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## Contents



# INTERNATIONAL JOURNAL OF BIOMEDICAL LABORATORY SCIENCE

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## IJBLS for Biomedical Laboratory Scientists

The International Journal of Biomedical Laboratory Science (IJBLS) is an on-line peer-reviewed journal published bi-annually by International Federation of Biomedical Laboratory Sciences (IFBLS).

The journal is intended to disseminate information and knowledge to the international laboratory community by accepting a variety of manuscripts for publication. Those manuscripts should be original research articles, literature or mini-reviews, case studies, brief communications and letters to the editor describing original investigations in all fields of biomedical laboratory sciences.

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**Editorial**

# International Journal of Biomedical Laboratory Science - Beyond the Experience!

**Patricia Tille Ph.D MLS(ASCP) AHI (AMT) FASCs**
*IJBLS Editor in Chief*

On behalf of the International Federation of Biomedical Laboratory Science, I would like to extend my sincere gratitude for the opportunity to serve as Editor-in-Chief of the International Journal of Biomedical Laboratory Science (IJBLS) over the past six years. It has been a privilege to contribute to the advancement of our profession through this role.

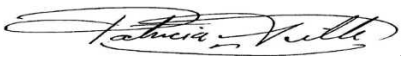
I am deeply appreciative of the trust and support provided throughout my tenure. Leading the journal has been both professionally rewarding and personally meaningful, allowing me to collaborate with an exceptional community of authors, reviewers, and editorial colleagues committed to scientific excellence.

I would also like to express my sincere thanks for the opportunity to serve as Chair of the Microbiology Scientific Committee since 2016. Working alongside such dedicated microbiology experts has been an enriching experience, and I am grateful for the collective commitment to advancing knowledge and strengthening global laboratory practice.

Together, these roles have provided a unique platform to support the mission of the Federation, promote high-quality scholarship, and foster international collaboration within the biomedical laboratory science community.

Thank you for your continued support, partnership, and dedication to our shared goals. I am honored to have contributed to this important work and look forward to seeing the continued growth and impact of the Federation and the IJBLS. I have gained so much more than simply serving in these roles and excited about future opportunities!

With sincere appreciation,



*Patricia Tille Ph.D. MLS(ASCP) AHI(AMT) FACSc*

Research article

# Improving Detection and Management of Impaired Kidney Function in Primary Care via Diagnostic Management Team Approach

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***PURPOSE*. Chronic kidney disease (CKD) is a growing public health challenge with substantial morbidity, mortality, and cost. Early detection is critical, yet abnormal kidney function results in primary care are often lacking timely follow-up.**
***MATERIALS AND METHODS*. This study evaluated a Diagnostic Management Team (DMT) intervention in which a Doctor of Clinical Laboratory Science (DCLS) and an internal medicine physician provided patient-specific laboratory recommendations to primary care providers for abnormal glomerular filtration rate (GFR) results. A post-test control group design included 199 primary care patients without known CKD. Follow-up and laboratory utilization were assessed for four months post-intervention using chi-square analysis.**
***RESULTS*. Compared to controls, DMT-guided patients showed significantly higher laboratory test utilization ($p = 0.001$), follow-up rates ($p < 0.001$), and adherence to kidney disease: Improving Global Outcomes (KDIGO) guidelines ($p < 0.001$).**
***DISCUSSION*. A DCLS supported DMT improved recognition and management of early CKD indicators in primary care. Embedding laboratory professionals in multi-disciplinary care teams may enhance early intervention, reduce progression to end-stage disease, and decrease healthcare costs.**

***Abbreviations:*** CKD = chronic kidney disease; DMT = diagnostic management team; GFR = glomerular filtration rate

***Keywords:*** Chronic kidney disease, Doctor of Clinical Laboratory Science, diagnostic management team, glomerular filtration rate, laboratory test utilization

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## Introduction

Chronic kidney disease (CKD) is a substantial public health burden associated with significant morbidity, mortality, and associated healthcare costs. Current studies estimate the global prevalence to be 8-16%, with over 850 million people affected by some stage of CKD.[1] The rising prevalence of CKD is most often associated with increasing rates of associated risk factors such as diabetes mellitus and hypertension. According to the Centers for Disease Control and Prevention (CDC), approximately 37 million U.S. adults, or one in seven, are estimated to bear some stage of CKD.[2,3] It is estimated that up to 90% of individuals with CKD are unaware of having the diagnosis, as it is normally asymptomatic in early stages. Delayed detection of CKD until a person reaches symptomatic stages comes with a multitude of downstream effects such as increased risks for cardiovascular disease, end stage renal disease requiring dialysis, and kidney transplantation. The Global Burden of Disease study remains the most comprehensive effort to track epidemiological trends across both diseases and injuries that is used by clinicians and policy makers worldwide to make informed decisions.[4] Information in this study revealed that addressing the detection and management of CKD is necessary to meet the United Nation's goal of decreasing premature mortality from non-communicable diseases by a third by 2030.[4]

Along with the downstream effects of morbidity and mortality, the United States Renal Data System (USRDS) also reports that the healthcare cost burden of CKD to be approximately 114 billion dollars annually in the United States.[5] The early detection, management, and slowing of progression of CKD to later stages and end-stage renal disease (ESRD) have large economic implications for potential cost savings in the amount spent annually towards treating this disease. Approximately one third of the total cost of CKD treatments is focused on patients with ESRD.[6]

Despite the importance of early detection and management of CKD, recent studies show that follow up on abnormal glomerular filtration rate (GFR) values in asymptomatic patients in a primary care setting are not common.[7,8] The lack of timely detection is likely a multifactorial issue. In-depth study of laboratory medicine is largely neglected in the U.S. medical schools leaving a knowledge gap between healthcare providers and the thousands of complex laboratory tests currently available.[9] The lack of equitable access to routine primary care across socioeconomic statuses remains a major contributor to most preventable public health issues. This causes disproportional burdens especially among minorities and vulnerable populations. Another contributing factor is the sheer number of clinical guidelines that rapidly change over time for healthcare professionals to understand and follow.

To address these issues effectively, a multidisciplinary approach is needed such as that of a diagnostic management team (DMT). A DMT is a group of diagnostic experts in a certain specialty working together to ensure the appropriate performance of diagnostic tests in a timely manner and provide patient specific interpretations of the tests. At Vanderbilt University, a coagulation DMT review was implemented for pulmonary embolism and intracranial hemorrhages and successfully decreased the hospital length of stay from 4 to 2 days.[9] In the same hospital system, a leukemia and lymphoma DMT improved diagnostic turnaround time and resulted in an annual savings of approximately $1M USD.[10] In 2008, the Institute for Healthcare Improvement (IHI) described the way forward in healthcare improvement as a "Triple Aim. The IHI Triple Aim consists of "improving the individual experience of care; improving the health of the population; and reducing the per capita costs of care for population".[11] This study conducted at an academic medical center sought to determine whether implementing a DMT would improve follow up on abnormal kidney function results in a primary care setting.

## Materials and Methods

*DCLS Supported Diagnostic Management Team Intervention*

Using a multidisciplinary approach, a DMT was developed for this study's intervention. A Doctor of Clinical Laboratory Sciences (DCLS) student developed a DMT which included a practicing DCLS professional and a board-certified internal medicine physician at UTMB. The DMT reviewed charts and determined what recommendations to provide for PCPs. The PCPs who were taking care of patients in the intervention group received DMT reports via email which included brief medical and family history, current medications, laboratory values interpretations relevant to kidney function, and recommendations for additional testing in line with the kidney disease: Improving Global Outcomes (KDIGO) clinical guidelines. No action was taken on the control group participants.

*Subjects*

This post-test control group consisted of 199 total patients from UTMB primary care clinics across a five-week period beginning in January of 2021. Patients were sampled based on convenience approximately twice per week and then placed randomly into the intervention group or the control group. The intervention group was provided patient specific laboratory testing interpretations and recommendations regarding follow up to the abnormal GFR, and no further action was taken on the control group. Patients were filtered in UTMB's electronic health record EPIC by age, clinic, and eGFR value. The eGFR value was filtered to the abnormal level, which described possible CKD stage II, between 60-90 mL/min/1.73m$^2$. Exclusion criteria included patients with a diagnosis of CKD or under the care of nephrology. Inclusion criteria included no prior CKD diagnosis and no prior nephrology referrals.

*Data Collection*

The data was extracted from UTMB's electronic health records (EHR) from January 2021 through early March of 2021. An extensive and thorough chart review of potential patients was performed to ensure they met the inclusion criteria. Spreading the collection across five weeks allowed the preparation of recommendations and interpretations followed by a thorough review from the internal medicine provider. The data collected following the intervention and four-month waiting period included proper follow-ups, laboratory test utilization, and adherence to clinical guidelines. For this study, proper follow up is defined as a basic metabolic panel (BMP) ordered three months to four months from the date of the original appointment to establish chronicity and a test for proteinuria ordered to determine any tubular damage present. Tests incorporated in laboratory test utilization included a repeat BMP, which include GFR, and proteinuria assays such as urine protein dipstick, random urine creatinine/protein ratios and urine microalbumin assays. A post-intervention chart review was performed in the EHR four months post appointment for both patients in the control and intervention groups. The UTMB Institutional Research Board (IRB) deemed the study a quality improvement project.

*Statistics*

All variables were compared between the intervention and control groups using chi-square analysis to assess for statistically significant differences between groups. Statistical significance was defined as $P < 0.05$.

## Results

Of the initial 236 participants recruited for this study, 37 (15.6%) were excluded due to previous diagnosis of CKD or being currently under the care of a nephrologist. A total of the remaining 199 participants were included in the study. Participant demographic characteristics are summarized in **Table 1**. Of the 199 participants, 27% were between 40–50 years old, 35% between 51–60 years, and 38% between 61–70 years. The racial/ethnic distribution included 59% Caucasian/White, 6% Black/African American, 31% Hispanic/Latino, and 4% Asian or Native American. The gender

**Table 1.** Demographic Data of Study Population

| Category | Sub-Category | Control Group (n=102) | Intervention Group (n=97) | Total Percent (%) |
|---|---|---|---|---|
| **Age** | 40-50 | 26 | 29 | 27 |
| | 51-60 | 35 | 34 | 35 |
| | 61-70 | 41 | 34 | 38 |
| **Gender** | Male | 47 | 43 | 46 |
| | Female | 55 | 54 | 54 |
| **Race/Ethnicity** | Caucasian | 63 | 53 | 59 |
| | Hispanic/Latino | 29 | 33 | 31 |
| | African American | 5 | 7 | 6 |
| | Asian | 2 | 1 | 1 |
| | Native American | 3 | 2 | 3 |

**Table 2.** DMT Impact

| | Control N (%) | Intervention N(%) | P Value |
|---|---|---|---|
| **Lab Tests Ordered** | | | 0.001 |
| **Zero** | 95 (93.1) | 71 (73.2) | |
| **One** | 3 (2.9) | 13 (13.4) | |
| **Two** | 4 (3.9) | 13 (13.4) | |
| **Follow Up Performed** | | | < 0.0005 |
| **No** | 95 (93.1) | 71 (73.2) | |
| **Yes** | 7 (6.9) | 26 (26.8) | |
| **Clinical Guidelines Adherence** | | | < 0.0005 |
| **No** | 97 (95.1) | 76 (78.4) | |
| **Yes** | 5 (4.9) | 21 (21.6) | |

*Note. P values were determined by performing a chi-square analysis.*

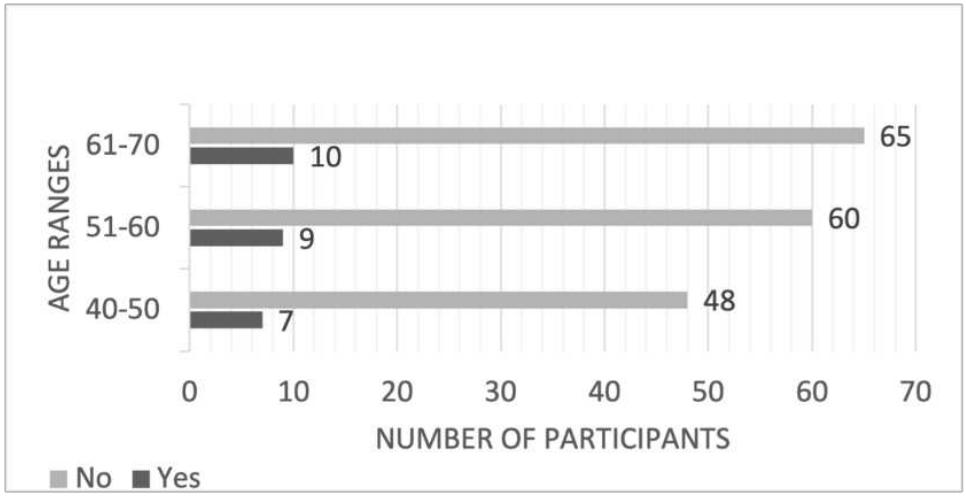


**Figure 1. Guidelines Followed by Patient's Age Group**

Graph showing number of participants who had follow ups adhering to clinical guidelines stratified by age. P=0.995

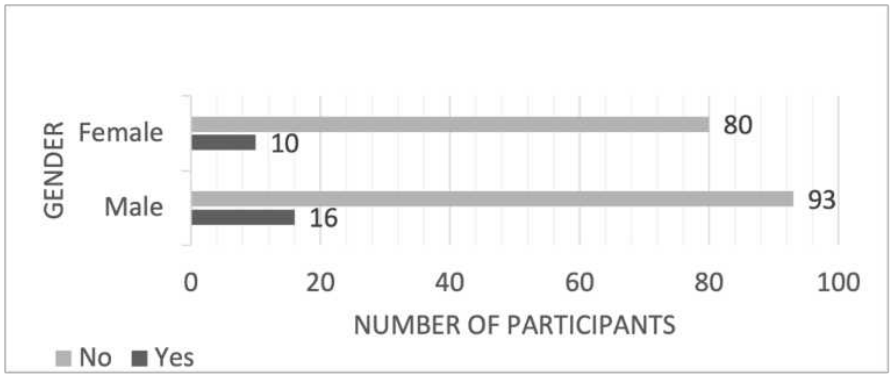


**Figure 2. Guidelines Followed by Patient's Gender**

Graph showing number of participants who had follow ups adhering to clinical guidelines stratified by gender. P=0.457

distribution was 54% female and 46% male. Participants were distributed randomly between UTMB primary care clinics.

To test the hypothesis on whether the DMT intervention improved proper laboratory test utilization, the control group was compared to the intervention group using the chi-square statistical test. Across the participants, there were zero, one, or two laboratory tests ordered to assess kidney function of the participants. The tests included albumin/ creatinine ratio, BMP, or serum creatinine. These categories are summarized in **Table 2**. Of the 199 participants, zero laboratory tests were ordered on 95 (47.7%) of the control group participants and 71 (35.7%) from the intervention group. One laboratory test was ordered on 3 (1.5%) of the control group and 13 (6.5%) of the intervention group. Two laboratory tests were ordered on 4 (2%) of the control group and 13 (6.5%) of the intervention group. Each of the three categories showed statistical significance ($x^2$ (2, N=199) = 14.368, p = 0.001).

To test the hypothesis that DMT intervention improved provider follow-up and adherence to the current KDIGO clinical guidelines, a chart review was performed after the predetermined 4-month interval. Any participant who had mention of kidney function assessment as a reason for the follow up was marked "Yes" and the others "No" for follow-up. For follow-up for abnormal GFR scores, there was a significantly higher proportion of individuals from the intervention group 26 (26.8%) compared to the control group 7 (6.8%) ($x^2$(1, N=199) = 14.293, p < 0.0005). Adherence to the current clinical guidelines showed a similar pattern with 21 (21.6%) of participants from the intervention group and only 5 (4.9%) from the control group adhering to the guidelines ($x^2$(1, N=199) = 12.277, p < 0.0005) (Table 2). Age group and gender further stratified the analysis of adherence. There was no effect of age ranges of 40-50, 51-60, and 61-70 (*p*=0.995). (Figure 1) There was also no significant effect of gender (*p*=0.457). (Figure 2)

## Discussion

In this study, the DMT approach was associated with a statistically significant improvement in primary care provider ordering and follow-up of abnormal GFR results compared with usual care. In addition to improved laboratory utilization, statistically significant differences were observed between groups in physician follow-up and adherence to clinical guidelines. The laboratory's input into the ordering behaviors of providers is a relatively novel concept in healthcare. Studies reveal that such multidisciplinary groups, as seen with DMTs, are more effective at preventing diagnostic error and improving patient outcomes.[12] Adherence to clinical guidelines was also stratified by age ranges and gender in the total study population, but there was no difference between the groups.

It is evident that there is a need to focus more on detection and management of CKD, as reflected by the inclusion of screening for CKD

in the United Nation's Sustainable Development Goal to decrease deaths due to non-communicable diseases by one third by the year 2030. A potential tool to address this is clinical decision-making software to help identify and properly manage individuals requiring CKD related follow-ups.[13] However, additional research is required in this field as to how DMTs can be effectively and efficiently integrated in the implementation of these types of electronic interventions. Another area needing further research where the expertise of DCLS is vital is the developing and testing of novel biomarkers for kidney function. With the well-known limitations to creatinine and cystatin C values making the eGFR formulas difficult to interpret, more stable biomarkers to identify kidney dysfunction are required to standardize diagnosis and management.[14] Beta-trace protein and B-microglobulin are two of the more promising candidates.[15] DCLS are uniquely suited for helping to test these analytes for clinical utility and help to integrate them into clinical practice.

While the results of this study demonstrate the potential impact of DMTs on laboratory utilization and guideline adherence, several limitations should be considered. The short four-month follow-up period may not adequately capture long-term effects on provider behavior or patient outcomes. Also, while the sample was racially and ethnically diverse, the small number of participants from certain subgroups may limit subgroup analysis and broader applicability. Future studies should consider multi-center designs, longer follow-up durations, and expanded outcome measures to better assess the clinical utility and scalability of DMT interventions.

As highlighted by the Institute of Medicine in its landmark report "To Err is Human," medical errors are more common than perceived and has led to healthcare systems striving for improvements including the Triple Aim framework.[16] This study demonstrates the inclusion of DCLS within Diagnostic Management Teams has the potential to significantly improve laboratory test utilization, provider follow-up, and adherence to clinical guidelines for patients with early signs of impaired kidney function in primary care settings. By integrating laboratory expertise into frontline care decisions, the intervention helped close a well-documented gap between abnormal GFR findings and appropriate clinical follow-up. These findings support the value of diagnostic stewardship and interdisciplinary collaboration in enhancing patient safety and reducing the risk of delayed diagnosis. Broader implementtation of DMT models may offer scalable, cost-effective strategies to improve chronic disease management, particularly in high-burden conditions like chronic kidney disease. Future research should assess long-term outcomes and explore integration into health systems at scale.

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## Declaration of Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Research article

# Barriers and Motivators for Research Among Biomedical Laboratory Scientists: A Mixed-Method Study in a Danish Pathology Department

**Tanja Würtz Jørgensen[1*], Stine Asferg Petterson[2]**

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**Clinical laboratories are essential to evidence-based healthcare, providing data critical for diagnosis and treatment. International ethical codes emphasize the role of biomedical laboratory scientists (BLS) in research and implementation of scientific advances. Despite this, Scandinavian literature reveals limited knowledge on BLS research, although barriers such as limited research culture, and academic confidence are explored in other healthcare professions. Hence, this study aims to explore barriers and motivators for BLS research.**

**This mixed-methods study was conducted at the Department of Pathology, Odense University Hospital. Seventy-four BLS's were invited to complete a questionnaire, and ten participated in follow-up semi-structured interviews. The questionnaire covered aspects and perceptions of research. Interviews were recorded and fully transcribed. Data was analyzed by descriptive statistics and thematic content analysis.**

**The survey response rate was 69%. All agree that BLS research is important in evidence-based practice, but fewer perceive it important for developing personal competencies. Awareness of the local research frameworks is limited, and insecurities about research skills and a wish for further training were expressed. Likewise, three main themes emerged from the interviews: limited awareness of research opportunities, motivators and barriers to conduct research, and self-perceived research competencies. Despite being motivated, barriers include work-life balance, impression of limited support from management and colleagues and a notion of inferiority to other professions. Most informants feel confident in laboratory tasks but uncertain about initiating projects and academic writing, expressing a need for mentorship and further research training.**

**In conclusion, this study reveals that BLS's recognize the importance of research for evidence-based practice but fewer in relation to their own professional growth. Most perceive research as an area for specialists or other professions, which limits their engagement. Barriers include limited knowledge on research opportunities, support systems and internal hierarchies. The informants emphasize the need for research culture, improved communication, mentorship, and collaboration to enhance motivation.**

***Keywords:*** Barriers, Motivators, Biomedical Laboratory Science, Research

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## Introduction

Clinical laboratories play an essential role in patient care by ensuring high-quality medical testing, which supports clinical decision-making.[1-5] This provides healthcare professionals with objective, evidence-based data critical for disease prevention, diagnosis and treatment. A key goal of evidence-based and value-based laboratory medicine is to maximize the impact of laboratory tests. Thus, improving patient outcomes while optimizing resource use and minimizing unnecessary costs.[1,2,4,6-9] This calls for a continuous process to ensure development and research meet the goals of evidence-based and value-based laboratory medicine.

The International Federation of Biomedical Laboratory Scientists (IFBLS) suggests a code of ethics for biomedical laboratory scientists (BLS) worldwide, that emphasizes the obligation of BLS's to contribute to healthcare through their professional competencies in laboratory medicine.[10] The code highlights the duty of the BLS to implement scientific advances in laboratory analysis that benefit patients. This underscores the need for BLS's research to enhance practice and laboratory quality.[10]

Scandinavian publications addressing perspectives on BLS core competencies do not include references to laboratory research.[11,12] However, the IFBLS guidelines explicitly identify planning, performing and implementing research as core competencies.[13] Thus, there is a pressing need to enhance the focus on BLS research. Scandinavian laboratories often report BLS research projects as in-house implemented and rarely publish the results.[14,15] This calls for a paradigm shift in sharing of research data, by publishing original evidence-based data to implement research.[16]

To date, there has been limited focus in Danish and international literature on BLS barriers and motivators to conduct research. However, such topics have been explored in other healthcare professions. Literature on research culture and implementation of research findings in the nursing- and allied professions identifies considerable challenges.[17-24] These include a lack of research culture, dedicated time, financial resources and self-reported academic competencies as the most reported barriers. Likewise, Scandinavian studies examined barriers and motivators to research in the radiography profession.[25-27] The studies revealed that radiographers are willing to conduct research. Despite this, the number of actively involved remains low due to multiple factors, including the lack of a robust research culture and a clear strategy for implementing clinical research. The Norwegian radiography profession even proposed a national research strategy to address the growing attention on research and implementation to accommodate barriers.[26]

Integrating evidence into patient care is an ethical and professional duty for laboratory professionals.[11,13,28] Despite this, getting research results into practice is often challenged or delayed.[4] This emphasizes the importance of local applied laboratory research close to practice.[4,23] In 2019, chief management of the Department of Pathology at Odense University Hospital (OUH), Denmark, provided an initiative to enable non-academic BLS's to conduct in-house laboratory research. This included financial support, five days of dedicated time for data collection, access to in-house support from researchers and opportunities for international conference participation. Even though several BLS's expressed interest in conducting research, none engaged in projects over a three-year period, suggesting the presence of unknown barriers. The aim of this study was to identify barriers and motivators to conduct research at the Department of Pathology, OUH, Denmark.

## Method

*Study Design*

This mixed-method study was conducted in The Department of Pathology, OUH, Odense, Denmark, between June 2022 and November 2023, using a combination of questionnaires and individual semi-structured interviews. Seventy-four BLS working at the department

were invited to complete an online questionnaire, and ten BLS voluntarily signed up to participate in follow-up interviews.

*Questionnaire Development and Validation*

A draft of the questionnaire, written in Danish, was developed using Survey XACT. The content, comprehensibility, wording and response categories were evaluated by two BLS, with experience in questionnaire development, from other departments at the hospital, the department research leader and two patients from the in-house research committee. Based on the evaluation, the authors revised and improved the questionnaire. The final draft was accepted by both authors and the department research leader.

The questionnaire comprised of 42 items, including respondent characteristics, individual experiences and knowledge regarding research opportunities, prior and current participation in research projects, and opinion on BLS possibilities of research activities. The questionnaire included various formats: yes/no questions, multiple-choice questions, statements rated on a 5-point Likert scale (1 = lowest, 5 = highest), and a few open-ended questions. The inclusion of a neutral response category was carefully evaluated and deliberately incorporated into selected response options. The questionnaire was distributed via the in-house mailing system, and a reminder was distributed 2 weeks after to increase response rate. All questions were mandatory for the respondents to complete the questionnaire.

*Semi-Structured Interviews*

Ten BLS voluntary participated in the follow up individual interviews. Besides motivation to talk about BLS research, no further inclusion criteria were determined. The informants comprised eight females and two males, reflecting the approximate gender distribution of BLS at the department. None of the informants were employed as laboratory specialists or had any further education besides a bachelor's in biomedical laboratory science. To ensure anonymity, no background information was collected besides gender and time of graduation, which was no longer than ten years for any of the informants. A semi-structured interview guide was developed prior to interviews and used to ensure dialog on the most important topics. Both authors participated on equal terms in conducting the interviews, which each lasted 40-60 minutes. The interviews were audio recorded and subsequently transcribed in full length by both authors.

*Data Collection and Analysis*

The questionnaire response rate was calculated and evaluated. Data was cross tabulated in Survey XACT and analyzed in Microsoft Excel by descriptive statistics. The authors and the two patients from the in-house research committee individually evaluated the responses and provided suggestions for cross-tabulations to accommodate the data in various ways. Responses identified as particularly relevant for the aim of this study were marked to be elaborated in the follow-up interviews.

Both authors thoroughly reviewed and evaluated the transcriptions from all ten interviews by a phenomenological approach to identify key items using a thematic content analysis. The transcriptions were synthesized and scope themes were defined. Statements were categorized according to the themes identified.

*Ethical Considerations*

Ethical considerations in line with the Helsinki Declaration were reviewed.[29] The questionnaire did not include personal information, and participants were informed in an introduction cover letter ensuring that their participation was voluntary and anonymous. Consent from the respondents was considered given upon completion and submission of the questionnaire.

Prior to interviews, all informants were thoroughly notified both written and orally about their rights to withdraw statements, the interview being audio recorded, and their

participation was voluntary with their statements being anonymized. None of them declined, and none has since withdrawn their statements.

## Results

*Questionnaire.*

Response rate was 69% (n = 51/74). Responses were analyzed to assess the perception of barriers and motivators to initiate research. An attrition analysis revealed that nine respondents initiated the questionnaire but did not complete. Hence, these respondents are not included in the statistics or response rate. The characteristics of respondents are presented in Table 1.

**Table 1: Characteristics of respondents.**

Laboratory specialists cover assignments as: expert resource person in specific laboratory technologies, union representative, working environment representative, expert in laboratory information systems, quality assurance expert, etc.

| Variable | n (%) |
|---|---|
| **Age (years)** | |
| 20-30 | 15 (29) |
| 31-40 | 11 (22) |
| 41-50 | 15 (29) |
| 51-60 | 6 (12) |
| >60 | 4 (8) |
| **Graduation year** | |
| Before 1999 | 10 (20) |
| 1999-2003 | 9 (18) |
| 2004-2012 | 4 (8) |
| 2013-2018 | 13 (25) |
| 2019-2022 | 15 (29) |
| **Further educations** | |
| None | 30 (59) |
| Education before BLS | 7 (14) |
| One diploma module | 6 (12) |
| More than one diploma module | 0 |
| Diploma of Health | 5 (10) |
| Masters Education | 0 |
| Master's degree | 2 (4) |
| Other | 3 (6) |
| **Employment time at the department (years)** | |
| 0-5 | 23(45) |
| 6-10 | 9 (18) |
| 11-15 | 5 (10) |
| 16-20 | 4 (8) |
| 21-25 | 3 (6) |
| >26 | 7 (14) |
| **Laboratory specialists** | |
| No | 39 (76) |
| Yes | 12 (24) |

Abbreviations: n: numbers of answers; %: percentage of the total number of answers. BLS: biomedical laboratory scientists.

