Algorithmic Approach With Clinical Pathology Consultation Improves Access to Specialty Care for Patients With Systemic Lupus Erythematosus

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ABSTRACT

Objectives: Harris Health System (HHS) is a safety net system providing health care to the underserved of Harris County, Texas. There was a 6-month waiting period for a rheumatologist consult for patients with suspected systemic lupus erythematosus (SLE). The objective of the intervention was to improve access to specialty care.

Methods: An algorithmic approach to testing for SLE was implemented initially through the HHS referral center. The algorithm was further offered as a “one-click” order for physicians, with automated reflex testing, interpretation, and case triaging by clinical pathology.

Results: Data review revealed that prior to the intervention, 80% of patients did not have complete laboratory workups available at the first rheumatology visit. Implementation of algorithmic testing and triaging of referrals by pathologists resulted in decreasing the waiting time for a rheumatologist by 50%.

Conclusions: Clinical pathology intervention and case triaging can improve access to care in a county health care system.

The Harris Health System (HHS) is the safety net health care system for Harris County, Texas, which is the third largest county in the United States. This health care system consists of two hospitals, 23 community health centers, five school-based clinics, and several clinics that provide specialist care. The HHS provides access to care for many patients who would otherwise be unable to see a physician outside of an emergency department setting. However, this system is challenged by a shortage of clinic visit spots available for patients, especially for specialist care. For example, it was taking as long as 6 months for a patient to get an appointment with a rheumatologist in the HHS. Rheumatologic conditions such as systemic lupus erythematosus (SLE) necessitate prompt diagnosis and early treatment to avoid permanent end-organ damage.1 Thus, the prolonged waiting period to see a rheumatologist is anticipated to delay timely diagnosis, postpone initiation of therapy, and cause dissatisfaction for both patients and their
referring primary care providers. Other safety net health care systems report similar difficulties in obtaining timely access to specialist care.2-4

Cause analysis and discussions with clinicians and referral center personnel revealed a number of inefficiencies within the HHS referral system to the rheumatology clinic. First, there were many patients arriving for their first rheumatology clinic visit without appropriate laboratory studies performed. Laboratory testing often was initiated only after the first rheumatologist visit, and a second round of laboratory testing was frequently required based on the results of the initial laboratory tests. Thus, patients were requiring two or three rheumatology clinic visits to obtain the appropriate laboratory workup. Second, clinicians were often ordering each individual test for their workup separately, often performed over many weeks with several phlebotomist visits. Due to the test volume in HHS, some special immunology tests (such as anti-Smith, anti-ribonucleoprotein [RNP], anti-Ro [SSA], and anti-La antibodies [SSB]) are run weekly, causing test results to appear at different times. Regardless of the test result turnaround time, ordering clinicians must follow up test results to assess the clinical significance each time a laboratory result is available. This inefficient practice causes unnecessary interruptions for a clinician’s busy clinic day. Furthermore, it was determined that as many as 50% of patients referred to the rheumatology clinic did not have a rheumatologic condition after completion of diagnostic workups and in some cases would have been better served by seeing a different specialist.

The objective of this joint intervention by clinical pathologists, rheumatologists, primary care physicians (PCPs), and laboratory administration was to improve diagnostic efficiency of rheumatologic conditions within the HHS. This was accomplished by the creation and implementation of a predefined diagnostic algorithm for the diagnosis of SLE with supervision of testing and case triaging by clinical pathology with involvement of laboratory supervisors and the HHS referral center personnel. We show that successful implementation of this process can improve the diagnostic efficiency of rheumatologic conditions in a busy safety net health care system.

Materials and Methods

Data Review Prior to Intervention

Patient electronic medical records (EMRs) were reviewed for availability of laboratory studies at the first rheumatology clinic visit and the number of laboratory visits made by each patient to obtain all laboratory tests needed for the rheumatologist to make a diagnosis. These patient records were randomly selected from the rheumatology clinic visit logs in 2011 at LBJ Hospital (Lyndon B. Johnson Hospital of the HHS). The detailed phlebotomy visits are based on medical chart review retrospectively for each case.

Creation and Implementation of a Diagnostic Algorithm for SLE

A predefined diagnostic algorithm for the diagnosis of SLE was created by rheumatologists based on clinical guidelines5 in collaboration with pathologists, as shown in Figure 1. The algorithm begins with the performance of antinuclear antibodies (ANAs). If the ANA screen is negative, it is highly unlikely that a patient has a diagnosis of lupus given the high sensitivity of ANAs.6 Nonetheless, the clinical documentation is reviewed by a pathologist for features of SLE such as photosensitivity, a malar or discoid rash, arthralgias, pleuritis, and neurologic manifestations to avoid missing a rare case of ANA-negative lupus.7

Patients with a positive ANA screen are further assessed with testing for antibodies with higher specificity for SLE,5 specifically for anti–double-stranded DNA, anti-Smith, anti-RNP, anti-Ro (SSA), and anti-La antibodies (SSB). Patients with thyroid disease and hepatitis may have symptoms that overlap with collagen vascular disease and positive ANAs.8-11 Thus, screening for thyroid disease with thyroid-stimulating hormone (TSH) and a hepatitis panel that includes hepatitis C virus immunoglobulin G, hepatitis B virus immunoglobulin M (IgM) to core antigen and surface antigen, and hepatitis A virus IgM is performed.

