Lung Ultrasound Implementation in the Management of Patients Hospitalized With COVID-19

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Background/Significance

The pandemic of coronavirus 2 (SARS-CoV-2) began in December of last year Hubei Province of China has now spread to 124 countries. The number of confirmed cases and deaths grow daily by the thousands. The Institute for Health metrics and Evaluation (IHME) at University of Washington most conservative estimates indicate that even if all preventative measures taken to slow the spread of this disease, 100,000-200,000 people will predicted die from COVID globally7. Given what is currently known about the pace of its spread and the prevalence of severe disease requiring hospitalization, it is projected that even the most advanced healthcare systems will be overwhelmed, and resources will be severely constrained8 which is the current reality at the proposed study site, University of Colorado Hospital.

Interstitial pneumonia and Acute Respiratory Distress Syndrome (ARDS) are the most common serious manifestation of COVID-19 which has an estimated case-fatality rate of 0.25-3%, with a definitive increased risk for patients older than 609 who have an estimated mortality rate of 10%. Patients evaluated using chest CT have shown to present with bilateral ground-glass opacities (GGO) that are peripheral in distribution that progress to and consolidative pulmonary opacities as the disease progresses. Changes in CT due to COVID have been shown to manifest in many patients prior to symptoms and before the PCR for the virus becomes positive. Although CT has been shown to be more sensitive than PCR in the detection of this disease10the American College of Radiology has recommended against using this modality as a screening tool in patients with suspected COVID-19 and recommends only sparing use in patients with known COVID in largely because of the infectious risk to hospital staff and the stress it will put on the imaging services of a health care system given the number of patients with COVID-19 that will be affected with respiratory failure.

LUS is known to have comparable sensitivity to CT in the diagnosis of interstitial processes like pulmonary edema11, the earliest manifestation of COVID lung involvement. Other LUS findings described thus far in COVID patients include irregular or thickened pleura, and subpleural consolidations. In Italy, where LUS is more commonly used than other parts of the world, clinicians report using LUS as their primary imaging modality in COVID patients due to its accuracy and practical advantages over CT and chest x-ray and have already published a proposed standardized protocol for LUS in patients with suspected or confirmed COVID- 1912. Even prior to the COVID pandemic multiple society guidelines4,13 have endorsed the use of LUS by generalists for the diagnosis of pulmonary edema and pneumonia because of the robust data demonstrating it high accuracy, feasibility (easy to learn and perform), patient centeredness (avoids radiation and improves patient satisfaction), and the reduction in time to diagnosis associated with its use14. In addition, there is growing evidence that it improves patient outcomes15. This endorsement by multiple national societies are in part driven by recent improvement in affordability and portability of handheld ultrasound machines. Devices with good image resolution that can be plugged into small tablet devices and cost $2000-5000 dollars are now available.

LUS has the potential to greatly improve resource utilization and management of COVID patients in both high and low resources settings. In high resource settings, like the proposed

pilot site, University Colorado Hospital, implementation of LUS will conserve PPE, technician exposure and help prevent monopoly of the CT scanner and radiology services by COVID patients which would otherwise overwhelm hospital resources given the number of COVID patients and additional time needed to perform appropriate disinfection which would delay care to all hospitalized patients. In resource limited settings, given that nearly half of the world have no access to imaging including x-ray16, LUS will provide chest imaging where no imaging is otherwise available and provide more certainty in diagnosis of COVID where the PCR, currently the gold standard test, is not available. The data collected from the proposed study will serve as pilot data for a larger multicenter study to evaluate implementation in settings of diverse typologies allowing for the expedited dissemination of LUS to all clinical settings.

Brief Approach

Objective: Evaluate this pilot implementation of LUS by adult hospitalists using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework.