*Development of the department and individual competences*

Nearly all respondents agree that BLS research is necessary to develop and implement evidence-based laboratory research to ensure high-quality standards (Figure 1). However, the importance of research activities related to developing individual competencies is more evenly distributed (Figure 1). Moreover, the youngest BLS' report research activities as important in developing individual competencies, compared to senior BLS' (Figure 2).

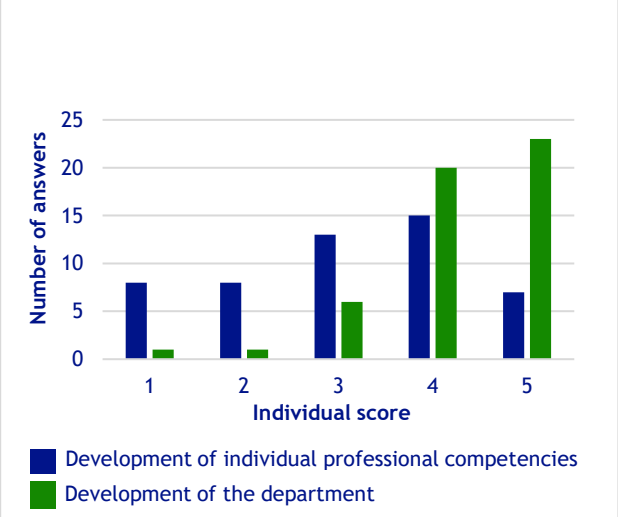


**Figure 1: Importance of BLS research activities:**

Respondents perceived importance of BLS research activities when it comes to individual competencies and developing the department. With 1 representing not important and 5 representing highly important.

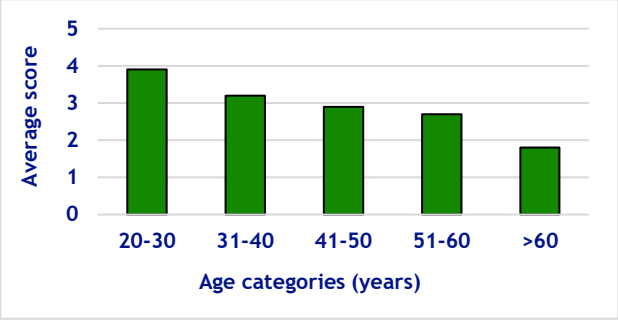


**Figure 2: Biomedical laboratory scientist research and development of individual competencies.**

Responders perceived importance of research and development of individual competencies compared to age. With 1 representing not important and 5 representing highly important.

*Personal Research Competencies*

Regarding personal research competencies (Figure 3), 37% of respondents identify lack of knowledge and skills to conduct research, while 41% are unsure. Additionally, 49% indicate the need for further training or education, while 37% are unsure.

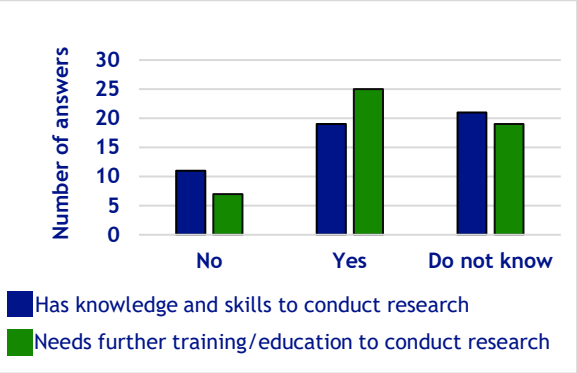


**Figure 3: Personal research competencies.** Respondents perceived personal competencies in research practices. Responses "Yes", "No" and "Do not know" as a neutral response.

*Awareness of Research Frameworks*

Generally, respondents are unaware of the framework for research projects (Figure 4). Around half of the respondents (51%) do not know who to contact to initiate projects, 67% are unfamiliar with opportunities for financial support, and 88% do not know how to apply for external funding. Furthermore, 78% are unaware about the option of dedicated research time.

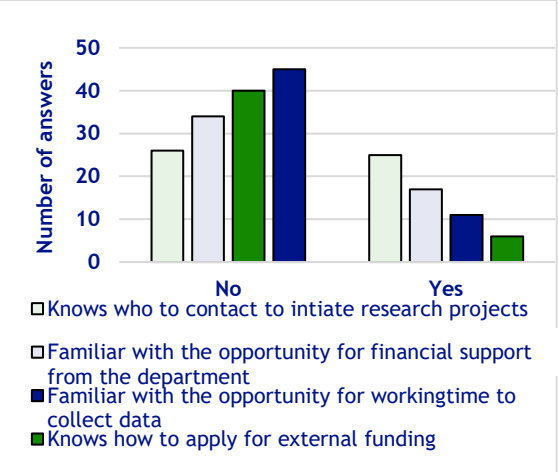


**Figure 4: Research organization.** Responses on knowledge about research organization and framework surrounding in-house research possibilities. Responses reflecting "yes" and "no" without a neutral category.

*Respondent's opinion on support to conduct research*

Most of the respondents do not know whether they feel support to conduct research (Figure 5). Feelings of support from both chief management and daily management are 22%, research leader 29% and other professions 33%. Whereas support from colleagues seems to be more pronounced (37%).

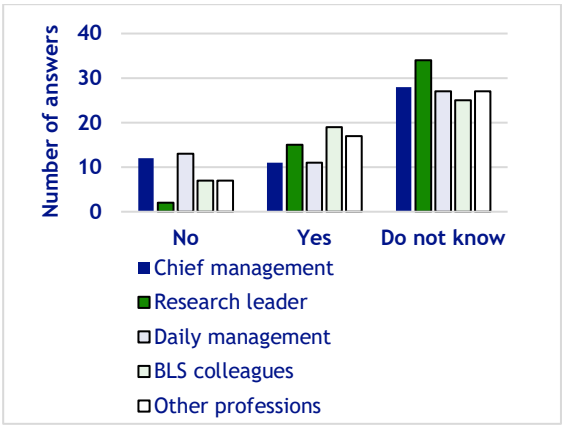


**Figure 5: Support to conduct research.** Respondents perceived opinion on support to conduct research. Response categories "No", "yes" and "Do not know" reflects the options of responses.

*Semi-structured interviews*

Based in the thematic analysis three main themes emerged:

1. One's perception of research competencies.
2. Perception of BLS research and research framework
3. Barriers and motivators for BLS research

*One's perception of research competencies.*

The informants partially feel confident in performing laboratory work on their own. Hence, they are most concerned about their qualifications to develop and initiate research. This appears to be linked to a feeling of insecurity about deciding the scientific and clinical value of projects. Some informants highlight the benefit of BLS sharing research experiences potentially reducing some insecurities. Moreover, they highlight a feeling of an internal hierarchy in the department, leaving them feeling not as competent as doctors, pathologists and molecular biologists. Even

though they receive research training during their education, they wish for further education directly related to scientific research.

*Perception of BLS research and knowledge about the research framework and support at the department level.*

Most informants do not know that BLS research is an opportunity at the department level. Some informants view BLS research only to be possible for BLS' employed in special positions. Moreover, there seems to be a perception of BLS only doing laboratory research for other professions. Hence, they perceive their core competences primarily as routine-based laboratory analysis and some feel insecure about the requirements and complexity of BLS research. In line with these perceptions, they repeatedly mention the need for BLS research culture containing definitions and framework of possibilities. Moreover, they highlight the need for support from department management and awareness about current research conducted by other professions, to inspire BLS for future research projects.

*Barriers and motivators for BLS research*

The ten informants all express motivation to initiate and conduct research projects. Besides the obvious prospects of BLS research generating enhancements in laboratory tests beneficial to patients, they are intrigued by the potential to develop, use and maintain their current research skills. The BLS feel that this would improve their job satisfaction and keep them stimulated with new challenges. Moreover, motivators such as a dedicated go-to person, with research experience, and teamwork were suggested.

All informants mention work-life balance as a barrier to BLS research when asked about performing some research tasks, like researching literature or scientific writing, outside working hours. Although personal interest in a specific laboratory area seems to motivate a few of them to prioritize research activities outside working hours. Barriers include lack of guidelines in relation to project initiation. The informants all express uncertainty about the extent of a BLS research project compared to projects carried out by other professions. They are unsure if the scope of their research ideas meets the department's requirements for project approval.

Furthermore, general support from colleagues working in the department is requested. Thus, some feel this as a prerequisite, especially in the development and initiation of projects to ensure high quality. An additional barrier is difficulties with balancing research projects and work responsibilities, exemplified by the feeling of leaving their colleagues with extra work. Some even feel hindered by their own perception and concerns about acceptance from colleagues. Finally, they highlight the importance of research being prioritized by the management, which would contribute to a more research-oriented work environment.

## Discussion

Most respondents from the survey agree that BLS research activities are highly important when it comes to developing the department (Figure 1). The informants support this in their statements by elaborating the importance of BLS research generating laboratory tests beneficial to patients. The findings underscore the relevance of the IFBLS Code of Ethics, which emphasizes the responsibility of BLS professionals to improve laboratory practice.[10] Moreover, it aligns well with chief management's recognition of the importance of BLS research. Similarly, studies from the Radiography profession found, that the majority of participating radiographers agree on the need for further research in the field of radiography.[26,27] Despite this, like BLS in this study, the proportion of Radiographers involved in research is very low.[27] In the nursing- and allied profession there has been a dedicated focus on research over the last decade with great success.[17,18,23,24,28,30] This suggests that the respondent's perspective on BLS research activities as being very important, aligns with the goals and perspectives in other healthcare professions.

When it comes to BLS research and development of individual professional competences, the responses are evenly distributed ranging from "not important" to "highly important" (Figure 1). Analysis of the average responses with age of respondents reveal a correlation (Figure 2). This indicates that the youngest BLS' and new graduates perceive research activities as very important for developing individual competences, while senior BLS' evaluate it as less important. The obvious reasons could be descending personal ambitions as senior BLS compared to younger BLS. Moreover, this might reflect that the educational system for BLS in Denmark has developed during the past 25-30 years from a technician apprenticeship to a bachelor's degree.[3,14] The Danish BLS education has continuously progressed since 2001 towards enhancing academic skills like methodologies, biostatistics, poster presentations and scientific writing. Some BLS students already participate in scientific studies during their education, which gives them opportunities to gain experience through participation research projects.[14]

In general, the informants feel intrigued by the potential to develop, use and maintain their research skills. They declare possibilities for conducting research as a motivational factor that will enhance their job satisfaction. Feelings of being stimulated with new assignments is in general considered a motivational factor, which is also addressed in the literature considering motivators for research in other professions.[22,31,32] When asked about their own perception of research competence, less than half of the respondents declare to have knowledge and skills to conduct research and less than half do not know (Figure 3). At the same time half of the respondents state the need for further training or education and less than half do not know (Figure 3). These statements seem contradictory and were elaborated in the interviews. All informants wish for further education directly related to scientific research. They feel confident in laboratory procedures but specifically highlight developing and initiating project ideas and deciding the scientific and clinical value of projects as challenging areas. This reflects their insecurity about whether their research ideas are sufficiently aligned with the department's requirements for project approval. Developing research projects or implementing technological advancements is often the responsibility of laboratory specialists, pathologists or molecular biologists. Therefore, it is understandable that BLS find these skills particularly challenging. In general, BLS in the department rarely participate in scientific writing or conferences, which might lead to insecurities and barriers in these areas. In response to this, the informants highlight the importance of sharing experiences on research process, scientific writing and conference participation among the BLS.

From the interviews, it became clear that the informants perceive in-house research only to be possible for other professions or laboratory specialists. Most of the informants do not have any knowledge about opportunities for conducting research. This correlates with the respondents' perception of the research organization. Even though they were not asked directly in the questionnaire, responses to questions related to research organization indicate missing communication (Figure 3). It is exemplified by the fact that most respondents are unaware of financial support or dedicated working time. This correlates with the informants repeatedly mentioning the need for a research-based culture and knowledge about possibilities of BLS research. Several studies concerning other healthcare professions also states the importance of a research culture and clear definitions of research possibilities.[17–19,22,25–27,31–35] Despite this, establishing research practices and fostering a strong research culture remains a significant challenge.[18,19,21,27,36] Studies in the nursing-, radiography- and allied professions suggests, that a strong research culture relies on fostering a positive attitude toward research in general.[18,22,25,34] To ensure success, it is suggested that research must become an integral part of

daily practice, complementary to clinical activities.[18,22,37] It would be beneficial to enhance focus on motivators rather than barriers to research and secure a strategic and strong communication to overcome barriers. Establishing a clear infrastructure for BLS research is a suitable step toward fostering an in-house research culture.

The informants mention a dedicated go-to person as a motivational factor but are unaware that this role was appointed by chief management. Interestingly, half of the respondents know who to contact to initiate a research project (Figure 4). The survey did not include a question requiring respondents to specify the appropriate contact for initiating projects. Consequently, it remains uncertain whether respondents referred to the individual formally designated by chief management or another relevant person in the department. The intention behind a dedicated go-to person is to provide a mentor for BLS interested in research. Mentorship is widely recognized as an essential component of research infrastructure and the development of early-career researchers.[22,32,34,36,38,39] Thus, mentorship opportunities should be communicated as a key priority and correlate very well with the informants wish for collaboration in projects. Research is time-consuming, and most of the informants are aware that one week of dedicated time is not enough to ensure research of high value. Access to external funding could facilitate the reallocation of time from routine laboratory tasks to research activities. Data from this survey indicates that the BLS' do not have skills and knowledge to apply for external funding, which potentially could be a task for the mentor (Figure 4). Moreover, the informants have concerns about work-life balance. Hence, time is a well-known barrier to research in other professions.[22,25,32,37,38] Securing external funding can be a time-consuming process, but investing the time may prove beneficial and ensure research that would otherwise be difficult to prioritize. In line with this, literature in radiography and allied health professions suggest, that establishing partnerships and teaming up in research projects will strengthen the access of external founding, resources, and support implementing research into practice.[22,23,25,32,38,39]

The informants in this study have concerns about support from both leaders and colleagues towards BLS in-house research. These overall concerns are also reflected in the respondents' answers to the questions about support to research. Most respondents are insecure or do not feel support from chief management (Figure 5). Lack of support for conducting research is a well-known barrier in various professions, which can be partially addressed through clear and systematic communication.[21,23,25,40] The informants in this study also highlight the need for communication about possibilities for BLS research together with general support from colleagues. They have concerns about leaving colleagues with a heavier workload, if they engage in research. Acknowledgement and acceptance from colleagues is a motivational factor for conducting research.[25] However, data from the questionnaire imply a missing correlation between the perceptions of lacking support from colleagues, since the respondents find BLS research activities very important for developing the department (Figure 1). This indicates not only lacking communication from management about research possibilities but also missing communication between BLS.

The informants express experiences of intern hierarchy among healthcare professions at the department, challenging their aspiration of a BLS research culture. More than half of the respondents express "No" or "Do not know" to the question about support from other professions (Figure 5). These findings are also reflected in the radiography profession and by laboratory personnel as a barrier to research.[25,41] Structures of hierarchy due to former professional boundaries must be assessed as outdated, if the aim is to maintain high performance in laboratory medicine.[14] The studies from the radiography profession advise

to address hierarchy challenges by clear communication and support.[25,41] To establish a strong research culture, it is essential to highlight the significance of BLS research and encourage a supportive and open positive attitude across professional groups.

Literature on research culture and capacity among other professions propose a clear strategy for establishing a research culture in clinical practice.[22,24,25,30,35,39] It will be beneficial to enhance focus on motivators rather than barriers to research and secure a strategic and strong communication to overcome barriers. Establishing a well-organized infrastructure is a suitable step toward achieving the goal of fostering an in-house research culture within the BLS profession.

## Conclusion

This study highlights that BLS recognize the critical role of research in developing the department and improving patient care through evidence-based laboratory practices. Despite this awareness, many BLS perceive research as the domain of specialized or academic colleagues, leading them to limited engagement in research activities.

Barriers identified are limited knowledge about the research framework, funding opportunities, and the processes involved in initiating and conducting research projects. Most BLS are uncertain about their own research competencies, which impact their motivation. Additionally, internal hierarchies contribute to feelings of uncertainties and diminish the development of a BLS research culture.

Lacking support from management and colleagues is a barrier, together with concerns about the workload for colleagues. This perception along with a low awareness of a dedicated go-to person further highlights a gap in communication that could otherwise empower BLS researchers.

The findings underscore the necessity of establishing a supportive research culture within the department that actively promotes BLS involvement. Key motivators include fostering collaboration, mentorship and targeted research training. Encouragement from management to emphasize the importance of BLS research, along with recognition of BLS contributions, appears crucial in overcoming existing barriers. Ultimately, a supportive research culture would enhance the motivation, skills, and participation of BLS in research. This will not only benefit the individual professional development of BLS but also strengthen the overall quality and capacity of laboratory medicine.

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**Research article**

# Finding My Place; Experiences of Sense of Belonging in Lunchrooms During Clinical Placements

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**This study explores how biomedical laboratory science (BLS) students at UCL University College (UCL) experience social groupings in lunchrooms during their clinical placements at Odense University Hospital (OUH) and how these interactions influence their sense of belonging. The study was designed by a mixed-method approach, including a survey and individual semi-structured interviews. The survey included students from 2nd to 7th semester, and 6 interviews were conducted with students from 4th to 7th semester. Empirical data has been interpreted using the concepts of humans' need for groups and concepts regarding humans' sense of belonging. It is evident that social dynamics and groupings within the lunchroom impact students. Being included and feeling like they belong influence students' perception of the department as well as the perception of their own performance. The experiences in the lunchroom could either enhance or diminish a student's learning.**

***Keywords:*** Mixed-method, Clinical placements, Sense of belonging, Social dynamics, Groupings

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## Introduction

Clinical placements (CP) are an essential part of the biomedical laboratory science (BLS) education program in Denmark. BLS students studying at UCL University College have five mandatory periods of CP throughout their three-and-a-half-year-long education. All placements are of varying lengths, ranging from three to twenty weeks of CP. Altogether, students participate in a total of fifty-one weeks of CP. The rest of the education is spent on campus with theoretical and practical teachings. Each CP can take place at one of seven different departments at Odense University Hospital (OUH). During the CP the students conduct clinical analyses according to the department's specialty and learn the department's theoretical basis.

Sense of belonging is a fundamental human emotional need and can be described as a unique and subjective experience that relates to the longing, desire, and need to have and maintain relationships with other people.[1] Maslow argues its importance, as humans aim to gain it and a lack of it can have dire consequences, such as loneliness and mental distress.[2] Achieving a sense of belonging is a fundamental human need affected by other people's actions and behaviors, which can either enhance or diminish it.[1,3] Earlier studies have shown that students' sense of belonging is one of the most important factors for students' ability to learn during CP.[4-8] Thus, the lack of sense of belonging is thereby correlated with weak learning experiences, and it is furthermore shown that a positive sense of belonging contributes to the students' feeling of successfulness in learning environments during CP.[4-9] Therefore, it is essential for students to experience successful CP, as it gives them the best opportunities to foster their knowledge and practical skills.

Getting to experience CP allows the students to become familiar with different specialties and different social groups. Furthermore, earlier studies indicate that a sense of belonging can be easier to achieve in environments where there are fewer employees, as it becomes easier to communicate with each other, thus making it easier to create interpersonal relationships.[10,11]

Studies have shown that gaining interpersonal relationships with the staff is crucial to the development of students' sense of belonging.[3,5,12] Socialization with the staff often happens during breaks in their day-to-day work, and it can prove to be significant for students as it can establish a sense of belonging.[3,5,12-14] Alienation of students and not allowing them the opportunity to engage in informal socialization, on the other hand, increases students' feelings of exclusion from the department.[5,12]

As the study group experienced the lunchrooms and the shift from one lunchroom to the other, the shifts played a larger role for students than first anticipated. Students must relate to new people, new norms, and new habits in every department they are placed in. This emphasizes the interest in investigating the environments that students experience when entering the departments' respective lunchrooms.

Investigating this topic is particularly interesting regarding the BLS education, as existing studies and literature primarily focus on research conducted within the nursing profession. Thus, this study explores how BLS students at UCL experience the lunchrooms during their CP's at OUH, and how these experiences affect their sense of belonging during their CP's.

## Method

### Design

The study utilizes a mixed-method approach that includes a quantitative questionnaire followed by qualitative semi-structured individual interviews. The combination of data from quantitative and qualitative methods enables a deeper understanding of the social phenomena. This study explored the students' experiences in the lunchrooms during their CP's.

**Participants and data collection**

***Sample and study population***

The study took place in the spring of 2023 and included BLS students from UCL and OUH. The BLS bachelor program in Denmark is seven semesters long. The program includes various lengths of theoretical terms at UCL, combined with CP's at OUH. By including students from both UCL and OUH, the study includes students who were currently in CP's and students who were not. Due to the first-semester students' lack of clinical experience, only students from the second semester to the seventh semester were eligible to participate in the questionnaire in this study. The questionnaire was distributed to 126 students. Inclusion criteria for the interviews required that students be in the fourth to seventh semester of the educational program. Six students who met the criteria volunteered for individual semi-structured interviews.

***Questionnaire***

The questionnaire was developed by using the online software SurveyXact and pre-tested before distribution. Four individuals selected from the study group's network answered the questionnaire and gave feedback on each question. The questionnaire was adjusted based on the feedback, which was mainly regarding comprehensibility. To increase the possibility of a significant response rate, the length of the questionnaire consisted of nineteen questions. Six demographic questions, nine yes/no questions, and four questions consisted of response options by a Likert scale of 1 to 5, representing: 1 *very high extent, 2 high extent, 3 some extent, 4 low extent*, and *5 very low extent*. All the questions were mandatory for the students to answer.

Students were required to answer questions regarding experiences in the lunchrooms during their CP's. The questionnaire was distributed via the online learning management system ItsLearning. To encourage students to participate in the study, the students were addressed during their CP at UCL and OUH. A reminder was sent ten days after the first distribution to increase the response rate.

**Interview**

An interview guide was developed that focused on the objective of the study and comprehensibility of the questions. Prior to the six interviews, the interview guide was tested by four individuals selected from the study group's network who gave their feedback on the comprehensibility of the questions. The interview guide was adjusted based on feedback. The questions in the guide consisted of open-ended questions. The 20 to 45-minute-long interviews were audio-recorded and fully transcribed. A character system was designed and used during the transcription that included abbreviations for the interviewer and co-interviewer. Additionally, the students were assigned a pseudonym consisting of an arbitrary letter. Finally, the atmosphere during the interview, the student's tone of voice, and pauses were noted.

**Ethical considerations**

The study followed the ethical codes of the Helsinki Declaration of Volunteering. All participants were informed orally and in written format of their rights and the aim of the study. The students responses to the questionnaire were anonymized, and students from the interview were registered with an alias. Students agreed to participate by completing the questionnaire, while the students for the interview consented to participate before it was initiated. All the participants were informed of their rights to withdraw from the study at any time.

**Data analysis**

***Questionnaire***

The response rate was calculated, and data was cross tabulated in SurveyXact and evaluated with descriptive statistics using Microsoft Excel. The students based their answers on a department of their choice when completing the questionnaire. Departments were defined by the number of employees, minor departments equaled less than 100 employees and major departments equaled more than 100 employees. Data was then

stratified according to minor or major departments.

***Interviews***

The transcribed data was thoroughly reviewed employing a phenomenological approach. Themes were identified by open coding and relevant statements categorized under the themes. Relevant quotes were identified and integrated into the themes.

## Results

### Quantitative findings

***Baseline characteristics***

The response rate was 75% with 96 out of 126 students completing the questionnaire. The baseline characteristics of students are presented in Table 1. Figure 1, 2, 3 and 4 show that the baseline characteristics of the students did not differ remarkably for minor and major departments respectively.

**Table 1.** Distribution of data on gender, age, students' current semester at the time of answering, size of the department students based their response on and number of clinical placements at OUH.

| | |
|---|---|
| **Gender (%)** | |
| Male | 17,7 |
| Female | 81,3 |
| Other gender identity | 1 |
| **Age (%)** | |
| <20 | 5,2 |
| 21-25 | 56,3 |
| 26-30 | 19,8 |
| 31-35 | 10,4 |
| 36-40 | 3,1 |
| 41-45 | 3,1 |
| 46-50 | 2,1 |
| **Size of department the student based their response on (%)** | |
| Minor | 21,9 |
| Major | 78,1 |
| **Students' current semester when answering (%)** | |
| 2. semester | 15,6 |
| 3. semester | 14,6 |
| 4. semester | 22,9 |
| 5. semester | 12,5 |
| 6. semester | 21,9 |
| 7. semester | 12,5 |
| **Number of clinical placements at OUH (%)** | |
| 1 | 16,7 |
| 2 | 6,3 |
| 3 | 15,6 |
| 4 | 31,3 |
| 5 | 14,6 |
| 6 | 8,3 |
| 7 | 7,3 |

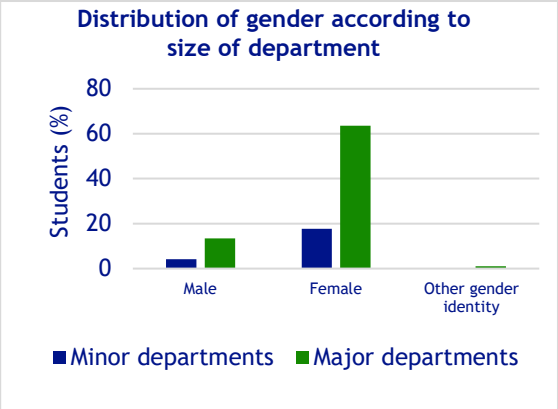


**Figure 1.** Distribution of gender in minor and major departments respectively

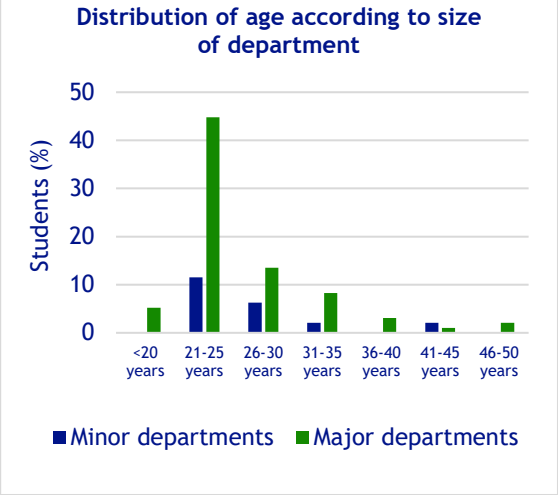


**Figure 2.** Distribution of age in minor and major departments respectively.

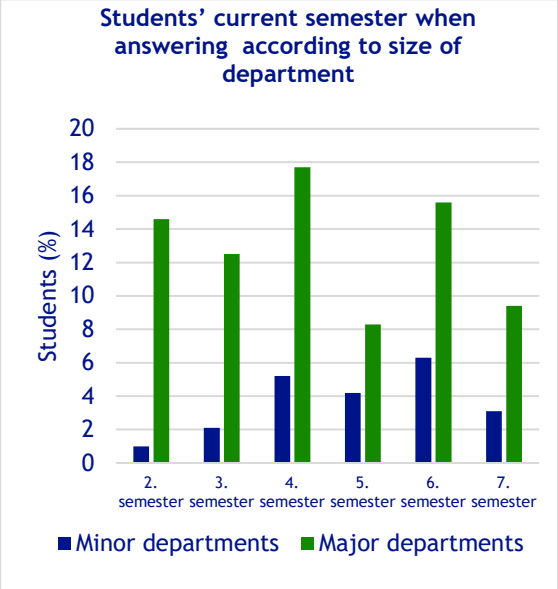


**Figure 3.** Distribution of students' semester when answering in minor and major departments respectively.

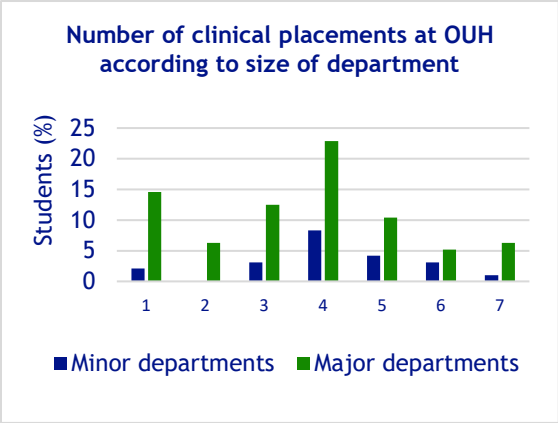


**Figure 4.** Distribution of students' number of clinical placements at OUH in minor and major departments respectively.

