

Feasibility and Safety of Substituting Lung Ultrasonography for Chest Radiography When Diagnosing Pneumonia in Children

A Randomized Controlled Trial



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BACKGROUND: Chest radiography (CXR) is the test of choice for diagnosing pneumonia. Lung ultrasonography (LUS) has been shown to be accurate for diagnosing pneumonia in children and may be an alternative to CXR. Our objective was to determine the feasibility and safety of substituting LUS for CXR when evaluating children suspected of having pneumonia.

METHODS: We conducted a randomized control trial comparing LUS with CXR in 191 children from birth to 21 years of age suspected of having pneumonia in an ED. Patients in the investigational arm underwent LUS. If there was clinical uncertainty after ultrasonography, physicians had the option to perform CXR. Patients in the control arm underwent sequential imaging with CXR followed by LUS. The primary outcome was the rate of CXR reduction; secondary outcomes were missed pneumonia, subsequent unscheduled health-care visits, and adverse events between the investigational and control arms.

RESULTS: There was a 38.8% reduction (95% CI, 30.0%-48.9%) in CXR among investigational subjects compared with no reduction (95% CI, 0.0%-3.6%) in the control group. Novice and experienced physician-sonologists achieved 30.0% and 60.6% reduction in CXR use, respectively. There were no cases of missed pneumonia among all study participants (investigational arm, 0.0%; 95% CI, 0.0%-2.9%; control arm, 0.0%; 95% CI, 0.0%-3.0%), or differences in adverse events, or subsequent unscheduled health-care visits between arms.

CONCLUSIONS: It may be feasible and safe to substitute LUS for CXR when evaluating children suspected of having pneumonia with no missed cases of pneumonia or increase in rates of adverse events.

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ABBREVIATIONS: CXR = chest radiography; EDLOS = ED length of stay; LUS = lung ultrasonography; PED = pediatric ED

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Pneumonia is the leading cause of death in children worldwide.¹ Children with pneumonia may initially present with fever, cough, and tachypnea. However, these signs and symptoms are commonly seen in viral respiratory infections as well and therefore do not reliably predict bacterial pneumonia.² Other clinical examination findings, including those obtained by means of auscultation, have also proven to be unreliable.³⁻⁵ Chest radiography (CXR) is considered the test of choice for diagnosing pneumonia in children. The World Health Organization, however, has estimated that as many as three-quarters of the world's population do not have access to diagnostic imaging.⁶

Use of point-of-care lung ultrasonography (LUS) is growing,⁷⁻⁹ with published international evidence-based recommendations available.¹⁰ LUS for diagnosing

pneumonia in children has been shown to be highly accurate in multiple settings.^{9,11,12}

Given the limited availability of radiography in the developing world, LUS may be a substitute for CXR in the diagnosis of pneumonia.⁶ In health-care settings with access to advanced imaging, LUS may also function as a triage instrument to determine the need for CT or magnetic resonance imaging (in cases of complex pneumonia) or as an add-on test when prior imaging, such as CXR, is nondiagnostic.¹³ Additionally, as ultrasonography is portable, less costly than radiography, and safe for children,¹⁴ it may be the imaging modality of choice for all health-care settings for the diagnosis of pneumonia. Our objective was to determine the feasibility and safety of substituting LUS for CXR when evaluating children suspected of having pneumonia.

Materials and Methods

We conducted a randomized control trial of diagnostic tests¹⁵ from August 1, 2012, to July 31, 2013, at an urban pediatric ED (PED). Our institutional review board, the Program for the Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai, approved this study 12-00153. The study population was a convenience sample of patients (enrolled 24 hours a day, 7 days a week by available study physicians) who met predetermined inclusion criteria and from whom written informed consent and assent in those ≥ 7 years of age had been obtained from the patient or guardian prior to enrollment into the study.

Inclusion criteria consisted of patients from birth to 21 years of age presenting to the PED with clinical suspicion of having pneumonia requiring CXR for evaluation. Pneumonia was suspected in patients with a combination of fever, cough, tachypnea, or abnormal findings at auscultation. We excluded patients with a previously performed CXR or those who were hemodynamically unstable.

