CASE STUDY REPORT

Clinical Decision Support for Community-Acquired Pneumonia

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Acronyms

ACO	Accountable Care Organization
AHRQ	Agency for Healthcare Research and Quality
APRN	Advanced Practice Registered Nurse
BTS	British Thoracic Society
BUN	Blood Urea Nitrogen
CAD	Computer-Aided Detection
CAP	Community Acquired Pneumonia
CDS	Clinical Decision Support
CMS	Centers for Medicare & Medicaid
COPD	Chronic Obstructive Pulmonary Disease
CPOE	Computerized Provider Order Entry
ED	Emergency Department
EHR	Electronic Health Record
HITECH	Health Information Technology for Economic and Clinical Health
ICU	Intensive Care Unit
IDSA/ATS	Infectious Diseases Society of America/American Thoracic Society
IOM	Institute of Medicine
IT	Information Technology
MD	Medical Doctor
PSI	Pneumonia Severity Index
USE	Usefulness Satisfaction and Ease of Use

Glossary of Terms

Alert

Alerts (active CDS) are typically designed as modal dialog boxes (requiring an action to dismiss) and have one or more buttons and advisory content. They are inherently and purposely disruptive as their explicit acknowledgment by a mouse click or a keystroke is necessary to continue.¹

Clinical Decision Support (CDS)

A CDS system is a common feature of EHR systems that provides clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times to enhance health and health care. A CDS system can encompass a number of tools and interventions like computerized alerts and reminders, clinical guidelines, order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools.

Community-Acquired Pneumonia (CAP)

An illness that develops in people with limited or no contact with medical institutions or settings. The most commonly identified pathogens are Streptococcus pneumoniae, Haemophilus influenzae, atypical bacteria (i.e., Chlamydia pneumoniae, Mycoplasma pneumoniae, Legionella sp), and viruses.

CRB-65

A validated tool that estimates mortality of CAP to help determine inpatient vs. outpatient treatment. The tool takes into consideration the following symptoms: Confusion, Respiratory rate, Blood pressure, and the person is 65 years of age and older. A CRB-65 score ranges from 0 to 4. This tool is useful when blood tests are not readily available. The term "CURB/CRB-65" is used in this report to refer more generally to the tool.

CURB-65

A validated tool that estimates mortality of CAP to help determine inpatient vs. outpatient treatment. The tool takes into consideration the following signs and symptoms: Confusion, Urea nitrogen, Respiratory rate, Blood pressure, and the person is 65 years of age and older. A CURB-65 score ranges from 0 to 5. The term "CURB/CRB-65" is used in this report to refer more generally to the tool.

Pneumonia Severity Index (PSI)

A validated tool that helps identify CAP patients who can safely be treated with outpatient antibiotics. The PSI involves calculating a score using 20 clinical factors and places a given patient into one of five risk classes.

Executive Summary

NORC at the University of Chicago and Yale School of Medicine (the NORC team) are pleased to present this Case Study Report on our project, Clinical Decision Support (CDS) for Community-Acquired Pneumonia (CAP), funded under contract with the Agency for Healthcare Research and Quality (AHRQ) (Contract No. HHSP233201500023I).

Introduction

The NORC team conducted a research project to address the safety concerns over diagnostic errors. Specifically, we developed clinical decision support (CDS) for community-acquired pneumonia (CAP), and tested its implementation in two ambulatory care settings: an emergency room and a primary care practice. In addition, we developed an implementation toolkit, which can serve as a guide for other ambulatory care practices interested in implementing the CDS for CAP in the future.

This project was motivated by the gaps in patient safety identified in the AHRQ's *Technical Brief Number 27: Patient Safety in Ambulatory Settings*.² The brief identified important differences between inpatient and ambulatory safety, as well as areas of research that could help identify strategies to improve patient safety in ambulatory settings, including evaluations of patient safety practices related to diagnostic errors in ambulatory settings.

Diagnostic errors are a significant issue in health care settings and have been especially understudied in ambulatory care.^{3,4,5} It is estimated that about 5 percent of the adult population in the United States will experience a diagnostic error in an outpatient setting, and diagnostic errors have contributed to 10 percent of patient deaths over time.⁶

This case study report will examine the extent to which careful development and implementation of CDS for CAP could support ambulatory care providers to more effectively diagnose the severity of CAP, and subsequently identify the site of care for pneumonia. Given the extent to which health information technology (health IT) is transforming ambulatory care, this case study will focus on the implementation of CDS within the increasingly common environment of electronic health records (EHRs) in order to explore its potential benefits to patient safety.

The case study describes the design and implementation of a CDS alert in a medium-sized primary care outpatient clinic and a large emergency department (ED). It presents evaluation findings that describe provider perceptions and experiences with the use of the alert in the two settings and the perceived value of the CDS to manage CAP patients. It concludes with lessons learned and recommendations for clinicians in ambulatory care practices seeking to implement similar diagnostic tools.

Background

CAP is the eighth leading cause of death in the United States.⁷ Approximately six million cases are reported annually, resulting in an estimated 4.2 million ambulatory care visits.⁸ Despite such a high number of cases, pneumonia is among the top most commonly missed diagnoses in ambulatory care settings. Adults aged 65 or older have four times the incidence of CAP as other age groups; they also

have higher rates of hospitalization and are more likely to die from CAP.⁹ CAP can be treated in the hospital or at home, depending on severity.

The Infectious Diseases Society of America and the American Thoracic Society (IDSA/ATS) recommend two clinical decision support tools to help determine the severity of CAP and subsequent site of treatment: the CURB-65 and the Pneumonia Severity Index. Of the two, we found the CURB-65 to be the most actionable in an ambulatory setting because it relies on five factors: confusion, uremia, respiratory rate, low blood pressure, and age 65 years or older.¹⁰ Calculating the CURB-65 score requires an assessment of each of the five factors. Each of the factors is assigned a point if a patient's assessment is at or over a threshold determined to increase mortality of CAP. The points for the individual factors are then added to get the composite score. Each point is weighted equally. Altogether, the CURB-65 severity score ranges between 0 and 5, with higher scores representing increased mortality risk and need for hospital admission.¹¹ Exhibit 1 illustrates the factors and the threshold for each risk score, as well as the recommended disposition based upon the score.

For primary care practices and outpatient settings without access to blood urea nitrogen (BUN) testing, CRB-65 is an appropriate alternative to the CURB-65 for decision-making. ¹² CRB-65 uses a similar scoring system as the CURB-65 with high risk also attributed to scores of three or four, instead of three through five since it has one less criteria (no BUN).

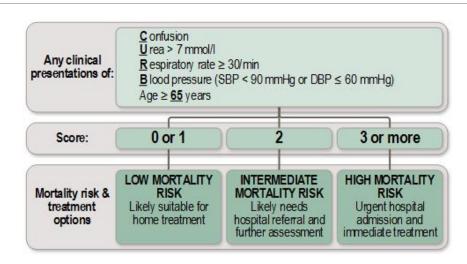


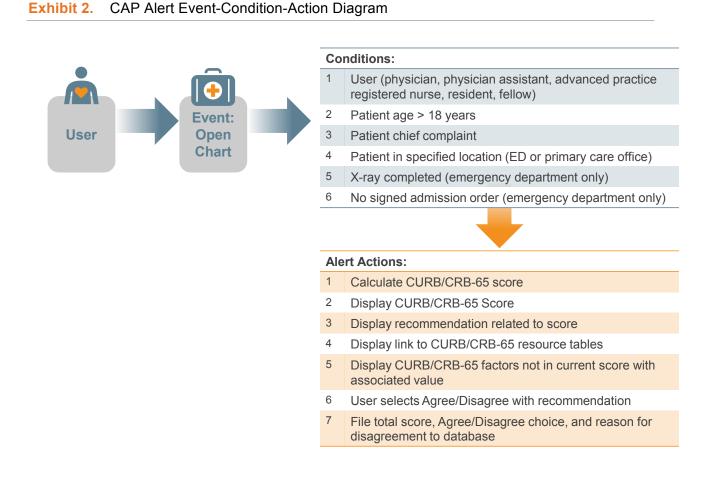
Exhibit 1. CURB-65 Assessment for Pneumonia Severity¹³

Design and Development of the CDS

To enhance and encourage use of the CURB/CRB-65, the NORC team developed a clinical decision support tool to assist ambulatory clinicians in quickly and accurately diagnosing CAP and in deciding on a site of care.

Information gathered from an initial workflow assessment, as well as the needs expressed by pilot practice clinicians, drove team discussions around potential design elements for the CDS tool. Based upon the workflow analysis, the CURB/CRB-65 requirements, and available design options, the team decided that the alerts would share certain design elements, but also differ in style depending upon the

EHR environment in each practice setting. Exhibit 2 is an event-condition-action diagram that represents the actions and triggers of the CDS alert in both the primary care and the ED settings.ⁱ The figure shows that after opening a patient's electronic chart, if the conditions are present, then it results in action of firing the alert.



The design elements for using clinical or laboratory data, calculating the score, and displaying the recommended disposition involved the direct translation of the CURB/CRB-65 tool to an electronic alert. The elements of listing the mortality rates and providing a hyperlink for further information on the CURB/CRB-65 were intended to help clinicians understand the significance of the score and ultimately trust its associated recommendation. The inclusion of a hard stop for users to record their agreement/disagreement with the score, and the functions of recording usage were created primarily for the sake of evaluating the implementation of the alert, as it allowed for direct feedback on the alert from the user during the pilot phase of its development.

The trigger to display the alert in both settings is determined by applicable chief complaints, which are recorded by either the medical assistant rooming patients in the primary care setting, or the nurse triaging patients in the ED. Patients in both settings would also have to be over 18 years old to trigger the alert.

ⁱ The design team had to take into account several limitations when creating the alert. They are described in detail in the full case study report.

Based upon the workflow analysis, the chief complaint triggers varied between the two settings. The ED's triggers were general complaints associated with pneumonia that often lead to ordering of chest X-ray in the ED, whereas the primary care setting had the general complaints, as well as more specific diagnosis of pneumonia, which may be made based on previously conducted chest X-rays. Therefore, triggers in the ED setting included the chest X-ray being marked as "Exam Completed" by the radiology technician. Exhibit 3 lays out the necessary triggers for the alert in each setting.

Attribute	Characteristics	
Alert	CURB-65	CRB-65
Patient Location	Emergency department	Primary care office
Age	Age >= 18 years	Age >= 18 years
Chief Complaints	 Cough Respiratory difficulties Respiratory distress Breathing problem Shortness of breath 	 Cough Shortness of breath Malaise Bronchitis Confusion Pneumonia Recurrent pneumonia Respiratory difficulties Breathing problem Respiratory distress Fever
Other	 No admission order Chest X-ray marked as "Exam Completed" by radiology technician 	No admission order

Exhibit 3. Alert Triggers in the ED and Primary Care Settings

The triggers would prompt the alert to pull labs and clinical data, then calculate and display the CURB/CRB-65 score and recommendation. Whereas confusion is commonly recorded in the EHR by the ED nurse when triaging patients, it is generally not recorded by the medical assistant in the primary care setting. The ED could therefore pull the confusion score into the CURB-65 calculation, whereas the primary care setting could not. Further, the rules used to retrieve the clinical information to calculate the score did not allow input of clinical factors such as confusion by clinicians. Therefore, in the primary care setting, a decision was made to ask clinicians to mentally add one point for confusion if it was present, then ask them to mentally adjust the score and recommendation based upon the guidance given in the hyperlinked document. This was considered both feasible and resource-efficient given the simplicity of the task.

Though the alert shared seven common design features and the use of chief complaint triggers for its activation, it also differed in important ways based upon the EHR environment in which it was being deployed. Exhibit 4 summarizes key differences between the alert in the ED and primary care setting.

Exhibit 4. Key Differences in Design of CAP Alert between ED and Primary Care Setting

Design Feature	ED	Primary Care
Alert	Interruptive alert	Non-interruptive alert
CAP Tool	CURB-65	CRB-65

Design Feature	ED	Primary Care
Criteria	Confusion automatically included if available	Confusion manually included once assessed
Triggers	Chest X-ray included	Chest X-ray not included
Hard Stop	Requires response upon firing	May be delayed until close of encounter

Usability testing was conducted in a laboratory setting with clinician participants from the Bridgeport Hospital in Bridgeport, Connecticut, on March 8, 2017, and minor refinements were made before full implementation in March 2017.

CDS Implementation

To test implementation and adoption of the tool for purposes of the pilot, the NORC team recruited sites serving sizable populations of adults age 65 and older, and having an interest in using health IT to improve patient safety. The Emergency Department at Bridgeport Hospital and PriMed Stratford, a primary care office, are representative of other ambulatory care settings in the U.S.

Using findings from the initial site visit as well as usability testing, the NORC team developed a suite of supporting materials to frame up the relevance and need of the CDS tool and the CURB/CRB-65 test, as well as to train potential users on how to integrate it into their workflows. This toolkit was used as an accompaniment to training for the pilot implementation and will also help future implementers adopt and implement this tool in their own practice. Most tools have a version specific to settings using the CURB-65 and one specific to settings using the CRB-65. The following is a list and brief description of each tool in the implementation toolkit:

- **CDS Implementation Toolkit Handbook:** a document that orients a practice to the CURB/CRB-65 CDS tool, as well as instructions for how to adopt and implement it in a practice.
- Low-fidelity prototype: a vendor-agnostic visual representation of the design of the tool to assist developers in adapting the tool to their own system.
- Workflow diagrams: current state workflows for managing CAP in a practice, workflows highlighting CURB/CRB-65 data elements, and future state workflows integrating the CURB/CRB-65 CDS tool.
- **Pamphlet:** a two-page informational sheet highlighting the clinical relevance of CAP and the CURB/CRB-65, as well as the benefits of the tool.
- **Training slide deck:** PowerPoint presentation, including textual and graphic instructions for how and when to use the tool, as well as background information related to the guidelines supporting the CURB/CRB-65 test.

Go-Live

The NORC implementation team met with the clinician champions at each setting and provided them with toolkit materials and a tip sheet, which provided a vendor-specific set of instructions to help orient users to the alert. Adoption and training took different forms in each setting.

Evaluation

The CAP alert evaluation focused on assessing implementation of the CDS alert in two practices, including the successes and challenges with its implementation, and variation across the two settings. Using both quantitative and qualitative data collection, the evaluation provides insights into the facilitators and barriers to implementing the alert in real world settings. Our findings describe clinicians' perceptions of both the design and the concept, and guidance on potential refinements that could enhance its use in other settings.

The quantitative component of this evaluation was comprised of the periodic monitoring of alert usage and CAP incidence rate in the participating clinics over the course of the study period. Implementation began on March 23, 2017, in the primary care practice, and March 27, 2017, in the ED, and ran in both settings through July 31, 2017. Data are presented in aggregate across the study period, and analysis was conducted to determine any trends in the frequency of its use by month, as variation in its use may be attributable to seasonal changes in the incidence of CAP.

To collect qualitative data regarding the implementation of the alert, the NORC team conducted a site visit to Bridgeport and Stratford, Connecticut, on June 20-21, 2017. A total of nine clinicians and two clinician champions were interviewed across the two settings.

Findings

Exhibit 5 summarizes the number of times that the alert was triggered in each setting, the number of clinicians who interacted with the alert, and the number of patients who had chief complaints that would trigger it.

Exhibit 5. Usage of CAP Alert in ED and Primary Care Office, March 23–August 18, 2017

Summary Counts	Bridgeport Hospital ED	Primed Stratford Primary Care Office	Total
Number of times alert fired	666	71	737
Number of clinicians who interacted with alert	133	5	138
Number of patients who triggered alert	563	56	619

These figures indicate that 138 unique clinicians interacted with the alert during the study period, and that it was used on nearly 620 unique patients. Each ED clinician interacted with it on average of close to five times, and each primary care clinician on average of 14 times. In our review of EHR data, we found that the rate of CAP in the ED was three times that of the primary care setting during the study period (ED: 1.8 percent; primary care: 0.5 percent), and that the overall number of encounters with patients was nine times greater in the ED than the primary care setting (ED: 26,880 encounters; primary care: 2,945). The majority of the clinicians who interacted with it agreed with the recommendation for site of care (55 percent in ED; 76 percent in primary care).

Whereas the quantitative findings speak to the volume of usage of the alert in both the ED and primary care settings, our qualitative findings offer insight into the extent to which clinicians with varying levels of clinical experience and expertise found it useful in their everyday practice and why. Key findings are:

- Most of the interview participants currently use a decision support tool for pneumonia, whether mentally or via a mobile phone app like MD-Calc.
- Few recalled receiving any formal training on the alert in either setting.
- Earlier career clinicians have more success integrating it into their workflow and finding it to be useful. They were also more likely to consider using the tool than clinicians with more experience.
- By opening the EHR and preparing to see the patient, clinicians reported seeing the alert before the
 patient, which presented a challenge as they were not ready to make the clinical decisions required of
 the alert at that time.
- ED clinicians were more familiar with how to technically use the alert than the primary care clinicians.
- Clinicians would have appreciated knowing more about the clinical criteria fed into the alert in order to better decide whether to agree or disagree with it.