Initial Implementation of the SLE Algorithm

All referrals for specialist care within the HHS are placed by PCPs, followed by case review by nurses in a referral center. Prior to our intervention, referrals to rheumatology were based on a checklist of physical examination documentation and a list of laboratory orders. However, these criteria were inconsistently applied, and there was no accounting for the results of the laboratory studies.

The SLE algorithm was first implemented through the referral center in May 2012 by training the referral center nurses to follow the algorithm in Figure 1. All patients referred to rheumatology for a possible diagnosis of SLE were required to undergo laboratory testing according to this laboratory algorithm, and referrals to rheumatology were approved based on the algorithm and review criteria.

Implementation of Automated Reflex Testing, Data Review, and Case Triaging by Clinical Pathology

A simplified, automated process for ordering the SLE algorithm with clinical pathology consultation was created and implemented in July through August 2014. The PCP initiates the SLE algorithm with “one-click” electronically. Then, the
patients make a single visit to the phlebotomist, where all specimens needed to run the SLE algorithm (Figure 1) are collected in one laboratory visit. The providers, phlebotomists, and laboratory technicians were properly trained on the process. The laboratory testing algorithm begins with performance of ANAs. No additional testing is performed for patients with a negative ANA. Patients with a positive ANA are automatically reflexed to the additional algorithm testing of ANA subsets, TSH, and the hepatitis panel. Clinical documentation is reviewed. Patients with positive ANAs also have testing for thyroid-stimulating hormone (TSH) and a hepatitis panel. Clinical documentation is reviewed. Patients with ANA titers of 160 or more or a positive ANA subset with appropriate clinical symptoms are referred to rheumatology, whereas patients with low titer ANAs and negative subsets generally do not require rheumatology referral. Patients with abnormalities of TSH or hepatitis panel are referred back to primary care for appropriate evaluation. CMP, comprehensive metabolic panel; ESR, erythrocyte sedimentation rate.

**Figure 1** Algorithm for the diagnosis of systemic lupus erythematosus developed by clinical pathologists and rheumatologists. The laboratory algorithm begins with performance of antinuclear antibodies (ANAs). Patients with negative ANAs undergo review of clinical documentation but usually do not require referral to rheumatology. They are sent back to the primary care physician for further assessment. Patients with positive ANAs undergo further testing with specific antibody subsets, including anti–double-stranded DNA, anti-Smith, anti-ribonucleoprotein (RNP), anti-SSA, and anti-SSB. Patients with positive ANAs also have testing for thyroid-stimulating hormone (TSH) and a hepatitis panel. Clinical documentation is reviewed. Patients with ANA titers of 160 or more or a positive ANA subset with appropriate clinical symptoms are referred to rheumatology, whereas patients with low titer ANAs and negative subsets generally do not require rheumatology referral. Patients with abnormalities of TSH or hepatitis panel are referred back to primary care for appropriate evaluation. CMP, comprehensive metabolic panel; ESR, erythrocyte sedimentation rate.
results, the pathologist’s assessment if a rheumatology referral is indicated, and the pathologist’s rationale if a referral is not placed. This consultation report is finalized by a pathologist as a formal pathology report, the same as other pathology reports that are interfaced into the EMR under a “Clinical Pathology Reports” tab, and the ordering physician is notified for each case through the EMR system when the report is available. Patient notification of results is performed by the PCP’s office as routine practice, and scheduling of rheumatology appointments is performed by the HHS referral center. Patients may still be referred to rheumatology by the PCP independently of the clinical pathologist at the discretion of the ordering provider. Complete details of this clinical pathology consultation service have been previously described.12

Outcomes of Algorithm Implementation

The EMRs of patients for whom a clinician ordered the SLE algorithm were accessed. Laboratory results and final rheumatologic diagnosis were obtained. The records of patients not referred to rheumatology by pathology were accessed for any new diagnosis of a rheumatologic condition 1 year after pathology consultation report finalization. This study was approved by the Committee for the Protection of Human Subjects, which is the institutional review board for the University of Texas Health Science Center at Houston (HSC-MS-15-0689).

