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ORIGINAL RESEARCH

The potential value of rapid, cloud-enabled onsite testing for the diagnosis of rheumatoid arthritis in the United States

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ABSTRACT

Aims: Improvements in information technology have granted the recent development of rapid, cloud-enabled, onsite laboratory testing for rheumatoid arthritis (RA). This study aims to quantify the value to payers of such technologies.

Materials and methods: To calculate the value of rapid, cloud-enabled, onsite laboratory testing to diagnose RA relative to traditional, centralized laboratory testing, an Excel-based decision tree model was created that simulated potential cost-savings to payers who cover routine evaluations of RA patients in the US. First, a conceptual framework was created to identify the value components of rapid, cloud-enabled onsite testing. Second, value associated with patient time savings, savings on visit fees, change in treatment costs, and QALY improvements was measured, leveraging existing literature and information from an observational study. Lastly, these value components were combined to estimate the total incremental value accruing to payers per patient-year relative to centralized laboratory testing.

Results: Rapid, cloud-enabled, onsite testing is estimated to save one office and 1.81 laboratory visits during the evaluation period for the average patient. Results from an observational study found that rapid, cloud-enabled testing increased the likelihood of completing diagnostic orders from 84.5% to 97%, resulting in an increased probability of early treatment (3.5 percentage points) with disease-modifying anti-rheumatic drugs among patients eligible for treatment. The combined total value was $5,648 per evaluated patient-year. This value is primarily attributed to health benefits of early treatment ($5,048), fewer visit payments ($459), and patient time savings due to fewer office ($216) and laboratory visits ($255).

Limitations and conclusions: Data on the impact of rapid, cloud-enabled, onsite testing on patient health, care delivery, and clinical decision-making is scarce. More robust real-world data would confirm the validity of our model. Rapid, cloud-enabled, onsite testing has the potential to generate significant value to payers.

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Introduction

In the US, most moderate-to-high complexity diagnostic tests are evaluated in centralized laboratories[1]. While the centralization of laboratory testing enables rigorous quality control over the evaluation of samples, requiring physicians to send and receive samples to and from these centralized laboratories can create discontinuities in patient care. Diagnosis and treatment decisions are often delayed due to the wait time associated with receiving laboratory test results[1,2].

To address these delays, during the last few decades, point-of-care testing was introduced as an approach to improve diagnostic and evaluative processes and facilitate continuity in patient care. Point-of-care testing deviates from traditional, centralized laboratory testing by incorporating a heightened element of convenience for the patient. Although convenient, point-of-care testing has faced challenges in quality assurance[3]. Because point-of-care testing is generally conducted by clinical staff as opposed to laboratory-trained personnel, technical errors are common[4]. As a result, point-of-care testing has been used predominantly, and almost exclusively, for low complexity diagnostic testing, i.e. glucose monitoring[1]. The restricted use of point-of-care testing suggests the benefits of decentralized testing and high quality evaluation were not previously available in any existing technology on the market.

The advent of rapid, cloud-enabled, laboratory testing technology, however, may permit the practice of decentralized testing while simultaneously maintaining rapid, high-quality review of higher complexity tests. The combination of available rapid analyzers and cloud based quality systems enables comprehensive blood testing onsite, digitizes the sample, and transfers clinical data to the cloud for review by

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highly-trained, off-site laboratory scientists. For example, during disease monitoring visits, rheumatologists frequently order a complete metabolic profile (CMP), a complete blood count (CBC) with automated differential, erythrocyte sedimentation rate (ESR), and c-reactive protein (CRP). If the patients are prescribed a DMARD, then assessments for hepatitis B, hepatitis C, and tuberculosis are added to the test order. For patients who are initially assessed for RA, the test menu would be expanded to include rheumatoid factor (RF), cyclic-citrullinated peptide (CCP) antibodies, and possibly quantitative immunoglobulins.

By using existing, rapid blood analyzers and cloud-based quality management systems, high quality laboratory data for most tests listed above can be quickly relayed to the physician[5]. In fact, these results can be communicated back to the physician within the timeframe of a standard physician visit[6]. This symbiosis of technologies accelerates delivery of laboratory test results within a standard rheumatology practice setting. Particularly, a high-quality diagnostic laboratory test panel can be delivered to the provider within ~15 min of blood collection, compared to up to 2 weeks post-visit when using centralized laboratory technology. Overall, by combining the strengths of centralized quality control and point-of-care testing, rapid, cloud-enabled onsite laboratory testing technology offers the promise of improving continuity of care, accelerating diagnosis and treatment decisions, and increasing patient convenience at office visits.

In this study, we aim to quantify the value of the adoption of rapid, cloud-enabled onsite laboratory testing within a rheumatology practice, particularly focusing on patients evaluated for rheumatoid arthritis (RA). The typical diagnostic process for RA requires extensive laboratory testing as well as a careful evaluation of patient history[7]. As described above, blood test results indicative of RA include high-positive RF, high-positive anti-CCP, elevated CRP, and elevated ESR[8]. RA diagnosis is ultimately classified into two categories: seropositive (appearance of symptoms in addition to testing positive for antibodies) and seronegative (appearance of symptoms without testing positive for antibodies). The complexity and length of the RA diagnostic process decreases the probability of patients completing evaluation, and thus decreases the likelihood of a prompt diagnosis[9,10]. A rapid, cloud-enabled onsite laboratory service has the potential to aid in streamlining the needed continuity in care processes, and may ultimately increase patient compliance, the likelihood of timely diagnosis, and eventual initiation of treatment for those who need it.