Before enrollment, study physicians assessed for signs and symptoms of pneumonia. Physicians obtained a history on a standardized data collection form, documenting presence or absence of fever, cough, difficulty breathing, chest pain, and abdominal pain. Triage vital signs were recorded.

Study sonologists (physicians who obtained and interpreted ultrasonographic images) consisted of 15 PED attending physicians and fellows with varying levels of point-of-care ultrasonographic experience. They underwent a 1-hour LUS training session prior to study start. A six-zone scanning protocol of the chest (video with scanning protocol, normal lung and pneumonia: <https://youtu.be/R60PgPKQNeU>)

was used as described by Shah et al,¹² imaging the chest in perpendicular planes in the midclavicular line anteriorly and posteriorly on the chest, and in the midaxillary line from the axillae to the diaphragm. Training consisted of a 30-minute lecture on recognition of disease¹⁶⁻¹⁸ (Fig 1) and potential errors followed by a 30-minute hands-on scanning session of normal models.¹² Similar to methods used in prior studies,^{11,12} study sonologists used the sonographic finding of lung consolidation with air bronchograms as the definition of pneumonia on LUS.¹⁰ For purposes of analysis, subcentimeter pneumonia was defined as focal lung consolidations with sonographic air bronchograms less than 1 cm in diameter that are undetectable with CXR (video: <https://www.youtube.com/watch?v=JHmBillu5oQ&feature=youtu.be>).¹² B-lines (defined as hyperechoic vertical reverberation artifact arising from the pleural line to the bottom of the ultrasound screen without fading, and move synchronously with lung sliding),¹⁰ confluent B-lines, and small subpleural consolidations (with no air bronchograms) as described by Caiulo et al¹⁷ and Tsung et al¹⁸ were considered ultrasonographic findings viral in etiology.

Random Assignment

Eligible subjects were randomly assigned using an Internet-based randomization program (www.SherlockMD.org). Patients were assigned to investigational and control arms with the use of permuted blocks of variable lengths, stratified by sonologist experience. All PED staff, patients, and guardians were aware of group assignments, as blinding of allocation was not feasible for this study.

Study Intervention

All subjects randomly assigned to the investigational arm underwent LUS with use of a 10- to 5-MHz linear-array transducer (M-Turbo; SonoSite). If there was clinical uncertainty, or if the referring physician, admitting service, or guardian requested CXR, the enrolling physician had the option of performing CXR. These reasons for performing CXR were documented on our data collection form. All subjects randomly assigned to the control arm underwent sequential imaging with CXR first followed by LUS. All treatment decisions were left to the physician's discretion. In the investigational arm, enrolling physicians documented LUS interpretations prior to CXR to maintain blinding to CXR results.

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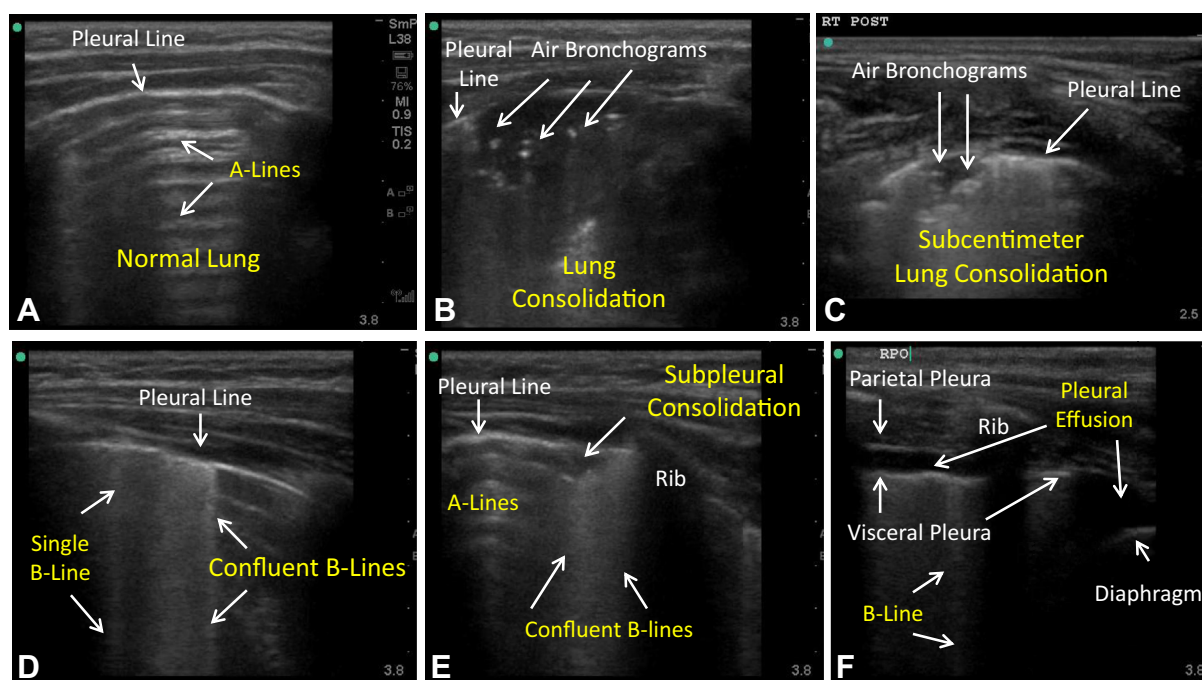


