# THE SOCIAL AND FINANCIAL BURDENS OF THE UNDERUTILIZATION OF LABORATORY TESTS: A SCOPING REVIEW (January 1997 – January 2024)

by

ALEIX CATALANI

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Approved: *Dr. Alia Yasen*
Primary Thesis Advisor

Nearly every adult in the United States will experience a misdiagnosis in their lifetime.[1–3] Each year, 64,000 deaths in the US can be attributed to misdiagnoses, but the true number of undetected cases likely dwarfs this figure.[4] The widespread issue of diagnostic error is partly due to the underutilization of laboratory tests as both screening and diagnostic tools. Between 1997 and 2012, the rates of the underutilization and the overutilization of laboratory tests were found to be 44.8% and 20.6%, respectively.[5] Still, the underutilization of laboratory tests remains understudied compared to overutilization. Although overutilization studies often emphasize the financial savings associated with cutting out unnecessary tests, focusing on the underused tests to prevent late or missed diagnoses may yield greater cost savings. For instance, the lifetime cost of a single HIV treatment is worth 7,000-20,000 high-sensitivity HIV screening tests.[6] It is perhaps unsurprising that issues of misdiagnosis and underusage of laboratory tests disproportionately affect certain racial groups. To illustrate, African American and Hispanic patients were found to be less likely to receive laboratory tests to rule out myocardial infarctions when presenting to the emergency room with chest pain. This scoping review aimed to investigate the underutilization of laboratory tests in the emergency department, inpatient settings, primary care settings, obstetric services, and genetic specialty services through the lenses of racial and financial

considerations to answer the following questions: 1. In which healthcare settings is the underutilization of laboratory tests a known concern? 2. Is there a financial incentive to address the problem of the underutilization of certain laboratory tests in healthcare? 3. Do racial biases of healthcare providers or cultural attitudes toward medicine affect the rates of underutilization of laboratory tests between racial groups?

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# Table of Contents


List of Figures 7
Key Terms 9
Introduction 11
  Background 11
  Historical Barriers to Medicine 14
  Financial Considerations to Medicine 15
  Purpose 16
Methods 17
  Identification of Relevant Studies 17
  Study Selection 19
  Charting of Results 20
  Summarizing and Reporting Results 21
Results 22
  Emergency Department 22
    General 22
    Abdominopelvic Symptoms 24
    Cardiovascular Symptoms 25
    Dehydration 26
    Infectious Disease 26
    HIV Screening 27
  Inpatient Services 27
    Autoimmune Conditions 28
    Hematology 29
    Infectious Disease 30
  Mixed Inpatient & Outpatient Services 31
    Infectious Disease 32
    HIV 32
    Hematology 33
    Gastroenterology 33
  Primary Care 33
    General 34
    Cardiovascular 35

Diabetes (Mellitus) 36
HIV 37
Infectious Disease 38
Pediatrics 39
Obstetrics 39
Prenatal Testing 40
Postnatal Testing 41
Genetic Specialty Services 42
Genetic Services by Primary Care Providers 42
Cancer (General) 43
Breast Cancer 44
Cardiovascular 45
Attitudes toward Genetic Tests 45
Discussion 47
HIV Screening 47
Breast Cancer Screening 50
Diagnostic Laboratory Tests 52
Underutilization by Healthcare Setting 53
Limitations and Strengths 54
Conclusions 55
Funding 56
References 57

# List of Figures

**Figure 1**: Literature review flowchart

**Figure 2**: Adjusted odds ratios for laboratory test ordering and head imaging for head injuries for white (referent), African American, Hispanic, and Native American patients (n=75,254). Patients presented to the emergency room with final diagnoses of fever, vomiting, gastritis/colitis, upper respiratory infection, asthma, or head injury. * indicates $p \leq 0.02$ between white (referent) patients and minority racial or ethnic group.

**Figure 3**: Percentage of urinary tract infection (UTI) diagnoses confirmed with a urine culture. Patients were women who presented to the emergency department with urogenital symptoms (n=264).

**Figure 4**: Percentage of dehydration diagnoses confirmed with independent testing by researchers. Patients were ≥65 years old and had diagnostic codes for dehydration in their medical records (n=102).

**Figure 5**: Percentage of cases with misutilizations (overutilization or underutilization) of laboratory tests in patients suspected of having autoimmune conditions (n=246). Misutilizations were identified by an expert panel of pathologist physicians and a doctorate-level medical laboratory scientist.

**Figure 6**: Percentage of cases with an underutilization of a laboratory test in patients suspected of having coagulation disorders (n=200). Underutilizations were identified by an expert panel of pathologist physicians and a doctorate-level medical laboratory scientist.

**Figure 7**: Percentage of eligible primary care patients who did not receive an annual lipid screening test (n=59,604). Patients were considered to be eligible if they met guidelines set by the US Preventive Service Taskforce for cardiovascular disease risk.

**Figure 8**: Percentage of eligible primary care patients who did not receive diabetes screening tests (n=12,787, 7,088, & 1,573). Unique methodologies were used to determine the rate of underutilization of diabetes laboratory tests in the three studies.

**Figure 9**: Percentage of cases with an underutilization of laboratory tests among pregnant individuals suspected of having thyroid conditions (n=321). Determinations of underutilizations were made by a doctorate-level medical laboratory scientist.

**Figure 10**: Percentage of infants at risk for vertical transmission of the hepatitis C virus (HCV) who were adequately tested for HCV (per CDC guidelines) (n=4,072) & adjusted odds ratios of receiving adequate HCV testing for African American and white (referent) infants. Data were retrospectively analyzed from the mothers' and infants' medical records.

**Figure 11**: Percentage of white, Hispanic (English-speaking), Hispanic (Spanish-speaking), and African American women recently diagnosed with early-onset breast cancer who had discussions

of genetic testing with their primary care provider, received genetic testing, or were diagnosed with triple-negative breast cancer (n=1,622). * indicates $p < 0.0001$ between white, Hispanic (English-speaking), Hispanic (Spanish-speaking), and African American patients.

## Key Terms

**Diagnostic Error**: An error in the process of diagnosing a condition. This may be a missed diagnosis, a delayed diagnosis, or a misdiagnosis.

**Misdiagnosis**: A healthcare error in which a provider mistakes one condition for another.

**Laboratory Test**: A type of diagnostic test used by healthcare providers to diagnose, monitor, or rule out various conditions. Laboratory tests analyze various specimens from the body, such as blood, stool, urine, saliva, hair, sputum, or biopsied tissues. For the purpose of the current study, studies on laboratory tests of biopsied tissues were omitted.

**Underutilization**: The omission of a laboratory test order when it would have been clinically relevant to the case. This will be the focus of the current study.

**Overutilization**: An unnecessary laboratory test order that was not clinically relevant to the case.

**Misutilization**: A blanket term for underutilization and overutilization

**Boolean Operator**: The words "AND," "OR," and "NOT" used in library database searches. When placed between two search terms, the term "AND" ensures the search yields articles that include both terms. When placed between two search terms, the term "OR" ensures the search yields articles that include one term, the other term, or both terms. When placed between two search terms, the term "NOT" ensures the search yields articles that contain the first term, but not the second. These terms were used extensively in the database searches of the current study.

**Significance**: Statistical significance refers to the high likelihood that a difference between two groups is due to certain factors rather than random chance alone. This is often accompanied by a p-value, which describes the likelihood of the observed difference between groups being due to random chance alone. For example, $p=0.05$ indicates that the observed difference (or a greater difference) between groups would be measured 5% of the time due to random chance alone. Commonly, a p-value of $\leq 0.05$ is considered to be "(statistically) significant." In the current

study, p-values and significance were used to show that differences between racial and ethnic groups were unlikely to be due to random chance alone.

**Odds Ratio**: This is a measure of the odds of an event occurring in one group, compared to the odds of it occurring in another group. In the current study, the event was typically the ordering of a laboratory test, and the groups were racial and ethnic groups. White patients were commonly the reference group to which the odds of other groups are compared. If the odds ratio for receiving a laboratory test within a non-white racial group was >1, then that group had higher odds of receiving the laboratory test than the white patients. If the odds ratio for receiving a laboratory test within a non-white racial group was <1, then that group had lower odds of receiving the laboratory test than the white patients.

**Inpatient**: A patient who remains at a hospital for one night or more.

**Outpatient**: A patient who presents to a healthcare setting but does not stay overnight.

# Introduction

## Background

Nearly every adult in the United States will experience a misdiagnosis in their lifetime.[1–3] A misdiagnosis may be extremely minor, like mistaking the common cold for the flu. A misdiagnosis can also result in extreme consequences, such as mistaking a heart attack for a panic attack. Due to grave circumstances such as the latter example, an estimated 64,000 deaths in the United States can be attributed to misdiagnoses – making this the ninth leading cause of death in the United States.[4,7] This crisis of healthcare in the United States can be partly attributed to the *underutilization* of laboratory tests as both screening and diagnostic tools. The current study sought to use this specific crisis to highlight several salient problems in healthcare, such as racial, gender, and economic inequalities in patient care, as well as gaps in provider education.

The use of laboratory tests in the process of diagnosing conditions is becoming a critical aspect of modern medicine. An estimated 60-70% of all medical decisions by physicians are aided or completely facilitated by the use of laboratory test results, and 80% of diagnostic guidelines include the use of a laboratory test.[8] A laboratory test is a blanket term for the clinical analysis of specimens from patients' bodies, such as blood, urine, stool, sputum, saliva, hair, or various tissue biopsy samples. From the 1980s to the 2010s, the number of laboratory tests available for providers to order would grow from 2,000 to over 4,000.[2,9,10] In the same time frame, the number of laboratory tests ordered per year in the United States steadily increased 6-7% annually.[10]

At the beginning of the 1980s, attending physicians were well aware that their resident physicians were not proficient in ordering the correct laboratory tests.[9] Despite the awareness of this problem and the rapid growth of the laboratory science industry, the curricula of medical

schools have not changed appreciably to address these issues.[9] Through the four years of medical school, future physicians are commonly given ten or fewer hours of dedicated training or education on the science of laboratory tests.[9]

Given the prevalence of laboratory tests in a physician's everyday practice and the lack of formal training on laboratory sciences, it is perhaps unsurprising that physicians are still not confident in their abilities to order the correct laboratory tests. In a survey of primary care physicians, physicians reported being uncertain of the correct laboratory test to order in 14.7% of their cases.[2] Although this is a relatively low percentage, there are 500 million primary care appointments in the US every year, with 30% requiring laboratory tests. Thus, there is likely a degree of uncertainty in ordering laboratory tests in tens of millions of visits each year.[2]

The lack of proficiency, confidence, or both in ordering laboratory tests by providers results in frequent misutilizations of laboratory tests. An overutilization of a laboratory test is a form of misutilization in which a provider orders a test that is unnecessary to a patient's case. The overutilization of a laboratory test incurs an unnecessary cost to the laboratory and patient, but more importantly it may yield a false positive result. This inaccurate result may cause a patient to be treated for a condition they do not have in actuality, incurring further unnecessary costs to the patient. An *underutilization* of a laboratory test is a form of misutilization in which a test that should have been ordered was not. The *underutilization* of a laboratory test may result in delayed, or even missed, diagnoses. Although there are no initial costs of *underutilizing* laboratory tests, progressions of patient conditions, transmissions of infectious diseases, or complications of conditions while the patients are undiagnosed may incur hefty downstream costs to patients and healthcare systems.