Methods

In-office laboratory and cloud system

For the in-office laboratory, several instruments are available to provide the desired test menu for a standard rheumatology practice. Several different analyzers are FDA approved and CLIA waived for the purpose of generating chemistry results. Examples include the Abaxis Piccolo analyzer and the Arkay SPOTCHEM EZ chemistry analyzer. Furthermore, several hematology analyzers are FDA approved for providing a complete blood count with automated differential, such as the Abbot Emerald analyzer family. Recently, the Sysmex XW-100 was CLIA waived as a hematology analyzer. However, as the mobile laboratory can operate moderate or high complexity testing (with the appropriate certified laboratory personnel), laboratory developed tests are also available to be used to generate rapid, high-quality laboratory data.

The quality system underlying the described mobile laboratories begins with a LIS that operates in the cloud. As with blood analyzers, several cloud-based LIS are available commercially, such as Pathagility or SimpleLIMS. These systems allow the reviewing and verification of data prior to release, from remote locations, enabling a central core of certified scientists to monitor and review data generated on-site within mobile laboratories. As such, a cloud-based quality system ensures that only verified, quality controlled results are released to physicians and patients. In addition to LIS cloud capabilities, proprietary algorithms working in concert with the LIS enable real-time monitoring of instrument and external control performance. Patient data is securely stored on Amazon Web Services in a HIPAA-compliant environment. Taken together, these systems are designed to ensure that on-site laboratories have the equivalent quality control system as implemented in large central laboratories.

Model

To calculate the monetary value of rapid, cloud-enabled onsite testing, we created an Excel-based decision tree model that simulated potential cost-savings to payers who cover the routine evaluation of RA patients at a rheumatologist practice in the US. Existing frameworks[11] aiming to evaluate the efficacy of diagnostic tests emphasize that the value of a diagnostic test is not measured solely by its accuracy, but rather by how it affects a patient's overall health outcome and care delivery. These frameworks identify the following components as being most relevant in assessing a diagnostic test's value: a test's effect in expediting time to treatment, modifying patient perceptions and behavior, and altering diagnostic and treatment decisions.

To build our model, we followed a three-step approach. First, we created a conceptual model to identify pathways over which rapid, cloud-enabled onsite testing can affect stakeholders' value relative to centralized laboratory testing. Second, we searched for information from the literature, an observational study, and stakeholder interviews to quantify the value associated with each component. Finally, we combined the value components from step one with information from step two to determine the total incremental value of using rapid, cloud-enabled onsite laboratory testing in evaluating patients for RA at a rheumatology practice relative to centralized testing. The following sections describe the value components and the calculations we used to quantify each one in the context of a standard rheumatology practice in the US.

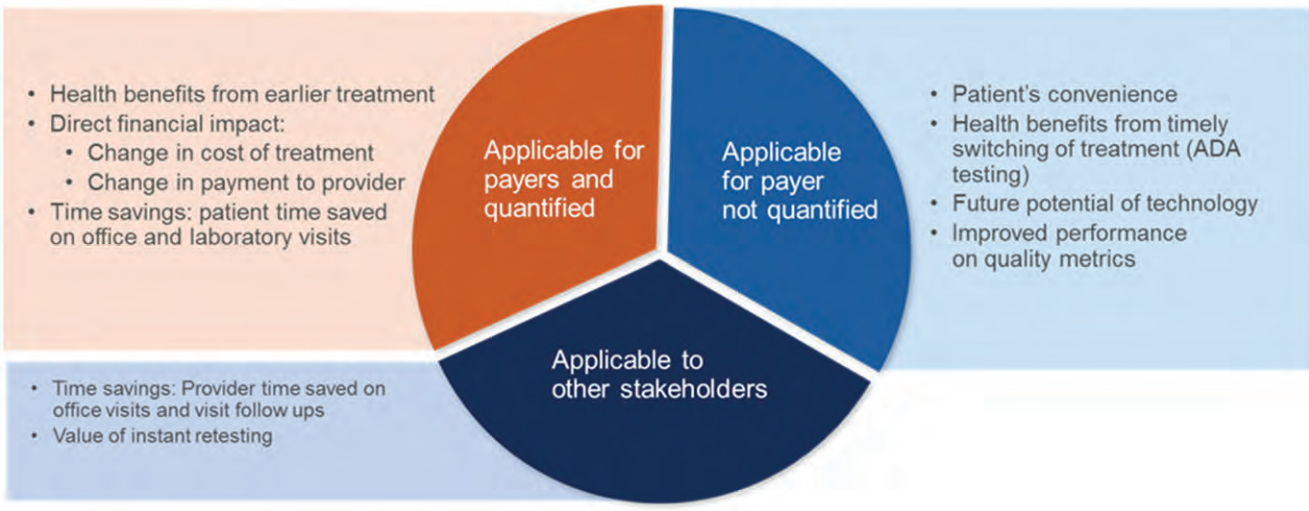


Figure 1. Components of value provided by rapid point of care testing.

