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Incorporation of Molecular Diagnostics into Medical Laboratory Science Curriculum: Clinical
Facilities Expectations. An Asynchronous, Iterative, Online Delphi Study.

A dissertation submitted in partial fulfillment of the requirements
for the degree of Doctor of Philosophy at Virginia Commonwealth University

by

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List of Abbreviations

ABMG = American Board of Medical Genetics and Genomics

AGT = Association of Genetic Technologists

ASCLS = American Society for Clinical Laboratory Science

ASCP = American Society for Clinical Pathology

ASCP Categorical (Technologist/Scientist) Certifications: BB (blood banking), C (chemistry),
CT (Cytotechnologist), H (hematology), M (microbiology), MB (molecular biology)

ASCP Specialist Certifications: SBB, SC, SCT, SH, SM,

BCR/ABL = breakpoint cluster region and Abelson murine leukemia fusion gene

BOC = Board of Certification

CLA = Clinical Laboratory Assistant

CLT = Clinical Laboratory Technician

CLS = Clinical Laboratory Scientist

CMV = Cytomegalovirus

CT/NG = *Neisseria gonorrhoe* / *Chlamydia trachomatis*

CYP2C19 = Cytochrome P450 2C19 gene

FACMG = Fellow of the American College of Medical Genetics and Genomics

HBV = Hepatitis B Virus

HCV = Hepatitis C Virus

HIV = Human Immunodeficiency Virus

HPV = Human Papilloma Virus

HLA = Human Leukocyte Antigen

KRAS = Kirsten Rat Sarcoma gene

LDT = Laboratory Developed Test

MLS = Medical Laboratory Scientist

MRSA = Methicillin Resistant *Staphylococcus aureus*

MT = Medical Technologist

MTHFR = methylenetetrahydrofolate reductase

NAACLS = National Accrediting Agency for Clinical Laboratory Science

NCA = National Credentialing Agency for Laboratory Personnel

NRCC = National Registry of Certified Chemists

qPCR = quantitative polymerase chain reaction

RSV = Respiratory Syncytial Virus

VRE = Vancomycin Resistant Enterococci

Abstract

INCORPORATION OF MOLECULAR DIAGNOSTICS INTO MEDICAL LABORATORY
SCIENCE CURRICULUM: CLINICAL FACILITIES EXPECTATIONS.
AN ASYNCHRONEOUS, ITERATIVE, ONLINE DELPHI STUDY.

By Barbara Kraj

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of
Philosophy at Virginia Commonwealth University.

Virginia Commonwealth University, 2015.

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Chairman and Associate Professor,

Department of Clinical Laboratory Sciences

The medical laboratory science (MLS) profession is in need for published molecular diagnostics competency-based standards and curriculum. To assess their expectations of new MLS graduates, professionals performing and supervising performance of clinical molecular assays were surveyed to rate the importance of relevant cognitive and psychomotor learning objectives. A modified, asynchronous, iterative online Delphi process was utilized for assessment of consensus on the importance of the objectives. The survey was delivered through

online REDCap application. Program directors of 221 MLS programs accredited by the National Accrediting Agency for Clinical Laboratory Science (NAACLS) were asked to forward the first Delphi survey to target participants at their affiliated clinical sites. Ninety-four experts submitted complete surveys, including 88 who provided email addresses, indicating agreement to participate in future Delphi rounds. Most of the participants were certified by ASCP or NCA (81.9%), had over 10 years of laboratory experience (76.6%), and worked in a hospital setting (43.6%). The reliability of the surveys, assessed using Cronbach's alpha, was 0.96 and 0.97. In the second survey, the objectives assigned low importance by the majority were removed; and others, assigned high importance were expanded. Respondents were given the opportunity to confirm or change their opinion on the objectives after reviewing quantitative results and narrative comments collected in the preceding survey. Upon completion of the Delphi process, 25 essential items were identified as necessary for inclusion in the entry-level MLS curriculum. These concepts and objectives focused on basic molecular biology principles and general molecular laboratory operations, including practical knowledge of techniques designed to maintain specimen integrity and intense theoretical background of the polymerase chain reaction, as well as comprehension of the principles of laboratory assays designed for pathogens most commonly tested for using molecular methods. In this study, the investigator also provided information on the preferred number of contact hours devoted to each group of the identified essential items. The goal of creating the list of essential concepts and objectives was to share it with MLS educators, the NAACLS and the provider of MLS certification exam, the American Society for Clinical Pathology Board of Certification (ASCP-BOC), to contribute to the existing exam content guidelines.

Chapter One: Introduction

This introductory chapter provides the reader with background information regarding the addition of new content area, molecular diagnostics, to the curriculum in clinical/medical laboratory science (hereafter referred to as medical laboratory science). The chapter is divided into seven sections. In the beginning, the incorporation of molecular methods to the laboratory testing menu is addressed with focus on obstacles and factors that contributed to the introduction of this methodology. Next, the initial efforts to include molecular diagnostics content into the medical laboratory science (MLS) educational curricula upon the National Accreditation Agency for Clinical Laboratory Science (NAACLS) requirements are described. The subsequent sections present a brief overview of a previous study performed by the author/principal investigator to assess the extent to which these requirements were adhered to in 2005 and the American Society for Clinical Laboratory Science (ASCLS) Levels of Practice taskforce efforts to delineate the competencies of the practitioners in view of the changes in scope of practice prompted by the inclusion of molecular methodology. The justification for seeking input from practicing experts when modifying MLS curriculum is provided. The chapter concludes with the description of molecular diagnostics teaching experience of the author and the statement of dissertation purpose and research questions.

Incorporation of Molecular Methods in the Clinical Laboratory Testing

Various laboratory techniques based on nucleic acid testing, commonly known as “molecular methods,” have been used in basic science research for about half a century, since the

memorable deciphering of DNA double helix (Watson & Crick, 1953). The development of molecular methods rapidly increased following Kary Mullis' discovery of polymerase chain reaction (PCR), an efficient, sensitive and relatively quick method of nucleic acid amplification utilizing impressively small quantities of source material (Saiki, 1988). However, the introduction of molecular based methods into clinical setting initially stumbled on some difficulties due to large amount of manipulation to detect the amplified PCR product, which included laborious gel castings, carcinogenic ethidium bromide staining, and UV-light photography (Kraj & Nadder, 2007). The risk of cross-contamination among samples and lack of molecular diagnostics training among medical technologists have also contributed to the absence of this technology in medical laboratories. And finally, the delay may have been caused by some ethical concerns regarding the use of human genetic material for diagnostic purposes (Kraj & Leibach, unpublished).

In 1987 an *Ad Hoc* Committee on DNA Technology, DNA Banking and DNA Analysis of the American Society of Human Genetics compiled several recommendations regarding DNA based testing, specifically the ownership of the deposited DNA samples, risks of misunderstanding of the results by the lay public, conditions of the release of genetic information gained upon testing to third parties, and evaluation of the competency of the laboratory's director. The recommendations of the Committee were published as "Points to Consider" (ASHG, 1988).

Outside factors have initiated the incorporation of molecular assays to microbiology, immunology, hematology and blood bank testing menus. In 1997 the European Committee for Proprietary Medicinal Products had requested that as of July of 1999 all fractionated plasma products are tested for HCV using nucleic acid testing (NAT) assays. This had prompted NAT

implementation in the United States (US) since many blood banks exported blood and blood products to Europe (Gallarda & Dragon, 2000). High sensitivity and specificity of molecular procedures have caused FDA to approve many of the assays for clinical use which in turn encouraged diagnostic laboratories to offer molecular based assays in their test services. However, the average hospital laboratory was limited in the types of molecular assays due to cost of newly developed automated instruments adaptable to high throughput technologies. Because of the cost limitation, molecular diagnostics was and still is mostly performed in reference laboratories which is the reason for limited number of internship sites for students trained in molecular methods.

To help the medical laboratory science professionals become more familiar with the new methodology upon entry of molecular diagnostics into the clinical setting, the researchers from the Departments of Clinical Laboratory Sciences and Pathology at Virginia Commonwealth University discussed the advantages and limitations of molecular-based clinical methods, identified the gold standard assay by which other molecular tests may be evaluated, compared principles and applications of hybridization, amplification and sequencing based techniques available at the time and described quality control issues in molecular testing (Nadder & Langley, 2001). This work was published as American Society for Clinical Laboratory Science sponsored continuous education (PACE) resource for the clinical laboratory professionals on molecular diagnostics.

According to 2007 Washington G-2 Report on Business Strategies for Molecular Diagnostics in the Lab (Murg & Terry, 2007), the average number of billable molecular tests performed by 300 surveyed laboratories across the United States increased almost 30% from January 2004 to December 2006 and will continue to grow as more traditional procedures are

converted into molecular tests (Bogert, 2007). The inclusion of growing numbers of molecular based assays into the available clinical laboratory test menu justifies review of the traditional MLS responsibilities and expansion of their training.

Inclusion of Molecular Diagnostics in the MLS Curriculum

Due to increasing demand for medical laboratory scientists to be proficient in molecular-based techniques, the National Accreditation Agency for Clinical Laboratory Science expanded their Accreditation Standards to include molecular diagnostics in the MLS curriculum (NAACLS, 2001):

“The curriculum shall include [...] components of laboratory services such as hematology, hemostasis, chemistry, microbiology, urinalysis, microscopy, MOLECULAR DIAGNOSTICS, immunology and immunohematology. This includes [...] PERFORMANCE OF ASSAYS [...]”.

According to workforce analysis by the Bureau of Health Professions, introduction of molecular content (Figure 1) was the most frequent curricular change among the programs surveyed by the American Society for Clinical Pathology in 2001 (Ward-Cook, Daniels, & Gueroguieva, 2002; USDHHS, 2005). It is logical to infer that the changes were a direct result of the revised NAACLS Standards. However, with few resources available in this new content area, educators of MLS programs expressed dissatisfaction with molecular diagnostics instruction they provided (Miller & Abbate, 2002).

The idea for the study presented in this manuscript began to emerge during an intense search for molecular diagnostics educational materials appropriate for students pursuing a Bachelor of Science (BS) degree in Medical/Clinical Laboratory Science. A search in 2005 revealed that there was not one repository available to new molecular diagnostics instructors

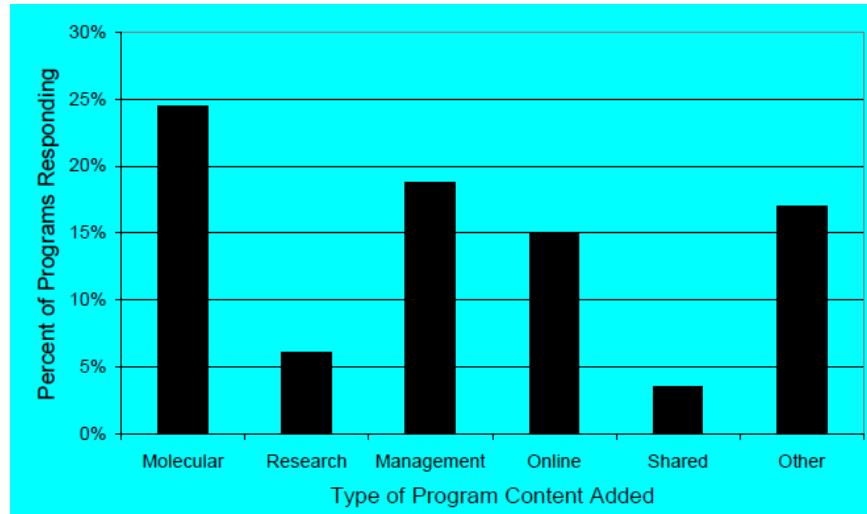


Figure 1. New Content of Program Curricula per ASCP Board of Registry Survey of MLS Programs. From: “The Clinical Laboratory Workforce: The Changing Picture of Supply, Demand, Education and Practice” with permission (USDHHS, 2005).

where they could find materials describing specific molecular diagnostic tests performed in clinical laboratories even though the market offered numerous basic science molecular biology textbooks. Some of the sources were dated prior 1995. Other resources included only lecture outlines for MLS instructors but lacked accompanying text or were too complex for a BS level student Textbook (Farkas, 1993; Tsongalis & Coleman, 1997; Tsongalis & Coleman, 2002). An instructional CD, “DNA 101: A Simple Guide to DNA & Its Use in Laboratory Testing” and a National Institute of Health sponsored website with information on molecular diagnostics of cancer were available (Polancic, 2003; Kelly & Kerrigan, 2005). However, these sources were not familiar to the majority of MLS instructors informally inquired by the author (personal communication, 2005). The lack of readily available textbooks and procedure manuals could be the source of the frustration revealed by the surveyed educators (Miller & Abbate, 2002).

Previous Study Results

To determine if the incorporation of molecular diagnostics information into MLS programs has improved since 2002 and to identify teaching materials that had gained the

acceptance of the molecular diagnostics instructors, a brief informal electronic survey containing six questions was emailed in June 2005 to over 220 accredited MLS (formerly CLS/MT) program directors listed on the NAACLS website (NAACLS, Accredited and Approved Programs, 2005). All but one out of the total of 40 respondents stated that molecular diagnostics was taught in their programs although only in one-third of the programs was this topic covered as a separate course. Less than one-third of the programs included student laboratory instruction. Respondents' comments about teaching materials have revealed frustration among the educators and approximately 40% recommended specific sources. Not one textbook was preferred by a statistically significant number of instructors. One institution revealed their plans to open a Diagnostic Molecular Scientist (DMS) program in 2006. Only 15% reported familiarity with the "Human Genetics Curricula for the Health Professionals Project" in which the NAACLS participated since 2000. These results indicated that in 2005 MLS educators still needed guidance with incorporating molecular diagnostics into their curricula in order to comply with NAACLS requirements. The results of this informal survey were presented at Clinical Laboratory Educators Conference in San Antonio (Kraj B. , Status of Molecular Diagnostics Incorporation into Clinical Laboratory Science Curricula: Results of a National Survey, 2006) and during the annual American Society for Clinical Laboratory Science – Georgia meeting in Macon, GA (Kraj B. , Molecular Diagnostics Issues Discussed at CLEC, 2006). Graph representations of survey results are summarized in Appendix A. The survey, although informal, contributed significantly to the author's knowledge about the status of introducing molecular diagnostics into medical laboratory science curricula in the United States four years after the NAACLS mandated teaching molecular diagnostics as one of the accreditation requirements. Results of the survey revealed that even though the MLS community was well aware of the

accreditation Standards, the programs represented by the respondents were not uniform with regards to the extent of teaching theoretical concepts and laboratory performance of assays. This could be partially due to the fact that programs that have received NAACLS accreditation renewal prior to September 30, 2001; and new programs that requested renewal between October 1, 2000 and September 30, 2001 had a choice of using either the 2001 or the 1995 Standards. This suggests that some programs may not have introduced molecular diagnostics as they would still be in compliance with the old Standards until September 2008. The survey had also revealed lack of preferred teaching resources, recognized by the majority of instructors. It should be mentioned here that high frequency with which the respondents were avoiding answering certain questions pointed to less than ideal survey design which justified development of a new, improved instrument.

Addressing the Need for Students Trained in Molecular Diagnostics – Reevaluating the MLS Scope of Practice

The Clinical Laboratory Workforce: The Changing Picture of Supply, Demand, Education and Practice document addressed to a certain extent the dynamic character of medical laboratory scientist scope of practice (USDHHS, 2005). Periodic reevaluating the scope of MLS practice and levels of practice is warranted due to dynamic nature of the profession resulting from continuous changes that occur in the clinical laboratory, one of which is frequent implementation of newly developed technologies, especially in the area of broadly understood genetic testing. In 2005, the Board of Directors of ASCLS, the professional organization that represents the medical laboratory workforce and leadership, has initiated formation of a special taskforce with the goal of evaluating the levels of practice in the laboratory based on knowledge,

skills, competencies, and defined attributes. The taskforce has proposed a model for Levels of Practice (LOP) in MLS (formerly CLS) (Table 1).

Table 1.

Clinical Laboratory Levels of Practice Assigned to Established Credentials.

	Title	Credential
Level I	Clinical Laboratory Assistant I	CLA
Level II	Clinical Laboratory Assistant II	CLA
Level III	Clinical Laboratory Technician I	CLT
Level IV	Clinical Laboratory Technician II	CLT
Level V	Clinical Laboratory Scientist I	CLS
Level VI	Clinical Laboratory Scientist II	CLS
Level VII	Clinical Laboratory Specialist	CLS
Level VIII	Doctor of Clinical Laboratory Science	DCLS

Note: Table from “Report of the Implementation workgroup of the Levels of Practice Task Force” (ASCLS, 2008).

The model, consisting of total of eight levels, also attempted to define the skills expected of the new professionals (ASCLS, 2008). How do molecular skills and knowledge fit these levels as defined by the taskforce? Generally described molecular skills are found under levels IV, V and VI presented in Appendix B (ASCLS, Levels Of Practice Position Paper, 2009). Practice skills listed for level IV (experienced, associate degree CLT/MLT certified technician) are described as “simple molecular testing that follows established protocols including DNA probes”. Practice skills listed for level V, appropriate for an entry level practitioner with a baccalaureate and certification as a clinical laboratory scientist, are “advanced molecular testing that follows established protocols including DNA probes”. Exact “established protocols” are not specified for either level in the paper, and qualities that set the “simple” testing apart from the “advanced” testing are not provided. Various target and signal amplification methods are currently the standard established molecular based diagnostic assays offered by clinical laboratories.

However, PCR, one of the first amplification assays, is not found in the model until level VI

which is reserved for the MLS who, in addition to being certified BS level practitioners, have completed unspecified additional education required to perform microarrays and PCR, listed as Advanced Techniques in Body Fluids. Additional description of the term “DNA probes” is also lacking. Practice level VI, according to the model, also includes personnel holding specialty certification in an area such as blood bank, hematology, coagulation, cytogenetics, etc. In this model, the MLS with specialty in molecular biology would be qualified to modify, troubleshoot and evaluate molecular assays categorized as “Advanced Techniques in Body Fluids (Micro Array and PCR)”. They would also be involved in research and development of molecular methods. Perhaps careful defining the molecular practice skills applicable to each level in the model could be a project on its own. The model was developed by the taskforce and then distributed with a request for feedback from representatives of ASCLS and ASCP, as well as American Medical Technologists (AMT), and Clinical Laboratory Management Association (CLMA). Practice skills attributed to each level and listed as they are in the 2009 position paper have been chosen based on the feedback, which may not be representative of the total workforce (ASCLS, 2008). From the documentation available from ASCLS website, it cannot be inferred whether input was received from experts experienced in performance of molecular testing.

The Necessity to Seek Input from Practitioners

Aside from discussion with colleagues who teach, input from experts who are current practitioners is necessary to design a program (course) which will produce desirable qualities of graduates. A senior lecturer in the Professional Development Centre at the University of New South Wales, in her extensive text *Designing Courses for Higher Education* (Toohey, 1999), Susan Toohey cites the Australian education authorities to describe these desirable qualities, categorized in three major groups: generic skills, body of knowledge, and professional/technical

skills (National Board of Employment Education and Training, Higher Education Council, 1992). In summary, the academics are known to emphasize the generic analytical skills. However, the employers or future co-workers may expect the graduates to be able to efficiently perform specific tasks and troubleshoot. It may be anticipated that the expectations regarding the extent of new graduates knowledge base and manual dexterity required to work in molecular environment will be different in a hospital laboratory and in a reference laboratory. For example, a facility in which the only molecular test offered is *Neisseria gonorrhoe/Chlamydia trachomatis* (NG/CT) assay (like many hospital laboratories) would not require the knowledge of cycle sequencing principles upon hire. According to Emmes Survey of US Laboratories Report, the focus of molecular diagnostics is on the topics presented in Table 2 (Who's Doing What in Molecular Diagnostics? , February 2009).

Table 2.

The Focus of Contemporary Molecular Diagnostics.

Test categories	Conditions/Pathogens
Infectious Disease Testing	Chlamydia and Gonorrhea HBV Viral Load HCV Viral Load, HCV Genotyping HIV Viral Load, HIV Genotyping HPV, HPV Genotyping Herpes Simplex Virus (HSV)
Hospital Acquired Infections	MRSA, VRE
Coagulation Factors	Factor II, Factor V Leiden
Oncology Testing	BCR/ABL, Bladder Cancer, Her2Neu, MTHFR
Transplant Medicine	HLA Typing
Hereditary Disorders	Cystic Fibrosis (CF), Fragile X
Respiratory Infections	Influenza A/B, Group A Strep, MTB (Tuberculosis), <i>Bordetella pertussis</i> , Adenovirus, Respiratory Virus
Communicable Diseases	CMV (Cytomegalovirus), EBV (Epstein-Barr Virus)

Note: Data adapted from “Emmes Survey of US Laboratories Report” Summary (Who's Doing What in Molecular Diagnostics? , February 2009)

The current diagnostic test menu offered by a particular clinical site could be the factor contributing to the laboratory's expectations towards the incoming MLS. Further, the opinion regarding the skills required of entry level practitioners may be also influenced by the current employees' educational and certification status. Presently, under Clinical Laboratory Improvement Amendment (CLIA'88 - 42 CFR §§493.1461 and 1462), the supervisory personnel in the molecular diagnostic laboratories do not have to be a certified MLS (CLIA, 2004); (CDC, 2009). This and other nuances of the contemporary molecular diagnostic facility should be taken into consideration when assessing the laboratory's expectations.

Development of Molecular Diagnostics Instructional Materials

In addition to defining the LOP, the goals of the ASCLS taskforce listed in the position paper are the development of a process that would evaluate the changing practice needs and matching the educational curriculum to these needs (ASCLS, 2008). These goals are in concordance with the general aim of this study to assess expectations of clinical laboratories that offer molecular diagnostic services which would facilitate development of teaching materials for clinical molecular methods educational course. In order to meet the needs of the contemporary clinical laboratory to hire competent personnel, specific content must be taught in educational programs.

The American Society for Clinical Pathology Board of Registry (ASCP BOR) Study Guide for the Clinical Laboratory Certification Examinations contains a "Molecular Pathology" section providing examples of molecular questions that could be expected on the exam (Tanabe & Holladay, 2009). However; the examination guidelines for new graduates applying for the Medical Laboratory Scientist (MLS) certification, available online on ASCP Board of Certification (ASCP-BOC) website until September 2014 only included unspecified "Molecular

Techniques” under “Instrumental and Analytical Techniques” in the Laboratory Operations section. This entire section contributed overall 6% to the exam content (ASCP, 2009). The updated, guidelines mention molecular concepts without much detail in three areas: molecular genetics of blood group systems, and molecular methodologies required for identification and detection of microorganisms and antimicrobial susceptibility testing, and in laboratory operations (ASCP, 2014). The document provides Matrix Assisted Laser Desorption Ionization Time-Of-Flight (MALDI-TOF) as an example of the “molecular methodologies”. No other types of assays are listed. This example does not represent a typical technology based on nucleic acid testing as it is based on mass spectrometry of vaporized proteins (Lehman & Manuselis, 2015). It should be noted here that ASCP-BOR united with the National Credentialing Agency for Laboratory Personnel (NCA) in the fall 2009, at which time NCA ceased to exist and ASCP-Board of Certification (ASCP-BOC) was created (ASCP BOR and NCA Form Single Certification Agency. News Release, 2009). Merging of the two certification agencies resulted in a change in nomenclature of the credentials awarded to those passing the examination. The MT and CLS credentials were replaced with MLS.