Results

Availability of Diagnostic Laboratory Studies at the First Rheumatology Clinic Visit

As a baseline, we randomly selected 51 patients from the records of the first rheumatology clinic visit in 2011 prior to implementation of the SLE algorithm intervention. Only 10 (19.6%) of 51 had all laboratory studies available at the first specialist clinic visit required for the rheumatologist to make a diagnosis at this initial visit (Table 1). Of these 10 patients with all laboratory studies available, three had all laboratory tests drawn in one phlebotomist visit, two patients made two phlebotomist visits to obtain all laboratory tests, and five patients made three or more visits for blood draws.

Most patients (41/51, 80.4%) visited the rheumatologist without complete laboratory studies (Table 1). Of these 41 patients, 12 had only basic laboratory studies such as a CBC or basic metabolic panel; these 12 patients made one additional visit to the phlebotomist after the first rheumatologist visit due to most orders for laboratory tests being made at one time by the rheumatologist. The remaining 29 had partial laboratory workups available at the first rheumatology clinic visit due to some studies ordered by the PCP. All 41 patients required a second visit to the rheumatologist to review the laboratory results and make a diagnosis. Based on these preliminary studies, there were only three (5.9%) of 51 patients with a complete laboratory workup in one phlebotomist visit, and 80% of patients seen in the rheumatology clinic required additional phlebotomy visits to complete the laboratory workup. The mean of the phlebotomist visits for this group is 2.7.

Outcomes After Initial Implementation of the SLE Algorithm Within the HHS Referral Center

The SLE algorithm in Figure 1 was implemented through the HHS referral center as a requirement to refer patients with suspected SLE to the rheumatology clinic at LBJ Hospital. It was directed by nurses in the referral center as a pilot project. Fifty-four patients who underwent testing by this algorithm through the referral center were randomly selected (Table 1). Twenty-three (42.6%) patients were approved for referral to rheumatology after completion of the SLE algorithm testing, 29 (53.7%) were determined not to require a rheumatology consult and referred back to the PCP, and two (3.7%) were lost to follow-up before all laboratory testing was completed. The availability of detailed laboratory workups and number of phlebotomy visits are shown in Table 1. The mean of the phlebotomy visits for the second group is 2.15.

Of the 23 patients referred to rheumatology, most had SLE or another related rheumatologic condition (Table 2). The records of patients who were not referred to rheumatology were also reviewed, and there are no apparent missed cases of a rheumatologic condition. Of the 29 patients who were not referred to rheumatology, three (10.3%) had abnormal thyroid function tests and two (6.9%) had an abnormal hepatitis panel, necessitating a different diagnostic workup with potential referral to a specialist other than rheumatology.

The waiting time to see a rheumatologist was 4 to 6 months prior to implementation of the SLE algorithm through the referral center. After implementation of this algorithm, we successfully decreased the wait time for a rheumatology consultation to 2 to 3 months.

Outcomes After Implementation of Reflex Testing and Pathology Consultation

The initial SLE algorithm was directed by nurses in the HHS referral center. While the initial implementation of the algorithm helped with ensuring availability of laboratory results prior to the initial rheumatologist visit, patients were frequently being sent back to the PCP due to missing laboratory studies and still requiring multiple phlebotomist/laboratory visits for a complete workup, causing delay of consultation in these patients. Thus, a “one-click” algorithm with automated reflex testing for our SLE algorithm was
created and implemented. With this implementation by clinical pathology, we eliminated unnecessary phlebotomy visits (Table 1).

Clinical pathologists also began to integrate the clinical and laboratory data into a clinical pathology consultation report that explains the meaning of the laboratory results and if a rheumatologist consult is appropriate.12 The clinical pathologist places the patient referral to rheumatology if indicated. A total of 220 orders for the SLE reflex algorithm with pathologists consults were placed from July 1, 2014, to January 30, 2015 (Table 3). These orders were placed by 72 of 136 PCPs from 18 HHS community clinics. Ninety-three (42.3%) of 220 patients had a positive ANA. However, only 27 (12.3%) of 220 were considered likely to have SLE or a related rheumatologic disorder after completion of the full diagnostic algorithm with clinical and laboratory data review by clinical pathology (Table 3). All 27 patients were referred to rheumatology by the clinical pathologists. Seventeen of the 27 patients have since seen a rheumatologist. Among them, 13 (76%) of 17 patients have SLE or a related rheumatologic disorder confirmed by a rheumatologist; one patient was seen in the rheumatology clinic with an uncertain rheumatologic disorder, and he was instructed to follow up with a rheumatologist in 6 months. Ten patients were lost to follow-up. We also followed up cases with denied rheumatology consultation; there are no apparent cases of a missed rheumatologic diagnosis. This intervention successfully decreased the multiple phlebotomy visits previously needed to obtain all diagnostic tests for the evaluation of SLE.