Figure 1 – Lung ultrasonographic images. A, Normal lung (A-lines). B, Focal pneumonia, radiographically apparent (≥ 1 cm lung consolidation with air bronchograms). C, Focal pneumonia, radiographically occult (< 1 cm lung consolidation with air bronchograms). D-E, B-lines, confluent B-lines, subpleural consolidation more commonly associated with viral pneumonia or bronchiolitis; note subpleural consolidations (< 0.5 cm) without sonographic air bronchograms visible. F, Pleural effusion (anechoic space between lung and chest wall or diaphragm).

Radiologists interpreting CXRs (posterior-anterior and lateral views) were blinded to all LUS results.

Outcome Measures

The primary outcome was to determine whether LUS can be a safe substitute for CXR when evaluating children suspected of having pneumonia. Specifically, we hypothesized that LUS could reduce CXR use in the investigational arm compared with the control arm (with control patients possibly leaving PED prior to CXR). Analysis was further stratified by experience, defining *novice* and *experienced* sonologists as those who had performed ≤ 25 and >25 LUS examinations, respectively, on the basis of the American College of Emergency Physicians ultrasonographic guidelines.¹⁹ The secondary outcomes included the following: (1) unscheduled health-care visits within 1 to 2 weeks after the index ED visit to determine disposition and clinical course of enrolled children, (2) rates of antibiotic use, (3) ED length of stay (EDLOS), and (4) hospital admission rates.

Study physicians monitored children for adverse events (death or clinical deterioration requiring resuscitation) during observation in the PED. We defined missed pneumonia as diagnosed by a health-care provider during a repeat ED or other health care visit with radiographic or clinical evidence of pneumonia and initiation of antibiotics. A patient safety monitoring board, included physicians not involved with patient enrollment, monitored for any adverse events.

Quality assurance was performed by investigators-sonologists (B. P. J., E. T. T., and J. W. T.). They reviewed all ultrasonographic images and video to classify errors made by study sonologists and to calculate interobserver agreement (Cohen's kappa) for the diagnosis of

pneumonia between enrolling sonologists' interpretations and an investigator sonologist (J. W. T.) blinded to clinical examination findings.

To measure potential cost savings from a payer perspective, we performed a cost analysis by using the difference between \$370²⁰ as the average CXR cost in the United States and \$140, the cost for point-of-care ultrasonography at our institution, which is similar to national estimates (J. Resnick, MD, personal communication, August 2015), and multiplied by the number of times CXR was not used in the investigational arm.

Statistical Analysis

We calculated the sample size required to provide more than 80% power (with a two-sided alpha level of .05) to detect an absolute reduction in CXR use of 15% or more in the investigational group. The enrollment period was planned for at least 1 year or a minimum of 60 subjects per arm. An interim analysis for monitoring of excess adverse events, including missed pneumonia, was performed on 60 enrolled subjects with the patient safety monitoring board.