The NCA, which was founded in 1978 by the American Society for Clinical Laboratory Science (ASCLS) to ensure the credibility of the profession, had periodically published examination content guidelines based on job market analyses (Beck, Doig, & Nettles, 1997; Doig, Beck, & Kolenc, 2001; AGT, 2009). Table 3 lists the molecular content of CLS certification exam, which became effective in January 2009 (NCA, 2007). The content is no longer available online and the items listed in the table are not found in the current ASCP-BOC content guidelines for entry-level MLS certification.

Table 3.

National Credentialing Agency for Laboratory Personnel Molecular Content for CLS.

VII. MOLECULAR TECHNIQUES
A. Specimen Suitability and Processing
1. Evaluate specimen suitability and process specimens according to laboratory protocol to isolate/extract nucleic acids considering type and test required
2. Evaluate suitability of processed specimen (e.g., nucleic acid yield and quality)
B. Analytical Techniques
1. Perform nucleic acid detection and manipulation to include <ul style="list-style-type: none">• digestion• labeling (e.g., amplification, nick translation)• separation• detection
2. Perform nucleic acid amplification (e.g., PCR, RTPCR, real-time PCR)
3. Perform molecular technique applications according to lab protocol, analyze data to accept/reject results, recognize factors interfering with test results, and take corrective action, record/report results for: <ul style="list-style-type: none">• organism detection (e.g., M. tuberculosis)• viral load (e.g., HIV, HBV, HCV)• genetic disease (e.g., cystic fibrosis, Factor V Leiden)• malignancy (e.g., CML, bcr/abl oncogene)• transplantation matching• forensics• paternity matching
4. Correlate results to available information including: <ul style="list-style-type: none">• diagnosis, patient history• results from previous / concurrent tests
5. Respond to inquiries from other health professionals about tests, results, reference intervals, and specimens

Note: Content from: Section VII. Molecular Techniques. “Clinical Laboratory Scientist (CLS) Content Outline”. National Credentialing Agency for Laboratory Personnel, 2007.

In 2012 the ASCLS formed a Body of Knowledge Committee in an effort to redefine the medical laboratory technician and medical laboratory scientist areas of expertise. The Committee asked scientific assemblies’ members to provide comments on documents developed by medical laboratory scientists selected by the committee (Ray & Rydell, 2013). The molecular scientific

assembly members (including the author of this proposal) received the respective document outlining molecular diagnostics BOK in August 2013 and provided feedback by October 1, 2013. Although the ASCLS BOK document listed molecular diagnostics terms and techniques, not all of them were linked to specific learning objectives.

Another stakeholder, the Training and Education Committee Medical Laboratory Scientist Curriculum Task Force of the Association for Molecular Pathology (AMP), was engaged in seeking opinion on employee expectations in molecular diagnostics laboratories. In fall 2012 the Director of Scientific Programs distributed a survey to managers of molecular diagnostic laboratories (Limson, 2012) for the purpose of developing a curriculum in molecular pathology and genomics for MLS (Taylor, Bennett, Deignan, Hendrix, Orton, Verma, Schutzbank, 2014). The respondents were asked to rate the expected expertise of recent graduates of a baccalaureate degree program in medical laboratory science and Master's degree program in molecular diagnostics in a variety of molecular tests/skills using the following levels: unfamiliar, familiar with concept, familiar with skill and expert. The graph representing the data showed, side by side, the levels of expertise in 20 diagnostic techniques expected of baccalaureate degree graduates and master's degree graduates though no differentiation was made between graduates of MLS and DMS programs. Nevertheless, the authors provided recommendations for molecular pathology curricula for baccalaureate programs in medical laboratory science, baccalaureate programs in diagnostic molecular science; and master's programs in diagnostic molecular science. The authors' recommendations consisted of a list of topics and techniques for a molecular curriculum but did not include specific cognitive or psychomotor objectives.

To fulfill the NAACLS requirement of introducing molecular diagnostics into the curriculum, in response to emergence of some molecular techniques in student internship sites, and in anticipation of the possibility of molecular content on certification exams in the future, the author of this study developed a week-long molecular diagnostics module that was incorporated in the clinical chemistry course at her institution. In 2005, the module only consisted of a lecture sequence supplemented with virtual exercises (Goss, Warren, & Hallick, 1996; Amagai, Bonetta, Liu, Relman, Buffington, Pietsch, non-dated), while in 2006 and 2007 manual rapid DNA isolation from finger stick blood deposited on FTA Elute cards (Whatman Ltd., cat# WB120401) and PCR-based DNA typing laboratory exercises were included (Edvotek, Bethesda, MD, cat # 334 and 333). Course exam performance of the students exposed to virtual versus hands-on laboratories was compared to assess whether the inclusion of assay performance resulted in significantly higher test scores. Ten multiple choice questions derived from the molecular module (numbered 86-96) were included in the written final clinical chemistry course examination. The hands-on group scored significantly higher than the virtual laboratory group in their responses to the test questions (Figure 2). Upon closer examination of the data, it became evident that scores achieved by students performing in the middle percentiles were responsible for the overall outcomes as the inclusion of advanced hands-on exercises did not significantly improve the scores of students performing in the lowest and in the highest percentiles. These results were presented at Clinical Laboratory Educators Conference in Savannah, GA (Kraj, Pretlow & Russell, 2008) and published (Kraj, Pretlow, & Russell, 2011). In fall 2008, the department introduced a revised curriculum with a three credit hour lecture and two credit hour laboratory courses to be offered in the senior year. In 2009 a working version of laboratory manual was developed by the author and included guidelines for 12 laboratory sessions. The

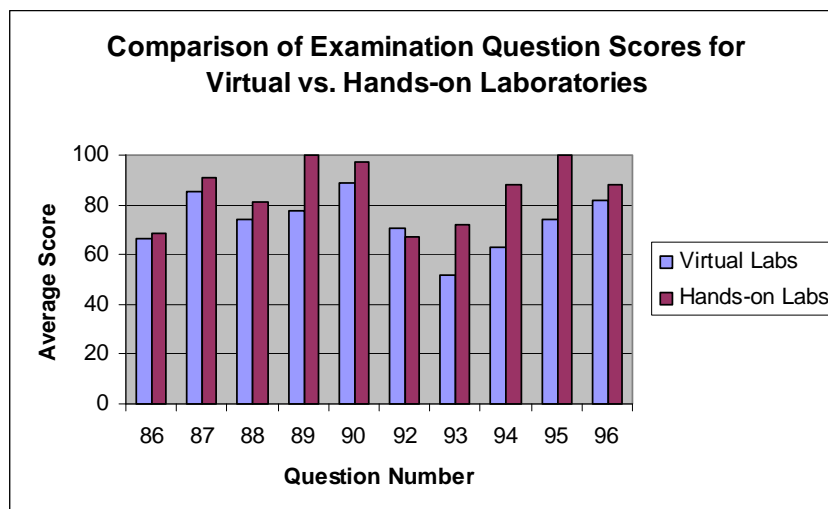


Figure 2. Scores Achieved on Molecular Questions in the Final Clinical Chemistry Course Exam (Kraj, Pretlow, & Russell, Student Molecular Laboratory Performance Outcomes in a Baccalaureate CLS Program., 2011). Reprinted.

manual was updated yearly and available for the students online in the learning management system (Kraj, 2013 unpublished). Out of 12 laboratory activities designed, nine were hands-on, two were computer based and one included a visit to a reference lab. One activity, involving PCR primer design, included an additional assignment designed for graduate MLS students (Russell, Kraj, Pretlow, Ranne, & Leibach, 2011).

Purpose of the Study and Research Questions

The purpose of the presented project was to survey molecular diagnostics experts who were supervisory personnel at clinical sites offering molecular testing to assess their expectations from graduating entry-level MLS with regards to molecular skills. Interviewing experts has been frequently achieved using questionnaire based method known as Delphi (Aichholzer, 2009). For this project, an asynchronous, iterative, online Delphi was used as a method to identify and prioritize the expected molecular skills.

The skills identified by the experts are anticipated to match most closely with practice level V in the current ASCLS LOP model, plus or minus one level, pending better definition of

“established procedures” and clarification of “molecular probes”. The questions regarding the desired skills reflect modified instructional cognitive and psychomotor objectives listed in the syllabi for Clinical Molecular Methods courses developed and taught by the author in the MLS program at Georgia Regents University (Kraj, 2013 unpublished).

The research questions addressed in the study are:

1. Which molecular cognitive skills are expected of an entry level MLS upon hire in facilities that offer molecular diagnostics services?
2. Which molecular psychomotor skills are expected of an entry level MLS upon hire in facilities that offer molecular diagnostics services?
3. Which of the cognitive and psychomotor skills are considered the most important to be included in the MLS curriculum?
4. In which areas (e.g., hematology, microbiology, chemistry, blood banking, immunology, body fluids) of the clinical laboratory are entry level skills in molecular diagnostics utilized?

The outcomes of the analysis will be shared with the stakeholders involved in development of competency-based curricula: laboratory professionals, educators, and relevant certifying, accrediting and other professional organizations: the NAACLS, ASCP and ASCLS.

Chapter Summary

In this chapter, the author reviewed the emergent process of inclusion of molecular diagnostics discipline into clinical/medical laboratory science practice and presented the results of a previous study conducted to informally assess the extent of new content incorporation into the MLS curriculum. The author chose engaging medical laboratory professionals currently practicing in laboratories offering molecular diagnostics services in defining expectations

relevant to this discipline in graduating entry-level MLS with an ultimate goal of sharing the information so that it may be used in the development of curriculum reflecting current knowledge and scope of practice. Research questions were listed and Delphi survey was identified as study tool. The following two chapters will review several Delphi studies performed to develop various healthcare curricula and the methodology of Delphi.

Chapter Two: Literature Review

This literature review begins with the description of the outcomes of the study performed by Miller and Abbate (2002) which ignited the initial interest of the author with the incorporation of molecular diagnostics into the MLS curriculum. The following sections reviewed the current science of interviewing experts using Delphi survey with focus on studies that had utilized this method in needs assessment and education research, especially studies on competence-based curriculum development to include but not limited to curricula in several healthcare disciplines such as medicine (especially genetics and pathology), dentistry, nursing and allied health. Delphi studies relevant to clinical laboratory were also presented. The chapter also provided an overview of the method, focusing on its validity and general research guidelines; it addressed recruitment of subjects, anonymity, and attrition, number of rounds, survey question formats and rating scale, feedback on answers and analysis of numeric values. Various types and modifications of the conventional Delphi method were described.

The Extent of Molecular Diagnostics Education in MLS Programs in 2001

In 2001 the NAACLS introduced new Standards of Accredited Educational Programs for the Clinical Laboratory Scientist/Medical Technologist which specified the inclusion of molecular diagnostics in the MLS curriculum (NAACLS, Standards of Accredited Educational Programs for the Clinical Laboratory Scientist/Medical Technologist, 2001). It should be noted here that Programs that received NAACLS Accreditation Renewal prior to September 30, 2001 and new programs that submitted an interest of renewal between October 1, 2000 and September

30, 2001 had a choice of using either the 2001 or the 1995 Standards (which did not require the inclusion of molecular diagnostics). As a result, some MLS programs may not have introduced molecular content into their curriculum upon new Standards release, yet were still in compliance until September 2008 because the maximum accreditation period was seven years.

Concurrently with the introduction of the 2001 NAACLS Standards, researchers from the SUNY Upstate Medical University at Syracuse and Samaritan Medical Center, Watertown, NY, mailed a multiple choice survey to 263 MLS programs in order to assess the extent in which genetics and molecular diagnostics concepts were taught at the time (Miller & Abbate, 2002). The relatively high response rate (62%) indicated that this was a timely topic; when the survey was distributed, program directors may have already heard about the upcoming changes in the NAACLS Standards. Many educators who responded to the survey (44%) expressed dissatisfaction with the instructional delivery of the genetics/molecular content. The listed factors that contributed to the dissatisfaction were lack of time in the curriculum to teach the material, lack of knowledgeable faculty, and prohibitive cost. Less than 5% of the dissatisfied respondents listed lack of affiliated clinical sites that performed molecular methods as the reason of dissatisfaction. These results may reflect the fact that 44% of the respondents were from hospital based programs and 17% were from state academic medical center programs. The respondents were program directors (86.8%) or faculty and clinical coordinators (13.2%). The survey addressed the methods that were taught in theory and with hands-on practice and provided useful information regarding some specific applications taught (Tables 4 and 5). However, it is not known if these concepts and applications reflected the expectations of technologists and supervisory personnel responsible for molecular testing of patients' specimens.

Table 4.

Survey Results on Molecular Diagnostic Methods in MLS Curricula.

Method	Theory	Hands-on any location
Polymerase chain reaction	133 (88.1%)	64 (42.4%)
Southern blot	109 (72.2%)	27 (17.9%)
Fluorescent in situ hybridization	86 (60%)	14 (9.3%)
Ligase chain reaction	81 (53.6%)	21 (13.9%)
DNA sequencing	76 (50.3%)	10 (6.6%)
NASBA	64 (42.4%)	13 (8.6%)
Transcription-mediated amplification	61 (40.4%)	10 (6.6%)
Dot blot hybridization	60 (39.7%)	5 (3.3%)
Branched DNA amplification	50 (33.1%)	6 (4%)
DNA chip technology	44 (29.1%)	1 (0.7%)
Strand displacement amplification	32 (21.2%)	3 (2%)

Note. Adapted and reprinted from “Genetics and molecular diagnostics in the clinical laboratory science curriculum” (Miller & Abbate, 2002) with permission.

Table 5.

Survey Results on Clinical Applications of Molecular Methods in MLS Curricula.

Clinical Application	Theory	Hands-on any location
Detection of microorganisms	122 (80.8%)	77 (51%)
HLA typing	119 (78.8%)	30 (19.9%)
Hematologic malignancy detection	113 (74.8%)	50 (33.1%)
Genetic disorders detection	109 (72.2%)	28 (18.5%)
Viral load assays	105 (69.5%)	24 (15.9%)
Paternity testing	105 (69.5%)	18 (11.9%)
DNA fingerprinting	66 (43.7%)	16 (10.6%)

Note. Adapted and reprinted from “Genetics and molecular diagnostics in the clinical laboratory science curriculum” (Miller & Abbate, 2002) with permission.

Therefore, it is not clear if the curricula were designed based on competencies expected of the graduating MLS upon entry to the profession.

Collecting Information Regarding the Requirements of the Profession

The common methods to gather information on the current requirements of professional practice and on its anticipated future directions include surveys and interviews with professional practitioners and employers (Toohey, 1999). These requirements are typically collected by professional organizations and translated into sets of competency standards. NCA compiled a list of molecular objectives from which examinees should expect related questions on the certification exam (Table 3). Since the organization's dissolution, the ASCP-BOC has not published specific molecular competence standards for an entry level MLS. However, the examination guidelines updated in September 2014 included molecular genetics of blood group systems, molecular methodologies for identification and detection of microorganisms and antimicrobial susceptibility testing, and list unspecified "Molecular Techniques" under Laboratory Operations section which constitutes total of 5-10% of the exam content (ASCP, 2014). The profession is in need for published molecular competency standards and competency-based molecular diagnostics curriculum.

There are many examples of studies performed to develop competency-based curricula in a variety of disciplines. They all require a thorough review of information on the current requirements of professional practice which may be gathered using several research techniques to include critical incident analysis, functional analysis, DACUM (Developing a Curriculum) technique and various types of face-to face interviews and written surveys (Toohey, 1999). A significant number of such studies have been undertaken using the Delphi technique (Burke, Martyn, Stone, Bennett, Thomas, Farndon, 2009; Choudaha, 2008; Edgren, 2006; Elder & Nick,

1997; Fried & Leao, 2007; Perkins, Barrett, Bullock, Gabbott, Nolan, Mitchell, Short, Smith, Smith, Todd, Bion, 2005; Sizer, Felstehausen, Sawyer, Dornier, Matthews, Cook, 2007).

The Delphi method was originally used in military and industry forecasting and planning and involves gathering information in several sequential rounds of surveys sent to the same experts to either generate ideas or answer a number of questions with a purpose to reach a consensus on the investigated subject. The participants of Delphi surveys do not know the other participants' identity which prevents intimidation due to dominance of the discussion by the authority of the most persuasive members of the group, a phenomenon known as "halo" or "bandwagon effect" (Linstone & Turoff, 1975; Francis, 1977; Landeta, 2006). Gathering the information in several rounds (instead of one) gives the experts the opportunity to change their opinion based on the summarized outcomes of the analysis of the previous round provided by the researcher, without fear of being called indecisive, or to maintain the original opinion without confrontation, even if not in agreement with the majority. The first Delphi study was published by RAND Corporation (Gordon & Helmer, 1964). The method was soon adopted for research in social studies and characterized as "a method for structuring a group communication process, so that the process is effective in allowing a group of individuals, as a whole, to deal with complex problems" (Linstone & Turoff, 1975). As noticed by Toohey (1999), the Delphi is useful to collect information from practitioners when significant changes occur in the profession. Such changes call for revisions of the competencies taught in programs graduating practitioners entering the occupation.

Choudaha used a three round online Delphi survey to assess theoretical and conceptual foundations for developing a competency-based curriculum for an interdisciplinary master's degree program in Service Science, Management and Engineering (Choudaha, 2008). The study

was conducted as a doctoral dissertation under advisement of Frank Tuitt, assistant professor in the Department of Higher Education, University of Denver, CO (Choudaha, 2008). Choudaha's study lists other doctoral dissertations using Delphi method for curriculum development (Table 6). A comprehensive analysis of number of defended and published Delphi studies, encompassing the years of 1970 through 2004 was provided by Landeta (Landeta, 2006).

Table 6:

Doctoral Dissertations using Delphi method for Curriculum Development.

Dissertation Title and Author
Defining a competency framework to shape the professional education of national security master strategists: A web-based Delphi study (Clark, 2005).
Use of a Web-based Delphi for identifying critical components of a professional science master's program in biotechnology (Kantz, 2004).
An investigation and critique of competencies needed by human resource development (HRD) master's degree graduates in Korea (Lee, 2006).
Consensus of academic and industry experts and practitioners on essential information systems curriculum elements: A Delphi study (Matkin, 2000).
Key competencies for institutional researchers in the first decade of the twenty-first century: A Delphi technique for curriculum planning (Polk, 2001).
Cross-cultural competencies in international management curricula: A Delphi study of faculty perspectives (Senyshyn, 2002).

Note: Table from "Competency-based curriculum for a master's program in Service Science, Management and Engineering (SSME): An online Delphi study" with permission (Choudaha, 2008) available at <http://gradworks.umi.com/33/37/3337048.html>

Competency-Based Curricula in Healthcare Education

Literature reveals various completed and still ongoing traditional or modified Delphi studies used in the development of competency-based curricula in healthcare education worldwide. The British Journal of General Practice published a study designed to identify key knowledge, skills and attitudes required of physicians undergoing training in genetic testing at the Royal College of General Practitioners (Burke, et al., 2009). The authors pointed out that the curriculum developed based on the outcomes of the study was "firmly grounded in clinical

practice”. The approach represented a modified Delphi survey which in the first round was not only distributed among the experts who included educational program directors and geneticists but also to the general practitioners who were the anticipated students in the curriculum, and, as such, couldn’t be considered experts.

A consensual curriculum developed using a four step Delphi was described by faculty from the Federal University of Rio de Janeiro Dental School (Fried & Leao, 2007) who recruited 40 dentists who were lecturers in nine Brazilian dental schools. The researchers stated that the study was prompted by changes in periodontics practice and therapeutic approaches that occurred during several decades due to new advances in science, including the completion of human genome sequencing. In the initial phase of the study, the participants identified 339 items that should be considered for inclusion in the curriculum. The items were grouped into two categories: a) foundational concepts or basic principles and b) laboratory training or clinical experience. In the next phase a 1-5 Likert-type scale was used for rating the importance of inclusion of the items in the curriculum (Likert, 1932). The subsequent stage of the Delphi process included only the participants who gave the most extreme ratings of the items, described as “indispensable“ and “should not be included”. Inclusion of only the “extreme raters” in the third round was a departure from the classical Delphi technique and no information on the validation of the approach was provided. In the last stage, each item for which consensus could not be reached were put on the questionnaire distributed to all original participants for a definite “yes” or “no” decision. Twenty broadly defined items, such as “identification of periodontal instruments” or “laboratory training” were included in the resulting syllabus.

In Great Britain, the Resuscitation Council has awarded a research grant to identify consensus-based core competencies which graduating medical students should have relevant to

care of patients acutely ill or in cardiac arrest. The study was conducted by researchers from several universities and hospitals who created a website to which 359 physicians, nurses, other health professionals; educators and students submitted a total of 2629 suggested competencies which were then grouped into 88 common themes by two authors of the study (Perkins, et al., 2005). The terminology describing each theme was discussed for 7 hours by a group of seven experts (a nominal group consisting of physicians, nurses and one student) who, upon editing the themes, rated them on a 1-5 Likert-type scale. The median scores obtained for each theme were posted on the website for feedback from the professionals who originally suggested the competencies. Upon 14 comments provided during two months after posting, the nominal group decided that 71 themes which obtained scores 4 and 5 would be considered essential competencies, necessary at graduation. It should be noted that, even though the term “theme” suggests a broad description, the themes were actually very specific skills, for example “describes how to recognize and initiate treatment for meningococcal septicemia”. The inclusion of the face-to-face discussion is not a common practice in the Delphi process due to authority effect.

Another example of identification and evaluation of competencies using Delphi process was a study initiated by nursing education researchers after 1999 American Medical Informatics Association (AMIA) Congress on the informatics education of health professionals. The study targeted informatics competencies for nurses (Staggers, Gassert, & Curran, 2002). To justify their study, the researchers claimed that previous surveys on perceptions about nursing informatics (NI) competencies mostly included educators rather than bedside clinical nurses and that there was a very limited number of computer literacy skills integrated into nursing curricula. They also stated that, even though the changing nursing practice would benefit from informatics

skills, there was no research-based, validated master list of NI competencies available to guide formal education curricula. Before the three-round Delphi process was initiated, the researchers reviewed literature to identify 1159 various competencies described in 35 articles published from 1986 to 1998 and in 14 job descriptions of practicing informatics nurse in the Washington, DC, area (Staggers, Gassert, & Curran, 2001). The next step included consolidation of the competencies into 313 items by the authors of the study, who then decided to ask a panel of 26 AMIA Working Group Members to state if each of the items actually reflected the nursing practice. This step was unsuccessful, which the authors attributed to failure to provide context and had to recruit a panel of doctoral prepared nursing experts in informatics to refine the competencies through discussions. This “refinement” process resulted in separation of the competencies into the four informatics levels of nursing practice defined as beginning, experienced, informatics specialists and informatics innovators and included application of Bloom’s taxonomy to the competencies for clarity (Bloom, Engelhart, Furst, Hill, & Krathwohl, 1956). Further consolidation of some items ended with the final number of 304 competencies. At this point the list of competencies was ready for the Delphi three-round survey to achieve consensus on the validity in the nursing practice and assignment into beginning, experienced, informatics specialists and informatics innovators levels. Out of 110 invited nurses with set criteria, 82 agreed to participate in the study and 79 were confirmed to qualify. The number of usable responses was 72 in the first round. In the subsequent rounds only the items for which no consensus was reached were redistributed for opinion. After three rounds (lasting 14 months), 13% attrition rate and 80% consensus threshold in each round, 92% of the competencies were identified as valid and properly assigned to the respective levels.