In a meta-analysis of the utilization of laboratory tests from 1997 to 2012, the mean rate of overutilization was calculated to be 20.6%, meaning that one in five laboratory tests were unnecessarily ordered in that timespan.[5] The mean rate of *underutilization* was calculated to be 44.8%, meaning that two in five patients did not receive adequate laboratory testing.[5] Despite the higher rate of the *underutilization* of laboratory tests, this topic remains understudied when compared to overutilization.[5] This 15-year meta-analysis used 114 studies on overutilization and 18 studies on *underutilization*.[5] The current study will focus on the widespread problem of the *underutilization* of laboratory tests.

Although these rates provide a general understanding of the prevalence of these errors, they do not show in which healthcare settings these errors occur most frequently in, nor do they show to whom this problem is the most significant for. Thus, another focus of the current study will be to determine if there are differences in *underutilizations* of laboratory tests depending on the healthcare settings they are ordered in, or depending on the racial or ethnic identities of the patients the tests are ordered for.

There are three common methodologies for measuring the rates of the underutilization of laboratory tests: 1) researchers analyze medical records or patient histories to determine if a laboratory test could have been performed to aid in diagnosis; 2) researchers study large populations of patients to determine if the rates of usage of certain laboratory tests are different between individuals of different races or ethnicities when there is no medical reason for them to be; 3) surveys. To the author's knowledge, there is no existing literature that has combined the results of the three types of studies into one broad overview of the topic. Given the wide scope of selected studies in this review, the presented findings of these studies will be largely incomparable on a one to one basis due to the unique methodologies, scopes, and populations of each study. The

purpose of a scoping review is rather to present a wide snapshot of the current knowledge of a particular topic.

**Historical Barriers to Medicine**

There are several reasons why laboratory tests are underutilized in the United States, in addition to physician oversight. Although entire healthcare systems and individual healthcare provides may lack cultural competency, historically marginalized racial and ethnic groups may also refuse certain medical treatment due to mistrust in healthcare institutions. This mistrust may stem from well-documented historical events, anecdotal evidence, cultural differences in how to approach healthcare, or other barriers. In the case of African American individuals, there have been several well-documented instances of healthcare institutions or healthcare providers betraying their trust. In the 19th century, Black, enslaved, pregnant women were the chosen population to experiment with new surgical techniques for the field of gynecology.[11] In the 20th century, the Tuskegee syphilis study needlessly subjected their African American subjects to the risks of untreated syphilis, the cell line of Henrietta Lacks was secretly distributed and profited from, and African American individuals were disproportionately affected by the onset of the HIV epidemic.[12–14] Hispanic individuals face similar reasons for distrust due to the ethical violations of the Puerto Rican birth control studies of the 1950s.[15] Additionally, Hispanic individuals are disproportionately affected by issues of documentation status and language barriers.[16] Asian individuals commonly refuse Western healthcare with the beliefs that they will be better served by medicine traditional to their cultures or that they will be financial burdens on their family.[17]

There are several other considerations to the delivery of healthcare to minority racial and ethnic groups that come before the initial patient-provider interaction. In the United States, there are great disparities in accessing healthcare between white individuals and most other minority

racial and ethnic groups. Hispanic American and African American individuals were less likely to have adequate access to healthcare, to own private health insurance, to receive urgent healthcare when it was needed, or to receive routine healthcare on an annual basis than white individuals.[18] Given the scope of the current study, it will not address most of these important aspects of the delivery of healthcare, although they remain important areas for future research. The current study will focus on the *underutilization* of laboratory tests, thereby focusing only on whether the provider orders the laboratory test or whether the patient elects to receive the laboratory test.

**Financial Considerations to Medicine**

The use of preventive medicine, such as laboratory tests to diagnose or screen for disease, can be largely dictated by the patterns of health insurance reimbursement. The United States employs several systems of health insurance: employer-based, for-profit insurance for much of the workforce, tax-funded healthcare for military, veterans, and Native Americans, government-based, non-profit insurance for those over 65, or no health insurance at all for tens of millions of Americans.[19] The tens of millions of uninsured individuals who live in the United States are largely unable to pay out-of-pocket for preventive healthcare at primary care clinics. Further, as the name suggests, for-profit insurance policies spend a great deal of time determining how to maintain a profit line. This may come at the cost of not covering healthcare deemed to be unnecessary. American health insurance companies deny as much as 30% of the claims they receive.[19] Claims for diagnostic tests are not immune from denials. These financial barriers undoubtedly result in patients who present to emergency departments with outcomes that were preventable had they been diagnosed earlier, causing increased long-term costs for tax-funded healthcare.[19]

Among countries considered to have developed economies by the United Nations with unified health insurance systems, the responsibility of whether or not to pay for preventive

medicine is still debated.[19,20] In the United Kingdom, receiving healthcare places no out-of-pocket cost on individuals, but the tax-funded pool of money for healthcare is shared between all citizens for every medical cost.[19] As such, providers are judicious with the use of preventive laboratory tests as to not divert funds from patients who will urgently require healthcare.[19] Conversely, certain provinces of Japan believe the cost of preventive medicine lowers long-term healthcare costs.[19] As such, some Japanese insurance plans will cover extensive annual laboratory diagnostic tests.[19] It is perhaps no surprise that Japan leads the world in metrics of public health such as the healthy life expectancy and the under-five mortality rate.[21,22] Still, the healthcare expenditure of the United States dwarfs those of Japan and the United Kingdom. When measured by % GDP, the United States, the United Kingdom, and Japan pay 19%, 12%, and 11%, respectively.[23] Perhaps these findings speak to the efficacy of preventive medicine, in part. Within the scope of the current study, this may explain differences in laboratory test ordering frequencies and definitions of appropriate utilization between selected studies carried out in different countries.

**Purpose**

The purpose of this scoping review is to summarize and disseminate the research findings of the work that has been done in the topic of the underutilization of laboratory tests. Although a meta-analysis has been performed to yield the overall rate of the underutilization of laboratory tests from 1997-2012 (44.8%),[5] there is no discernable conclusion of which healthcare settings this problem is most serious in or to whom this problem occurs most frequently to. Thus, this scoping review will seek to determine in which healthcare settings the rate of underutilization of laboratory tests is highest in and if certain racial and ethnic groups are disproportionately affected by this issue. This scoping review makes no attempt to determine the validity or the strength of the results of the selected studies.

# Methods

This scoping review used the methodological framework authored by Arksey and O'Malley: 1) identification of the research question(s); 2) identification of relevant studies; 3) study selection; 4) charting of data; 5) summarizing & reporting results.[24] The purpose of this study was to provide a broad overview of the evidence pertaining to the following research questions: 1. In which healthcare sectors is the underutilization of laboratory tests a known concern? 2. Is there a financial incentive to address the problem of the underutilization of certain laboratory tests in healthcare? 3. Do racial biases of healthcare providers or cultural attitudes toward medicine affect the rates of underutilization of laboratory tests between racial groups? The PRISMA Extension for Scoping Reviews was followed to ensure standardization and methodological transparency.[25] This is a checklist used to ensure that all scoping reviews adhere to a standardized outline.

## Identification of Relevant Studies

The database Medline/PubMed was used to find relevant articles. The most recent search was performed in January 2024. The purpose of the first search term on Medline (NCBI) was to retrieve studies pertaining to research question #1 (n = 5,234):

> ((((((("medical laboratory science"[MeSH Terms]) OR ("clinical laboratory services"[MeSH Terms])) OR ("clinical laboratory techniques"[MeSH Terms])) OR ("laboratories, clinical"[MeSH Terms])) OR ("diagnostic tests, routine"[MeSH Terms])) AND ((("diagnostic errors"[MeSH Terms]) OR ("patient safety"[MeSH Terms])) OR ("health services misuse"[MeSH Terms]))) NOT (((((((("biopsy"[MeSH Terms]) OR ("biopsy, fine needle"[MeSH Terms])) OR (aspiration biopsy, fine needle[MeSH Terms])) OR (aspiration biopsy[MeSH Terms])) OR ("false negative reactions"[MeSH Terms])) OR ("false positive reactions"[MeSH Terms])) OR ("unnecessary procedures"[MeSH Terms]))
> Filters: from 1997-2024

The purpose of the second search term on Medline (NCBI) was to retrieve studies pertaining to research question #3 (n = 6860):

> (((((("clinical laboratory services"[MeSH Terms]) OR ("clinical laboratory techniques"[MeSH Terms])) OR ("laboratories, clinical"[MeSH Terms])) OR (diagnostic test[MeSH Terms])) AND ((((((((((((("asian"[MeSH Terms]) OR ("asian american native hawaiian and pacific islander"[MeSH Terms])) OR ("ethnicity"[MeSH Terms])) OR ("ethnic and racial minorities"[MeSH Terms])) OR ("racial groups"[MeSH Terms])) OR ("health disparate minority and vulnerable populations"[MeSH Terms])) OR ("black or african american"[MeSH Terms])) OR ("caribbean people"[MeSH Terms])) OR ("central american people"[MeSH Terms])) OR ("south american people"[MeSH Terms])) OR ("hispanic or latino"[MeSH Terms])) OR ("black people"[MeSH Terms])) OR ("indians, north american"[MeSH Terms])) OR ("racism"[MeSH Terms]))) NOT ((((((((((("biopsy"[MeSH Terms]) OR (aspiration biopsy, fine needle[MeSH Terms])) OR (aspiration biopsy[MeSH Terms])) OR ("biopsy, fine needle"[MeSH Terms])) OR ("false negative reactions"[MeSH Terms])) OR ("false positive reactions"[MeSH Terms])) OR ("unnecessary procedures"[MeSH Terms])) OR ("oximetry"[MeSH Terms])) OR ("covid 19"[MeSH Terms])) OR ("reference values"[MeSH Terms]))

Studies were identified between January 1997 and January 2024 with the purposes of determining the rates of underutilization of laboratory tests or comparing the rates of utilization between racial/ethnic groups. The start date of 1997 was selected for the following reasons: 1) the largest known meta-analysis of the rates of underutilization of laboratory tests began its analysis of data in 1997;[5] 2) the number of laboratory tests available to providers has doubled to over 4,000 in that 20 year time frame;[2,9,10] 3) since 1999, laboratory test ordering volume has risen 6-7% annually.[10]