### *Social grouping*

Students' responses show that 68 (71%) encountered social grouping among the BLS in the lunchroom at the departments on which their responses were based. Out of 96 students, 37 (39%) experienced belonging to a group. Students' perceptions of belonging to a group varied based on their placement in minor or major departments (Figure 5).

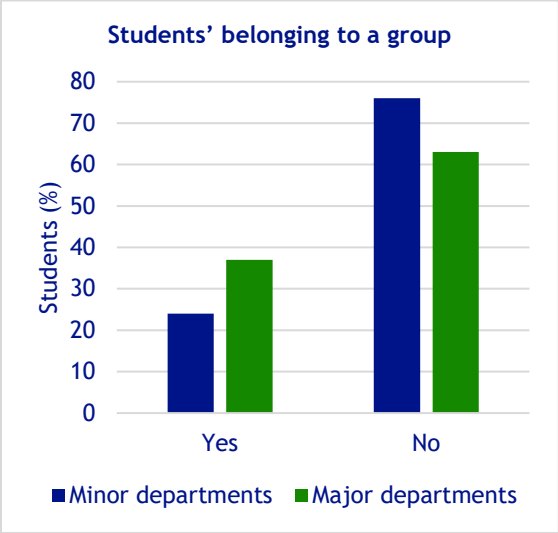


**Figure 5.** Comparison of students' belonging to a group in minor vs major departments.

### *Feeling included in conversations*

When asked about the feeling of being included in conversations in the lunchroom, 59 (61%) of the students answered they felt included to either a *very high extent*, *high extent*, or *some extent*. The feeling of being included in conversations in the lunchroom differed depending on whether students based their responses on a minor or major department (Figure 6). When asked whether the feeling of being included in conversations in the lunchroom mattered to them, 78 (81%) of all students answered yes.

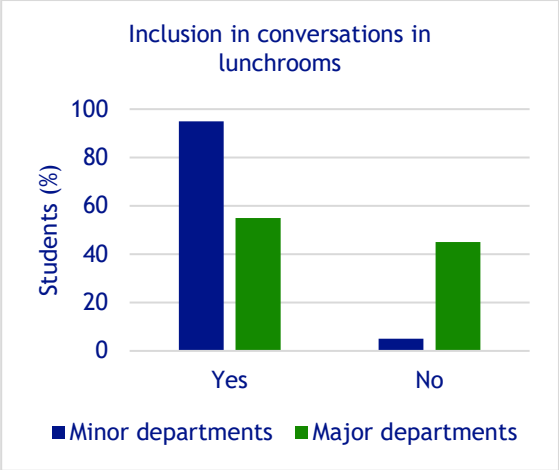


**Figure 6.** Comparison of students' feeling of inclusion in conversations in minor vs major departments.

### *Feelings of concern*

Students were asked about feelings of concern when going to lunch, and 42 (44%) of the students answered they had occasional concerns. This outcome also differed depending on whether students based their responses on a minor or major department (Figure 7).

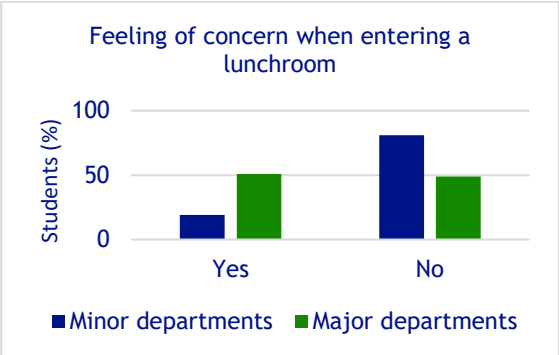


**Figure 7.** Comparison of students' feeling of concern in minor vs major departments.

*Preferences for social grouping at lunch areas*

When asked about social preferences, 55 (57%) of the students expressed they would prefer to eat lunch with fellow students. This outcome also differed depending on whether the

students based their responses on a minor or major department (Figure 8).

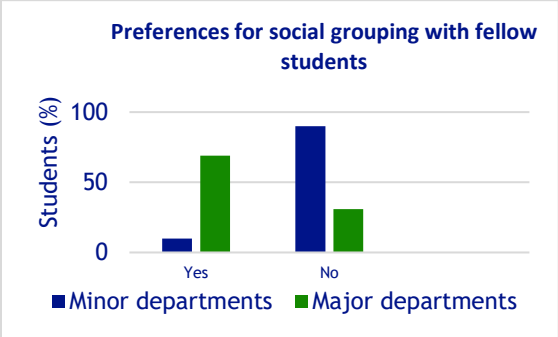


**Figure 8.** Comparison of preferences for social grouping among students in minor vs major departments.

**Qualitative findings**

Four overall themes emerged in the analysis of the interviews: grouping, inclusion, belonging, and concerns.

***Grouping***

During the clinical placements, students experienced grouping among the BLS in the lunchroom. They found it challenging to navigate the unspoken guidelines and complex social dynamics that governed these groupings, which often left the students feeling awkward and uncomfortable. Student A reported having an unpleasant experience when attempting to join a group of BLS in the lunchroom and was informed that the seat was reserved for another person. This left student A feeling unwelcome and excluded.

Some students expressed that having their fellow students around in the department could enhance their feeling of assurance during the clinical placements. However, they admitted that they also tended to form groupings among themselves. Student A explained that the desire to have fellow students around emerged from a need for social support during the CP.

However, student B expressed a different opinion. It was elaborated that, claiming that it did not solely depend on whether a student belonged to a group or not, but more about how the BLS made each individual student feel welcome, regardless of being a part of a group at the department.

Student B: *"… whether they placed themselves randomly, with whomever they wanted, or in groups of their choice, wasn't important to me. What mattered was that they made an effort to make me feel welcome, asked me questions, and showed some interest in me." (Quote 1)*

Some students described that sitting with their fellow students during lunch break gave them a pause from the learning environment. They felt it was essential to engage with other students during the lunch break to mutually process their experiences. They clarified how the lunchroom often did not feel like a place for an actual break, but rather an environment where they needed to be engaged and present in the same manner as in the laboratory. Student C gained energy by spending time with fellow students. It was described how one was always actively participating as a student, even at lunch with the BLS, and how one constantly tried to do their best and give the best impression. It felt like a draining experience instead of an actual break and this was when lunch with fellow students became a much-needed break. It was a moment to relax and share experiences with other students, and a moment to gain energy for the rest of the day. Student A also sought out other students during CP's and described this behavior as a natural reaction.

Student A: *"It's probably because you need to have some kind of acquaintances. It's incredibly awkward to sit in a gathering where you don't know anyone, because then you don't feel welcome. That's what it's all about. If you don't know anyone, you seek out those you do know and usually that´s your fellow students, so you end up sitting with them." (Quote 2)*

Seeking out fellow students can also be viewed as a response to not knowing anyone in the department, providing students with a way to find some familiarity in an unknown environment.

***Inclusion***

The students believed that the feeling of being included depended on the BLS to show interest and include them in lunch break conversations. In general, these elements were highly valued by the students during their CP's. Students perceived it as inclusion when BLS's engaged in casual conversations regarding everyday life and personal subjects. It made them feel that the BLS's cared about them, which positively impacted their day. On the contrary, student D explained that not feeling included in the lunchroom, usually led to complete withdrawal from the social environment.

Student D: *"If I sense that the BLS I'm working with doesn't appreciate my presence, and I'm being ignored in the lunchroom, I would rather find a different place to spend my lunch break and call my dad and have a conversation with him, because he usually has his lunch break at the same time as me. After all, talking to him provides more companionship than sitting at a table in the lunchroom where I feel like an inconvenience." (Quote 3)*

The feeling of inclusion was not exclusively limited to the lunch breaks. The experiences throughout the day leading up to lunch influenced students' feelings of inclusion. However, several students knew they were also expected to actively participate in conversations during the lunch break, leading to an increased sense of feeling included, just as they expected the BLS's to do. Student E emphasized that expecting the BLS's to contribute to conversations without trying themselves did not make sense. The feeling of inclusion requires contributions from both BLS's and students.

However, some students described situations where the BLS's seemed uninterested and dismissed students' attempts to engage in lunch break conversations with brief and dismissive responses. Due to this behavior, student A felt excluded and overall unwelcome in the department. Likewise, student D described how the experience of not being included in the conversations made it challenging to participate in overall conversations.

Student D: *"If I sensed that I was an inconvenience or that they [the BLS's] preferred me not to be there, I withdrew. I became very quiet and would keep myself in the background, so I didn't interrupt anyone. Then I would just wait until my workday was over and then leave the department." (Quote 4)*

Student D felt as though joining the ongoing conversations would be an interruption and eventually chose to withdraw from the lunchroom altogether. These feelings persisted throughout the day, impacting the possibilities for learning by creating hesitation to ask clarifying questions in the laboratory.

***Belonging***

The lunchroom served as a major component in fostering the students' sense of belonging within the department. The students recognized that the lunchroom contained much more than a place to consume their meals. In fact, the lunchroom had the potential to influence their overall perception of the department. It was a space where the students evaluated their own sense of belonging and assessed their performance in their clinical placements. Student A expressed the association with the lunchroom and emphasized its importance within the department.

Student A: *"Overall, I have had a positive experience with the lunchroom. It provides a space where we can have private conversations during our lunch breaks, allowing us to form closer connections with each other. And that also affects how well you feel socially included within the department… The better experiences in the lunchroom, the more you feel like a part of the department." (Quote 6)*

The students wanted more than just to excel at the mandatory requirements for learning in their clinical placements. They desired a stronger social connection with the BLS's and a feeling of belonging to the department. Moreover, they wished to feel included and be seen as equals.

***Worries and concerns***

The students expressed their concerns and mixed emotions about the lunchroom. They shared their experiences of trying to fit in and not being excluded from the groups of BLS. To accomplish this, student C described how one speculated on this issue when entering the lunchroom.

Student C: *"Actually I really don't think that much about the lunch break before the break is about to start. It´s at that time, I use a bit of energy right before I enter the room to assess, if I should rush to grab my food and find someone I know to sit with, or if I should take my time getting my food and wait for the person I'm working with to finish so we can sit together. …" (Quote 7)*

Entering the lunchroom ended up being quite challenging for some students as they didn´t possess the same understanding of the underlying social dynamics among the BLS's during lunch breaks. Unlike the BLS's, who seemed to possess an understanding of this process, the students found it to be taxing. Student D found entering the lunchroom to be a constant struggle. It was a preference to enter an empty lunchroom or to be the last person to enter the room because it made it easier to figure out where to sit. Student D worried about making the wrong choices in a crowded lunchroom and breaking the unspoken social guidelines and professional boundaries upheld by the BLS's. It was a way of avoiding potentially awkward and uncomfortable situations with the BLS's. It was a mindset that may have seemed necessary for some students to be successful in maneuvering through the lunchroom and getting closer to obtaining a sense of belonging.

## Discussion

**Social grouping and inclusion**

In this study, the data indicates that students (n=68; 71%) encountered social grouping among the BLS in the lunchroom. Additionally, it was found that less than half of the students (n=37; 39%) experienced belonging to a group. The students' responses, however, showed that a majority (n=59; 61%) felt included in conversations in the lunchroom. These points were raised during the interviews where student A, as an example, experienced rejection when the student tried to join a group of BLS's at lunch. In response, students formed their own groups to gain support during the clinical placements, as they highly valued socializing with their peers (n=55; 57 %). In the interviews, it also became clear that sitting with fellow students allowed them to get a break from the learning environment and to process what they had experienced. Student A explained that a lack of prior knowledge of BLS was the main reason, and as a result, the student gravitated toward familiar students (Quote 2). The need to belong to a group is not unique for the students in this study since it has been documented that humans thrive better in groups and that it has a positive correlation between well-being and relationships with other people.[2,15,16] In a study by Berkman et al., it indicates that establishing social networks and relationships positively impacts overall well-being and mental health, emphasizing that humans thrive in groups.[15] Maslow also suggests that we thrive better in groups, as it is an innate urge for humans to form social bonds, as it can contribute to a sense of security as well as recognition from the groups.[2] Furthermore, in another study by Kleine et al., the importance of social integration is highlighted, where it suggests that strong workplace relationships contribute to the overall well-being of the employees.[16] Overall, these findings showcase the fundamental role of social connections in human well-being, and it clarifies the natural behavior of student A which is shown in the situation. Furthermore, achieving a sense of belonging does not only depend on belonging to a group as much as on how much each BLS made the students feel welcome, as student B expressed in the interviews (Quote 1). The social groupings did not matter as much, as the primary concern was whether the BLS would try to make the students feel welcome (Quote 1). These findings are in line with several other

studies, which emphasize the importance of including the students in work tasks, social groups, or informal conversation when wanting to enhance the student's capability to learn while in clinical placement.[4,5,12,17-20] The students are more motivated to engage in learning situations and activities about unspoken social rules or fitting in.[3] In contrast, the students did recognize the importance of being as inclusive towards the BLS as they expected the BLS to be towards them. They were eager to make a good impression and, at the same time, show the BLS that they were interested in joining them, even during lunch. This is also supported by a study by Levett-Jones et al. who described that students seek out connectedness and genuinely want to develop a positive staff-student relationship, resulting in a more successful clinical placement for the students.[12] It is crucial for the students to feel included in creating these staff-student relationships. This aligns well with the questionnaire results, where 59; 61% of students reported feeling included in conversations in the lunchroom to a very high, high, or to some extent.

**Worries, concerns, and belonging**

In this study the students (n=42; 44%) expressed concerns when going to lunch, however, the specific reason for their worries was not disclosed in the questionnaire. The interviews provide insight into the possible underlying reasons for their concerns, respectively. The concerns seemed to arise from the students not possessing the same understanding of the underlying social dynamics among the BLS's during lunch breaks. To avoid these concerns from occurring, student D preferred an empty lunchroom. The student did not have to worry about unwritten rules and the unspoken guidelines of the lunchroom. This is additionally supported by student C, who was aware of the energy one put into entering the lunchroom and assessing where to sit to keep away from overstepping the implicit customs (Quote 7). For some students, this created anxiety about being excluded by the BLS's, and the solution to this was either to sit with their fellow students in their own group or to leave the lunchroom altogether. Student D gave an example of how interactions with the BLS's could have an impact, and to such an extent that it felt preferable to avoid the BLS's in the lunchroom altogether rather than sit with them (Quote 3). The student had the same approach during the workday as well if the student felt like an inconvenience to the BLS (Quote 4). Regardless of that as mentioned in a study by Levett-Jones et al., if the students do not feel like they have a sense of belonging during the clinical placement, it can diminish their motivation to learn. Therefore, could student D's approach, in response to not feeling a sense of belonging, potentially reduce the academic outcome of the placement if the student had this ongoing feeling around the BLS?[5]

The lunchroom appeared to be much more than just a room, but rather a place where the extent of a sense of belonging and social inclusion became clear. The students wanted to develop relationships with the BLS and be perceived as equals to the BLS staff. These desires could often be fostered in the lunchroom, as this area allows people to engage in informal conversation and focus on other things than the daily work and tasks in the laboratory. Inclusion in social engagements and casual conversations in the lunchroom made the students experience a greater sense of belonging, and positively affected their perception of the department overall, as was described by student A (Quote 6). These findings align with a study by Borrot et al., which concluded that a strong sense of belonging during clinical placements could essentially enhance the student's workplace satisfaction.[17] In the context of this study, workplace satisfaction can be interpreted as equivalent to clinical placement satisfaction.

**Differences between minor and major departments**

Although the study indicates that students, who answered based on minor departments, felt less likely to belong to a group compared to students placed in major departments (n=5

vs. n=28; 24% vs. 37%) (Figure 5), an overwhelming majority felt more included in conversations at minor departments compared to major departments (n=20 vs. n=4; 95% vs 55%) (Figure 6). The study showed that compared to students at major departments, students at minor departments had less tendency to be concerned about going to lunch (n=38 vs. n=4; 51% vs. 19%) (Figure 7). Some students in the minor departments would rather eat lunch with fellow students, where in comparison, most students at major departments would rather eat lunch with their fellow students (n=3 vs. n=52; 10% vs. 69%) (Figure 8).

The findings suggest that minor departments foster more inclusive interactions, regardless of the students reporting a weaker sense of belonging to a group. The difference between the findings in minor and major departments could indicate that smaller departments are easier to socially navigate, as is reported in studies by Lampinen et al. and Radford et al., respectively.[10,11] This additionally supports that students may experience more frequent interactions with the BLS and staff when they are in the minor departments, therefore making the possibility of establishing interpersonal relationships easier, compared to the major departments. This is supported by Baumeister et al. whose study argues that the components of achieving belongingness consist of frequent positive interactions and stable long-term support.[21] This may explain why students in minor departments feel more included, as fewer employees can make interactions easier. Major departments may have fostered a greater sense of belonging due to more stable groups. In contrast, students in minor departments felt more included in conversations, supporting the idea that frequent positive interactions with diverse individuals enhance social connectedness without necessarily creating a deep sense of belonging. Furthermore, Baumeister et al. suggest that social interaction and inclusion do not always equal long-term emotional bonds, which are important for developing a sense of belonging and could possibly explain the tendencies seen in the questionnaire.[21]

When going to lunch, only a small group of students from the minor departments appeared concerned, while students from the major departments expressed more concerns. As previously mentioned, interactions can be easier to engage in with fewer employees,[10,11] which may explain the difference. This could also be reflected in the way that the students from the major departments would rather eat with their fellow students compared to the staff. It highlights the need for student groups while in CP. Student A and C interviews indicated that their fellow students and the choice between sitting with them versus the staff was more related to gaining energy and social support and catching a break from the CP. The likelihood of having fellow students at the CP in major departments is higher than at the minor ones, which could also explain the increased need for contact with fellow students.

**Study strengths and limitations**

The response rate in the questionnaire indicates good external validity. As shown in Table 1 and Figure 1, 2, 3 and 4, the demographics of students at minor vs. major departments did not differ, which indicates that no selection bias in this study. It is, however, observed that significantly more students based their responses on major departments, which may be because there are generally more CP positions in larger departments. As a result, more students have had placements and experiences in major departments. Based on this, drawing conclusions from the data on minor departments should be interpreted with caution, as they are underrepresented. Since students were asked to choose which department to base their responses on in the questionnaire, this imbalance could not be avoided. Allowing students to select the department they want to focus on ensures that the choice is not limited by external influence but rather reflects the experience they wish to

highlight. The responses will always represent a snapshot of how students felt at the specific moment when they completed the questionnaire.

Additionally, the students' demographics align with the target group and are, therefore, representative of all BLS students at UCL and OUH. This is evident based on the participants, gender, age, and number of students at each semester at UCL during the study. Since the BLS education in Denmark is predominantly female, the study group did not take the demographics of gender into account. The results in this study are self-reported, which creates a possibility for information bias. Efforts were made to minimize this by pretesting the questionnaire to ensure the comprehensibility of the questions. In the meantime, the risk of information bias cannot be entirely excluded since the study relied on students past clinical experiences causing a risk of recall bias.[22]

Another factor to consider is that the restrictions because of the COVID-19 pandemic were experienced by nearly all participants. This could impact the students' perceptions of the work environment and potentially lead to a biased view of socialization with staff. However, this was not explicitly mentioned by the students.

## Conclusion

The social dynamics within the lunchroom during CP's have a significant impact on student's experiences of their CP's. Students' perception of social groupings, inclusion, feeling of belonging, and concerns can all impact the perception of the department and of their own performance. These are factors that either enhance or diminish students' learning and well-being.

Social groupings can foster a sense of belonging or, conversely, contribute to feelings of exclusion among students. However, the sense of belonging does not necessarily depend on students being part of a group, but also on how each staff member includes them in informal conversations and overall if they contribute to making them feel welcome in the department. Inclusion impacts a students' learning ability positively, as it reduces concerns of social interactions in the lunchroom. The lunchroom provides social interaction, however, for students it still must remain a place where they are able to relax with fellow students and gain energy to continue the rest of the day.

Future considerations include evaluating initiatives for implementation across different departments, to enhance a stronger sense of belonging and improve the overall CP's for BLS students.

## Acknowledgments

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**Research article**

# Autoimmune Disease-Associated Reference Intervals for Routine Laboratory Tests Among Adult Outpatients

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***Background:*** **Current health-associated reference intervals (RIs) used in clinical practice are less applicable in patients with autoimmune diseases, creating the need for RIs aligned with the patient population. This study identified autoimmune disease-associated RIs and compared them to gold-standard RIs using analytical and biological variation.**
***Methods:*** **Retrospective data for 16 laboratory tests were collected on outpatients with diagnosis codes for 5 autoimmune diseases (rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), ulcerative colitis (UC), Crohn's disease (CD), and Hashimoto's thyroiditis (HASHD) to establish RIs, using the Clinical Laboratory Science Institute guidelines. The reference population delta was calculated between disease-associated and health-associated RIs to determine significance based on a defined critical z score.**
***Results:*** **Of the 1,023 patient records reviewed, most were white (85%, n = 848) females (80%, n = 818) between the ages of 45 and 64 (44%, n = 451). Rheumatoid arthritis (RA) was the most prevalent condition (43%, n = 437). Separate RIs were established for the populations based on sex, age, and ethnicity. Statistically significant RIs included: SLE-associated changes in red blood cells (RBC's), hemoglobin, and lymphocyte counts in females; SLE-associated albumin levels in diabetic patients; RA-associated hemoglobin in black, white, and older females; RA-associated RBC counts in males and females with cardiovascular disease; UC-associated changes in RBC, hemoglobin, and chloride in males; CD-associated hemoglobin in both sexes; CD-associated platelet count in males; and HASD-associated hemoglobin in females.**
***Conclusions:*** **The autoimmune diseases impact chloride, RBC, hemoglobin, platelet, and lymphocyte RIs, suggesting the respective disease-associated RIs could be used to improve laboratory-based clinical decisions.**

***Keywords:*** Confidence interval, systemic lupus erythematosus, ulcerative colitis, white blood cell, red blood cell, Hashimoto's thyroiditis, autoimmune thyroiditis, rheumatoid arthritis, alanine transaminase, aspartate transaminase, Crohn's disease.

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## Introduction

Population-based reference intervals (RIs) are the central 95% of measured values between, and including, an upper and lower cutoff value from a population with at least 120 reference individuals.[1] In accordance with the guidelines of the International Federation of Clinical Chemistry andand Laboratory Medicine (IFCC), RIs can either be established directly from a study of enrolled healthy participants or indirectly using statistics from patient results in a database. Additionally, the inclusion criteria of study participants can be applied either before (*a priori*), or after (*a posteriori*) specimen collection. If an RI is previously established in an alternate location or via the test manufacturer, laboratories should perform in-house verifications to ensure the adoption of the RI is applicable to the local patient population. Most laboratories opt for this approach since verifying RIs is less demanding on laboratory operations than establishing them. However, continual adoption of previously established RIs leaves the field of laboratory medicine with "studies performed decades ago, when both the analytical methods and populations were different."[1,2]

RIs are a hallmark in laboratory medicine, since physicians use them to compare patient data against healthy individuals, yet there are drawbacks. The definition of "healthy" is subjective and region-specific.[1] Therefore, the exclusion of truly "unhealthy" individuals cannot be achieved, risking patient misclassification from a possibly biased RI. Specimen selection, analytical variation, and biological variation can also independently impact a RI, and further amplify the error of RI comparison.[1] Depending on the literature from which the RI is adopted, such information may not be disclosed, and therefore the laboratory assumes congruency of these variables. This describes why RI adoption from previous literature is considered the lowest of the three quality model standards defined by the Stockholm Hierarchy of Models, and developed by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM).[3,4] Because medical comparisons using RIs can become less applicable and more elusive in patients with multiple comorbidities and medications, there is a need to interpret laboratory results to account for underlying conditions. For the most appropriate laboratory-based medical decision-making, approaches to reference intervals must be routinely revisited for improvements.

To overcome the obstacles in creating population-specific RIs, alternatives have been proposed, including common RIs, continuous RIs, and subject-based RIs. For common RIs, massive datasets from an assortment of laboratories and methodologies worldwide are compiled and analyzed to create universal intervals, consequently accounting for a majority of the analytical, geographical, and biological variation.[5] Continuous RIs reduce pediatric patient misclassification by replacing rigid age cutoffs with dynamic ranges for each age, based on physiological stages of human development.[5,6] Subject-based, or personalized RIs, compare one laboratory result to the previous result within a single individual for statistically significant changes.[5,7] Other research modifies the population-specific RI approach by applying it to subgroups of reference individuals instead of using healthy participants (i.e., age-specific, disease-associated, obesity-associated, or ethnic-specific RIs). In Norway, Mikkelsen et al. performed a disease-associated RI study to assess three tumor markers reported to be elevated in chronic kidney disease patients without clinical evidence of cancer. The results revealed no statistically significant difference between RIs of the healthy population and patients with chronic kidney disease.[8] However, another publication by the same investigators used the disease-associated RI approach to determine if patients with rheumatoid arthritis (RA), ulcerative colitis (UC), or Crohn's disease (CD), have different reference limits of laboratory tests between healthy subjects, and those with and without major comorbidities. They discovered a significant difference between disease-associated and health-associated RIs for non-specific inflammatory markers, along

with slight differences in RIs for patients with major comorbidities compared to the healthy population.[9] Inspired by Mikkelsen et al., this study aims to develop disease-associated RIs for RA, UC, CD, systemic lupus erythematosus (SLE), and Hashimoto's thyroiditis (HASHD) and use biological and analytical variation data to evaluate the significance between the gold-standard health-associated RIs. This data may be used to provide higher quality disease-associated reference intervals that improve the clinical classification of patients and help decipher whether the abnormal results should be attributed to an acute episode, or a chronic condition.