Most competencies identified and evaluated in the study by Staggers et al., were specific cognitive or psychomotor skills. Nursing professionals have also utilized a 5-round Delphi consensus process to identify critical thinking components which were characteristic of an affective domain and included confidence, creativity, flexibility, contextual perspective, intuition, inquisitiveness, intellectual integrity, open-mindedness, perseverance and reflection (Scheffer & Rubenfeld, 2000).

Delphi technique was also used in various allied health disciplines to develop a competency-based curricula to include cognitive, psychomotor and affective domains. A study to identify orthopedic manual therapy (OMT) skill sets, essential in physical therapist education, was conducted by researchers from Texas Tech University Health Science Center and Duke University Medical Center who used data reduction via factor analysis following an online three-round Delphi survey administered to 80 PT educators who taught manual therapy at entry or post-entry level (Sizer, et al., 2007). To help the educators choose teaching methods which would improve learning outcomes and successful transition of a student from the classroom into the clinical setting, the authors “distilled” critical OMT skill sets out of numerous stand-alone skills, identified in the Delphi process via 75% consensus threshold.

Four Delphi studies were simultaneously conducted to reach consensus regarding knowledge and skills required of graduates from the programs of physical therapy, health information management, occupational therapy and medical laboratory science (Elder & Nick, 1997). The studies focused on knowledge and skills that extended beyond and above what was required to satisfy the criteria for programs’ accreditation and successful completion of national and state credentialing exams by the graduates (e.g., “oral communication skills at a level commensurate with college degree,” “knowledge of ethical codes and principles of practice of

own profession”). The panel experts who participated in the studies were chairs of educational programs from the above allied health disciplines. They were asked to make their own suggestions and to rate 19 items previously identified in another study of allied health school deans and were able to define components of a core allied health curriculum (Elder & Andrew, 1992). Delphi technique was also successfully used by the deans of allied health schools accredited by the Southern Association of Colleges and Schools (SACS) to identify 13 most important educational goals related to student learning and valid feasible outcome measures that were applicable to the set goals (McKenzie, 1994). During the process, the author realized that inconsistency in definitions contributed to problems in identification of the outcomes.

Dr. Richard Haspel from Beth Israel Medical Center was awarded in 2007 a Rabkin Fellowship Project to use the Delphi method to develop a clinical pathology curriculum for the third year medical students (Haspel R. , 2010). The Fellowship is awarded yearly to the faculty affiliated with Harvard Medical School to support studies in medical education research. The specifics of the project have not yet been published. In a personal communication, Haspel said the survey was adopted from a Swedish Delphi study conducted by Dr. Gudrun Edgren at Lund University Centre for Teaching and Learning to develop a competence-based curriculum for “biomedical scientists” who, in Sweden, are the laboratory personnel working in clinical laboratories (Haspel, personal communication, 2010a). In the initial phase of the study, 26 participants were asked by Edgren to identify competencies that they considered absolutely necessary for a recently graduated biomedical scientist upon beginning their first job (Edgren, 2006). The 407 identified competencies were classified into skills, knowledge, attitudes and generic categories and were used to form a first round questionnaire in which the participants were asked to grade the importance of the competencies on a 1-4 Likert-type scale.

Competencies with a mean score ≥ 3.25 and competencies scored the highest (4) by all participants from the same type of laboratory were used for a second round questionnaire in which the participants were to state if they did or did not agree that these entry-level competencies had indeed been essential. The final list of 77 competencies to be included in the biomedical scientist curriculum consisted of those that were deemed necessary by 75% of the respondents. Some skills relevant to molecular diagnostics were: the specific knowledge of DNA, RNA, amino acids, protein structure and synthesis, replication, transcription, and techniques such as polymerase chain reaction (PCR), Northern blot and unspecified “work with DNA, RNA and proteins”. There were no procedures designed for diagnosis of specific pathogens or conditions on the list. The author has noted that many of competencies, such as knowledge of molecular biology, genetic analysis and gene therapy, although identified in the initial phase of the study, were lost during the consensus process which resulted in the final list being representative of a traditional rather than modern curriculum, possibly due to perceived inability to include everything. In personal communication via e-mail, Edgren stated that the competencies were expressed in general terms (such as “ability to use pipettes, centrifuges or electrophoresis equipment” or “ability to work with isotopes and antibodies”) and that the initial list was not available in English (Edgren, electronic communication 6/10/11).

Several learning objectives relevant to molecular diagnostics in laboratory medicine curriculum courses for medical students were suggested by an *ad hoc* committee appointed by the Academy of Clinical Laboratory Physicians and Scientists (Smith, et al., 2010). These objectives (e.g., “Explain the general principles of molecular diagnostics testing in the screening, diagnosis, and/or monitoring of infectious, genetic, and oncologic diseases”) were very broadly defined and would have to be extensively modified to address specific

competencies necessary for an entry level clinical laboratory scientist. Some objectives pertaining to genomics and personalized medicine were suggested for medical residents (Haspel, et al., 2010).

Delphi Studies in Medical Laboratory Science Performed in the US

Edgren (2006), in the introduction to her publication on competencies for an entry level biomedical scientists in Sweden, refers to a modified Delphi survey performed in the United States in order to develop a competency-based, career-entry certification examination for clinical laboratory personnel (Davis, 1978). The survey was described by the author, the Chairman of the American Society for Medical Technology (ASMT) Certification Examination Subcommittee, as the first formally performed process to include such large number of practicing professionals and result in the generalist examination at career entry for the two levels of practice defined at the time: medical technologists and technicians. In order to delineate competencies appropriate for the two levels of practice, over 200 professionals practicing in the field nationwide were asked to modify and apply Bloom's taxonomy to the competencies previously described in another document (ASMT, 1976). The professionals represented staff, technologists who performed administrative functions, faculty and laboratory directors. Consensus was reached after six review cycles performed by 12 groups of participants representing three regions: East, Middle and West. The lengthy process described by Davis would benefit from using Bloom's taxonomy in the original document and from more contemporary methods of electronic survey distribution.

Another three-round Delphi study relevant to clinical laboratory focused on development of indicators which could be used to compare performance efficiencies among laboratories (Zinn & Zalokowski, 1999). Through Delphi process, six different expert panels representing different stakeholders (hospital executives, referring physicians, laboratory managers, etc.) identified and

prioritized the areas of performance but were not able to prioritize performance indicators as a result of differences in environmental pressures for different stakeholders which may suggest that Delphi produces better results when the expert panel is relatively homogenous.

Indicators of student professional behavior were successfully identified in a small scale modified, non-anonymous Delphi in the process of development of student professional behavior evaluation tool implemented at the proposal's author's institution (Russell B. , Owen, Leibach, Meaders, & Kraj, 2011). Didactic and clinical faculty have successfully used the tool in the programs of clinical laboratory science, diagnostic medical sonography, nuclear medicine technology, and radiation therapy.

Originally, designed for industry forecasting, the Delphi method was used to complete a study on the future of the medical laboratory science to predict events that would occur in the profession within the next two decades, as identified from among 147 events by a panel of 24 experts (Kirby, 2008). The events for which a three-round Delphi-based consensus was achieved were used for development of future scenarios including continuous decrease in reimbursement for laboratory services, critical shortage of laboratory workforce, development of clinical doctorate in CLS and technological advances changing the scope of practice. Examples of events relevant to technological advances in molecular diagnostics which were predicted by the study to have significant impact on practice were as follows: the contribution of pharmacogenomics to laboratory testing, increased assay development rate by means of proteomics, use of genetic and molecular testing for disease prevention, and use of DNA-based assays as sole technology in microbiology testing. These predictions provide further justification to identify the expectations of the professionals currently involved in performance of molecular-based assays towards the incoming graduates to develop a competency-based curriculum appropriate for future workforce.

Historical Remarks on the Name and Definition of the Delphi Method

In 2003, at the United Nations Industrial Development Organization (UNIDO) Technology Foresight Seminar in Prague, a German author implied that the famous ancient Greek oracle Pythia's predictions may have resulted from the knowledge accumulated in the Delphic monastery located 173 km northwest of Athens, by the slope of Mount Parnassus. The monastery was a destination of numerous ambassadors whose questions for the oracle (along with the answers) were written on stone or metal plates (Cuhls K. , The Delphi Method, 2003). Named by UCLA's professor of philosophy, Dr. Kaplan, after the place where Pythia foretold the future (Kaplan, Scogstad, & Girshick, 1950), the Delphi method was originally used in 1950s in a military "Project Delphi" designed by the Californian Rand Corporation in Santa Monica, CA (Dalkey & Helmer, 1963). Delayed by 12 years, publication of this Air Force sponsored project was a measure of military security (Landeta, 2006). As described in lay terms by Linstone and Turoff in their seminal book discussing the method, Project Delphi, through a series of questionnaires, sought an opinion on the estimated number of A bombs that would have to be used [by the Soviets] on strategic industrial U.S. targets to decrease the strength of the American defense system by a certain value (Linstone & Turoff, 1975). Rand Corporation also sponsored the first not-strictly-military study that applied the Delphi method to predict scientific breakthroughs, population growth, automation, future weapon systems, war prevention and space progress (Gordon & Helmer, 1964).

Linstone and Turoff estimated that by mid-1970s, over a thousand Delphi studies were conducted which prompted both plausible and opposing assessments (Linstone & Turoff, 1975). A critique of conventional Delphi technique, described as a "new version of an old crystal ball," was prepared by one of Rand's own analysts for the United States Air Force and approved for

public release in the 1970s (Sackman, Delphi Assessment: Expert Opinion, Forecasting and Group Process, 1974). Fifty years later, the method enhances effective decision making in policy development, social sciences and health care; it is used in major national, holistic endeavors with large impact on society, such as periodic Science and Technology Agency foresight studies in Japan and Germany, as well as in smaller business and education applications, including doctoral dissertations (Cuhls, 2003).

The survey-based Delphi research method is considered a structured group facilitation technique, which through an iterative, multistage process, allows the group to deal with complex problems and aims at transformation of opinions into a group consensus (Linstone & Turoff, 1975). The four classical research objectives which could be achieved using the technique were: a) to explore or expose underlying assumptions or information leading to differing judgments; b) to seek out information which may generate a consensus on the part of the respondent group; c) to correlate informed judgments on a topic spanning a wide range of disciplines; and d) to educate the respondent group as to the diverse and interrelated aspects of the topic (Turoff, 1970).

Reliability and Validity of the Delphi Method

In his oppositional critique of conventional Delphi, Sackman (1974) claimed that the conventional method could only be used as an exploratory technique because the investigators, participants and end-users neglected the standards jointly established by the American Psychological Association (APA), the American Educational Research Association and the National Council on Measurement in Education to evaluate development and use of psychological tests (American Psychological Association, 1966). As a riposte to this accusation, Linstone stated that the procedures developed by the APA to evaluate the testing of individuals

should not be assumed as appropriate to evaluate opinion questionnaires (Linstone & Turoff, 1975).

A researcher from the Institute of Applied Business Economics at the University of the Basque Country at Bilbao, Spain, evaluated the validity of Delphi using a three-partite approach (Landeta, 2006). First, he reviewed several articles which authors had compared the method with other interaction techniques used in decision making, such as group interviews or nominal groups technique (NGT) where the participants openly present their opinions or problem solutions and then vote on each solution presented. For example, two researchers from Western Kentucky and Louisiana State Universities indicated that the Delphi produced the highest quality decisions because they had a higher level of acceptance than decisions made using other consensus, interacting, and NGT methods (Erffmeyer & Lane, 1984). Landeta concluded that in other reviewed studies where the comparison resulted neither in favor, nor against Delphi, the outcome could be attributed to the disappointment with the method by researchers who lacked the knowledge required to use the technique successfully. To further justify the validity of Delphi, Landeta quoted researchers from East Carolina University in Greenville, North Carolina, who analyzed the numbers of studies performed using this technique over the period of 1970-1994. He concluded that, starting in 1975, 53-57 Delphi studies were consistently published per year (Gupta & Clarke, 1996). Landeta used four online databases (ABI inform, Science Direct, Medline and Psycho) to continue the search until 2004 and has shown an increase in yearly numbers of Delphi studies in each database. The analysis of the numbers of doctoral dissertations utilizing Delphi has shown that after the peak in the 1980s attributed to the novelty effect, the number has slightly declined but remains at a steady level which, according to the author, results from the acceptance of the method by the scientific community.

Finally, Landeta performed three Delphi studies in the area of social science himself. In the first study the participants (tourism experts) were providing information that would allow the Statistics Institute of Catalonia for a reliable estimation of minimum tourist expenditures of Catalonia visitors coming from other regions in Spain. Similarly, in the second study, the participants (Catalan firm directors) were providing information which would allow the Statistics Institute of Catalonia to create the economical input-output tables for the region. In the third study, opinions from the university lecturers were sought in order to design a Basque University Organization Act. Landeta concluded that with respect to the validity of the method, the input obtained was as intended and usable, and that it contributed to either reliable estimates of the parameters sought by the Statistics Institute of Catalonia or to successful design and passing of the Act (Landeta, 2006).

The researchers from the University of Ulster, Ireland, stated that the evidence of reliability of Delphi was lacking because it was not known if different panels of experts could ever arrive at the same results if provided the same information (Hasson, Keeney, & McKenna, 2000). However, a study performed in Australia to identify nursing management competencies using two different panels of experts reported a 92.86% convergence of results (Duffield, 1993). Hasson and his colleagues have suggested that the criteria for reliability of Delphi were the same as for other qualitative studies, namely the assurance of subjects' truthfulness (credibility), applicability (fittingness), consistency (auditability) and confirmability (Lincoln & Guba, 1985). Major threats to the validity of Delphi, as discussed by these authors, were the response rate and pressure for reaching consensus. The remedies aimed at these threats were: 1) the fact that several people were less likely to make an incorrect decision than a single person (Kaplan, Scogstad, & Girshick, 1950), 2) knowledge and interest of the subjects in the topic, and 3) the

process of iteration in which successive rounds of surveys are accompanied by feedback of results of the preceding round to the participants which allowed for a thoughtful revision or clarification of individual responses. However, two British researchers from De Montfort University and Kings College thought that the knowledge of other respondents' answers which could prompt change in opinion was a threat to the reliability as it, by nature, prevented reproducibility (Beretta, 1996; Goodman 1987). Cuhls (2003), who at the UNIDO seminar addressed predominately the forecasting applications of Delphi, questioned the validity of the sample of experts due to frequent self-estimation of the expertise and suggested that not only the anticipated "users" of the results (such as educators) should be surveyed but also the decision-makers who are responsible for future implementation (practicing professionals and supervisors responsible for hiring). It may be implied from Cuhls' presentation, that Delphi studies are more appropriate to conduct when researching highly innovative fields because the experts in such fields are open minded and less prone to bias. Delbecq, Van de Ven, and Gustafson (1975) insisted that high motivation of the participants increased the validity. Duffield agreed that the selection of the panel participants by nomination rather than by random sampling increased response rate and the validity because it prevented the classification of the participants as experts due to overinflated self-estimation (Duffield, 1993). Penelope Mullen, an experienced Delphi researcher and senior lecturer at Health Services Management Centre of the University of Birmingham, UK, discussed the critique of Delphi, specifically with regards to psychometric validity and non-random sampling (Mullen, 2003). She concluded that Delphi was best defended by Olaf Helmer, who claimed that Delphi was not an opinion poll and, as such, did not require random sampling. Helmer, the designer of the pioneering Santa Monica study and over a

dozen of other Rand projects, described Sackman's paper (1975) as a "singularly vituperative attack" (Helmer, 1977).

The inter-rater reliability of the Delphi surveys resulting in quantitative data may be assessed mathematically using Cronbach's alpha coefficient of equivalence (Cronbach, 1951; Tevacol & Dennick, 2011). This coefficient is a measure of internal consistency defined as the relationship between all the results obtained from a single survey (round). To compute the coefficient, all responses to a single question are randomly split in two sets (split-half test). Then the scores achieved for both sets are correlated. This process is performed for all questions in the survey to achieve an estimate of the average of all split-half estimates (Roberts & Priest, 2006). An example of a Delphi study where reliability was checked using Cronbach's alpha concerned clarifying diagnostic criteria for carpal tunnel syndrome (Graham, Regehr, & Wright, 2003). In another study of curriculum assessment conducted by nursing students upon completion of evaluated learning modules, high coefficients were reported indicating a good consistency among rated curriculum items (Hartley, 1995). A lecturer from the Jagiellonian University in Poland reported specific values of 0.944 and 0.85 in two rounds of Delphi study on the development of hypertension guidelines for family physicians. This indicated that the reliability decreased over time in that particular study (Tomasik, 2010). The author stated that 6 months elapsed between the two rounds of survey, distributed by mail (Tomasik, electronic communication 1/10/14).

General Guidelines

Many authors have summarized the Delphi preparation process, its steps and challenges, and provided guidance for researchers willing to use the method. Whitman (1990), Beretta (1996), Hasson et al., (2000), and Mullen (2003) focused on guidance for nursing researchers.

Similar aspects of Delphi must be considered in the study presented in this proposal. The following subsections will summarize the guidelines published by the above authors as well as the authors representing other professions and will conclude with description of various types and modifications of the method.

Recruitment of subjects (experts)

A fundamental feature presented as both its strength and disadvantage of the Delphi process is the non-probability, purposive or criterion sampling process, where the participants of the study are selected by the investigators based on their expertise in the topic. These “informed individuals” (panelists, experts) could identify themselves by self-reporting of their expertise in the initiating question of the survey. Alternatively, they could be selected based on objective evidence of expertise (such as a record of scholarly publications), or by nomination by “gatekeepers” who help the investigator in the recruitment process because they know individuals knowledgeable in the subject (Hasson, 2000).

The “objective evidence of expertise”, specifically the mentioned record of scholarly publications (“research performance”, “citation rate”), is well respected in the area of basic science research. However, publishing productivity may be still lacking in the medical laboratory science profession. Dr. Gudrun Edgren, the author of the Delphi study on competency based curricula for Swedish MLS (Edgren, 2006), has shared her opinion that “respected professionals usually didn’t have publications, because that is not common in Sweden” (Edgren, electronic communication 6/10/11). Another medical technologist from a large diagnostic laboratory in Northwestern US, when approached to co-author an instrument validation study manuscript based on a national competition winning poster presentation, stated:

“To be honest, [the company] does not particularly support publication. Our focus is more on adding efficiency internally and across our system. So while I think it is appropriate to share the data for use by other labs, the path that involves the least time investment (posters) works best for me. My current focus is now in implementation of two [other instruments] (Suter, 2011)”.

Nomination by the gatekeepers has been also referred to as chain referral sampling (Heckathorn, 2002) or a “snowball” or “ripple” sampling technique (Lincoln & Guba, 1985). Initially, the snowball technique was defined as a method which started with random sample of individuals drawn from a finite population. These randomly selected individuals were to name other individuals from that population (Goodman, 1961). Other researchers have not strictly adhered to the requirement of random selection in the initial stage of the process. A graduate student from Texas A&M University utilized this technique in a study which aim was to identify components of a novel Master’s program in biotechnology combined with business (Kantz, 2004). Another graduate student from Walden University used the technique to seek respondents for a survey on factors that affect use and acceptance of information and communication (ICT) among laboratory science students (Barnes, electronic communication, 6/18/2012). The “gatekeepers” in her study were not randomly selected. They were the MLS subscribing to the ASCLS educators listserv and NAACLS listserv.

The controversy over the Delphi does not end with expertise assessment of the subjects. The opinions also vary significantly with regards to the recommended number of participants. As noted by Beretta (1996), a British author reviewed published studies in which the size of the panels ranged from 10 to 1685 and claimed no justification for the size had been provided (Reid, 1988). Hasson and colleagues, outlining the guidelines for conducting Delphi, reported a

narrower range of 15 to over 60 experts (Hasson, Keeney, & McKenna, 2000). Smaller numbers of panelists would be more appropriate if the participants were to be personally approached (invited) to the study by the principal investigator, as recommended by one of the co-authors of the guidelines based on his previous experience (McKenna, 1994). With the widespread acceptance of electronic communication (e-mail) following McKenna's report inviting expert numbers, oscillating in the upper range for participant number became more feasible.

An argument against the high number of participants is that generation of large amount of data may cause difficulties in the analysis. Hasson and colleagues specifically referred to such difficulties in the traditional Delphi studies when the first, qualitative round of questionnaire is conducted to identify the problems, issues or competencies that would be discussed or rated in the following rounds. In modified Delphi studies, deprived of the initial round due to investigator's own expertise or existing preliminary data, the difficulties resulting from participation of large numbers of experts could be diminished. Cuhls stated that in national foresight studies it is desired to obtain about 100 responses on a subject, but she also pointed out that the sought number of respondents should realistically reflect the number of experts existing in the country in the investigated field of study (Cuhls, 2003). She reported that an "almost perfect" correlation was found between the number of experts and their rating of German research performance. In her study, molecular biology was considered an area represented by the largest percentage of the total of 73 experts in the field of biotechnology.

A researcher from the University of Virginia reported that some nurse investigators recommended using 10-50 participants in a Delphi study while others claimed that a sample of only 15 participants could be satisfactory with careful selection process (Whitman, 1990). In her review, she also mentioned an in-service education needs assessment Delphi study with 120

participants conducted over a three and a half week period (Chaney, 1987). Whitman stated that if the decisions made based on a Delphi study were to affect a large number of nurses (with over 500 being considered a large number), a minimum of 10-15% of the affected population should be surveyed.

Anonymity

The anonymity of Delphi participants among each other has been considered superior over traditional group interaction methods because it prevents the negative psychological influence of dominant personalities and intimidation due to the status of some experts known as “bandwagon effect” or “halo effect” (Linstone & Turoff, 1975; Francis, 1977; Landeta, 2006). Typically, the identities of the participants are known to the investigator since the investigator selects the panelists based on their expertise or due to nomination. This is referred to as the “essential anonymity” (Mullen, 2003). In some Delphi studies, the participants may know each other, but their answers and comments remain anonymous throughout the study (Landeta, 2006). Landeta (2006) reported that some researchers thought this incomplete anonymity (quasi-anonymity) due to the investigator’s active role in subject recruitment contributed to “impurity” of answers (Becker & Bakal, 1970). On the other hand, knowing the PI may motivate the surveyed individuals and prevent them from providing thoughtless or irresponsible answers or even from neglecting the survey. Sackman claimed that anonymity of the participants in the conventional Delphi prevented accountability for their responses (Sackman, 1975).

The anonymity was abandoned completely in a small scale modified Delphi process conducted at Georgia Regents University (at the time the Medical College of Georgia) to identify indicators of student professional behavior subsequently used in the student professional behavior evaluation tool (Russell et al., 2011). The tool had been used successfully by university

professors and clinical preceptors for five years prior to publication, and the validity of behavior indicators selected in the process was not questioned by the users. This fact attests to the limited value of complete anonymity and serves as proof that non-anonymous Delphi processes may be successful. Mullen (2003) reported that Delphi studies had been described previously with face-to-face meetings in the beginning or at the end of the study and concluded that Delphi required the anonymity to be preserved only for part of the study, not throughout the entire process.