## Study Selection

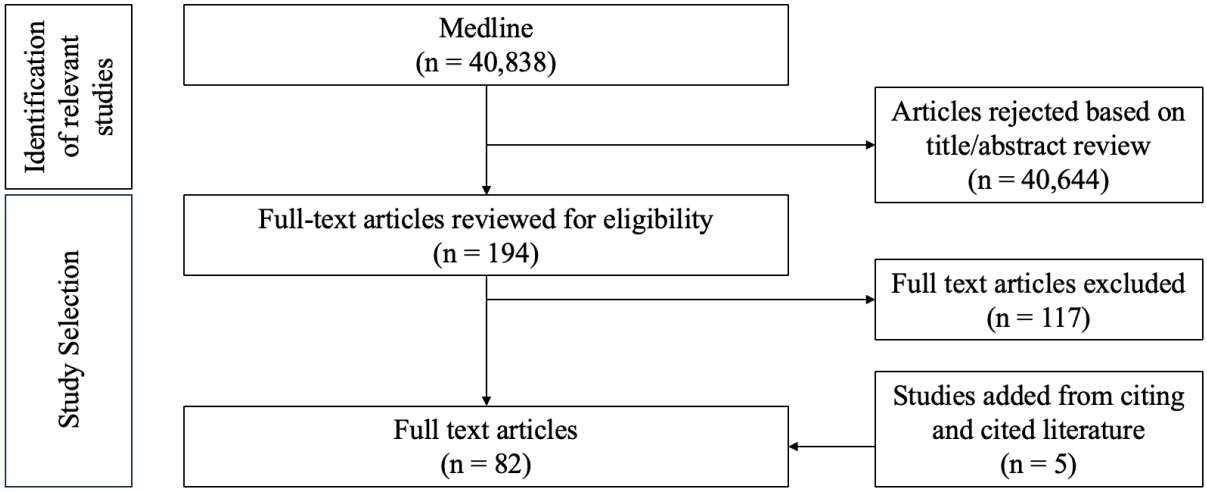


Figure 1: Literature review flowchart

The database search and study selection processes are reported by Figure 1. The initial search strategy generated a collection of 40,838 articles. Pre-defined search terms were excluded via the Boolean operator "NOT" (described below), resulting in the removal of 26,706 articles. The titles and abstracts of the remaining 14,132 articles were manually reviewed – of which 13,938 articles were removed. The remaining 194 articles were read in full – of which 117 full text articles were excluded. Five articles were found from the references of the 194 articles and were included in the final pool of selected articles. A total of 82 articles remained for further analysis.

The following pre-defined inclusion criteria were used: 1) research published between 1997 and 2024; 2) research published in countries defined as having developed economies by the United Nations;[20] 3) inclusion of a quantification of the rate of underutilization of laboratory tests, 4) inclusion of a quantification of the difference of laboratory test use between racial/ethnic groups, or 5) a qualitative study on the etiology of the difference of laboratory test use between racial/ethnic groups.

The following pre-defined exclusion criteria were used to exclude articles from the initial collection of 40,838 articles via the Boolean operator "NOT": 1) studies concerning the use of biopsies as diagnostic and screening tools; 2) studies concerning the rate of false-positive results of laboratory tests; 3) studies concerning the rate of false-negative results of laboratory tests; 4) studies concerning only the rate of overutilization of laboratory tests; 5) studies concerning the use of pulse-oximetry; 6) studies concerning the use of laboratory tests to diagnose infections of SARS-CoV-2; 7) studies concerning racial/ethnic differences in reference values.

The following exclusion criteria were used to remove articles from the remaining 13,932 articles on the basis of their title and abstracts: 1) case studies; 2) studies concerning pre-analytical errors in laboratory medicine; 3) studies concerning post-analytical errors in laboratory medicine; 4) studies concerning only the rate of overutilization of laboratory tests; 5) studies comparing the utilization rates of laboratory tests between individuals of different genders or sexualities.

**Charting of Results**

Data from the remaining 82 articles were extracted and tabulated into Microsoft Excel. The following data were collected and charted from each article: authors, publication year, country of study, study design, populations, healthcare settings, quantitative results, and qualitative results. The rate of underutilization or a comparison of usage rates of laboratory tests was noted for each selected study. The data were subsequently arranged by healthcare settings to yield the following prevalent categories: emergency departments, inpatient settings, primary care settings, mixed inpatient and outpatient settings, obstetric services, and genetic specialty services.

## Summarizing and Reporting Results

This scoping review did not attempt to assess the validity of the selected articles based on their methodologies, nor did it attempt to synthesize quantitative results from articles with different study designs. Rather, the heterogeneous nature of the collection of articles lent itself to a quantitative and qualitative review of their findings. It was chosen to categorize the findings in groups by specific healthcare settings (described above). The findings of this scoping review are presented below.

# Results

## Emergency Department

The literature search yielded fourteen studies that investigated laboratory test utilization in the emergency department. Thirteen studies were carried out in the United States. One study was carried out in the United Kingdom. The methodologies of the selected studies were heterogenous, including retrospective results, prospective results, and results from surveys.

### *General*

In a retrospective analysis of patient safety incident reports from the emergency department (n=2288), 65% of the reports were attributed to breakdowns in the delivery of diagnostic testing.[26] Safety incident reports are filed in cases of unexpected or unintended incidents that could have harmed or did harm a patient. However, underreporting of incidents was hypothesized to occur frequently in instances of provider self-preservation and unawareness. Thus, diagnostic errors were said to occur at a rate greater than 10-15% in the emergency department.

In a retrospective cohort study of laboratory test usage among pediatric patients in the emergency department (n=75,254), African American (aOR 0.57, 95% CI: 0.49-0.66), Hispanic (aOR 0.61, 95% CI: 0.52-0.72), and Native American (aOR 0.59, 95% CI: 0.37-0.93) patients were significantly less likely to receive a diagnostic test of any type, regardless of condition than white patients (referent) (Fig. 2).[27] No significant differences were found between racial groups in the frequency of ordering radiological imaging for head injuries. The strict protocol for imaging in cases of pediatric head injuries was hypothesized to be a significant contributing factor to this finding. Thus, the difference in laboratory test usage amongst racial and ethnic groups was thought

to be due to several factors, including racial bias in clinical judgement. In a high-paced environment such as the emergency department, providers are often stretched thin in terms of their time and mental capacity. Prolonged exposures to settings such as these are thought to erode the empathy and patience of providers towards vulnerable groups, such as racial and ethnic minority groups. Alternate explanations consider the fact that racial and ethnic minority patients are more likely to use the emergency department for routine medical care.[28] Thus, providers may opt to use recent laboratory test results to treat returning patients, rather than re-ordering new laboratory tests. Conversely, providers may dismiss the concerns of returning patients, thereby opting not to order laboratory tests for their treatment.[27]

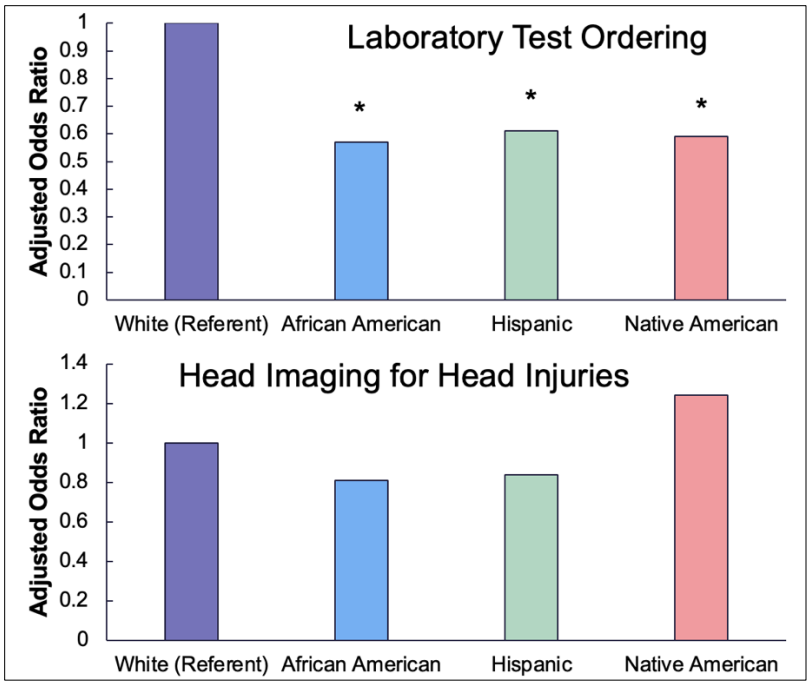


Figure 2: Adjusted odds ratios for laboratory test ordering and head imaging for head injuries for white (referent), African American, Hispanic, and Native American patients (n=75,254). Patients presented to the emergency room with final diagnoses of fever, vomiting, gastritis/colitis, upper respiratory infection, asthma, or head injury. * indicates $p \leq 0.02$ between white (referent) patients and minority racial or ethnic group.[27]

*Abdominopelvic Symptoms*

In a retrospective case analysis (n=51,164), African American and Hispanic children were significantly more likely to have a missed diagnosis of acute appendicitis (aOR: 2.48, 95% CI: 1.96-3.13; aOR: 2.10, 95% CI: 1.75-2.52, respectively) than white patients (referent), which was associated with a lack of diagnostic testing.[29] In a similar retrospective chart review (n=1,884), African American and Hispanic children were significantly less likely to have laboratory tests ordered in cases of suspected gastroenteritis (OR: 0.47, 95% CI: 0.30-0.73; OR: 0.45, 95% CI: 0.29-0.70, respectively) than white patients (referent).[30] In a prospective, observational study (n=324), diagnostic tests for abdominal pain were ordered more frequently for non-English speakers than for English-speakers ($p<0.05$).[31] This was perhaps due to a lack of symptom communication between non-English speaking patients and English-speaking providers.

An observational cohort study (n=264) investigated the overdiagnosis of urinary tract infections (UTIs) in women with urinogenital symptoms in the emergency department.[32] Urine cultures were not ordered for 57% of the patients diagnosed with a UTI, resulting in an overdiagnosis in 39-52% of the participants (Fig. 3). Eight percent of the patients diagnosed with a UTI were later revealed to have sexually transmitted infections by the study results, in actuality. Importantly, the reluctancy to employ urine cultures also resulted in an underdiagnosis of UTIs in 32% of the participants.