## Methods

*Sample selection*

To determine which analytes to include, the effects of the 5 autoimmune diseases on different laboratory tests were assessed. Typical pathophysiologic features in autoimmune conditions involve chronic recruitment of proinflammatory cytokines; predominant infiltration of mononuclear cells; tissue necrosis; and prolonged attempts of tissue repair via fibrosis, leading to clinical signs of malnutrition, anemia, cardiovascular issues, and protein abnormalities.[10,11] In RA and SLE, the produced autoantibodies are involved in the skin, heart, and blood vessels, and often lead to elevated positive acute phase reactants, reduced negative acute phase reactants, increased liver enzymes, underlying anemias, eosinophilia, and occasionally lymphocytosis.[10-13] Platelets and neutrophils are also affected depending on the disease and drug therapy.[11,13] Though SLE is an autoinflammatory condition, its effect on the positive acute phase reactant, C-reactive protein (CRP), is counterintuitive and only marginally increases.[14] HASHD, also named chronic lymphocytic thyroiditis, or autoimmune thyroiditis, is characterized by autoantibodies to thyroid antigens and lymphocytic infiltration of the thyroid, leading to megaloblastic anemia, hyperlipidemia, and hyponatremia.[15-18] Lastly, CD and UC are both inflammatory bowel diseases that reveal similar extraintestinal manifestations: malnutrition, hypoalbuminemia, electrolyte deficiencies, eosinophilia, and malabsorption of Vitamin B12 due to dehydration and diarrhea.[19,20] Based on these changes, 16 lab measurements were included that correlate with the diseases: albumin, aspartate transaminase (AST), alanine aminotransferase (ALT), sodium, chloride, total cholesterol, low density lipoprotein (LDL), CRP, red blood cell count (RBC), WBC, platelet, hemoglobin, absolute neutrophil count, absolute lymphocyte count, absolute eosinophil count, and Vitamin B12.

Data from the main laboratory were retrieved retrospectively from electronic medical records between January 2016 and August 2023. Adults (≥ 18 years of age) from a university hospital's outpatient clinics were selected by ICD-10-CM codes corresponding to their autoimmune disease. Pregnant individuals, patients with documented alcohol or drug abuse, prisoners, and patients with medical histories of cancers were excluded. Confounding variables such as self-reported race, ethnicity, and sex; age; body mass index (BMI); disease-modifying antirheumatic drugs (DMARDs); and triiodothyronine/thyroxine hormone replacement were collected, and assessed for significance to either stratify the RI, or remove it from the RI calculation. Comorbidity data for diabetes mellitus, chronic obstructive pulmonary disorder (COPD), cardiovascular disease (CVD), and chronic kidney disease were also analyzed for statistical differences. Supplemental Table 1 details the operational definitions for each variable collected. Ethical approval was obtained from the Institutional Review Board (IRB# 23-0238) with waived patient consent prior to data collection.

*Data analysis*

Results from the last documented patient encounter were collected based on the inclusion criteria, and any duplicates, results with incomplete information, or results analytically indicating acute inflammation or infection were excluded from further calculations. The

**Table 1.** Description of Sample Patient Population by Autoimmune Disease.

| | No. (%) of patients by disease | | | | |
|---|---|---|---|---|---|
| | **Rheumatoid arthritis (n = 437)** | **Systemic lupus erythematosus (n = 153)** | **Ulcerative colitis (n = 126)** | **Crohn's disease (n = 111)** | **Hashimoto's thyroiditis (n = 196)** |
| **Sex** | | | | | |
| Female | 361 (83) | 141 (92) | 70 (56) | 71 (64) | 175 (89) |
| Male | 76 (17) | 12 (8) | 56 (44) | 40 (36) | 21 (11) |
| **Race** | | | | | |
| White/Caucasian | 366 (84) | 109 (71) | 109 (87) | 92 (83) | 172 (88) |
| Black/African American | 65 (15) | 38 (25) | 13 (10) | 13 (12) | 19 (10) |
| Asian | 5 (1) | 4 (3) | 4 (3) | 3 (3) | 5 (3) |
| Alaskan/American Indian | 1 (<1) | 1 (1) | 0 (0) | 3 (3) | 0 (0) |
| Unknown | 0 (0) | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| **Ethnicity** | | | | | |
| Hispanic/Latino | 88 (20) | 37 (24) | 19 (15) | 19 (17) | 29 (15) |
| Not Hispanic/Latino | 341 (78) | 112 (73) | 105 (83) | 91 (82) | 163 (83) |
| Patient Refused | 1 (2) | 2 (1) | 0 (0) | 0 (0) | 1 (1) |
| Unknown | 7 (<1) | 2 (1) | 2 (2) | 1 (1) | 3 (2) |
| **Age Group** | | | | | |
| 18-24 | 11 (3) | 10 (7) | 10 (8) | 17 (15) | 11 (6) |
| 25-34 | 32 (7) | 28 (18) | 17 (14) | 20 (18) | 39 (20) |
| 35-44 | 66 (15) | 36 (24) | 22 (18) | 10 (9) | 47 (24) |
| 45-54 | 90 (21) | 37 (24) | 24 (19) | 21 (19) | 52 (27) |
| 55-64 | 132 (30) | 22 (14) | 27 (21) | 23 (21) | 23 (12) |
| 65+ | 106 (24) | 20 (13) | 26 (21) | 20 (18) | 24 (12) |
| **Cardiovascular Disease** | 199 (46) | 69 (45) | 43 (34) | 40 (36) | 69 (35) |
| **COPD** | 32 (73) | 8 (5) | 6 (5) | 4 (4) | 4 (2) |
| **Diabetes Mellitus** | 9 (2) | 5 (3) | 0 (0) | 2 (2) | 2 (1) |

*Percentages may not equate to 100 due to rounding.*

*Analyse-It Software*, Version 6.15.4, Ltd (Leeds, United Kingdom) was used for descryptive and inferential statistics. Normality was reviewed using a frequency density plot and the Shapiro-Wilk test.[21] Any non-Gaussian distributions were transformed using the logarithmic, or the Box-Cox method, then back-transformed to establish the parametric RIs. Outliers were identified using the Tukey detection method, and then removed based on clinical indication, effects from comorbidities or medications, and visual inspection. Covariates were then nonparametrically assessed for either removal, or partitioning. The Mann-Whitney U test was used to assess the significance of age (adults and geriatric adults), and sex variables. The Kruskal-Wallis test was used to assess race and ethnicity. RIs for each test were established in triplicate using the parametric, simple nonparametric, and Harrell-Davis nonparametric technique. In cases of

sample size (n) ≤ 120 and ≥ 40, the simple non-parametric method was bootstrapped with 1,000 repetitions. For 20 ≤ n < 40, the Robust method was used, and for n < 20, an RI was not established, as this can be impractical.[1] Once derived, the RI method producing the narrowest 90% confidence interval (CI) for the limit of interest was selected for further data analysis. The widths of the 90% CIs were then compared to the widths of the RIs themselves (width ratio, *w*) to assess the RI relevance. If $w \geq 0.20$, the CI is too wide for the RI to be practical, and additional samples are recommended.[1]

Statistical significance between RIs of the established disease-associated reference limits ($RL_E$), and the published health-associated reference limits ($RL_P$) was determined using the reference population delta (RPΔ) (Equation 1) — a rearranged version of the reference change value (RCV) formula with the addition of between-subject biological variation.[22] Historically, the RCV determines significance between two consecutive laboratory results within a single patient. The RCV equation also requires dispersion expressed as Standard Deviation (SD) for calculation, but since the ratio and the sum of normally distributed variables are not equal, a transformation is required from coefficient of variation (CV) to SD based on Equation 2, then calculated using an alternate RCV equation.[22] The university laboratory provided analytical variation ($CV_A$), and the EFLM database houses ample data for within-subject biological variation ($CV_I$), and between-subject biological variation ($CV_G$).

Equation 1: $$RP\Delta_{decimal} = \exp\left(\pm z \times \sqrt{2} \times \sqrt{SD_A^2 + SD_I^2 + SD_G^2}\right) - 1$$

Equation 2: $$SD^2 = ln\left[(\%CV/100)^2 + 1\right]$$

An autoimmune disease-associated RI was considered significantly different from the health-associated RI if the $RL_E$ was not producible from the RPΔ applied to the $RL_P$ (i.e., the reference limit of the autoimmune disease falls beyond the allowable variation of the healthy population reference limit). This is empirically expressed as $RL_E = RL_P \times (1 + RP\Delta)$, then rearranged to determine the *z* score (Equation 3).

Equation 3: $$\pm z = \frac{ln(RL_E / RL_P)}{\sqrt{2} \times \sqrt{SD_A^2 + SD_I^2 + SD_G^2}}$$

The computed *z* scores from Equation 3 were compared to the defined critical *z* values for each analyte (Supplemental Table 2). Since autoimmune diseases affect each analyte differently, a positive, or negative unidirectional change per analyte was expected; therefore, critical *z* values at $\alpha = 0.05$ were defined at +1.65, or -1.65. Only neutrophil and platelet in RA have been reported to be bidirectional; thus, $\alpha = 0.05$ was defined at ±1.96. Statistical significance was defined as the observed $|z| \geq$ critical $|z|$ for each RI.

The index of individuality (IoI) for each analyte was calculated using the same analytical and biological variation data to assess the usefulness of the population-based RI. An IoI < 0.6, has more variation between subjects than within subjects and the analytical system; therefore, results could be abnormal for an individual, yet still found within the normal interval.[22,23] In this case, a subject-based (personalized) RI is more appropriate. An IoI > 1.4, has more variation within subjects and analytical system than between subjects, suggesting the population-based RI is more clinically useful.[22,23]

## Results

*Population demographics*

A total of 1,023 outpatient medical records were evaluated, after excluding 74 records of moderate to end-stage chronic kidney disease, and two records of hemoglobin less than 7 mg/dL. The sample population was 80% (818/1,023) female, 83% (848/1,023) White, and 44% (451/1,023) between the ages of 45 to 64. The most prevalent diseases were RA at 43% (437/1,023), and HASHD at 19% (196/1,023). Outpatients with diagnosis codes related to cardiovascular disease (CVD) included 41% (420/1,023) of the overall sample, followed by

**Table 2.** Autoimmune Disease-Associated Reference Intervals by Analyte and Statistical Method

| | | | | | Reference Interval | | |
|---|---|---|---|---|---|---|---|
| | | | | | Parametric | Simple nonparametric | Harrell-Davis nonparametric |
| Analyte (unit) | Disease | | n | Mdn | LRL (90% CI)<br>URL (90% CI) | LRL (90% CI)<br>URL (90% CI) | LRL (90% CI)<br>URL (90% CI) |
| Albumin (g/dL) | RA | | | | | | |
| | | Female | 258 | 4.2 | 3.3 (3.2-3.4)<br>4.8 (4.8-4.9) | 3.2 (2.7-3.5)<br>4.9 (4.7-5.1) | 3.2 (2.8-3.4)<br>4.9 (4.7-5.0) |
| | | Male | 55 | 4.3 | 3.7 (3.6-3.8)<br>4.9 (4.8-5.0) | 3.8 (3.7-3.8)[b]<br>5.1 (4.8-5.3)[b] | 3.8 (3.7-3.9)<br>5.1 (4.8-5.3) |
| | SLE | | | | | | |
| | | w/o Diabetes | 88 | 4.3 | Fails normality<br>Fails normality | 3.3 (3.2-3.5)[b]<br>5.1 (4.8-5.2)[b] | 3.3 (3.3-3.5)<br>5.1 (4.9-5.2) |
| | | with Diabetes | 21 | 4.1 | 2.9 (2.6-3.4)[a]<br>5.1 (4.8-5.3)[a] | Not established<br>Not established | 3.0 (3.0-3.2)<br>4.6 (4.5-4.6) |
| | UC | | 93 | 4.4 | 3.5 (3.3-3.6)<br>5.0 (4.9-5.1) | 3.2 (2.7-3.7)[b]<br>5.0 (4.9-5.1)[b] | 3.2 (2.8-3.7)<br>5.0 (4.9-5.1) |
| | CD | | 91 | 4.4 | 3.4 (3.2-3.5)<br>5.0 (4.9-5.0) | 3.2 (2.9-3.6)[b]<br>5.0 (4.9-5.2)[b] | 3.2 (3.0-3.6)<br>5.0 (4.9-5.2) |
| ALT (U/L) | RA | | | | | | |
| | | Adult | 161 | 22 | 11 (10-12)<br>71 (60-86) | 11 (8-13)<br>81 (60-92) | 11 (10-13)<br>78 (62-88) |
| | | Geriatric | 59 | 18 | 9 (8-10)<br>60 (45-86) | 9 (8-11)[b]<br>76 (41-97)[b] | 9 (8-11)<br>77 (40-93) |
| | SLE | | 81 | 19 | 10 (9-11)<br>50 (42-60) | 10 (8-11)[b]<br>58 (40-71)[b] | 10 (9-11)<br>57 (42-68) |
| | HASHD[c] | | 117 | 22 | 10 (10-11)<br>68 (55-85) | 11 (9-12)[b]<br>70 (53-88)[b] | 11 (10-12)<br>70 (55-81) |
| | | Female | 104 | 21 | 10 (10-11)<br>61 (50-78) | 10 (9-12)[b]<br>61 (51-88)[b] | 10 (10-12)<br>61 (52-78) |
| | | Male | 13 | 33 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| AST (U/L) | RA | | 220 | 29 | 18 (17-18)<br>59 (54-66) | 18 (16-19)<br>63 (56-76) | 18 (17-19)<br>63 (56-70) |
| | SLE | | 81 | 26 | 18 (17-19)<br>55 (47-66) | 18 (17-19)<br>57 (46-63) | 18 (17-19)<br>57 (46-62) |
| | HASHD[c] | | 117 | 26 | 18 (17-18)<br>57 (49-69) | 17 (16-18)[b]<br>62 (52-68)[b] | 17 (16-18)<br>62 (53-66) |
| | | Female | 104 | 26 | 8 (6-11)<br>48 (45-50) | 17 (16-18)[b]<br>62 (51-68)[b] | 17 (16-18)<br>62 (50-66) |
| | | Male | 13 | 31 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| Chloride (mmol/L) | UC | | | | | | |
| | | Female | 55 | 104 | 96 (94-98)<br>108 (108-109) | 95 (94-97)[b]<br>108 (108-109)[b] | 95 (94-99)<br>108 (108-109) |
| | | Male | 44 | 102 | 93 (88-96)<br>107 (106-108) | 89 (87-96)[b]<br>107 (107-107)[b] | 90 (87-97)<br>107 (106-107) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | CD | | 94 | 103 | 97 (97-98)<br>108 (107-109) | 96 (95-98)[b]<br>109 (107-111)[b] | 96 (95-98)<br>109 (107-110) |
| Cholesterol, total (mg/dL) | HASHD | | 54 | 200 | 121 (102-139)<br>262 (251-273) | 107 (91-138)<br>269 (251-281) | 107 (94-146)<br>269 (246-279) |
| CRP (mg/dL) | RA | | 204 | 0.5 | Not applicable<br>Fails normality | Not applicable<br>3.0 (2.1-7.3) | Not applicable<br>3.3 (2.3-5.5) |
| | SLE[c] | | 45 | 0.6 | Not applicable<br>4.4 (2.6-7.6) | Not applicable<br>4.5 (3.2-5.4)[b] | Not applicable<br>4.5 (2.7-5.3) |
| | UC | | 34 | 0.4 | Not applicable<br>2.1 (1.3-3.2)[a] | Not applicable<br>Not established | Not applicable<br>2.2 (1.6-2.4) |
| | CD | | 35 | 0.4 | Not applicable<br>3.3 (2.6-8.2)[a] | Not applicable<br>Not established | Not applicable<br>2.5 (1.8-2.7) |
| Eosinophil, absolute ($10^3$/µL) | RA | | | | | | |
| | | Female | 253 | 0.14 | Fails normality<br>Fails normality | 0.03 (0.03-0.03)<br>0.49 (0.39-0.54) | 0.03 (0.03-0.03)<br>0.49 (0.41-0.54) |
| | | Male[c] | 56 | 0.20 | 0.00 (0.00-0.02)<br>0.43 (0.39-0.48) | 0.03 (0.03-0.04)[b]<br>0.48 (0.39-0.51)[b] | 0.03 (0.03-0.05)<br>0.48 (0.37-0.51) |
| | UC | | | | | | |
| | | Female | 41 | 0.15 | 0.02 (0.01-0.04)<br>0.46 (0.38-0.56) | 0.02 (0.01-0.03)[b]<br>0.50 (0.37-0.54)[b] | 0.02 (0.01-0.04)<br>0.50 (0.34-0.53) |
| | | Male | 38 | 0.14 | 0.04 (0.03-0.05)[a]<br>0.42 (0.36-1.07)[a] | Not established<br>Not established | 0.04 (0.03-0.07)<br>0.42 (0.28-0.46) |
| | CD | | | | | | |
| | | Female | 53 | 0.15 | 0.05 (0.04-0.06)<br>0.55 (0.43-0.72) | 0.05 (0.04-0.06)[b]<br>0.51 (0.43-0.56)[b] | 0.05 (0.04-0.06)<br>0.51 (0.42-0.55) |
| | | Male | 32 | 0.14 | 0.04 (0.02-0.04)[a]<br>0.51 (0.39-0.82)[a] | Not established<br>Not established | 0.04 (0.04-0.05)<br>0.52 (0.27-0.57) |
| Hemoglobin (g/dL) | RA | | | | | | |
| | | Female | 265 | 13.0 | 9.1 (8.6-9.5)<br>15.4 (15.2-15.6) | 9.0 (8.0-9.5)<br>15.3 (14.9-16.2) | 9.0 (8.4-9.4)<br>15.3 (14.9-15.9) |
| | | Black, F | 40 | 12.4 | 9.3 (8.6-10.0)<br>15.5 (14.8-16.2) | 9.1 (8.7-10.0)[b]<br>15.7 (14.3-16.2)[b] | 9.1 (8.8-10.3)<br>15.7 (14.2-16.1) |
| | | White, F | 214 | 13.1 | 9.2 (8.6-9.7)<br>15.5 (15.2-15.7) | 9.2 (7.9-9.6)<br>15.4 (14.9-16.2) | 9.1 (8.4-9.5)<br>15.3 (15.0-15.8) |
| | | Adult, F | 207 | 13.1 | 9.5 (9.0-9.9)<br>15.5 (15.3-15.7) | 9.4 (8.0-10.0)<br>15.5. (14.9-16.2) | 9.3 (8.6-9.9)<br>15.5 (15.0-16.1) |
| | | Geriatric, F | 58 | 12.3 | 8.7 (8.0-9.3)<br>15.5 (14.8-16.1) | 8.4 (7.9-9.1)[b]<br>14.9 (14.5-15.2)[b] | 8.4 (8.0-9.2)<br>14.9 (14.4-15.1) |
| | | Male[c] | 55 | 14.8 | 10.9 (10.3-11.6)<br>17.9 (17.2-18.5) | 9.9 (9.0-11.2)[b]<br>17.4 (16.4-18.0)[b] | 9.9 (9.2-11.4)<br>17.4 (16.3-17.9) |
| | SLE | | | | | | |
| | | Female[c] | 113 | 13.2 | 7.7 (5.8-9.0)<br>15.3 (15.1-15.5) | 7.9 (7.1-9.3)[b]<br>15.2 (14.9-15.5)[b] | 7.8 (7.3-9.1)<br>15.2 (14.9-15.4) |
| | | Male | 9 | 12.9 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | UC | | | | | | |
| | | Female | 48 | 13.5 | 10.8 (10.3-11.4)<br>15.9 (15.4-16.4) | 10.8 (10.7-11.1)[b]<br>15.9 (15.2-16.1)[b] | 10.8 (10.7-11.2)<br>15.9 (15.1-16.1) |
| | | Male | 38 | 14.4 | 9.1 (5.6-10.2)[a]<br>17.0 (16.8-17.4)[a] | Not established<br>Not established | 9.4 (9.2-10.8)<br>16.8 (16.3-17.0) |
| | CD | | | | | | |
| | | Female | 56 | 12.9 | Fails normality<br>Fails normality | 9.1 (8.1-10.5)[b]<br>16.2 (14.7-16.8)[b] | 9.1 (8.3-10.7)<br>16.3 (14.6-16.7) |
| | | Male | 32 | 14.0 | 9.5 (7.3-10.2)[a]<br>17.2 (16.8-18.1)[a] | Not established<br>Not established | 10.2 (9.9-11.2)<br>16.8 (16.2-16.9) |
| | | Adult, M | 26 | 14.4 | 10.1 (8.3-11.6)<br>17.0 (16.4-17.6) | Not established<br>Not established | 10.2 (9.9-12.2)<br>16.8 (16.2-16.9) |
| | HASHD | | | | | | |
| | | Female[c] | 125 | 13.4 | 10.1 (9.5-10.6)<br>15.5 (15.3-15.8) | 9.5 (9.3-10.6)<br>15.6 (15.1-16.2) | 9.8 (9.5-10.5)<br>15.6 (15.2-16.0) |
| | | Male | 17 | 14.9 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| LDL (mg/dL) | HASHD | | 51 | 115 | Not applicable<br>163 (153-173) | Not applicable<br>167 (157-183) | Not applicable<br>166 (154-177) |
| Lymphocyte, absolute ($10^3$/µL) | RA | | | | | | |
| | | Female | 254 | 1.9 | 0.7 (0.6-0.8)<br>3.8 (3.6-4.0) | 0.6 (0.4-0.8)<br>3.9 (3.5-4.6) | 0.6 (0.5-0.8)<br>3.9 (3.5-4.4) |
| | | Adult, F | 198 | 2.0 | 0.7 (0.6-0.8)<br>4.0 (3.7-4.2) | 0.5 (0.4-0.8)<br>4.0 (3.7-5.4) | 0.6 (0.4-0.8)<br>4.1 (3.7-4.8) |
| | | Geriatric, F | 53 | 1.6 | 0.4 (0.2-0.7)<br>2.9 (2.6-3.1) | 0.7 (0.6-0.8)[b]<br>3.0 (2.8-3.1)[b] | 0.7 (0.6-0.8)<br>3.0 (2.7-3.0) |
| | Male | | 56 | 1.8 | 0.5 (0.2-0.7)<br>3.2 (3.0-3.5) | 0.6 (0.4-0.9)[b]<br>3.3 (3.1-3.5)[b] | 0.6 (0.4-0.9)<br>3.3 (3.0-3.4) |
| | SLE | | | | | | |
| | | Female | 103 | 1.9 | 0.7 (0.6-0.8)<br>3.7 (3.4-4.0) | 0.6 (0.5-0.7)[b]<br>3.8 (3.3-4.5)[b] | 0.6 (0.5-0.8)<br>3.8 (3.3-4.2) |
| | | Male | 9 | 1.3 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| Neutrophil, absolute ($10^3$/µL) | RA | | | | | | |
| | | Female | 252 | 4.20 | 1.74 (1.61-1.89)<br>10.14 (9.38-10.96) | 1.64 (1.35-2.00)<br>10.82 (9.13-11.30) | 1.67 (1.46-1.95)<br>10.61 (9.47-11.32) |
| | | Black, F | 46 | 3.33 | 1.44 (1.23-1.69)<br>10.39 (7.96-13.86) | 1.44 (1.30-1.69)[b]<br>10.34 (8.09-10.87)[b] | 1.43 (1.32-1.77)<br>10.34 (7.61-10.81) |
| | | White, F | 202 | 4.33 | 1.90 (1.74-2.07)<br>9.92 (9.16-10.73) | 1.88 (1.35-2.22)<br>10.45 (8.64-11.3) | 1.87 (1.56-2.21)<br>10.31 (9.18-11.23) |
| | Male | | 50 | 4.72 | 2.03 (1.69-2.44)<br>10.91 (9.33-12.74) | 1.90 (1.66-2.47)[b]<br>11.08 (9.66-11.91)[b] | 1.88 (1.70-2.67)<br>11.07 (9.16-11.77) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SLE | | | | | | |
| | | Female | 109 | 4.22 | 1.64 (1.43-1.87)<br>9.49 (8.51-10.57) | 1.51 (1.22-2.01)[b]<br>9.92 (8.17-12.21)[b] | 1.51 (1.30-1.99)<br>9.94 (8.18-11.28) |
| | | Male | 9 | 3.78 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| Platelet ($10^3$/μL) | RA | | | | | | |
| | | Female | | | | | |
| | | w/o CVD, F | 89 | 280 | 134 (111-157)<br>437 (414-460) | 154 (127-171)[b]<br>462 (437-483)[b] | 153 (135-176)<br>462 (430-477) |
| | | with CVD, F | 168 | 255 | 109 (92-126)<br>417 (400-434) | 110 (62-137)<br>450 (406-498) | 111 (95-129)<br>448 (411-479) |
| | | Male | 58 | 238 | 126 (102-150)<br>380 (356-404) | 134 (115-162)[b]<br>399 (364-420)[b] | 134 (118-165)<br>399 (363-416) |
| | SLE | | | | | | |
| | | Female | 111 | 265 | 135 (121-150)<br>461 (431-493) | 121 (97-157)[b]<br>499 (421-560)[b] | 121 (103-154)<br>499 (424-544) |
| | | Male | 9 | 215 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| | UC | | | | | | |
| | | Female | 52 | 279 | 142 (116-167)<br>403 (377-429) | 153 (134-180)[b]<br>388 (380-391)[b] | 153 (137-181)<br>388 (374-390) |
| | | Male | 37 | 235 | 117 (93-130)[a]<br>425 (398-500)[a] | Not established<br>Not established | 118 (108-148)<br>419 (354-432) |
| | CD | | | | | | |
| | | Female | 61 | 292 | 169 (153-186)<br>493 (445-545) | 167 (163-184)[b]<br>521 (424-557)[b] | 167 (163-188)<br>521 (423-549) |
| | | Male | 32 | 269 | 154 (135-165)[a]<br>624 (517-879)[a] | Not established<br>Not established | 160 (151-190)<br>571 (446-587) |
| | HASHD | | | | | | |
| | | Female | 124 | 264 | 144 (127-160)<br>400 (383-416) | 156 (135-170)<br>433 (383-447) | 157 (145-168)<br>426 (391-439) |
| | | Male | 17 | 229 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| RBC ($10^6$/μL) | RA | | | | | | |
| | | Female | | | | | |
| | | w/o CVD, F | 97 | 4.40 | 3.33 (3.10-3.53)<br>5.23 (5.13-5.33) | 3.20 (3.03-3.53)[b]<br>5.22 (5.13-5.31)[b] | 3.19 (3.09-3.53)<br>5.22 (5.12-5.29) |
| | | with CVD, F | 155 | 4.28 | 3.24 (3.12-3.37)<br>5.38 (5.26-5.50) | 3.00 (2.56-3.32)<br>5.25 (5.15-5.54) | 3.08 (2.86-3.50)<br>5.27 (5.15-5.40) |
| | Male | | 55 | 4.82 | 3.55 (3.31-3.79)<br>6.02 (5.78-6.26) | 3.45 (3.26-3.74)[b]<br>6.13 (5.86-6.34)[b] | 3.45 (3.29-3.82)<br>6.13 (5.78-6.30) |
| | SLE | | | | | | |
| | | Female | 103 | 4.46 | 3.25 (3.01-3.47)<br>5.22 (5.12-5.31) | 3.00 (2.07-3.67)[b]<br>5.26 (5.01-5.60)[b] | 3.01 (2.39-3.59)<br>5.25 (5.01-5.49) |
| | | Male | 9 | 4.43 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |

