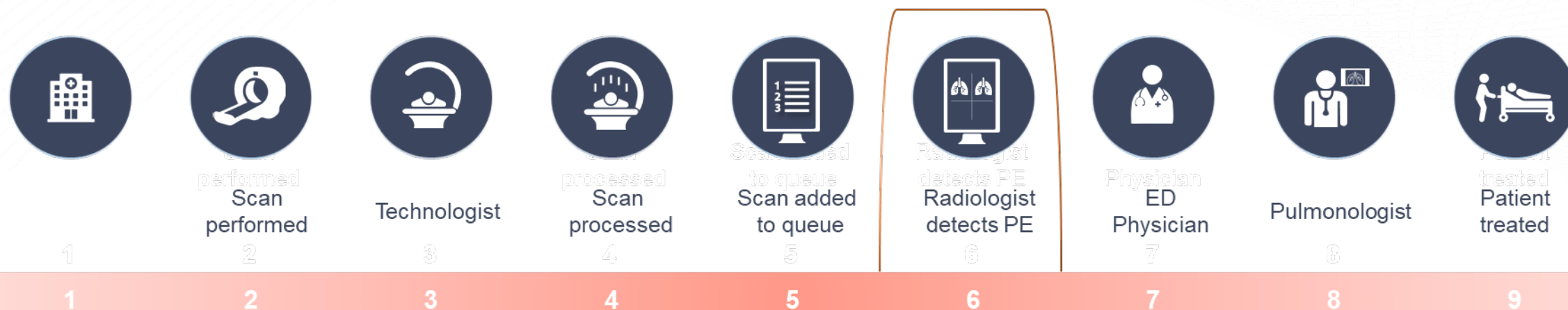
- A first-in-first-out (FIFO) clinical workflow for diagnosis applies, resulting in delays in treatment, including wait time for formal radiology report ^{10,11}

BRIEFCASE FOR PULMONARY EMBOLISM

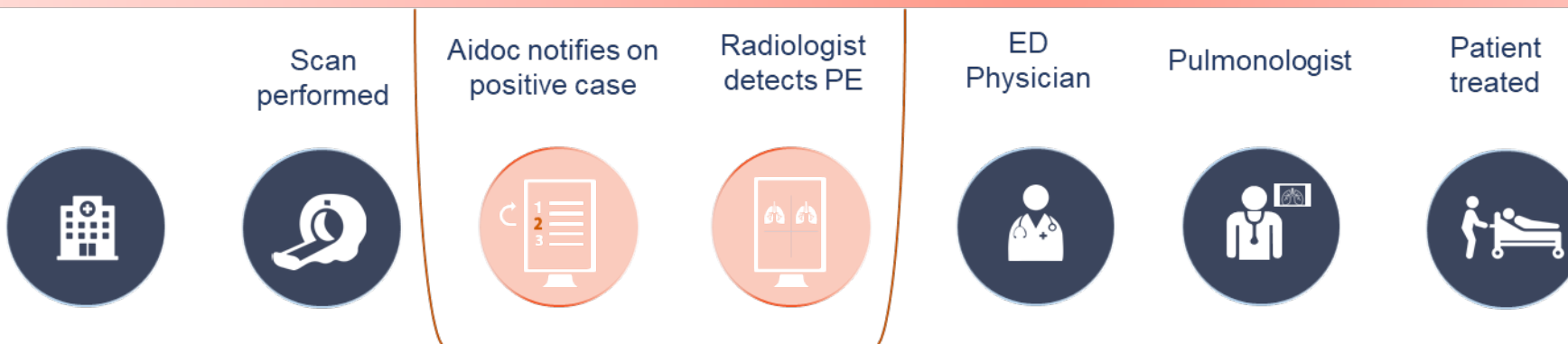
- Aidoc's Briefcase for PE is an FDA cleared solution providing AI-based triage and notification of suspected PE
 - Software as a Medical Device (SaMD)
- The device identifies, flags and communicates to radiologists suspected positive findings in CTPA studies
- Image triage and radiologist notification facilitates earlier review of the relevant original images in the PACS
- The suspected positive case is viewed earlier than it would be under the standard of care facilitating earlier diagnosis and treatment