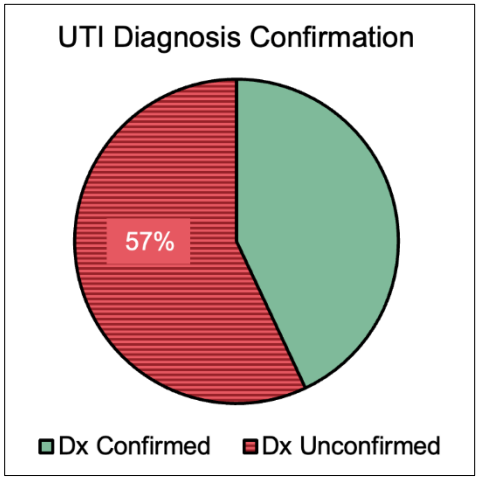


Figure 3: Percentage of urinary tract infection (UTI) diagnoses confirmed with a urine culture. Patients were women who presented to the emergency department with urogenital symptoms (n=264).[32]

*Cardiovascular Symptoms*

In a retrospective case analysis of patients who presented to the emergency department with chest pain not due to myocardial infarction (n=356), 22% of patients did not receive the necessary diagnostic tests to rule out the presence of coronary artery disease.[33] Higher rates of underutilization were observed among African American and Hispanic patients, although these differences did not reach significance due to the low sample size. In two retrospective chart analyses of pediatric and adult patients who presented to the emergency department with chest pain, African American and Hispanic patients were less likely to receive laboratory tests than their white counterparts. African American and Hispanic adults were less likely to receive cardiac enzyme testing (aOR: 0.69, 99% CI: 0.49-0.97; aOR: 0.73, 99% CI: 0.47-1.08, respectively) to determine if myocardial infarctions were present than white adults (referent).[34] African American children who presented with chest pain received complete blood counts at a rate of 17%, while white children with similar symptoms were found to receive complete blood counts at a rate of 27% ($p<0.01$).[35]

*Dehydration*

In an observational cohort study, the misdiagnosis of dehydration in older adults in the emergency department was investigated (n=102).[36] Thirty one percent of the participants diagnosed with dehydration had no indication of dehydration in their laboratory test results ordered by researchers (Fig. 4). Although this was not directly determined in the study, researchers believed these results were indicative of physicians frequently forgoing the necessary laboratory tests to confirm their diagnoses of dehydration.

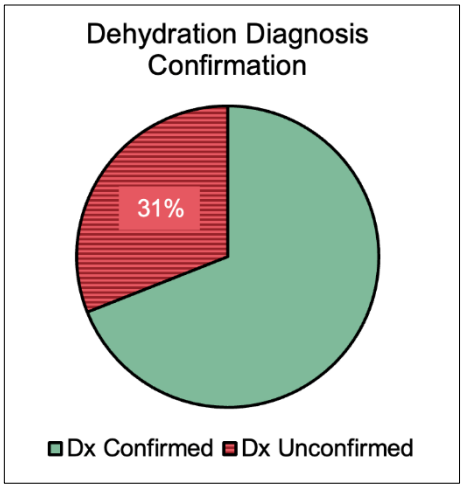


Figure 4: Percentage of dehydration diagnoses confirmed with independent testing by researchers. Patients were ≥65 years old and had diagnostic codes for dehydration in their medical records (n=102).[36]

*Infectious Disease*

In a large retrospective cohort study of sepsis pathway activation (n=97,338 emergency department visits), white patients (aOR: 3.4, 95% CI: 1.8-6.4) were more likely to be tested and treated for sepsis from clinician judgement alone than African American patients (referent).[37] No significant differences were found between racial groups when the procedural sepsis activation pathway was used. Researchers hypothesized the difference between these findings was due to racial bias in clinical judgement.

*HIV Screening*

In a retrospective review of medical records from patients with evidence of drug use at the emergency department (n=13,426), only 10% of patients received any form of HIV screening.[38] African American and Hispanic patients with evidence of drug use had lower odds of receiving any form of HIV screening (aOR: 0.69, 95% CI: 0.59-0.83; aOR: 0.68, 95% CI: 0.55-0.84, respectively) than their white counterparts (referent). In a survey of African Americans and Hispanic immigrants who presented to the emergency department (n=2,265), 23% of patients reported engagement in high-risk behavior for HIV (multiple partners, unprotected sex, intravenous drug use).[39] Twenty three percent of those patients did not receive screening tests for HIV. The findings from both studies were believed to be the product of both patient refusal and provider inattentiveness.

A randomized control trial investigated the rate of patient refusal for confirmatory HIV testing in the emergency room.[40] The initial rapid HIV screening test was reactive in 1.5% of patients (n=4,065). Of the patients with reactive tests, 22% of patients refused to receive a confirmatory test. From the results of the confirmatory tests of the 78% of patients who consented, it was estimated that a third of the patients who refused the confirmatory test were HIV-positive.

**Inpatient Services**

The literature search yielded eleven studies that investigated laboratory test utilization in inpatient settings. Seven studies were carried out in the United States. The remaining four studies were carried out in Spain, Germany, Austria, and South Korea. The methodologies of the selected studies were heterogenous, including retrospective results, prospective results, and results from surveys.

*Autoimmune Conditions*

In a retrospective chart review of pediatric patients presenting to a rheumatologic specialist (n=2125), the prevalence of celiac disease in children with autoimmune or rheumatologic conditions was measured to be higher (2%) than that of the general population (0.7%).[41] Thirty six new diagnoses of Celiac Disease were made in the 7-year span of this study. Although national guidelines of Celiac Disease screening in the US did not consider children with autoimmune and rheumatologic conditions to be a high-risk population, it was shown that this population is afflicted with celiac disease nearly three times as frequently as the general population. Thus, screening tests for celiac disease are highly underused in this population.

In a retrospective chart review of patients undergoing diagnostic testing for lupus (n=1146), the number of tests ordered before and after a standardized protocol for test ordering was implemented was compared.[42] The number of confirmatory tests, initial ($p=0.0061$) and repeat ($p<0.001$), significantly increased after the standardized panel was implemented. These improvements were considered to be indicative of a history of false-positive diagnoses due to the underutilization of laboratory tests prior to the establishment of the standardized panel.

In a retrospective chart review of patients suspected of systemic autoimmune rheumatic disorders (n=246), there was a misutilization of laboratory tests in 60.6% of cases (Fig. 5).[43] Although the authors did not make the distinction of underutilizations and overutilizations in their results, similar study designs from the same research group at the University of Texas Medical Branch found that the rates of underutilization were at least twice as high as the rates of overutilization.[44,45] Additionally, the rate of misutilization was higher in African American patients, however the low sample size did not lend to statistical significance.

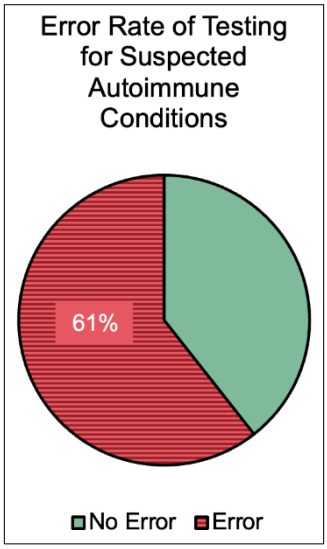


Figure 5: Percentage of cases with misutilizations (overutilization or underutilization) of laboratory tests in patients suspected of having autoimmune conditions (n=246). Misutilizations were identified by an expert panel of pathologist physicians and a doctorate-level medical laboratory scientist.[43]

*Hematology*

In an observational study investigating the misutilization of laboratory tests in cases of current or suspected thrombotic or bleeding disorders (n=200), the rate of misutilization was 77.5%.[45] In 61.5% of cases, one or more tests were considered to be underutilized (Fig. 6). The error to no error ratio for white, African American, and Hispanic patients were found to be 2.5, 11, and 8, respectively. Only the difference between white and Hispanic error to no error ratios reached significance (p=0.012). In a follow-up study of the same nature, the rate of misutilization decreased to 36% after a diagnostic management team was implemented (a program to increase collaborations between physicians, laboratory staff, expert pathologists, and expert hematologists).[46] Importantly, the rate of underutilization dropped to 28%.

In a similar observational study, the rate of laboratory test misutilization in cases of platelet refractoriness was determined before and after a diagnostic management team was implemented.[47] Due to the small sample size (n=35), statistical differences were not calculated. Prior to the introduction of the diagnostic management team, the rate of underutilization was 33% for initial

testing and 60% for confirmatory testing. After the introduction of the diagnostic management team, the rate of underutilization decreased to 0%.

In a retrospective chart review of patients whose complete blood count results indicated microcytic anemias (n=2,244), the rate of underutilization of follow up testing was determined.[48] Over forty percent of cases lacked timely and sufficient follow-up testing to determine the cause of the microcytic anemias. As an example of a basic follow-up test, 32.8% of cases lacked any follow-up testing of patients' iron levels to determine the presence of iron deficiency anemia.

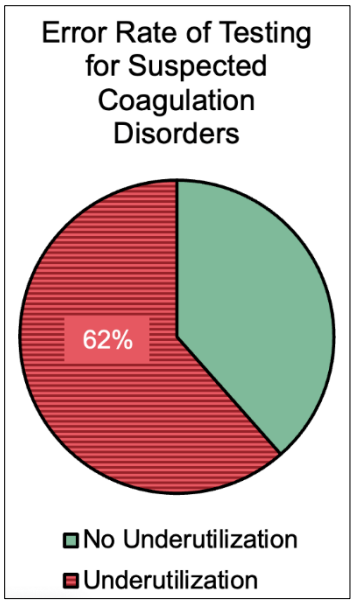


Figure 6: Percentage of cases with an underutilization of a laboratory test in patients suspected of having coagulation disorders (n=200). Underutilizations were identified by an expert panel of pathologist physicians and a doctorate-level medical laboratory scientist.[45]

*Infectious Disease*

In a prospective cohort study, the rates at which pediatric patients with signs of respiratory infections at a hospital (n=6,073) were tested and labelled with an ICD-10 code (international classification of diseases) on their charts were determined.[49] Of the symptomatic patients, just 8.7% were given the appropriate diagnostic tests. Further, 61% of children with influenza, 50% with RSV (respiratory syncytial virus), and nearly all with adenoviruses, rhinoviruses, and

metapneumoviruses were not labelled with the appropriate ICD-10 code. Physicians tended to label symptomatic pediatric patients with non-specific codes such as “bronchitis” or “acute upper respiratory infection.” This reluctance to properly diagnose respiratory infections caused significant difficulties in tracking the infections through the hospital and in the community.

In a retrospective observational study, the rate at which bloodstream infections would have been missed without a third blood culture set was determined.[50] The collection of two or three blood culture sets is called for in the guidelines for the diagnosis of sepsis. Seven to eight percent of bloodstream infections would have been missed if just two blood culture sets were used. In a similar observational study, the rate at which *Clostridium difficile* infections would have been missed with standard test ordering protocols was determined.[51] The hospital’s testing practices missed 40.4% of the *Clostridium difficile* infections diagnosed by the researchers.