Attrition

As reported for studies conducted in the era of pre-electronic communication, a positive correlation existed between the size of the panel and attrition rate (Reid, 1988). High attrition (or dropout) rate has been attributed to the iterative process of Delphi which includes gathering information in several rounds of a modified survey sent to the same panel of experts. This causes a phenomenon of panel exhaustion or fatigue which results in dropouts between the rounds. Sackman, in his critique, noted that other authors had not provided empirical data supporting the reported 50% or lower response rate to the initial questionnaire of the study. He further categorized the reasons for the participants to stay in the study as either positive, such as high interest in the subject and motivation, or negative, such as personal acquaintance with the investigator (Sackman, 1974). From this critique it could be implied that efforts should be made to nurture the positive reasons, while diminishing the influence of the negative ones. According to some researchers, in order to maintain the acceptable rigor of the study, the investigator should be aiming at response rate of at least 70%; however, much lower and much higher rates, ranging from 8 to 100%, have been documented (Walker & Selfe, 1996). The main purpose of the reported personal (including face-to-face) contacts between the investigator and participants of Delphi studies is to prevent high attrition by ensuring that the participants are compelled to

contribute to the success of the project and understand the significance of their dedication throughout all rounds of the study until the iterative process is completed.

In Chaney's study of over 120 nurses surveyed by the staff development educator on the in-service education, the investigator personally hand-delivered the questionnaires, allowed three days to fill them out, avoided weekends to prevent misplacing of the questionnaires and made reminder phone calls to expedite the pick-up (Chaney, 1987). Despite the time consumed in these efforts, this personal approach for the purpose of decreasing attrition was recommended by McKenna (1994). However as noted in the guidelines which he co-authored later, time consuming undertakings, such as personal contact, apply to many qualitative studies and are not limited to Delphi (Hasson, Keeney, & McKenna, 2000). Due to current acceptance of electronic communication as a norm, the necessity of face-to-face meetings to explain the process and personal delivery of questionnaires is not as evident.

Number of rounds: reaching consensus or diminishing returns

In the cornerstone paper by Linstone and Turoff, the authors stated that Delphi was a structured group communication technique characterized by a repetitive (iterative) process which required that the experts were consulted at least twice on the same question so that they could reconsider the answer based on the information provided by other experts dealing with the same complex problem (Linstone & Turoff, 1975). In other words, the multistage iteration was designed to make sure the participants have a chance to either confirm their original standing on an investigated subject or stand corrected upon consideration of other participants' views with the ultimate goal of reaching a consensus. However according to Landeta, in order to assure continuous participation and hence decrease panel fatigue and subsequent attrition, it may be necessary to sacrifice the number of survey questions and rounds of surveys (Landeta, 2006).

Towards the end of the 1980s, it has been postulated that three or four rounds allowed the participants to react to the ideas of others, yet minimized the fatigue and urge to conform, which certainly was a factor in studies with number of rounds as high as 25 (Whitman, 1990). A tendency towards decreasing number of rounds and attempts of conducting a roundless (real-time) Delphi can be found in literature (Gordon, 2009; Turoff & Hiltz, 2010).

Hasson and colleagues, in their guidelines for Delphi survey technique, listed several items, which determined the number of rounds that would have to be conducted in order to reach a consensus, namely the desired level of agreement, the type and breadth of questions, amount of time available and consideration of the predicted level of sample fatigue. They noted that various authors had suggested that there was no established desired level of agreement between the respondents; the recommended numbers ranged from 50 to 80% (Hasson, Keeney, & McKenna, 2000). Instead of a set value, stability of the results between subsequent rounds, a law of diminishing returns or a prior decision regarding the number of rounds may dictate the end of iteration, with understanding that searching a consensus is no longer possible or obligatory (Landeta, 2006). Cuhls noted that high level experts tend not to change opinion so it may be implied that if level of disagreement is high in the beginning of the study in which the majority of experts are high level experts, reaching a consensus would be very difficult (Cuhls, 2003). A Swiss researcher from the Institute of Management in Technology at the University of Freiburg published an article on an exploratory online Delphi with “dissensus” approach aiming to maximize range of expert opinions entered into the system by the participants and to expose all differing positions and arguments that supported these positions (Steinert, 2009).

As for the type and breadth of intended questions, these significantly influence the investigator’s decision on the necessity of the initial Delphi round, which in the original,

classical design had an exploratory, qualitative, open-ended character. This exploratory round permitted collection of multitude of data which were subsequently grouped into a “seed list” of categories of issues, problems, competencies, skills or events which the participants would evaluate (rank) in the following rounds (Linstone & Turoff, 1975). Mullen (2003) summarized examples of items explored in typical initial rounds by various nursing researchers. She reported that panelists have been asked to predict the future of nursing education or to identify issues in clinical research (Mullen, 2003). A researcher from the University of Denver inquired which courses and competencies were considered important for inclusion in a master’s program in Service Science, Management and Engineering (Choudaha, 2008). A Clinical Laboratory Scientist from West Virginia University asked a panel of 24 experts to predict events that would occur in the profession within the next 20 years (Kirby, 2008).

As an alternative to conducting a classic first exploratory round, an investigator with sufficient level of expertise in the subject or with access to existing preliminary data gathered from literature or in focus groups, may themselves prepare the seed list of items that require evaluation by the Delphi panel, thus decreasing the number of rounds and shortening the duration of the study (Mullen, 2003). As an example, Mullen cited a study performed in Australia by a researcher from Northern Territory University who himself compiled a list of factors contributing to the length of hospital stay based on available literature (Xiao, Lee, & Vemuri, 1997). Mullen herself authored a project in which a seed list of 52 impact factors was generated during two invited workshops and several meetings (Mullen, 2009). A curriculum development Delphi study was conducted without the typical first round by Canadian educators who themselves developed the content of pediatric trauma curriculum and distributed across Canada for feedback from 11 trauma centers (Valani, Yanchar, Grant, & Hancock, 2010).

Another example of a Delphi deprived of the exploratory round was a study performed to investigate the application of statistics to measure the consensus achieved in evaluation of previously published statements (Holey, Feeley, Dixon, & Whittaker, 2007). Successful decisions made based on studies completed without the classical initial round justified the development of the seed list of competencies by the author of the project presented in this manuscript due to prior experience in performing and teaching molecular methods.

The discussion on the number of recommended Delphi rounds is not exhausted without referring to a roundless Delphi, also called real-time Delphi, concurrently developed by two independent groups of researchers once affiliated with Rand Corporation (Gordon & Pease, RT Delphi: An Efficient, "Roundless" Almost Real Time Delphi Method, 2006), and with the Information Systems Department at New Jersey Institute of Technology (NJIT) (Turoff, Hiltz, Cho, Li, & Wang, 2002). The term "real-time Delphi" was defined originally by Linstone and Turoff to describe computer-aided "Delphi Conference" in which the computer compiled the results (Linstone & Turoff, 1975). However, the meaning of "real-time" has evolved significantly and currently refers to feeding back the compiled results immediately to the participants who do not have to wait for the next round to modify their responses. The implementation of real-time feedback is based on a concept of continuous, "dynamic voting" that allows for a reciprocal group process in which an anonymous participant's comment or a change in ranking an item, visible to others, may influence their position as they are entering their own vote. This phenomenon of making one's opinion while knowing how others have voted (or ranked the items) has roots in the Thurstone's Law of Comparative Judgment (Thurstone, 1927).

Researchers, encouraged by the immediate availability of real-time Delphi results, seemingly superior over the delays caused by the classical method's iteration, have attempted to

assess correlation of the results achieved using the two processes (Zipfinger, 2007; Gnatzy, Warth, von der Gracht, & Darkow, 2011). These researchers from Johannes Kepler University in Linz and the Center for Futures Studies and Knowledge Management, European Business School (EBS), Germany, have concluded that the results of their studies were not affected by the type of the method. Zipfinger (2007), who in her doctoral dissertation compared the opinions on Delphi method using the two types of Delphi, stated that the feasibility of the round-based method might have been “more workable in practice at the time”. Improved access to an affordable tool with good information technology support may be the necessary incentive for more ubiquitous utilization of the real-time technique in the future. Successful implementation of real-time Delphi could prevent the two threats to the validity of the method: panel fatigue and attrition.

Besides factors already discussed, time available to perform the study and predicted level of panel fatigue should be taken into consideration when making decisions concerning the number of survey rounds. The current tendency is to complete Delphi based projects within two or three rounds (Hasson, Keeney, & McKenna, 2000).

Survey questions’ rating scale

The feature distinguishing the Delphi from other methods used in typical qualitative studies is the required format of questions which must be designed in such a way that the answers can be summarized quantitatively and analyzed statistically (Linstone & Turoff, 1975) (Landeta, 2006). The Delphi guidelines, as published by Whitman (1990), Mullen (2003), and Cuhls (2003) describe several approaches to ranking the non-open ended questions, typically following the first classical Delphi round which reveals a list of items that subsequently require grading of likelihood of occurrence, importance, priority, urgency, desirability, feasibility, probability of success, etc.

The desirability, feasibility and importance, along with confidence, were the four scales originally identified by Turoff as these voting dimensions which represented the minimum information necessary to evaluate the investigated problem or event. The confidence scale consisted of four levels: certain, reliable, risky and unreliable. All levels of confidence, as well the levels of the other three scales were defined by brief statements (Turoff M. , The Policy Delphi, 1975).

Grading of the likelihood of occurrence was and is a typical process in seeking opinions in early and current business and industry forecasting Delphi studies (Gordon & Helmer, 1964), (Cuhls, Beyer-Kutzner, Ganz, & Warnke, 2009). One study which utilized this process addressed the events that would occur in the medical laboratory science profession within the next two decades (Kirby, 2008). However, a researcher from the University of Michigan stated that making probability estimates for fixed periods of time (for example for a period between 1971 and 1980) and fixed levels of probability (for example 25, 50 or 75 percent) appeared to be difficult for the respondents (Ludlow, 1975).

According to Whitman (1990), the participants of the study on nursing staff ideas on in-service education, ranked the educational topics and procedures on a 5-point Likert scale from extremely important (5), through very important (4), important (3), minimally important (2) to not important (1). The numerical values assigned to each level of importance are used to compute descriptive statistics, such as modes, medians, means and interquartile ranges. Whitman stated that the means were most often used to provide a measure of the final ranking of the items, while the interquartile ranges were helpful to identify the boundaries of middle responses. The participants who provided responses beyond these ranges would be approached to comment on their choice.

There are many examples of studies that follow similar guidelines, with the highest numerical value being attributed to the highest ranked item. However, the highest numerical value may also be assigned to the lowest ranked item. In a 1974 national drug abuse study, three such scales were used to assess a) feasibility/practicality, b) desirability/benefits, and c) importance of 55 drug abuse policy objectives for the next five years (Jillson, 1975).

Specific definitions for each reference value on each scale were provided and closely resembled those outlined by Turoff (1975). For example, on the feasibility/practicality scale “definitely unfeasible”, assigned the value of 5, was defined as “cannot be implemented (unworkable), basic research needed (no relevant technology exist, basic scientific knowledge lacking), unprecedented allocation of resources would be needed, politically unacceptable, completely unacceptable to the general public”. The definitions used in the importance scale are shown in Table 7. It should be noted that many studies do not explicitly define all values with such detail, assuming the definitions as obvious.

Table 7.

Definitions of Values for Scale of Importance of Drug Abuse Policy Objectives.

Scale Reference	Definitions
1. Very important	A most relevant point, first order of priority, has direct bearing on major issues, must be resolved, dealt or treated
2. Important	Is relevant to the issue, second order of priority, significant impact but not until other items are treated, does not have to be fully resolved
3. Moderately important	May be relevant to the issue, third order of priority, may have impact, may be a determining factor to major issue
4. Unimportant	Insignificantly relevant, low priority, has little impact, not a determining factor to major issue
5. Most unimportant	No priority, no relevance, no measurable effect, should be dropped as an item to consider

Note. Adapted from “The National Drug Abuse Policy Delphi: Progress Report and Findings to Date” (Jillson, 1975), in (Linstone & Turoff, 2002) with permission, available at <http://is.njit.edu/pubs/delphibook/delphibook.pdf>

Three to six-point scales starting at one (1) or zero (0) have been used most frequently. British researchers from the University of Manchester, in cooperation with RAND, have used a nine-point scale in their study on indicators of quality of primary care in the United Kingdom (Campbell, Hann, Roland, Quayle, & Shekelle, 1999). In some studies, “yes” or “no” choices are being provided or a scale without numerical values assigned is used.

A graphic rating scale may replace the numerical scale to allow the rater evaluate an item when they cannot decide between two adjacent values. The values/ratings (also called scale alternatives) are connected by horizontal lines so the rater may place a check anywhere on the line, including intermediate points (Gronlund, 1971). Visual analog scale was used in a study designed to achieve a consensus on the best criteria for the clinical diagnosis of carpal tunnel syndrome (Graham, Regehr, & Wright, 2003). See Appendix C for further examples of rating scales used in published studies.

Likert scale based ranking allows for generation of priority lists; however, it does not allow for assessment of interval distance between each item on the list (Walker & Selfe, 1996). In a study on desired allocation of funds to seven major health services, researchers from Medical School of London addressed this by the application of a “budget pie” system which required distribution of a given set of points between items on the list (Charlton, Patrick, Matthews, & West, 1981). Walker and Selfe (1996) stated that this system may be very frustrating to the respondents due to the necessity to use arithmetic. However; Mullen (1983) concluded that the budget pie system was simple enough for the respondents to use without extensive explanation as only one participant did not understand it but acknowledged he had not read the instructions. She also concluded that the rank positions of the problems identified by the study participants were different when using multi-vote verses budget pie systems. Some

problems voted on by a small number of participants received high number of combined points in the pie system due to intensity of the personal preference of these problems over others. These results indicated that the scoring method chosen for a study had to be carefully considered (Mullen, 1983).

Mullen also conducted a Delphi study seeking a relationship between characteristics that impact successful business performance, as well as successful health and policy outcomes (Mullen, 2009). She stated that variations in assessment of potential impact of the selected characteristics could reflect differences in knowledge of panel members. In order to properly weigh the responses, the researcher, in the first Delphi round, asked the participants to assess the degree of confidence (ranging from very, through fairly, to not very confident) in their own responses. Mullen did not provide any recommendations with regards to inclusion or exclusion of subjects with low degree of confidence.

Cuhls (2003) used two approaches called “agreement ranking” and “qualitative clustering” In a multiquestionnaire study, global megatrends, such as the increase of unemployment rate, rationing of energy or population growth, were ranked based on the number of participants who agreed or disagreed that the trend would occur (Cuhls, Blind, & Grupp, 1998). The “qualitative clustering” referred to ranking topics which could be described under a joint headline (e.g. “product recycling and sustainable agriculture”). She illustrated the clusters of two or more topics on a timeline based on the anticipated decade to which the respondents assigned the forecasted events representative of the topics (Cuhls, 2003).

Analysis of answers and feedback on numeric values

As previously mentioned, the ability to analyze Delphi outcomes statistically, distinguishes this method from other qualitative methods (Linstone & Turoff, 1975; Landeta, 2006). There are several statistical approaches that deserve consideration.

Researchers from the University of Cambridge described three types of graphical presentations of means and standard deviations illustrating the stability of group opinion over the course of several rounds as well as the extent of agreement (or consensus) between the panelists rating the investigated items using a selected interval scale. The graphs were defined as “item”, “fountain” and “trajectory” graphs (Greatorex & Dexter, 2000). The “item” graphs plotted the means and standard deviations (recorded on the Y axis) for each rated item across the appearances of the item in the questionnaire. The “fountain” graphs were formed by plotting standard deviation against the mean of all items rated in individual round. On the “trajectory” graphs several item’s rating means were plotted against their corresponding standard deviations calculated for all rounds. The authors monitored consensus and opinion stability during the Delphi process by checking how mean rating and standard deviations of the items changed over the rounds. They stated that, over time, the decreasing standard deviations and means getting closer to the integer values indicated stabilization of the entire Delphi process. In conclusion, Greatorex and Dexter (2000) pointed out that the results of any Delphi process must not be interpreted in the context of the outcomes of the final round only and that what happens between the rounds contributes to the reliability and thus must be taken into consideration when making decisions based on the results.

Researchers from the University of Teesside and Kings Mill Hospital assessed the percentage of agreement and compared the rankings of items between the rounds by computing

weighted Kappa (κ) statistics for the within-subject level of agreement using Excel Hospital (Holey, Feeley, Dixon, & Whittaker, 2007). The agreement was assessed as poor when the Kappa statistics ranged from zero to 0.2, while it was considered an almost perfect agreement when ranging from 0.81 to 1. An increasing trend in Kappa values was considered a demonstration of reaching stability.

According to Rosner (2006), the Kappa statistics, quantifies the degree of association between variables (in this case the ranks as assigned by the same panelist in different rounds) and is used to check the reproducibility of the variable when measured or surveyed more than once (Rosner, 2006). The statistics is computed according to the formula:

$$\kappa = (p_o - p_e) / 1 - p_e$$

where p_o denotes observed probability of concordance (agreement) between two surveys (rounds of Delphi) and p_e denotes the expected probability of concordance between the two surveys.

Rosner's guidelines stated that excellent reproducibility was demonstrated by κ values exceeding 0.75 and marginal reproducibility was demonstrated by κ values below 0.4. To provide justification for using the within-subject Kappa values, Holey et.al. (2007) cited the researchers from Old Dominion University who claimed that individual panelist's stability of opinion across the rounds provided more information than the group's stability (Chaffin & Talley, 1980).

Besides Kappa coefficient, other means of stability measures used by Delphi researchers are Kendall's W coefficient of concordance and several interclass correlation coefficients, ICCs , (Kendall & Smith, 1939; Okoli & Pawlowski, 2004). Some researchers have cautioned that different ICC may produce significantly different results when used with the same data (von der Gracht, Darkow, Walter, Jahns, & Thomsen, 2008). Kendall W statistics was recommended as a nonparametric coefficient appropriate for ranking type Delphi studies (Schmidt, 1997). The

interpretation of Kendall W approaching the value of 1 is that all raters ranking the investigated items are using the same criteria in assessing the rank (Brencheau & Wetherbe, 1987). Schmidt assessed confidence in survey ranking from none when ($K = 0.1$), through fair ($K=0.5$) to very high confidence ($K=0.9$). This coefficient was used as a measure of stability in a survey Board of Directors and members of Research Advisory Committee of the Clinical Laboratory Management Association to develop indicators of laboratory performance (Zinn & Zalokowski, 1999). The study allowed a much lower Kendall W values than the ones recommended by Schmidt (1997).

Delphi process outcome analysis has not been limited to tracking patterns in opinion stability and consensus. Factor analysis was applied to distinguish five different expert types (Blind, Cuhls, & Grupp, 2001). Factor analysis is used when investigated items form independent subsets of variables which correlate among each other (Tabachnik & Fidell, 2007). The primary goal is the reduction of number of variables to smaller number of interpretable factors (parsimony). The subset of correlating variables (for example politeness, eloquence and having multiple siblings) may be given a common description as a factor, such as “predisposition to work with others”.

The process of “extraction” of the factors from among the multitude of investigated variables is based on eigenvalues, which are defined as values representing percent variance explained by the factor relative to the number of variables. A set of variables may be considered a factor if the eigenvalue is greater than 1. The types of experts, as identified by Blind et.al (2001), were determined based on their attitudes towards multiple research and development trends. Factor analysis was also used by therapists from Texas Tech University and Duke University Medical Center who were able to identify several sets of skills important to achieve

competency in orthopedic manual therapy, OMT (Sizer, et al., 2007). References to factor analysis in Delphi process evaluation were made by others as well (Hasson, Keeney, & McKenna, 2000; Sackman, 1974; Derian & Morize, 1973).

Meaningful analysis of numeric values must follow correct protocols depending on type of data collected. These protocols are different for Likert scale data, and for Likert-type data (Boone & Boone, 2012). Likert scale was originally developed to measure character and personality traits (Likert, 1932). The analysis of Likert data is based on a composite score (a sum or a mean) from a series of survey answers that, when combined, represent a particular trait. Likert-type data are collected when a composite score has no merit as each question is asking about a different aspect. Surveys used in Delphi studies are not psychometric tests and so the values collected in Delphi ranking process fall into Likert-type data category. The Boones' (2012) suggested that the Likert-type data are in the ordinal measurement scale and that the analysis should include computation of median or mode rather than the mean (more appropriate for interval scale) and that frequencies of answers are used as a measure of variability rather than standard deviation. Perkins et al. used analysis of median ratings to identify competencies for acute care curriculum. The competencies with median ratings equal to two top scores on the scale (4 and 5) were considered essential, the competencies with median rating of 3 were considered optional, while ratings of 2 and 1 eliminated the competencies from considerations (Perkins, et al., 2005). Fried & Leao analyzed frequencies of importance ratings obtained in a four stage Delphi to successfully select items for inclusion in periodontics curriculum. They considered an item for inclusion if at least 50 percent plus one respondents rated the item "important" or "indispensable", which were the two top values on the scale (Fried & Leao, 2007).

Comments on answers

One of the main characteristics of the original Delphi, according to the method authorities and their followers, was a controlled feedback (Linstone & Turoff, 1975; Landeta, 2006). This meant that the exchange of information between the experts was not direct but occurred by means of study coordinator (principal investigator) which allowed for elimination of information considered irrelevant. This feature of Delphi would be challenged in the real-time surveys (Gordon & Pease, 2006). In real time applications the narrative comments provided by the participants are readily visible to all who access the survey online which diminishes the ability of the investigator to have control over the released information. Theoretically the investigator could delete or hide comments he/she deems irrelevant or inappropriate. Practically this would mean, however, that the investigator must be on continuous watch for incoming survey answers and comments. Gordon and Pease (2006) stated that, typically, the feedback sent by the researcher to the participants before starting the next round included, besides the numerical values, comments submitted by individuals who represented extreme positions. These comments were provided as justification for ratings that significantly differed from the averages or medians. However, a graduate student who designed a Delphi survey on Delphi implementation (round based vs. roundless) and administered it to Delphi method experts, concluded that helpful and desired narrative comments provided by the participants were not only these made by extreme raters but also comments made by those who provided answers representing the average (Zipfinger, 2007).

Types and Modifications of the Method

There are several types of Delphi methods and different ways to classify them. The classification may be based on 1) the generally understood purpose of the study, 2) iteration (or its lack) and 3) delivery mode (paper-based verses electronic).

Early classification based on the purpose distinguished between classical, policy and decision Delphi (Rauch, 1979; Turoff, 1975; Zipfing, 2007). Classical Delphi was a tool for obtaining a group opinion about forecast statements and was referred to as “conditional scientific prognosis” relevant to natural sciences and engineering advances. Policy Delphi was considered a tool of analysis of social and political events determined by the existing laws and cultural context. Finally, the decision Delphi was a tool used to implement regulations. According to this classification, the classical and policy Delphi processes seek an opinion of experts, while the decision Delphi uses individuals who are in position to make decisions, regardless of their expertise. Although this theoretical classification is frequently referred to, in reality every practical application of Delphi is a modified blend of the three types (Rauch, 1979). The types of the method distinguished depending on survey delivery (iterative verses roundless) were discussed in the section on number of rounds.

A rather straightforward but nevertheless worth mentioning is the classification into paper-based and electronic methods (Zipfing, 2007). The electronic method may be divided into computer-aided (understood as off-line) and online. A British study reported that, when offered a choice, 37% questionnaires were completed electronically and returned by e-mail; 63% were returned by traditional mail delivery (Mullen, 2009). Several software options have been described, including easily available Excel, online survey software such as Zoomerang (currently merged with Survey Monkey) or proprietary programs owned by the institutions which

developed them (Choudaha, 2008; Gordon & Pease, 2006; Turoff & Hiltz, 2010; Zipfinger, 2007).