Discussion

A major finding was the difference in the volume of alert usage in the ED compared to the primary care setting. Though the study did not occur during the peak CAP season, ED clinicians may have been more likely to interact with the alert due to overall differences in patient volume and rates of CAP diagnosis in each setting. While this finding may suggest that the alert has more relevance in the ED than the primary care setting, such an alert may also be useful in a primary care setting as the extra guidance may be more useful to those who diagnose the condition less often.

Findings also confirm what is known in the literature, which is that ED providers were much more familiar with alerts than primary care providers. Over 130 clinicians in the ED interacted with the alert with little training, whereas the few primary care providers who interacted with the alert needed guidance from the clinician champion in how to interact with it initially. For example, though the primary care alert was designed to allow clinicians to navigate around it, the clinicians in the pilot site were generally unfamiliar with alerts and did not use it this way. Instead, they addressed it immediately upon viewing, which made it seem poorly timed.

Both settings offered minimal trainings through announcements at staff meetings and email circulation of a tip sheet and pamphlet. The limited training raised questions among staff in both locations about what criteria were used in the alert, where the information came from, why the criteria were important, and what the responses of "agree" or "disagree" were meant to capture. Lack of training in the primary care setting led in part to the mistaken impression that the alert required an immediate response.

Overall, ED clinicians interviewed were able to integrate the alert into their workflow more easily than clinicians in the primary care setting due to their greater overall familiarity with alerts. A few ED clinicians early in their career felt the alert was helpful in supporting their clinical judgment, but most senior clinicians, including advanced practice registered nurses (APRNs), preferred to use their clinical judgment instead of the alert. However, in both settings, the alert was perceived to have limited utility because of design features that impeded a smooth workflow.

As tools intended to influence diagnostic decision-making regarding the severity of CAP patients and their disposition, our CAP alerts faced similar challenges to those of other diagnostic CDSs as described in the literature. As described by Berner (2014), underutilization of diagnostic decision support is due to 1) lack of perceived need for diagnostic decision support on the part of clinicians; 2) time and cost pressures that further reduced perceived utility; and 3) lack of feedback mechanisms of incorrect diagnosis that would then prompt consultation with a diagnostic decision support.¹⁴ The author's suggestion to develop active alerts that fire or appear to fire for clinicians would encourage utilization, and registers with the approaches used for this project. In fact, though the alert for the primary care practice was not designed as an interruptive alert, the design team was pleased that clinicians perceived it that way anyway, as it encouraged them to engage with it.

In our project, we identified several challenges with designing and implementing an active alert for CAP that provided access to diagnostic reference information and guidelines. They included:

- 1. Clinicians not being near the computer but with the patient when making the diagnosis.
- 2. Clinical guidelines that often do not account for temporal evolution of findings during clinical care. Translating them into real-time interventions is challenging because all information is not available at the start of the process and occurs over time.
- 3. Nuances in how clinicians interact with patients during a clinical encounter that make it difficult to identify a universally suitable time for an alert.

While having appropriately timed diagnostic decision support may improve its perceived utility, it may also require a change in the way the provider interacts with the patient. A recent study of a diagnostic decision support intervention in an ambulatory primary care setting in England found that while most providers studied (74 percent) found the intervention to be useful, they were also critical of the need to engage with it while seeing their patients. While patients noticed this as well, the satisfaction measure of patients was no different among those in the intervention group than those in the comparison group without the tool.¹⁵ While this is promising, the primary care practice in our study encouraged clinicians to complete their planning for their patients prior to seeing patients, which led to the perceived inappropriate firing of the alert.

Further study is needed to both refine the instrument and identify outcome measures that would appropriately assure that the alert is being used as intended, and that it is achieving desired outcomes. Participants in the evaluation were most interested in outcome measures related to cost and utilization of services, given that the tool is meant to help clinicians determine severity and site of treatment.

Introduction

NORC at the University of Chicago and Yale School of Medicine (the NORC team) are pleased to present this Case Study Report on our project, Clinical Decision Support (CDS) for Community-Acquired Pneumonia (CAP), funded under contract with the Agency for Healthcare Research and Quality (AHRQ) (Contract No. HHSP233201500023I). The NORC team conducted a research project to address the safety concerns over diagnostic errors. Specifically, we developed a CDS for community-acquired pneumonia (CAP), and tested its implementation in two ambulatory care settings: an emergency room and a primary care practice. In addition, we developed an implementation toolkit which can serve as a guide for other ambulatory care practices interested in implementing the CDS for CAP in the future.

This project was motivated by the gaps in patient safety identified in the AHRQ's *Technical Brief Number 27: Patient Safety in Ambulatory Settings.*¹⁶ Groundbreaking reports by the Institute of Medicine (IOM) indicate that threats to patient safety are more likely to occur in ambulatory than inpatient settings and that promising evidence-based patient safety practices and development of patient safety systems for ambulatory settings are lacking.^{17,18} The sheer volume of care delivered in ambulatory settings warrants concern over the implementation of patient safety practices in such settings. AHRQ's brief further identified important differences between inpatient and ambulatory safety, as well as areas of research that could help identify strategies to improve patient safety in ambulatory settings. Based on interviews with key informants and a literature review, the brief specifically identified a lack of evaluations of patient safety practices related to diagnostic errors in ambulatory settings.

Diagnostic errors are a significant issue in health care settings and have been especially understudied in ambulatory care.^{19,20,21} Defined as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient," a diagnostic error can result in serious consequences such as negative health outcomes, psychological stress, financial loss, and even death. It is estimated that about five percent of the adult population in the United States will experience a diagnostic error in an outpatient setting, and diagnostic errors have contributed to 10 percent of patient deaths over time.²²

This case study report will examine the extent to which careful development and implementation of a CDS for CAP could support ambulatory care providers to more effectively diagnose the severity of CAP, and subsequently identify the site of care for pneumonia. Given the extent to which health information technology (health IT) is transforming ambulatory care, this case study will focus on the implementation of a CDS within the increasingly common environment of electronic health records (EHRs) system in order to explore its potential benefits to patient safety.

The case study describes the design and implementation of a CDS alert in a medium-sized primary care outpatient clinic and a large emergency department (ED). It presents evaluation findings that describe clinician perceptions and experiences with the use of the alert in the two settings and the perceived value of the CDS to manage CAP patients. The intended audience for this case study report includes AHRQ, policymakers involved in the field of patient safety, the broader clinician community, and implementers and researchers of CDS.

This report begins with background on the burden of CAP in ambulatory care settings and the potential benefits of health IT, particularly diagnostic decision support tools, in reducing diagnostic errors in CAP. We also describe the CURB-65, a validated tool for diagnosing the severity of CAP upon which the CDS

is based. This is followed by a discussion of the steps taken to develop a CDS for this study, as well as the two implementation sites where the study occurred. The report then describes the evaluation of the CDS at the two sites, including the methodology, quantitative and qualitative findings on the use of the tool, training, workflow integration, and usefulness. The report concludes with a discussion on implementation, as well as recommendations on the design, training, and workflow for future implementation of diagnostic decision support tools.

Background and Context

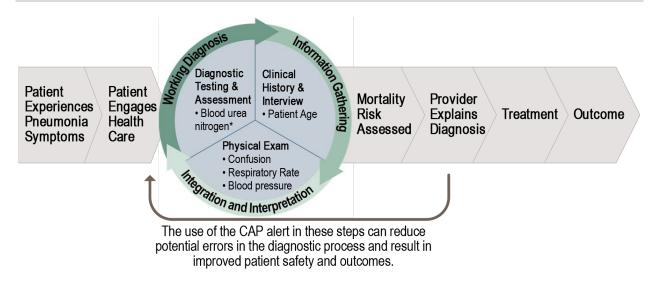
CAP is the eighth leading cause of death in the United States.²³ Approximately six million cases are reported annually, resulting in an estimated 4.2 million ambulatory care visits.²⁴ Despite such a high number of cases, pneumonia is among the top most commonly missed diagnoses in ambulatory care settings. Adults aged 65 or older have four times the incidence of CAP as other age groups; they also have higher rates of hospitalization and are more likely to die from CAP.²⁵

CAP can be treated in the hospital or at home, depending on severity. Home treatment is often patients' preference, and it tends to be lower in cost and prevents exposure to hospital-acquired conditions. Diagnosed by clinical features and lung imaging, CAP outcomes can vary substantially depending on the associated pathogen, the host's response, and treatment.^{26,27} Patients can be unnecessarily admitted to the hospital, and thus exposed to all the iatrogenic events associated with the inpatient setting, or sent home when close monitoring and intensive services are warranted. In addition, they may receive inappropriate antibiotic treatment, and in severe cases have a sepsis-triggering event.²⁸ A two-site study of 190 diagnostic errors occurring in an ambulatory setting found that pneumonia was among the top most commonly missed diagnoses.²⁹

According to the consensus guidelines from the Infectious Diseases Society of America/American Thoracic Society (IDSA/ATS), "almost all of the major decisions regarding management of CAP, including diagnostic and treatment issues, revolve around the initial assessment of severity." ³⁰ Based on an assessment of severity, clinicians must make immediate and critical decisions about the site in which the patient will receive subsequent care; sites include the hospital—an intensive care unit (ICU) or general ward—or the home. The decision to opt for home-based care is based on not only disease severity, but also a clinician's assessment of a patient's ability to safely and reliably take medication orally and receive support from family, friends, or other caregivers.

Given the burden of CAP in the U.S., and the potential to intervene with a tool that helps diagnose severity, we developed a conceptual model of how a CDS can be integrated into a health care system to improve outcomes. Exhibit 6 is a model of how the CAP CDS alert may lead to a reduction in diagnostic errors, and explains relevance to the project. By appearing at the stage when a patient with pneumonia symptoms interacts with clinicians, we suggest that the CDS can aid providers in interpreting patients' chief complaints, their clinical history, and information gathered from the physical exam to make more accurate diagnosis of the severity of pneumonia, and thereby choose the appropriate treatment options. We believed that the CDS should be part of a health IT infrastructure that is increasingly part of the diagnostic and treatment process of providers, as will be described below.





Health IT Addresses Patient Safety

Since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, electronic health record (EHR) adoption among ambulatory practices has grown significantly, making it more feasible to test health IT interventions in these settings.³²

In today's health care systems, health IT can positively contribute to the diagnostic process when it supports diagnostic team members with accurate information and user-friendly designs. Health care has become increasingly complex and requires clinicians to know and apply vast amounts of knowledge. El-Kareh et al. (2013) stated that "unaided clinicians often make diagnostic errors" because they are "vulnerable to fallible human memory, variable disease presentation, clinical disease processes plagued by communication lapses, and a series of well-documented 'heuristics,' biases and disease-specific pitfalls."³³ Health IT has the potential to reduce these challenges.

Well designed and evaluated health IT tools such as CDSs in EHRs can create potential benefits and reduce the potential harm that could be caused in health systems. Specifically, they can "facilitate timely access to information; communication among health care professionals, patients, and their families; clinical reasoning and decision making; and feedback and follow-up in the diagnostic process."³⁴ A CDS system is a common feature of EHR systems that "provides clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times to enhance health and health care."³⁵ The purpose of CDS is to ensure that clinical decisions are more evidence-based and customized to an individual patient and the specific clinical situation. A CDS system can encompass a number of tools and interventions like "computerized alerts and reminders, clinical guidelines, order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools."³⁶ Most CDS systems operate as components of EHR systems have been shown to be a promising intervention to improve management and quality of care. ^{37,38,39,40} Existing

studies have shown that when CDS is used in conjunction with an EHR system, it can influence clinician behavior, diagnostic test ordering, and costs of care, and impact clinical outcomes.⁴¹

Across acute care, hospital, and ambulatory/primary care settings, CDS systems have been shown to be a promising intervention to improve management and quality of care. ^{42,43,44,45} CDS is used in chronic disease management to provide tailored recommendations for treatment, patient education, adequate follow-up, or timely monitoring of disease indicators. A systemic review comparing the use of CDS to usual practice found that just over half of the studies showed an improvement in care processes in chronic disease management and only some improved patient health outcomes.⁴⁶ CDSs are also often used within computerized provider order entry (CPOE), which are systems clinicians use to place medicine orders electronically.⁴⁷ Incorporating CDS within CPOE reduces errors when ordering and dispensing medication as CDS can suggest default values for drug doses, routes of administration, and frequency. A systematic review found that CDS within CPOE also "increased adherence to radiology test ordering guidelines, resulting in an overall decrease in radiology utilization," thus, reducing the potential harm of exposing patients to dangerous levels of radiation.⁴⁸

While CDS systems can be used for both therapeutic and diagnostic decision-making, they are more commonly used for therapeutic decision-making, specifically around clinical orders (e.g., medications, referrals, and procedures).⁴⁹ It is important to note distinctions between each type of decision-making as they have bearing on the design of CDS. During diagnostic decision-making, clinicians must consolidate a large set of subjective clinical exam findings and patient complaints to arrive at a logical diagnosis.⁵⁰ Therapeutic decision-making takes into account an established diagnosis, and seeks a course of treatment. For example, in making a therapeutic decision, the clinician must know the appropriate drug dose based on several characteristics of the patient while taking into consideration potential drug interactions. This process requires not only clinical judgment but also knowledge of established therapies.

Though not as commonly utilized as therapeutic decision support tools, diagnostic decision support tools have the potential to assist clinicians during each stage of the diagnostic process from acquiring, integrating, and interpreting information, to forming a working diagnosis and making the final diagnosis. El-Kareh et al. (2013) compiled a list of tasks accomplished by diagnostic CDS tools. Such tools can assist clinicians in:⁵¹

- Gathering information
- Aiding cognition through enhanced organization and display of information
- Generating a differential diagnosis
- Weighing diagnoses
- Selecting diagnostic tests/plans
- Accessing diagnostic reference information and guidelines
- Providing reliable follow-up, and assessment of patient course and response
- Screening for the early detection of disease in asymptomatic patients
- Using diagnostic collaboration, particularly with specialists
- Facilitating feedback and insight into diagnostic performance

In addition to these tasks, some diagnostic decision support tools are beginning to apply new computational methods, such as artificial intelligence and natural language processing, to analyze large

amounts of complex patient data such as patient notes, diagnostic testing results, genetic information, and clinical and molecular profiles. By incorporating all of the patient's data as well as that of thousands of other patients' data, such tools are able to identify similarities and associations with other patients, diseases, and trends in outcomes and disease management. Diagnostic decision support tools are also being integrated into radiology and have the potential to improve diagnostic accuracy. Computer-aided detection (CAD) analyzes radiology images for patterns associated with underlying diseases. Although this technology is more broadly accepted, there is mixed evidence demonstrating its effectiveness.⁵²

Despite the wide array of existing diagnostic decision support tools, questions about their validity and utility remain, and research correlating CDS systems with diagnostic error outcomes is limited. This gap in research may be due to a combination of factors, including the difficulty of performing a longitudinal study to measure a meaningful difference in diagnostic error outcomes and the possibility of interference from other interventions on the diagnostic error of interest.⁵³ Bond et al. (2012) used an established scoring system for diagnostic decision support accuracy and found that diagnostic decision support tools were "subjectively assistive and functional for clinical diagnosis and education."⁵⁴ Further, a systemic review found that an overreliance on CDS has the potential to reduce independent clinician judgment and critical thinking. For example, Friedman et al. (1999) found that the use of diagnostic decision support was linked to a small increase in diagnostic accuracy in six percent of cases. However, "clinicians overrode their own correct decisions due to erroneous advice from the decision support system."⁵⁵

Other challenges to these tools include poor usability, "alert" fatigue, and lack of integration of tools into clinician workflows, all of which can compromise patient safety.^{56,57,58,59} The main barrier to the adoption of CDS tools is the lack of integration with the EHR, which is essential to trigger relevant information at the appropriate times.^{60,61} Researchers agree that in order for CDS tools to be useful, they should be used only when appropriate and within existing workflows. Otherwise they contribute to "alert" fatigue. In addition, diagnostic CDS may threaten clinicians' sense of professional authority and autonomy.⁶² Clinicians may be more reluctant to acknowledge that they need support for judgment-based tasks, such as diagnosis, rather than memory-based tasks such as prescribing medication or ordering screening tests. Clinicians may also be reluctant to use CDS tools if they believe they are too time-consuming or that they will change their method of consultation. It is also important to tailor the system based on clinicians' workload and experience. For example, a highly trained clinician with more health IT or CDS knowledge may be able to learn and navigate the interface faster than others.

Best Practices in the Design of CDS Alerts

Given the number of different types of CDSs (e.g., alerts, order sets, clinical guidelines, reports), different designs must be employed to create them. Many vendors use their own proprietary guidelines, but their recommendations and the quality of their research vary widely. Here we present recommendations for therapeutic and diagnostic decision supports in the form of alerts as they are most relevant to the CDS designed for this CAP project.

Horsky et al. (2012)'s overview of the design of CDS and alerts in particular provides background on the design process used in this project. ⁶³ He and his colleagues focused on designs of mostly therapeutic CDS for clinical prescribing since the bulk of CDS fall into that category. However, the design principles may apply to both diagnostic and therapeutic CDS designs.