The primary analysis was based on the intention-to-treat principle, with all patients included in their assigned group. A secondary subgroup analysis for EDLOS examined patients who did and those who did not undergo CXR in the investigational group.

All outcomes between groups were compared by using a Pearson chi-squared test. The alpha level was set at .05 for all analyses, 95% CIs were calculated, and all comparisons were two tailed. Data analysis was performed with the use of SPSS 20.0 (IBM).

Results

Two hundred eleven children were screened for study eligibility, and 191 were enrolled and randomly assigned (Fig 2). All baseline demographic and clinical characteristics were similar in both groups (Table 1). Mean (SD) LUS examination duration was 7 (3) minutes.

Main Outcomes

We found a 38.8% (95% CI, 30.0%-48.9%) reduction in CXR use in the investigational arm compared with no reduction (95% CI, 0.0%-3.6%) in the control arm. The number needed to treat per scan was 2.5, so for every 2.5 children who undergo LUS, 1 can be spared CXR. Pneumonia was diagnosed radiographically in 14 of 103 patients in the investigational arm and 12 of 88 patients in the control arm. Dispositions and outcomes are presented in e-Figure 1. A sample of correlated CXR and LUS images are available at this link: https://youtu.be/AuIeQaZs7EI?list=PLHg2xyua_KjtS_bBnMWlmJH1ujUPnA92n.

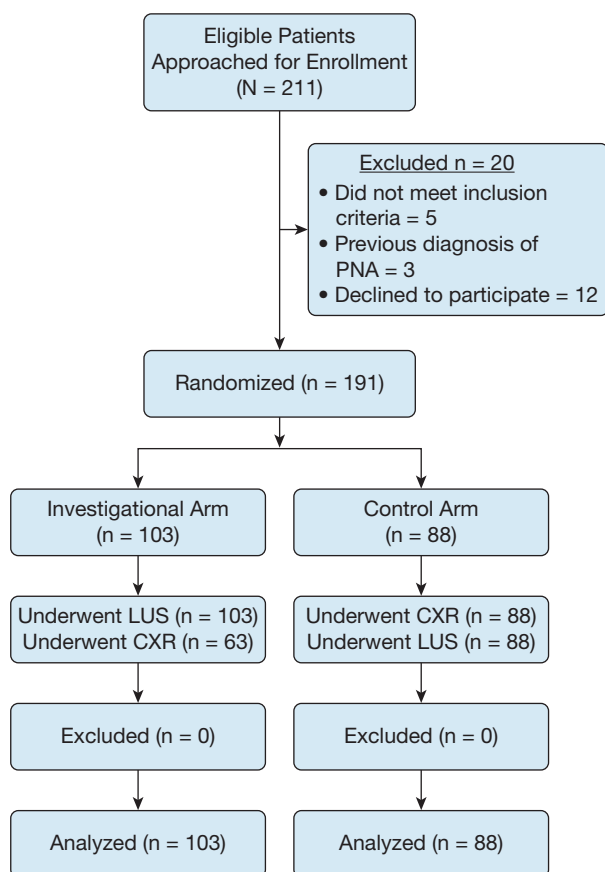


Figure 2 – Consolidated Standards of Reporting Trials (CONSORT) flow diagram. CXR = chest radiography; LUS = lung ultrasonography; PNA = pneumonia.

TABLE 1] Baseline Characteristics

| Characteristic | Investigational Group (n = 103) | Control Group (n = 88) |
|-----------------------------|---------------------------------|------------------------|
| Age, median, y ^a | 3 (1.6, 6.0) | 3 (1.7, 5.7) |
| Sex (female) | 49.5 (51) | 55.7 (49) |
| Tachypnea for age | 26.2 (27) | 28.4 (25) |
| Fever at triage ≥ 38°C | 46.6 (48) | 46.6 (41) |
| Cough | 98.1 (101) | 97.7 (86) |
| Difficulty breathing | 54.4 (56) | 54.5 (48) |
| Chest pain | 16.5 (17) | 11.4 (10) |
| Abdominal pain | 11.7 (12) | 11.4 (10) |
| History of fever | 84.5 (87) | 85.2 (75) |

Data are presented as No. (%) unless indicated otherwise. There were no statistically significant differences in baseline characteristics.