Chapter Summary

In this chapter, a study by Miller and Abbate (2002) was reviewed to provide context for development of this current project. Their study assessed the extent in which concepts relevant to molecular diagnostics were being taught in the NAACLS accredited MLS programs in the United States and described some reasons for dissatisfaction of the educators with teaching this subject area. The Delphi method was introduced as a technique used to gather information from and achieve consensus among experts to develop competency-based curricula in healthcare education, specifically in medicine, dentistry and several allied health professions, to include medical laboratory science. Several studies reviewed in this chapter are a testament of application of the Delphi process to identify broadly defined curricular goals and affective components or specific skills which may be used to develop cognitive and psychomotor objectives necessary in an effective curriculum. The articles presented in this literature review outlined the specifics of Delphi survey data collection and analysis as the methodology for the study on expectations of clinical laboratory professionals performing or supervising the performance of molecular based assays towards entry-level MLS with regards to their relevant skills.

Chapter Three: Methodology

This chapter restates the research questions and outlines the specific plan for conducting the approved study on clinical molecular facilities' expectations from clinical/medical laboratory scientists entering the profession starting with the selection of experts through questionnaire design and revision to analysis of outcomes. Some studies presented in the Chapter 2 are recalled to illustrate the technical details of Delphi process.

Objectives and Research Questions Addressed by the Study

The project was undertaken to achieve the following objectives:

- A. Assess expectations of clinical laboratories that offer molecular diagnostic services for entry-level MLS with regards to their relevant molecular skills.
- B. Share the outcomes and developed learning objectives with the stakeholders involved: laboratory professionals, educators, certifying and accrediting organizations.

To achieve the above objectives, survey data were collected using a modified, asynchronous, iterative, online Delphi process. The analysis of the data provided answers to the following research questions:

1. Which molecular cognitive skills are expected of an entry level MLS upon hire in facilities that offer molecular diagnostics services?
2. Which molecular psychomotor skills are expected of an entry level MLS upon hire in facilities that offer molecular diagnostics services?

3. Which of the cognitive and psychomotor skills are considered the most important to include in the MLS curriculum?
4. In which areas (e.g., hematology, microbiology, chemistry, blood banking, immunology, body fluids) of the clinical laboratory are entry level skills in molecular diagnostics utilized?

Prior the start of the study, the PI provided Virginia Commonwealth University Institutional Review Board (IRB) with proper documentation, including proof of completion of required training. Due to low probability of risk of harm or discomfort resulting from survey participation and due to essential anonymity of the subjects, VCU IRB classified the study as exempt from review based on guidelines for exemption provided by the Written Policies and Procedures Section VIII, Title 1 (WPP, 2013). On August 7, 2014, VCU IRB notified the Principal Investigator that study HM20002003 was approved on July 29, 2014.

Selection of Experts and Anticipated Survey Response Rate.

The intended participants of the study were medical laboratory professionals actively involved in or supervising the performance of diagnostic assays based on molecular technology. These professionals due to their scope of practice are considered informed individuals or “experts” for providing relevant information which would enable the selection of molecular diagnostics objectives corresponding to skills expected from entry-level MLS and ultimately the development of competency-based curriculum. The selection of participants was conducted using chain referral (snowball) sampling (Heckathorn, 2002; Lincoln & Guba, 1985). Participant selection was facilitated by directors of the NAACLS accredited MLS programs (221 programs at the time the study was initiated) in the US who were contacted using e-mail addresses published on the NAACLS website (NAACLS, Accredited and Approved Programs, 2014). It

was assumed that the educators in each program, due to their close collaboration with laboratories providing internship experience for their students, were able to identify at least one clinical facility where molecular-based assays were performed and as such were credible candidates for the “gatekeeper” role.

The response rate for an informal survey of NAACLS accredited programs conducted by the author of this manuscript in 2005 was 18% (Kraj, 2006). To determine the response rate achieved in formal surveys conducted by other researchers a PubMed search using “NAACLS survey” keywords revealed seven studies published in the journal *Clinical Laboratory Science* between 2000 and 2011. According to the authors, at least some of the surveys in each of these studies were distributed to NAACLS accredited programs. One study did not report response rate due to inability to assess the total number of electronic survey recipients. Response rates reported for the remaining six surveys are presented in Table 8.

Table 8.

Survey Response Rates Published in Clinical Laboratory Science (2000-2011).

Survey study	Response rate (%)
(Laudicina, et al., 2011)	7.3
(Mundt & Shanahan, 2009)	10
(Stevens, 2000)	26.6
(Bamberg, 2004)	47
(Delost & Nadder, 2011)	47.3
(Beck & Doig, 2002)	58
Median	36.8

To achieve the response rate representative of the median published response rate, at least 81 Program Directors or their designees would have to forward the survey to at least one professional at their affiliated clinical site where molecular based testing was performed. This was a very conservative expectation. It was speculated that for this study, the response rate

among the program directors would actually be higher than the median because they were only to serve as gatekeepers forwarding the survey and, thus, not investing much time and effort in the process, yet indirectly benefitting from the outcomes of the study. An assumption was made that the response of the gatekeepers would be reflecting the published response rate's upper limit of 58% which corresponded to 128 forwarded surveys. It was difficult to predict how many of the 128 forwarded surveys would be actually completed by the target experts. Beck and Doig (2002) in their article on entry-level competencies had not only sent their survey to educators but also to managers and laboratory practitioners and reported that the corresponding response rates in each of these last two groups were 39% and 28%, respectively. Based on these results, the expected minimum number of completed surveys was 36 (as it corresponded to 28% of 128). This expected minimum sample size was confirmed by VCU Statistics and Analytics Consulting Lab on February 12, 2014. If the number of surveys completed in the first Delphi round was below 36, the PI would consider using the professional online listserv maintained by the NAACLS (CLSEUDUC) as well as the listserv maintained by the American Society for Clinical Laboratory Science to solicit further snowballing.

Questionnaire Design and Iteration

The first Delphi survey (Appendix D) was created and distributed on August 8, 2014, to five previously recruited testers using a secure, web-based REDCap (Research Electronic Data Capture) survey and data storage software developed at Vanderbilt University (Harris, Harris, Taylor, Robert, Payne, Gonzales & Conde, 2009). The software is offered by Virginia Commonwealth University Technology Services free of charge to VCU faculty and graduate students (CTSA Award Number UL1TR000058). The testers were five professionals from clinical laboratories affiliated with the author's institution: technical and education program

director (Quest Diagnostics, Tucker, GA), former laboratory manager (Georgia Esoteric and Molecular Labs, Augusta, GA), molecular medical technologist (Mid America Clinical Laboratories, Indianapolis, IN), director of Clinical Molecular Genetics (Oregon Health Science University, Portland, OR), and education coordinator (PeaceHealth Laboratories, Springfield, OR). The author of the study also sent the survey link to herself and her advisor to check for any technical errors and contacted VCU Statistics and Analytics Consulting Lab to confirm (per REDCap instructions) appropriate length of all variables' names to allow proper data export.

In the first of three sections of the Delphi survey (Participant Demographics) the respondents were to provide information on completed education, professional credentials, years of experience in clinical laboratory overall and in performing molecular based assays in clinical, as well as other settings, the state they worked in at the time of the study, the type of facility they were employed at, number and type of molecular tests run at their facility, and their experience as a MLS students' preceptor. In the second section (Basic Concepts in Molecular Biology) the respondents were asked to rate the importance of teaching five basic concepts in molecular biology, as a basis for understanding the scientific background of molecular diagnostic procedures. These five concepts included breakthrough genetic discoveries, modes of gene inheritance, chemical and physical features of nucleic acids, and molecular processes of the cell cycle. The third section (Specific Cognitive and Psychomotor Learning Objectives in Molecular Diagnostics) contained a seed list of learning objectives developed by the author and taught in university based NAACLS accredited, entry-level medical laboratory science program in Georgia since fall 2005 (Kraj, 2013 unpublished). The list contained 41 cognitive and psychomotor objectives. These objectives were grouped in seven categories: molecular lab operations, pipetting skills, nucleic acid isolation, DNA polymorphism, gel electrophoresis,

polymerase chain reaction and its modifications, and specific molecular applications in clinical diagnosis. The basic concepts in the second section of the survey and learning objectives in the third section of the survey were to be rated on a modified 5 point Likert-type scale of importance (with 0 being not important, 1 being of little importance, 2 being of moderate importance, 3 being very important and 4 being the most important) used in numerous studies (Fried & Leao, 2007; Perkins, et al., 2005; Elder & Nick, 1997). Presenting a seed list of competencies for rating instead of an open ended request to suggest the skills has been successfully utilized in modified Delphi studies (Staggers, Gassert, & Curran, 2002; Xiao, Lee, & Vemuri, 1997; Mullen, 2009; Valani, Yanchar, Grant, & Hancock, 2010). Following the three sections, one open-ended question asked the participants if they would expand the existing objectives developed by the author or if they would include any additional objectives for entry-level MLS curriculum. The purpose to include the open-ended question was to allow for narrative comments which, upon completion of each survey round, by Delphi design, would be shared with the participants along with a summary of quantitative results before proceeding to the next round.

Following examples of other studies (Mullen, 2009; Edgren, 2006; Zinn & Zalokowski, 1999; Jairath & Weinstein, 1994) and based on provided feedback, several amendments were made upon survey testing:

1. The participants were told the survey would take less than 15 minutes and were provided with a specific date by which the survey should be submitted before they started answering the questions.
2. The question regarding participant's education distinguished between baccalaureate in medical technology (CLS/MLS) and baccalaureate in another field, and asked to specify the field of study of the highest degree achieved.

3. The question regarding professional credentials spelled out specialist credentials vs. categorical credentials.
4. The question regarding molecular laboratory workflow specified “unidirectional (clean to dirty) workflow”.
5. The question regarding reporting the results specified FDA regulation of laboratory developed tests.

The email to MLS Program Directors with a public link to the edited survey (Appendix E) was distributed on September 4, 2014 with an initial due date of September 19, 2014. Additionally, the author, being a program director herself, also distributed the survey to 38 individuals at her MLS program’s clinical affiliates. She also asked 11 members of ASCLS Molecular Diagnostics Scientific Assembly and educators participating in the CLSEDUC listserv if they would like to be sent the link if they had not been already reached by other gatekeepers. A request for the link was made by six individuals. Finally, the executive director of the Association for Genetic Technologists who expressed interest in the study in the past, distributed the link to their membership. On September 15, 2014 a reminder was sent to CLS/MLS program directors in the states from where no surveys were submitted. On September 19, 2014 a final reminder was sent to all gatekeepers thanking them for their role and offering to extend the due date over the weekend. The gatekeepers were informed that all communication from then on would be directly with the respondents. Upon request, the link remained active for five additional days.

Seeking expert opinions has been frequently achieved using Delphi (Aichholzer, 2009). The repetitive process characteristic of Delphi requires that the experts are consulted at least

twice on the same question so that they can reconsider the answer based on the information provided by other experts dealing with the same complex problem (Linstone & Turoff, 1975).

The multistage iteration, typical of Delphi, allows the participants to have a chance to either confirm their original opinion on an investigated subject or stand corrected upon consideration of other participants' views with the ultimate goal of reaching a consensus. In the study presented here, the target participants were told that there would be at least two, but no more than three Delphi surveys to complete to prevent the anticipated panel fatigue and attrition, two major threats to Delphi validity (Hasson, Keeney, & McKenna, 2000; Landeta, 2006). The first survey started with a request to provide the preferred email address so that the subsequent Delphi surveys could be emailed by the REDCap system using a personal instead of a public link. Providing email address by the respondent of the first round was considered an agreement to participate in subsequent rounds. Among 41 objectives rated in the first round, there were 13 learning objectives, predetermined for expansion in subsequent Delphi rounds, if deemed at least moderately important by at least 70% of the first Delphi respondents (those who assigned the objectives a rating of 2, 3 or 4). The reason behind this was that if a particular objective, such as an objective to extract nucleic acids from blood samples, was not considered important, there was no point asking if the preferred method taught in class was a manual or automated method. This "staging" process was another way to prevent the anticipated panel fatigue while answering too many survey questions in the first round. The list of these objectives and their predicted follow-up Round II objectives is provided in Appendix F.

The purpose of the first survey was to collect respondents' demographic data and to identify learning objectives that could be excluded from further considerations due to low number of participants considering it at least moderately important (participants who assigned

the item a score of 2, 3 or 4). The items to be retained in the second round were the ones assigned scores 2, 3 and 4 by at least 70% of the respondents.

VCU IRB specified that prior releasing any new survey in the approved study, the survey must be submitted as an amendment for an exempt review along with all anticipated communications with the respondents. The second Delphi survey was built upon the analysis of the results of the first survey, and it included a total of 100 learning objectives. Per Delphi design, counts and frequencies of each objective rating provided in round one were shown below each objective in round two so that the participant could review the outcomes of the first round before re-rating. As in the case of the first round, the last question of the survey was open-ended and asked if the participant would include in the curriculum any additional methodologies, pathogens and diseases other than already listed. Upon suggestion from Statistics and Analytics Consulting Lab, the second survey also contained eight questions asking to select the most appropriate amount of time the respondents thought should be devoted to each group of concepts and learning objectives (given that a semester lasts 16 weeks on average) to provide additional way to choose objectives to be included in the curriculum. The choices were 1-3 contact hours, 4-6 contact hours and over 6 contact hours. A list of all participants' narrative comments made in the first round to be emailed to all respondents a few days prior release of the second round was also created and submitted to the IRB along with the survey and corresponding email text (Appendix G). The amendment was approved on November 13, 2014. Narrative comments were sent to the respondents on November 14 for their review, and round two Delphi was released using REDCap invitation feature on November 17 with due date of December 1, 2014 (Appendix H). The REDCap release was followed by a confirmatory message sent using VCU email on November 19, 2014 to ensure the participants received their personal link. Several participants

asked to resend the link and confirmed that they received it. Reminders were sent on November 24 and December 1, 2014. Upon request, Round Two survey remained opened after due date. It was closed on December 8, 2014. Upon analysis of round two data and permission by the doctoral committee, the study was considered complete and the third Delphi survey was not released. A thank you email was sent to the respondents announcing the end of the study on January 16, 2015.

Analysis of Data

The data collected during both surveys were transferred into Excel 2013 installed on a password protected Dell Latitude E6530 laptop using REDCap export data tool. Cronbach's alpha coefficient of equivalence was used to assess survey reliability of each Delphi round (Cronbach, 1951). The coefficient was computed by R statistics system, also referred to "R environment", Version 3.1.1 (2014-07-10), using Latent Trait Models (ltm) application package, Version 1.0.0 (2013-12-20) (Rizopoulos, 2006). The selection of the package was determined by the necessity to handle missing data and was approved by VCU Statistics and Analytics Consulting Lab on September 28, 2014.

The demographic data collected in Round I were analyzed to characterize the sample and indirectly assess the validity of expert opinion provided in the surveys. Percentages of respondents were tabulated according to geographic location, education, professional credentials, experience in clinical laboratory setting and experience with molecular testing, as well as experience as medical laboratory science student preceptor.

In this descriptive study objective rating data were analyzed according to recommendations published for data collected using Likert-type scales typical in questionnaires with unique, stand-alone items that cannot be combined into a composite score (Boone &

Boone, 2012). The ratings assigned to each learning objective were analyzed in terms of frequencies, expressed as percentage of respondents who rated an objective with the same score. Computation of frequencies and graphical data representation was performed by REDCap software. Upon computation, the data were manually tabulated. The selection of objectives to be included in entry-level curriculum was determined using modified recommendations of Fried & Leao (2007) who stated that competencies to be included in the curriculum were the ones assigned the two top values on the scale (i.e., “very” and “most important”) by a significant number of participants. The percentage of participants considered significant by Fried & Leao (2007) was 50 plus one respondent. To increase the stringency of the choice, in this study the cut-off percentage of participants determining the objectives necessary to include in the entry-level competency-based MLS curriculum was 70, meaning that upon completion of round II, objectives rated “very” and “most important” by at least 70% participants were identified as necessary. Objectives rated “very” and “most important” by 50-69% were considered optional, depending on the number of credit hours available to teach molecular diagnostics; and objectives rated “very” and “most important” by 25-49% were suggested for extra credit. The objectives rated “very” and “most important” by less than 25% of the respondents were not recommended for inclusion in entry-level curriculum. In addition to selection using rating frequencies, the data were also analyzed following the example of the study by Perkins et.al. (2005) who suggested that competencies included in the curriculum are the ones with median rating scores equal to 3 and 4.

The narrative comments provided in each Delphi round were compiled into a list with a purpose to identify items important for inclusion in the curriculum that were not present on the

seed list of learning objectives developed by the author of this study. The comments were only redacted for spelling errors.

Chapter Summary

In this chapter the objectives of the study were verbalized and the research questions were re-stated. Selection of experts, anticipated response rate, survey development, testing and delivery as well as data analysis were described. Survey instruments were presented along with the corresponding communication with the participants. The following chapters include presentation of results, data analysis, discussion and conclusions.

Chapter Four: Results

In this chapter, study results are presented including demographic features of the respondents, analysis of participants' ratings assigned to specific molecular diagnostics cognitive and psychomotor learning objectives regarding their importance in entry-level medical laboratory science curriculum, the amount of time to teach objectives as recommended by study participants, and summary of narrative comments provided in two Delphi survey rounds.

Participant Demographics

Ninety-four experts from 32 states submitted usable surveys in the first Delphi (Table 9).

Table 9.

Demographic Characteristics of Round I and Round II Respondents: Geographic Location.

Number of Respondents from the State	U. S. States Represented in Each Round	
	Round I	Round II
1	AL, HI, ID, IL, KS, KY, LA, NE, NM, NC, OH, OK, RI, UT	AL, FL, HI, KS, LA, MO, NJ, NM, NC, RI, UT
2	MD, MA, NH, VA	CO, MD, MA, NH, VA
3	FL, NJ, SD	DE, OR, PA, SD
4	CO, DE, MO, PA	IN, TX, WA
5	IN, OR, MI, WA	MI
6	TX	GA
7	N/A	MN
10	MN	N/A
11	GA	N/A
Total Number of Participating States	32	26
Total Number of Respondents	94	63

Eighty-eight experts provided email addresses, indicating agreement to participate in future rounds. Sixty-three respondents (71.6%) submitted usable surveys in the second Delphi, almost twice as many respondents as the expected sample size calculated based on the median response rate reported in surveys published in *Clinical Laboratory Science* between 2000 and 2011 (Stevens, 2000; Beck & Doig, 2002; Bamberg, 2004; Mundt & Shanahan, 2009; Delost & Nadder, 2011; Laudicina, et al., 2011).

In the first round, the largest number of surveys was submitted by respondents from Georgia (11.1%), followed by Minnesota (10.6%) and Texas (6.4%) with other states being represented by 1-5 respondents (1.1 – 5.3% of all respondents each state). In the second round Idaho, Illinois, Kentucky, Nebraska, Ohio and Oklahoma were no longer represented. In other states the observed attrition ranged from 20% (Indiana) to 75% (Missouri). The states where there was no attrition were Alabama, Hawaii, Kansas, Louisiana, Maryland, Massachusetts, Michigan, New Hampshire, New Mexico, North Carolina, Rhode Island, South Dakota, Utah and Virginia. Minnesota was represented by the largest number of respondents in the second round.

More than 73% of the respondents had a Bachelor of Science degree in clinical/medical laboratory science or post-baccalaureate certificate in medical technology, and approximately 55% held a Master's or Doctoral degree. The most represented field of study of highest degree were education and molecular biology/biochemistry and cell biology (Table 10). Nearly 82% of the participants were certified by the American Society for Clinical Pathology (ASCP) or by the National Credentialing Agency (NCA). Nearly 24% of respondents in the second round were certified as Technologist in Molecular Biology, MB(ASCP) and over 18% planned to achieve that credential in the future (Table 11). Over 76% of the respondents had over 10 years of laboratory experience, and 71.3% had at least 5 years of experience performing molecular tests

Table 10.

Demographic Characteristics of Round I and Round II Respondents: Education Completed.

Education Completed (% Respondents)			Field of study of highest degree* (% Respondents)					
Round		%	Round		%	Round		%
I	A.A. degree	1.1	I	Education	9.6	I	Genetics/ Medical	2.1
II		1.6	II		9.5	II	Genetics	3.2
I	CLT/MLT certificate	3.2	I	Mol. Biol/ Biochem/Cell Biology	8.5	I	Chemistry/ Toxicology/	3.2
II		3.2	II		9.5	II	Pharmac. Sciences	4.8
I	BSMT (BS- CLS/MLS)	45.7	I	Biology	8.5	I	Molecular	1.1
II		44.4	II		6.3	II	Pathology	0.0
I	Other BS	23.4	I	Administration	6.4	I		1.1
II		23.8	II		6.3	II	Immunology	0.0
I	MT/CLS/ MLS post- baccal. certificate	27.7	I	Biomedical Sciences	4.3	I	Blood	1.1
II		28.6	II		3.2	II	Transfusion Medicine	1.6
I	Masters degree	37.2	I	Microbiology	4.3	I	Natural	1.1
II		32.3	II		4.8	II	Resources	0.0
I	Doctoral degree	19.1	I	MLS	5.3	I	Neuroendo- crinology	1.1
II		22.2	II		6.3	II		1.6
I	Other degree	1.1	I	Public Health/ Epidemiology	3.2	I		1.1
II		1.6	II		3.2	II	Kinesiology	1.6

Note: *Field of study categories: Education also included Adult Education, MLS Education, Science Education, Education Administration Leadership, Educational Psychology; Administration included Business Administration, Health Services Administration, Health Care Management/Administration; Biomedical Sciences also included Basic Medical Sciences, Biotechnology/Genetic Engineering, Biomedical Informatics; Microbiology also included Medical Microbiology and Molecular Microbiology; MLS also included dual MLS and Biology.

Table 11.

Demographic Characteristics of Round I (RI) and Round II (RII) Respondents: Professional Credentials.

Professional Credentials (% Respondents)			Type of ASCP or NCA specialist credential			Type of ASCP or NCA categorical credential			Plan to obtain MB(ASCP) credential		
Round		%	Round		%	Round		%	Round		%
I	MLS (ASCP)	27.9	I	SBB	4.3	I	BB	0	I	Y	14.7
II		24.6	II		4.7	II		0	II		18.8
I	MT (ASCP)	58.1	I	SC	0	I	C	0	I	N	64
II		57.9	II		0	II		0	II		64.6
I	CLS (NCA)	11.6	I	SCT	0	I	CT	1.1			
II		10.5	II		0	II		1.6			
I	ASCP or NCA specialist	19.8	I	SH	4.3	I	H	1.1			
II		15.8	II		1.6	II		1.6			
I	ASCP or NCA categorical certification	22.1	I	SM	7.4	I	M	3.2			
II		26.3	II		6.3	II		4.7			
I	Other** certification	10.5	I	SV	2.1	I	MB	17.0			
II		12.3	II		3.2	II		23.8			

Note: ** Other certifications listed: NRCC, FACMG, ABMG in cytogenetic (1 of each in both rounds); MLT (2 in both rounds including 1 also with a Canadian credential of Registered Technologist: RT (CSMLS); and MT(AMT) (2 including 1 who did not participate in round II). in clinical laboratory. In the first Delphi round, over 43% of respondents worked in hospital

setting. In the second round that number decreased to 33%, as a result of an increase of the percentage of respondents working in academic medical centers and reference laboratories.