Before implementation of this algorithm, the approval rate for rheumatology consultation was 55% of a randomly reviewed sample of 314 requests. It had decreased to 42% when the algorithm was implemented by referral center nurses without pathologist interpretation and to 12% with clinical pathologist intervention that included testing supervision, data review, and interpretation along with issuing a diagnostic consult. With concerns of possible overinterpretation of laboratory tests, we followed up the patients in the “denied group” and found no cases of a missed rheumatologic condition.

Based on these data, the number of phlebotomy visits to complete the laboratory workup for the initial rheumatology visit was significantly reduced from a mean of 2.7 to 2.2 and then eventually to 1 visit per patient after pathologist intervention. Unnecessary rheumatology visits were also eliminated simultaneously in approximate 80% of patients in their initial rheumatology assessment (Table 1). Surprisingly, we received no complaints from PCPs about the increased number of denied rheumatology consultation requests. Instead,
they expressed gratitude for the detailed explanations of the workups and reasons for the denials.

Discussion

Our data demonstrate that implementation of a diagnostic algorithm for SLE with case review and triaging by clinical pathology can significantly decrease unnecessary visits to phlebotomists and rheumatologists. Availability of all laboratory results at the initial rheumatology visit may facilitate making a diagnosis at the first clinic visit, initiating treatment earlier for patients with a rheumatologic illness, and using less clinic visits for patients who end up not having a rheumatologic condition. As a result, satisfaction from patients, their PCPs, and rheumatologists was improved. Furthermore, we also issue a pathology interpretation report for those without indication of referral. These consultation reports provide the PCPs with a summary of the SLE workup and help them communicate with patients. With a concern about overinterpretation in the “denial of referral” group, we retrospectively reviewed medical charts in these patients. There was no inappropriate denial of referrals in all patients reviewed. These results confirm the efficiency and accuracy of the implemented integrative clinical pathology consulting service for SLE.12

A nationwide study revealed a shortage of rheumatologists that is expected to cause problems for patients with chronic rheumatologic conditions in obtaining specialist care.13 Safety net health care systems such as ours are further challenged to provide specialist care.2-4 These data highlight the potential role of a clinical pathologist in improving access to specialist care in a busy safety net health care system.

Health care delivery is shifting from a volume-based model to one that is value based.14 Thus, practitioners of laboratory medicine will need to seek out ways to demonstrate measurable value in a changing health care reimbursement environment that is focused on patient outcomes while maximizing cost savings. Clinical pathology interventions in collaboration with other specialties such as we describe here have the potential to improve the value of laboratory medicine in a number of ways. Moreover, the number and complexity of laboratory testing have increased while PCPs are challenged with seeing more patients due to declining reimbursements. Conditions such as SLE are relatively rare and have undergone expansion in the number of diagnostic tests available that is associated with frequent confusion of which tests to order and their interpretation.5,15 Our algorithm approach to SLE testing simplifies the ordering process for PCPs, enabling them to place one order to perform the laboratory evaluation for this condition. Patients need to undergo only one laboratory visit to collect all of the specimens needed to make a SLE diagnosis, thus decreasing the costs associated with multiple visits and blood draws. It also ensures that all relevant laboratory tests are performed prior to the first rheumatologist visit so that management decisions can be made during the initial visit. Thus, unnecessary visits to phlebotomists and rheumatologists are avoided to improve diagnosis efficiency. Additional to the cost-effective approach, this intervention can also improve physicians’ and patients’ satisfaction by cutting down unnecessary visits.

Other clinical pathology initiatives to improve the value of laboratory medicine are described in the literature. Kratz et al16 describe the creation of multidisciplinary rounds that result in patient-specific interpretations for the evaluation of a number of disorders, including those of coagulation, anemia, transfusion medicine, and molecular testing. A new pathology clinical consultation service for laboratory support and transfusion management during major cardiac surgery resulted in decreased blood product use and reduction in surgical reoperation rates.17 Other reports in the literature highlight improved outcomes and cost savings by pathology consultation. For example, pathology consultation for coagulation factor replacement for patients with hemophilia in a tertiary care center resulted in appropriate therapy and significant financial savings.18 Blood bank monitoring of blood components and intervention when suboptimal transfusion practice was identified resulted in improved survival and decreased transfusion need in the postoperative period of massively transfused patients.19 Tormey and Smith20 review additional potential models by which clinical pathologists can integrate consultation into daily practice.

This study is limited by the relatively small number of patients. Loss to follow-up was commonly found in patients selected for data review and occurred because of loss of eligibility for HHS services, inability to contact the patient to schedule an appointment, and missed appointments. Nonetheless, the decrease in waiting time to see a rheumatologist after implementation of this joint clinical pathology and rheumatology initiative highlights the potential of this intervention to improve access to specialist care in a safety net hospital system. Additional algorithms with clinical pathology supervision and consult for other conditions are in development.

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References