^aData are presented as the median (interquartile range).

For novice and experienced sonologists, we found a 30.0% (95% CI, 23.5%-36.5%) and 60.6% (95% CI, 47.0%-74.1%) reduction in CXR use, respectively, between arms. For patients ≤ 2 years and > 2 years, there were 47.9% (95% CI, 34%-62%) and 30.9% (95% CI, 19.5%-44.9%) reductions in CXR use, respectively, between arms.

Including CXR performed after conclusive LUS results at the request of the admitting service (n = 16), referring primary care physician (n = 6), or parent or guardian (n = 7), there was a potential maximal reduction in CXR of 67% (95% CI, 59.9%-75.0%). The number needed to treat per scan was 1.5, so for every 1.5 children who undergo LUS, 1 can be spared CXR.

Secondary Outcomes

Results for secondary outcomes are presented in Table 2. There were no statistically significant differences with respect to missed pneumonia (investigational arm, 0.0%: 95% CI, 0.0%-2.9%; control arm, 0.0%: 95% CI, 0.0%-3.0%), unscheduled health-care visits, rates of consolidated pneumonia visible radiographically, rates of antibiotic use at the index ED visit, overall median EDLOS, and hospital admission rates between groups. A statistically significant difference was observed for the EDLOS in the LUS-only subgroup of the investigational arm compared with the control arm (Table 2).

Antibiotic treatment and diagnoses are presented in e-Figure 2. Correlations between LUS and CXR results and test performance characteristics are presented in

TABLE 2] Secondary Outcomes

| Secondary Outcome Measure | Investigational Group (n = 103) | Control Group (n = 88) |
|--|---|---------------------------|
| Missed pneumonia | 0.0 (0.0-2.9) | 0.0 (0.0-3.0) |
| Unscheduled health-care visits | 8.7 (3.3-14.1) | 11.4 (4.8-18.0) |
| Antibiotic use at index ED visit | 37.9 (28.5-47.2) | 27.3 (17.9-36.6) |
| LUS or CXR confirmed pneumonia | 28.2 (20.0-36.9) | 18.1 (10.1-26.1) |
| CXR positive for pneumonia | 13.6 (6.9-20.2) | 13.6 (6.4-20.8) |
| LUS positive for pneumonia (≤ 1 cm) | 14.6 (7.8-21.4) | 4.5 (0.2-8.8) |
| Median EDLOS overall, ^a min | 153 (120, 252) | 180 (139, 241) |
| Median EDLOS (LUS only vs control), ^a min | LUS only (n = 40) 132 (103, 138) | 180 (139, 241) |
| Median EDLOS (LUS only vs LUS and CXR), ^a min | LUS only (n = 40) 132 (103, 138) LUS and CXR (n = 63) 190 (129, 272) | ... |
| Admission rate | 19.4 (11.8-27.0) | 17.0 (9.2-24.8) |

Data are presented as % (95% CI) unless indicated otherwise. All $P > .05$ except LUS only vs control EDLOS. CXR = chest radiography; EDLOS = ED length of stay; LUS = lung ultrasonography.

^aData are presented as the median (interquartile range).

supplemental e-Tables 1 and 2. There were no adverse events as a result of subjects' undergoing LUS. No changes in treatment or missed pneumonia were found in those investigational patients for whom enrolling sonologists thought CXR was unnecessary but who performed CXR because of parental, primary care physician, or admitting team request. There was one death among subjects enrolled in the control arm (sepsis from central line infection) that was determined to be unrelated to the study by the data safety monitoring board. The reduction in CXR use in the investigational arm resulted in an overall cost reduction of \$9,200 in our study.

The Cohen's kappa between enrolling sonologist and expert reviewing sonologist for the overall study was 0.81 (95% CI, 0.71-0.90). No dynamic air bronchograms, a highly specific finding for pneumonia described in adults,²¹ were noted in any lung consolidations identified by enrolling sonologists or at expert quality assurance review.