In general, CDS could be described as passive or active. Passive CDS tools allow clinicians to pull up information at the time of their choosing by clicking on links, whereas active CDS tools push out an alert automatically in real-time and may act as alerts, critiques, warnings, recommendations, or reminders. Horsky et al. suggest that active alerts are more appropriate for high-severity conditions since they disrupt clinicians' activities, which can lead to "alert" fatigue and arbitrary responses to dismiss it. Limiting the use of active alerts for high-severity conditions can help reduce "alert" fatigue.

Horsky et. al also present a series of recommendations for CDS around clinical prescribing. They are to:

- Allow clinicians to readily access the algorithm used by the system and the specificity of the tool in order to "promote trust in the reasoning process."
- Apply the same visual attributes to related items, such as similar clinical terms. Color, font, or placement on the screen should be used in a meaningful way so that they adhere to universally understood terms. This reduces the time it takes clinicians to recognize and answer the alert and reduces the error of commission (e.g., the confusion of screen objects that look similar). Given that 7-11 percent of male clinicians have some type of color blindness, using similar hues of red vs. green should be avoided.
- If severity or mortality levels are displayed by the tool, use two or three levels (e.g., low, moderate, high) that are appropriately color-coded, which is generally sufficient.
- Use consistent terminology and wording, condense long lists and tables, and use headers.
- To reduce confusion over the definitions of terms, present lookup tables that are formatted consistently with other existing CDSs in the EHR.
- If the alert requires a response by the clinician, have a simple display and clearly defined response options. Multi-worded responses should be avoided to reduce confusion.
- Provide advice from the CDS, rather than commands, since advice is less prescriptive and does not infringe on clinicians' sense of professional autonomy. Alternative options should also be present on the alert when possible since clinicians are more likely to resist a suggestion if acceptable alternatives are not offered.
- Create an area for comments within the tool so reasons for overriding the tool can be logged.

Berner (2014) explains that while diagnostic decision supports use different knowledge sources, algorithms, and designs, they all share a few common features. First, they contain information that is compelling to clinicians with a diagnostic puzzle. Second, they provide suggestions of possible diagnosis. Third, the clinician considers the suggestions. She reports that most diagnostic CDSs are passive by design, and that active alerts may encourage clinician use. She suggests they be created to provide automated follow-up and feedback mechanisms to providers, particularly in cases of potential missed diagnosis based on test results. For example, an alert could notify a clinician if a patient has not improved within a certain time and give information on ways of contacting the patient, checking on outcomes, and providing alternative diagnostic hypothesis. An active diagnostic alert could allow clinicians to modify diagnoses and thus, reduce diagnostic errors.⁶⁴

Best Practices in Implementation

In a report published by Byrne et al. (2011), researchers identified several best practices in CDS implementation. Their recommendations did not differentiate between therapeutic or diagnostic decision supports, but apply more broadly to the CDS tools.⁶⁵

- Stakeholder engagement: Stakeholders should be involved from the onset since CDS implementation is a system-wide change, and stakeholders' objectives, clinical knowledge, and technology may evolve over time. It is imperative to understand each stakeholder's role in clinical processes that may be affected by the CDS. Collaboration and a mutual understanding of the goals and clinical objectives of the CDS will also impact its success. Clinician buy-in and support will more likely occur after the goals of the CDS are aligned with organizational priorities and clinical goals and objectives. Organizational support is also needed to reaffirm the importance of the using the CDS.
- Workflow analysis and integration: The most frequently cited reason for clinician resistance to CDS is workflow disruptions. Workflow analysis should include understanding an organization's current workflow, if people are following the designed workflow, their comfort level with CDS, the functionalities that may be impacted by the CDS, and common work-arounds to the system that may occur after CDS implementation. A successful CDS will be integrated with and support clinicians' workflow.
- Readiness assessment: The success of a CDS system also requires a readiness assessment as it helps to understand the organizational culture, viewpoints of end-users, and the degree to which an organization or team can adapt to change. Clinician resistance may occur if clinicians are concerned about maintaining their autonomy or the legal and ethical ramifications of following or overriding the CDS.
- Clinician champion: A successful CDS also requires a leader who is an effective communicator and clinically active. Clinician champions act as the liaison between the end-users and the technical staff, and use their knowledge in the health care environment to identify and communicate the goals, priorities, and needs of the organization. They should also lead CDS education, training, and follow-up.
- Training and ongoing support: CDS training should be tailored to the type of end-user and integrated into the context of EHR. Along with a training on the basics of what the CDS is, the training should also inform users about its reliability. Organizations have not found lengthy or day-long trainings to be useful. Some organizations have found that clinicians preferred online self-paced modules as an alternative to classroom trainings because they provided flexibility. However, in many cases, clinicians may not have sufficient time to dedicate to these trainings. CDS implementation may also require ongoing support. Organizations have found the following as effective means of providing support to clinicians: help-desks, IT training, 24/7 IT support, and other forms of real-time support.

Tools to Support Diagnosis of CAP

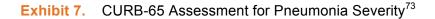
The IDSA/ATS guidelines strongly recommend two validated tools for assessing the severity of CAP during the diagnostic process: CURB- 65 and the Pneumonia Severity Index (PSI). ⁶⁶ Either tool can aid clinicians in determining whether patients can appropriately receive care at home or if they should be admitted to a hospital.

The CURB-65 score was developed and validated by WS Lim et al. (2003) in an initial study pooling data from over 1,000 patients from three countries: the United Kingdom, New Zealand, and the Netherlands.⁶⁷ Whereas the modified British Thoracic Society (mBTS) rule could identify patients with severe pneumonia, Lim and his colleagues sought a tool that could also identify patients with moderate CAP who could be treated at home. CURB-65 was derived from categorized variables collected by one or more existing severity prediction rules used by the British Thoracic Society (BTS), such as respiratory rate, diastolic blood pressure, uremia, confusion, white blood cell count, and arterial pressure.⁶⁸ In Lim et al.'s initial study, the strength of association between the CURB-65 variables and 30-day mortality was examined to determine whether the CURB-65 could be used to stratify CAP patients into different severity and management classes. Among the derivation and validation cohorts, the overall specificity and sensitivity of CURB-65 were found to be similar to other validated instruments for assessing CAP severity: the mBTS and the PSI. Since its initial derivation and validation study, CURB-65 has been studied as a severity assessment and management tool for CAP patients in at least eight validating studies.⁶⁹ The five clinical factors required for the CURB-65 assessment tool are common elements to collect for a patient presenting with symptoms suggestive of pneumonia.

Although both CURB-65 and PSI are recommended by the IDSA/ATS, the CURB-65 is the more practical tool in guiding patient safety practice because it is dependent on the availability of five easily measurable factors that are routinely entered into an EHR in an outpatient setting: confusion, uremia, respiratory rate, low blood pressure, and age 65 years or older.⁷⁰ These five clinical factors are standard elements to collect for a patient presenting with symptoms suggestive of pneumonia. Of these five clinical data elements, demographics (i.e., patient age), vital signs (i.e., blood pressure and respiratory rate), and lab tests are all required to be included in EHRs as part of the Centers for Medicare & Medicaid (CMS) EHR incentive program. This would mean that a CDS based on the CURB-65 would have access to four of the five clinical factors needed to calculate severity of CAP in a typical EHR. The fifth variable— patient confusion—will most likely need to be assessed by a clinician at the time of the visit and entered into the EHR to fully run the CURB-65. In contrast, the PSI model calculates a severity section 20 separate clinical factors, which is more than can typically be measured in an ambulatory setting.

Calculating the CURB-65 score requires an assessment of each of the five factors. Each of the factors is assigned a point if a patient's assessment is at or over a threshold determined to increase mortality of CAP. The points for the individual factors are then added to get the composite score. Each point is weighted equally. Altogether, the CURB-65 severity score ranges between 0 and 5, with higher scores representing increased mortality risk and need for hospital admission.⁷¹ Patients with a composite score of three or more are at higher mortality risk and require urgent hospital admission and immediate treatment; patients with a score of two are considered to be at moderate mortality risk, and likely need hospital referral and further assessment; and patients with scores of 0 or 1 are considered to have low mortality risk, and can be treated as an outpatient at home. Exhibit 7 provides an overview of the CURB-65 severity guide calculation, including the threshold limits for each factor.

For primary care practices and outpatient settings without access to blood urea nitrogen (BUN) testing, CRB-65 is an appropriate alternative to the CURB-65 for decision-making. ⁷² CRB-65 uses a similar scoring system as the CURB-65 with high risk also attributed to scores of three or four instead of three through five since it has one less criteria (no BUN).



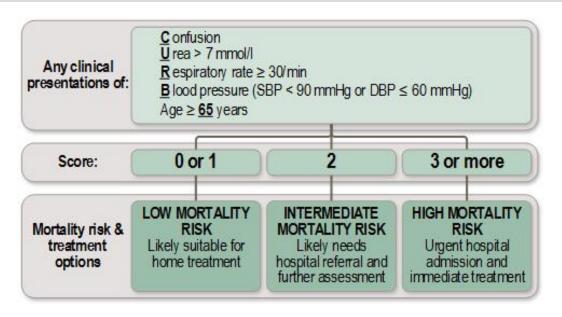


Exhibit 8 elaborates on the evidence-based estimate of anticipated mortality associated with each score by showing the 30-day mortality and CAP management recommendation that corresponds to each score.

Exhibit 8. CURB-65 and CRB-65 30-Day Mortality

Score	30-Day Mortality	Management	
0	0.7%	Treat as outpatient	
1	2.1%	Treat as outpatient	
2	9.2%	Admit to wards	
3	14.5%	ICU	
4	40%	ICU	
5	57%	ICU	

CRB-65 30-Day Mortality

Score	30-Day Mortality	Management	
0	0.9%	Treat as outpatient	
1	5.2%	Admit to wards	
2	12.0%	Admit to wards	
3 or 4	31.2%	ICU	

To summarize, CURB/CRB-65 can:

CURB-65 30-Dav Mortality

- Help determine the severity of CAP, a key step in making an accurate diagnosis and deciding between treatment settings: inpatient or outpatient.
- Predict mortality among patients with CAP based on five factors commonly available in ambulatory settings: confusion, uremia, respiratory rate, low blood pressure, and age 65 years or older.

Design and Development of the CDS

To enhance and encourage use of the CURB/CRB-65, the NORC team developed a clinical decision support (CDS) tool to assist ambulatory clinicians in quickly and accurately diagnosing CAP and in deciding on a site of care.

Proposed Settings and Rationale

The NORC team identified two settings for the pilot implementation of the CDS tool; an Emergency Department and a primary care practice (PCP), which are settings that CAP patients are most likely to visit for diagnosis and management. The implementation in two different kinds of ambulatory practices will inform future implementation in each type of setting, as well as within an integrated health system, with primary care settings working in close cooperation with hospital-based ambulatory care and inpatient care.

This project provided important opportunities for findings on the implementation of the intervention at the ED to inform use of the intervention in primary care, given that we expected to get different data from each site. First, given that the ED may see a higher volume of patients and the CAP management workflow is different, we expected more use of the CAP alert in the ED than in the primary care practice, which could lead to the identification of refinements to the CDS tool or the workflow in both settings. Second, the ED is the site—for many patients—where decisions about admission versus home management are made. The objective of the CURB-65 tool is to inform the critical decision of where pneumonia can best be managed. Similar to the primary care office, CURB-65 findings at an ED will be useful to decide appropriate site of care. Third, information gathered in the ED will be reflected in the ED discharge plan. Information can be shared between EDs and primary care practices.

CDS Development

Development of the CDS tool began with site visits to each practice to gather requirements. A member from the NORC team visited each setting to observe practice workflows and speak with clinical staff to gather initial feedback on the CURB/CRB-65 test, as well as the proposed tool and supporting implementation toolkit materials. The team member also explored how the practice teams currently handle cases of CAP and what their current workflow is for managing these cases. It was also important to learn what the clinicians' preferences were for a CDS tool to manage CAP. Exhibit 9 below contains the key questions we used to gather requirements.

Exhibit 9. Baseline Workflow Assessment Questions

- 1. How is disease severity of CAP currently assessed?
- 2. What are the tasks of the clinical workflow?
 - a. What is the most common sequence in which these tasks are performed?
 - b. How is the patient engaged for each task?
- 3. Is the CURB-65 tool used by your practice/department?
 - a. If yes, how is it used?
 - b. Who completes the tool?

- c. Are the elements captured electronically?
- 4. If the CURB-65 tool is not used, is another tool such as the Pneumonia Severity Index (PSI) tool used?
- 5. Are other assessment tools integrated into the EHR?
 - a. If so, how effective have they been?
 - b. Are there preferences in presentation and layout of those?
- 6. To what extent do clinicians rely on CDS systems in your practice?
 - a. What do clinicians like about them, and what would they like to see changed?
- 7. Would clinicians launch the CDS tool or want it to be triggered automatically?

The initial workflow assessments indicated that most clinicians at both practices relied on clinical assessment for diagnosing CAP rather than using a diagnostic support tool. One clinician in the ED setting reported using the CURB-65 mentally, but others did not use any formal assessment. From a workflow standpoint, in the ED patients were triaged by a nurse, and then the clinician typically ordered lab tests, as well as a chest X-ray for suspected cases of pneumonia. In the primary care setting, the medical assistant recorded the patient's vitals, and then the clinician made an assessment.

During the initial workflow assessment visits, the team also inquired about provider preferences around the CDS tool's ability to launch automatically through a trigger, or whether clinicians would manually launch the CDS for diagnosing CAP. Clinicians in the ED preferred a trigger to launch the tool as an alert, while those in the primary care office preferred a less intrusive mode of accessing the tool.

In the ED, the uremia element of the CURB-65 test is often collected through the BUN lab test, and could be used in a timely manner for pneumonia severity assessment and site of care decision-making. In the primary care office, while labs may be done, results are not routinely delivered while the patient is still in the office, so the NORC team made the decision to implement the CRB-65 (which excludes the BUN test) in this setting.

Workflow Diagrams

After synthesizing the findings from each site visit, the NORC team developed two sets of workflow diagrams unique to each setting, with the purpose of documenting current protocols and the workflow for managing CAP cases in each setting. One set of workflow diagrams is applicable to most outpatient clinic settings that do not have rapid availability of lab tests, and the other set is applicable to settings such as emergency departments where stat lab results can be obtained. For each setting, we provide the following diagrams:

- A view of the workflow prior to the CDS installation.
- A view where the required data elements for the CURB/CRB-65 are likely to become available.
- A view demonstrating where the CDS tool is likely to fit in the workflow.
- The workflow diagrams can be found in Appendix C.

Design Criteria

Information gathered from the workflow assessment, as well as the needs expressed by pilot practice clinicians, drove team discussions around potential design elements for the CDS tool. Based upon the

workflow analysis, the CURB/CRB-65 requirements, and available design options, the team decided that the alerts would share certain design elements, and also differ in style depending upon the EHR environment in each practice setting. In both the ED and PCP setting, the alert was designed to:

- 1. Use existing clinical or lab data in the EHR to calculate the CURB/CRB-65 score.
- 2. Display the CURB/CRB-65 score and the clinical factors that were met to generate the score (i.e., 1 for age over 65, 1 for respiratory rate).
- 3. Display the anticipated mortality rates associated with the score.
- 4. Display the recommendation to treat the patient at home or admit for inpatient treatment.
- 5. Provide a hyperlink with more detailed information on the CURB/CRB-65 guidelines to help providers interpret the mortality rate and recommendation.
- 6. Have a hard stop for users to indicate whether they agreed or disagreed with the recommendation, and allow users to type in the reason why they disagreed with the score.
- 7. Record in the EHR whether the alert was used, which provider used it, whether the user agreed or disagreed with the recommendation, and reason for disagreeing.

The design elements on using clinical or laboratory data, calculating the score, and displaying the recommended disposition involved the direct translation of the CURB/CRB-65 tool to an electronic alert. The elements of listing the mortality rates and providing a hyperlink for further information on the CURB/CRB-65 were intended to help clinicians understand the significance of the score and ultimately trust its associated recommendation. The inclusion of a hard stop for users to record their agreement/disagreement with the score, and the functions of recording usage were created primarily for the sake of evaluating the implementation of the alert, as it all promoted direct feedback on the alert from the user during the pilot phase of its development.

The trigger to display the alert in both settings is determined by applicable chief complaints, which are recorded by either the medical assistant rooming patients in the primary care setting, or the nurse triaging patients in the ED. Patients in both settings would also have to be over 18 years old to trigger the alert. Based upon the workflow analysis, the chief complaint triggers varied between the two settings. The ED's triggers were general complaints associated with pneumonia that often lead to ordering of chest X-ray in the ED, whereas the primary care setting had the general complaints, as well as more specific diagnosis of pneumonia, which may be made based on previously conducted chest X-rays. Therefore, triggers in the ED setting included the chest X-ray being marked as "Exam Completed" by the radiology technician. Exhibit 10 below lays out the necessary triggers for the alert in each setting.