| | | | | | | |
|---|---|---|---|---|---|---|
| | UC | | | | | |
| | Female[c] | 51 | 4.53 | 3.72 (3.56-3.88)<br>5.30 (5.14-5.46) | 3.70 (3.60-3.86)[b]<br>5.44 (5.29-5.54)[b] | 3.70 (3.62-3.91)<br>5.44 (5.19-5.52) |
| | Male | 38 | 4.66 | 3.42 (3.10-3.77)[a]<br>6.07 (5.76-6.33)[a] | Not established<br>Not established | 3.17 (3.09-3.66)<br>5.72 (5.50-5.76) |
| | CD | | | | | |
| | Female | 63 | 4.42 | 3.67 (3.54-3.81)<br>5.21 (5.07-5.34) | 3.62 (3.49-3.89)[b]<br>5.36 (5.04-5.52)[b] | 3.62 (3.52-3.89)<br>5.36 (5.03-5.49) |
| | Male[c] | 33 | 4.66 | 3.54 (3.24-3.66)[a]<br>6.17 (5.89-6.90)[a] | Not established<br>Not established | 3.71 (3.68-3.88)<br>5.94 (5.50-5.98) |
| | HASHD | | | | | |
| | Female | 124 | 4.51 | 3.52 (3.36-3.66)<br>5.32 (5.22-5.41) | 3.26 (3.11-3.66)<br>5.33 (5.08-5.85) | 3.37 (3.19-3.62)<br>5.37 (5.12-5.65) |
| | Hispanic, F | 22 | 4.79 | 3.62 (3.29-4.05)[a]<br>5.88 (5.55-6.18)[a] | Not established<br>Not established | 3.73 (3.70-4.07)<br>5.79 (5.28-5.84) |
| | Non-Hispanic, F | 71 | 4.44 | 3.49 (3.28-3.69)<br>5.07 (4.97-5.16) | 3.33 (3.18-3.64)[b]<br>5.09 (4.91-5.27)[b] | 3.34 (3.21-3.65)<br>5.09 (4.92-5.23) |
| | Male | 17 | 4.98 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| Sodium (mmol/L) | UC | | | | | |
| | Female | 56 | 140 | 135 (134-136)<br>145 (144-145) | 133 (131-136)[b]<br>144 (144-144)[b] | 133 (131-136)<br>144 (143-144) |
| | Male | 41 | 138 | 132 (131-134)<br>143 (142-144) | 132 (131-133)[b]<br>143 (141-143)[b] | 132 (131-133)<br>143 (141-143) |
| | CD | 94 | 139 | 134 (133-135)<br>144 (143-145) | 134 (132-135)[b]<br>145 (143-146)[b] | 134 (133-135)<br>145 (143-146) |
| | HASHD | 152 | 139 | 135 (134-135)<br>143 (143-143) | 134 (134-135)<br>144 (142-144) | 134 (134-135)<br>144 (142-144) |
| Vitamin B12 (pg/mL) | UC | 40 | 539 | 184 (97-272)<br>961 (874-1049) | 278 (261-336)[b]<br>984 (882-1000)[b] | 277 (263-345)<br>983 (868-998) |
| | CD | 31 | 520 | Fails normality<br>Fails normality | Not established<br>Not established | 294 (292-307)<br>971 (885-984) |
| WBC ($10^3$/μL) | RA | | | | | |
| | Female | 261 | 7.1 | 3.8 (3.5-4.0)<br>13.8 (13.0-14.6) | 4.1 (3.8-4.2)<br>14.9 (12.8-16.5) | 4.1 (3.8-4.2)<br>14.8 (13.3-16.0) |
| | Black, F | 40 | 5.7 | 3.1 (2.8-3.5)<br>12.4 (10.2-15.4) | 3.1 (2.9-4.0)[b]<br>11.6 (11.1-11.8)[b] | 3.1 (2.9-4.1)<br>11.6 (10.6-11.8) |
| | White, F | 210 | 7.2 | 4.2 (4.0-4.5)<br>14.4 (13.2-15.9) | 4.2 (4.1-4.7)<br>15.1 (12.8-16.5) | 4.3 (4.1-4.6)<br>14.7 (12.8-15.9) |
| | Male | 56 | 7.4 | 4.1 (3.6-4.5)<br>15.3 (13.3-17.7) | 4.1 (3.9-4.6)[b]<br>14.6 (13.4-15.0)[b] | 4.1 (3.9-4.7)<br>14.6 (13.1-15.0) |
| | SLE | | | | | |
| | Female | 112 | 6.7 | 3.0 (2.7-3.4)<br>13.2 (12.2-14.2) | 2.9 (2.1-3.4)[b]<br>13.8 (12.3-15.8)[b] | 2.9 (2.4-3.4)<br>13.8 (12.3-15.0) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | Male | 9 | 5.9 | Not established<br>Not established | Not established<br>Not established | Not established<br>Not established |
| | UC | | | | | | |
| | | Female | 52 | 7.1 | 4.2 (3.9-4.6)<br>14.0 (12.0-16.6) | 4.2 (4.0-4.6)[b]<br>14.4 (11.5-15.9)[b] | 4.2 (4.1-4.7)<br>14.4 (11.2-15.6) |
| | | Male[c] | 33 | 6.4 | 3.2 (2.6-3.9)[a]<br>9.6 (8.9-10.5)[a] | Not established<br>Not established | 3.7 (3.7-4.2)<br>8.9 (8.3-9.0) |
| | CD | | | | | | |
| | | Female | 62 | 6.7 | 3.7 (3.3-4.1)<br>13.0 (11.5-14.6) | 3.7 (3.4-4.3)[b]<br>12.7 (11.2-13.9)[b] | 3.7 (3.5-4.4)<br>12.7 (11.1-13.6) |
| | | Male | 32 | 7.2 | 3.8 (3.2-4.1)[a]<br>12.6 (11.8-14.5)[a] | Not established<br>Not established | 4.1 (4.1-4.7)<br>11.7 (10.9-11.8) |

*Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; CD, Crohn's disease; CI, confidence interval; CRP, C-reactive protein; CVD, cardiovascular disease; F, female; HASHD, Hashimoto's thyroiditis; LDL, low density lipoprotein; LRL, lower reference limit; M, male; Mdn, median; n, sample size; RA, rheumatoid arthritis; RBC, red blood cell; SLE, systemic lupus erythematosus; UC, ulcerative colitis; URL, upper reference limit; WBC, white blood cell.*

*[a]Derived using the Robust method described in CLSI-EP28-A3c, and using 1000 bootstrap replications.*

*[b]Derived using the Bootstrapped method, based on 1000 replications.*

*[c]A subpopulation within this sample was found to be significant, but could not be partitioned because of too small sample sizes; the subpopulation may have an over- or under-estimated reference limit.*

chronic obstructive pulmonary disease comprising 5% (54/1,023). 14% (147/1,023) of outpatients had at least two comorbidities, and about 1% (14/1,023) of outpatients had all three comorbidities. The most prevalent age groups were 35 to 54 for SLE; 45 to 54 for HASHD; 55 to 64 for RA and CD; and above 54 for UC. Table 1 summarizes the population demographics for each autoimmune disease.

*Autoimmune disease-associated RIs*

Table 2 depicts the RIs established in triplicate for each disease, analyte, and any partitioned demographic. In RA, albumin was significant by sex, $z$ = 2.42, $P$ = .015, with an effect size of 0.14, and males having an increased lower limit than females. ALT by age demographic was significant, $z$ = -2.87, $P$ = .004, and a small effect size of -0.19; adults had a lower ALT median than geriatric outpatients. Eosinophils in males by age demographic was significant, $z$ = -2.09; $P$ = .04, and small effect size of -0.28. However, the RI for geriatric males could not be established due to n < 20. The eosinophil median for geriatric males was 0.15 x$10^3$/µL, and for adult males was 0.21 x$10^3$/µL. Hemoglobin was partitioned by race and age in females, and significant by age in males. Black and White females were found to be different with $x^2_2$ = 11.86, $P$ = .005. Despite these RIs having almost identical limits, the median for Black females was lower than the median for White females. Hemoglobin in females by age was significant, $z$ = -3.20, $P$ = .001 with a small effect size of -0.20. Males by age was significant, $z$ = -2.01, $P$ = 0.045 with a small effect size of -0.27, yet an RI for geriatric males was not established because of low sample sizes; adult males had a hemoglobin median of 15.1 g/dL, and geriatric males had a median of 14.0 g/dL. Lymphocyte was significant in females by age group, $z$ = -2.95, $P$ = .003, and effect size of -0.19; the median for geriatric females was lower than the median for adult females. Platelet in females diagnosed with CVD compared to those not diagnosed with CVD was significant, $z$ = -2.00, $P$ = .046, and a small effect size of -0.13. Neutrophils in females was also partitioned by race, $x^2_2$ = 10.2, $P$ = .006, and Black females had a decreased, lower reference limit and median than White females. WBC in females was significant, $x^2_2$ = 10.4, $P$ = .006, with Black female patients having a wider RI.

In SLE, CRP by ethnicity was significant, $x^2_2$ = 6.16, *P* = 0.04. The median for non-Hispanics was 0.8 mg/dL and the median for Hispanics was 0.3 mg/dL, but an RI for the latter could not be established due to n < 20. Hemoglobin was also significant by age in females, *z* = 2.12, *P* = .034, with a small effect size of 0.20, but due to a low sample size, the geriatric RI was not established. Geriatric females had a higher median, 13.9 g/dL, than adult females, 13.0 g/dL. Albumin was partitioned for diabetics, *z* = -2.74, *P* = .006, and a small effect size of -0.26; the median for diabetes-diagnosed patients was higher than in those not diagnosed with diabetes.

In UC, chloride was partitioned by sex, *z* = -2.60, *P* = .009, with a small effect size of -0.26; the lower reference limit for males was lower compared to females. RBC in females was significant by ethnicity, $x^2_2$= 9.63, *P* = .016; however, due to low sample sizes for each ethnic group, separate RIs could not be established. Hispanic females had a higher median at 4.78 $x10^6$/µL, than non-Hispanics at 4.49 $x10^6$/µL. Sodium by sex was significant, *z* = -3.14, *P* = .002, and a moderate effect size of -0.31, despite the RI being almost identical between sexes. WBC in males was significant by ethnicity, *z* = -2.15, *P* = .032 with a moderate effect size of -0.37; however, a separate RI could not be established. Hispanic males had a higher median of 8.12 $x10^3$/µL, compared to non-Hispanic males with a median of 6.18 $x10^3$/µL.

In CD, hemoglobin in males was significant by age group, *z* = -2.17, *P* = .030, with a moderate effect size of -0.38. Low sample sizes in geriatric males prevented RI establishment; therefore, they may be overestimated with median of 11.7 g/dL, compared to adult males, median of 14.4 g/dL. RBC in males by ethnicity was significant, *z* = -2.01, *P* = .044, with a moderate effect size of -0.35. Similarly, Hispanic males had a low sample size preventing the establishment of this RI; therefore, this subpopulation was underestimated. The median for Hispanic males was 5.20 $x10^6$/µL, but for non-Hispanic males was 4.58 $x10^6$/µL.

In HASHD, ALT and AST by sex was significant, *z* = 3.50, *P* < .001, and a moderate effect size of 0.32 for ALT; and *z* = 2.61, *P* = .009, and a small effect size of 0.24 for AST. Hemoglobin in females was significant by race; $x^2_2$ = 10.77, *P* = .003; however, the RI for Black females was not established because n < 20. The median for Black females was 12.1 g/dL, and the median for White females was 13.5 g/dL. Lastly, RBC in females was partitioned by ethnicity, $x^2_2$ = 8.38, *P* = .015, and Hispanic females had slightly higher medians and reference limits than non-Hispanic females.

*Significance of autoimmune disease-associated RIs*

Table 3 lists the established RIs, the selected establishment technique, calculated *z* scores, respective *P* values, and width ratios. The sources of published RIs with their respective analytical and biological variation data are found in Supplemental Table 3. Comparisons of the disease-associated to health-associated RIs revealed *P* < .001 for hemoglobin RIs in females with SLE, and in geriatric females with RA. Results with *P* < .01 included the RBC RI in males with UC; and the hemoglobin RIs in Black and White females with RA, males with UC, and females with CD. Significance with *P* < .05 was found for the albumin RI for diabetic patients with SLE; chloride RI in males with UC; platelet RI in males with CD; lymphocyte RI in females with SLE; hemoglobin RIs in both males with CD and females with HASHD; and RBC RIs in females with SLE, males with RA, and females with CVD. Ethnicity was significant in RIs for RBC, CRP, and WBC; however, they could not be established for Hispanics due to insufficient data.

Of the significant RIs, the RA-associated hemoglobin RIs had *w* < 0.20, suggesting narrow enough CIs to attest to the significances. For females in both the HASHD-associated hemoglobin RI, and the SLE-associated lymphocyte RI, the width ratios are low at *w* = 0.172 and *w* = 0.067 respectively. The RA-associated RBC RI in males was also significant and contained a satisfactory width ratio, *w* =

0.194. Conversely, the SLE-associated hemoglobin RI in females was the most statistically significant finding, yet it had an unsatisfactory width ratio, $w$ = 0.243, despite having n = 113. Of the remaining significant RIs, CD-associated hemoglobin, CD-associated platelets in males, SLE-associated RBCs in females, UC-associated RBCs in males, and UC-associated chloride in males similarly had unsatisfactory width ratios.

**Table 3.** Statistical Significance of Autoimmune Disease-Associated Reference Intervals by Analyte

| Analyte (unit) | Disease, demographic | Established RI | Selected technique | *z* | *P* | *w* |
|---|---|---|---|---|---|---|
| Albumin (g/dL) | RA | | | | | |
| | Female | 3.3-4.8 | Parametric | -0.74 | .23 | 0.133 |
| | Male | 3.8-5.1 | Nonparametric (Simple) | 1.03 | .85 | 0.077 |
| | SLE | | | | | |
| | w/o Diabetes | 3.3-5.1 | Nonparametric (Harrell-Davis) | -0.74 | .23 | 0.111 |
| | with Diabetes | 3.0-4.6 | Nonparametric (Harrell-Davis) | -1.93* | .03 | 0.125 |
| | UC | 3.5-5.0 | Parametric | 0.00 | .50 | 0.200 |
| | CD | 3.4-5.0 | Parametric | -0.36 | .36 | 0.188 |
| ALT (U/L) | RA | | | | | |
| | Adult | 11-71 | Parametric | 0.65 | .26 | 0.433 |
| | Geriatric | 9-60 | Parametric | 0.32 | .38 | 0.804 |
| | SLE | 10-50 | Parametric | -0.04 | .52 | 0.450 |
| | HASHD[a] | 10-70 | Nonparametric (Harrell-Davis) | 0.62 | .27 | 0.458 |
| | Female | 10-61 | Nonparametric (Harrell-Davis) | 0.35 | .36 | 0.510 |
| AST (U/L) | RA | 18-59 | Parametric | 1.29 | .10 | 0.293 |
| | SLE | 18-57 | Nonparametric (Harrell-Davis) | 1.18 | .12 | 0.410 |
| | HASHD[a] | 17-62 | Nonparametric (Harrell-Davis) | 1.46 | .07 | 0.289 |
| | Female | 8-48 | Parametric | 0.61 | .27 | 0.356 |
| Chloride (mmol/L) | UC | | | | | |
| | Female | 95-108 | Nonparametric (Simple) | -0.99 | .16 | 0.231 |
| | Male | 93-108 | Parametric | -1.67* | .048 | 0.571 |
| | CD | 97-108 | Parametric | -0.33 | .37 | 0.091 |
| Cholesterol, total (mg/dL) | HASHD | 121-262 | Parametric | 1.17 | .12 | 0.156 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| CRP (mg/dL) | RA | | <3.3 | Nonparametric (Harrell-Davis) | 1.23 | .11 | n/a |
| | SLE[a] | | <4.5 | Nonparametric (Simple) | 1.49 | .07 | n/a |
| | UC | | <2.2 | Nonparametric (Harrell-Davis) | 0.88 | .19 | n/a |
| | CD | | <2.5 | Nonparametric (Harrell-Davis) | 0.99 | .16 | n/a |
| Eosinophil, absolute ($10^3$/μL) | RA | | | | | | |
| | | Female | 0.03-0.49 | Nonparametric (Harrell-Davis) | 0.27 | .39 | 0.283 |
| | | Male[a] | 0.03-0.48 | Nonparametric (Simple) | -0.12 | .55 | 0.267 |
| | UC | | | | | | |
| | | Female | 0.02-0.50 | Nonparametric (Simple) | 0.30 | .38 | 0.354 |
| | | Male | 0.04-0.42 | Nonparametric (Harrell-Davis) | -0.28 | .61 | 0.474 |
| | CD | | | | | | |
| | | Female | 0.05-0.51 | Nonparametric (Harrell-Davis) | 0.32 | .38 | 0.283 |
| | | Male | 0.04-0.52 | Nonparametric (Harrell-Davis) | -0.02 | .51 | 0.625 |
| Hemoglobin (g/dL) | RA | | | | | | |
| | | Female | 9.1-15.4 | Parametric | -2.51** | .006 | 0.143 |
| | | Black, F | 9.1-15.7 | Nonparametric (Simple) | -2.51** | .006 | 0.197 |
| | | White, F | 9.2-15.5 | Parametric | -2.40** | .008 | 0.175 |
| | | Adult, F | 9.5-15.5 | Parametric | -2.08* | .02 | 0.150 |
| | | Geriatric, F | 8.4-14.9 | Nonparametric (Harrell-Davis) | -3.34*** | <.001 | 0.185 |
| | Male[a] | | 10.9-17.9 | Parametric | -1.17 | .12 | 0.186 |
| | SLE | | | | | | |
| | | Female[a] | 7.8-15.2 | Nonparametric (Harrell-Davis) | -4.11*** | <.001 | 0.243 |
| | UC | | | | | | |
| | | Female | 10.8-15.9 | Nonparametric (Simple) | -0.74 | .23 | 0.078 |
| | | Male | 9.4-16.8 | Nonparametric (Harrell-Davis) | -2.70** | .003 | 0.216 |
| | CD | | | | | | |
| | | Female | 9.1-16.3 | Nonparametric (Harrell-Davis) | -2.51** | .006 | 0.333 |
| | | Male | 10.2-16.8 | Nonparametric (Harrell-Davis) | -1.85* | .03 | 0.197 |
| | | Adult, M | 10.2-16.8 | Nonparametric (Harrell-Davis) | -1.85* | .03 | 0.348 |
| | HASHD | | | | | | |
| | | Female[a] | 9.8-15.6 | Nonparametric (Harrell-Davis) | -1.75* | .04 | 0.172 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| LDL (mg/dL) | HASHD | | ≤163 | Parametric | 0.06 | .48 | n/a |
| Lympho-cyte, absolute ($10^3$/μL) | RA | | | | | | |
| | | Female | 0.7-3.8 | Parametric | 0.40 | .34 | 0.129 |
| | | Adult, F | 0.7-4.0 | Parametric | 0.55 | .29 | 0.152 |
| | | Geriatric, F | 0.7-3.0 | Nonparametric (Simple) | -0.27 | .61 | 0.130 |
| | | Male | 0.6-3.3 | Nonparametric (Simple) | 0.09 | .46 | 0.148 |
| | SLE | | | | | | |
| | | Female | 0.7-3.7 | Parametric | -1.78* | .04 | 0.067 |
| Neutrophil, absolute ($10^3$/μL) | RA | | | | | | |
| | | Female | 1.74-10.14 | Parametric | -0.21<br>1.00 | .83<br>.32 | 0.03<br>0.19 |
| | | Black, F | 1.44-10.34 | Nonparametric (Simple) | -0.74<br>1.05 | .46<br>.29 | 0.04<br>0.31 |
| | | White, F | 1.90-9.92 | Parametric | 0.03<br>0.93 | .98<br>.35 | 0.04<br>0.20 |
| | | Male | 1.90-11.08 | Nonparametric (Simple) | -0.13<br>1.30 | .90<br>.19 | 0.09<br>0.25 |
| | SLE | | | | | | |
| | | Female | 1.64-9.49 | Parametric | -0.38 | .35 | 0.056 |
| Platelet ($10^3$/μL) | RA | | | | | | |
| | | Female | | | | | |
| | | w/o CVD, F | 153-462 | Nonparametric (Harrell-Davis) | -0.32<br>1.01 | .75<br>.31 | 0.13<br>0.15 |
| | | with CVD, F | 109-417 | Parametric | -1.65<br>0.60 | .10<br>.55 | 0.11<br>0.11 |
| | | Male | 134-399 | Nonparametric (Harrell-Davis) | -0.44<br>0.78 | .66<br>.44 | 0.18<br>0.20 |
| | SLE | | | | | | |
| | | Female | 135-461 | Parametric | -0.81 | .21 | 0.089 |
| | UC | | | | | | |
| | | Female[a] | 153-388 | Nonparametric (Simple) | 0.32 | .37 | 0.068 |
| | | Male | 118-419 | Nonparametric (Harrell-Davis) | 0.97 | .17 | 0.259 |
| | CD | | | | | | |
| | | Female | 169-493 | Parametric | 1.27 | .10 | 0.309 |
| | | Male | 160-571 | Nonparametric (Harrell-Davis) | 2.20* | .014 | 0.343 |
| | HASHD | | | | | | |
| | | Female | 144-400 | Parametric | 0.44 | .33 | 0.129 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| RBC ($10^6$/μL) | RA | | | | | | |
| | | Female | | | | | |
| | | | w/o CVD, F | 3.33-5.23 | Parametric | -1.54 | .06 | 0.226 |
| | | | with CVD, F | 3.24-5.38 | Parametric | -1.80* | 0.04* | 0.117 |
| | | Male | | 3.55-6.02 | Parametric | -1.70* | .045 | 0.194 |
| | SLE | | | | | | | |
| | | Female | | 3.25-5.22 | Parametric | -1.77* | .04 | 0.234 |
| | UC | | | | | | | |
| | | Female[a] | | 3.70-5.44 | Nonparametric (Harrell-Davis) | -0.56 | .29 | 0.167 |
| | | Male | | 3.17-5.72 | Nonparametric (Harrell-Davis) | -2.76** | .003 | 0.224 |
| | CD | | | | | | | |
| | | Female | | 3.67-5.21 | Parametric | -0.64 | .26 | 0.175 |
| | | Male[a] | | 3.71-5.94 | Nonparametric (Harrell-Davis) | -1.29 | .10 | 0.090 |
| | HASHD | | | | | | | |
| | | Female | | 3.52-5.32 | Parametric | -1.03 | .15 | 0.167 |
| | | | Hispanic, F | 3.73-5.79 | Nonparametric (Harrell-Davis) | -0.49 | .31 | 0.180 |
| | | | Non-Hispanic, F | 3.49-5.07 | Parametric | -1.11 | .13 | 0.259 |
| Sodium (mmol/L) | UC | | | | | | | |
| | | Female | | 135-145 | Parametric | 0.00 | .50 | 0.200 |
| | | Male | | 132-143 | Nonparametric (Harrell-Davis) | -0.92 | .18 | 0.182 |
| | CD | | | 134-144 | Parametric | -0.30 | .38 | 0.200 |
| | HASHD | | | 135-143 | Parametric | 0.00 | .50 | 0.125 |
| Vitamin B12 (pg/mL) | UC | | | 278-984 | Nonparametric (Simple) | 0.28 | .61 | 0.106 |
| | CD | | | 294-971 | Nonparametric (Harrell-Davis) | 0.39 | .65 | 0.022 |
| WBC ($10^9$/μL) | RA | | | | | | | |
| | | Female | | 3.8-13.8 | Parametric | 0.76 | .23 | 0.160 |
| | | | Black, F | 3.1-11.6 | Nonparametric (Simple) | 0.15 | .44 | 0.082 |
| | | | White, F | 4.2-14.4 | Parametric | 0.90 | .18 | 0.265 |
| | | Male | | 4.1-14.6 | Nonparametric (Simple) | 1.08 | .14 | 0.152 |
| | SLE | | | | | | | |
| | | Female | | 3.0-13.2 | Parametric | -1.25 | .11 | 0.069 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | UC | | | | | |
| | Female | 4.2-14.4 | Nonparametric (Harrell-Davis) | 0.90 | .18 | 0.431 |
| | Male[a] | 3.7-8.9 | Nonparametric (Harrell-Davis) | -0.64 | .74 | 0.135 |
| | CD | | | | | |
| | Female | 3.7-12.7 | Nonparametric (Harrell-Davis) | 0.47 | .32 | 0.278 |
| | Male | 4.1-11.7 | Nonparametric (Harrell-Davis) | 0.31 | .38 | 0.118 |

*Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; CD, Crohn's disease; CI, confidence interval; CRP, C-reactive protein; CVD, cardiovascular disease; F, female; HASHD, Hashimoto's thyroiditis; LDL, low density lipoprotein; M, male; n/a, not applicable; RA, rheumatoid arthritis; RBC, red blood cell; RI, reference interval; SLE, systemic lupus erythematosus; UC, ulcerative colitis; w, width ratio; WBC, white blood cell.*

*[a]A subpopulation within this sample was found to be significant, but could not be partitioned because of too small sample sizes; the subpopulation may have an over- or under-estimated reference limit.*

**P <.05, **P <.01, ***P <.001*

*Underlined limits were the reference limits used in the RCV equations to determine significance between published and established RIs; only limits in RIs comprised of two limits are underlined.*

## Discussion

The study population mostly consisted of white, non-Hispanic females between the ages of 45-64, which echoes the national prevalence data.[24,25] Sex was the most influential covariate, as females had a reduction in reference limits compared to males, thus, sex-specific RIs were established within RA-associated albumin, and HASHD-associated ALT and AST. Conversely, for UC- and CD-associated sodium and chloride, males had reduced lower limits compared to females. This agrees with heavily studied trends of females having lower values of albumin than males; however, the higher electrolyte values in UC and CD for females is unexpected and may be from hormone differences playing a role in the regulation of the intestinal microenvironment.[26,27] Race also influenced many hematological parameters, depicting decreased reference limits in the Black population compared to the White population for hemoglobin, neutrophil, and WBC RIs in female patients with RA. This, too, matches with the literature, as studies reveal the Black population as having reduced values for the parameters.[26] Age group was another major factor in the RIs as ALT, hemoglobin, and lymphocyte limits were lower in the geriatric population, as expected.[26] Ethnicity also affected RIs, as the self-reported Hispanic population showed higher medians for WBCs in males with UC; and RBCs in females with UC and males with CD, compared to Non-Hispanics. Research supports this finding and describes the Hispanic population as having higher hematological values than Non-Hispanics, despite this study's inability to establish many RIs for this population due to low sample sizes.[28,29] Only HASHD-associated RBCs for Hispanic females had a sufficient sample size to establish an RI, and the lower limit was still higher than the Non-Hispanic lower limits. To further substantiate the influence of ethnicity, additional samples would be required. Though, some studies examining inflammatory bowel disease in various ethnicities have noted the Hispanic population as having higher values for WBCs and less phenotypical complications, citing low incidences of risk alleles as an attributing factor.[28-30]

Most diseases altered the laboratory tests as predicted by the *z* scores, including the duality of neutrophil and platelet limits in RA, suggesting the assigned critical *z* values were appropriate and reliable. Additionally, many of the RI limits established in this study were

comparable to those reported for the non-comorbidity ("Included") population in Mikkelsen et al. 2021, despite differences in inclusion criteria and study methodology.[9]

For example, in RA-associated albumin among females, the lower reference limit decreased to the same value in both studies (3.3 g/dL; 3.3 g/L) (Figure 1). Similarly, the upper reference limit for RA-associated platelet counts in females increased to 462 $x10^3/\mu L$ in this study and to 486 $x10^9/L$ in the comparison study (Figure 2). For RA-associated WBC counts in females, the upper reference limit was approximately 1.2 times the health-associated limit, whereas the comparison study reported an upper limit that is nearly double. Despite these differences, both studies identified similar upper limits of approximately 14 $x10^3/\mu L$ ($10^9/L$) (Figure 3). Across all RIs, the 90% CIs were comparable to or narrower than those reported, despite smaller sample sizes for WBCs and platelet measurements in this study. RA-associated CRP values increased similarly between both studies. Notably, the combined RA CRP upper reference limit in this study matched the reported male RA reference limit (Figure 4). However, the comparison study stratified CRP reference intervals by sex and observed substantially higher limits in females, whereas this study found no significant sex-based differences in CRP values among RA outpatients. RA-associated hemoglobin reference limits were reduced in both studies (Figure 5). In this study, the lower hemoglobin reference limit aligned with the other study's comorbidity and anemia of chronic disease ("Sick") population. Although this finding suggests that further refinement of inclusion criteria may be necessary to better exclude patients with comorbidities, the comparison study similarly questioned this result, proposing that adequate treatment among patients may explain the observed overlap. Lastly, UC-associated CRP limits increased modestly in this study (2.75-fold) compared with the markedly higher increase (12.2-fold) reported in the compared study (Figure 6).