In a survey of infectious disease specialist physicians at the CDC, it was found that delayed diagnoses of common infectious diseases were caused by diagnoses not being considered 37-58% of the time and the appropriate diagnostic test not being ordered 14-41% of the time.[52] This finding of two similar causative events of delayed diagnoses prompted a recommendation for early consulting of infectious disease specialists in complex cases of infection.

**Mixed Inpatient & Outpatient Services**

The literature search yielded six studies that investigated laboratory test utilization from mixed populations of outpatient and inpatient participants. Two studies were carried out in the United States. Three studies were carried out in Australia, Spain, and South Korea. One meta-analysis utilized data from several countries. The methodologies of the selected studies were heterogenous, including retrospective and prospective results.

*Infectious Disease*

In an observational study of laboratories that received patient specimens from inpatient and outpatient settings, test results from participating laboratories were compared to those of a reference laboratory to determine the rate at which cases of *Clostridium difficile* were undiagnosed.[53] Of the stool specimens that were delivered to the participating laboratories (n=809), 5.6% (45 specimens) contained toxigenic strains of *Clostridium difficile*. By contrast, 1.7% (14) of the stool specimens were found to have true positive cases of *Clostridium difficile* infections by the participating laboratories (31% of total). Of the 31 stool specimens with toxigenic *Clostridium difficile* that would have been missed, 71% did not have diagnostic tests ordered for *Clostridium difficile* infections and 29% had false negative results due to the use of tests with low sensitivity. Put differently, 69% of the total *Clostridium difficile* infections were missed because an inappropriate test was ordered, or no test was ordered at all.

*HIV*

In a retrospective chart review of patients diagnosed with AIDS (n=28,382), 61.2% of patients were considered to have late diagnoses of HIV.[54] Cases with late diagnoses of HIV were defined as patients that were subsequently diagnosed with AIDS within one year. In a smaller retrospective chart review of patients newly diagnosed with HIV (n=218), 31% of patients were considered to have late diagnoses of HIV.[55] In this study, cases with late diagnoses of HIV were defined as patients with CD4 lymphocyte counts of less than 200 cells/$mm^3$ at the time of their diagnosis – indicative of prolonged immune system damage due to HIV. Eighty two percent of late diagnosis cases were African American or Hispanic patients.

In a meta-analysis of HIV screening practices among 98 countries, 71.0% of patients received HIV tests when receiving sexual care services, 61.3% of patients tested for various STIs

are also tested for HIV (although this rate decreased to 18.5% in emergency departments), 35.3% of patients with known STIs received HIV tests, and 27.1% of patients with symptoms of an STI received an HIV test.[56]

*Hematology*

In an observational study of laboratories that perform diagnostic testing for von Willebrand disorder (VBD), sample specimens of normal plasma and VBD type 1-3 plasmas were sent to participating laboratories to determine the rates of misdiagnoses.[57] Laboratories that performed advanced assays of von Willebrand factor activity by measuring its level of binding to collagen were found to misdiagnose VWD type 1 six times less frequently (3.3% and 19%), VWD type 2 three times less frequently (9.8% and 28%), and normal plasma 10 times less frequently (0.4% and 4.5%) than laboratories that performed a more primitive von Willebrand factor activity assay.

*Gastroenterology*

In a retrospective medical record review of all clinical tests in South Korea, the low prevalence of celiac disease in the country was hypothesized to be a function of low testing.[58] Among over 300 million clinical tests in a 9.5 year span, just 108 diagnostic tests of celiac disease were performed on 79 patients. One patient was found to have a positive test result of a biomarker of celiac disease (1.3%). The researchers considered this sufficient evidence to show that diagnostic tests of celiac disease are grossly underused in South Korea.

**Primary Care**

The literature search yielded twenty four studies that investigated laboratory test utilization in primary care services. Twenty one studies were carried out in the United States. Two studies were carried out in Spain and Australia. One meta-analysis was carried out with studies performed

in fifteen countries. The methodologies of the selected studies were heterogenous, including retrospective results, prospective results, and results from surveys.

*General*

In a retrospective laboratory test requisition analysis, previous ordering practices of primary care physicians were compared to currently accepted reflex testing practices to determine rates of over- and underutilization.[59] The rate of underutilization of laboratory tests in this metric was 24.3% (16,137/66,434 requisitions). In a meta-analysis of specific laboratory test ordering practices in primary care across 15 counties, the rate of underutilization ranged from about 18% to nearly 100%.[60] Serum STI screens had the highest rates of underutilization. Serum electrolyte and serum TSH (thyroid stimulating hormone) tests had the lowest rates of underutilization. In a retrospective analysis of malpractice claims, 55% of diagnostic breakdowns were caused by failures to order the correct diagnostic or laboratory test.[61] It should be noted that only 7% of diagnostic breakdowns were due to failures to order appropriate blood tests.

In a survey of primary care physicians (n=1768), physicians reported to have some degree of uncertainty in ordering laboratory tests in 14.7% of the patient encounters in which they must do so.[2] Given 500 million patient visits to primary care physicians each year, with 31.4% requiring laboratory testing, it was estimated that 23 million patients could be affected by physician uncertainty in laboratory test ordering. In a correlational study of primary care physician board exam scores and patient outcomes, there was a small, but significant, difference in the patient outcomes of the top third performers and the bottom third performers.[62] The top third of exam scorers had 2.9/1000 fewer patient deaths and 4.1/1000 fewer patient hospitalizations than the bottom third of exam scorers.

*Cardiovascular*

In a retrospective cohort study of adults seen at a major health system in Washington (n=59,604), physician adherence to the US Preventative Service Task Force's guidelines on lipid testing was investigated.[63] Thirty six percent of men and 61.5% of women received lipid screenings without meeting the criteria for receiving them. In terms of underutilization, 24.0% of men and 21.6% of women did not receive lipid screenings despite meeting the criteria for receiving them (Fig. 7). Thus, physician adherence to lipid screening guidelines was determined to be relatively low. In a retrospective chart analysis of diabetic patients at a Boston group practice (n=7,088), the rates of lipid screenings of white and African American patients increased from 43.2% to 65.3% and 29.4% to 61.6%, respectively, in the four years after electronic medical records were introduced.[64] In a study with mixed methods of retrospective chart reviews and surveys, the rate at which African American and Hispanic patients received preventive care, such as lipid screenings, was overestimated by self-reporting and underestimated by review of their charts.

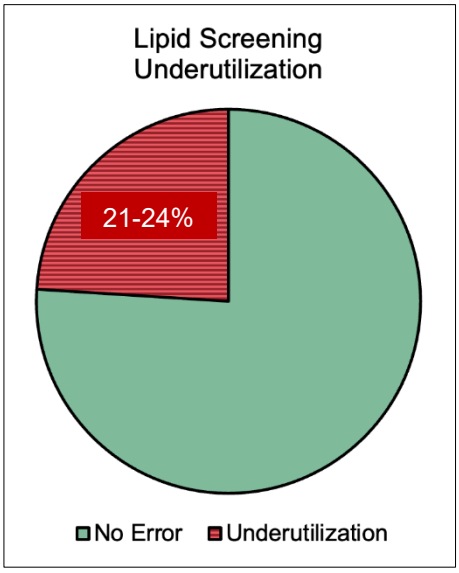


Figure 7: Percentage of eligible primary care patients who did not receive an annual lipid screening test (n=59,604). Patients were considered to be eligible if they met guidelines set by the US Preventive Service Taskforce for cardiovascular disease risk.[63]

*Diabetes (Mellitus)*

In a survey of primary care physicians (n=140), just 6% of physicians could identify all risk factors of prediabetes from the American Diabetes Association and 17% of providers could identify the laboratory test results that would indicate prediabetes.[65] In another survey of primary care physicians (n=31), just 38.7% of physicians could identify the correct interval to administer prediabetes screenings.[66] Of those physicians' nondiabetic patients (n=12,787), 24.1% of patients who met the criteria for prediabetes screening were not screened in any capacity. In a retrospective chart analysis of diabetic patients at a Boston group practice (n=7,088), 75% of African American and white patients annually received hemoglobin A1C tests.[64] Thus, hemoglobin A1C tests were underutilized in 25% of the patients.

In a prospective cohort study that sought to determine the efficacy of a fast diagnostic test in predicting dysglycemia (diabetes & prediabetes) among patients without diagnoses of diabetes (n=1,573), 4.6% of patients had diabetes and 18.7% had prediabetes.[67] The test was found to be most cost effective with cut-off values resulting in relatively high specificity and relatively low sensitivity. With confirmatory, gold-standard testing for positive results, the cost per dysglycemia case identified was predicted to be just $84. These results are comparable to the findings of the previous two retrospective chart analyses. In all three studies, the rates of the underutilization of diabetes screening tests were between 23-25% (Fig. 8).

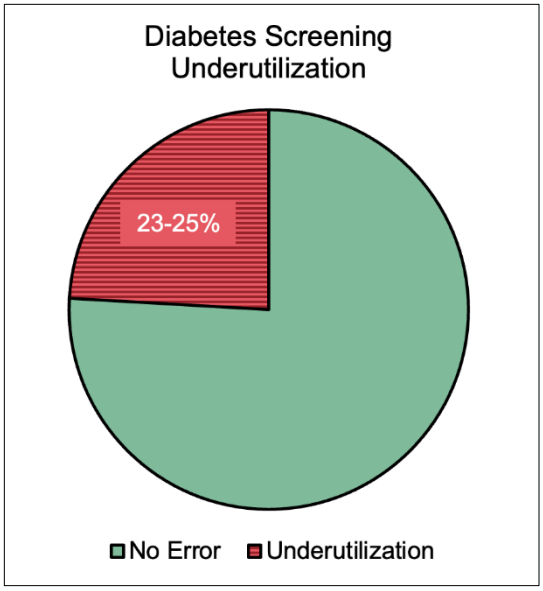


Figure 8: Percentage of eligible primary care patients who did not receive diabetes screening tests (n=12,787, 7,088, & 1,573). Unique methodologies were used to determine the rate of underutilization of diabetes laboratory tests in the three studies.[64,66,67]

*HIV*

The literature search yielded nine studies that utilized surveys to investigate HIV screening in outpatient settings. Low rates of Asian & Pacific Islander women self-reported being tested for HIV (<20% annually) despite growing rates of infection in those communities.[68] Among high-risk Asian & Pacific Islander men (men who have sex with men, men with two or more sexual partners, and intravenous drug users), just 47% self-reported being tested in the last year.[69] In a separate survey of Asian & Pacific Islander men, reasons for not being tested included low perceptions of risk, financial barriers, laziness, lack of knowledge of testing centers, and fear of familial shame.[70] Among Hispanic individuals, just 33% reported ever receiving an HIV test and 90% reported having no intention of receiving an HIV test in the next year.[71] There was a negative association between the degree of assimilation to the US and the likelihood of ever having received an HIV test. This was thought to be explained by language barriers, information barriers, and cultural preferences to keep sexual matters private. In a survey of patients who use a predominantly Hispanic community health clinic, 73.6% of patients reported not being offered an HIV test at their appointments.[72] For those who were offered HIV tests, 59.3% declined to take them and 14.3%

did not comment on the question. Among African American women in lower-income cities, 31.9% rejected a free HIV test when offered one.[73] The reasons for rejection included privacy concerns, low perceptions of risk, and fears of social rejection if positive. However, among women who utilized sexual care services, African American women were slightly more likely to receive HIV testing than white women – although the overall rate was low at 18.4%.[74] Among incarcerated men, just 27% had been tested in the prior year, despite a recommendation from the CDC for high-risk individuals to be tested annually.[75]

The low screening rates of all communities is suggestive of a high rate of undiagnosed HIV cases and HIV cases that are diagnosed late. Among newly diagnosed HIV patients, 51% had evidence of late diagnoses in their test results.[76] A late diagnosis was considered to be a case in which the patient presented with a CD4 T lymphocyte count of less than 200 cells/$mm^3$. Curiously, patients who had late diagnoses had greater trust in healthcare systems than those who had early diagnoses.