Attribute	Characteristics	
Alert	CURB-65	CRB-65
Patient Location	Emergency department	Primary care office
Age	Age >= 18 years	Age >= 18 years

Exhibit 10. Alert Triggers in the ED and Primary Care Settings

Attribute	Characteristics		
Chief Complaints	 Cough Respiratory difficulties Respiratory distress Breathing problem Shortness of breath 	 Cough Shortness of breath Malaise Bronchitis Confusion Pneumonia 	 Recurrent pneumonia Respiratory difficulties Breathing problem Respiratory distress Fever
Other	 No admission order Chest X-ray marked as "Exam Completed" by radiology technician 	No admission order	

The triggers would prompt the alert to pull labs and clinical data, then calculate and display the CURB/CRB-65 score and recommendation. Whereas confusion is commonly recorded in the EHR by the ED nurse when triaging patients, it is generally not recorded by the medical assistant in the primary care setting. The system in use in the ED could therefore pull the confusion score into the CURB-65 calculation, whereas the primary care setting could not. Further, limitations of the EHR did not allow both retrieval and display of information (i.e., recorded values of CURB/CRB-65 factors) and simultaneous manual input of the observation of confusion into the record. Therefore, in the primary care setting, a decision was made to ask clinicians to mentally add one point for confusion if it was present, then ask them to mentally adjust the score and recommendation based upon the guidance given in the hyperlinked document. This was considered both feasible and resource-efficient given the simplicity of the task.

Though the alerts shared seven common design features and the use of chief complaint triggers for their activation, they also differed in important ways based upon the EHR environment in which they were being deployed. In the ED setting, the alert was designed to be an interruptive alert, whereas in the primary care setting it was a non-interruptive display. This difference was necessary given the ways the EHR environments differ between the two settings. The primary care setting allows for alerts to be "parked" in a planning section; these alerts can be worked around in the chart and do not need to be addressed until the close of the encounter. They appear as a highlighted section at the top of the planning tab, but they could be ignored until the provider is ready to address them. As chief complaints are often entered upon arrival, the non-interruptive alert could appear in the planning tab before the provider has seen the patient.

The ED EHR environment does not have a way to passively "park" an alert. Given that the chart passes through many hands, an alert generally requires the immediate attention of whoever has received it. Given that the entry of chief complaints may occur over an extended time period, an interruptive alert was designed that would fire only once every 12 hours. Therefore, it could fire when the chart is opened by one clinician based upon chief complaints, and then fire for the same or different clinician 12 hours later when a chest X-ray has been read by the radiologist. Each time it fires, it has to be addressed by the clinician in order to do any other task in the EHR; addressing the alert means responding to "agree" or "disagree" with the recommendation, at which point the alert would close. Exhibit 11 summarizes key differences between the alert in the ED and primary care setting.

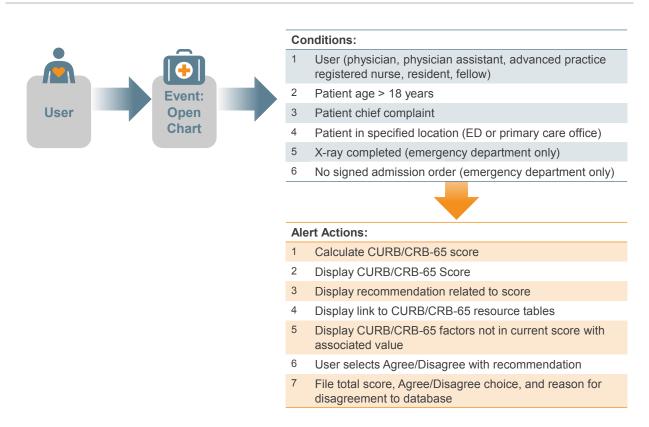
Exhibit 11. Key Differences in Design of CAP Alert between ED and Primary Care Setting

Design Feature	ED	Primary Care
Alert	Interruptive Alert	Non-interruptive alert

CAP Tool	CURB-65	CRB-65
Criteria	Confusion automatically included if available	Confusion manually included once assessed
Triggers	Chest X-ray included	Chest X-ray not included
Hard Stop	Requires response upon firing	May be delayed until close of encounter

Exhibit 12 is a diagram of the events, conditions, and actions that bring together all the pieces of the CDS design and usage discussed above. The figure shows that after opening a patient's chart, if the conditions are present, then it results in the firing of the alert.





The design team members had to take into account these limitations when creating the alert:

- First, though they did not hit a character limit, they chose to use abbreviations for the clinical factors that fed into the score so that the text could fit on a single line without spilling over to the next.
- Second, in the interest of creating a "pop-up" type of alert, they were unable to present the actual clinical value that led to the "0" or "1" for each clinical factor in the overall score. If the alert were created in the reports or patient lists section of EHRs, they could have presented the values, but they would have lost the "alert" function, making it more passive.

Finally, color coding of red, yellow, and green based upon the score was not allowed in the design of the alert because of the placement of the alert in the planning section of the EHR; such colors are available in the reports and patient lists in sections of the EHR, but that was considered too late in the workflow for

the alert. Ultimately, one CAP alert was developed for the ED and another for the primary care setting, and both were tested among a group of clinicians prior to their full implementation. Exhibits 13 and 14 depict the tools for the ED setting and the primary care setting that we tested for usability, as described in the next section.

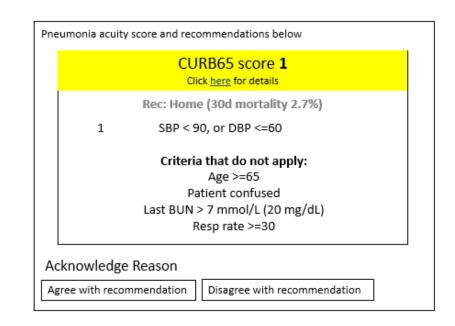
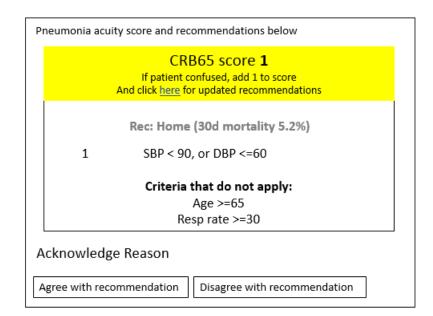


Exhibit 13. Pre-Usability Testing Low-Fidelity Prototype CDS for ED Setting

Exhibit 14. Pre-Usability Testing Low-Fidelity Prototype CDS for Primary Care Setting



Usability Testing

Usability testing was conducted in a laboratory setting with clinician participants from the Bridgeport Hospital in Bridgeport, Connecticut, on March 8, 2017. The NORC team developed a protocol for testing on both of the CDS tools that was comprised of three parts. The first part involved a controlled user test in which the facilitator asked participants to complete a task and think aloud as they walked through the task and the system. The second part was a set of qualitative interview questions to get a sense of the participant's thoughts and feelings about using the system. The third part was a paper survey adapted from the Usefulness Satisfaction and Ease of Use (USE) questionnaire.⁷⁴ The protocols can be found in Appendix A.

Testing Results

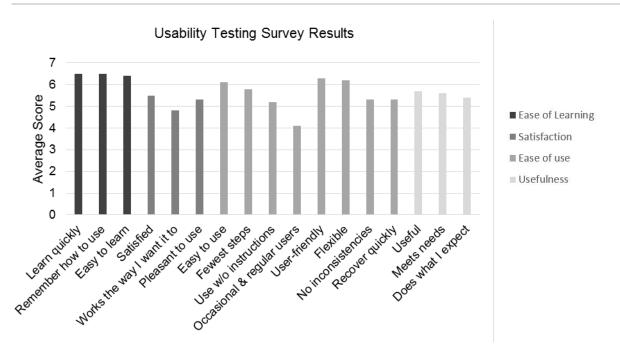
There were a total of nine participants for the usability testing. Analysis of the results revealed valuable user feedback for refining both tools. We synthesized comments into the following categories:

- Highlighted box on the alert
- Recommendation section
- Hyperlink under the score
- Display of the CURB-65/CRB-65 criteria
- "Acknowledge Reason" section
- General impressions/recommendations

In general, participants appreciated that their attention was drawn to the highlighted section and that the CURB-65/CRB-65 score was presented in large font. The primary care alert, which required users to mentally add 1 to the score if the patient presented with confusion, presented dichotomous reactions: some did not understand what they had to do, while others intuitively understood the required action. Some participants wanted to be able to update the score dynamically. In the recommendation section, there were recommendations about font and presentation. Many users missed the hyperlink entirely, while a few clicked on it immediately. With regards to how the score criteria were displayed, most users were appreciative of what was there, but felt some simple organization could improve it. In the "Acknowledge Reason" section, many participants felt that they wouldn't consider the buttons for "Agree" or "Disagree" very carefully in order to make the alert disappear. Some other general impressions included an appreciation for the intent of the alert overall, and some users felt the tool would integrate well into the clinicians' workflow. Some were unsure about the nature of the ED alert being a pop-up, while others wanted to be able to open the alert on their own. Participants also had some recommendations for a better flow of information.

Exhibit 15 shows the results of the third component of the testing, the USE questionnaire.





Refinement of the Intervention

After usability testing, the NORC team discussed the key findings and identified enhancements that could be implemented to the low-fidelity prototypes. Based on the synthesized feedback from usability testing, the team made updates to the CDS tools. In Exhibit 16, we show some of the desired features users expressed in usability testing, both ones that were implemented and ones that were not.

Exhibit 16. Proposed Refinements to the Intervention

Features Implemented	Features not Implemented	
Moved confusion action statement closer to the score for the primary care alert	Move site of care recommendation/mortality information to be positioned above "Acknowledge Reason"*	
Improved clarity of the necessary action required by users if they determine confusion to be present in the patient for the primary care alert	Label criteria included in the score as "Criteria included"*	
Spelled out "Rec" → "Recommendation"	The ability to dynamically add 1 to the score if confusion is present in the patient for the primary care alert*	
Relabeled "Criteria that do not apply" as "Criteria not included"	Use colored text to make the mortality information and recommendation stand out	
	Include evidence and CURB/CRB-65 calculation table in the alert itself	

*Indicates features not implemented due to the limitations of the vendor's system for the pilot testing, but recommended for future development.

In Exhibits 17 and 18, we present the revised versions of the low-fidelity prototype alert in each setting.

Exhibit 17. Post-Usability Testing Low-Fidelity Prototype CDS for ED Setting

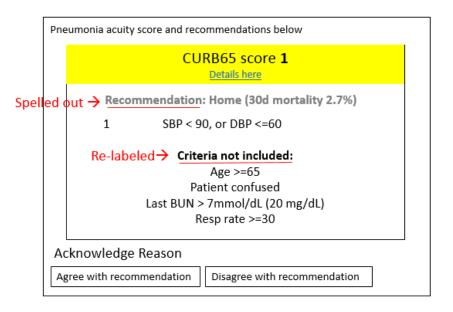
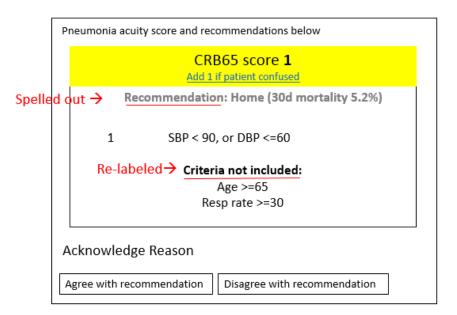


Exhibit 18. Post-Usability Testing Low-Fidelity Prototype CDS for Primary Care Setting



CDS Implementation

Below we describe specifics on the two sites selected for the pilot implementation.

Site Selection

To facilitate implementation and adoption of the tool for purposes of the pilot, the NORC team recruited sites serving sizable populations of adults age 65 and older, and having an interest in using health IT to improve patient safety. The sites' willingness to test the CAP alert tool minimized several potential barriers to successful implementation and adaptation to a new CDS, including difficulties gaining clinician buy-in and seamlessly integrating the system into clinical workflow.^{75,76} We identified clinician champions at each site to help lead implementation and adoption.

The Emergency Department at Bridgeport Hospital and PriMed Stratford, a primary care office, are representative of other ambulatory care settings in the U.S. In Exhibit 19 below, we compare practice size (number of providers), patient demographics, relevant health care events (ED admission rates and bacterial pneumonia admission rates), as well as operational characteristics to demonstrate representativeness of the sites we selected for this project.

According to a 2015 study from the American Medical Association, the majority of providers work in practices of 10 or fewer providers (60.7 percent), and just over six percent of practices include 25 to 49 physicians. Practices of two to four physicians increased by two percentage points between 2012 and 2014 to 22.3 percent.⁷⁷ Our two small- to mid-size practices, with two and 25 providers respectively, represent the spectrum of practice sizes in the U.S.

In Exhibit 19 below, we compare additional characteristics of the Bridgeport Hospital Referral Region (HRR, including both practices) against national data.ⁱⁱ

Characteristic	Bridgeport HRR	National
Average Patient Age ⁷⁸	74 years	71 years
Race ⁷⁹	78.42% non-Hispanic white, 9.65% African-American, 7.44% Hispanic, 4.49% Other	79.94% non-Hispanic white, 9.67% African- American, 5.84% Hispanic, 4.55% Other
Medicaid Eligibility Population ⁸⁰	22.62%	20.66%
Average (hierarchical condition categories) Hierarchical Condition Category (HCC) Score ⁸¹	1.03	1.00
Absolute number of ED visits ⁸² ED visits per 1,000 beneficiaries ⁸³	 50, 267 visits 687 per 1,000 beneficiaries 	 72,624iii visits 652 per 1,000 beneficiaries
Bacterial pneumonia admission rates ⁸⁴	 <65 population: 629 per 100,000 65-74 population: 319 per 100,000 75+ population: 1,032 per 100,000 	 <65 population: 660 per 100,000 65-74 population: 480 per 100,000 75+ population: 1,367 per 100,000

Exhibit 19. Comparison of Bridgeport Hospital Referral Region with National Data

ⁱⁱ As derived from the Dartmouth Atlas, a hospital referral region is a service area defined by where most patients are referred for major cardiovascular procedures and neurosurgery; 3,439 hospital service areas were aggregated into 306 hospital referral regions.

ⁱⁱⁱ This is a calculated average, based on the total number of ED visits divided by 306 hospital referral regions.

Characteristic	Bridgeport HRR	National
	PriMed: Yes	■ 25.59% of physicians participate in an ACO
ACO (Accountable Care Organization) participation ⁸⁵	 Bridgeport: No Bridgeport HRR: >20% of population covered by an ACO 	 744 total ACOs in U.S. 23.5 million lives covered by ACOs (7% of U.S. population)
EHR use ⁸⁶	 PriMed: Fully implemented Bridgeport: Fully implemented 	 No EHR: 8.77% Partial EHR implementation: 35.17% Full EHR implementation: 56.06%
Meaningful Use attestation ⁸⁷	 PriMed: Stage 2 Bridgeport: Stage 2 	 Provider Stage 2 attestation: 12% Hospital Stage 2 attestation: 37%

Implementation

Once site selection and CDS tool development were finalized, the NORC team prepared for the implementation and go-live in each practice.

Implementation Toolkit

Using findings from the initial site visit, as well as usability testing, the NORC team developed a suite of supporting materials to frame up the relevance and need of the CDS tool and the CURB/CRB-65 test, as well as to train potential users on how to integrate it into their workflows. This toolkit was used as an accompaniment to training for the pilot implementation and will also help future adopters adopt and implement this tool in their own practice. Most tools have a version specific to settings using the CURB-65 and one specific to settings using the CRB-65. The following is a list and brief description of each tool in the implementation toolkit:

- **CDS Implementation Toolkit Handbook:** a document that orients a practice to the CURB/CRB-65 CDS tool, as well as instructions for how to adopt and implement it in a practice.
- Low-fidelity prototype: a vendor-agnostic visual representation of the design of the tool to assist developers in adapting the tool to their own EHR system.
- Workflow diagrams: current state workflows for managing CAP in a practice, workflows highlighting CURB/CRB-65 data elements, and future state workflows integrating the CURB/CRB-65 CDS tool.
- **Pamphlet:** a two-page informational sheet highlighting the clinical relevance of CAP and the CURB/CRB-65, as well as the benefits of the tool.
- **Training slide deck:** PowerPoint presentation, including textual and graphic instructions for how and when to use the tool, as well as background information related to the guidelines supporting the CURB/CRB-65 test.

Go-Live

The NORC implementation team met with the clinician champions at each setting and provided them with toolkit materials and a tip sheet, which provided a vendor-specific set of instructions to help orient users to the alert. Adoption and training took different forms in each setting. At the PriMed primary care practice, the clinician champion distributed the pamphlet and tip sheet, and held a meeting to explain the rationale for the CDS implementation to practice staff. In the Bridgeport ED, the chief medical

information officer spoke to the ED leadership, and they agreed to follow their own channels of communication in order to inform the clinicians of the upcoming alert implementation.