Sources of value

In assessing the value of rapid, cloud-enabled onsite testing for payers, we identified three key elements to consider in our conceptual framework: time savings, direct financial impact, and health benefits due to facilitation of better care (Figure 1).

To begin, patients benefit from time savings due to the utilization of rapid, cloud-enabled onsite testing. Studies citing the economic value of rapid testing in other contexts have demonstrated that there are significant time savings for patients[12]. For example, implementation of rapid diagnostics in an emergency department eliminated the laboratory test turnaround time, which typically took 35 min, and the need to check back for results to determine treatment, which took 5 min using current practices with electronic health records[12]. Although we were not able to identify published literature specific to rapid, cloud-enabled onsite testing, and the diagnostic process in an outpatient facility differs from that of an emergency department, it is plausible to believe that eliminating laboratory visits and follow-up appointments results in similar significant travel time, waiting time, and appointment time savings.

Rapid, cloud-enabled onsite testing can reduce the number of visits required to diagnose patients with RA. With traditional testing technology, patients may require an initial patient assessment, a laboratory test, and a follow-up appointment to review the results of the laboratory tests. A rapid, cloud-enabled onsite system enables providers to consolidate services provided within the patient's initial visit to the rheumatologist. By bundling laboratory testing and subsequent treatment decisions into fewer appointments, payers forgo additional fees required for these visits.

Lastly, rapid, cloud-enabled onsite testing may increase patient compliance with diagnostic orders and decrease the likelihood of an incomplete evaluation. Thus, this technology may lead to increased likelihood of timely diagnosis of the disease and, thus, increased likelihood of timely treatment. The benefits of earlier treatment initiation among patients with RA is well established[13–15]. While evidence suggests that introducing disease-modifying anti-rheumatic drugs (DMARDs) within 12 weeks of onset of symptoms may lead to an optimal response to treatment[16], a study found that only 50% of patients were assessed by a rheumatologist within this window of opportunity[17]. By minimizing the length of time required to complete diagnostic testing, patients have an increased chance of initiating treatment within 12 weeks of symptom onset, and thus achieving improved outcomes relative to those who initiate treatment at a later date[13–15].

Sources of parameters

Parameters to estimate the model came from three sources: peer-reviewed literature, primary research with rheumatologists, and an observational field experience study of the use of rapid, cloud-enabled onsite laboratory testing in rheumatology practices. For the primary research, 100 rheumatologists from across the country completed an online survey where they addressed, among other things, test ordering patterns by patient type and the number of new patient visits needed to establish a diagnosis. The rheumatologists were required to have been in practice between 2 and 25 years, see over 200 patients per month, be in a private practice, and be a decision-maker for laboratory services. The field experience study was a two-arm study designed to measure improved patient adherence to blood test orders and patient and physician satisfaction with rapid, cloud-enabled onsite testing. The first arm included historical claims review and site observation to identify patient compliance with blood test orders under the current laboratory process. The second arm measured patient compliance and physician and patient satisfaction with the laboratory process under rapid, cloud-enabled onsite testing. We used observations from this study to parametrize our model.

Calculation of value components

Based on the conceptual framework, we modeled a cohort of patients being evaluated for RA at a typical rheumatologist practice. We built a decision tree model that allowed us

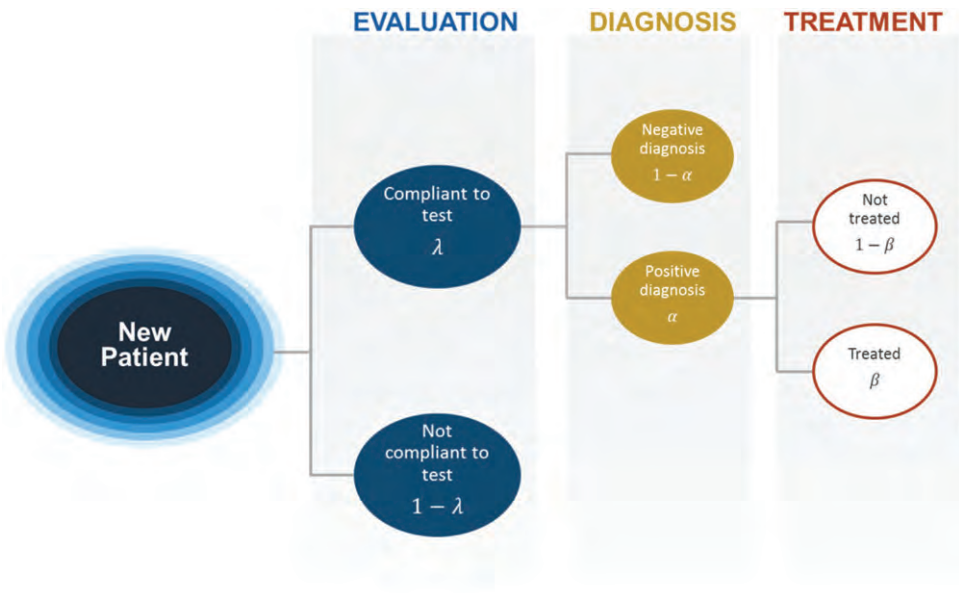


Figure 2. Pathway of patients to treatment.

to tie together the different value components mentioned in the previous section and monetize them (Figure 2). We assumed that the typical time of evaluating a patient for RA and developing a treatment plan is 3 months. Our model then calculated the monetized incremental value of rapid, cloud-enabled onsite diagnostic testing per evaluated patient year for the average payer insuring four consecutive patient cohorts.