Discussion

Determining whether a new diagnostic test can serve as a substitute, a triage instrument,¹⁸ or an add-on test to an existing test¹³ requires more than a simple assessment of its sensitivity and specificity.¹⁵ Data demonstrating the high accuracy of LUS for evaluating pneumonia in children has been published and reviewed from multiple settings around the world.⁹⁻¹² Data comparing important patient-centered outcomes between diagnostic testing pathways using point-of-care

ultrasonography by using randomized control trial design are available for adults^{8,22} but have not been obtained for children.

Our study comparing LUS first with selective CXR against CXR followed by LUS in evaluating children suspected of having pneumonia decreased CXR use by 38.8%. There were no cases of pneumonia missed based on clinical follow-up or adverse patient outcomes among those who underwent LUS alone, thus demonstrating that it may be feasible and safe to substitute LUS for CXR when evaluating children suspected of having pneumonia.

Widespread use of LUS could have large savings in health-care costs. The reduction in CXR use in the investigational arm resulted in an overall cost reduction of \$9,200 in our study. Substantial cost savings may be obtained because of the large decrease in radiography use demonstrated in our study. However, we did not perform a formal economic analysis incorporating precise medical costs; hospital costs; and indirect costs such as radiation-induced cancers, parental days off work, patient utilities, or sensitivity analyses.

Ultrasonography emits no radiation and poses no increased lifetime cancer risk in infants and children.¹⁴ LUS may be an alternative imaging option in children who are at high risk for radiation-induced cancers²³ and have undergone multiple radiographic or CT imaging studies.²⁴⁻²⁷

Another potential benefit is more efficient ED throughput. Our mean LUS examination times were

the same as those reported by Shah et al.¹² Our intention-to-treat analysis showed a nonsignificant 26.5-minute reduction in EDLOS in favor of the investigational arm. Nevertheless, our result is consistent with data published by Kocher et al.²⁸ and Stiell et al,^{29,30} showing radiography added at least 27 or more minutes to EDLOS.

We suspected LUS would increase the rate of antibiotic treatment because of its ability to detect subcentimeter lung consolidations.^{12,18} CXR can miss solitary pulmonary nodules averaging from 1.6 to 1.8 cm (range, 0.4-5.5 cm) in patients suspected of having lung cancer.³¹⁻³³ Similarly, Shah et al¹² (in table 2 in their article) observed that subcentimeter consolidations in patients suspected of having pneumonia were not detected with CXR and that in the three cases that involved equivocal CXR readings for pneumonia, the corresponding lung consolidations on LUS measured 1.5 to 1.8 cm (in depth from the pleural line), suggesting a limit for CXR in detecting small pneumonia.

In our study, there was a 10.6% difference (Table 2) (37.9%, investigational arm; 27.3%, control arm) in the rates of antibiotic use between the two arms. This statistically nonsignificant difference was likely because of LUS's ability to detect small, subcentimeter lung consolidations undetectable on CXR.¹² There were 14.6% children with subcentimeter lung consolidations in the investigational arm and 4.5% children with subcentimeter lung consolidations in the control arm. We speculate that the enrolling sonologists may have relied on CXR more than on the subsequent ultrasonographic images in the decision to treat with antibiotics in the control arm, or were more concerned with missing pneumonia in patients in the investigational arm or both. However, a minority of the enrolled patients with subcentimeter lung consolidations with air bronchograms required admission to the hospital with intravenous antibiotics because of fever, hypoxia, or respiratory distress (five of 13 in each arm) (e-Fig 1); this number was similar to that observed and documented by Shah et al¹² (three of 12). Further research is needed to determine whether subcentimeter lung consolidations require treatment with antibiotics or whether a watchful waiting approach can be adopted similar to treatment for acute otitis media for improved antibiotic stewardship.