Technically implementing the alert in each practice involved transitioning from a test environment to a live environment. The transition occurred centrally since the practices share the same EHR. The rules and logic for the alert are built inside a Proof of Concept environment. An administrator runs a program that automates the copying of all build-related files into a Test environment. Once the build is tested, the program is used to copy the files over into the Production environment. Once the implementation team received the go-ahead from each setting, the alert was "turned-on" within the EHR for each instance inside the Production environment. The go-live in the primary care setting took place on March 23, 2017, and in the ED on March 27, 2017.

Over the course of the pilot implementation, the team worked with a data analyst at Yale University to monitor CDS usage and pneumonia incidence in each practice. The reports included data on the following:

- Number of times the best practice alert "fired"/initiated
- Number of clinicians who interacted with the alert
- Number of patients for whom the alert "fired"
- Number of times the recommendation was "agreed" with
- Number of times the recommendation was "disagreed" with

Recommendation for Clinicians Interested in Implementing the CAP Alert

Given the knowledge gained through the team's lifecycle development and evaluation of the CAP alert, we offer some recommendations for the adoption, implementation, and usage of this tool.

Adoption

Prior to adopting the CAP alert, we recommend conducting an internal analysis at your practice to assess the need for CDS for CAP. In addition to the many resources that may help decide on adopting a CDS developed by the Health Information and Management Systems Society (HIMSS) such as CDS 101, we suggest you consider the following when consider the CAP alert specifically:⁸⁸

- 1. Is your practice an ambulatory care practice, including primary care offices and emergency departments? This will determine whether you will use the CURB-65 or CRB-65 version of the alert.
- 2. Is community-acquired pneumonia (CAP) a prevalent condition in your geographic area and among your practice's population?
- 3. Do the clinicians at your practice need or want guidance in assessing pneumonia severity?

It is important to gain buy-in from the potential users of the alert from an early stage so that they will understand the significance of the decision support and will help others learn how to use it.

Once your practice has made the decision to adopt the CDS tool, we recommend conducting a workflow analysis to determine how your practice currently manages CAP patients and where the alert might fire in this workflow to provide support at the right time to clinician users. The implementation toolkit that accompanies this case study contains a set of example workflow diagrams and baseline workflow

assessment questions for you to conduct your own workflow analysis. The toolkit is available here. (Placeholder for AHRQ website URL where the CAP CDS Toolkit lives)

Implementation

Once you have completed the workflow analysis, you can move forward with implementation. Included in the implementation are low-fidelity prototypes that your local IT teams can use to help inform the design of the CDS suitable for your practice setting.

Training

Although alerts are generally intuitive in nature, our evaluation results show that users of this CDS tool can benefit from a brief training in order to understand its relevance, workflow impact, and origins. We have developed several materials to aid in training your clinician users:

- Workflow diagrams: use this tool to help end-users understand the workflow impacts of the tool.
- **Pamphlet:** use this tool to inform CDS end-users of the clinical relevance of CAP, as well as the CURB/CRB-65 tool, and the benefit of this alert.
- **Training slide deck:** use this tool to provide a comprehensive training of the clinician users of the alert, including detailed instructions for how to regard the alert and an explanation of how the alert is triggered.

All of these materials are available online. (Placeholder for AHRQ website URL where the CAP CDS Toolkit lives)

Our recommendation would be to conduct periodic quantitative and qualitative assessments of the use of the CDS, and use this information to refine the tool iteratively.

Evaluation

The CAP alert evaluation focused on assessing implementation of the CDS in two practices, including the successes and challenges with its implementation, and variation across the two settings. Using both quantitative and qualitative data collection, the evaluation provides insights into the facilitators and barriers to implementing the alert in real world settings. Our findings describe clinicians' perceptions of both the design and the concept, and guidance on potential refinements that could enhance its use in other settings. Below we present an overview of the main research domains and questions for the evaluation. We then present our methods and findings based on the usage data, as well as qualitative interviews before concluding with a discussion about the overall effectiveness of the implementation in the specific ambulatory settings selected for this study.

This evaluation sought to answer research questions across six domains: training, technical implementation, workflow, clinician perspectives on the CDS, identification of outcome measures, and replicability of the CDS in other practices. Primary research questions are listed in Exhibit 20 below.

Exhibit 20. Evaluation Research Questions

1. How did the implementation vary between the ED and primary care settings in terms of integrating

the CDS into the EHR, timing, and completion of trainings, and number and types of clinicians using the CDS?

- 2. How well were clinicians able to integrate the CDS into their workflow, and how does this differ between the ED and the primary case setting?
- 3. To what extent did the clinicians believe the CAP alert aided diagnosis of the severity of CAP?
- 4. How often did clinicians utilize the CDS to completion in each practice, and how does this compare to the incidence of CAP in each practice? What factors influenced its use/disuse across practices?
- 5. What are the minimal resources needed to implement in each practice? How could they inform implementation in other practices?

These questions guided the development of our methods and discussion guides, and have been considered throughout the analysis of our findings. We will relate back to these questions through our findings in the discussion section of the evaluation. Before presenting our findings, we present a full description of the methods used to evaluate the pilot of the CAP alert.

Methods

The evaluation of the implementation of the CAP alert in two ambulatory practices utilized both quantitative and qualitative methods. Quantitative methods included the monitoring and analysis of CDS usage in participating practices, and qualitative methods included interviews conducted during site visits to participating practices.

The quantitative component of this evaluation comprised periodic monitoring of alert usage and CAP incidence rate in the participating clinics over the course of the study period. Implementation began on March 23, 2017, in the primary care practice, and March 27, 2017, in the ED, and ran in both settings through July 31, 2017. Data are presented in aggregate across the study period, and analysis was conducted to determine any trends in the frequency of its use by month, as variation in its use may be attributable to seasonal changes in the incidence of CAP.

To collect qualitative data regarding the implementation of the alert, the NORC team conducted a site visit to Bridgeport and Stratford, Connecticut, on June 20-21, 2017. At the PriMed Stratford primary care office, we conducted discussions with two advanced practice registered nurses (APRNs), one physician partner, and the clinician champion for the practice. At the Bridgeport ED, we conducted discussions with the clinician champion, the chairman of the emergency department, a physician assistant, three residents, and one staff physician. The interviews were about 45 minutes to an hour in length and were based the tailored discussion guides. Exhibit 21 gives an overview of our discussants.

Interview Participants	Quantity
Chairman of the Emergency Department	1
Clinician champion	2
Physician assistant	1
Emergency department resident	3

Exhibit 21. Site Visit Discussants

Interview Participants	Quantity
Emergency department staff physician	1
Advanced practice registered nurse (APRN) in primary care practice	2
Primary care physician partner	1
Total	11

Protocols for the semi-structured discussions were based on the overall research domains and questions described in the previous section. We sought to gauge the clinicians' opinions on their experience interacting with our alert in their practice. The protocols were tailored for three potential types of discussants: practice administrators, advanced practice providers/clinicians, and clinician champions. The protocols began with introductions and background on the project, as well as some questions to ascertain each participant's role in the practice, clinical experience, and familiarity with CURB/CRB-65. Next, we asked about the amount of training each participant received on the CAP alert, their thoughts on the training, as well as recommendations to improve training materials and content. We asked a series of questions on workflow impact and integration, and overall thoughts on satisfaction with the CDS. For the clinician champions only, we asked them to identify some potential outcome measures for future studies on this work and their opinions on the replicability of its implementation in other settings. All protocols were reviewed and approved by NORC and Yale's Institutional Review Boards; they can be found in Appendix B.

Prior to each discussion, the NORC team reviewed an information sheet on the purpose of the interview, explained our confidentiality policy, and obtained participants' verbal consent to participate and record the discussion. During each discussion, up to two NORC researchers took notes. After the site visit wrapped up, they cleaned up the notes, filled in the gaps by reviewing the interview recordings, and prepped the notes for synthesis.

To conduct analysis of the discussions, we developed a matrix to code the findings in Excel. The matrix consisted of headings for each of the major research domains and questions, as well as some breakdowns of those areas. The main areas included current use of decision support for CAP, training, workflow integration, alert acknowledgment (the hard stop Agree/Disagree), usefulness, comparison to other CDSs, and design recommendations. We filled in the cells for each participant with text summarizing the participants' responses. We also pulled out salient quotes from the notes that could be used to illustrate specific opinions or experiences. Each column of the matrix allowed us to summarize, either with a tally or text, the range of responses to each question. Below, we present the results of our findings from both the quantitative analyses, and call out the differences and similarities in each setting. We also mention participants' recommendations for improvement in each area.

Results

We start with a presentation of findings on the alert usage in each setting, and then present the qualitative findings to help explain patterns we see in the usage data. While the quantitative data provide the overview of how much the alert was used, the qualitative findings provide a detailed look at how it was used, as well as challenges and opportunities for its use in the future. We follow each of these sections with a discussion section on some of the implications for its use in similar settings and opportunities to further refine its implementation and measurement of its impacts.

Quantitative Findings

In monitoring EHR data from March 23 through August 18, 2017, we found that the rate of CAP in the ED was three times that of the primary care setting (ED: 1.8 percent primary care: 0.5 percent), and that the overall number of encounters with patients was nine times greater in the ED than the primary care setting (ED: 26,880 encounters; primary care: 2,945 encounters). Accordingly, the alert was triggered more frequently in the ED than in the primary care setting. As reported earlier in this case study (Exhibit 10), the alert is triggered by chief complaints; it is presented as an interruptive alert in the ED, and an active alert in the primary care setting. The large difference in frequency and overall usage between the ED and primary care practice suggests that it is much more likely for a patient with symptoms associated with pneumonia to seek care in an ED than a primary care practice. This cannot be confirmed from the alert itself because it did not register the chief complaints for which it fired.

Exhibit 22 summarizes the number of times that the alert was triggered in each setting, the number of clinicians who interacted with the alert, and the number of patients who had chief complaints that would trigger it.

Summary Counts	Bridgeport Hospital ED	Primed Stratford Primary Care Office	Total
Number of times alert fired	666	71	737
Number of clinicians who interacted with alert	133	5	138
Number of patients who triggered alert	563	56	619

Exhibit 22. Usage of CAP Alert in ED and Primary Care Office, March 23 – August 18, 2017

These figures indicate that 138 unique clinicians interacted with the alert during the study period, and that it was used on over 619 unique patients. Each ED clinician interacted with it on average of close to five times, and each primary care clinician on average of 14 times.

Once the alert was fired, users had to either agree or disagree with its recommendation in order to close the alert. This hard stop was created for the sole purpose of the study, and in doing so, the alert registered whether the clinician agreed or disagreed with the alert's recommendation of either admitting a patient or treating the patient at home. It did not, however, register the actual recommended site of treatment. Among those who used the alert, the majority of users "agreed" with its recommendation. Exhibit 23 provides the breakdown of the agreement or disagreement with the alert.

Exhibit 23. Registered Agreement or Disagreement with the CAP Alert, March 23-August 18, 2017

Responses to Alert	Bridgeport Hospital ED N (%)	Primed Stratford Primary Care Office N (%)
Will address suggested intervention (agree) (n, %)	368 (55)	54 (76)
Other follow-up action taken (disagree) (n, %)	293 (43)	12 (17)

No associated reason (n, %)	5 (1)	5 (7)
Total responses (n)	666	71

While it appears that the majority of clinicians in each setting agreed with the alert's recommendation, clinicians were also given the option of registering their reason for disagreeing with the alert in free text. Twenty-six clinicians offered brief explanations for why they did not agree. The most common was that the clinician reported that the patient did not have pneumonia but another condition, including asthma, chronic obstructive pulmonary disease (COPD), or cancer. Several commented that the timing of the alert was inappropriate, and some disagreed with the alert in order to close it. Further discussion of the clinician's decision-making regarding the hard stop will be provided in the summary of qualitative findings on this topic below.

Qualitative Findings

Whereas the quantitative findings speak to the volume of usage of the alert in both the ED and primary care settings, our qualitative findings offer insight into the extent to which clinicians with varying levels of clinical experience and expertise found it useful in their everyday practice and why. Below we present findings from interviews conducted with clinicians in both settings by themes related to their perspectives on the use of the alert, starting with their familiarity with the CURB/CRB-65 and any training they received on the CAP alert, and moving on to its integration in their workflow, their comments on its design, and their overall sense of its utility. In thinking about future studies, we also asked clinician champions to consider outcomes measures that could demonstrate its effectiveness, and present that information here.

CURB/CRB-65 Familiarity

Overall, most of our interview participants reported that they currently use a decision support tool for pneumonia, whether mentally or via a mobile phone app like MD-Calc. Most reported being familiar with such tools from

"It's a decision tool that I am using a lot of times anyway when I'm thinking about pneumonia. It's nice to have a reminder that pops up."

their training, and many used the CURB/CRB-65 tool itself, particularly in the emergency department.

Training

As described in the Implementation Toolkit section of this report, the clinician champions had several tools available to them for purposes of conducting trainings with their staff, including a tip sheet and a pamphlet. Although the clinician champions in both settings promoted the debut of a CAP alert in staff meetings, there was a difference in the level of training/communication that was provided in each setting, as well as training/communication actually received by staff members. Among our interview participants, few actually recalled receiving any formal training on the alert in either setting. This was due to several factors:

- Little dissemination of training materials beyond staff meetings
- Missed emails
- Non-attendance at the staff meeting(s) where the announcement was made, including the addition of new staff or residents following the announcements and trainings

The chairman of the ED noted that it's often difficult to get more than 80 percent staff attendance at monthly meetings due to Bridgeport being a training hospital with a constant fluidity of staff on site at any given time.

In the few cases where interviewees recalled receiving training of any kind, they reported receiving information about the alert through announcements at staffing meetings, a PowerPoint presentation at staff meetings, email announcements, emails containing the tip sheet and pamphlet, and a face-to-face training.

Recommendations for Training

Half of the participants mentioned that they would like some additional training. For the most part, these participants hadn't previously received any training, and would have liked training on workflow integration, how the alert is triggered (chief complaints), and an explanation of the criteria used to calculate the score and recommendation. Training could also include an explanation of the CURB/CRB-65 tool. As far as mode of training, participants requested signs or fliers posted near computer stations, a demonstration of the intended function of the alert, and a short handout/pamphlet on the alert. One participant said that training should cover both the CURB/CRB-65 and the alert itself.

Workflow Integration

"I feel like I definitely paid attention [to the alert]. It wasn't too intrusive." Two clinicians who were early in their career reported that they were able to integrate the alert into their workflow successfully. A physician's assistant said it integrated easily into her workflow because it just required her to answer one question, agree or disagree. A resident also

reported that it integrated well into his workflow, and called it a "gentle reminder" of pneumonia considerations. In the primary care setting, the clinician champion said he liked that the alert is located in the Planning tab before he sees the patient so that it can inform his prep work. A few others had mixed opinions on how well the alert integrated into their workflow.

However, most participants were dissatisfied with the degree to which the alert fit into their clinical workflow. Most simply put, an ED staff MD said, "It's impeding my workflow." Top reasons for dissatisfaction across both settings included:

- Inappropriate timing of the alert
- Not having sufficient information for a decision on site of care, particularly in the ED with the timing
 of chest X-ray results
- The hard stop (both its existence and general confusion surrounding it)

Two residents said that by the time the alert appeared, they had already made their decision about a pneumonia diagnosis and site of care, rendering the alert ineffective. Others said that they didn't have the chest X-ray result, but were forced to make a decision on the site of care when the alert popped up.

Variances in workflow seemed to be a major cause of dissatisfaction with integration. The ED clinician champion emphasized that, "the linearity of care in the ED is much less predictable [than in primary care]." Thus, not only did this make it very difficult from an implementation standpoint to select a point in time for the alert to fire, but it also led to "click-through"

"I don't really even pay that much attention. I just click through whatever to move on." behavior, wherein a user felt that the alert was disrupting patient care, so clicked through the alert quickly to make it disappear, often without reading the information. A couple of the clinicians also reported that they tended to click through other alerts that existed in the EHR. The literature shows that "alert" fatigue has been a common challenge with implementing CDS tools in the form of alerts.⁸⁹

In the primary care setting, the clinician champion described institution-wide efforts to encourage clinicians to conduct planning in the EHR before seeing a patient. Given this focus, the alert often appeared before the clinician saw the patient. This type of workflow often resulted in clinicians viewing this particular alert "too early." This issue was compounded as some clinicians perceived the alert to be a hard stop, requiring some action before they could proceed. PriMed clinicians, including two APRNs, one physician partner, and one clinician champion, felt forced to make a site of care decision if they saw the alert before the patient, not realizing that they didn't have to record their decision to agree or disagree with the alert until the visit was completed.

Sometimes satisfaction with workflow integration simply came down to preferences with the design of the alert. One APRN said: "[The alert] doesn't really sufficiently set up a trail of how my clinical decision-making evolved, and it doesn't really add to my clinical decision-making. I don't mind having an alert, but don't find this particular setup to be helpful." We will summarize findings on the design features and its limitation below.