Within the model, we identified three phases in the patient journey to treatment: (i) evaluation, (ii) diagnosis, and (iii) treatment initiation. During evaluation, the provider performs a physical examination and orders diagnostic tests. We assumed that the physical examination always takes place during the office visit, but the patient may or may not follow-up with the diagnostic order and the provider may or may not receive and follow-up on diagnostic test results. Overall, the evaluation process is completed if the patient complies with the test order and the provider receives the results and communicates it to the patient. Then, either a diagnosis for RA or lack thereof is established for the patient. Once a positive diagnosis for RA is made and a treatment plan is developed, the patient may or may not comply with the recommended treatment. If the patient complies with the treatment, he or she benefits from positive health effects. Patients with no RA diagnoses do not receive treatment and corresponding health benefits.

Time savings

To monetize the value of time savings to patients, we considered the average number of office and laboratory testing visits for a typical patient during the evaluation process, assuming centralized, standard of care laboratory testing. Then, we assessed the change in the number of either type of visits (office and laboratory) associated with implementing rapid, cloud-enabled onsite testing. The change in the number of visits was multiplied by the average length of time patients spend at these visits (including travel time) and then by the wage of the average patient.

With rapid, cloud-enabled onsite testing, we estimated that a follow-up visit will no longer be needed, thereby reducing the number of office visits needed during a typical evaluation process by one office visit. According to rheumatologist interviews, the number of visits required by patients awaiting diagnosis is 2.81, thus we anticipated a reduction to 1.81. Further, it is highly probable that, with the traditional central laboratory-based testing, the rheumatologist would request a laboratory test following each of the 2.81 office visits. Therefore, we assumed that 2.81 laboratory visits would be required with standard of care diagnostics. However, because rapid, cloud-enabled onsite testing systems digitize the sample and store information in the cloud, we assumed that only one laboratory test would be required.

Because of the reduction in laboratory and office visits, patients benefit from reductions in time spent at the rheumatologists' office, laboratory, and in transit to and from each location. Research on care delivery at rheumatology clinics found that patients spend 69.6 min at the rheumatologist per office visit and 5.4 min on blood draw per laboratory visit[18]. Further, estimates of patient transportation times to rheumatologists' office were 22.2 min[19]. We monetized these time costs using the average hourly wage of all occupations obtained from the 2016 Bureau of Labor Statistics Occupational Employment Statistics[20] and inflated to 2017 USD ($28.54 per hour).

Cost savings from fewer office visits

The measured savings on visit fees were also based on the reduction in the number of visits due to implementing rapid, cloud-enabled onsite testing at the practice, described above. We calculated reimbursement corresponding to a patient visit by payer type and then derived an average per visit reimbursement by considering a mix of commercial,

Medicare, and Medicaid patients at a typical rheumatology practice. To calculate total savings, we multiplied the number of visits saved by the average reimbursement rate.

We obtained Medicare Evaluation and Management (E/M) reimbursement rates by levels of visits for established patients. For the purposes of this analysis, we assumed that rheumatology visits are between levels 3 and 5, due to complex evaluation and decision-making required in this setting[21]. Thus, we calculated the average Medicare reimbursement across levels 3–5 outpatient office visits for existing patients as $109.34. To derive average reimbursement for Medicaid and commercial payers, we relied on a prior study[22] reporting an average ratio of non-facility reimbursement rates for Medicaid compared to Medicare and for commercial payers compared to Medicare, 0.61 and 1.15, respectively. Thus, we used $66.70 for reimbursement for established visits from Medicaid and $125.74 for reimbursement for established visits from commercial payers. Based on the field experience study, we assumed that 32% of patients at a typical rheumatology practice were covered by Medicare, 10% by Medicaid, and 59% by commercial insurance. Using these proportions as weights, we calculated the visit fees for the average established patient visit: $114.76.

Health benefits

To measure the third value component, we measured how changes in patient diagnostic compliance due to adoption of a rapid, cloud-enabled onsite testing system would affect the likelihood of early treatment and corresponding health benefits. Using centralized laboratory testing, patients are expected to schedule and attend a laboratory testing appointment, but oftentimes patients may not follow-up with either this laboratory visit or subsequent follow-up visits at rheumatology clinics[23]. Because rapid, cloud-enabled onsite testing allows providers to consolidated intake, laboratory testing and follow-up appointments into one visit, we expect a significant reduction in loss to follow-up with this technology. Furthermore, we assumed that the testing technology only affects the likelihood of the patient taking the test that is ordered and the provider receiving the result, but it does not impact the probability of a positive diagnosis or the probability of treatment compliance.

To estimate the value of this health benefit, we first derived the difference in probability of diagnostic compliance and the corresponding difference in probability of early treatment. Then, using quality adjusted life year (QALY) gains associated with receiving early RA treatment, we calculated the increase in the expected QALY for the typical patient evaluated for RA at a rheumatology practice. Finally, to derive the monetary value of health gains, we multiplied the expected increase in QALY by the monetized value of an additional life year. Additionally, higher treatment rates lead to higher treatment costs for the payer. We calculated the change in expected treatment costs by multiplying the change in probability of early treatment, as described above, and the incremental costs associated with early treatment of RA.