*Infectious Disease*

In a retrospective chart analysis of adolescent children at a primary care clinic (n=600), the rate of administration of sexual health services was investigated.[77] Sexual histories were taken from 15% of adolescent boys and 45% of adolescent girls. Given the low administration of sexual services to adolescent boys, their testing behaviors were not recorded. In sexually active adolescent girls, 15-41% received a chlamydia test in the prior year. No differences in testing behaviors were found between racial groups. Asian, adolescent girls had the lowest testing rate at 15.4%, but this did not reach significance due to the low sample size. Just 3.1% of non-English speakers received chlamydia tests ($p<0.002$).

In a retrospective cohort study of adults with diagnoses of STIs (n=15,357), just 17.2% were tested for the hepatitis B virus in their initial diagnostic process and 28.1% were tested within 90 days of their diagnosis.[78] African American patients received hepatitis B tests at the lowest rate with 14.0% tested initially and 23.4% tested within 90 days (aOR: 0.73, 95% CI: 0.64-0.82, white patients were referent). Among patients with chronic comorbidities (diabetes, chronic liver disease, chronic kidney disease), these patients had lower odds (aOR: 0.76, 95% CI: 0.62-0.94) to receive a hepatitis B test than their otherwise healthy counterparts (referent). This finding may have been due to providers who placed greater focus on the patients' chronic conditions than their new conditions.

*Pediatrics*

A retrospective cohort study of children with Medicaid sought to determine the rate of appropriate lead testing among vulnerable populations (n=1714).[79] Sixty five percent of children who were eligible to receive a lead test under CDC guidelines received one over the course of the study. The rate of overutilization of lead tests was 5% in this cohort.

**Obstetrics**

The literature search yielded seven studies that investigated laboratory test utilization in obstetric care services. Three studies were carried out in the United States. Two studies were carried out in Australia. Two studies were carried out in the United Kingdom and Canada. All selected studies utilized retrospective methodologies.

*Prenatal Testing*

Two retrospective chart analyses sought to determine the proportions of pregnant women who chose to receive early genetic testing for aneuploidy in their fetuses. In Australia, 58% of women elected to receive this test in the first two trimesters of pregnancy (n=35,142).[80] Sixty nine percent of white women chose to receive this test. Fifteen percent of aboriginal women chose to receive this test ($p<0.0001$). In Canada, 9.6% of First Nation-identifying women and 28.4% of non-First Nation-identifying women chose to receive this test at any point during their pregnancy.[81]

In a retrospective chart review of pregnant women suspected of having thyroid conditions (n=321), 77% of cases had at least one error in thyroid function test selection (Fig. 9).[44] Sixty percent of cases had an underutilization of at least one thyroid function test. There were no significant differences between racial groups in terms of error rate.

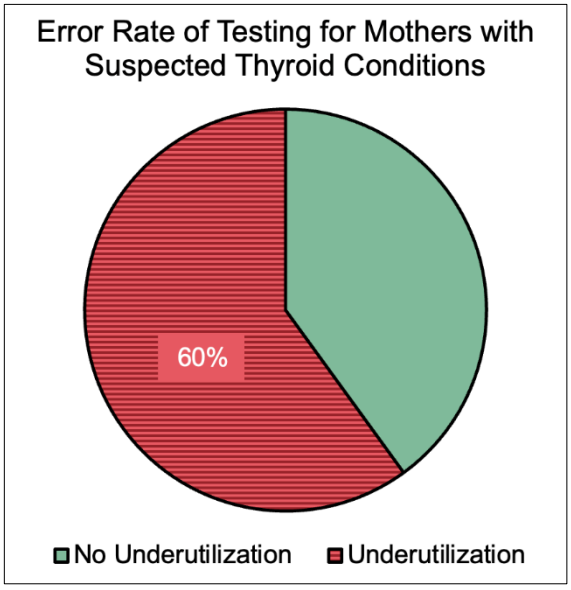


Figure 9: Percentage of cases with an underutilization of laboratory tests among pregnant individuals suspected of having thyroid conditions (n=321). Determinations of underutilizations were made by a doctorate-level medical laboratory scientist.[44]

*Postnatal Testing*

In a retrospective chart review of recent mothers with diagnoses of hepatitis C and their children (n=4,072), 23% of infants were screened for the hepatitis C virus within 2 years of delivery (Fig. 10).[82] Eighteen percent of infants were adequately screened for the virus per CDC recommendations. African American infants had lower of receiving a hepatitis C test (aOR: 0.32, 95% CI: 0.13-0.78) than white infants (referent) (Fig. 10). The low rate of screening was predicted to have resulted in 94-187 missed diagnoses of hepatitis C.

In a retrospective chart review carried out in Australia, the time for mothers with gestational diabetes to receive a postnatal oral glucose tolerance test (OGTT) was significantly greater for Indigenous women than non-Indigenous women (HR: 0.62, 95% CI: 0.48-0.79, $p<0.0001$).[83] In 2004, 5% of Indigenous women with gestational diabetes and 15% of their non-Indigenous counterparts received a postnatal OGTT within 6 months of delivery. By 2010, 17.9% of Indigenous women with gestational diabetes and 27.2% of their non-Indigenous counterparts received a postnatal OGTT within 6 months of delivery. In a retrospective cohort study of a diverse group of American mothers with gestational diabetes (n=32,253), 23.9% received any form of testing for dysglycemia within the first year of delivery.[84] In the first 12 weeks post-partum, 13.1% received any form of testing and 5.5% received the gold standard OGTT. Little differences were seen in the uptake of tests for dysglycemia between racial groups. In a review of British literature, the rate of screening for dysglycemia among women with gestational diabetes averaged 34.2% from 1999 to 2007.[85]

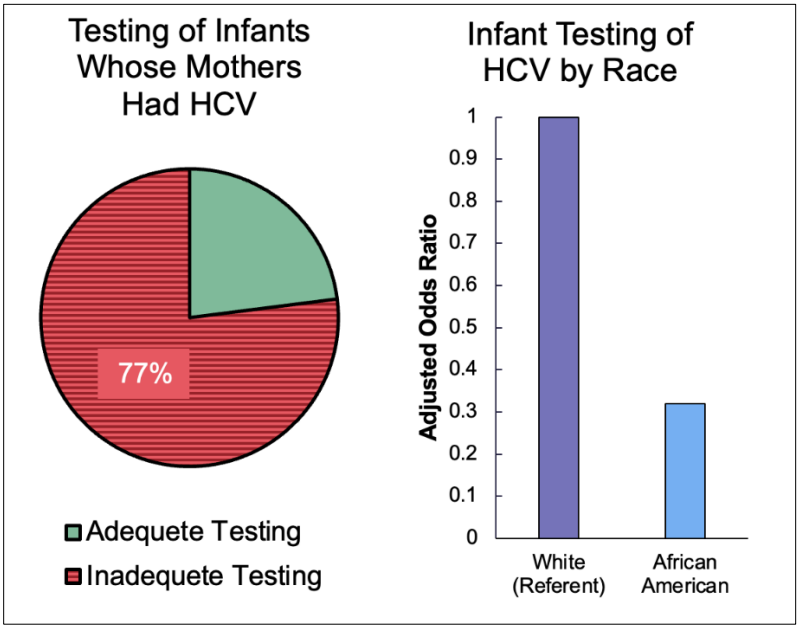


Figure 10: Percentage of infants at risk for vertical transmission of the hepatitis C virus (HCV) who were adequately tested for HCV (per CDC guidelines) (n=4,072) & adjusted odds ratios of receiving adequate HCV testing for African American and white (referent) infants. Data were retrospectively analyzed from the mothers' and infants' medical records.[82]

## Genetic Specialty Services

The literature search yielded twenty studies that investigated laboratory test utilization in genetic specialty services. Nineteen studies were carried out in the United States. One study was carried out in Canada. The selected studies employed retrospective methodologies and survey protocols.

### *Genetic Services by Primary Care Providers*

In a survey of primary care providers (n=29 physicians, 46 nurse practitioners, and 2 physician assistants), 40% received some form of genetics training.[86] Twelve percent of primary care providers self-reported very good clinical genetics knowledge. Twenty five percent of providers reported not using genetic testing in their practice. One provider in this survey reported

having great confidence in their ability to take a family history. Just 19% of providers reported feeling comfortable that they could begin using genetic testing with additional training.

*Cancer (General)*

In a review of the literature on genetic screening differences between racial groups, African American patients were referred for genetic screenings for breast cancer, ovarian cancer, prostate cancer, and colorectal cancer less frequently than Hispanic and white patients were.[87] African American patients adhered to referrals for genetic screenings for colorectal cancer less frequently than Hispanic and white patients did.

In a retrospective cohort study of patients who tested positive for pathogenic germline variants in cancer predisposition genes (n=10788), 11.9% of African American patients had at least one at-risk relative who was subsequently tested for inheritance.[88] Nearly 22% of white patients had at least one at-risk relative that was subsequently tested for inheritance ($p<0.0001$). The cascade testing of relatives is crucial for the early detection of cancer risk.