The Hard Stop

Interview participants in both settings felt it was difficult to strike a balance between the alert appearing too early and too late in the patient encounter, and this was highly dependent on both general and personal workflow of clinicians. The real or perceived presence of a "hard stop" only compounded this. In the ED, we heard complaints such as "there are so many hard stops in [the EHR]," and in the primary care practice, clinicians thought that the alert forced them to make a decision before seeing the patient. As explained in the Development and Refinement of the Intervention section earlier in this report, the alert in the ED setting is indeed a hard stop upon first appearance that requires the user to "Agree with recommendation" or "Disagree with recommendation" in order to close the alert. However, in the primary care setting, the alert appears as an informational/non-interruptive alert in the "Planning" section and does not require any action of the user until the visit is complete. All of the clinicians at PriMed perceived this to be a hard stop that prevented them from navigating elsewhere in the record and required them to make a site of care decision before seeing the patient. However, the design in fact allows clinicians to exit the record to see the patient without clicking "Agree" or "Disagree" as long as the visit is not complete. Only when a visit is complete does the clinician have to choose a response to this alert. Thus, if clinicians in the primary care setting wished to conduct prep work before seeing the patient, they would be able to do so without acknowledging or closing the alert.

Other confusion surrounding the hard stop was that the participants often did not know whether they were meant to agree or disagree with the score, the site of care recommendation, or even the diagnosis of pneumonia. This sometimes caused clinicians to click either button just to make the alert disappear. One ED resident admitted that she usually solely selected "Disagree" for this reason. One primary care clinician recalled "agreeing" with a recommendation to discharge to the home because the patient was likely going to go home since he was being seen on as an outpatient even though he hadn't seen the patient yet.

It's worth noting here that the "Agree" and "Disagree" buttons were designed for the purposes of data collection during the pilot study, and may not be a final component of the design. A hard stop acknowledgment, in some other form, however, may still be included.

Recommendations for Workflow Integration

Participants had a range of recommendations for improving the workflow around this alert. In the ED, participants were divided between their preferences for the alert to appear at the point of disposition so that it might act as a double-check with their thinking, or for the alert to appear much earlier since some clinicians have already made up their mind on site of care and did not want advice at disposition. Some participants in the ED wanted to be able to choose when they wanted to see it—having it available as a tool to call upon inside the EHR. The most common recommendation in both settings was to include the ability to "snooze" the alert like an alarm clock, so that it could return when a clinician wanted to see it, typically after seeing the patient and/or receiving further lab work.

Usefulness

A few clinicians found the CAP alert to be useful. They believed it was a helpful reminder of the mortality risks and recommended disposition for patients with particular indicators who may have pneumonia. Junior staff, including one physician's assistant and two residents, were more likely to consider it useful and to consider using it than more experienced staff. The physician's

"I thought [the alert is] very good because it's always good to have a check to make you stop and think, especially with computers nowadays."

assistant said she was more likely to choose the CURB-65 over other pneumonia diagnostic tools, and for that reason appreciated that this was now an alert. The two residents reported that it was a simple tool that was easy to interpret, and one resident indicated that he already uses CURB-65 on the MD-Calc app.

Among more senior clinicians, both clinician champions reported that they thought the alert could be useful for less certain cases, such as someone with a score of two or three but who looked well, as it would prompt them to really consider the safety of recommending the treatment for the patient at home. Two APRNs in the primary care practice thought the alert may be useful if the score and criteria could be documented in a patient's chart, and then referenced when talking to an insurance company about a referral for hospital admission. One also reported a spillover effect in that the alert prompted her to check if a patient had been immunized for pneumonia.

However, by and large, the clinicians who did not find it useful felt that their clinical training and experience were sufficient in making a diagnostic decision about the severity of pneumonia and the site for disposition. The inappropriate timing of the alert and the lack of sensitivity to patients with pneumonia were other reasons for them to assert the primacy of their clinical judgment over the alert.

Design

In general, discussants expressed appreciation for the simplicity and clarity of the design of the alert. Clinicians considered several elements when thinking about the design of the CAP alert and suggestions for its improvement. They considered the extent to which it is an interruptive alert and the best placement for such an alert, as well as the presentation of the criteria and the visual content of the alert once it is viewed. They also discussed the hard stop, and how they could respond to the alert in terms of "agreeing" or "disagreeing." They did not take into account limitations that the designers had when creating the alert, and rather presented their suggestions as ideals for improvements.

Importantly, clinicians often took into account their previous experiences with other alerts when considering the design of the CAP alert. More than one participant said the alert was similar to the sepsis alert, with one explaining that it had similar timing. A physician's assistant at Bridgeport ED thought the CAP alert was easier and quicker than other alerts because it required little reading and selecting options. An ED resident thought that other alerts are too cumbersome because there are too many questions. A PriMed physician felt that he'd like to have more of a choice to use this alert as a tool, like the health maintenance advisory he uses. Another PriMed physician compared this alert to the health maintenance advisory, saying that was more a helpful CDS because it was "in the background" and provided an easy way to order what he needed within his workflow and did not require navigating to other places in the record. Comparatively, the CAP alert felt like a pop-up (or interruptive alert) to him since it appeared in the Planning section.

With regard to it being an interruptive alert, most clinicians in both settings would have preferred if it was not automatically activated, but rather could be sought out when needed. Such decision support could then be consulted at the most appropriate time in the workflow of the clinician, which could vary from patient to patient and clinician to clinician. Such a CDS tool would be used similarly to the way clinicians currently use CURB-65 calculators on MD-Calc, but would be in the system. A couple suggested that if it were an interruptive alert, clinicians be given the option to "snooze" the alert, and come back to it when more information had been gathered, including when the clinician had seen the patient or had received notice that a radiologist had read an X-ray. One clinician, an ED resident, also suggested that the alert appear at disposition rather than upon entering a patient's chart.

Clinicians questioned the display of the criteria that went into the alert, and requested that more information be given on the criteria in the display. Several offered suggestions to improve the display. While there was no single or dominant suggestion, we summarize the feedback we received on the display and the reasons for the design choices (if appropriate) in Exhibit 24.

User Feedback	Design Considerations
Use of acronyms problematic as all the terms used in the alert were not uniformly understood.	Acronyms were used because of a design limitation on the number of characters per line before the line breaks. The designer attempted to keep each criteria to a one-line display.
Provide clear information on "how" the score was calculated and what were the criteria that were included.	The designer did not include information on how the score was calculated in order to prevent the alert from being too "text heavy," thereby adding to provider cognitive burden.
The denominator (four for CRB-65 and five for CURB-65) should be placed in the design to give quick context and include color coding based upon the score.	The designer intended for the scores to be color-coded such that 1-2 were green, 3 was orange, and 4-5 were red, and so the severity of the score would be more readily understood, but the colors could not be used in the planning section of EHR.
Automatic recalculation of the score if confusion was present.	The alert could pull information only to inform the score and could not be edited through interaction or input from the clinician. This was a limitation within the EHR. Some argued that this was unnecessary given the simple addition of one extra point for the confusion criteria in cases when it applied, and only in the primary care setting.
Discussants suggested using the more common BUN threshold of 20 mg/DL instead of both it and the less common variation (7 mmol/L).	This change was implemented.

With regard to the acknowledgement or dismissal of the alert, clinicians had suggestions on the language or prompts that could be used to close it. At least one discussant recommended eliminating the buttons altogether and replacing them with a button to close the alert once viewed, allowing the clinician to continue with patient care. One suggested that a drop-down menu of common reasons for disagreeing with the alert could appear if the clinician suggested disagree, and could include choices such as, "patient does not have pneumonia," "haven't seen the patient yet," or "patient does not have a good support system to allow for discharge."

Most questioned the need for a hard stop alert, particularly when there were issues with the timing of the alert. If it were to be a hard stop, a clinician champion recommended changing the language to "this helped me," or "this did not help me" in making a decision about the severity of the patient's condition and site of treatment. He also believed a hard stop would be valuable if the alert could populate the EHR with a record of acknowledging it. For example, a record could allow the clinician to explain why the alert was helpful or not with language such as, "I reviewed this alert, the score was 1, the 30-day mortality is x%...but I'm comfortable that their social supports are fine, they have a community I can send them to, and therefore I will be discharging them to their home." When taken in conjunction with recommendations to make the alert more passive, the hard stop may become less problematic if the alert did not fire automatically, but was used only when needed.

Potential Outcome Measures

One goal of the site visit interviews was to elicit ideas for outcome measures to assess the various impacts of the CAP alert tool in future studies. One of the clinician champions offered the following potential outcomes for consideration:

- Whether the alert produced cost savings for encouraging outpatient treatment for lower-severity pneumonia, based on the scores generated for each patient and chosen disposition.
- Whether the recommendation provided by the alert led to a reduction in utilization and testing.
- Whether the alert influenced the disposition of the patients, using chart review and registering the disposition in the alert.
- Whether the high sensitivity of the alert, or its tendency toward false positivity, impacts its perception of utility by comparing its use and impact on clinical decision-making across different emergency departments.

In the future, researchers with an interest in further investigating this work can consider these issues when exploring impact of this alert.

Discussion

The evaluation of the CAP alert through monitoring of usage data and qualitative interviews with clinicians and clinician champions revealed lessons that could shape future implementation of such a tool in similar settings. It also helped answer the research questions that drove the study.

A major finding was the difference in the volume of alert usage in the ED compared to the primary care setting. Though the study did not occur during the peak CAP season, ED clinicians may have been more likely to interact with the alert due to overall differences in patient volume and rates of CAP diagnosis in each setting. While this finding may suggest that the alert has more relevance in the ED than the primary care setting, such an alert may also be useful in a primary care setting as the extra guidance may be more useful to those who diagnose the condition less often.

Findings also confirm what is known in the literature, which is that ED providers were much more familiar with alerts than primary care providers. Over 100 clinicians in the ED interacted with the alert with little training, whereas the few primary care providers needed guidance from the clinician champion in how to interact with it initially. Given the relative lack of use of alerts in primary care, more training may be warranted in this setting.

Both settings offered minimal trainings through announcements at staff meetings and email circulation of a tip sheet and pamphlet. The limited training raised questions among staff in both locations about what criteria were used in the alert, where the information came from, and why the criteria were important, and what the responses of "agree" or "disagree" were meant to capture. Lack of training in the primary care setting led in part to the mistaken impression that the alert required an immediate response.

Overall, interviewed ED clinicians were able to integrate the alert into their workflow more easily than clinicians in the primary care setting due to their greater overall familiarity with alerts. However, in both

settings, the alert was perceived to have limited utility because of design features that impeded a smooth workflow. A few ED clinicians early in their career felt the alert was helpful in supporting their clinical judgment, but most senior clinicians, including APRNs, preferred to use their clinical judgment instead of the alert.

Given the shared EHR system and centralized programming of alerts, the technical implementation of the alert required minimal resources. The design of the alert required the most resources for its implementation, but activating it was done remotely, and did not require participation from the host sites. Such an approach may be comparable in other integrated delivery systems. With the increased consolidation of health care systems and trend toward single source EHRs, the implementation of the alert in such settings could be similarly simple. However, lessons from the evaluation indicate that further training of staff may have enhanced the perceived utility of the alert, particularly given the inevitable design limitations that may prevent every user from intuitively understanding the purpose and use of the alert.

As tools intended to influence diagnostic decision-making regarding the severity of CAP patients and their disposition, our CAP alerts faced similar challenges to those of other diagnostic CDSs as described in the literature. As described by Berner (2014), underutilization of diagnostic decision support is due to 1) lack of perceived need for diagnostic decision support on the part of clinicians; 2) time and cost pressures that further reduced perceived utility; and 3) lack of feedback mechanisms of incorrect diagnosis that would then prompt consultation with a diagnostic decision support.⁹⁰ The author's suggestion to develop active alerts that fire or appear to fire for clinicians would encourage utilization, and registers with the approaches used for this project. In fact, though the alert for the primary care practice was not designed as an interruptive alert, the design team was pleased that clinicians perceived it that way anyway, as it encouraged them to engage with it.

In our project, we identified several challenges with designing and implementing an active alert for CAP that provided access to diagnostic reference information and guidelines. They included:

- 1. Clinicians not being near the computer but with the patient when making the diagnosis.
- 2. Clinical guidelines that often do not account for temporal evolution of findings during clinical care. Translating them into real-time interventions is challenging because all information is not available at the start of the process and occurs over time.
- 3. Nuances in how clinicians interact with patients during a clinical encounter that make it difficult to identify a universally suitable time for an alert.

While having appropriately timed diagnostic decision support may improve its perceived utility, it may also require a change in the way the provider interacts with the patient. A recent study of a diagnostic decision support intervention in an ambulatory primary care setting in England found that while most providers studied (74 percent) found the intervention to be useful, they were also critical of the need to engage with it while seeing their patients. While patients noticed this as well, satisfaction measures of patients were no different among those in the intervention group than those in the comparison group without the tool.⁹¹ While this is promising, the primary care practice in our study encouraged clinicians to complete their planning for their patients prior to seeing patients, which led to the perceived inappropriate firing of the alert.

Further study is needed to both refine the instrument and identify outcome measures that would appropriately assure that the alert is being used as intended, and that it is achieving desired outcomes.

Participants in the evaluation were most interested in outcome measures related to cost and utilization of services, given that the tool is meant to help clinicians determine severity and site of treatment.

Appendix A: Usability Testing Protocols

Usability Testing Protocol: Emergency Department Setting

Below is the usability testing protocol used in the emergency department setting.

Part 1: Controlled User Testing in a Laboratory Setting

"Thank you for taking the time to meet with us. My name is [INTERVIEWER NAME], and I work for NORC at the University of Chicago, a national, not-for-profit research and social service organization. The Agency for Healthcare Research and Quality in the Department of Health and Human Services has contracted with NORC to develop clinical decision support for community-acquired pneumonia. We are conducting a usability assessment of the decision support prototype that our team has developed. There will be three parts to this testing, the first of which involves an exploration of the decision support tool.

We will present a scenario to you, and ask you to use the prototype advisory to complete the task. We'll observe you as you use it and we may ask questions along the way. We ask that you think aloud as you work through the task.

Do you have any questions?"

- 1. Ask the user to think aloud as they go
- 2. Observe
 - Critical errors
 - Non-critical errors
 - *Time spent on each section (and any hesitation)*
 - Use of resources

Proposed Scenario:

John Smith arrives in your practice and has been complaining of having a productive cough, chest pain and fever for 3 days.

For the ED: The doctor examines the patient and orders a chest X-ray and a lab test

- 1. Have the participant sign in as <u>Test User</u> A and select today's encounter for <u>Patient X</u>, per the written instructions.
 - The facilitator will fill out the form indicating which test station the user has as well as which test patient.

2. Physician views vital signs screen

- Say: "Assume the nurse has already entered the patient's vital signs."
- May need to prompt: "Where would you go next?"
- User should navigate to the Planning section

3. View pneumonia advisory

- The user will view the Planning section and the Best Practice Advisories; the Pneumonia Advisory will be listed first.
- Ask: "What information do you see presented here in the advisory?"

- Ask: "What assumptions would you have at this point in the encounter?"
- o Observe:
 - \Box How does the user react to the advisory?
 - \Box Does the user read the top heading?
 - \Box What does the user make of the colored box?
 - □ Does the user see the link for more details in the colored box?
 - □ Does the user understand the information below the colored box?
 - \Box Is there any information presented to the user that seems to be confusing?
 - \Box Does the user notice the evidence link?

4. Assessment of confusion in the patient

- Ask: "What would you do if the patient was *not* presenting with confusion (i.e., oriented to person, place, and time)?"
- Ask: "What next step would you take if the patient *is* confused?"
- o Observe:
 - □ Does the user click on the "updates" link in the colored box if the patient is presenting with confusion?
- o May need to prompt: "What does this information on the new screen mean?"

5. Review recommendation

- Ask: "Now that you've assessed the patient's confusion, what would you do next?"
- o Observe:
 - □ Does the user see the acuity information and site of care recommendation?
- o May need to prompt: "What do you think the information below the colored box means?"

6. Make site of care decision

- Ask: "How would you proceed once you've reviewed all the information on the advisory?"
 - □ Ask: "What would you do if you didn't agree with the advisory?"
 - □ "How would you document so that your reason can be retrieved later?"
- o Observe:
 - How does the user interact with the "Acknowledge Reason" section?
- o Ask: "Are the options in the Acknowledge Reason section adequate?"

Part 2: Interview (Individual or Group Discussion)

After the conclusion of the controlled user testing, we will hold individual discussions with those who have participated in the testing. This will be a semi-structured discussion.

Thank you again for taking the time to speak with us. Now that you have explored the clinical decision support system for opioid prescribing, we'd like to get your thoughts on that experience. We are conducting this discussion with you in order to learn more about your use of the clinical decision support (CDS) system for community-acquired pneumonia and your experience with the new tool.

Before we start, I would like to take a second to assure you:

1. There is no right or wrong answer to the questions I will ask. We are interested in hearing your thoughts, whether they are positive or negative.

- 2. We may use your comments, but we will not include any names or identifying information in our report. All information you share is confidential.
- 3. Remember, your participation is voluntary, and you may stop the discussions at any time.

Our conversation today should take about 10 minutes; is this acceptable for you?