Conceptual Framework

We will use the Practical, Robust, Implementation, and Sustainability Model (PRISM) as the conceptual framework for our study. PRISM is the conceptually expanded version of RE-AIM developed from different models arising from other spheres important to implementing evidenced-based practice including chronic illness care, diffusion of innovation, and quality improvement concepts17. The contextual domains of PRISM allow for evaluation of how an intervention is received by recipients of the health care setting, helping to identify implementation strategies that will result in a better fit between intervention and setting and ultimately resulting in improved implementation and effectiveness as measured by the RE-AIM domains of PRISM which are Reach, Effectiveness, Adoption, Implementation, and Maintenance. Contextual domains in PRISM include: External context (i.e. national policies, guidelines, incentives) and Internal context (i.e. multilevel organizational characteristics, perspectives, implementation and sustainability infrastructure). Use of

PRISM allows for consideration of a multilevel, dynamic context and will guide us in adapting and tailoring our implementation strategies to our dynamic inpatient context enhancing implementation and effectiveness.

Study overview:.

We will begin LUS implementation using strategies that target barriers already identified by hospitalists in our prior qualitative work. We will then proceed to conduct weekly rapid Plan-Do-Study-Act cycles informed by Rapid Iterative RE-AIM, in order to ensure timely identification of implementation barriers. Rapid Iterative RE- AIM18 is an innovative application of the RE-AIM framework in which screening assessments of RE-AIM outcomes (e.g. level of reach, adoption, implementation) which is performed at regular intervals during implementation and has been shown to be a feasible means of assessing interval implementation. For outcomes not meeting target implementation at our interval assessments, we will perform rapid qualitative interviews of key stakeholders to identify current barriers. Using the contextual domains of

PRISM and rapid qualitative data from stakeholders we will select new or adapt existing implementation strategies, facilitating robust implementation. Study outcomes will be measured using the RE-AIM outcomes from PRISM including Reach, Adoption, Implementation. Effectiveness and Maintenance will not be evaluated given this is a pilot study. Data collection will occur over 12 months.

Study Setting: University of Colorado Hospital is a 620 beds academic level 1 trauma center in Denver, Colorado.

Participant Recruitment: Hospitalist participants will be recruited from among the faculty of University of Colorado Hospital Division of hospital medicine which has over 100 physician and advanced practice clinicians (APPs) and who care for 190 hospitalized patients daily. All hospitalized patients with COVID that are not triaged to the ICU are admitted to the hospitalist service.

Study Procedures:
All hospitalist physicians and APPs will be offered training in LUS. Once a provider has completed training, they may begin performing LUS on COVID patients. The images will be wirelessly uploaded into PACS. The provider's LUS interpretation will be documented in the EMR. Rapid Iterative RE-AIM will be performed on a bi weekly basis as a means of iteratively screening for implementation barriers. The implementation outcomes of both fidelity and adaptation will be prioritized although all aspects of implementation will be evaluated. Interval Reach will be screened for using EMR data. For RE-AIM domains with poor implementation, we will use qualitative methods19 to obtain stakeholder perspectives of barriers and suggestions for adaptations to existing strategies or new strategies.

Measures/Data Collection Study Outcomes:
Reach: We will measure the percentage of patients hospitalized with a positive COVID test result who received a LUS during the hospitalization. We will compare the demographics and characteristics of the eligible patients who received a LUS versus those that did not in order to identify disparities in implementation that can be addressed by adapting our implementation strategies. We will explore the underlying reasons for disparities in Reach using qualitative interviews of providers and other stakeholders as appropriate.

Adoption:
Adoption by clinicians will be measured by calculating the percentage of clinicians who completed the LUS training module within the UCH hospitalist group. We will also measure the percentage of clinicians who performed at least 1 LUS exam. We will evaluate for differences between providers who did and did not complete training. We will interview hospitalists who did not complete training or did not perform LUS to understand why LUS was not adopted.

Implementation:

We will focus on collecting implementation outcomes that are particularly relevant to the evaluation of diagnostic tests. Fidelity will be measured using data available through the EMR and through qualitative interviews of providers regarding their clinical decision-making. EMR data will be gathered by random selection of at least 10% of LUS exams within the EMR over the prior 30 days using the following 3 components to evaluate fidelity. 1. Image quality: Through the EMR, we will assess whether image acquisition was adequate using a checklist of image requirements. 2. Image interpretation: we will review interpretation of POCUS by assessing ultrasound reports in the EMR using a checklist 3. Clinical Decision-making using the LUS result: Assess appropriate integration of POCUS findings into the clinical decision-making by review of the LUS report in the EMR and daily clinician progress notes well as through qualitative interviews of providers.

Analysis:

Descriptive statistics will be performed for the outcome