Almost 13% of the second round respondents were at a university based health science/MLS program at the time the study was performed, and nearly 10% worked in public health

laboratories. The respondents had experience with a variety of molecular based assays (Tables 12 and 13).

Table 12.

Demographic Characteristics of Round I and Round II Respondents: Experience.

Number of years in clinical laboratory (% respondents)			Number of years performing molecular tests in clinical laboratory			Prior experience with molecular assays in research or industry		
Round		%	Round		%	Round		%
I	Less than 5 years	5.3	I	Less than 5 years	28.7	I	Y	26.6
II		3.2	II		20.6	II		28.6
I	5-10 years	18.1	I	5-10 years	50.0	I	N	73.4
II		20.6	II		55.6	II		71.4
I	Over 10 years	76.6	I	Over 10 years	21.3			
II		76.2	II		23.8			

Table 13.

Demographic Characteristics of Round I and Round II Respondents: Laboratory Setting and Assays Performed.

	Delphi Round											
	I		II		I		II		I		II	
Place of employment (% respondents)	Hospital Laboratory		Academic Medical Center		Reference Laboratory		Other Setting*					
	43.6	33.3	14.9	19.0	19.1	23.8	22.3	23.8				
Number of molecular assays run in the lab**	1 to 3		4 to 10		More than 10							
	24.7	25.9	29.2	22.4	46.1	51.7						

Note: * Other setting: Currently at University (not academic medical center) with Health Professions/CLS Program: 10 (10.6%) in Round I and 8 (12.7%) in Round II; Public Health State/Government Lab: 9 (9.6%) in Round I and 6 (9.5%) in Round II; Pathology Group: 1 (1.1% in Round I and 1.6% in Round II). One respondent selected "other setting" but did not state what setting it was.

**Assays listed for facilities where the number of molecular assays was 1-3, starting with most common: GC/Chlamydia (w/ or w/o Trichomonas), *C. difficile*, Influenza A/B, MRSA, Respiratory Viral Panel, RSV, HCV viral loads, HPV, Human Erythrocyte Antigen BioArray, *B. pertussis*, EBV, Enterovirus, Mycobacteria probe hybridization, Dengue, Gene expression arrays, qPCR for multiple gene markers. Additional assays listed for facilities where the number of molecular assays was more than 3 (alphabetically): Arbovirus, Array comparative genomic hybridization, Argininosuccinic aciduria mutation test, B&T cell rearrangements, Bioterrorism agents, BK, chimerism analysis, CMV, CYP2C19, Cystic Fibrosis, DNA fingerprinting, Factor II and Factor V, FISH -leukemia/lymphoma, glioma, sarcoma tests, Fragile X, GI virus panel, Group A/B strep, HbS, HBV, HCV genotyping, Hereditary Hemochromatosis HFE, HIV Viral Load, HSV I and II, KRAS, Norovirus, Prostate LDT Mutation analysis, Pyro-sequencing mutation analysis/ methylation/Sanger sequencing/MLPA, Shigella Toxin, t(9:22) BCR-ABL, Varicella zoster.

Over 60% of the respondents in both rounds had experience as a preceptor for MLS students, most of them in the area of microbiology and molecular diagnostics (Table 14).

Table 14.

Demographic Characteristics of Round I (RI) and Round II (RII) Respondents: Experience as an MLS Preceptor.

Experience as MLS student preceptor (% respondents)			Area of preceptorship			Satisfaction with performance of students trained in molecular testing		
Round		%	Round		%	Round		%
I	Y	64.9	I	Blood bank	11.5	I	Very Satisfied	20.0
II		61.9	II		10.3	II		20.7
I	N	35.1	I	Chemistry	11.5	I	Satisfied	51.1
II		38.1	II		5.1	II		41.4
			I	Hematology	11.5	I	Somewhat Satisfied	26.7
			II		2.6	II		34.5
			I	Immunology	19.7	I	Not Satisfied	2.2
			II		15.4	II		3.4
			I	Microbiology	50.8			
			II		41			
			I	Molecular Testing	72.1			
			II		71.8			

Those with experience as a preceptor in hematology and chemistry contributed most to survey attrition. However, the proportion of respondents with experience in preceptorship in the area of molecular diagnostics remained stable over the two rounds.

Survey Reliability

The reliability of the first survey, assessed by Cronbach's alpha computed using ltm package for R statistics system, was 0.96. In the second Delphi round, the coefficient was 0.97.

Delphi Round I Results

Aside from collecting the respondents' demographic data, the purpose of the first survey was to identify learning objectives that could be excluded from further considerations due to low

number of participants considering them at least moderately important, to determine which objectives were to be retained and expanded in the second round, and to inquire about items important for inclusion in the curriculum that were not present on the seed list of learning objectives developed by the author of this study.

To identify learning objectives that could be excluded from further considerations, the author of the study identified objectives that were assigned a score of 2, 3 or 4 by less than 70% of the respondents (Appendix I). The search revealed only one such item in the group of objectives relevant to general laboratory operations: “Identify companies that manufacture molecular assays utilized in the clinical laboratory.” Only 61% of the respondents considered the item at least moderately important in round one. All other 5 basic concepts and 40 learning objectives were given a score of 2, 3 or 4 by at least 76% of the respondents and were, thus, to be retained and expanded in the second round as shown in Appendix F. Aside from the one excluded objective, the items that were rated at least moderately important by the lowest percentage of the respondents were in the group of objectives relevant to DNA polymorphism (“predict the sizes of DNA fragments obtained following restriction enzyme digestion”) and objectives relevant to specific molecular applications (“apply basic karyotyping terms to chromosomal localization of clinically important genes”). The item that was rated at least moderately important by 100% of the respondents was a psychomotor objective in the group of objectives of general laboratory operations: “observe precautions against nucleic acids degradation and contamination”. The ranges and average percentages of respondents who considered each concept or learning objective at least moderately important within each group of objectives are presented in Table 15.

Table 15.

Delphi Round I Ranges and Average Percentages of Respondents Who Considered Each Concept or Learning Objective at Least Moderately Important Within Group.

Groups of Concepts or Objectives Rated in Delphi Round I	Range of percentages of respondents with ratings 2, 3 or 4	Average percentage (%) of respondents with ratings 2, 3 or 4
Basic Concepts in Molecular Biology (5 concepts)	83-95	90
General Laboratory Operations (7 items)	92-100	92
Pipetting Skills (2 items)	80-98	89
Nucleic Acids Isolation (6 items)	84-98	90
DNA Polymorphism (4 items)	76-88	82
Gel Electrophoresis (3 items)	91-95	94
Polymerase Chain Reaction and Modifications (5 items)	90-99	96
Specific Molecular Applications (13 items)	76-96	87

Three learning objectives assigned the highest score of 4 (most important, absolutely must be included in MLS curriculum) by the largest number of respondents were cognitive objectives: “explain the principle of the Polymerase Chain Reaction” (70.2%), followed by “justify the unidirectional (clean to dirty) workflow in the molecular laboratory” (61.7%) and a psychomotor objective “perform Polymerase Chain Reaction” (60.9%).

The narrative comments provided by the respondents in the first Delphi Round are listed in Appendix G. The purpose of seeking comments was, according to instructions, to modify the second round of the Delphi to include expansion of items offered in the first round or additional items absent in the first round. There were 10 narrative comments that either addressed molecular course prerequisites, stated that the list was extensive, or that the curriculum should be basic and not include all the objectives. Eighteen respondents specifically mentioned concepts and learning objectives they considered the most important including clinical presentation of

most common viral/bacterial infections detected by Polymerase Chain Reaction, comparison of molecular methods with other assays and the correlation of molecular test results with diagnosis and disease. These comments appeared as items in round one or were designed to appear in round two. Appendix J presents the objectives corresponding to the narrative comments of these respondents. Due to the fact that clinical presentation, correlation of laboratory tests with diagnosis and method comparison are taught throughout the MLS curriculum, these single comments were not verbalized into new objectives to be rated in round two.

Delphi Round II Results

Per Delphi design, the respondents were given the opportunity to confirm or change their opinion on the importance of the objectives after reviewing the results of the first survey, including narrative comments. The items to be retained in the second round were those assigned scores of 2, 3 or 4 by at least 70% of the respondents in round one.

In the development of the second survey, one low level cognitive learning objective was removed due to insufficient number of participants considering it at least moderately important in the first round; other objectives (listed in Appendix F), were expanded. The total number of evaluated items was 100. Sixty-three respondents (71.6% of all who provided email addresses, indicating agreement to participate in subsequent rounds) submitted usable surveys in the second Delphi round.

All quantitative results are presented in Appendix I. The ranges and average percentages of respondents who considered each concept or learning objective at least moderately important within each group of objectives are presented in Table 16. Following the example of Fried and Leao (2007), the author determined the percentage of respondents who assigned the two top scores (3 and 4) to each rated concept or objective.

Table 16.

Delphi Round II Ranges and Average Percentages of Respondents Who Considered Each Concept or Learning Objective Very and Most Important Within Group.

Groups of Concepts or Objectives Rated in Delphi Round II	Range of percentages of respondents with ratings 3 or 4	Average percentage (%) of respondents with ratings 3 or 4
Basic Concepts in Molecular Biology (5 concepts)	16-95	71
General Laboratory Operations (7 items)	84-100	91
Pipetting Skills (2 items)	59-94	76
Nucleic Acids' Isolation (7 items)	38-71	60
DNA Polymorphism (7 items)	23-56	42
Gel Electrophoresis (9 items)	36-78	52
Polymerase Chain Reaction and Modifications (17 items)	24-89	62
Specific Molecular Applications (46 items)	12-82	46

The concepts and objectives were separated into 4 groups based on the percentage of respondents who assigned them a score of 3 and 4, as also shown in Table 17.

Table 17.

Groups of Concepts and Objectives by Percentage of Respondents with Ratings of 3 and 4.

% of Round II Respondents with ratings 3 and 4	Concepts or Learning Objective (as numbered in Round II)	
	Cognitive	Psychomotor
70% and up	#2-9, 12, 29, 38, 40-42, 44-45, 54-55, 66-68	# 10-11, 13, 18
50-69%	#15, 17, 22-23, 35, 39, 43, 52-53, 56, 61, 63-65, 69-73, 76-79, 81-82, 84, 87, 92	#14, 19-21, 30, 33-34, 46-47
25-49%	#16, 24-26, 32, 36-37, 48, 57-60, 62, 74-75, 80, 85-86, 88-91, 93-96	#27, 31, 49
Less than 25%	#1, 28, 83, 97-100	#50

The second Delphi round, revealed 4 concepts and 21 learning objectives (17 cognitive and 4 psychomotor) rated "very" and "most important" by at least 70% of the participants. These

items were identified as necessary for inclusion in the competency-based, entry-level MLS curriculum. There were 37 learning objectives (28 cognitive and 9 psychomotor) rated “very” and “most important” by 50-69% of the respondents. These were considered optional for an MLS curriculum, depending on the number of credit hours available to teach molecular diagnostics. There were 30 learning objectives (27 cognitive and 3 psychomotor) rated “very” and “most important” by 25-49% of the respondents and suggested for extra credit. Finally, there were 7 learning objectives (including one psychomotor) and one basic concept considered “very” and “most important” by less than 25% of the respondents. These would not be recommended for entry-level MLS curriculum.

Following the example of Perkins et.al. (2005) who suggested that competencies included in the curriculum are the ones with medians equal to 3 and 4, median rating scores were recorded (Appendix I). The concept of DNA melting point (#4) and objectives pertaining to unidirectional workflow and precautions against nucleic acids’ degradation and contamination (# 7 and 11), as well as proper micropipetting (#13) were the only ones with median rating equal 4. Objective #42 referring to PCR controls had a median equal to 3.5. The objectives with medians 3 and 4 are the same objectives that are rated “very” and “most important” by at least 50% of the respondents. All objectives rated as “very” and “most important” by less than 50% of participants had a median equal 2, except for objective #61 (importance of inclusion of automated Sanger sequencing) which had a median equal 2.5.

The median method does not seem to be useful to separate the extra credit objectives from the ones that should be removed as there were no objectives with median equal 1. Lack of objectives with medians equal to 1 indicates that there were not any objectives that would be

deemed unimportant, validating the seed list of the objectives used in the survey and justifying forfeiture of the exploratory round typical of classical Delphi.

Based on good separation of the necessary, optional, and extra credit objectives, it was decided that a third Delphi round was not necessary. It would be necessary if most or almost all objectives fell into the optional or extra credit category. Fried and Leao (who used 50% of respondents as the cutoff) recommended taking the objectives that could not be clearly accepted or rejected (such as the extra credit objectives) and sending these back for re-rating to the participants who provided extreme ratings of these objectives (such as 0 or 4). In this current study, the number of such respondents would be very small (as most rated these objectives as moderately important); therefore, even if the rating changed, it would not have affected the outcome. The response rate in the third round was likely to decrease.

In the second Delphi round survey, the researcher also included eight questions asking to select time the respondents thought should be devoted to each group of concepts and learning objectives, given that a semester lasts 16 weeks (on average). The results are shown in Table 18. Table 18.

Instructional Time Assigned to Each Objective Category Group (% respondents).

Contact hours	Basic Molecular Biology	General Lab Operations	Pipetting Skills	Nucleic Acid Extraction	DNA Polymorphisms	DNA Gel Electrophoresis	PCR Method and Modifications	Specific Clinical Applications
1-3	33.9	58.1	69.4	50	66.1	69.4	24.2	40.3
4-6	40.3	24.2	25.8	41.9	27.4	24.2	59.7	40.3
Over 6	25.5	17.7	4.8	8.1	6.5	6.5	16.1	19.4

The last question in the second round Delphi survey asked the participants if, upon consideration of all learning objectives, they would add any methodologies, pathogens and

diseases/conditions, other than already listed, to include in entry-level medical laboratory scientist curriculum. There were five answers simply stating “no” or that the list covered the most important concepts and objectives. There were eight answers with specific comments as presented in Table 19.

Table 19.

Narrative Comments Provided in Delphi Round II.

My thoughts are that you should cover the concepts pertaining to molecular methods and include information about specific conditions that concern any one target in particular. The main thing is to cover the concepts that are common to many protocols. You'll never know what types of work your students will be doing, so to spend a great deal of time working on one particular area (i.e. infectious diseases) may be wasted time if the person who is doing training will be working in a karyotyping lab. The molecular concepts are KEY, along with QUALITY CONTROL and UNIDIRECTIONAL WORK!!!

No, infectious disease and basic molecular is entry level. Human polymorphisms and cytogenetics as well as HLA is NOT B.S. level molecular diagnostics. I would only add that any dedicated MDx course should annually assess 'which methodologies, pathogens/conditions, etc.' should be considered. In other words, a MDx course syllabus may need to be adjusted annually due to this fields rapid evolution. For instance, we may need to stop teaching basic gel electrophoresis b/c of the rapidly expanding platforms for direct fluor detection of nucleic acids and/or proteins.

Troubleshooting failed runs.

Perhaps diabetes and lupus.

There is limited time to teach the concept for every gene mutation or pathogen, so I generally select one from each area (infectious disease, gene mutations, HLA) to teach in lab and cover some of the more common test methods in lecture.

Non-small cell lung cancer and melanoma.

Chapter Summary

In this chapter the results of the study on the importance of inclusion of specific molecular diagnostics cognitive and learning objectives in entry-level medical laboratory science curriculum were presented. The chapter started with presentation of participant demographic data, followed by quantitative data as well as narrative comments collected in both Delphi rounds. In the next chapter, answers to specific research questions are provided based on the results.

Chapter Five: Discussion

This chapter presents a summary of the descriptive study on clinical molecular facilities' expectations from medical laboratory scientists entering the workforce and conclusions based on data reported in Chapter Four. It provides a discussion of findings, limitations of the study and implications for MLS educators and the profession.

Summary of the Study

The medical laboratory science profession is in need for published molecular diagnostics competency-based standards and curriculum. To assess their expectations of new MLS graduates, professionals performing and supervising performance of clinical molecular assays were surveyed to rate the importance of relevant cognitive and psychomotor learning objectives, developed by the author while teaching molecular methods courses in an MLS Program.

Following the approval by VCU Institutional Review Board, a modified, asynchronous, iterative online Delphi process was completed in two survey rounds using Research Electronic Data Capture (REDCap) application. The reliability of the first and second surveys, assessed by Cronbach's alpha computed using R statistics system, was 0.96 and 0.97, respectively. Program directors of 221 MLS programs accredited by the National Accrediting Agency for Clinical Laboratory Science (NAACLS) were asked to serve as "gatekeepers" and forward the first Delphi survey to target participants. Ninety-four experts from 32 states submitted usable surveys in the first round. Eighty eight experts provided email addresses, indicating agreement to participate in future Delphi rounds.

More than 73% of the respondents had Bachelor of Science in clinical/medical laboratory science degree or post-baccalaureate certificate in medical technology. Nearly 82% of the participants were certified by the American Society for Clinical Pathology (ASCP) or by the National Credentialing Agency (NCA). Almost 77% had over 10 years of laboratory experience and 71.3% had at least 5 years of experience performing molecular tests in clinical laboratory (over 43% in hospital setting).

Per Delphi design, the respondents were given the opportunity to confirm or change their opinion on the importance of the objectives after reviewing the results of the first survey, including narrative comments. One low level cognitive objective was removed from the second survey, due to insufficient number of participants considering it at least moderately important; and 13 other objectives were expanded so that the total number of evaluated items was 100. Sixty three respondents (71.6%) submitted usable surveys in the second Delphi Round.

Upon completion of Delphi process four groups of concepts and objectives emerged, depending on the percentage of round two respondents who deemed the item “very” and “most important” with thresholds of 70, 50, and 25% of the respondents. The recommended essential items identified as necessary for inclusion in the entry-level MLS curriculum focused on basic molecular biology principles and general molecular laboratory operations, including practical knowledge of techniques designed to maintain specimen integrity and intense theoretical background of the polymerase chain reaction, as well as comprehension of laboratory assays for pathogens most commonly tested for using molecular methods. In addition to the essential MLS molecular learning objectives, the investigator also identified optional objectives that could be used to expand the students’ knowledge, depending on the number of contact hours available to teach molecular diagnostics; The remaining objectives rated by the respondents of the survey

were suggested for extra credit beyond the available contact hours or were not recommended to include in entry-level MLS curriculum. The list was created with ultimate goal to share with MLS educators, accrediting agency (NAACLS) and the provider of MLS certification exam (ASCP), to contribute to the existing exam content guidelines.

The Expert Opinion

Based on respondents' credentials, work experience in the area of molecular diagnostics, as well as experience as a preceptor for MLS students in area of molecular testing (Tables 10-14), it may be concluded that the Delphi study reached the intended target population sample, validating the provided expert opinion. The demographic characteristics of the sample confirm that the gatekeepers (program directors of NAACLS accredited MLS programs) have forwarded the initial public survey link as intended.

When seeking expert opinion, Delphi process has two advantages when compared to other methods: the selection of the participants by nomination rather than by random sampling and the essential anonymity of the experts (Duffield, 1993; Mullen, 2003). The selection of participants by nomination prevents self-classification as experts due to perceived estimation of one's own knowledge, and the essential anonymity of Delphi respondents prevents the influence of dominant personalities, known as "bandwagon effect" or "halo effect", which may result in pressure to conform regardless of personal opinion.

One cannot exclude the possibility that some respondents may have proceeded with the survey regardless of their actual or perceived knowledge. In this study, one participant, despite nomination, reported that she lacked sufficient knowledge to complete the first Delphi survey and withdrew from the project. One participant answered all the questions but, in the space devoted to the narrative comments, stated she had a limited knowledge base indicating low self-

confidence. Upon review of this respondents' credentials, it was noted that she had over 5 years of experience performing at least three clinical molecular assays at her institution. She participated in the second Delphi round. Mullen (2009) attempted to address this issue by asking the participants of her study to assess their own confidence in their answers. However, Mullen did not provide recommendations regarding exclusion of participants with low confidence levels. Hence, in this study, the collected demographic data provided means to evaluate the validity of the sample.

Delphi provides a safe environment for reconsideration of one's own opinion upon review of the overall results and comments submitted by others in the previous round without the threat of being labeled as indecisive (Linstone & Turoff, 1975; Francis, 1977; Landeta, 2006). In this study, the anonymous narrative comments provided in the first survey (Appendix G) were sent to the respondents three days prior the release of the second survey. To assure that everyone had a chance to review the comments, the investigator had inquired twice if the respondents had not received the comments. In absence of such reports, it was assumed that everyone considered the comments when re-rating the objectives in the second survey and provided informed opinion.

Cognitive and Psychomotor Skills Expected of an Entry-Level MLS

It is the author's recommendation that, at a minimum, the entry-level MLS curriculum must include basic concepts of gene inheritance, cell cycle events, nucleic acids' chemistry relevant to molecular techniques and fundamentals of quality assurance practices characteristic of molecular diagnostic laboratory including cognitive comprehension of the unidirectional workflow. A graduating MLS must be versed in specimen transport and storage conditions recommended for specimens and purified nucleic acids and the regulations regarding reporting patients' results obtained in laboratory developed tests. MLS training must also include practical

experience in micropipetting, manual extraction of nucleic acids using precautions to assure specimen integrity as well as handling chemical and biohazard waste. The curriculum must address theoretical background of gel electrophoresis and polymerase chain reaction, including the operation of thermal cycler, the specifics of reaction conditions, components and quality control. Furthermore, the MLS should recognize the difference between the standard and reverse-transcriptase PCR, be able to name specific applications of such assays, as well as real-time and multiplex PCR assays; and have the cognitive ability to troubleshoot unsuccessful reactions. The MLS should differentiate between target and signal amplification assays and be able to provide examples of molecular technologies and instrumentation used in detection, quantitation and/or genotyping of the agents commonly assayed for using molecular tests: *N. gonorrhoe*/*C. trachomatis*; HIV-1, and HCV. This content reflects the expectations of a significant majority of those asked to provide their expertise in this study and is captured by specific learning objectives listed in Table 20.

Using the upper time limits recommended by the majority of round two respondents, the total instructional time devoted to molecular diagnostics is 32.5 contact hours (Table 21). In a 16 week semester, this equals to approximately two hours per week, if the ratio of contact to credit hours is approximately 1:1 for didactic courses and 2:1 for laboratory courses (DOE, 2010). Thus, 1.5 credit hours is recommended for a single molecular diagnostics course with a combination of lecture and laboratory. Alternatively, the psychomotor objectives could be covered during other courses that have a laboratory component and in clinical internships. This would allow for inclusion of more cognitive objectives in the lecture course.

To make sure that the essential content corresponds to the expectations of a significant majority of experts, in this study a high threshold of 70% of the respondents was used as a criterion

Table 20.

Essential Concepts and Objectives in Entry-Level MLS Curriculum.