Contrary to the assigned *z*-scores, limits for albumin in males with RA, and for absolute eosinophils in males with UC or CD shifted in the opposing direction. Males had higher results for albumin, and lower results for eosinophils compared to the health-associated RIs. For albumin, this may be because the disease-associated RI is stratified by sex, and females have a lower albumin limit while males have a higher albumin limit. If these two populations were not stratified, they would average out and match the combined health-associated RI. In SLE, CRP limits showed a drastic increase from the health-associated limit. This differs from research as SLE would likely have a dampened effect on CRP from overproduced type I interferons inhibiting its production, or CRP-autoantibodies causing its destruction.[14] This drastic increase may be further evidence to refine the sample population, as it suggests the inclusion of outpatients with underlying acute conditions, such as infections, in the population. In females with UC, the WBC upper limit unexpectedly decreased by 1.2 times the health-associated limit; contrary to the Mikkelsen study, which the upper limit increased about 1.5 times the health-associated limit (Figure 7). Though reasoning has not been fully studied, there is some evidence that UC patients with complete mucosal healing can have substantially lower WBC values than expected, and some of the reference individuals could be included in the population.[31] Another contributing factor might be the low sample size affecting the RI.

When assessing significance of the established disease-specific RIs, 22% (19/88) were statistically significant, 25% (22/88) had $n \geq 120$, and 50% (44/88) had a satisfactory $w < 0.20$. Of the significant RIs, 58% (11/19) had a satisfactory $w < 0.20$. Overall, the hemoglobin and RBC RIs showed statistical significance across autoimmune diseases, while platelet, lymphocyte, and chloride RIs were significant for at least one disease. The RA-associated hemoglobin RIs in females had the strongest significance (i.e., a combination of the highest *z* score with the lowest *w*). RIs

for SLE-associated albumin in diabetic patients, and RA-associated RBCs in females with CVD were both significant; however, these were only secondary findings, as diabetes and CVD consisted of clusters of ICD-10-CM codes used to "purify" the RIs. Additional steps are needed to further evaluate the comorbidities for the impact on the RIs in these populations. When reviewing analyte IoIs, sodium and chloride produced an IoI close to, or above 1.4, followed by albumin at IoI = 0.95. The remaining analytes produced IoIs close to, or below 0.6; therefore, subject-based RIs for these analytes would be the higher quality approach.

*Limitations*

One major limitation of the study were the unverifiable ICD-10-CM codes, as reviewing a thousand patients for agreeance with medical criterion of their respective disease was not feasible. Trust was placed in healthcare providers to accurately report diagnosis codes and in the correct location. Additionally, despite other studies developing precise methods for improved participant selection based on ICD codes, access to such technology and time constraints were limiting factors in this study. The other major limitation of this study was small sample sizes, which directly affects the strength of established RIs. However, the CLSI endorses techniques to develop RIs with sample sizes as low as 40, and RIs in this study were determined based on those standards. Another limitation is the certainty of biological variation data. Though EFLM provides quality data from metanalyses of appraised evidence, many analytes still have vastly wide 90% CI for variation. This weakens the application of the RPΔ in this study and could alter significances of established RIs. Moreover, biological variations for the "healthy" population and the autoimmune disease-specific population are likely different, introducing further uncertainty in the RPΔ. Other limitations associated with this study includes the differences in drug mechanisms of action, dosages, and patient compliance prior to sample collection, and the lack of BMI data to account for the effects on certain analytes.

Overall, additional prospective studies should focus on refining inclusion criterion, increasing generalizability, and strengthening statistical power—especially in the geriatric, Black, and Hispanic female populations. Clinical utility studies should also be included to measure outcomes of applying the disease-associated RIs in a real-world setting. However, since many analytes have low IoIs, research should pivot towards implementing the next highest quality model of subject-based RIs in medicine.

## Conclusion

This study demonstrates that RIs in patients with autoimmune diseases are different than the RIs currently used in healthcare. Based on the collective strength of RI significance, 90% CIs, width ratios, and IoIs, clinical validation for appropriateness is needed. The nonsignificant RIs, though informative, may be optional since available data suggests the health- and disease-associated RIs were equivalent. The UC-associated chloride RI in males was statistically significant and is mathematically the most clinically useful RI but cautiously recommend it for clinical validation because of the wide 90% CI. RA-, SLE-, and UC-associated hemoglobin; RA-associated RBC; CD-associated platelet; and SLE-associated lymphocyte RIs were all significant with satisfactory confidence, thus clinical validation is strongly recommended.

In addition to clinical validation, the integration of the autoimmune disease-associated RIs must be considered. Most LIS systems store RIs based on age and sex, and physicians should not have to memorize RIs. Though the established RIs could be thought of as clinical decision limits for easier adoption, they technically do not equate to actionable laboratory values, because they only serve as a reference. The best approach is to upgrade electronic health records with the logic to provide guidance on laboratory interpretation based on the entirety of the patient's chart.

With the advancement of artificial Intelligence, implementation of more advanced diagnostic algorithms may improve the calculation and application of RIs.

Overall, considering the findings and the limitations, this study provides a method and starting point for further research on the interpretation of laboratory tests based on underlying disease. These findings provide insight into the interpretation of routine laboratory results in patients with underlying autoimmune diseases, based on the university hospital's serving population. However, if the autoimmune disease-associated RIs are utilized at other facilities with different analyzers and patient populations, verifications are necessary. More appropriately, population-specific interval studies are needed to support the specific patient population.

Ultimately, each of the established autoimmune disease-associated RIs provide a higher quality standard, as they reflect the patient population and improve laboratory-based patient management.

Along with the downstream effects of morbidity and mortality, the United States Renal Data System (USRDS) also reports that the healthcare cost burden of CKD to be approximately 114 billion dollars annually in the United States.[5] The early detection, management, and slowing of progression of CKD to later stages and end-stage renal disease (ESRD) have large economic implications for potential cost savings in the amount spent annually towards treating this disease. Approximately one third of the total cost of CKD treatments is focused on patients with ESRD.[6]

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## Ethical Approval

This study was reviewed by the UTMB institutional IRB and considered a quality assessment/quality improvement study.

## Conflict of interest statements

All authors declare no conflicts of interest.

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Research article

# Seasonal Variations in the Prevalence of Intestinal Parasites in Pediatric Patients at Sacré Cœur Pediatric Center in Guinea-Conakry

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***Background***. **Intestinal parasites are a major cause of illness and death among children worldwide, especially from resource-poor areas. However, limited pediatric data from these regions make the true prevalence unknown. The goal of this study was to determine the current rate of intestinal parasites in pediatric patients with a high likelihood of infection seen at Sacré Cœur Pediatric Center in Guinea-Conakry, West Africa, during wet and dry season (2024-2025).**

***Materials and Methods***. **The laboratory used direct microscopy to examine stool samples for parasites and a lateral flow device (Operon, Inc., Spain) to detect the three most common intestinal protozoa reported in the region: *Cryptosporidium* spp., *Entamoeba histolytica*, and *Giardia duodenalis*.**

***Results***. **Microscopy consistently showed low levels of *Schistosoma mansoni* (4-7%), hookworms (0. 0.7-1%), and *Ascaris* spp. (1-4%) in both seasons. The prevalence of Ascaris *lumbricoides* was higher during the dry season (p = 0.04). The incidence of intestinal protozoa in the seasons was as follows: *G. duodenalis* (28. 7% during rainy vs. 14. 1% during dry), *E. histolytica* (10. 2% vs. 1. 5%), and *Cryptosporidium* spp. (14. 6% vs. 3. 0%). The prevalence of all protozoa was greater during the rainy season (p < 0.001). Eight percent of samples contained multiple protozoa.**

***Conclusion***. **This study highlights a significant burden and seasonality of parasitic infections among pediatric patients. These findings will help improve clinical care in the region and aim to enhance children's health and preventable deaths.**

***Keywords:*** *Guinea-Conakry, protozoal infections, Cryptosporidium, Entamoeba; Giardia*

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## Introduction

Intestinal parasitic infections are a widespread issue globally, mainly affecting school-aged children. In some areas, prevalence can surpass 50%.[1] According to the World Health Organization, over 1.5 billion people worldwide are infected with intestinal parasites, with 450 million experiencing severe illness and approximately 155,000 deaths annually attributed to these infections.[2]In subtropical and tropical regions, these infections are endemic and are leading causes of disease and death.[3,4] Among children under five years of age, diarrheal diseases are linked to poor growth, impaired cognitive development, and mortality.[5-12] Low- and middle-income countries, especially in sub-Saharan Africa, South and Central America, China, and East Asia, are most impacted by these infections.[1,12] While soil-transmitted helminths such as *Ascaris lumbricoides, Ancylostoma duodenale*, and *Trichuris trichiura* are responsible for many cases, protozoa also significantly contribute.[12] Notable intestinal protozoans include *Entamoeba histolytica, Giardia duodenalis, Blastocystis* spp., and *Cryptosporidium* spp.

Throughout much of Africa, reliable epidemiological data on parasitic intestinal infections is limited, mainly due to underreporting. However, some studies show a high prevalence of intestinal parasites with regional differences. For example, an overall positivity rate of 84.7% was reported in a study from Burkina Faso[13], 15.8% in Senegal[14], and 55.2% in Côte d'Ivoire[15]. Other African countries also report prevalence above 40%, such as Mozambique, where the most common parasites were *A. lumbricoides* (65.8%), *T. trichiura* (54.0%), hookworms (38.7%), *Entamoeba* spp. (31.2%), *Giardia duodenalis*(19.0%), *Taenia* spp. (5.8%), and *Hymenolepis nana* (5.2%). A study by Adoubryn and colleagues in Côte d'Ivoire found a high prevalence of helminths, including *Schistosoma mansoni* (35.5%), *Necator Americanus* (25.9%), and *A. lumbricoides* (5.2%).[15]

The main goal of this study was to determine the point prevalence of intestinal parasites in pediatric patients with a high pretest probability of parasitic infection seen Sacré Cœur Pediatric Center in Guinea-Conakry (The Republic of Guinea), West Africa, during two periods: June–August 2024 (rainy season) and November 2024–February 2025 (dry season).

## Material and Methods

For this study, the Sacré Cœur laboratory used a) direct microscopy to examine stool for ova and parasites and b) a lateral flow device to detect the three most common intestinal protozoa previously reported in the region: *Cryptosporidium* spp., *E. histolytica, and G. duodenalis*.

*Study environment*

Dubréka is an urban community situated in Lower Guinea within the Dubréka prefecture of the Kindia region. It lies about 50 miles north of Conakry, the capital of Guinea. Located between the Kogon River to the east and the Fouta Djallon mountains to the west, Dubréka spans roughly 3,350 square kilometers. The area includes urban, rural, and semi-rural zones, with landscapes that range from coastlines to mountains and forests. The population is estimated at 100,000 to 120,000 people, representing various ethnic groups such as the Malinké, Peulh, and Soussous. The city features densely populated neighborhoods as well as nearby rural areas involved in activities like rice farming and logging.

*Sample collection*

If indicated by a clinical order, a small amount (10-15 g) of fresh stool was collected from each patient in a labeled sterile container. Direct microscopy was the standard of care for patients with a clinical concern for parasitic infection. Samples with sufficient material were anonymized and included in the lateral flow testing part of the research protocol.

*Microscopy*

Approximately 1-2 g of fresh stool was mixed with a Lugol iodine solution on a microscope slide. The stool samples were then observed at 100 and 400x for cysts, trophozoites, oocysts, and helminth eggs.

*Lateral Flow Assay*

The Simple Crypto-Giardia-Entamoeba 4R test (Operon, Inc., Zaragoza, Spain) was performed following the package insert. In brief, the included test vial collection stick was used to pick up approximately 75 mg of stool. The sample was added to the dilution buffer vial and shaken vigorously to ensure homogenization. The top seal was broken on the vial, and four drops of sample were added to the reaction zones of each of the two strips. Results were read and recorded at 15 minutes.

*Statistical analysis*

Demographic information was assessed and mean age of patients as well as sex ratio were calculated. Chi-square analysis was used to evaluate the significance of difference in the point prevalence of each parasite between wet and dry seasons. Statistical significance was defined as a p-value of <0.05.

## Results

*Demographics*

The patient age in this study ranged from one month to 29 years. The mean and median age were 7.2 and 6 years, respectively, with a standard deviation of 5.2 years. The patients tested were 55% (n = 223) male and 45% (n = 180) female.

*Microscopy Results*

A total of 507 microscopic samples were analyzed over two seasons: the rainy season (June 10, 2024 – August 5, 2024) and the dry season (December 10, 2024 – February 4, 2025). During the rainy season, 306 samples were examined microscopically, with 21 (6.9%) testing positive for parasites (Table 1). In this period, 12 samples (3.9%) were positive for *S. mansoni*, three for *A. lumbricoides*, two each for *S. stercoralis*, hookworms, or *Balantioides coli*, and none for *H. nana*.

During the dry season, 198 samples were examined using microscopy with 26 (13.1%) testing positive for parasites (Table 1). Of these, 14 samples (7.1%) contained *S. mansoni*, 8 (4.0%) had *A. lumbricoides*, and two were positive for hookworms or *H. nana*. *S. stercoralis* and *B. coli* were not detected.

Using microscopy, *S. mansoni* and *A. lumbricoides* were more prevalent in dry seasons. The point prevalence of *A. lumbricoides* was significantly higher in the dry season than the rainy season (p = 0.04). For more detailed results from the stool analyses, see Table 1.

**Table 1.** Percentage of samples positive by microscopy (n=507)

| Parasite | Rainy Season (n=306) | Dry Season (n=198) | p-value |
|---|---|---|---|
| *Schistosoma mansoni* | 12 (3.9%) | 14 (7.1%) | 0.175 |
| *Strongyloides stercoralis* | 2 (0.7%) | 0 | 0.679 |
| Hookworm | 2 (0.7%) | 2 (1.0%) | 1 |
| *Balantioides coli* | 2 (0.7%) | 0 | 0.679 |
| *Ascaris lumbricoides* | 3 (1.0%) | 8 (4.0%) | 0.047 |
| *Hymenolepis nana* | 0 | 2 (0.1%) | 0.3 |
| Total | 21 (6.9%) | 26 (13.1%) | |

*Lateral Flow Results*

403 lateral flow assays were evaluated across two seasons: the rainy season (June 10, 2024 – August 5, 2024) and the dry season (December 10, 2024 – February 4, 2025). During the rainy season, 65 specimens (31.7%) tested positive by lateral flow assay (Table 2). Of these, 59 (28.7%) were positive for *G. duodenalis*, 21 (10.2%) were positive for *E. histolytica*, and 30 (14.6%) were positive for *Cryptosporidium* spp. Notably, 15 specimens were positive for all three parasites, and 10 were positive for two parasites.

During the dry season, 37 specimens (18.7%) tested positive with the lateral flow assay. Of these, 28 (14.1%) were positive for *G. lamblia*, 3 (1.5%) for *E. histolytica*, and 6 (3.0%) for *Cryptosporidium spp.* Four specimens tested positive for all three parasites, and two were positive for two parasites.

When comparing prevalence between the wet and dry seasons using the lateral flow assay, all three parasites showed significant

differences in occurrence, as determined by chi-square analysis. *G. duodenalis*, *E. histolytica*, and *Cryptosporidium spp.*, with p-values less than 0.001, indicated a consistently higher occurrence of these parasites during the rainy season.

**Table 2.** Percentage of samples positive by lateral flow assay (n=403)

| Parasite | Rainy Season (n=205) | Dry Season (n=198) | p-value |
|---|---|---|---|
| *Giardia duodenalis* | 59 (28.7%) | 28 (14.1%) | <0.001 |
| *Entamoeba histolytica* | 21 (10.2%) | 3 (1.5%) | <0.001 |
| *Cryptosporidium parvum* | 30 (14.6%) | 6 (3.0%) | <0.001 |
| Total | 65 (31.7%) | 37 (18.7%) | |

## Discussion

This is the first modern study to describe seasonal differences in intestinal parasitic infections in children of Guinea, West Africa. Findings from this study also support previous reports on the burden of intestinal parasites of children in West Africa. These results are notable in the context that although temperatures vary by region in Guinea, there is little variation throughout the year, with temperatures between 28-32°C. The seasons are divided into the dry season, which lasts approximately from December through May each year, and the rainy season, which lasts approximately from June through November. At the height of the rainy season, precipitation can exceed 30 inches of rainfall per month in some areas.[16,17]

There is a risk of acquiring intestinal parasites during both the rainy and dry seasons. During the rainy season, increased precipitation can cause flooding and runoff, which carry sewage, chemicals, and other agents that cause enteric diseases into contact with humans.[18] The prevalence of diarrheal diseases often peaks during rainy seasons in tropical and subtropical climates.[19-23] However, during the dry season, drought may concentrate enteric pathogens in limited water sources, and high temperatures may cause people to seek out and consume water from these sources.[18] In this study, the parasites *G. duodenalis*, *E. histolytica*, and *Cryptosporidium spp.* were found at significantly higher rates during the rainy season than during the dry season, while *A. lumbricoides* was detected at significantly higher rates during the dry season.

Efforts to reduce rates of communicable diseases, including diarrheal illnesses, have included programs such as Safe Water, Sanitation, and/or Hand Washing (safe WASH) interventions.[24-25] In 2019, it was estimated that approximately 1.4 million people die each year due to unsafe drinking water, inadequate sanitation, and poor hygiene practices.[26] The 2030 Agenda for Sustainable Development Goal 6 aims to 'ensure availability and sustainable management of water and sanitation for all' and includes targets for universal access to safe drinking water, sanitation, and hygiene.[27] As of 2023, although there has been progress with global efforts in safe drinking water, sanitation, and hygiene, achieving Sustainable Development Goal 6 universally will require a six-fold increase in current rates of progress.[25,27]

The limitations of this study include small sample sizes collected for analysis. Further research is needed to strengthen these findings and make them applicable across the region. Since different areas in Guinea experience varying seasonal rainfall, additional studies are necessary to identify any regional differences in intestinal parasite prevalence. Understanding local epidemiology is essential for guiding healthcare providers in managing patients effectively, thereby reducing morbidity and mortality from diarrheal diseases. Another limitation is the absence of clinical data regarding outcomes. Although each sample was taken from a symptomatic child, it was not recorded whether the child survived, died, or lived with comorbidities.

This study was designed, conducted, analyzed, and written up in collaboration with local partners at the field site, where the idea for the work was inspired by the need to understand the local epidemiology of diarrheal illnesses in children. To the authors' knowledge, this study is the first to describe seasonal variation in intestinal parasite prevalence in Guinea, which will help local providers and patients improve management and recovery.

## Conclusion

Diarrheal disease is a leading cause worldwide of illness and death among children under the age of five years. The burden mainly affects children in low- and middle-income countries. This study reports the local prevalence of intestinal parasites in children with diarrhea who visited a pediatric clinic in Guinea. Results show seasonal variation, with some parasites being more common during the rainy season. Further research is needed to confirm these epidemiological findings and to improve prevention strategies through safe WASH initiatives. Diarrheal illnesses are preventable, and increased efforts are essential to reduce the yearly morbidity and mortality, especially among the most vulnerable.


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Operon Simple Crypto-Giardia-Entamoeba 4R test (Operon, Zaragosa, Spain) provided support for testing materials.


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**Research article**

# Relevant Quality Assurance of Point-of-Care Testing in Emergency Home Health Nursing: An analysis of factors affecting Clinical Practice

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***Purpose:*** **The study aims to identify factors affecting clinical practice related to QA for POCT analyses in EEH nursing services. This is to support collaboration between EHH nursing services and BLS's located at hospital-based clinical laboratories, in designing relevant and functional QA programs for POCT performed in the EHH nursing service.**

***Material and Methods:*** **EHH nursing services from four Danish districts participated in the project. The findings of this project are based on participant observations and interviews. Participant observation among EHH nurses in all four districts served as the foundation for a moderator guide, which was used for two focus group interviews among the nurses. Finally, the findings were refined through an interview formalized with two hospital-based BLS's responsible for POCT QA. All three interviews were transcribed and processed through thematic analysis.**

***Outcomes/discussion:*** **The EHH nursing services participating in this project all have a collaboration with a hospital-based BLS for their POCT QA. However, they all have experience with QA strategies, which have proven inefficient. The results showed that the following themes influence the EHH nurses' involvement in QA for POCT analyses: Management, Organization of QA, Approach to QA and Skills in QA. All the themes have factors that affect QA for POCT but also affect the EHH nurses' quality of work life and/or professional values.**

***Conclusion:*** **The findings indicate that an incentive to participate in QA programs for POCT must be established before collaboration between the management of EHH nursing service and the clinical laboratories is plausible. But if a collaboration has been established, key factors for QA-BLS include establishing collaboration with relevant districts management; organizing QA programs with attention to local structures and workflows; and encouraging strong relationships between QA-BLS and the EHH nurses to ensure correct training and follow-up among the EHH nurses.**

***Abbreviations:*** EHH = Emergency Home Health, POCT = Point-of-Care Test, QA = Quality Assurance, BLS = Biomedical Laboratory Scientists

***Keywords:*** Point-Of-Care Testing (POCT), quality assurance (QA), home health nursing, cross-sector collaboration

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## Introduction

Globally, healthcare systems are shifting from a hospital-centered model to a more patient-centered approach, thereby reinforcing the primary healthcare sector to ensure optimal health outcomes and cost-effectiveness.[1] This transformation in the healthcare systems, is driving a significant growth in the use of point-of-care testing (POCT) and enables laboratory testing with rapid results to be performed outside hospital settings and directly at the patient's location.[2] To ensure that the POCT analysis gives valid results it is important to ensure quality assurance (QA) of both the POCT equipment and the operator. The significance of sufficient QA of POCT analysis have been reported in several studies, including articles from England and Norway.[3,4]

In Denmark it is a legal requirement for all municipalities, hereby referred to as districts, to have an emergency home health (EHH) nursing service that can perform POCT analysis. This aims to facilitate faster discharges of hospitalized patients and to provide supervision for vulnerable patients to ensure that hospitalization occurs only when clinically warranted. In Denmark it is a requirement to perform QA related to POCT used by the EHH nurses in the districts, but how and to which extent is not specified.[5] Danish Society for Clinical Biochemistry[6] (DSKB) along with authority´s in many countries here among Belgium and Norway recommend that QA for POCT analysis in the primary sector is performed in collaboration with clinical laboratories.[4,6] But as of September 2025, it is still less than half of the Danish districts and thereby the EHH nursing services, that have a formalized collaboration with a hospital-based clinical laboratory to ensure the QA for POCT analysis.[7]

The aim of this project is to support interdisciplinary and cross-sector collaboration between EHH nursing services in the districts, which use POCT, and biomedical laboratory scientists (BLS) located at hospital-based clinical laboratories. The project seeks to draw benefit from the knowledge and knowhow of various professions and sectors to develop High-quality QA programs for POCT analysis that are perceived as relevant by EHH nursing service and thereby enhancing patient safety. To achieve this, the project seeks to identify factors that affect QA for POCT analysis among EHH nurses working out in the districts. Hopefully, this will pave the way for developing QA programs that the district EHH nursing service will fully commit to.

## Materials and methods

This study employed a qualitative approach to explore EHH nurses' perspectives on QA for POCT analysis, with particular attention to the factors influencing their participating in QA programs.

The empirical data was gathered primarily from EHH nurses working in four different districts and obtained by participant observation and focus group interviews. To refine these findings, a group interview with two QA-BLS's was also conducted.

### Initiating contact

The access to relevant information in the districts has primarily been promoted by our network consisting of; an external lecturer who works as an EHH nurse, and QA-BLS's. Our District 1 committed to participate from day one granting us access to conduct participation observation of work-situations and carry out a focus group interview with the relevant EHH nurses. In the three other districts we were granted access to conduct participation observation, by shadowing their QA-BLS when having QA meetings with the EHH nurses in the district. One of these districts (district 2), also consented to a focus group interview involving the EHH nurses.

The four districts, that participated in the project, are all connected to the island of Funen, Denmark. The four districts already have existing agreements with a hospital-based clinical laboratory regarding the QA of their POCT equipment and analyses, and they actively engage in these collaborations. However, the structure of the QA programs varies depending on which hospital-based clinical laboratory the district is affiliated with.

Until 2022, the QA programs in the relevant districts followed a uniform structure. Due to insufficient participation in the QA program, however, one hospital-based clinical laboratory decided to revise its procedures. The new approach shifted from conducting QA through the submission of patient samples for control analysis at the hospital-based clinical laboratory to performing QA collaboratively with the QA-BLS responsible for quality in the relevant QA program with the relevant EHH nurses out in the districts.

### Ethics

Prior to each observation, verbal consent was obtained among the EHH nurses to allow our presence as observers. No audio or video recordings were made during the observations; instead, field notes were taken continuously. Selected excerpts from these notes are included in project-related publications.

Before conducting the interviews, written informed consent was obtained regarding participation in the interview and the subsequent use of empirical data, including the use of quotations in project-related publications.

All participants were anonymized, and for the same reason, age and years of experience were grouped for the EHH nurses in each district during the focus group interviews.

### Participant observation

Participant observation was employed with the aim of gaining insight into the work and everyday practices of EHH nurses, and their approach to QA for POCT analyses. This method was chosen to expand the understanding of the field and to identify important factors that may not be accessible through existing literature. Accordingly, the participant observation was of an exploratory nature.[8]

Field notes were produced either during the observation or as soon as possible after the observation to ensure as accurate and comprehensive notes as possible. It is clearly indicated when an interpretation is made of what occurred by the observer, to distinguish objective observations from subjective interpretations. Since the project focuses on a specific aspect of EHH nurses' daily work, QA for POCT analyses, focused notes were taken, and other observed aspects were deliberately excluded.[9]

We were granted access to conduct observations on three occasions in district 1, where QA activities are integrated into daily tasks and carried out as time permits. During these visits, we followed the work that was underway at the time. In the other three districts, where QA for POCT was planned with sessions four times annually, observations were performed at these sessions, one session per district. All observations were obtained in the last half of 2023.

Duration, number of nurses observed, and number of observers are listed in table 1.

**Table 1.** Participant observation: *Districts, duration of observation, number of nurses observed and number of observers.*

| Districts | Duration | Number of nurses observed | Observers |
|---|---|---|---|
| District 1 | Over the course of three days | 2 (one observer at the time) | One observer at a time |
| District 2 | 2 hours | 3 | Both observers present |
| District 3 | 2 hours | 2 | Both observers present |
| District 4 | 2 hours | 3 | Both observers present |

### Focus group interviews

The participation observation was followed by focus group interviews, as this approach allows for further exploration and elaboration of topics that emerged during the observations and the analysis of the adhering field notes.[10] A semi-structured moderator guide was developed based on the funnel technique and was revised between the interviews to reflect the findings and to adapt to the specific setting of the interviews (Appendix 1).

The number of participants in each interview was determined by the number of EHH

nurses employed in the respective districts, as well as practical considerations related to working hours and available resources. The two focus group interviews were conducted in a room adjacent to the EHH nurses' workplace in the respective districts and the interviews were audio-recorded.[11]

Most of the participating EHH nurses were also present at the participation observation, meaning they were already familiar with the project and the project managers. When conducting the interviews both project managers were present: one acted as moderator, while the other served as observer and note-taker. Details regarding the participating districts, duration of the interview, number of participants, and the seniority of the EHH nurses are presented in Table 2.

**Table 2:** Focus group interviews - *districts, duration of interview, number of EHH nurses interviewed and years of employment in the role of EHH nurse*

| District | Duration | Number of nurses interviewed | Years of employment in the role of EHH nurse |
|---|---|---|---|
| District 1 | 45 min | 4 - named nurse 1-4 | 1 to 20 years |
| District 2 | 43 min | 3 - named nurse 5-7 | 1,5 to 15 years |

The first focus group interview was conducted in district 1 in December 2023, shortly after the final observation session had concluded. All four EHH nurses employed in the EHH nursing service participated. Three of the four nurses had previously been involved in the project, either through direct observation or informational meetings, while the fourth was newly hired.