BRIEFCASE BYPASSES FIFO WORKFLOW ENABLING FASTER TIME TO PE DIAGNOSIS & TREATMENT

WITHOUT BRIEFCASE

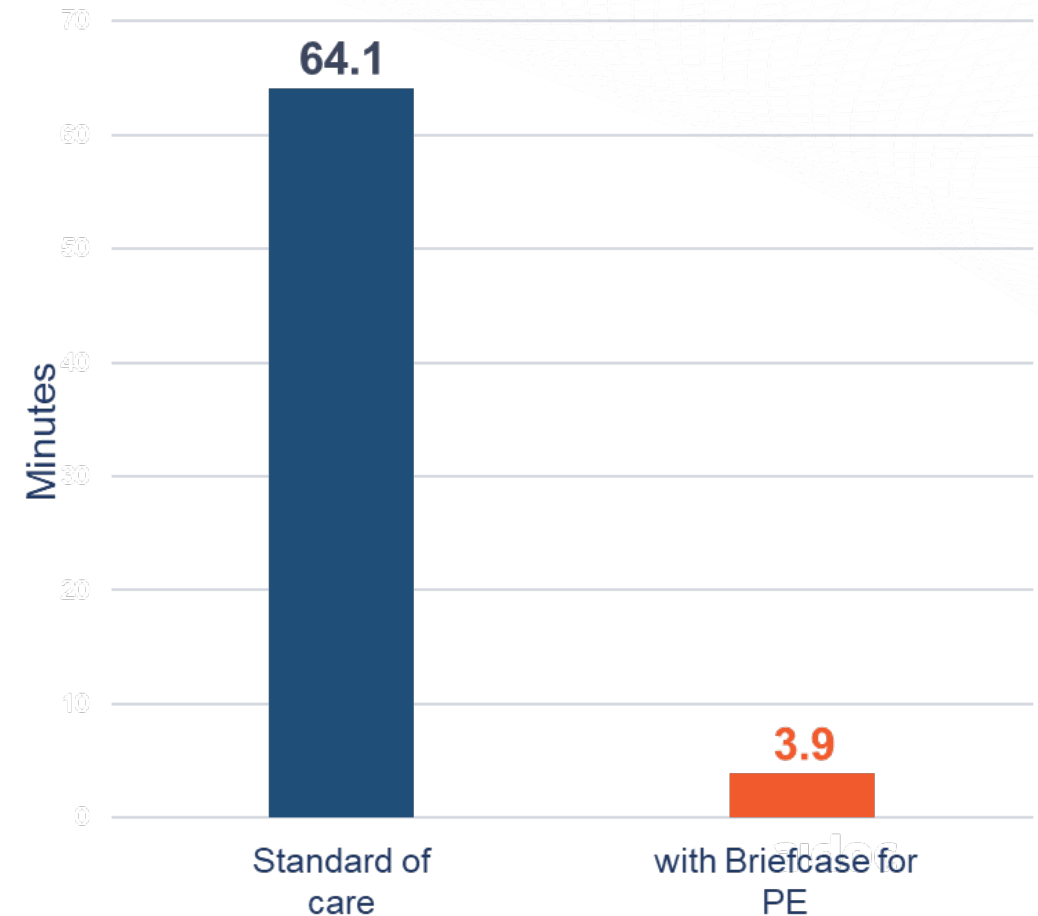


WITH BRIEFCASE



FDA PIVOTAL STUDY DEMONSTRATES SUBSTANTIAL TIME REDUCTION

- Pivotal study evaluated 184 cases from 3 clinical sites (2 US and 1 OUS)¹⁶:
 - Primary endpoint: accuracy of PE detection
 - Secondary endpoint: time-to-notification compared to the standard of care
- Data from the study showed Aidoc's Briefcase for PE substantially shortened the time to PE notification as compared to the standard of care:
 - Average time-to-notification with Aidoc was 3.9 minutes (95% CI: 3.7-4.1) compared with the standard of care time-to-exam-open of 64.1 minutes (95% CI 36.6-91.5)
 - Sensitivity was 93.0% (95% CI: 90.2%-95.1%)
Specificity was 93.7% (95% CI: 92.7%-94.6%)

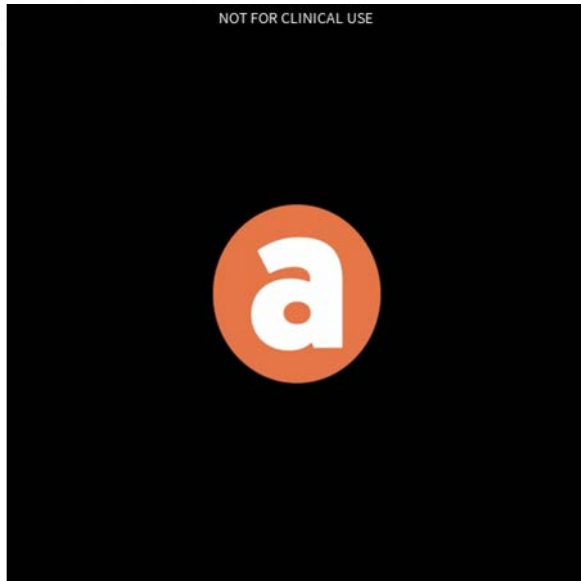


HOW DOES BRIEFCASE FOR PE WORK?



1. CTPA images are automatically forwarded to Aidoc's cloud-based engine where they are analyzed by an AI algorithm
2. When Aidoc detects a suspected PE, the radiologist is notified
3. The notification prompts the radiologist to review the CTPA images

DOCUMENTING BRIEFCASE IN THE MEDICAL RECORD



Processed by Aidoc

- A record is created by Aidoc directly in the PACS each time Aidoc Briefcase for PE is used for a particular patient
- A record in the PACS consists of adding a new single slice image series in the existing patient study indicating the study was processed by Aidoc
- This information can then be added to the EMR by the reporting radiologist (some EMRs also utilize application program interfaces or API that can pull this data into the EMR automatically)

SUMMARY

- There are currently no unique ICD-10-PCS codes that identify when CTPA with radiological computer-assisted triage and notification is used
- Aidoc recommends creation of a new ICD-10-PCS code to identify when CTPA with radiological computer-assisted triage and notification is used