We will begin our discussion on the specific features of the CDS.

Utility

- What functions, capabilities, and/or features did you like? Why?
- What functions, capabilities, and/or features did you find lacking? Why?
- Please comment on how you anticipate this process will integrate into your clinical workflow.
- Did you feel that you had enough information to complete the task? If no, please discuss what additional pieces of information you need.

We would now like to focus on gathering feedback on how easy or difficult you found it to use the CDS.

Usability

- How intuitive did you find the pneumonia advisory to use?
- What did you find most challenging about using the clinical decision support tool?
- What did you find easiest about using the system?
- How did you feel about the amount of time it took you to complete the task?

We'd like to gather some general thoughts from you on the CDS prototype.

General Comments

- What did you like the best about the system?
- What did you like the least about the system?
- How would you enhance the system?

Part 3: Usefulness, Satisfaction, and Ease of Use Survey

We'd now like to give you a survey to complete on the usefulness, satisfaction, and ease of use of the clinical decision support prototype. It is based on an industry-standard questionnaire for assessing usability.

Adapted from the Usefulness, Satisfaction and Ease of Use (USE) Questionnaire: Arthur Lund, Sapient, 2001.

1=Strongly Disagree, 7=Strongly Agree							
Please rate each statement on a scale of 1 to 7.	1	2	3	4	5	6	7
Usefulness							
1. It is useful.							
2. It meets my needs when treating patients with community acquired pneumonia.							
3. It does everything I would expect it to do.							
Ease of Use							
4. It is easy to use.							
5. It is user-friendly.							
6. It requires the fewest steps possible to accomplish what I want to do with it.							
7. It is flexible.							
8. I can use it without written instructions.							
9. I don't notice any inconsistencies as I use it.							
10. Both occasional and regular users would like it.							
11. I can recover from mistakes quickly and easily.							
Ease of Learning			<u> </u>				
12. I learned to use it quickly.							
13. I easily remember how to use it.							
14. It is easy to learn to use it.							
Satisfaction				1			
15. I am satisfied with it.							
16. It works the way I want it to work.							
17. It is pleasant to use.							

Usability Testing Protocol: Primary Care Setting

Below is the usability testing protocol used in the primary care setting.

Part 1: Controlled User Testing in a Laboratory Setting

"Thank you for taking the time to meet with us. My name is [INTERVIEWER NAME], and I work for NORC at the University of Chicago, a national, not-for-profit research and social service organization. The Agency for Healthcare Research and Quality in the Department of Health and Human Services has contracted with NORC to develop clinical decision support for community-acquired pneumonia. We are conducting a usability assessment of the decision support prototype that our team has developed. There will be three parts to this testing, the first of which involves an exploration of the decision support tool.

We will present a scenario to you, and ask you to use the prototype tool to complete the task. We'll observe you as you use it and we may ask questions along the way. We ask that you think aloud as you work through the task.

Do you have any questions?"

- 1. Ask the user to think aloud as they go
- 2. Observe
 - Critical errors
 - Non-critical errors
 - Time spent on each section (and any hesitation)
 - Use of resources

Proposed Scenario:

John Smith arrives in your practice and has been complaining of having a productive cough, chest pain and fever for 3 days.

For the primary care setting: The Medical Assistant takes a medical history and the doctor then examines the patient.

- 1. Have the participant sign in as <u>Test User</u> A and select today's encounter for <u>Patient X</u>, per the written instructions.
 - The facilitator will fill out the form indicating which test station the user has as well as which test patient.

2. Physician views vital signs screen

- Say: "Assume the medical assistant has already entered the patient's vital signs."
- May need to prompt: "Where would you go next?"
 - □ User should navigate to the Planning section

3. View pneumonia advisory

- The user will view the Planning section and the Best Practice Advisories; the Pneumonia Advisory will be listed first.
- Ask: "What information do you see presented here in the advisory?"
- Ask: "What assumptions would you have at this point in the encounter?"
- Observe:

- \Box How does the user react to the advisory?
- \Box Does the user read the top heading?
- \Box What does the user make of the colored box?
- □ Does the user see the link for more details in the colored box?
- □ Does the user understand the information below the colored box?
- □ Is there any information presented to the user that seems to be confusing?
- \Box Does the user notice the evidence link?

4. Assessment of confusion in the patient

- Ask: "What would you do if the patient was *not* presenting with confusion (i.e., oriented to person, place, and time)?"
- Ask: "What next step would you take if the patient *is* confused?"
- o Observe:
 - □ Does the user click on the more details link in the colored box if the patient is presenting with confusion?
- May need to prompt: "What does this information on the new screen mean?"

5. Review recommendation

- o Ask: "Now that you've assessed the patient's confusion, what would you do next?"
- o Observe:

□ Does the user see the acuity information and site of care recommendation?

o May need to prompt: "What do you think the information below the colored box means?"

6. Make site of care decision

- Ask: "How would you proceed once you've reviewed all the information on the advisory?"
 - □ Ask: "What would you do if you didn't agree with the advisory?"
 - □ "How would you document so that your reason can be retrieved later?"
- o Observe:

□ How does the user interact with the "Acknowledge Reason" section?

o Ask: "Are the options in the Acknowledge Reason section adequate?"

Part 2: Interview (Individual or Group Discussion)

After the conclusion of the controlled user testing, we will hold individual discussions with those who have participated in the testing. This will be a semi-structured discussion.

Thank you again for taking the time to speak with us. Now that you have explored the clinical decision support system for opioid prescribing, we'd like to get your thoughts on that experience. We are conducting this discussion with you in order to learn more about your use of the clinical decision support (CDS) system for community-acquired pneumonia and your experience with the new tool.

Before we start, I would like to take a second to assure you:

- 1. There is no right or wrong answer to the questions I will ask. We are interested in hearing your thoughts, whether they are positive or negative.
- 2. We may use your comments but we will not include any names or identifying information in our report. All information you share is confidential.
- 3. Remember, your participation is voluntary, and you may stop the discussions at any time.

Our conversation today should take about 10 minutes; is this acceptable for you?

We will begin our discussion on the specific features of the CDS.

Utility

- What functions, capabilities, and/or features did you like? Why?
- What functions, capabilities, and/or features did you find lacking? Why?
- Please comment on how you anticipate this process will integrate into your clinical workflow.
- Did you feel that you had enough information to complete the task? If no, please discuss what additional pieces of information you need.

We would now like to focus on gathering feedback on how easy or difficult you found it to use the CDS.

Usability

- How intuitive did you find the pneumonia advisory to use?
- What did you find most challenging about using the clinical decision support tool?
- What did you find easiest about using the system?
- How did you feel about the amount of time it took you to complete the task?

We'd like to gather some general thoughts from you on the CDS prototype.

General Comments

- What did you like the best about the system?
- What did you like the least about the system?
- How would you enhance the system?

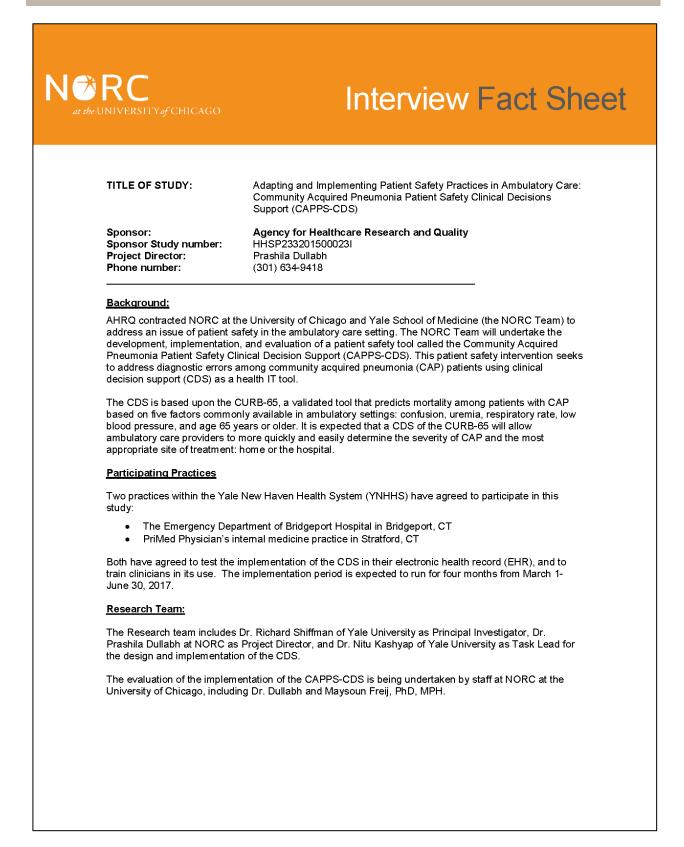
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We'd now like to give you a survey to complete on the usefulness, satisfaction, and ease of use of the clinical decision support prototype. It is based on an industry-standard questionnaire for assessing usability.

Adapted from the Usefulness, Satisfaction and Ease of Use (USE) Questionnaire: Arthur Lund, Sapient, 2001.

1=Strongly Disagree, 7=Strongly Agree						ree	
Please rate each statement on a scale of 1 to 7.	1	2	3	4	5	6	7
Usefulness			<u> </u>	<u> </u>			
1. It is useful.							
2. It meets my needs when treating patients with community acquired pneumonia.							
3. It does everything I would expect it to do.							
Ease of Use							
4. It is easy to use.							
5. It is user-friendly.							
6. It requires the fewest steps possible to accomplish what I want to do with it.							
7. It is flexible.							
8. I can use it without written instructions.							
9. I don't notice any inconsistencies as I use it.							
10. Both occasional and regular users would like it.							
11. I can recover from mistakes quickly and easily.							
Ease of Learning							
12. I learned to use it quickly.							
13. I easily remember how to use it.							
14. It is easy to learn to use it.							
Satisfaction	<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>	
15. I am satisfied with it.							
16. It works the way I want it to work.							
17. It is pleasant to use.							

Appendix B: Evaluation Protocols



Interview Procedures:

During the interview, you will asked about your experiences with the CAPPS-CDS in your practices. Topics will include trainings, workflow, overall utility, lessons learned, and recommendations. We may also discuss how to measure the impact of the CDS better in the future. The interview last for about 30 minutes.

In addition to the NORC staff facilitating the discussion, a staff member will take notes during the interview. With your permission, we will record the discussion to help develop transcripts of the interview, and to make sure comments are captured accurately. Only NORC researchers assigned to this study will be listening to the recordings as they will help us write a report about the key findings from these discussions.

NORC will keep these recordings and any associated data private to the extent permitted by law (as described in the Privacy Act of 1974).

Confidentiality:

You will not be identified in any report or publication of this study or its results. We will keep information about you confidential, and protect it from unauthorized disclosure, tampering, or damage. Any potentially identifying information, including audio recordings from the discussion, will be kept in a secure location during the period of the study. This information will be used only for the purposes of the study and will be destroyed after the project is over. Your name and any material that could identify you will remain confidential.

Risks and Benefits of Participation:

We will be asking you questions about your practice of medicine after the CAPPS-CDS tool was implemented. We understand that some of these questions may relate to the health circumstances of individual patients, and we ask that you not reveal any protected personal information in your answers.

To thank you for your time, we offering you a \$50 gift card. We hope the discussion will be interesting to you, as it will help give AHRQ ideas about how to improve this and similar patient safety tools.

Right to refuse or to withdraw from the study:

Your participation is voluntary. You may refuse to participate, skip questions, or end the interview at any time without penalty.

Institutional Review Board Approval

This study has been reviewed by NORC and Yale's Institutional Review Boards. If you have questions about your rights as a study participant, you may call the NORC Institutional Review Board Administrator, toll free, at 866-309-0542.

For questions about the study, please contact Dr. Richard Shiffman, 203-737-5213, <u>richard.shiffman@yale.edu</u>, or Dr. Prashila Dullabh, 301-634-9418, <u>Dullabh-Prashila@norc.org</u>.

Clinician Champions Interview Guide

- Introduce NORC staff
- Thank you very much for your time today.
- NORC at the University of Chicago is a nonprofit research organization, and we are working with the Agency for Healthcare Research and Quality (AHRQ) to study the implementation of the alert for pneumonia in your practice.
- In this interview we'd like to talk about your experiences implementing the alert for pneumonia in your practice and training clinicians. We'd also like to discuss how well you think the practice, and its providers were able to work it into their workflow. Finally, we'd like to know how useful you think the alert is, how you think its effectiveness could be measured, and whether or not it could be replicated in other practices.
- Just a few things before we get started.
 - We've scheduled this meeting to last [1 hour]. **If you need to stop for any reason**, that's fine. We know you're busy and your participation is voluntary.
 - As much as we want to hear what you have to say, it is completely **okay for you not to answer any question** if you don't want to.
 - Sharing your opinions or experiences using the alert will not impact your employment, or be reflected in any kind of assessment of job performance.
 - We won't share anything you have to say as coming from you personally. We will keep your name confidentially in any summaries or reports we make to AHRQ or the public.
- We have a member of our team from NORC taking notes so we can write our reports, and we'd like to make an audio recording to help make sure we get everything. The notes and recording will only be used by NORC to write our reports. Is that ok?
- Do you have any questions before we begin?

Introductions

We'd like to start with some brief introductory questions.

- 1. Could you briefly describe your role in this practice (Bridgeport ED or PriMed)?
- 2. How long have you been with the practice, and in your present role?
- 3. What made you interested in participating in this study?
- 4. Do you personally currently use any assessment tools for pneumonia?
 - Are you familiar the CURB-65 tool or CRB-65 tool?
 - Do you know what the components are of the CURB-65? (Age 65+, <u>c</u>onfusion, <u>u</u>rea, <u>respiratory rate</u>, and <u>blood pressure</u>)

Training

Now, we'd like to discuss the training on the alert for pneumonia in your practice/ED.

- 5. Could you please describe how you introduced the alert to the providers in your practice?
- 6. What was the training process like in terms of:
 - Was the training more about the CURB-65 tool or how to use the alert?
 - The number of providers trained?
 - The amount of time spent training providers in a group?
 - Amount of time spent training providers individually?
 - The amount of time you gave providers to self-train or get up to speed using the alert?
- 7. How useful were the training materials offered to you in training your clinicians?
 - What materials were particularly useful, and why?
 - What was unnecessary or not used? Why?
- 8. Did you need to provide any additional training or support to providers after the initial training?
 - What was it like? What kind of support was needed?
- 9. Do you have any recommendations for the training materials?
 - Anything that should be changed or improved in any way?

Technical Implementation

We'd like to ask some questions about technically implementing the alert in your EHR.

- 10. How easy or difficult was it to implement the alert in your EHR?
 - What facilitators were there to implementation?
 - What challenges?
- 11. What kinds of technical assistance did you need or receive from Dr. Raj Brar or Dr. Nitu Kashyap after implementation?
 - How often would you speak with them?

Workflow

We'd like to turn to your perspectives on how the alert fit into your ED's/ practices workflow.

- 12. As a provider, were you able to integrate the alert into your workflow?
 - Did it launch as planned in the EHR?
 - Do you think it launched at the most appropriate time in the workflow?
 - Did you have any technical problems using it?
 - We know the design intended for the alert to fire before decision-making. Do you have any suggestions for when would be an opportune time for it to fire?
- 13. <u>For ED:</u> We know the alert is designed to bring the confusion value recorded by nurses forward from the chart. If you had to look for it yourself, do you know where to access information on patient confusion in the chart?

- Is the alert then providing value to you by bringing it forward?
- 14. For Primary Care: How did you take patients' confusion into account when using BPA?
 - Did you add confusion mentally then adjust the recommendation based on the additional point?
 - Did the addition of a point for confusion affect whether you "agreed" or "disagreed" with the BPA's recommendation?
- 15. How do you feel about having a hard stop in the alert that you have to address before you move on?
 - Would you have answered "agreement" or disagreement if it were not a hard stop?
- 16. How often did you provide a reason for "agreeing" or "disagreeing" with the BPA recommendation?
 - What was the most common reason for disagreeing with it?
- 17. How would you compare the alert usage to other alerts operating in your practices?
 - clinical utility
 - Interrupting your work flow
 - overall design
- 18. Do you have any recommendations that would improve the workflow around the alert usage?
 - Why do you think you used it regularly, or not?
 - Were you encouraged to use it in any way? If so, how?
- 19. Do you think that the alert could be sustained after the study period (after June 2016)? Why or why not?
 - What would enable you to sustain it? What would discourage it?

Provider Perspectives on the CDS

Diving a little deeper, we'd like to hear more about your impressions of the alert as a provider.

- 20. Overall, how useful do you think this alert is to your practice of medicine?
 - How would you compare it to other assessment tools you may use for pneumonia?
- 21. How often would you say you used it to make a decision about whether to admit or treat a patient at home when you diagnosed them with pneumonia?
 - Why do you think you used it regularly, or not?
 - Were you encouraged to use it in any way? If so, how?
- 22. How often would you say you used it to make a decision about whether to admit or treat a patient at home when you diagnosed them with CAP?
- 23. Did the alert help your practice/ED in any way?
 - Making decisions?
- 24. Would you like to continue using the alert after the study period (after June 2016)? Why or why not?