In a retrospective analysis of family pedigrees paired with a survey of family histories, Asian and Hispanic participants underreported family histories of cancer when compared to white participants.[89] Compared to white participants, Asian and Hispanic individuals had 45% the amount of cancer within their families, according to self-reported family histories. However, the true incidence rate of cancer in Asian and Hispanic populations was 63.1% and 77.2% that of white populations.

In a survey of a diverse group of Americans (n=25,364), Hispanic (aOR: 0.47, 95% CI: 0.42-0.53, $p<0.001$), African American (aOR: 0.67, 95% CI: 0.59-0.75, $p<0.001$), and Asian participants (aOR: 0.50, 95% CI: 0.40-0.62, $p<0.001$) had significantly lower odds of being aware of genetic testing for cancer risk than white participants (referent).[90]

*Breast Cancer*

In a retrospective chart review of women diagnosed with early-onset breast cancer (n=1,622), African American women were significantly less likely to discuss genetic testing with a provider than white women ($p<0.00001$), less likely to be referred for genetic testing ($p<0.001$), and less likely to receive genetic testing than white and Hispanic women ($p<0.001$) (Fig. 11).[91] A similar retrospective study of women diagnosed with early-onset breast cancer (n=1,474) found that African American and Hispanic women were significantly less likely to receive genetic testing than white women prior to their diagnosis ($p<0.05$).[92] In a case-control study of women who received genetic counseling for breast cancer and a random sample of women who did not receive genetic counseling (n=408), women who received genetic counseling were significantly less likely to be African American ($p<0.01$).[93] In a retrospective medical record review, African American and Hispanic women were significantly more likely to be referred to a genetic specialist for personal histories of cancer ($p<0.001$).[94] White and Asian patients were significantly more likely to be referred for family histories of cancer (($p<0.001$). Of the African American and Hispanic patients, 39.1% and 32.1% of the patients, respectively, received genetic testing for the BRCA mutation after their diagnoses. However, in a retrospective chart review of Medicare patients with a breast cancer genetic test, the incidences of pathogenic or likely pathogenic variants were similar between patients who met the criteria for genetic testing and those who did not (10.5% and 9.0%, respectively).[95] Thus, the researchers concluded that the criteria for genetic testing was insufficient.

In a survey of Ashkenazi Jews (n=243), whom have a high prevalence of BRCA gene mutations (2.5%), 28% did not want to get tested and 46% had not considered getting tested.[96] Common factors for the rejection of testing included fear of stigmatization, loss of reproductive

ability, and loss of "marriageability." In a survey of white and Hispanic women with increased risk of having a BRCA gene mutation (n=147), Hispanic women reported being unaware of genetic testing for breast cancer risk more frequently than white women (56.9% and 34.8%, respectively).[97] In a survey of women who recently underwent genetic testing for pathogenic BRCA variants (n=242), BIPOC (black, indigenous, and people of color) individuals informed blood relatives of their positive results to initiate cascade testing significantly less frequently ($p<0.05$) than white individuals (79.3% and 96.4%, respectively).[98]

*Cardiovascular*

In a cohort study of patients referred to a tertiary care center for cardiac catheterization (n=8,574), 4.5% of patients had pathogenic or likely pathogenic gene variants associated with monogenic cardiovascular diseases.[99] Evidence of pathogenic phenotypes were found in the medical records of 1.7% of the cohort. Of this subset, just 35% of patients with pathogenic phenotypes and genotypes were previously diagnosed with the correct disease prior to their catheterization procedure.

*Attitudes toward Genetic Tests*

In the four selected studies that utilized surveys to determine attitudes toward genetic testing between racial and ethnic groups, non-white groups reported competing positive and negative attitudes toward genetic testing. African American and Hispanic individuals reported potential concerns about misuses of genetic test results and distrust of medical doctors more frequently than white individuals ($p<0.001$).[100] In a different survey, African American individuals reported distrust of people in general, medical institutions, and the US government more frequently than white individuals.[101] Further, African American individuals had lower scores on genetic knowledge assessments than white individuals ($p<0.001$).[102] Despite these previous findings,

African American individuals had more positive attitudes toward the clinical value of genetic information than white individuals ($p<0.001$).[102] In a focus group of indigenous Alaskan individuals, fears of stigmatization and confidentiality breaches were voiced, but the perceived reward of clinically relevant knowledge outweighed the risks.[103]

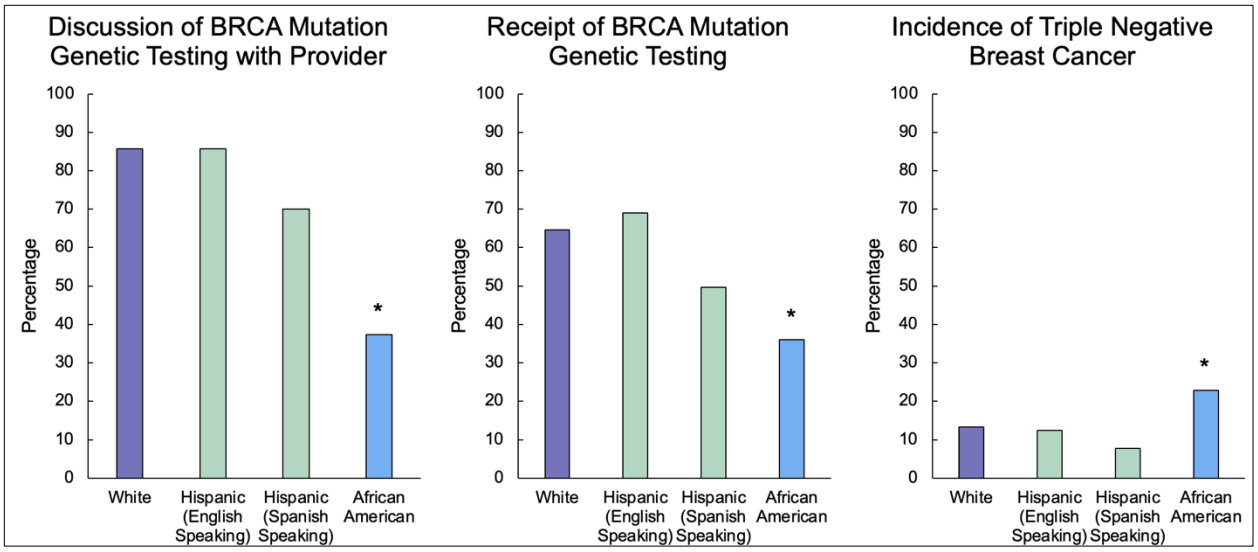


Figure 11: Percentage of white, Hispanic (English-speaking), Hispanic (Spanish-speaking), and African American women recently diagnosed with early-onset breast cancer who had discussions of genetic testing with their primary care provider, received genetic testing, or were diagnosed with triple-negative breast cancer (n=1,622). * indicates $p < 0.0001$ between white, Hispanic (English-speaking), Hispanic (Spanish-speaking), and African American patients.[91]

# Discussion

The aim of this scoping review is to determine what is currently known about the underutilization of laboratory tests in several sectors of medicine. This scoping review used studies of three general methodologies to do so: 1) reviews of medical records to determine if an indication for testing was missed, 2) reviews of medical records to determine if certain racial groups were tested less frequently than others, and 3) surveys. The aggregation of results from these heterogenous studies demonstrate the diffuse problem of the underutilization of laboratory tests across several specialties and settings of medicine.

Among the 82 selected studies, 16 explored the utilization of diagnostic HIV tests (19.5%). These studies were carried out in various settings, including emergency departments, primary care facilities, and combined inpatient and outpatient settings. Other prominent topics included various laboratory tests for pediatric patients (n=9, 11.0%), screening tests for breast cancer (n=8, 9.8%), diagnostic tests for infectious diseases (n=8, 9.8%), screening tests for pregnant women (n=7, 8.5%), diagnostic tests for cardiovascular conditions (n=6, 7.3%), and diagnostic tests for hematological conditions (n=5, 6.1%).

## HIV Screening

The underutilization of diagnostic tests for HIV is a pervasive issue across all sectors of medicine, particularly for intravenous drug users, African Americans, Hispanics, and incarcerated men.[38,39,55,71,72,75,76] In the United States, one in seven people with HIV infections are unaware of their condition.[104] Among those who are aware of their condition, many individuals receive their diagnosis too late to effectively control the infection. The rate of late diagnoses of HIV was between 31-61%, depending on the definition of a late diagnosis.[54,55,76]

From a financial perspective, the benefits of frequent, early diagnoses of HIV may not be immediately noticeable. The estimated cost of screening and counseling individuals for HIV infections averages $48.07 for negative results and $98.17 for positive results and subsequent confirmatory testing.[105] Additionally, the cost of beginning anti-retroviral treatments for tens of thousands of patients with newly diagnosed HIV would be significant. For instance, with just ten thousand new early HIV diagnoses (which represent 6.5% of the estimated undiagnosed individuals in the United States)[104] healthcare expenditure for their treatment could amass nearly $200 million over two years. However, the benefit of early diagnosis lies in the ability to control the disease and limit its adverse outcomes. Much of the additional spending that arises from late diagnoses of HIV results from hospitalizations due to opportunistic infections. The median 2-year cost per patient with a late diagnosis of HIV is $61,378.[106] Comparatively, the median 2-year cost per patient with an early diagnosis of HIV is $18,837.[92]

To illustrate the complexity of the financial incentives for diagnosing HIV, consider an extreme scenario. Assuming the aggregated proportion of late diagnoses of HIV among new diagnoses of HIV from two studies (39.8%)[55,76] would be true among the general undiagnosed population, an estimated 61,000 undiagnosed individuals already have late-stage HIV infections and 92,000 undiagnosed individuals have relatively early-stage HIV infections. If every individual with undiagnosed HIV could be diagnosed immediately, the collective cost of their treatments over two years would amount to an estimated $5.47 billion. Alternatively, if every undiagnosed individual with HIV allowed their infection to progress to AIDS, their collective hospitalizations and subsequent HIV treatments would cost $9.39 billion over the first two years of their late diagnoses. Furthermore, individuals with undiagnosed HIV are predicted to contribute to the transmission of half to two-thirds of all new HIV infections.[75,104] Thus, during the course of the

disease progression in an undiagnosed individual, many others will unknowingly become infected with HIV, resulting in further healthcare expenditures.

However, the theoretical $3.92 billion difference in treatment costs between immediate diagnosis and progression to AIDS would likely be offset by the expense of screening millions of individuals for HIV. Considering the average price of a positive test result and counseling, screening every HIV-positive individual would cost $14.4 million, leaving a difference of $3.905 billion. This remaining amount could theoretically be used to screen 81 million individuals with negative results, allowing a low positivity rate of 0.19%.

Although this scenario is highly unlikely and oversimplified with average prices for laboratory tests, counseling, and treatment costs from insurance reimbursement data, the elimination of hospitalization costs from individuals with HIV infections should serve as a significant financial incentive to promote programs for early diagnoses.