BASIC CONCEPTS IN MOLECULAR BIOLOGY
Modes of single gene inheritance: dominant, recessive, autosomal, X-linked. Chemical structure and bonds in DNA and RNA. DNA melting point and its relevance to DNA denaturation, renaturation, hybridization and annealing. The central dogma of molecular biology and the molecular processes occurring during the cell cycle.
GENERAL LABORATORY OPERATIONS
Recognize the differences in quality assurance practices utilized in clinical molecular diagnostic laboratories versus molecular biology laboratories. Justify unidirectional (clean to dirty) workflow in the molecular laboratory. Recommend proper transport for acceptable specimens for molecular pathology. Recommend proper storage conditions for specimens and purified nucleic acids according to Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP) guidelines. Observe correct protocols for disposal of biohazard and chemical waste in the molecular laboratory. Observe precautions against nucleic acids degradation and contamination. Recognize the complexity of reporting patients' results including regulation of laboratory developed tests and the FDA Analyte Specific Reagents (ASR) Rule.
PIPETTING SKILLS
Demonstrate proper use of automated, variable or fixed volume micropipettes.
NUCLEIC ACIDS' ISOLATION
Use manual DNA and RNA extraction protocols.
GEL ELECTROPHORESIS
State the principle of DNA gel electrophoresis.
POLYMERASE CHAIN REACTION METHOD AND MODIFICATIONS
Provide temperature ranges appropriate for the molecular events of the denaturation, annealing and extension steps of a PCR cycle. Explain the role of each component of a standard PCR mixture in DNA amplification. Describe the operation of a thermal cycler. Distinguish among the positive, negative, internal, and reagent blank PCR controls. Differentiate between standard PCR and reverse transcriptase PCR. Provide at least one specific application of each: standard end-point PCR, real-time PCR, reverse-transcriptase PCR and multiplex PCR. Troubleshoot in case of unsuccessful end-point or real-time PCR product analysis outcome.
SPECIFIC MOLECULAR APPLICATIONS
Differentiate between target amplification and signal amplification. Identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents: <i>NG/CT</i> , HIV-1, HCV

Table 21.

Recommended Number of Hours to Teach Essential Concepts and Objectives.

Groups of Concepts or Objectives	Instructional Time (hrs)*	Content	
		Cognitive	Psychomotor
Basic Concepts in Molecular Biology	4-6	nucleic acid chemistry, basic molecular theory, modes of inheritance	N/A
General Laboratory Operations	1-3	quality assurance in clinical vs. molecular biology labs, unidirectional workflow, specimen transport and storage, complexity of reporting results and FDA regulation of laboratory developed tests	disposal of waste, nucleic acid degradation and contamination precautions
Pipetting Skills	1-3	N/A	proper use of micropipettes
Nucleic Acids' Isolation	1-3	none	manual DNA and RNA extraction
DNA Polymorphism	1-3	none	none
Gel Electrophoresis	1-3	principle of DNA electrophoresis	none
Polymerase chain reaction and Modifications	4-6	reaction conditions and components including proper controls, knowledge how the thermal cycler works, differences between standard, reverse-transcriptase, end-point and real-time PCR, troubleshooting unsuccessful assays	none
Specific Molecular Applications	4.5**	differences between target and signal amplification, methods and equipment for detection, quantitation and/or genotyping <i>NG/CT</i> , HIV-1, HCV	N/A
Total (using the upper limit for group)	32.5		

Notes: *Based on a 16 week semester

**40.3% of the respondents recommended 1-3 hours and 40.3% respondents recommended 4-6 hours (4.5 is the average of the two recommended upper limits: 3 and 6).

to identify the items. Fried & Leao recommended an ambivalent 50% plus one threshold to

identify the items (Fried & Leao, 2007). In the study presented here, there were 62 objectives

that met Fried & Leao criteria (marked with dark and light green in Appendix I). To include all these objectives in the curriculum, one would have to significantly increase the instructional time beyond the 32.5 contact hours recommended by the largest percentage of the respondents. To respect the respondents' preferences, only the concepts and objectives with ratings 3 and 4 assigned by at least 70% of the respondents are suggested as essential, while the 37 objectives with such ratings assigned by 50-69% of the respondents may be considered optional, depending on available contact hours in an MLS program. These optional objectives (marked light green in Appendix I) are relevant to some more fundamental skills, such as evaluation of accuracy of micropipettes, spectrophotometric assessment of nucleic acid concentration and purity, comprehension of the principles and ability to perform automated nucleic acid extraction. The optional content also includes laboratory experience in gel electrophoresis with relevant safety precautions, as well as performance of the PCR. It is evident that completion of the optional objectives in the curriculum, would require not only additional contact hours but also physical and financial resources to purchase or access instrumentation, namely electrophoresis units, thermal cycler, and automated nucleic acid extractor. Availability of these resources may vary between university based and hospital based programs and should be taken into consideration when planning the curriculum. The cognitive objectives falling into the optional category may require seeking expertise outside the MLS program if the faculty teaching molecular course has no prior experience with such technologies as Sanger or Next Generation Sequencing, Microarrays and Fluorescent *In Situ* Hybridization. The topics covered by the optional objectives include applications of Single Nucleotide Polymorphisms (SNPs) and Short Tandem Repeats (STRs), deeper understanding of real-time PCR, comprehension of molecular diagnostic systems and ability to compare the principles of the technologies listed above, as well as identification of

instrumentation and diagnostic methods to detect multiple infectious agents (as listed in Appendix I). Finally, the category includes association of genetic markers with chronic myelogenous leukemia (CML), breast cancer and cystic fibrosis.

The objectives rated by the respondents in this study were developed while teaching molecular methods courses at the author's institution where the MLS curriculum includes 3 credit hours of lecture and 2 credit hours of laboratory in one semester. Thus, the number of hours dedicated to molecular diagnostics at that university exceeds the number of hours recommended by the participants of the study which permits for inclusion of a much higher number of learning objectives than may be taught during the 1.5 credit hour course recommended to cover the necessary objectives reflecting knowledge and skills expected from an MLS upon graduation.

Aside from objectives suggested as necessary/essential or optional, the author recommends 30 objectives (marked yellow in Appendix I) for extra credit beyond the available contact hours. These objectives were rated very and most important by 25-49% of the respondents in Delphi round two and are relevant to practical restriction enzyme fragment polymorphism (RFLP) analysis, principles of software-based PCR primer design, several molecular methods beyond PCR and genetic markers for a variety of conditions. The eight objectives (marked red in Appendix I) rated very and most important by less than 25% of the participants are not recommended for inclusion in the entry-level MLS curriculum. Most of these objectives, relevant to applications in transfusion therapy or tissue typing and pharmacogenomics may be more appropriate for a post-professional curriculum. Others (general concepts of scientific discoveries made by molecular scientists, usage of karyotyping terminology, manual PCR primer design and predicting DNA size fragments following restriction digestion) may have

been deemed obsolete or not representative of the scope of MLS practice. MLS program directors and educators have the responsibility to make sure the curricula reflect the scope of practice and follow the prescribed NAACLS guidelines to secure continuous accreditation and graduates eligibility for certification.

Traditionally, the NAACLS standards named seven areas of medical laboratory science: Clinical Chemistry, Hematology/Hemostasis, Immunology, Immunohematology/Transfusion Medicine, Microbiology, Urine and Body Fluid Analysis and Laboratory Operations. The 2001 Standards added “molecular diagnostics” to the list (NAACLS, Standards of Accredited Educational Programs for the Clinical Laboratory Scientist/Medical Technologist, 2001). However, the most current standards, updated in January 2014, section VIII A (MLS Curriculum requirements) no longer verbalize “molecular diagnostics” (NAACLS, Unique Standards Medical Laboratory Scientist (MLS), 2012). This change occurred because the molecular testing is now integrated in all the areas listed in the Standards. For this reason, many programs do not have a separate course devoted to molecular diagnostics but include this content in other courses. The Description of Entry-Level Competencies of the MLS states:

“At entry level, the medical laboratory scientist will possess the entry level competencies necessary *to perform* the full range of clinical laboratory tests in areas such as Clinical Chemistry, Hematology/Hemostasis, Immunology, Immunohematology/Transfusion medicine, Microbiology, Urine and Body Fluid Analysis and Laboratory Operations, and other emerging diagnostics, and will play a role in the development and evaluation of test systems and interpretive algorithms”.

Hence the list of laboratory areas includes “other emerging diagnostics” instead of previously listed “molecular methods”. The goal of this project was to assess which molecular concepts and objectives may be considered essential for inclusion in the MLS

curriculum. To achieve meaningful results, the target experts in this study were the professionals experienced in molecular based clinical assays.

There could be several reasons why only one fourth of all concepts and objectives developed by the author were rated “very” and “most important” by at least 70% of the experts and why no additional content was suggested, with the exception of very few items (such as non-small cell lung cancer or lupus) listed by single respondents. Many of the respondents may have been satisfied with their own past on-the-job training and did not see a reason to change the paradigm. If the respondents themselves were not allowed in the molecular section of the laboratory until they gained experience in other areas for several years, they may still identify molecular diagnostics with advanced education.

Some respondents, depending on how long ago they completed their education, may have graduated from programs where, based on the ASCP exam guidelines, students were not exposed to molecular diagnostics (ASCP, 2014). This may have triggered preconception that, since the certification agency did not place emphasis on certain concepts, one should not expect the new graduates to be versed and skilled in these concepts. On the other hand, the newest addition of MALDI-TOF technology to the ASCP BOC microbiology content guidelines in September 2014 was not reflected in the opinion of the surveyed experts as none suggested to include it in the objectives related to methods not considered PCR. Therefore, the impact of the guidelines on expert opinion is unlikely.

Another reason for only a small proportion of the items being selected may be that molecular diagnostic testing remains very costly, and as such is not considered appropriate for student training due to perceived risk of wasting or compromising the quality of reagents. Many educators share the same complaints of their students not being able to get

any hands-on training in the molecular area while in internships. Also, open opposition by an authoritarian individual in the laboratory to teaching certain concepts may have affected the opinion of some of the professionals. One respondent noted that the molecular testing was typically sent out in their area so laboratory directors and pathologists did not think molecular methods should be taught at all.

Finally, an important reason that only 25% of all molecular concepts and objectives were considered very and most important by at least 70% of the experts to include in MLS curriculum is the emergence of another laboratory professional: a Diagnostic Molecular Scientist (DMS). The informal survey distributed in 2005 revealed that one institution (out of 40 who responded) had planned to open a DMS program in 2006 (Kraj, 2006). In February 2015, the NAACLS reported that between 2007 and 2014 the number of accredited DMS programs in the US grew from four to eight (Simonian, 2015). There are three such programs in Texas and one in each of the following states: Connecticut, Kansas, New York, North Carolina and Michigan. According to the NAACLS Standards:

“Diagnostic molecular scientist professionals are qualified by academic and applied science education to provide service and research in the molecular diagnosis of acquired, inherited, and infectious diseases (NAACLS, Unique Standards Diagnostic Molecular Scientist (DMS), 2012)”.

Graduation from a NAACLS accredited DMS program is one of several routes of eligibility for an ASCP categorical certification as entry-level Technologist in Molecular Biology, MB(ASCP). The content guidelines for the exam provide a detailed listing of molecular concepts, techniques and laboratory applications (ASCP, Technologist in Molecular Biology, MB(ASCP) and International Technologist in Molecular Biology, MB(ASCPi) Examination content Guideline & Outline, 2014). The existence of NAACLS standards for DMS and detailed guidelines for

Technologist in Molecular Biology suggest that the preference of the accrediting and certification agencies is to have a molecular diagnostics professional devoted to that area of laboratory medicine.

However, there are at least two reasons why MLS curriculum should include well defined molecular diagnostics content. Firstly, due to low number of accredited DMS programs, graduating between 1 and 30 (on average 12) students per year, it will be impossible to staff all laboratories performing the growing number of molecular based assays with DMS for many years. The U.S. Bureau of Labor and Statistics projected MLS employment to grow 22% from 2012 to 2022 which translates to 70,600 more jobs in clinical laboratories (Occupational Outlook Handbook, 2012). Many of these jobs will require molecular testing expertise. The major resource for entry-level professionals for the laboratory workforce are the 221 NAACLS accredited MLS programs. In 2014, 3613 individuals received MLS(ASCP) certification and 492 received MB(ASCP) certification. Only about 11% of those certified as MB(ASCP) were the graduates of DMS programs (Brown, 2015). Secondly, most hospital based laboratories where molecular testing is performed on site, reference blood banks and other laboratories need technologists qualified to perform and verify a variety of diagnostics assays, including other non-molecular based tests which are not within the DMS scope of practice. It may be anticipated that a lab which is not a specialized molecular diagnostic facility would rather hire a generalist trained in molecular methods than a molecular diagnostic scientist, not trained in other laboratory areas.

Taylor et.al. (2014) in their report of the Association for Molecular Pathology Training and Education Committee provided recommendations for baccalaureate and master's degree DMS programs. The authors based their recommendations on a single survey in which molecular

diagnostics laboratory managers rated the expected expertise of baccalaureate MLS graduates and master's level DMS graduates in molecular tests and skills. There were no questions asking the respondents to rate the expected expertise of graduates of baccalaureate DMS programs, yet the authors provided recommendations for such programs. In the Delphi study presented here, the respondents rated the learning objectives considered for entry-level MLS curriculum in two surveys which gave them the opportunity to confirm or revise their opinion based on comments provided by other experts. The reported results only refer to the MLS curriculum and do not impose any content on the curriculum that was not explicitly named in the study. Although some similarities may be noted between the AMP's task force outcomes and the Delphi, Taylor et.al. (2014) did not aim to develop specific cognitive or psychomotor objectives. The Delphi study allowed for extraction of essential learning objectives to share with MLS educators and also established the number of hours that should be devoted to each group of objectives. For this reason, the outcomes of the Delphi should be very useful to those designing the MLS curricula and certification exam content. Both studies revealed that MLS graduates should have conceptual knowledge in nucleic acid chemistry, basic molecular theory (central dogma) and modes of inheritance. However, Delphi results provided specific content that should be included: types of modes of single gene inheritance, the relevance of melting point to DNA denaturation and annealing, etc. With regards to general laboratory operations such contamination control, reagent storage and specimen collection/handling, Taylor et.al recommended that an MLS has a conceptual understanding of such practices. Two relevant objectives selected as necessary to include in the MLS curriculum based on the ratings provided by the respondents of the Delphi study presented in this manuscript are in the psychomotor domain and as such extend beyond conceptual understanding: observe correct protocols for disposal of biohazard and chemical

waste in the molecular laboratory and observe precautions against nucleic acids degradation and contamination. Two additional objectives that are recommended as necessary for inclusion in the MLS curriculum based on the Delphi study that were not listed in the AMP report were to demonstrate proper use of automated, variable or fixed volume micropipettes and troubleshoot in case of unsuccessful end-point and real-time PCR analysis outcome. Another essential psychomotor objective that was identified using the Delphi process was to use manual DNA and RNA extraction protocols. The AMP study recommended that an MLS only has a conceptual understanding of nucleic acid isolation and that laboratory training in this skill belongs in the DMS program. As opposed to nucleic acid isolation, the AMP recommended that the MLS has laboratory training in electrophoresis. However, the Delphi process revealed that the only objective referring to gel electrophoresis that was considered very and most important by 70% of the respondents was the cognitive objective to state the principle of DNA gel electrophoresis, while all psychomotor objectives relevant to this technique and its interpretation were considered very and most important by much smaller percentage of the respondents and as such not considered necessary to include in the curriculum.

Although the outcomes of both studies suggest that MLS graduates should have a theoretical knowledge of standard, reverse transcriptase and real-time polymerase chain reaction, the Delphi study provides more detail with regards to specific aspects of PCR (Table 20). As for infectious disease testing, the AMP study recommends the knowledge of molecular pathology of infectious disease in general. The Delphi study specifies the importance to identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype such organisms as *N. gonorrhoe/C. trachomatis*, HIV-1 and HCV. Besides basic knowledge of the assays designed for the three listed pathogens, all non-PCR molecular

techniques rated in the Delphi study were not recommended for inclusion in the entry-level MLS curriculum. However, several of the techniques (e.g. microarrays, pyrosequencing, Sanger sequencing) were recommended by the AMP study for conceptual understanding only.

Clinical Laboratory Areas Where Entry-Level Molecular Diagnostics Skills are Utilized

The vast array of molecular-based assays performed at the respondents' institutions are listed in Table 13. However, the essential entry level skills reflected in the cognitive and psychomotor objectives identified as necessary for inclusion in the MLS curriculum based on the percentage of respondents who rated the objectives as very or most important included skills that primarily refer to general laboratory operations and infectious disease testing for the pathogens commonly tested for using molecular assays: CT/NG, HIV-1 and HCV. The skills relevant to molecular assays performed in cancer and cytogenetic diagnostics, HLA and immunohematology testing were not recommended for entry-level skill training.

Limitations

Panel fatigue and attrition are the largest threats to Delphi validity and should be monitored in order to avoid false consensus error resulting from drop out of participants with outlier opinions (Hartley, 1995). To prevent panel fatigue, the number of rounds was predetermined to be no more than three and the study was completed after the second round (Landeta, 2006). Another step that has been undertaken to prevent these two threats was using the seed list of objectives to be rated in the first round instead of conducting the exploratory round, typical of classical Delphi (Xiao, Lee, & Vemuri, 1997; Mullen, 2009; Elder & Andrew, 1992). Additionally, the author made sure to remind the respondents of the deadlines to complete the surveys, stressed the importance of participation in all rounds and offered the extension of

due dates. Despite these precautions 28% of the first Delphi respondents, did not participate in the second round. Financial or other incentives were not available in this study.

Other limitations of the study may be described in the context of common errors in rating process as described in the literature. These errors are the personal bias, halo effect and logical error (Gronlund, 1971). The personal bias error may be recognized by assigning the same score to each graded item. Some raters tend to use the high end of the scale, which is known as the generosity error. Others, prone to criticize, commit the severity error. Finally, some have a tendency to deliver neutral responses (Graham, Regehr, & Wright, 2003). To avoid error rating, the rating scale was clearly defined. The lowest and highest points on the scale had additional descriptors to assure the raters understood the meaning of the terms describing the points. Assigning a rating of zero to the objective meant that the objective was not important and should not be taught in the MLS curriculum, while assigning a rating of 4 meant that the objectives was considered most important and absolutely must be taught in the MLS curriculum).

The halo effect is decreased in Delphi by definition because of the essential anonymity feature. The acquaintance of some of the respondents with the principal investigator could not be prevented due to similar professional interests. There is no consensus on whether the acquaintance with the investigator is a limitation in Delphi studies as it may serve as both: deterrent and motivator to stay in the study. It should be noted that the testers, asked to evaluate the survey before distribution to the respondents, did not participate in the study themselves.

The logical error occurs when grading is based on preconceived assumptions. An example of simplistic preconception, provided by Gronlund, is that gifted students have poor social skills (Gronlund, 1971). This error is hard to avoid. One preconception regarding the rated objectives predetermined for expansion in the second round (Appendix F) was that if they were

not excluded following the analysis of the first round results, at least one of the follow-up objectives would end up on the list of essential items to be included in the curriculum. This assumption was incorrect in case of the objective relevant to clinical applications of DNA polymorphism analysis. Although 88 percent of the respondents in the first round evaluated this objective as at least moderately important, none of the specific polymorphisms were eventually assigned one of the two top scores on the scale by a significant number of respondents, which excluded them from the essential category. When asked about the preferred instructional time to assign to the polymorphism category, the respondents selected the lowest possible option (1-3 contact hours); however there was no objectives to include in the curriculum. This could have been avoided by inclusion of an option to select zero hours.

Future Implications

Ultimately, the outcomes of the study will aid in revision of the instructional objectives for clinical molecular methods educational courses in entry-level curricula in both baccalaureate and master's MLS programs at the author's institution with purpose to share with other MLS educators. Most importantly, the list is meant to share with the certifying agency to provide suggestions for inclusion of items in the MLS examination content guidelines which currently are limited. Additionally, upon distribution of the results, the list of skills expected of the MLS graduates may be used to re-evaluate the ASCLS Levels of Practice model and to contribute to the MLS Body of Knowledge (BOK).

Although the Delphi process successfully enabled identification of essentials of molecular diagnostics for an entry-level MLS, future studies conducted to re-evaluate the list of essentials should consider better approaches to retain the respondents and prevent their fatigue

due to the iterative process. Research indicates that with good information technology support, these approaches should be directed towards implementation of real-time Delphi.

One group utilizing the real-time Delphi technique is centered around Theodore Gordon, who has been involved in the Millenium Project (Gordon T. J., 2009), a futurist organization formed by Smithsonian Institution, the United Nations University, United States Environmental Protection Agency, United Nations Development Programme, and UNESCO. The Millenium Project began publishing annual "State of the Future" global forecasting reports in 1997. Since 2006, the reports have presented data collected using real time Delphi computer application developed by Articulate Software company, which was awarded a small grant from the U.S. Defense Advanced Research Projects Agency (DARPA). The 2006 "State of the Future" Report included the results of both conventional and real time Delphis on the evolution of global energy resources and events significant to its utilization (Gordon T. , Energy Forecasts using a "Roundless" approach to running a Delphi study., 2006). In 2010 the software was available to researchers not affiliated with the Millenium Project for a fee of \$5000 without IT support and \$35000 per project with support.

Additionally, several New Jersey Institute of Technology graduate students, under the advisement of Murray Turoff, have developed group decision projects based on a computer mediated, continuous, asynchronous process which is known as Social Decision Support System (SDSS). This voting system could be used in evaluating academic course objectives (Wang, Li, Turoff, & Hiltz, 2003) or in expeditious decision making during emergencies (White, Turoff, & Van der Walle, 2007). The system for emergency response decision making is free of charge and hosted by a Sahana Foundation at <http://delphi.sahanafoundation.org/eden/default/index> (White, electronic communication on July 5, 2012). In the current format, the SDSS does not allow for

ranking of the items. However, it may be anticipated that the product may be tailored towards the client needs. The MLS educators need to reach out for the expertise in technology that is best suited for regular updates of the MLS Body of Knowledge through an effective exchange of expert opinion.

Conclusions

In this modified, online, asynchronous, two-round Delphi study, the author selected four basic molecular biology concepts and 21 molecular diagnostics learning objectives that should be included in entry-level Medical Laboratory Scientist curriculum. The selected concepts and objectives were considered either very or most important by 70% of the experts who participated in the second round of the Delphi. The 70% cut-off was chosen to assure that the selection represented an unquestioned majority of respondents. These concepts and objectives, in view of the limited guidelines provided for MLS molecular curriculum by the accrediting and certifying agencies are recommended as a minimum for the educators developing molecular content for their students. Based on the specific cognitive and psychomotor objectives identified as essential (Table 20), the author's recommendation is that the guidelines specify the laboratory operations unique to molecular diagnostic laboratories such as unidirectional workflow, prevention of cross-contamination and nucleic acid degradation; isolation and quantitation of nucleic acids; the theoretical fundamentals behind the polymerase chain reaction, including selection of proper controls, operation of thermal cyclers and troubleshooting unsuccessful PCR-based assays, comprehension of standard, multiplex and reverse-transcriptase PCR, distinction between end-point verses real time assays; as well as target verses signal amplification and knowledge of principles of molecular assays used in testing designed for *N. gonorrhoe/C. trachomatis*, HIV-1 and HCV. Depending on the available instructional time, the faculty may choose to expand the

content by the objectives that were considered very and most important by at least 50% of the respondents.