Parameters used to quantify the disease diagnosis and treatment pathways were obtained from the field experience study and peer-reviewed literature. The field experience study suggested that only 84.5% of RA patients who are prescribed laboratory testing complete the testing if only centralized testing is available. Although we were not able to find information on compliance to laboratory diagnostic testing for RA patients in the published literature, observations from other diseases support this number. Specifically, Fischer *et al.*[24] found that compliance to laboratory tests to monitor treatment effectiveness ranged from 76.4–97.8% (mean = 91.8%; median = 92.0%), depending on the test and treatment. In another study, Moffet *et al.*[25] identified that laboratory attendance rates range from 73–86% (mean = 82.3%; median = 84.1%) for diabetes patients. Although studies were not specific to rheumatology practices, the variation in these estimates suggests that: (i) more complex tests have lower compliance rates, and (ii) our 84.5% baseline estimate from the field experience study is not unreasonable.

To model the magnitude of the change in compliance with rapid, cloud-enabled onsite testing, we used the compliance rate of 100% from the field experience study. Nevertheless, we conservatively assumed a 97% compliance rate for the model to take into consideration patients who may not complete testing at the practice because of adverse events during testing (e.g. dizziness)[23] or other reasons.

Our review of the literature found that, among patients who are evaluated for RA at a rheumatology practice, 41.7% received a positive diagnosis[26]. In addition, The Healthcare Effectiveness Data and Information Set (HEDIS) DMARD Therapy for Rheumatoid Arthritis use rates from 2016[27] indicated that 80.7% of diagnosed patients start treatment. We used these parameters in our model to transition patients through the diagnosis and treatment pathway, and assumed that all patients who start treatment are treated at the rheumatology practice under consideration.

We used incremental costs and health benefits of the early DMARD strategy when compared to the symptomatic treatment strategy to approximate incremental costs and health benefits of early diagnosis. Finckh *et al.*[28] developed a decision analytic model to measure health benefits and costs associated with different treatment strategies of early RA. The early DMARD strategy included prescribing DMARDS within 12 weeks of symptom onset, while a symptomatic strategy included non-steroidal anti-inflammatory drugs and therapeutic exercises for the first year from symptom onset and DMARDS afterwards. Treatment guidelines recommend DMARD use as soon as RA is diagnosed[7,29] and patients likely receive symptomatic treatment even before a conclusive RA diagnosis. Specifically, we assumed that the incremental health benefit of early diagnosis is 0.3 QALY (15.0 vs 14.7 QALY for the early DMARD and symptomatic strategy, respectively), while the incremental costs of early diagnosis (including drug costs and all medical costs associated with patients' disease status and possible side-effects) is $1,963.28 ($133,340 vs $131,890 in 2007 USD for the early DMARD and symptomatic strategy, respectively, inflated to 2017 USD in the model)[28].

Table 1. Component calculations.

Value component	Formula	Objective
Patient time savings	(change in number of visits) × (average time spent on visit) × (average wage)	Value the time saved by patients associated with rapid, cloud-enabled onsite testing
Care delivery cost impact—savings on visit fee	(change in number of visits) × (average provider fee corresponding to visits)	Financial savings on provider visit fees associated with rapid, cloud-enabled onsite testing
Care delivery cost impact—change in treatment costs	(change in probability of treatment) × (cost of treatment)	Incremental costs associated with higher likelihood of treatment
Clinical impact—improved health outcomes	(change in probability of treatment) × (treatment benefits in QALY) × (value of QALY)	Value of incremental health benefits associated with higher likelihood of treatment.

Abbreviation. QALY, quality adjusted life year.

All value calculations were performed in Excel 2013. Costs were inflated to 2017 US dollars using the Medical Care Consumer Price Index from the Bureau of Labor Statistics[30]. All values were annualized. Although the literature has demonstrated a wide range of value associated with QALY gains[31], we assumed the commonly used value of a QALY to be $100,000. Explanations of the calculations for each component can be found in Table 1. Parameters from literature and an observational study to quantify the value associated with each component can be found in Table 2.

Results

Rapid, cloud-enabled onsite testing generates significant value for payers, largely resulting from increasing compliance to diagnostic laboratory testing and, thus, facilitating early treatment initiation for patients. Below we describe estimated value by value components considered.

We found a non-trivial amount of value due to patient time savings. Based on the literature we assumed that the average patient spends ~92 min on each office visit (including travel time), ~28 min on each laboratory visit (including travel time), and has an hourly wage of $28.54. Thus, the four office and 7.24 laboratory visits saved for an incoming patient year corresponded to a value of time saved of $216.46 and $254.63, respectively.

Additionally, fewer visits result in savings for payers on visit fees paid to providers. We calculated that the average fee for a level 3–5 established patient E/M non-facility visit, weighted across payer types is $114.76. Thus, total savings on visit fees were estimated to be $114.76 for the average patient quarter and $459.05 for the average incoming patient year.