A 100% diagnosis rate of HIV is an impossibly optimistic idea. The United Nations has set what it considers to be a lofty goal in achieving a 90% diagnosis rate of HIV in all countries. Further, not enough people are willing to be tested. Among patients of all racial and ethnic groups, low perceptions of risk (whether that is true or not), fears of stigmatization, and limited access to testing are commonly reported as reasons for test rejection.[25,54-59,62] Hispanic individuals face language barriers and cultural norms of sexual modesty as impediments to receiving adequate sexual care from American providers.[39,71,72] Similarly, Asian and Pacific Islander individuals commonly fear bringing shame and burdens to their families if they test positive for HIV.[68–70] Although patient refusal is common, the underutilization of HIV tests is compounded by the infrequent ordering of HIV tests by healthcare providers. In a low-income, urban clinic, nearly three-quarters of patients reported that their providers did not discuss HIV testing.[72] As such, there

are opportunities for providers to recognize broader indications for ordering HIV tests and to address fears and barriers specific to each racial and ethnic group.

**Breast Cancer Screening**

The underutilization of genetic tests to screen for pathogenic mutations to the BRCA1/2 genes is primarily a problem among primary care centers. In the United States, primary care providers often act as gatekeepers to specialized care, including genetic counseling. Many primary care providers do not offer genetic counseling and may feel uncomfortable providing it even with additional training.[86] As such, they must be adept at recognizing indications for genetic counseling with a genetic specialist for their patients, thereby acting as gatekeepers to this specialized care. Individuals with pathogenic BRCA1/2 mutations carry a 50-85% lifetime risk of developing breast cancer.[93] Unfortunately, African American patients are less likely to have genetic counseling for breast cancer discussed with them, to be referred for genetic counseling, and to receive early genetic testing than non-Hispanic white patients.[91,92] African American and Hispanic individuals with early-onset breast cancer are also more likely to have had missed indications of BRCA1/2 testing prior to their diagnoses.[92]

Despite the clinical advantages of early detection of BRCA1/2 mutations, differences in the utilization of genetic counseling between racial and ethnic groups exacerbate healthcare disparities in the United States. Racial and ethnic minorities, such as Asian and Hispanic individuals, may have incomplete knowledge of their family histories of cancer due to language barriers among their own families, geographical distances between family members, or lack of historical diagnoses.[89,90,97,98] An incomplete family history may make it difficult for providers to determine whether a BRCA1/2 genetic test is warranted. However, the current criteria for ordering genetic tests for breast cancer are flawed. There was no significant difference in the rate of positive

results for pathogenic mutations in the BRCA1/2 genes between individuals who met the criteria for testing and those who did not.[95] There may be an opportunity to expand the criteria for testing to be inclusive of more individuals – especially African American and Hispanic individuals.

Although shortcomings among providers and healthcare systems contribute to the underutilization of genetic tests for breast cancer risk, patient refusal is also common. Among Ashkenazi Jewish individuals – who have a high prevalence (2.5%) of BRCA1/2 mutations – nearly 75% of Jewish individuals reported not wanting to be tested or not receiving testing.[96] Concerns for reproductive ability, "marriageability," and stigmatization were reported to be common fears about testing. African American, Hispanic, and Native American individuals frequently reported fears of the misuse of genetic results by providers and institutions.[100–103]

As this is a question of genetic risk factors, the possibility that white individuals harbor a higher incidence of BRCA1/2 mutations than all other racial and ethnic groups cannot be ruled out yet. The historical lack of participation in genetic studies and the continued disparity in access to care for minority racial and ethnic groups is responsible for the gaps in knowledge about non-white genomes.[107,108] Resultantly, it is easier for providers to prescribe the BRCA1/2 mutation test to white patients because of the wealth of genetic evidence to indicate its efficacy, when compared to minority racial and ethnic groups.

Thus, there are opportunities for providers to expand the criteria for testing of the BRCA1/2 genes and other similar genes to be inclusive of non-white racial and ethnic groups. Additionally, it will be crucial to address fears specific to those groups pertaining to genetic testing. From a financial perspective, the combined cost of genetic counseling and prophylactic mastectomies is comparable to the cost of treatment for stage 0-2 breast cancer.[109–111] Based on United States insurance reimbursement data, the average cost of genetic counseling and BRCA1/2 testing is

$2,053 and the cost of a prophylactic mastectomy with breast reconstruction averages $94,733.[109,110] In contrast, the average two-year costs of treatment for breast cancer are $71,909, $97,066, $97,066, $159,442, $182,735 for stages 0-4, respectively.[111] Given that African American and Hispanic individuals are more likely to present with late stage breast cancer than white individuals and more likely to die from breast cancer,[112] it is perhaps most financially beneficial to be vigilant when considering early testing in these groups.

**Diagnostic Laboratory Tests**

The timely use of the correct laboratory tests is evidently crucial to patient outcomes. A timely diagnosis reduces the likelihood of complications and increases the likelihood of effective treatment. However, the findings of this scoping review indicate that this is often not accomplished by providers across various medical settings, including emergency departments, primary care settings, and inpatient settings. In addition to laboratory tests for HIV and breast cancer, the selected literature commonly demonstrated evidence of the underutilization of laboratory tests for cardiovascular conditions,[33–35,63,99] urogenital conditions,[32,77] hematological conditions,[45–48,57] obstetric conditions,[44,80–85] and several others. It is beyond the scope of the current study to determine the costs of treatment for every complication of every condition presented in the results. However, several of the selected studies argued that the underutilizations of laboratory tests can lead to delayed diagnoses or misdiagnoses, resulting in increased downstream treatment costs due to increased lengths of hospitalization, unnecessary treatments, and treatments due to complications. For example, in a study of 634 inpatients suspected of having coagulation disorders, the underutilization of laboratory tests in 178 patients (28%) was estimated to have resulted in millions of dollars of unnecessary spending at that hospital.[46]

African American and Hispanic individuals were frequently shown to have lower odds of receiving necessary laboratory tests in outpatient settings, inpatient settings, and in the emergency department.[27,29,30,34,35,37,38,64,78,80–83,87,91–95] These laboratory tests may have been instrumental in determining diagnoses for cardiovascular conditions, screening for risks of cardiovascular conditions, screening risks of developing diabetes following pregnancy, screening infants for maternal-fetal transmissions, and diagnosing bloodstream infections. It's important to note that these findings often used odds ratios to compare laboratory test usage between racial and ethnic groups. Thus, the difference in utilization may have been due to providers correctly omitting laboratory tests for patients without indications for testing. However, for conditions with equivalent incidences between racial and ethnic groups, the rate of utilizing laboratory tests should be relatively similar among sample sizes ranging from thousands to tens of thousands of patients. Thus, the significant differences in odds ratios between racial and ethnic groups were unlikely to be due to chance alone. Researchers often cited racial biases in clinical judgement as an explaining factor for the significant differences.[27,29,34,35,37]

**Underutilization by Healthcare Setting**

Although the issue of the underutilization of laboratory tests exists in all healthcare settings, hospital settings (inpatient settings and emergency departments) exhibited the highest rates of underutilization when directly measured. In the emergency department, urine cultures were underutilized at a rate of 57%,[32] laboratory measures of dehydration were underutilized at a rate of 31%,[36] and HIV tests were underutilized at a rate of 77-90%.[38,39] In inpatient settings, coagulation tests were underutilized at a rate of 61%,[45] follow-up laboratory tests for microcytic anemias were underutilized at a rate of 40%,[48] and laboratory tests used to diagnose *Clostridium Difficile* infections were underutilized at a rate of 40-68%.[51,53] Underutilization was also measured

at high rates in obstetric services. Thyroid function tests were underutilized at a rate of 60% and hepatitis C virus panels were underutilized at a rate of 77%.[44,82]

In primary care, the measured rates of underutilization were relatively low. Among two commonly ordered laboratory tests in primary care, lipid screening tests were underutilized at a rate of 20-24% and diabetes screening tests were underutilized at a rate of 23-25%.[63,64,66,67] The difference in underutilization rates may be explained by the structured testing protocols provided by electronic medical records in primary care,[64] the severity and complexity of conditions that present at hospital settings, and the limited time available to emergency department providers to make decisions.[27]

**Limitations and Strengths**

This scoping review has several limitations and strengths due to the methodological framework that was used.[24] It should be noted that this scoping review selected a relatively high number of articles with widely different methodologies, scopes, and populations. The heterogeneity of the selected articles limits the degree to which comparisons and aggregations can be made with the findings. Within the methodological framework, scoping reviews are not intended to derive evidence from the selected articles. Further, this scoping review is limited in the breadth of its literature search. Due to the use of MeSH terms in Medline (NCBI), the search terms were unable to be recreated in any other database. As such, it is possible that relevant articles were excluded from this scoping review. Within the search results of Medline (NCBI), it is also possible that relevant articles were excluded based on titles and abstracts that did not effectively portray the content of the full length article. It should be noted that a single author of this scoping review performed the literature search, which included over 40,000 articles. The strengths of this

scoping review include the use of a structured framework, assistance from a research librarian in forming the search terms, and the relatively high number of selected studies.

The limitations of the findings on the racial and ethnic disparities of laboratory test utilization also warrant a discussion. Of the studies that compared the laboratory test utilization between different racial and ethnic groups, none selected the race or ethnicity of the providers as a factor of interest, to the author's knowledge. Thus, it is uncertain whether the racial or ethnic identity of the provider affects the rate at which different racial and ethnic groups receive laboratory testing. A single study on BRCA1/2 mutation testing reported that African American individuals are more likely than white individuals to be seen by primary care physicians who are not board certified or who self-report difficulties in delivering high-quality care.[93] In a correlational study, primary care physicians who scored lower on board certification exams were associated with higher hospitalization and death rates of their patients.[62] Therefore, low accessibility to high-quality physicians by racial and ethnic minority patients is likely a greater determinant of care than the racial or ethnic identity of the provider they see.[18,62,93]

**Conclusions**

This review describes what is currently known about the topic of the underutilization of laboratory tests. The selected studies show evidence of the underutilization of laboratory tests in all sectors in healthcare (inpatient, outpatient, emergency departments). Hospital settings were the sites with the highest recorded rates of underutilization. Among racial and ethnic groups in the United States, minority groups such as African Americans, Hispanics, Asians, and Native Americans commonly had laboratory tests ordered less frequently than white individuals, which was indicative of underutilizations due to racial biases. In the future, there will be opportunities for providers to address both their own biases and patients' concerns related to their racial or ethnic

identities. Future research should continue to identify areas of concern regarding the underutilization of laboratory tests and monitor the subsequent healthcare expenditures, following the examples set by the University of Texas Medical Branch.[43–46]

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