The second focus group interview took place in district 2 in March 2024 and included two of the districts' three EHH nurses, as well as one clinical nurse specialist.

To further contextualize and nuance the insights gained from participant observation and the focus group interviews, a group interview was conducted with two QA-BLS' responsible for overseeing the QA for POCT analysis in the districts of Funen. This interview was carried out in June 2024 and lasted 35 minutes. The interview was conducted online via Microsoft Teams and recorded as video; however, only the audio file was used for subsequent data processing. Both project managers participated - one as moderator and the other as observer and note-taker. The interview guide (Appendix 1) for this session was also semi-structured in design.

**Analysis**

The analysis of the field notes was conducted using an empirically driven approach, reflecting the exploratory nature of the observational study. The aim was to generate knowledge grounded in the participants' perspectives, actions, and attitudes. Field notes were indexed according to themes relevant to the project and subsequently informed the development of the interview guide used in the following focus group interviews.[12] The three interviews were transcribed in full, utilizing the "Transcribe" function in Microsoft Word as a supportive tool. Interview data were analyzed through an inductive thematic analysis, following the methodology outlined by Braun and Clarke[13]. This process involved coding of interesting features and thematization, and is finalized by interpretation of the data, based on selected quotations, emergent themes, and the interview material as a whole.[13,14] An inductive approach was chosen to ensure an open and curious engagement with the data, deliberately avoiding the use of theoretical models or prior empirical frameworks. Efforts were made to set aside preunderstandings throughout the analysis.

## Outcomes

This section presents findings from both the observational studies and accompanying field notes, as well as the focus group interviews and the group interview. The results are organized into the emergent four main the-

mes: (1) Management, (2) Organization of Quality Assurance, (3) Approach Toward Quality Assurance, and (4) Skills in Quality Assurance. Our findings are substantiated with quotes and field notes, and the emergent subthemes are summarized and collected in table 3, at the end of this section.

**Management**

As the Danish healthcare system is structured today, districts must pay the hospitals for participation in QA programs under a hospital-based clinical laboratory. Therefore, the management needs incentives that encourage them to commit to QA programs in collaboration with a hospital-based clinical laboratories. This was also highlighted in the interview with the QA-BLS´s. They described the challenge of establishing a formalized collaboration around POCT QA activities when participation in the QA program is not mandatory but merely recommended.

*"We need someone at a higher level [political] to engage with the districts that aren't participating, rather than it being us, as a QA-BLS from a hospital, trying to get their attention."* ***(QA-BLS 2)***

The management's commitment towards QA was found to significantly influence EHH nurses' engagement and motivation in their interactions with the QA-BLS and in their participation in the QA activities. This was evident in the observational studies, where it was observed that a lack of communication from management to the relevant EHH nurses regarding participation in QA activities led to reduced engagement and motivation. Observed not only in performing the QA activities but also in interactions with the QA-BLS, which are seen in the following field notes:

*"The newly employed nurse begins by questioning why she is even present, expressing that she has not been adequately informed. The nurses also indicate that they have received no information about what is going to happen or why they are expected to participate in the QA meeting. It is evident that this lack of communication results in low engagement and a reduced sense of relevance."* ***(Extract from field notes from a QA-meeting with district 3)***

During the focus group interviews, participants were asked about the management's involvement in QA activities, and it was evident in both districts that EHH nurses perceive the management commitment to QA important for their QA efforts. Specifically, management is expected to allocate resources to support QA initiatives. One EHH nurse articulated this in the following quote:

*"If they want this to have significant value - which they actually do - then they also need to ensure that there are enough time and resources allocated to it [QA]."* ***(Nurse 4, district 1)***

The interviews also revealed that the interviewed EHH nurses feel supported by their management in participating in QA activities, as illustrated in the following quote:

*"It is also important that management understands the situation - and they have, from day one. And I must say, our manager is highly skilled at communicating with our senior management, clearly articulating what is needed to succeed. From my conversations with her [the manager], I get the impression that she is genuinely receptive."* ***(Nurse 5, district 2)***

In one district the EHH nurses themselves attempted to initiate development of the QA program, however, this proved challenging. Political mandates or other explicit demands were perceived as more effective in motivating management to act than the EHH nurses' own initiatives. This is reflected in the fact that other healthcare professionals, in the districts, performing POCT analyses were not subject to QA activities, despite the EHH nurses identifying this as a concern:

*"This is exactly what we've been wanting [QA of other healthcare professionals in the districts]. I've seen a need for it for a very long time but haven't really been allowed to pursue it. It's as if the management couldn't see the relevance before, but now I believe they do. It's now clearly stated in the new quality*

*standard for emergency home health nursing, so we have to act — and move forward."* ***(Nurse 1, District 1)***

Management's support and commitment towards QA - particularly their prioritization of time and resources - reflect the perceived relevance of these efforts and, consequently, influence EHH nurses' motivation and engagement in participating in QA activities. Both EHH nurses and QA-BLS's expressed that it is difficult to motivate management to participate in QA programs unless there is a clear external requirement to do so.

**Organization of Quality Assurance**

Nationally, there are significant differences in how EHH nursing services are organized within the individual districts, including their geographic location, the POCT equipment used, and whether blood samples are collected capillary or venous. These variations were also observed during fieldwork and were further substantiated in the interviews. The interview with QA-BLS highlighted the importance of designing QA programs that align with the specific structure and organization in each district's EHH nursing services, ensuring both practical, feasible, and cost-effective QA programs:

*"Because it's a district that is structured quite differently, as it's not an EHH nursing service but rather 40 nurses providing general care, and covering the EHH nursing function as well. That leads to a completely different structure and setup [regarding the QA activities], which means it becomes a matter of making the best of it."* ***(QA-BLS 2)***

Logistical factors also have an impact on the QA activities for POCT. These include the delivery of samples for QA at the hospitals, the collection of relevant POCT equipment in a district which needs QA checks, and the scheduling and location of QA activities in the districts:

*"I must report that I take all the equipment [POCT] from the south of the district to the north, so they are allocated to me (…), which means things are somewhat shut down during the QA meeting, so it needs to be quick and efficient."* ***(Nurse 5, District 2)***

It was also observed that administrative aspects - particularly those related to IT - can be discouraging for participation in QA activities, if they are perceived as cumbersome and complex. In one of the focus group interviews, the EHH nurses reported that the administrative burden was minimal (the QA-BLS took care of most of the administration), while in the other district they described it as time-consuming and involving multiple IT systems and procedures. This was exemplified by an EHH nurse in the following quote:

*"I find that the procedures in the district are cumbersome, and you must navigate through many IT-systems. You [the observers] saw for yourselves how much documentation was required, and on several different platforms [It-systems]. At the hospital, when you perform QA activities, it is accessible and straightforward. That is not the case out here [in the district]."* ***(Nurse 2, District 1)***

EHH nurses in the focus group interviews emphasized the importance of ensuring that all healthcare professionals in the districts who perform POCT analyses should be included in QA programs. This is due to the codependence of health care personnel in the districts, as patient care is sometimes initiated by healthcare personnel other than the EHH nurses:

*"I think this setup [QA program] serves its purpose well. What we've been asking for is something [QA activities] for the nursing homes in the district, specifically the equipment for CRP analysis. I feel it´s where our QA program is lacking - as you [Nurse 7] also mentioned."* **(Nurse 6, District 2)**

In addition to the above-mentioned the data also shows that it is essential for the QA-BLS that QA activities are conducted across all phases of the test process: pre-analytical, analytical, and post-analytical. This is reflected in the following quote:

*"For QA activities to become comprehensive it is important to include all three phases: pre-analytical, analytical, and post-analytical phases. We have tried to*

*examine how we can optimize each of the three phases." **(QA-BLS 1)***

Overall, when organizing QA programs, it is important to consider which logistical concerns there might be in the individual district, make sure that the administration and IT-solutions are well-structured and user-friendly. But it is also important to incorporate QA across all phases of the test process and of all relevant staff.

**Approach to Quality Assurance**

Overall, the observational studies demonstrated that professionalism is a central element in EHH nurses' understanding of what constitutes good patientcare. When EHH nurses perceive QA activities and collaboration with the QA-BLS as relevant, their natural engagement increases, and a clear motivation to participate in QA is observed. The fieldwork showed that participants relate differently to QA activities and to their QA-BLS depending on their perceived relevance of the QA work. These differences are not often verbalized among participants but are evident in non-verbal interactions, including how they engage with each other, how they approach POCT equipment and blood sample collection, and how they interact with the QA-BLS:

*"One EHH nurse is highly motivated by the QA training. She expresses that she has not previously received instruction in sample collection, and she has felt the need to rely on self-directed learning. In contrast, the other EHH nurse clearly states that she does not find the training relevant, as she is accustomed to performing the analyses, and she does not feel the need for further instruction. She cannot understand why she should observe the calibration of the POCT equipment. However, during the QA meeting, valuable dialogue between the EHH nurse and the QA-BLS is observed, particularly concerning pre-analytical procedures". **(Extract from field notes from a QA-meeting with district 3)***

The above-mentioned is aligned with data from the group interview with the QA-BLS's.

In the focus group interviews, EHH nurses emphasized the importance of being able to trust the results from the POCT analysis. In one district the EHH nurses expressed strong confidence in their POCT equipment and results, while the EHH nurses in the other district have adopted a more critical stance due to previous experiences with errors in results from POCT analysis that have had clinical consequences. This is also demonstrated in the following quotes:

*"When the QA-BLS comes to the QA-meeting - and she has the correct results from the lab at her hospital - we can observe that they align closely to the results from our POCT equipment. That's why we have this sense of trust [in the POCT equipment] - because that has been our experience every time. It's the reason we have such a strong feeling that our POCT equipment is providing accurate results." **(Nurse 6, District 2)***

*"I also feel a bit puzzled - if the results don't match what you're seeing, you start to think, hey, maybe there's something wrong with the equipment." **(Nurse 3, District 1)***

Among the EHH nurses in the focus group interviews, QA and the work of the QA-BLS are viewed not as a form of control, but as a reassurance for maintaining professional standards. Moreover, QA is seen to enhance patient safety, for example by preventing unnecessary hospital admissions, which is illustrated in the following quotes:

*"That's why I make a point of emphasizing that this is an assurance - quality assurance - and not a control. I believe it's something we can all learn from." **(Nurse 1, District 1)***

*"I think, if I were a patient, I would actually also want someone to come and performed quality assurance and test that it was done correctly." **(Nurse 3, District 1)***

Another important factor is the relationship with the QA-BLS, which in both districts plays an important role in the QA process. In one district, contact with the QA-BLS is primarily written, by email, and only initiated when necessary:

*"If something is seriously wrong, she [QA-BLS] will contact us directly. Otherwise, we typically check the database four days later,*

*where the results should be available. It is then our own responsibility to verify that everything is in order."* ***(Nurse 1, District 1)***

In district 1, EHH nurses also noted a significant difference between working with QA in a hospital setting versus out in the district at the EHH nurse service. This can make QA collaboration between hospitals (QA-BLS) and districts more complex. In this district there is a desire for more structured support, such as a consultant or other facilitating solutions. In contrast, EHH nurses in district 2 unanimously agree that having the QA-BLS visiting them in person is beneficial for relationship and collaboration. They also noted that face-to-face contact encouraged more questions and fostered constructive dialogue:

*"I find our QA-BLS to be excellent—always approachable and responsive. She is highly competent in her role, and you never feel that any question is too trivial or inappropriate to be asked."* ***(Nurse 5, District 2)***

For the EHH nurses to form a positive approach to QA it is important to make sure that they perceive the QA activities as relevant, and a reassurance for both them and the patients. The EHH nurses should have a clear understanding of the useability of the POCT equipment, but also its pitfalls. Thise factors can all be facilitated by a good relationship with the QA-BLS, because it opens for constructive dialogue between the EHH nurses and the QA-BLS.

**Skills in Quality Assurance**

In the focus group interview, EHH nurses emphasized the importance of having QA-BLS responsible for training programs with new colleagues in QA procedures:

*"She [QA-BLS] also assists in training of our new colleagues in venipuncture techniques and related procedures. She performs significantly more venipunctures than we do, so it is highly beneficial that the training is conducted by someone with the most extensive experience. I find that very valuable."* ***(Nurse 6, District 2)***

The EHH nurses understand that QA-BLS' involvement in QA training for POCT analyses is essential to prevent the spread of improper practices or procedural inaccuracies, which is emphasized in following quote:

*"Naturally, we contribute with the knowledge we have. However, it is possible to adopt "poor" practices gradually, and if these are passed on to a new colleague, it may lead to a shift in clinical practice. Therefore, it is preferable that the responsibility for approving and overseeing training lies with the QA-BLS."* ***(Nurse 5, District 2)***

It is evident that EHH nurses rely heavily on knowledge sharing in their daily work, as illustrated by the following quotes:

*"… I believe we [nurses in the district] also make extensive use of knowledge sharing."* ***(Nurse 1, District 1)***

*"We also have a culture that supports knowledge sharing. I believe this is particularly evident across the entire nursing practice."* ***(Nurse 4, District 1)***

It is therefore expected that EHH nurses will engage in knowledge sharing in relation to QA, and this is also demonstrated in the following quote, where an EHH nurse describes her wants regarding training and follow-up in relation to POCT QA:

*"It involves experience, training, and follow-up […], as minor errors may be repeated if there is no subsequent review or discussion with a colleague."* ***(Nurse 4, District 1)***

Consequently, it is important that the QA-BLS is accessible for consultation to ensure that the QA-BLS is the first choice in training and knowledge sharing to secure proper follow-up and updates regarding QA.

The four main themes identified through the analysis, which are presented in the results section, are further elaborated in the discussion section below.

**Table 3.** Main themes and subthemes.

| Observational Study Themes | Municipality 1 Subthemes | Municipality 2 Subthemes | QA-BLS Subthemes | Main Themes |
|---|---|---|---|---|
| - Management | - Management support<br>- Commitment towards QA<br>- Relevance/incentive for management | - Management support<br>- Economy | - Management support<br>- Commitment towards QA<br>- Economy<br>- Relevance/incentive for management | **Management** |
| - Organization of QA | - IT and administration<br>- Operational Aspects of QA<br>- Comprehensive QA – Including Both Analytical Procedures and Staff Competence | - Comprehensive QA – Including Both Analytical Procedures and Staff Competence | - IT and administration<br>- Logistics of QA<br>- Comprehensive QA – Including Both Analytical Procedures and Staff Competence | **Organization of Quality Assurance** |
| - Approach Towards QA | - Confidence in POCT equipment<br>- QA as reassurance (ensuring Patient and Staff Safety)<br>- Collaboration with QA-BLS | - Confidence in POCT equipment<br>- Collaboration with QA-BLS<br>- Quality Assurance Must Be Contextually Relevant | - QA as reassurance (ensuring Patient and Staff Safety)<br>- Quality Assurance Must Be Contextually Relevant | **Approach Towards Quality Assurance** |
| | - Training<br>- Knowledge sharing<br>- Follow up on training | - Training<br>- Knowledge sharing<br>- Utilization of QA-BLS | | **Skills in Quality Assurance** |

## Discussion

This section interprets the findings in relation to existing literature and evaluates methodological strengths and limitations of the study. This is followed by a discussion of how the findings - specifically the identified subthemes - can be applied in the development of QA programs in clinical practice, both within the participating districts and potentially at a national and even international level.

### Interpretation of Findings

The analysis identified four main themes, which will be discussed separately in the section below.

In the main theme ***Management*** incentives and financial considerations strongly affect district participation in QA programs. Danish districts operate within fixed service budgets negotiated annually with the government, prioritizing mandatory tasks before optional initiatives.[15] As QA for POCT is not a legal requirement, management commitment becomes critical. Research from Brooks and Anderson[16] emphasizes that management support and resource allocation enhance nurses' job satisfaction and engagement. Our findings indicate that visible management support and managements prioritization of QA for POCT enhance motivation for QA activities and strengthen collaboration with the QA-BLS. This ultimately contributes to improved quality in EHH nurses' professional practice.[16]

In the main theme ***Organization of Quality Assurance***, it is important that QA programs are tailored to local structures, logistics, and IT systems. Uniform QA programs are impractical due to organizational diversity across districts. It is essential that QA procedures are perceived as meaningful, as these activities are not immediately aligned with nurses' primary tasks. Studies show that tasks perceived as irrelevant to nurses' primary tasks reduce work satisfaction.[16] Therefore, QA programs should be integrated into the clinical workflows of the individual district. Furthermore, it is important to ensure that QA programs are comprehensive, encompassing all relevant staff and phases (pre-, analytical, and

post-analytical) of the test process. Once nurses recognize the importance of QA for POCT, they tend to engage actively in these efforts. This is also aligned with the nurses' professional values described by Weis & Schank[17], that when the nurses see the relevance in a work task, they commit to it. [17] The perceived importance of QA for POCT also leads to the understanding that QA must be carried out by all personnel performing POCT analyses, not only by EHH nurses.

Within the main theme ***Approach to Quality Assurance*****,** the relationship with the QA-BLS emerges as a critical factor. This relationship influences EHH nurses' engagement and participation in quality-related work. Brooks and Anderson[16] emphasize that collegial relationships are essential for nurses' engagement and job satisfaction. Consequently, fostering a strong connection with the QA-BLS is vital, as it can positively shape approach toward QA. Nurses are highly aware that QA contributes to both patient and staff safety, and they do not perceive these efforts as a form of control over their professional competence. This perspective aligns with nurses' fundamental ethical value of Responsibility, where conducting QA is essential for ensuring patient safety. [17,18] Confidence in the analytical process may lead to unwarranted trust in other steps of the procedure, such as pre-analytical and post-analytical phases. This is an important consideration for the QA-BLS. Kaya and Boz[19] describe how prior experiences influence future behavior. Therefore, integrating patient cases that illustrate potential sources of error in POCT analyses is crucial for enhancing EHH nurses' experiential knowledge and reinforcing their overall commitment to QA.

The final main theme, ***Skills in Quality Assurance*****,** addresses how EHH nurses are trained and maintain their skills related to QA for POCT. Findings indicate that professional knowledge-sharing among the nurses are essential to their clinical practice. This is supported by Weis and Schank,[17] who emphasize that such interaction is a key factor in optimizing nursing and caregiving. Nurses perceive professional follow-up and updates as most effective when conducted in collaboration with relevant specialists. This interprofessional linkage can lead to strong collaboration between QA-BLS and EHH nurses, as well as cross-sectoral cooperation between districts and hospitals. [20,21] In daily practice, EHH nurses naturally seek professional knowledge-sharing, consequently, the accessibility of the QA-BLS significantly influences whether EHH nurses consult this expert or rely on discussion among themselves. However, this practice carries the risk of perpetuating inappropriate workflows if the QA-BLS is not perceived as available. This concern was explicitly raised by the EHH nurses during the two focus group interviews.

**Discussion of Materials and Methods**

This section examines the materials and methods applied in the project and how they may have influenced the results. Contact was established through our existing network within clinical practice, primarily QA-BLS. Consequently, the districts participating in the project were already engaged in some form of POCT QA in collaboration with a hospital-based clinical laboratory While this facilitated access and ensured a baseline of quality awareness, it may also have introduced a selection bias, limiting perspectives from districts without prior QA experience. Some districts have prior experience with QA programs operating suboptimal. These perspectives emerged in both observational studies and focus group interviews and were further substantiated by interview with QA-BLS. However, because these insights stem from participants already involved in QA programs, there is a risk that factors identified here reflect issues only within EHH nursing services already involved in QA for POCT rather than the full spectrum of challenges faced by districts starting from scratch. Therefore, while we believe the identified factors are broadly relevant for POCT QA in districts, they may not be exhaustive.

The number of EHH nurses participating in each focus group interview ranged from three

to four, which is relatively small for achieving the desired group dynamics.[10] This limited size may have constrained the diversity of viewpoints and reduced opportunities for interactional depth. However, it reflects the actual size of the EHH nursing teams in the district. In one focus group, the clinical nurse specialist also participated, as she collaborates closely with the district EHH nurses. Initially, only EHH nurses from the team were intended to participate, but the inclusion of the clinical EHH nurse specialist provided a more nuanced perspective. While this decision enriched the discussion, it also introduced heterogeneity that could have influenced group dynamics. Data analysis focused primarily on content rather than relational dynamics among participants. Nevertheless, the observer monitored whether any participants dominated the discussion and potentially influenced others. Although some participants spoke more than others, no overt dominance was observed, and the overall atmosphere was perceived as safe and trusting.[10]

**Discussion of Results Applied in Clinical Practice**

Our findings identified factors affecting participation in POCT QA among the EHH nurses. These findings may serve as a foundation for developing tailored QA programs for each district's EHH nursing service. However, the practical implementation of these QA programs may vary significantly across districts with different resource levels and organizational cultures. This variability underscores the need for flexible frameworks rather than rigid programs. The main point is to ensure that EHH nurses perceive these QA programs as relevant and thereby enhancing patient safety.

The knowledge derived from this study is primarily associated with the EHH nursing service; however, we would argue that its applicability extends to other contexts in which POCT equipment is employed outside of a hospital-based setting, and when used by healthcare personnel other than BLS.

## Conclusion and Perspectives

The project identified various factors affecting POCT QA in EHH nursing service across four main themes: Management, Organization of Quality Assurance, Approach toward Quality Assurance, and Skills in Quality Assurance. Key insights for QA-BLS include establishing cross-sectional collaboration with relevant districts leaders; organizing quality programs with attention to local structures and workflows; and encouraging strong interprofessional relationships between QA-BLS and the EHH nurses to ensure training and follow-up of skills. It is important to note that these findings do not provide a method for initiating contact between a district and the QA-BLS. Rather, the findings are a tool to support the establishment and maintenance of High-quality QA programs for POCT analysis in the districts and thereby enhancing patient safety.

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## Appendix 1 – Moderator Guides

### Moderator Guide for district 1 - Focus Group Interview

- To begin, I would like to ask each of you to briefly introduce yourselves by stating your name and sharing why you chose to become an EHH nurse within the district.
  We will start with a few exercises where you will first reflect on the questions individually and then discuss them in plenary.
- What do you associate with high-quality district EHH nursing service? (Core values for nurses). Please think broadly about your profession, not only in relation to POCT analyses.
- What do you associate with high quality in relation to POCT performed in district EHH nursing service? (You may also include elements that contribute to reducing quality).
- Currently, the QA for POCT analyses performed out in the district EHH nursing service is anchored at a hospital-based clinical laboratory. What are your experiences/opinions regarding this:
  - Advantages/disadvantages.
  - Is there a formal agreement document you actively use, and is the setup clear?
  - Contact QA-BLS (Accessibility and communication channels).
  - Time frame (Is this task a strain on your daily work?).
  - How do you stay updated and maintain competencies related to the QA for POCT?
- Do you find that performing QA according to the QA-BLS or the procedures you follow for POCT in the district EHH nursing service adds value:
  - For the patient.
  - For your professional practice.
  - For interdisciplinary collaboration. (As we understand it, there are also staff in the districts who perform POCT analyses but are not included in the QA-program – is this correct and what are your views on this?)
- How do you perceive the role and significance of your management in relation to the QA for POCT in the district EHH nursing service?
- To what extent do you think management influences the participation in QA for POCT in district EHH nursing service – in general?
- What do you consider to be an ideal setup for QA for POCT performed in district EHH nursing service or which elements should be included in such a setup:
  - Ideal scenario – just think in terms of elements, not a complete package (Feel free to think freely – disregard financial constraints).
  - Importance of management support (Management's stance on QA).
  - Resources for QA.
- Finally, is there anything we haven't covered that you think is relevant to the topic?

### Moderator Guide for District 2: Focus Group Interview

- To begin, I would like to ask each of you to briefly introduce yourselves by stating your name and sharing why you chose to become an EHH nurse within the district.
  We will start with a few exercises where you will first reflect on the questions individually and then discuss them in plenary.
- What do you associate with high-quality district EHH nursing service? (Core values for nurses). Please think broadly about your profession, not only in relation to POCT analyses.
- What do you associate with high quality in relation to POCT performed in district EHH nursing service? (You may also include elements that contribute to reducing quality).

- Currently, the quality assurance for POCT performed in EHH nursing service is anchored at a hospital-based clinical laboratory. What are your experiences/opinions regarding this:
    - New and old arrangement:
        - Advantages/disadvantages.
        - Is there a formal agreement document you actively use, and is the setup clear?
        - Contact QA-BLS – in relation to both the new and old arrangements.
        - Accessibility and communication channels with the QA-BLS.
        - Time frame (Is this task a strain on your daily work?).

- How do you experience maintaining your competencies in relation to QA for POCT – in relation to both the new and old arrangement?

- Do you find that performing QA for POCT in EHH nursing service adds value:
    - In relation to both the new and old arrangements.
    - For the patient.
    - For your professional practice.
    - For interdisciplinary collaboration. (As we understand it, there are also staff in the districts who perform POCT analyses but are not included in the QA-program – is this correct and what are your views on this?)
- How do you perceive the role and significance of your management in relation to the QA for POCT in the district EHH nursing service?
- To what extent do you think management influences the participation in QA for POCT in district EHH nursing service – in general?
- Or are there other individuals responsible for QA (POCT coordinator/contact person)?
- What do you consider to be an ideal setup for QA for POCT performed in district EHH nursing service, or which elements should be included in such a setup:
    - Ideal scenario – just think in terms of elements, not a complete package (Feel free to think freely – disregard financial constraints).
    - Importance of management support (Management's stance on QA).
    - Resources for QA.
- Finally, is there anything we haven't covered that you think is relevant to the topic?

**Moderator Guide for Group Interview**

- To begin with, I would like to ask each of you to briefly introduce yourselves by stating your name and job role.
- What do you associate with high quality in relation to POCT performed in district EHH nursing service, based on your job position?
- What do you perceive as facilitating or inhibiting the nurses' participation in QA in district EHH nursing service (i.e., from a nursing perspective):
    - Nurses' perception of relevance regarding QA:
        - What do they consider important?
        - Are there aspects of QA that seem disconnected from nurses' core tasks (i.e., elements that do not fit into their daily practice)?
        - Please address both the old and new arrangements.
    - How significant do you perceive the role of management and financial resources to be in relation to QA for POCT and the district's participation:
        - Management (within your own organization and in the districts).

        - Financial resources (within your own organization and in the districts):
            - What do the districts pay for your services?
- If management and financial resources were not a factor – what would you consider to be an ideal setup for QA for POCT performed in district EHH nursing service, or which elements should be included in such a setup?
- Finally, is there anything we haven't covered that you think is relevant to the topic?

**Mini review**

# Addressing the Molecular Diagnostic Workforce Gap: Development of a Post baccalaureate Certificate in Molecular Genetic Technology

**Peter Hu PhD, CG(ASCP)$^{cm}$, MB$^{cm}$, MLS$^{cm}$, FACSc, FASAHP$^{1*}$, Vihbuti Srivastava, PhD, MB(ASCP)$^{cm1}$**

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***Background:*** **Molecular diagnostic laboratories face a persistent shortage of skilled technologists that was exacerbated during the COVID 19 pandemic. Professional bodies have called for urgent expansion of accredited training programs.**
***Methods:*** **A seven item survey was disseminated to alumni, clinical affiliates, advisory board members, and professional networks from October 23 to November 24, 2023.**
***Results:*** **Of 300 responses, 291 were complete. Only 9.97 percent held a bachelor's in medical laboratory science and 5.15 percent in clinical laboratory science, yet 76.71 percent reported current involvement in molecular testing. Interest in an online certificate was high at 98.29 percent.**
***Discussion:*** **Findings indicate a mismatch between workforce skills and service demand and support targeted, flexible upskilling.**
***Conclusions:*** **A post baccalaureate certificate offers a pragmatic pathway to strengthen the molecular workforce and support quality patient care.**

***Keywords:*** Molecular diagnostics, clinical laboratory workforce shortage, online education, molecular technologist training, post-baccalaureate certificate

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## Introduction

Molecular diagnostics has emerged as a cornerstone of modern laboratory medicine, enabling precise detection and characterization of genetic, infectious, and oncologic conditions. Over the past decade, rapid technological advancements including real time polymerase chain reaction (PCR), next generation sequencing (NGS), and digital PCR have transformed clinical workflows and accelerated the adoption of precision medicine. These innovations have expanded the scope of molecular testing beyond specialized reference laboratories into routine clinical practice, where timely and accurate results are critical for guiding therapeutic decisions, monitoring disease progression, and implementing personalized treatment strategies.