Our model assessed the value of increased likelihood of early DMARD treatment associated with rapid, cloud-enabled onsite testing. In the model, we estimated a 12.5% (from 84.5% to 97% of patients evaluated) increase in the share of patients who receive a diagnosis from their provider. Since not all patients are diagnosed with RA at the end of the evaluation period, the corresponding increase in the likelihood of early treatment initiation among all patients undergoing evaluation was 4.2% (28.4% to 32.6%). We assumed that an additional 0.3 QALY was associated with early treatment initiation[28], and the value of a QALY was $100,000. Thus, receiving earlier treatment due to increased compliance with diagnostic procedures led to a monetized health benefit of $1,261.95 per patient quarter and $5,047.79 per average incoming patient year.

Besides providing health benefits, early treatment initiation increased costs of treatment. Therefore, a higher likelihood of early treatment initiation corresponded to higher expected costs of treatment per patient. Given the 4.2% increase in the likelihood of early treatment for each of the four cohorts evaluated during a year, and incremental costs of early treatment of $1,963.28, the increase in the expected treatment costs was $330.34 per average incoming patient year.

Combining the three elements, we estimated that the total value of rapid, cloud-enabled onsite laboratory testing was $5,647.58 per incoming patient year at a rheumatologist. The majority of this value corresponded to health benefits from ensuring diagnosis communication between the provider and patient and the resulting increased likelihood of effective treatment (Figure 3).

Sensitivity analyses

To evaluate the sensitivity of our results, we conducted one-way sensitivity analyses by changing parameter values by ±25% (Figure 4). Our results were most sensitive to the value of health benefits of early treatment and the change in probability of diagnostic compliance; and least sensitive to changes in number of diagnostic laboratory visits. A 25% decrease or increase in the impact that rapid, cloud-enabled onsite testing may have on compliance to laboratory test orders would lead to a total value of $4,468.22 or $6,779.77, respectively (a 20.9% change in total value) (Figure 4). In contrast, a 25% decrease or increase in the number of diagnostic lab visits saved would result in a total value of $5,642.74 or $5,652.43, respectively (a ±0.1% change in total value).

Changes in compliance to testing and the value of the corresponding health benefits are the key drivers in our model. Indeed, not considering value of health benefits, the total value of rapid, cloud-enabled onsite testing per incoming patient year would be $599.80.

Discussion

In this study we estimated value associated with rapid, cloud-enabled onsite testing per incoming patient year at a rheumatologist for payers. Our model suggests that rapid, cloud-enabled testing generates $5,648 for payers per incoming patient year, with most of the value corresponding to health benefits of early treatment initiation, $5,047.79. These

Table 2. Model parameters.

Parameter	Centralized testing	Rapid, cloud-enabled onsite testing	Source
Number of diagnostic office visits (per 3 month)	2.81	1.81	Genalyte interviews with Rheumatologists
Number of diagnostic laboratory visits (per 3 month)	2.81	1.00	We assume that, with rapid, cloud-enabled onsite testing all tests needed to diagnose RA can be completed in a single visit
Percentage of incoming patients completing evaluation at practice	84.5%	97.0%	Genalyte observational study minus 3% adverse reaction assumption
	Value		
Patient time savings			
Patient timer per office visit (hourly)		1.16	Davis *et al.*[18]
Patient time per laboratory visit (hourly)		0.09	Davis *et al.*[18]
Patient transportation time to office (hourly)		0.37	Schmajuk *et al.*[19]
Patient transportation time to laboratory visit (hourly)		0.37[a]	Schmajuk *et al.*[19]
Patient value of time (hourly wage)		$28.54[b]	Bureau of Labor Statistics, Occupational Employment Statistics, 2016[20], inflated to 2017 USD
Care delivery cost impact—savings on visit fee			
Proportion of Medicare patients		32%	Genalyte observational study
Proportion of Medicaid patients		10%	Genalyte observational study
Proportion of commercial patients		59%	Genalyte observational study
Rate of Medicaid and Medicare reimbursement		1.15	Krause *et al.*[22]
Rate of commercial and Medicare reimbursement		0.61	Krause, *et al.* Texas medicine 112.6 (2016): e1-e1.[22]
Average Medicare reimbursement rate for outpatient office visits of new patients Levels 3–5		$169.04	2017 Medicare National Evaluation and Management Fee Schedule, Non-Facility Fees[21] and calculation
Average Medicare reimbursement rate for outpatient office visits of established patients Levels 3–5		$114.76	2017 Medicare National Evaluation and Management Fee Schedule, Non-Facility Fees[21] and calculation
Care delivery cost impact—change in treatment costs			
Percentage of evaluated patients with positive diagnosis		41.7%	Cummins *et al.*[26]
Percentage of diagnosed patients starting treatment		80.7%	HEDIS DMARD use rates in 2016[27]
Incremental costs associated with early treatment		$1,963.28	Finckh, *et al.* Annals of Internal Medicine 151.9 (2009): 612-621.[28], inflated to 2017 USD
Clinical impact—improved health outcomes			
Incremental QALYs associated with early treatment		0.3	Finckh *et al.*[28]
Value of a QALY		$100,000.00	Hirth *et al.*[31]

Abbreviations. DMARD, Disease-modifying antirheumatic drugs; HEDIS, The Healthcare Effectiveness Data and Information Set; QALY, quality adjusted life year.
[a]22 min, based on a study of Medicare patients.
[b]Wages were reported annually, the average annual mean was converted to hourly mean assuming a 50 week work year, 5 work days per week, and 8 h work days.