Our study had several limitations. First, this was a single-center study performed in a PED of a general academic medical center and may not generalize to other PEDs or health-care settings. However, reports of LUS with highly accurate pediatric pneumonia diagnosis

from around the world have been published in a meta-analysis,⁹ and LUS has been used as the only imaging modality for evaluating childhood pneumonia in resource-limited settings,³⁴ which may suggest otherwise. Second, we were unable to calculate test performance characteristics adhering to the Standards for Reporting of Diagnostic Accuracy³⁵ because 38.8% of the subjects in the investigational arm did not undergo CXR that would have served as a practical reference standard (e-Tables 1, 2).¹² By design, the sonologists were not blinded to CXR results in the control arm so that the information could be used to guide treatment. Lack of blinding to a reference standard could be a potential source of bias in calculated test performance characteristics for LUS. Additionally, test performance characteristics of LUS in the investigational arm would not be directly comparable with test performance characteristics of LUS in the control arm (e-Table 2). Chest CT imaging would allow direct comparison of accuracy between CXR and ultrasonography³⁶; however, performing chest CT imaging in all patients was not practical and not standard of care. Furthermore, we have used the same techniques reported in our own prior study¹² and similar to those in other studies that have shown high test performance characteristics for LUS.^{9,11} No missed pneumonias occurred with selective use of CXR in the investigational arm and sequential imaging (LUS as an add-on test after CXR) in the control arm.

Third, because of the inherent design of our study, there was a high probability that the CXR use rate in the control arm would be at or near 100%. However, there was a small possibility of control patients leaving prior to CXR because of prolonged ED waiting times, which did not occur. Fourth, a control arm in which subjects did not undergo any imaging may have yielded valuable information in comparing diagnostic imaging with a purely clinical diagnosis of pneumonia. However, there were ethical concerns about withholding the option of performing CXR in patients enrolled into a nonimaging control arm. Fifth, physicians treating study participants could not be blinded to group assignments, so they were required to integrate LUS findings into the clinical decision-making process. This lack of blinding may have introduced bias toward more rapid provision of care in the investigational arm. Sixth, our study may not have had sufficient power to detect statistically significant differences in the secondary outcomes of interest, such as missed pneumonia, unscheduled health-care visits, subcentimeter lung consolidations, and antibiotic treatment rates. Lastly, we note an imbalance in subjects

enrolled between our investigational and control arms. To accomplish random assignment stratified by sonologist experience, sonologists were assigned variable block lengths of four to 20 subjects. This method was used to maintain allocation concealment prior to randomization but had the inadvertent effect of unblocking our overall study when sonologists did not complete their assigned block lengths to balance random assignment between groups. However, proportions of demographic and baseline characteristics between groups were similar and not statistically different from each other, and the imbalance did not appear to bias any of our study outcomes.

Future research can further refine specific scenarios in which LUS in conjunction with clinical prediction rules² can safely achieve higher substitution rates for CXR in

the evaluation of children suspected of having pneumonia. Additionally, pairing point-of-care LUS with the World Health Organization algorithm may improve management and outcomes for childhood pneumonia in resource-limited settings, particularly those with no access to diagnostic imaging technologies.^{6,34}

In conclusion, we observed a significant reduction in CXR use when LUS was used as the initial diagnostic imaging test. It may be feasible and safe to substitute LUS for CXR when evaluating children suspected of having pneumonia with no missed cases of pneumonia or statistically significant increase in rates of adverse events. However, further research is needed to investigate the effect of LUS on antibiotic use and stewardship.

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Author contributions: B. P. J. conceptualized and designed the study; enrolled patients; acquired, analyzed, and interpreted data for the study; drafted the initial manuscript; and reviewed, critically revised, and approved the final manuscript as submitted. E. T. T., I. E., and B. P. N. enrolled patients; acquired and assisted in the interpretation of data; and reviewed, critically revised, and approved the final manuscript as submitted. J. E. S., A. Z. P., and L. A. S. enrolled patients; acquired data; and reviewed, revised, and approved the final manuscript as submitted. J. W. T. conceptualized and designed the study; enrolled patients; acquired data; provided material and technical support; drafted the initial manuscript; supervised the overall study conduct and the analysis, plan, and writing of the manuscript; and approved the final manuscript as submitted.

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Additional information: The e-Figures and e-Tables can be found in the Supplemental Materials section of the online article.

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