The COVID 19 pandemic underscored the indispensable role of molecular diagnostics in global health. Molecular laboratories were at the forefront of SARS CoV 2 detection, driving unprecedented testing volumes and operational demands. However, this surge in testing coincided with significant workforce disruptions. Many skilled technologists transitioned to pandemic related roles or left the profession entirely, exacerbating preexisting shortages in molecular diagnostic staffing. National surveys and professional organizations have documented these trends and warned of a crisis in laboratory medicine that threatens the timely delivery of essential diagnostic services.[1,2] Beyond pandemic related attrition, structural challenges persist. The complexity of molecular platforms requires specialized competencies in assay design, nucleic acid extraction, amplification, sequencing, bioinformatics, and quality assurance. Yet, the number of accredited educational programs offering focused training in molecular diagnostics remains limited. The American Society for Clinical Pathology and its Board of Certification have repeatedly called for urgent action to expand training capacity, citing the negative impact of workforce shortages on patient care.[1] These concerns are amplified by growing demand for molecular testing in oncology, infectious disease surveillance, pharmacogenomics, and hereditary disorders where accurate interpretation of molecular data directly influences clinical outcomes.[3-5] In response to these challenges, innovative educational models are needed to bridge competency gaps and strengthen the molecular workforce. Post baccalaureate certificate programs represent a pragmatic solution, offering targeted, flexible, and scalable pathways for individuals with foundational scientific training to acquire specialized molecular skills. Such programs can enhance laboratory readiness, support career advancement, and serve as steppingstones to advanced degrees or certification. This manuscript describes the rationale, design, and implementation plan for a fully online Post baccalaureate Certificate in Molecular Genetic Technology, informed by a needs assessment survey conducted among stakeholders in clinical laboratory science.

## Methods

We conducted an institutional needs survey to assess interest in and requirements for a Post baccalaureate Certificate in Molecular Genetic Technology. The survey contained seven items and was open from October 23 to November 24, 2023. The link was distributed via the alumni listserv, to program directors of clinical laboratory sciences within and outside the School of Health Professions, to advisory board members, clinical affiliate laboratory heads, and to professional organizations with requests to cascade to laboratory staff. Duplicate and incomplete responses were excluded prior to analysis.

## Results

A total of 300 responses were received. After quality control, 291 responses were analyzed (Table 1). There were only 9.97% participants with a bachelor's in medical laboratory science and 5.15% participants with a Bachelor's in a Clinical laboratory sciences discipline (figure 1) yet 76.71% (224/291) were currently performing or involved in molecular testing in their

**Table 1. Respondent characteristics and survey highlights (n = 291)**

| Measure | Count | Percent | 95 percent CI lower | 95 percent CI upper |
|---|---|---|---|---|
| Bachelor degree in medical laboratory science | | 9.97 | 7.03 | 13.95 |
| Bachelor degree in clinical laboratory science | | 5.15 | 3.14 | 8.32 |
| Currently involved in molecular testing Yes | 224 | 76.71 | 71.52 | 81.20 |
| Interested in online certificate Yes | 287 | 98.29 | 96.05 | 99.27 |

Note: Counts for medical laboratory science and clinical laboratory science were not recorded in the dataset and are presented as percentages.

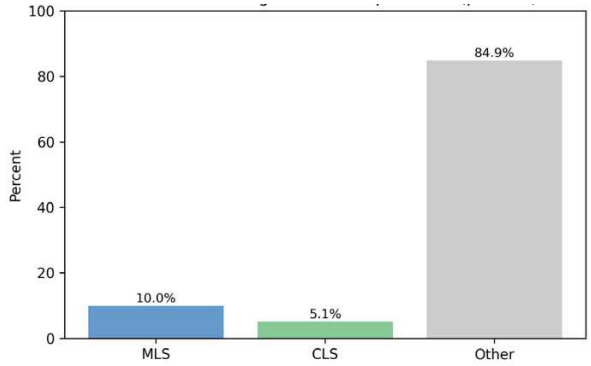


**Figure 1.** Educational background of respondents

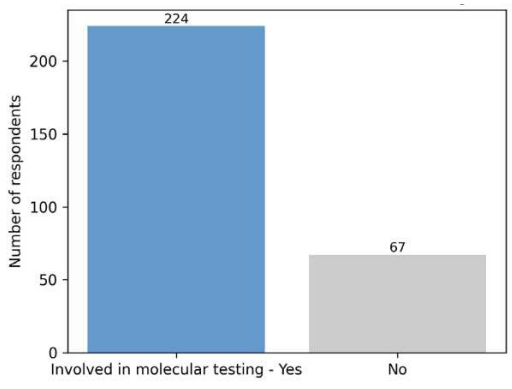


**Figure 2.** Current involvement in molecular testing

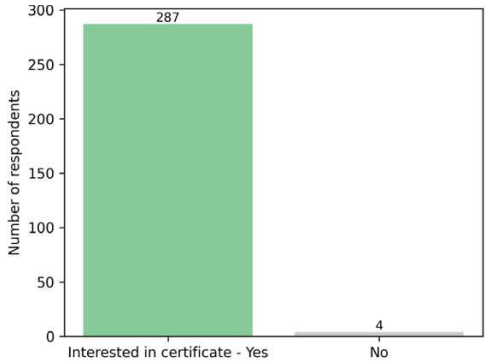


**Figure 3.** Interest in the online certificate program

current workplaces (figure 2). It is noteworthy that 98.29% (287/291) of participants expressed strong interest in online certificate program in molecular genetics to expand their knowledge and competency in molecular diagnostic testing (figure 3). These findings indicated two critical workforce gaps:

A. A substantial shortage of qualified and formally trained molecular technologists at the local, state, and national levels. As a result, many molecular laboratories reported employing individuals trained in unrelated or loosely related scientific disciplines to meet staffing needs.
B. A clear and significant need for additional structured education and skills development, reflected in the high level of interest in a molecular genetics certificate program among professionals currently engaged in molecular testing but lacking formal training.

Taken together, these results demonstrate a strong demand for targeted, high-quality education to support the expanding molecular diagnostics workforce. In response, school leadership elected to develop a Post-Baccalaureate Certificate in Molecular Genetic Technology to help bridge this training gap.

## Program Proposal: Post baccalaureate Certificate in Molecular Genetic Technology

As part of the school leadership's strategic response, the MGT faculty proposed the development of a Post-Baccalaureate Certificate in Molecular Genetic Technology.

Program structure: Four courses delivered fully online via the School of Health Professions learning management system and offered twice annually in fall and spring (table 2). Modules are self-paced and asynchronous with defined milestones and deadlines. Engagement includes weekly readings and video lectures, moderated discussion forums, graded assignments and exams, and virtual office hours (table 3).

This certificate, built on concentrated coursework in molecular genetics and diagnostic technologies, is designed to offer individuals with bachelor's degrees in traditional or labo-

**Table 2.** Curriculum overview and learning outcomes

| Course | Brief description | Key learning outcomes |
|---|---|---|
| **MG 4240 Introduction to Molecular Genetics** | Foundational principles of nucleic acid chemistry, genome organization, gene expression, and genetic variation with clinical relevance to diagnostics. | Describe molecular genetics; articulate DNA and RNA structure function; recognize genetic bases of disease; explain inheritance and variation. |
| **MG 4250 Fundamentals of Molecular Diagnostic Techniques** | Core laboratory methodologies and their application to disease detection and personalized medicine; critical appraisal of strengths and limitations. | Recognize principles underpinning diagnostic molecular biology; summarize foundational techniques; examine clinical utility; assess strengths and limitations. |
| **MG 4460 Advanced Concepts of Molecular Genetics** | Complex molecular mechanisms, gene regulation, genome architecture, and emerging diagnostic paradigms across oncology, inherited, and infectious diseases. | Demonstrate advanced understanding; explain regulatory networks and genome organization; contextualize genomic variants and rearrangements. |
| **MG 4470 Advanced Molecular Diagnostic Techniques** | Advanced detection and characterization of genetic anomalies with emphasis on validation, verification, quality control, and troubleshooting. | Evaluate advanced techniques; analyze complex datasets; apply quality control; assess clinical relevance and limitations. |

**Table 3.** Program structure and timing

| Element | Details |
|---|---|
| **Delivery** | 100 percent online and asynchronous |
| **Cadence** | Two intakes per year fall and spring |
| **Load** | One or two courses per semester |
| **Time to completion** | Two semesters minimum with up to two years allowed |
| **Learner support** | Virtual office hours, email, discussion boards, and formative feedback |
| **Assessment** | Assignments, quizzes, exams, and participation across the term |
| | |

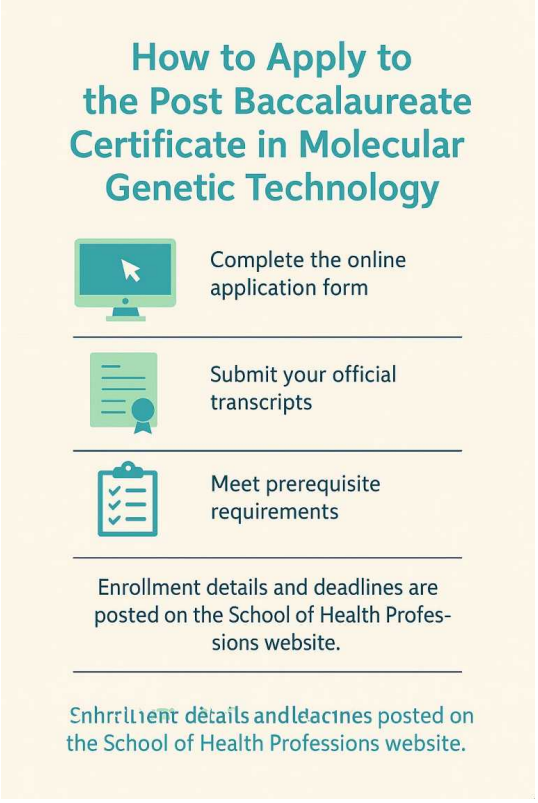


**Figure 4.** Steps to apply for the Post Baccalaureate Certificate in Molecular Genetic Technology[6]

ratory sciences a clear pathway to gain specialized competency, advance their careers, and pursue further graduate or clinical education. By implementing this program, the school aimed to establish a structured educational pipeline that equips technologists with the didactic foundation and practical understanding necessary to support molecular diagnostic testing in their current roles or successfully transition into dedicated molecular laboratory practice. Application Steps to apply for the Post Baccalaureate Certificate in Molecular Genetic Technology are provided in figure 4 and reference link.[6]

## Discussion

The survey highlights the gap between current workforce preparation and the complexity of contemporary molecular diagnostics. As testing expands across infectious disease, oncology, and genetics, laboratories require staff who are comfortable with assay design, sequencing workflows, quality systems, and data interpretation.[3-5] The proposed certificate offers a scalable pathway for scientists trained in adjacent disciplines to attain these competencies while maintaining employment. The online asynchronous format is designed to reduce access barriers and may help stabilize staffing by supporting upskilling without relocation or career interruption. [6]

## Limitations

This needs assessment used convenience sampling and self report, limiting generalizability. The brief seven item instrument constrained granularity of competency mapping. Future evaluations should incorporate multi institution sampling, objective pre post competency measures, and longitudinal tracking of workforce and patient care outcomes.

## Conclusion

A fully online post baccalaureate certificate in Molecular Genetic Technology is responsive to workforce needs and strongly supported by stakeholder interest. By emphasizing conceptual foundations, applied techniques, quality systems, and informatics, the program can enhance laboratory readiness and contribute to timely, high quality molecular testing.

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**Mini Review**

# Australia and New Zealand, So Close Yet So Far: A Mini Review of Educational and Professional Standards in Medical Laboratory Science

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**Medical scientists have a crucial role in diagnostic medicine but are undervalued as a profession. These practitioners must understand clinical laboratory tests and procedures and remain abreast of advancing technologies, emerging commercial analytical instruments and newly developed diagnostic testing kits. Globally all medical scientists require the same standard of training and professional performance.**

**Every country has professional and educational standards which are often aligned with the international standards and requirements for the quality and competence of medical laboratories (ISO15189 standards). Despite similarities in standards and increased global mobility of workforces, lack of formal recognition of medical scientists across the world has caused a shortage of competent and skilled laboratory professionals, who are restricted in their ability to move to other countries for work. This paper compares two very close countries which recognize and share many resources and professional standards. However, the oversight of medical laboratory science programs and staff varies significantly. One important factor is the lack of national registration for practicing medical scientists. Both countries have very high professional standards and high quality of patient care, but only New Zealand has both institutional and individual professional accountability while in Australia, medical scientists are not held responsible by the Australian Health Professional Regulation Agency (AHPRA).**

***Keywords:*** Medical science, professional regulatory standards, educational standards, New Zealand, Australia

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## Introduction and Background

For over more than a century, the medical scientist (laboratory medicine) profession has evolved by constantly adapting to changing technology and educational demands coupled with growing medical knowledge. The role of medical scientists involves the interpretation of clinical data and consultations with medical staff in addition to the traditional tasks of patient sample analysis and testing. Medical scientists work in clinical laboratories located in hospitals, community-based settings including physician offices and large privately run organizations, reference laboratories, biotechnology laboratories, and non-clinical industrial laboratories. There is a need for both greater specialization and/or multidisciplinary work force to meet the needs of the population, requiring uniform adherence to national and international professional standards to maintain public safety.[1] Despite performing similar roles in health care internationally, do the differences in training, education, laboratory regulation and standards pose a barrier to the global mobility of this specialized workforce? What does this mean for the future development of the medical scientists and technicians' role and diagnostic patient care in a very mobile global patient population? Will tertiary education and its educators perform a vital role in reaching the goal of a cross-border and cross disciplinary globally mobile workforce with the confidence of providing services of equally high standards?

A medical scientist (also referred to as a clinical laboratory scientist, biomedical scientist or medical laboratory scientist) is a healthcare professional who performs chemical, hematological, immunologic, microscopic, and bacteriological diagnostic analyses on body fluids and specimens. Given the key role of the medical scientists in the diagnostic chain of patient care, standardised training, national accreditation of educational programs and registration/certification of practising scientists is essential. The role of the medical scientist is similar across the globe, yet educational requirements vary greatly in terms of accreditation of educational programs, routes into the profession, clinical placement requirements and certification or registration of graduate practitioners. Due to continually advancing techniques in pathology, the practitioner is required to remain informed of scientific advancements, making sure their expertise is always evolving with the implementation of new technologies instead of being replaced by them.

National or international recognition of qualifications permits medical scientists to work and gain experience in diagnostic laboratories across the world. However, the global diagnostic training programs have developed to a point where this can occur. Most developed countries have formal registration of medical scientists and technical officers to protect the public and set minimum standards for ongoing assessment of competency and continuing professional development (CPD). Compulsory registration or certification of practising scientists and technicians not only strengthens and encourages adherence to national professional standards but also benefits the profession, the employers and public in the form of patient care.

Countries including Australia and a few others, do not have formal national registration of medical scientists. The Australian Health Professional Regulation Agency (AHPRA) ensures that health practitioners in Australia are suitably trained, qualified and safe to practise, however it does not currently oversee the registration of medical scientists.[2] Australia does have stringent professional standards and guidelines for organisational accountability but not at individual practitioner level. In New Zealand and the United Kingdom, the qualifications of each medical scientist in the country is standardized under a nationwide regulating body, while other countries such as United States of America have variations in educational requirements between different states.[3-5] In the absence of national registration, the Australian Institute of Medical and Clinical Scientists (AIMS) has initiated a voluntary self-regulated certification scheme,

which requires on going continuous professional development (CPD) beyond a basic undergraduate and/or post graduate degree in Laboratory Medicine. [6]

## Accreditation of clinical pathology laboratories

All public pathology laboratories must adhere to high standards in safety and quality.

**Australia**

Despite no formal recognition of medical scientist qualifications in Australia, most of the pathology laboratories in which they are employed (except some smaller specialized and private ones), must be registered with the National Association of Testing Authorities (NATA) which is the independent accreditation body for laboratories, inspection bodies, calibration services, producers of certified reference materials and proficiency testing scheme providers in Australia.[7] The National Pathology Accreditation Advisory Council (NPAAC) sets the standards and requirements that laboratories must meet in Australia for safe and quality laboratory practice.[8] Laboratories must adhere to these guidelines and obtain accreditation to be eligible for Medicare (publicly-funded universal health care insurance scheme in Australia, operated by the nation's social security department) rebate able services. NATA together with the Royal College of Pathologists Australia (RCPA) assesses laboratories against national standards set by NPAAC. A few testing protocols available through private pathologies may not be accredited, and as such they cannot offer services covered by the universal health care system and patients must pay out of pocket to cover diagnostic health care costs. The functions of NPAAC include providing advice to the Commonwealth, the States and the Territories on a range of accreditation issues. NPAAC also incorporates in its national standards the recommendations from Australian Commission on Safety and Quality in Health Care (the Commission) for improvements for safety and quality in health care across Australia.[1] In addition, medical laboratories are guided and governed by the National Blood Authority (NBA), established jointly by Australian, State and Territory Governments with an aim to improve and enhance the management and audit of the Australian blood and plasma products provided to hospital laboratories for patient care and research use. [9]

**New Zealand**

New Zealand requires most of their clinical pathology laboratories to be accredited by International Accreditation New Zealand (IANZ) which certifies medical laboratories in line with NZS/ISO 15189 "Medical Laboratories – Particular requirements for quality and competence."

A major difference to Australia besides laboratory accreditation, is that all practising scientists and technicians must also be registered and hold an annual practising certificate to work in pathology laboratories in New Zealand. This higher level of individual accountability is not seen in Australia.

## Accreditation of educational programs and competency standards in Australia and New Zealand

Accreditation of university programs ensures a high standard of medical laboratory science undergraduate and post-graduate programs. The purpose is to continue to set university program educational standards as the industry minimum for diagnostic medical scientists. Competency has been defined as "the ability to perform the activities within an occupation or function to the standard expected in employment."[10] It embodies attributes such as knowledge, skills, abilities, attributes, and attitudes required in professional practice.

**Australia**

Competency standards for Australian medical scientists working in a diagnostic pathology setting have been developed to reflect the contribution normally expected from a person with a degree in a relevant area of science or applied science from an Australian (or equivalent) university, together with two years

relevant professional experience in an accredited laboratory. This is the entry level of a medical scientist to this profession and reflects a combination of qualifications, skills and the assumption of personal responsibilities and accountability. Educational programs have been designed to provide graduates with these skills and competences.

In Australia, the primary qualification for medical scientists is a three- or four-year degree in medical laboratory science / laboratory medicine, which is reviewed and accredited by AIMS.[11] The programs are then reviewed every five years to ensure standards are maintained. In the final year of these programs, most students specialize in one or more medical science disciplines. Upon successful completion of a biomedical laboratory science program, graduates are classified as medical scientists and eligible for graduate membership of AIMS. Alternatively, a graduate with an AIMS accredited two-year full-time Master's degree in laboratory medicine, is also eligible to work as scientist in the discipline of their specialization.

In the absence of compulsory registration of practitioners, AIMS provides the required guidelines aligned with professional standards set by the NPAAC to ensure the graduates are work ready and trained to the highest standards.[8] One of the means of accomplishing that is through clinical placement. Clinical placement is a core component of an AIMS accredited degree program which can be spread over the 4 years of the program. It must include $\geq$560 hrs. placement in a NATA /ISO accredited laboratory but should not be only observational. Students must always work under supervision and cannot release any patient results.[11] The Australian *Qualifications* Framework (the national policy for regulated qualifications in Australian education and training, AQF) level 7 (graduates at this level will have broad and coherent knowledge and skills for professional work and/or further learning) in Australia is equivalent to New Zealand Qualifications Framework (NZQF) level 7 in NZ. Currently 13 universities in Australia offer AIMS accredited laboratory medicine specific degree programs.

**New Zealand**

In New Zealand, accreditation of Medical Laboratory Science programs is granted by the Medical Sciences Council (the Council) of New Zealand.[3] The council provides guidelines for medical laboratory science education programs to institutions and organizations that issue qualifications that enable graduates to apply for registration with the Medical Sciences Council in the medical science profession. Accreditation is based on the "Policy and Guidelines: Accreditation of Prescribed New Zealand Qualifications." This policy document applies to providers of New Zealand qualification programs accredited by the Medical Sciences Council for the purpose of registration in the medical laboratory science profession.[3]

The Medical Sciences Council 2014 publication (revised in 2020) states the standards and procedures for the accreditation of education programs leading to registration in the medical laboratory scientist scope of practice. [12] As a responsible authority under the Health Practitioners Competence Assurance Act 2003 (the Act), the Council is charged with describing the work of the medical laboratory science practitioners it regulates by setting competence Standards for Medical Laboratory Science Practitioners in Aotearoa New Zealand (revised November 2018).[13,14] The accredited educational programs are aligned with the council's competency standards.

Previously there was a 5-year cycle of accreditation of degree programs, which has changed now to an ongoing cycle of monitoring. Following the initial review of the program and subsequent accreditation, a qualification program is subject to an ongoing monitoring schedule. It maximizes the likelyhood that students/trainees enrolled in the program can complete their studies and graduate with a qualification recognized by the Medical Sciences Council for registration.

To become a fully qualified medical scientist in New Zealand, a minimum of a 4-year

Bachelor of Medical Laboratory Science degree and work as a trainee medical laboratory scientist for at least 6 months is required.[3] The graduates are then required to register as a Medical Laboratory Scientist with 'The Medical Science Council of New Zealand.' Every employee of a clinical laboratory must hold a current annual practicing certificate. Currently 3 universities in New Zealand offer the recognized laboratory medicine specific degree programs.

## Professional certification/registration and continuing professional development

The evolution of professions that must constantly adapt to both changing technologies and educational demands as the medical knowledge base grows, is maintained universally under the guidance and direction of professional bodies. The focus of registration or certification of practitioners in a profession is usually centred on the core areas of advocacy, members, events, professional development, continuing education, research and innovation. In addition to providing education, other activities include networking opportunities locally, nationally, and globally. As the medical science environment continues to change, certification and/or registration by professional organisations is a means of providing vital support to practitioners and an essential professional and educational partnership for their membership and the profession to ensure the sector is recognised and respected.

**Australia**

The AIMS offers voluntary certifications for medical scientists and technicians. Certification is valid for up to three years after a successful skills assessment. While this is not a requirement, certifications can help boost credibility in this field, and some employers require/recommend certification. Conditional certification runs for a maximum of two years, after which certified scientists/technicians are required to undergo competency assessment and provide CPD records to transition to full certification.

Status as a certified medical scientist is a formal recognition of scientific qualifications and is aligned with competency development and assessment processes and acknowledges their ongoing participation in CPD activities. Certification demonstrates increased professional credibility and prestige in the industry. It is anticipated and currently observed that employers are increasingly looking to certification as a desirable attribute during the recruitment process and online competency assessment tools used to register CPD. Certification demonstrates to employer the continued competence in a standardised way, reducing the burden of employers to update staff through providing professional development activities. This is one step closer to compulsory registration for all scientists and technicians working in the laboratory medicine industry. However currently, certification is voluntary and it does not guarantee uniform standards and accountability across the profession.

**New Zealand**

Medical scientists in Aotearoa New Zealand practise within a legislated regulatory framework under the Health Practitioners Competence Assurance Act 2003.[13] The Competence Standards revised in Nov 2018 (Aotearoa New Zealand) are directly linked to the three medical laboratory science scopes of practice defined by the Council under the Act.[14] Defined scopes of practice protect the health and safety of the public using professional titles. Only individuals who hold current registration with the Medical Sciences Council are permitted to use the professional titles of: Medical Laboratory Scientist, Medical Laboratory Technician and Medical Laboratory Pre-Analytical Technician.

New Zealand does have alternative pathways for the graduates of other non-accredited science degree programs. These graduates or medical laboratory science technicians may be able to do a shorter qualification in medical laboratory science courses to become a medical scientist, provided they are registered as a medical laboratory technician and have

worked in a New Zealand medical diagnostic laboratory for at least one year. Overseas trained scientists, including those from Australia, need to obtain provisional registration and apply for an annual practising certificate before working in a laboratory. Initially they work under supervision of their registered medical laboratory scientist for 3-24 months, before their provisional registration changes to full registration.

## Discussion

Medical scientists comprise a very large health practitioner workforce that are required to generate accurate results following the analysis of biological samples and tissues and to communicate the outcomes to medical practitioners for the diagnosis and subsequent treatment of disease. While medical scientists are educated and trained to a very high standard in accredited clinical pathology laboratories across the world, there are significant barriers to the mobility of this workforce due to the inconsistent oversight of the qualifications and training of medical scientists between countries. This article highlights these differences between two countries in the Australasia region, Australia and New Zealand.

As in most countries, the practice of a profession in Australia requires evidence of an appropriate level of education and practical experience. However, there is no statutory registration or licensing of medical scientists or technicians in Australia, although there is a voluntary certification scheme approved by the Australian Council for the Certification of the Medical Laboratory Scientific Workforce. There are additional fragmented checks and controls that oversee the quality of clinical pathology laboratories that ensure a very high standard of diagnostic health care delivery in Australia and the justification by the Australian government for the lack of individual registration or annual practicing certificate requirements to work as medical scientist in the country. As there is no formal registration of medical scientists in Australia, the Commonwealth Government would be required to legislate mandatory registration of medical scientists and if they were to do so, the profession would be administered by AHPRA.

New Zealand which is very close geographically, politically, fiscally and has economic cooperation with Australia has different requirements for the registration of practicing medical scientists. There are also similarities in professional standards aligned to ISO15189 in both countries, with a significant variation in the recognition and accountability of medical scientists and technicians' work. Scientists from New Zealand can work in Australia unconditionally, however scientists trained in Australia must go through registration if they seek employment in New Zealand. One of the criteria to easily obtain registration in New Zealand is through providing evidence of current registration status in the candidate's home country. This is not available to Australian trained and experienced scientists. Lack of national registration of medical scientists with AHPRA in Australia has an impact on the mobility of graduates and practicing scientists despite very high and equitable standards of tertiary education and professional standards in laboratory practice.

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IFBLS
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# IFBLS Scientific Network of Experts

## Introduction

The IFBLS Scientific Network of Experts was created to assist the IFBLS Board of Directors (BoD) in document review or projects which will benefit developments within laboratory medicine and our profession. Suitably qualified and experienced Biomedical Laboratory Scientists within all laboratory disciplines are invited to submit their CV.

IFBLS is a Non-State Actor in Official Relations with the WHO, which is underpinned by a triennial working agreement. The IFBLS Board of Directors receive calls for experts and volunteers for development of WHO documents and tasks.

Members of the Scientific Network of Experts may also be invited to submit articles, act as peer reviewers and editors for International Journal of Biomedical Laboratory Science (IJBLS). The Scientific Network will therefore contribute to development of IFBLS as the global voice of Biomedical Laboratory Scientists.

## Members of IFBLS Scientific Networks of Experts 2026-2029

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