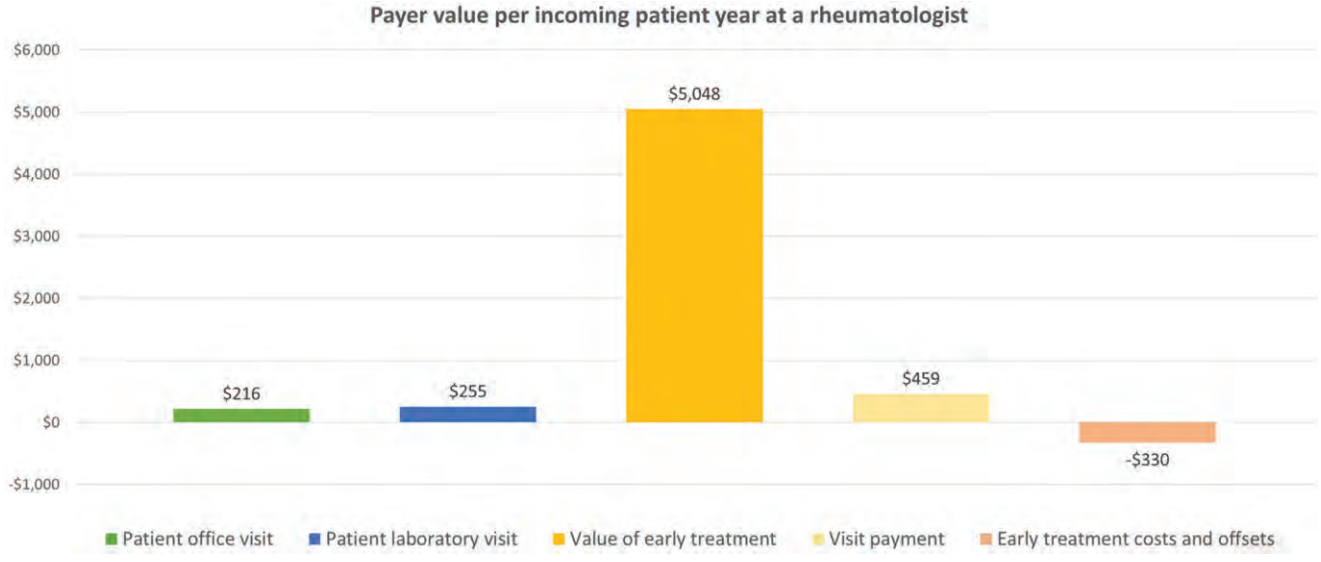
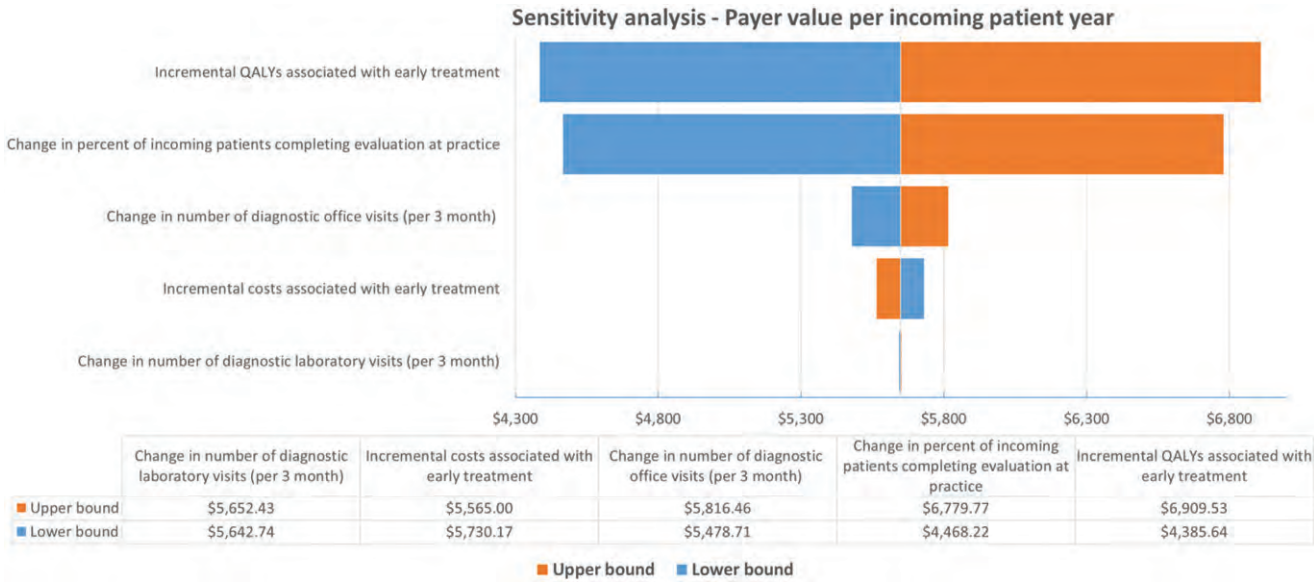


Figure 3. Components of payer value per incoming patient year.