Identification of Outcome Measures

In this study, we are mostly assessing the implementation and use of the alert to assist in the diagnosis of CAP. However, in the future, we would consider expanding to look at outcomes measures such as the impact of the alert on providers' decision-making, or patient outcomes, such as the rate of hospitalization or readmissions.

- 25. From your perspective, how could the impact of the alert on patient safety be measured?
 - How readily available are patient outcome measures such as the rate of hospitalization or admissions following an initial treatment plan at home?
 - What patient or practice factors should be considered when making such measures?
- 26. Do you have any recommendations on measuring the impact of the alert on provider decisionmaking or patient outcomes?

Replicability

Looking beyond this study, we'd like to ask a few questions that may help others implement the alert in other practices.

- 27. In terms of implementing this alert in other practices similar to your own, what are the minimum requirements needed to implement it?
 - What if the practice were larger (or smaller)?
- 28. Is there anything in particular about your practice that you think made its implementation particularly successful? Or particularly difficult?
- 29. Do you have any recommendations for similar practices seeking to implement this alert?
- 30. Do you have any thoughts on how we should report on the findings of this study so that providers can learn from your experience, or even be encouraged to implement such an alert? This could include suggestions on:
 - Format (i.e., report, blog, webinar, etc.)?
 - Style (technical/ nontechnical)?
 - Other?

Wrap Up

Thanks so much for your time. To wrap up, we just have a couple closing questions.

- Overall, how successful would you say the implementation of the alert was in your practice?
 Why do you consider it to be so?
- 32. Any final thoughts on the implementation of this alert or alerts on patient safety in general?

Thank you for your time!

Provider Interview Guide

Introduction

- Introduce NORC staff
- Thank you very much for your time today.
- NORC at the University of Chicago is a nonprofit research organization, and we are working with the Agency for Healthcare Research and Quality (AHRQ) to study the implementation of an alert for pneumonia in your practice.
- In this interview we'd like to talk about your experiences with the alert for pneumonia in your practice, including any training you received, how it fit into your workflow, and how useful you think it is. We'd also like to know your thoughts on how its effectiveness could be measured, and whether or not it could be replicated in other practices.
- Just a few things before we get started.
 - We've scheduled this meeting to last [1 hour]. **If you need to stop for any reason**, that's fine. We know you're busy and your participation is voluntary.
 - As much as we want to hear what you have to say, it is completely **okay for you not to answer any question** if you don't want to.
 - Sharing your opinions or experiences using the alert for pneumonia will not impact your employment, or be reflected in any kind of assessment of job performance.
 - We won't share anything you have to say as coming from you personally. We will keep your name confidentially in any summaries or reports we make to AHRQ or the public.
- We have a member of our team from NORC taking notes so we can write our reports, and we'd like to make an audio recording to help make sure we get everything. The notes and recording will only be used by NORC to write our reports. Is that ok?
- Do you have any questions before we begin?

Introductions

We'd like to start with some brief introductory questions.

- 1. Could you briefly describe what type of provider you are?
 - How long have you been with the practice/ED, and in your present role?
- 2. Do you currently use any assessment tools for pneumonia?
 - Are you familiar the CURB-65 tool or CRB-65 tool?
 - Do you know what the components are of the CURB-65? (Age 65+, confusion, urea, respiratory rate, and blood pressure)

Training

Now, we'd like to discuss training on the alert for pneumonia in your practice/ED.

- 3. Could you please describe how you first learned about the alert for pneumonia in your practice/ED?
 - What were you told about it?
 - What was your initial impression of it?
- 4. What kind of training did you receive on it?
 - Was the training more about the CURB-65 tool or how to use the alert?
 - Was it in a group or individually?
 - Who was leading it, and what is his/her role in this practice?
 - Did you spend any time on your own learning about it?
 - How much time did you spend in trainings overall?
- 5. How useful were the training materials offered given to you?
 - What materials were particularly useful, and why?
 - What was unnecessary or not used? Why?
- 6. Did you need any additional training or support after the initial training? If yes:
 - What did you need?
 - Did you receive it?
 - Was it helpful?
- 7. Do you have any recommendations for the training materials?
 - Anything that should be changed or improved in any way?

Workflow

We'd like to turn to your perspectives on how the alert for pneumonia fit into your workflow.

- 8. As a provider, were you able to integrate the alert into your workflow?
 - Do you think it launched at the most appropriate time in the workflow?
 - Did you have any technical problems using it?
 - We know the design intended for the alert to fire before decision-making. Do you have any suggestions for when would be an opportune time for it to fire?
- 9. <u>For ED:</u> We know the alert is designed to bring the confusion value recorded by nurses forward from the chart. If you had to look for it yourself, do you know where to access information on patient confusion in the chart?
 - Is the alert then providing value to you by bringing it forward?
- 10. For Primary Care: How did you take patients' confusion into account when using BPA?
 - Did you add confusion mentally then adjust the recommendation based on the additional point?
 - Did the addition of a point for confusion affect whether you "agreed" or "disagreed" with the BPA's recommendation?
- 11. How do you feel about having a hard stop in the alert that you have to address before you move on?
 - Would you have answered "agreement" or "disagreement" if it were not a hard stop?
- 12. How often did you provide a reason for "agreeing" or "disagreeing" with the BPA recommendation?
 - What was the most common reason for disagreeing with it?
- 13. How would you compare the alert for pneumonia to other alerts operating in your practice?
 - clinical utility
 - Interrupting your work flow
 - overall design
- 14. What recommendations do you have that would improve the workflow around the CDS usage?

Provider Perspectives on the CDS

Diving a little deeper, we'd like to hear more about your impressions of the alert for pneumonia.

- 15. Overall, how useful do you think this alert is to your practice of medicine?
 - How would you compare it to other assessment tools you may use for pneumonia?
- 16. How often would you say you used it to make a decision about whether to admit or treat a patient at home when you diagnosed them with pneumonia?
 - Why do you think you used it regularly, or not?
 - Were you encouraged to use it in any way? If so, how?

17. Did you have any formal or informal way of offering your feedback on the alert to administrators? And if so, did you?

Identification of Outcome Measures

In this study, we are mostly assessing the implementation and use of the alert to assist in the diagnosis of pneumonia. However, in the future, we would consider expanding to look at things such as the impact of the alert on providers' decision-making, or patient outcomes, such as the rate of hospitalization or readmissions.

- 18. From your perspective, how could the impact of the alert on patient safety be measured?
 - How readily available are patient outcome measures such as the rate of hospitalization or admissions following an initial treatment plan at home?
 - What patient or practice factors should be considered when making such measures?
- 19. Do you have any recommendations on measuring the impact of the alert on provider decisionmaking or patient outcomes?

Replicability

- 20. Looking beyond this study, we'd like to ask a few questions that may help others implement the alert in other practices. Is there anything in particular about your practice/ED that you think made its implementation particularly successful? Or particularly difficult?
- 21. Do you have any recommendations for similar practices seeking to implement this alert? If yes, please discuss.
- 22. Do you have any thoughts on how we should report on the findings of this study so that other providers can learn from your experience, or even be encouraged to implement such an alert? This could include suggestions on:
 - Format (i.e., report, blog, webinar, etc.)?
 - Style (technical/ nontechnical)?
 - Other?

Wrap Up

Thanks so much for your time. To wrap up, we just have a couple of closing questions.

- 23. Overall, how successful would you say the implementation of the alert was in your practice/ED?
 - Why do you consider it to be so?
- 24. Any final thoughts on the implementation of this alert or alerts on patient safety in general?

Thank you for your time!

Administrators' Interview Guide

- Introduce NORC staff
- Thank you very much for your time today.

- NORC at the University of Chicago is a nonprofit research organization, and we are working with the Agency for Healthcare Research and Quality (AHRQ) to study the implementation of an alert for pneumonia in your practice.
- In this interview we'd like to talk about your experiences implementing the alert for pneumonia in your practice and training clinicians. We'd also like to discuss how well you think the practice and its providers were able to work it into their workflow. Finally, we'd like to know how useful you think the alert for pneumonia is, how you think its effectiveness could be measured, and whether or not it could be replicated in other practices.
- Just a few things before we get started.
 - We've scheduled this meeting to last [1 hour]. **If you need to stop for any reason**, that's fine. We know you're busy and your participation is voluntary.
 - As much as we want to hear what you have to say, it is completely **okay for you not to answer any question** if you don't want to.
 - Sharing your opinions or experiences using the CDS will not impact your employment, or be reflected in any kind of assessment of job performance.
 - We won't share anything you have to say as coming from you personally. We will keep your name confidentially in any summaries or reports we make to AHRQ or the public.
- We have a member of our team from NORC taking notes so we can write our reports, and we'd like to make an audio recording to help make sure we get everything. The notes and recording will only be used by NORC to write our reports. Is that ok?
- Do you have any questions before we begin?

Introductions

We'd like to start with some brief introductory questions.

- 1. Could you briefly describe your role in this practice (Bridgeport ED or PriMed)?
- 2. How long have you been with the practice and in your present role?
- 3. Do you currently use any assessment tools for pneumonia?
 - Are you familiar the CURB-65 tool or CRB-65 tool?
 - Do you know what the components are of the CURB-65? (Age 65+, confusion, urea, respiratory rate, and blood pressure)

Training

Now, we'd like to discuss the training on the alert for pneumonia in your practice/ED.

- 4. Did you have any role in introducing the alert for pneumonia to the providers in your practice?
 - If so, could you please describe how you introduced the alert to the providers in your practice?

- 5. What was the training process like in terms of:
 - The number of providers trained?
 - The amount of time spent training providers in a group?
 - Amount of time spent training providers individually?
 - The amount of time you gave providers to self-train or get up to speed using the alert?
 - Was the training more about the CURB-65 tool or how to use the alert?
- 6. How useful were the training materials offered to you in training your clinicians?
 - What materials were particularly useful, and why?
 - What was unnecessary or not used? Why?
- 7. Did you need to provide any additional training or support to providers after the initial training?
 - What was it like? What kind of support was needed?
- 8. Do you have any recommendations for the training materials?
 - Anything that should be changed or improved in any way?

Workflow

We'd like to turn to your perspectives on how the alert fit into your ED's/ practices workflow.

- 9. At a practice level, was the alert integrated into its workflow?
 - Did it launch as planned in the EHR?
 - Were providers observed using the alert? If yes, what are your perceptions on the ease of use?
- 10. Do you have any recommendations that would improve the workflow around the alert usage?
- 11. Do you think that the alert could be sustained after the study period (after June 2016)? Why or why not?
 - What would enable you to sustain it? What would discourage it?

Replicability

Looking beyond this study, we'd like to ask a few questions that may help others implement the alert for pneumonia in other practices.

- 12. In terms of implementing this alert in other practices similar to your own, what are the minimum requirements needed to implement it?
 - What if the practice were larger (or smaller)?
- 13. Is there anything in particular about your practice that you think made its implementation particularly successful? Or particularly difficult?
- 14. Do you have any recommendations for similar practices seeking to implement this alert?
- 15. Do you have any thoughts on how we should report on the findings of this study so that providers can learn from your experience, or even be encouraged to implement such an alert? This could include suggestions on:
 - Format (e.g., report, blog, webinar, etc.)?

- Style (technical/ nontechnical)?
- Other?

Wrap Up

Thanks so much for your time. To wrap up, we just have a couple of closing questions.

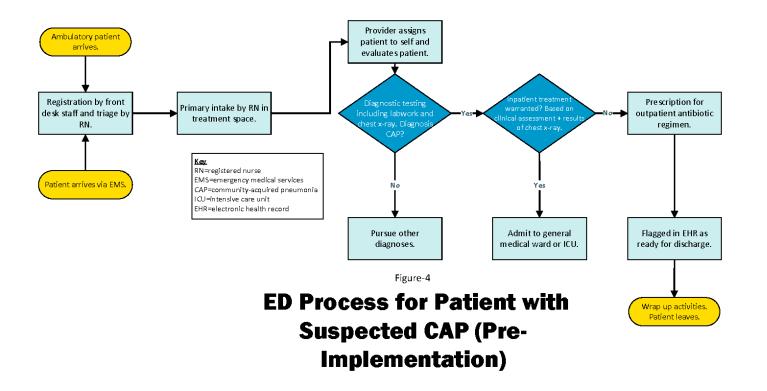
- 16. Overall, how successful would you say the implementation of the alert was in your practice?
 - Why do you consider it to be so?
- 17. Any final thoughts on the implementation of this alert or alerts on patient safety in general?

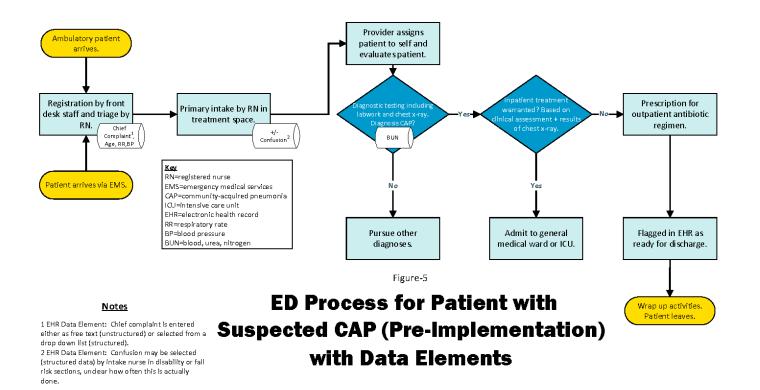
Thank you for your time!

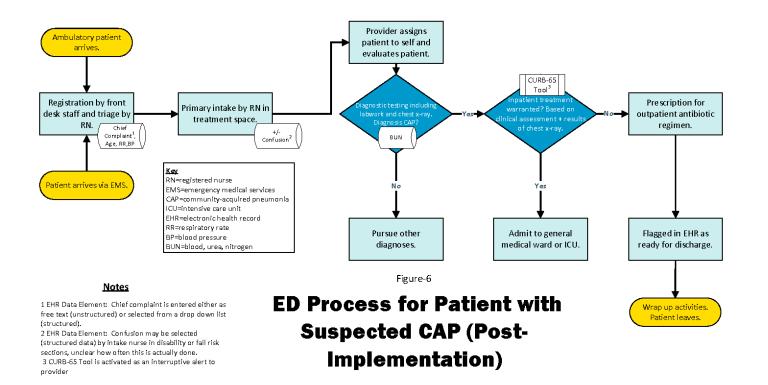
Appendix C: Workflow Diagrams

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Emergency Department Workflow Diagrams

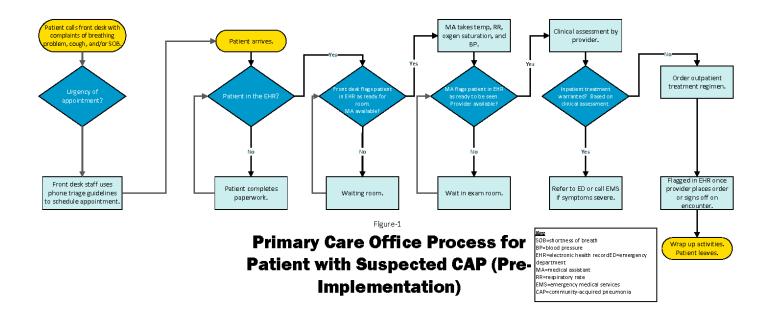


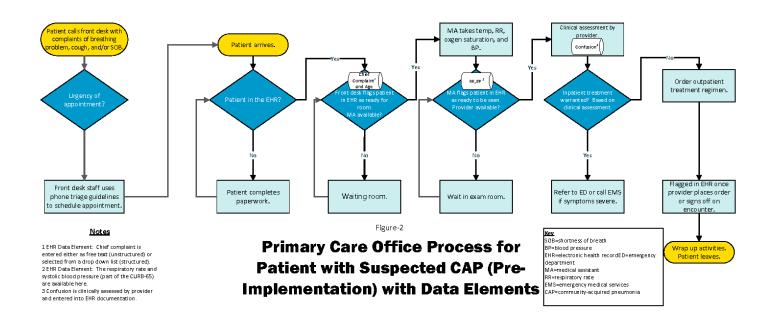


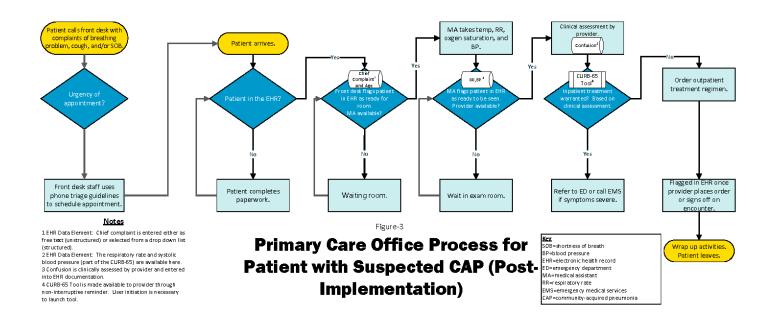


NORC | Clinical Decision Support for Community Acquired Pneumonia

Primary Care Workflow Diagrams







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