	Change in number of diagnostic laboratory visits (per 3 month)	Incremental costs associated with early treatment	Change in number of diagnostic office visits (per 3 month)	Change in percent of incoming patients completing evaluation at practice	Incremental QALYs associated with early treatment
Upper bound	$5,652.43	$5,565.00	$5,816.46	$6,779.77	$6,909.53
Lower bound	$5,642.74	$5,730.17	$5,478.71	$4,468.22	$4,385.64

Figure 4. Tornado diagram for sensitivity analyses. Abbreviation. QALY, quality adjusted life year.

benefits are significant compared to an average cost of $162 for test orders per patient year at a rheumatology practice.

Although this study focused on the quantifiable elements of value where robust evidence was available, we did not include a number of value components that were difficult to quantify or had less evidence among rheumatology practices. For instance, rapid, cloud-enabled onsite testing may help address the shortage of rheumatologists, particularly in non-metropolitan areas[32–34]. The 2015 study by the American College of Rheumatology projected a significant shortage of rheumatologists during the next two decades. Proposed solutions include increasing the supply of rheumatologists through fellowship programs, for example, as well as improving practice efficiency. Increasing the involvement of primary care physicians in the screening process or leveraging telehealth technology can reduce the number of patients referred to rheumatologists. Also, rapid, cloud-enabled onsite testing may allow for increased efficiency of care delivery process in the rheumatology practice and, thus, enable providers to serve more patients.

Our study suggests that rapid, cloud-enabled onsite testing generates value to society by more efficient care delivery and better health outcomes. However, in practice, measuring and attributing value will depend on how this new technology is integrated into provider workflow. Rapid, cloud-enabled onsite testing, in the short run, is likely to disrupt processes at the practice and may require a re-design of patient flow during office visits. Initial visits may take longer and, under fee-for-service, providers may lose out on reimbursement for follow-up visits, potentially offset by the ability to see more new patients.

Limitations

While our study only measured the benefit of rapid, cloud-enabled onsite testing through quicker diagnosis for incoming patients, this technology could also improve treatment modification choices (e.g. dose titration, medication switching) for established patients undergoing treatment. In particular, for RA patients, rapid, cloud-enabled onsite testing may facilitate treat-to-target, a treatment approach recommended by ACR and EULAR RA treatment guidelines[7,29]. Also, rapid, cloud-enabled onsite testing may also improve effectiveness of care delivery for patients currently under treatment by potentially eliminating follow-up visits[35]. However, as rapid, cloud-enabled onsite testing is a novel method of conducting diagnostic blood tests, data on its impact on patient health, care delivery, and clinical decision-making is scarce. Thus, these components were not quantified in our model. Moreover, rapid, cloud-enabled onsite testing is likely to generate value in settings beyond the rheumatologist office—such as in primary care practices—and to stakeholders other than payers. For example, rapid testing can reduce the stress for patients inherent in waiting for decisive diagnoses, thus it is more convenient. It allows providers to save time on office visits as well as on visit follow-up. Further, receiving rapid but still high quality results within 15 min can reduce the likelihood of lost test results and lower the risk of medical malpractice suits.

Second, we simulated the value of rapid, cloud-enabled onsite testing considering that rheumatologists are not able to alter the composition of patients entering their practice. By improving on care delivery, rapid, cloud-enabled onsite testing may enable providers to free capacity at rheumatology practices[32], and allow earlier access to beneficial treatment for more patients[35]. This element was not captured in our model as it focused on current patients at a rheumatologist practice, rather than multiple cohorts of patients over time.

Third, rapid testing may generate value within value-based payment frameworks. For example, improved performance on quality metrics, particularly on patient satisfaction[36] and effectiveness of care metrics[27] can contribute to higher payments to health plans. Our model did not capture this value component.

Fourth, our model did not fully capture heterogeneity among patients undergoing evaluation at the rheumatologist. We considered patients with positive and negative diagnoses at the end of the evaluation process, but did not account for factors such as disease severity and comorbidities that are likely to impact the value of rapid, cloud-enabled onsite testing. Further, our model assumes that part of the benefit of more rapid testing is more rapid access to DMARD treatment among those diagnosed with RA. On the one hand, this may over-estimate the value of rapid, cloud-enabled onsite testing if some people do not need DMARD treatment. On the other hand, it could under-estimate the value if some patients who could benefit from DMARD treatment never receive it due to a lack of follow-up after traditional off-site diagnostic testing.

Fifth, in the model we assumed that the cost and accuracy of rapid, cloud-enabled onsite testing was the same as centralized testing. Pricing for rapid, cloud-enabled onsite testing is not yet known, but clearly the net value of the technology relative to centralized laboratory testing depends on any price differentials.

Finally, our results were based on parameters from the literature, primary interviews with rheumatologists, and an observational study. Future research should measure the costs and benefits of implementing rapid, cloud-enabled onsite testing in the real-world. More robust real-world data would confirm the validity of our model.

Conclusion

Rapid, cloud-enabled onsite testing has the potential to generate significant value relative to centralized testing for patients undergoing evaluation for rheumatoid arthritis. Further research is needed to determine value of rapid, cloud-enabled onsite testing in evaluating and managing diseases other than RA and in healthcare settings other than a rheumatologist office.

Transparency

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Declaration of financial/other interests

KB, JS, MB, and LZ are employees of Precision Health Economics, a research consultancy to the health and life science industries owned by Precision Medicine Group. JS holds equity in Precision Medicine Group. RH and MO are employees of Genalyte, Inc. AJ is an employee of Harvard Medical School and is a consultant to Precision Health Economics. JME peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

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