The 30 objectives that were deemed very and most important by 25-49% of the respondents could be selected by the faculty for extra credit beyond the available contact hours or for graduate assignments. At the author's institution, the entry-level Master of Health Science in Clinical Laboratory Science (MHS-CLS) students have a 4 credit hour molecular internship which is not offered to entry-level undergraduate students. Whether there is any additional time devoted to molecular diagnostics in other entry-level master's programs is not known. Currently there are eight accredited MLS programs at this level. The emergence of entry-level Master's programs in MLS should be considered when selecting the objectives to include in the curriculum. Although graduates of both baccalaureate degree and master's degree entry-level MLS programs are eligible for the same MLS(ASCP) certification exam, the expected skills, especially for the comprehension of concepts and aptitude for research, in master's program graduates are higher than in the baccalaureate degree graduates. Thus, this may provide an advantage to graduate students seeking employment in molecular diagnostic facilities shortly after graduation.

References

- AGT. (2009). Retrieved 1 27, 2010, from Association of Genetic Technologists: <http://www.agt-info.org/NCA.aspx>
- Aichholzer, G. (2009). The Delphi Method: Eliciting Expert's Knowledge in Technology Foresight. In A. Bogner, & B. & Littig, Interviewing experts (pp. 252-274). Houndmills, England: Palgrave Macmillan.
- Amagai, S., Bonetta, L., Liu, D., Relman, D., Buffington, B., Pietsch, B., & al, e. (non-dated). Bacterial ID virtual lab [online]. Retrieved 11 22, 2010, from Howard Hughes Medical Institute: <http://www.hhmi.org/biointeractive/bacterial-identification-virtual-lab>
- American Psychological Association. (1966). Standards for Educational and Psychological Tests and Manuals. Washington, D.C.
- Anthony, D. M. (1999). Understanding Advanced Statistics: A Guide for Nurses and Health Care Researchers. New York: Churchill Livingstone.
- Armitage, P., Berry, G., & Matthews, J. N. (2002). Statistical Methods in Medical Research. Oxford: Blackwell Science Ltd.
- ASCLS. (2009). Practice Levels and Educational Needs for Clinical Laboratory Personnel Position Paper. Retrieved from American Society for Clinical Laboratory Science: <http://www.ascls.org/position/LevelsofPractice.asp>
- ASCP. (2009). Examination Content Guidelines. Retrieved from American Society for Clinical Pathology [online]:

<http://www.ascp.org/FunctionalNavigation/certification/GetCertified/ExaminationContentGuidelines.aspx>

ASCP. (2014, September). Medical Laboratory Scientist, MLS (ASCP) and International Medical Laboratory Scientist, MLS(ASCPi) Examination Content Guideline & Outline. Retrieved 1 23, 2015, from American Society for Clinical Pathology [online]:

<http://www.ascp.org/PDF/BOC-PDFs/Guidelines/ExaminationContentGuidelineMLS.aspx>

ASCP. (2014, June). Technologist in Molecular Biology, MB(ASCP) and International Technologist in Molecular Biology, MB(ASCPi) Examination content Guideline & Outline. Retrieved 3 29, 2015, from American Society for Clinical Pathology [online]:

<http://www.ascp.org/PDF/BOC-PDFs/Guidelines/Examination-Content-Guideline-MB-New.aspx>

ASCP BOR and NCA Form Single Certification Agency. News Release. (2009). Retrieved 1 27, 2010, from American Society for Clinical Pathology:

<http://www.ascp.org/MainMenu/AboutASCP/Newsroom/NewsReleases/ASCP-BOR-and-NCA-Form-Single-Certification-Agency.aspx>

ASHG. (1988). DNA Banking and DNA Analysis: Points to Consider. 781-783. American Society of Human Genetics. Retrieved from

http://www.ashg.org/pages/statement_ajhg42.shtml

ASMT. (1976, August). Statements of Competence of clinical laboratory practitioners (nonphysician). ASMT News, p. 4.

Bamberg, R. (2004). Assessment of graduate students background of CLS faculty in university based programs. *Clinical Laboratory Science*, 17(4), 209-17.

- Beck, S. J., Doig, K., & Nettles, S. S. (1997). CLT and CLS job responsibilities: definitions and distinctions. *Clinical Laboratory Science*, 10(1), 19-26.
- Beck, S., & Doig, K. (2002). CLS Competencies Expected at Entry Level and Beyond. *Clinical Laboratory Science*, 15(4), 220-228.
- Becker, G., & Bakal, D. A. (1970). Subject Anonymity and motivational distortion in self-report data. *Journal of Clinical Psychology*, 26(2), 207-209.
- Beretta, R. (1996). A critical review of the Delphi technique. *Nurse Researcher*, 3(4), 79-89.
- Blind, K., Cuhls, K., & Grupp, H. (2001). Personal attitudes in the assessment of the future of science and technology: A factor analysis approach. *Technological Forecasting & Social Change*, 68, 131-149.
- Bloom, B. S., Engelhart, M. D., Furst, E. J., Hill, W. H., & Krathwohl, D. R. (1956). Taxonomy of educational objectives: the classification of educational goals; Handbook I: Cognitive Domain. New York: Longmans, Green.
- Bogert, N. (2007, June). Going Molecular. Clinical Laboratory Products. Retrieved 12 29, 2009, from http://www.clpmag.com/issues/articles/2007-06_01.asp
- Boone, H. N., & Boone, D. A. (2012). Analyzing Likert Data. *Journal of Extension*, 50(2).
- Brencheau, J. C., & Wetherbe, J. C. (1987). Key Issues in Information System Management. *Management Information Systems Quarterly*, 11(1), 22-45.
- Burke, S., Martyn, M., Stone, A., Bennett, C., Thomas, H., & Farndon, P. (2009). Developing a curriculum statement based on clinical practice. *British Journal of General Practice*, 59, 99-103.

- Campbell, S. M., Hann, M., Roland, M. O., Quayle, J. A., & Shekelle, P. G. (1999). The Effect of Panel Membership and Feedback on Ratings in a Two-Round Delphi Survey: Results of a Randomized Controlled trial. *Medical Care*, 37(9), 964-968.
- CDC. (2009). Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions. Centers for Disease Control and Prevention. . Retrieved from <http://www.cdc.gov/mmwr/PDF/rr/rr5806.pdf>
- Chaffin, W. W., & Talley, W. K. (1980). Individual stability in Delphi studies. *Technological Forecasting and Social Change*, 16(1), 67-73.
- Chaney, H. S. (1987). Needs Assessment: A Delphi Approach. *Journal of Nursing Staff Development*, 3(2), 48-53.
- Charlton, J. R., Patrick, D. L., Matthews, G., & West, P. A. (1981). Spending priorities in Kent: a Delphi study. *Journal of Epidemiology and Community Health*, 35, 288-292.
- Choudaha, R. (2008). Competency-based curriculum for a master's program in Service Science, Management and Engineering (SSME): An online Delphi study. Retrieved June 2, 2010, from UMI Dissertations & Thesis Gradworks: <http://gradworks.umi.com/33/37/3337048.html>
- CLIA. (2004). The Clinical Laboratory Improvement Amendments (CLIA) regulations; laboratory requirements, 42 C.F.R. Part 493. Retrieved from <http://wwwn.cdc.gov/clia/regs/toc.aspx>.
- Cronbach, L. J. (1951). Coefficient alpha and the internal structure of tests. *Psychometrika*, 16(3), 297-334.
- Cuhls, K. (2003). The Delphi Method. Foresight Methodologies, Seminar Papers. Prague: United Nations Industrial Development Organization (UNIDO).

- Cuhls, K., Beyer-Kutzner, A., Ganz, W., & Warnke, P. (2009). The methodology combination of a national foresight process in Germany. *Technological Forecasting & Social Change*, 76, 1187–1197.
- Cuhls, K., Blind, K., & Grupp, H. (1998). Delphi '98, Umfrage, Studie zur globalen Entwicklung von Wissenschaft und Technik. Karlsruhe: German Federal Ministry of Education, Research, Science, and Technology.
- Dalkey, N., & Helmer, G. (1963). An Experimental Application of the Delphi Method to the use of Experts. *Management Science*, 9.
- Davis, B. G. (1978). Development of Competency-Based, Career-Entry Examination for Clinical Laboratory Personnel. *American Journal of Medical Technology*, 44(5), 402-405.
- Delbecq, A. L., Van de Ven, A. H., & Gustafson, D. H. (1975). Group Techniques for Program Planning: A Guide to Nominal Group and Delphi Process. Glenview, IL: Scott, Forsman.
- Delost, M., & Nadder, T. (2011). The utility of essential functions in clinical laboratory science programs. *Clinical Laboratory Science*, 24(4 Suppl), 21-30.
- Derian, J.-C., & Morize, F. (1973, October). Delphi in the Assessment of Research and Development Projects. *Futures*, 469-483.
- DOE (2010, 10 29). Program Integrity Issues. *Federal Register*, 75(209) Department of Education. Retrieved from Federal Register March 15, 2015.
- Doig, K., Beck, S. J., & Kolenc, K. (2001). CLT and CLS job responsibilities: current distinctions and updates. *Clinical Laboratory Science*, 14(3), 173-82.
- Duffield, C. (1993). The Delphi Technique: a comparison of results obtained using two expert panels. *International Journal of Nursing Studies*, 30(3), 227-237.

- Edgren, G. (2006). Developing a competency-based core curriculum in biomedical laboratory science: a Delphi study. *Medical Teacher*, 28(5), 409-417.
- Elder, O. C., & Andrew, M. E. (1992). Important curriculum content for baccalaureate allied health programs: a survey of deans. *Journal of Allied Health*, 21(2), 105-115.
- Elder, O. C., & Nick, T. G. (1997). Moving Toward a Core Curriculum in Schools of the Allied Health Professions: Knowledge and Skills Considered Important by Department Chairs of Four Disciplines. *Journal of Allied Health*, 26(2), 51-56.
- Erfmeyer, R. C., & Lane, I. M. (1984). Quality and Acceptance of an Evaluative Task: The Effects of Four Group Decision-Making Formats. *Group & Organization Studies*, 9(4), 509-529.
- Farkas, D. H. (1993). *Molecular Biology and Pathology, a Guidebook for Quality Control*. Academic Press.
- Francis, a. M. (1977). An Experimental Analysis of a Delphi Technique: The Effect of Majority and High Confidence-. Penn State University Libraries. Retrieved from <http://cat.libraries.psu.edu/uhtbin/cgiisirsi/?ps=SaqtkxVBrl/UP-PAT/278700021/123#>
- Fried, H., & Leao, A. T. (2007). Using Delphi Technique in a Consensual Curriculum for Periodontics. *Journal of Dental Education*, 71(11), 1441-1446.
- Gallarda, J. L., & Dragon, E. (2000). Blood Screening by Nucleic Acid Amplification Technology: Current Issues, Future Challenges. *Molecular Diagnostics*, 5(1), 11-22.
- Gnatzy, T., Warth, J., von der Gracht, H., & Darkow, I.-L. (2011). Validating an innovative real-time Delphi approach - A methodological comparison between real-time and conventional Delphi studies. *Technological Forecasting and Social Change*, 78(9), 1681-1694.

- Goodman, C. M. (1987). The Delphi technique: a critique. *Journal of Advanced Nursing*, 12, 729-734.
- Goodman, L. A. (1961). Snowball Sampling. *Annals of Mathematical Statistics*, 32(1), 148-170.
- Gordon, T. (2006). Energy Forecasts using a "Roundless" approach to running a Delphi study. Millenium Project. Emeral Group Publishing Limited.
- Gordon, T. J. (2009). The Real-Time Delphi Method. Retrieved from The Millenium Project: <http://www.millennium-project.org/millennium/tgordon.html>
- Gordon, T. J., & Helmer, O. (1964). Report on long-range forecasting study. Santa Monica, CA: Rand Corporation.
- Gordon, T., & Pease, A. (2006). An Efficient, "Round-less", Almost Real Time Delphi Method. *Technological Forecasting and Social Change*, 73, 321-333.
- Goss, D. V., Warren, D. K., & Hallick, R. B. (1996). DNA Forensics Problem Set 1. The Biology Project [Online]. Retrieved from University of Arizona: http://www.biology.arizona.edu/human_bio/problem_sets/DNA_forensics_1/DNA_forensics.html
- Graham, B., Regehr, G., & Wright, J. G. (2003). Delphi as a method to establish consensus fro diagnostic criteria. *Journal of Clinical Epidemiology*, 56, 1150-1156.
- Greator, J., & Dexter, T. (2000). An accessible analytical approach for investigating what happens between the rounds of a Delphi study. *Journal Of Advanced Nursing*, 32(4), 1016-1024.
- Gronlund, N. E. (1971). Measurement and Evaluation in Teaching. New York, NY: Macmillan Publishing Co., Inc.

- Gupta, U. G., & Clarke, R. E. (1996). Theory and Applications of Delphi technique: a bibliography (1975-1994). *Technological Forecasting and Social Change*, 53, 185-211.
- Harris, P. A., Taylor, R., Robert, T., Payne, J., Gonzales, N., & Conde, J. G. (2009). Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics*, 42, 377-381.
- Hartley, M. E. (1995). The development of module evaluation: a Delphi approach. *Nurse Education Today*, 15, 267-273.
- Haspel, R. (2010, 6 1). Beth Israel Deaconess Medical Center. Retrieved from <http://www.bidmc.org/MedicalEducation/CarlJ,d,ShapiroInstituteforEducationandResearch/RabkinFellowship/GraduateFellows/20072008/RichardHaspel.aspx>
- Haspel, R. L., Arnaut, R., Briere, L., Kantarei, S., Marchand, K., Tonellato, P., & al., e. (2010). Training Pathology Residents in Genomic and Personalized Medicine. *American Journal of Clinical Pathology*, 832-834.
- Hasson, F., Keeney, S., & McKenna, S. (2000). Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing*, 32(4), 1008-1015.
- Heckathorn, D. D. (2002). Respondent-Driven Sampling II: Deriving Valid Estimates from Chain-Referral Samples of Hidden Populations. *Social Problems*, 49, 11-34.
- Helmer, O. (1977). Problems in Futures Research: Delphi and casual cross-impact analysis. *Futures*, 9, 17-31.
- Holey, E. A., Feeley, J. L., Dixon, J., & Whittaker, V. J. (2007). An exploration of the use of simple statistics to measure consensus and stability in Delphi studies. *BMC Medical Research Methodology*, 7(52), 1-10. doi:10.1186/1471-2288-7-52

- Holloway, I., & Wheeler, S. (2002). *Qualitative Research in Nursing*. Oxford: Blackwell Science Ltd.
- Jairath, N., & Weinstein, J. (1994). The Delphi methodology: a useful administrative approach. *Canadian Journal of Nursing Administration*, 7, 29-42.
- Jillson, I. A. (1975). The National Drug Abuse Policy Delphi: Progress Report and Findings to Date. In H. A. Linstone, & M. Turoff, *The Delphi Method. Techniques and Applications* (pp. 124-159). Reading, MA: Addison-Wesley Publishing Company.
- Kantz, J. W. (2004). *Electronic Theses and Dissertations*. Retrieved 6 24, 2012, from Texas A & M University: <http://repository.tamu.edu/handle/1969.1/1412>
- Kaplan, A., Scogstad, A. L., & Girshick, M. A. (1950). The Prediction of Social and Technological Events. *The Public Opinion Quarterly*, pp. 93-110.
- Kelly, J., & Kerrigan, D. (2005, 1 28). *Understanding Cancer Series: Molecular Diagnostics*. Retrieved from National Institute of Health: <http://www.cancer.gov/cancertopics/understandingcancer/moleculardiagnosics/allpages>
- Kendall, M. G., & Smith, B. (1939). The Problem of m Rankings. *The Annals of Mathematical Statistics*, 10(3), 275-287.
- Kirby, B. (2008). The future of clinical laboratory science: A Delphi study . Retrieved 6 2, 2010, from ProQuest Dissertations and Theses: <http://gradworks.umi.com/33/00/3300902.html>
- Kraj, B. (2006). *Molecular Diagnostics Issues Discussed at CLEC*. Macon.
- Kraj, B. (2006). Status of Molecular Diagnostics Incorporation into Clinical Laboratory Science Curricula: Results of a National Survey. *Clinical Laboratory Science*. 19, p. 94.
- Kraj, B. (2013 unpublished). *Clinical Molecular Methods Laboratory Manual*.

- Kraj, B., & Nadder, T. (2007, 10 8). Blood Donor Screening Process and Infectious Disease Testing Using Molecular Methods. *ADVANCE for Medical Laboratory Professionals*, pp. 17-20.
- Kraj, B., Pretlow, L., & Russell, B. L. (2008). Student performance outcomes on molecular diagnostics laboratory modules incorporated into CLS program senior clinical chemistry course. *Clinical Laboratory Science*, 21(2), p. 92.
- Kraj, B., Pretlow, L., & Russell, B. L. (2011). Student Molecular Laboratory Performance Outcomes in a Baccalaureate CLS Program. *Clinical Laboratory Science*, 24(4), S31-35.
- Landeta, J. (2006). Current Validity of the Delphi method in social sciences. *Technological Forecasting and Social Change*, 73, 467-82.
- Laudicina, R., Fenn, J. P., McCoy, C., McLane, M. A., Mundt, L., Polancic, J., & K, S. (2011). Research in clinical laboratory science: professionals' involvement. *Clinical Laboratory Science*, 24(4), 235-42.
- Lieff, S. J. (2009). Evolving Curriculum Design: A Novel Framework for Continuous, Timely, and Relevant Curriculum Adaptation in Faculty Development. *Academic Medicine*, 84(1), 127-134.
- Likert, R. (1932). A Technique for the Measurement of Attitudes. *Archives of Psychology*, 140, 1-55.
- Limson, M. (2012, 9 24). Survey for Molecular Diagnostics Lab Managers/Directors .
- Lincoln, Y., & Guba, E. (1985). *Naturalistic Inquiry*. London: Sage.
- Linstone, H., & Turoff, M. (1975). *The Delphi Method. Techniques and Applications*. Reading, MA: Addison-Wesley.

- Ludlow, J. (1975). Delphi Inquiries and Knowledge Utilization. In H. A. Linstone, & M. Turoff, The Delphi Method (pp. 97-118).
- Martino, J. P. (1972, August). Technological Forecasting is Well and Alive in Industry. The Futurist.
- McKenna, H. (1994). The Delphi Technique: a worthwhile approach for nursing? *Journal of Advanced Nursing*, 19, 1221-1225.
- McKenzie, S. (1994). Identification of Core Educational Goals and Related Outcome Measures for Development of Assessment Programs in Selected Schools of Allied Health. *Journal of Allied Health*, 23(3), 245-256.
- Miller, L. E., & Abbate, S. (2002). Genetics and molecular diagnostics in the clinical laboratory science curriculum. *Clinical Laboratory Science*, 15(3), 160-166.
- Mullen, P. (1983). Delphi-Type Studies in Health Services: The Impact of the Scoring System. The University of Birmingham. Birmingham, UK: Health Services Management Centre, Park House.
- Mullen, P. (2003). Delphi: myths and reality. *Journal of Health Organization and Management*, 17(1), 37-52.
- Mullen, P. (2009). How management behaviors associated with successful health and safety performance relate to those associated with success in other domains. University of Birmingham, Health Services Management Centre. Birmingham, UK: Health and Safety Executive.
- Muller, R., & Buttner, P. (1994). A Critical Discussion on Intraclass Coefficients. *Statistics in Medicine*, 13, 2465-2476.

- Mundt, L., & Shanahan, K. (2009). ASCLS members perceptions regarding research. *Clinical Laboratory Science*, 22(3), 170-5.
- Murg, S., & Terry, M. (2007). Business Strategies for Molecular Diagnostics in the Lab Including State of the Market Report 2007. New York: Washington G-2 Reports.
- NAACLS. (2001). Standards of Accredited Educational Programs for the Clinical Laboratory Scientist/Medical Technologist. National Accrediting Agency for Clinical Laboratory Sciences. Retrieved from http://www.naacls.org/PDFviewer.asp?mainUrl=/docs/Standards_cls-mt.pdf
- NAACLS. (2012). Unique Standards Diagnostic Molecular Scientist (DMS). Retrieved February 3, 2014, from <http://www.naacls.org/docs/standards2012.pdf>
- NAACLS. (2012). Unique Standards Medical Laboratory Scientist (MLS). Retrieved February 3, 2014, from <http://www.naacls.org/docs/standards2012.pdf>
- NAACLS. (2014). Accredited and Approved Programs. Retrieved from National Accrediting Agency for Clinical Laboratory Sciences: <http://www.naacls.org/search/programs.asp>
- Nadder, T. S., & Langley, M. R. (2001). The New Millenium Laboratory: Molecular Diagnostics Goes Clinical. *Clinical Laboratory Science*, 14(4), 252-259.
- NCA. (2007). Clinical Laboratory Scientist (CLS) Content Outline. Retrieved from National Credentialing Agency for Laboratory Personnel, Oleta, KS.
- Occupational Outlook Handbook. (2012). Retrieved January 12, 2015, from Bureau of Labor and Statistics: <http://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm>
- Okoli, C., & Pawlowski, S. D. (2004). The Delphi Method as Research Tool: An Example, Design Considerations and Applications. *Information and Management*, 42(1), 15-29.

- Perkins, G. D., Barrett, H., Bullock, I., Gabbott, D. A., Nolan, J. P., Mitchell, S. S., Bion, J. F. (2005). The Acute Care Undergraduate TEaching (ACUTE) Initiative: consensus development of core competencies in acute care for undergraduates in the United Kingdom. *Intensive Care Medicine*, 31, 1627-1633.
- Polancic, J. (2003). DNA 101: A Simple Guide to DNA & Its Use in Laboratory Testing.
- Rauch, W. (1979). The Decision Delphi. *Technological Forecasting and Social Change*, 15(3), 159-169.
- Ray, L., & Rydell, R. (2013, July). July 2013 draft MLS Molecular Diagnostics. Draft.
- Reid, N. (1988). The Delphi Technique: it's contribution to the evaluation of Professional practice. In R. Ellis, Professional Competence and Quality Assurance in the Caring Professions. London: Chapman & Hall.
- Rizopoulos, D. (2006). ltm: An R Package for Latent Variable Modeling and Item Response Analysis. *Journal of Statistical Software*, 17(5), 1-25.
- Roberts, P., & Priest, H. (2006). Reliability and validity in research. *Nursing Standard*, 20(44), 41-45.
- Rosner, B. (2006). Fundamentals of Biostatistics. Belmont, CA: Duxbury, Press.
- Russell, B. L., Kraj, B., Pretlow, L., Ranne, A., & Leibach, E. K. (2011). Evidence Based Practice and Advanced Competencies in a MHS-CLS Program. *Clinical Laboratory Science*, 24(4), S47-53.
- Russell, B., Owen, M. A., Leibach, E. K., Meaders, E., & Kraj, B. (2011). Capturing Professionalism in Pre-Service Education: Professionalism Tool Development and Implementation. *Clinical Laboratory Science*, 24(4 Suppl), 11-20.

- Sackman, H. (1974). Delphi Assessment: Expert Opinion, Forecasting and Group Process. RAND, Santa Monica. Retrieved 12 19, 2011, from <http://www.rand.org/pubs/reports/2006/R1283.pdf>
- Sackman, H. (1975). Summary Evaluation of Delphi. *Policy Analysis*, 1(4), 693-718.
- SACL (2013, October 14). Statistics and Analytics Consulting Lab. Retrieved from Virginia Commonwealth University: <http://www.stat.vcu.edu/consulting.htm>
- Saiki, R. G. (1988). Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase. *Science*, 239, 487-491.
- Scheffer, B. K., & Rubenfeld, G. M. (2000). A consensus statement on critical thinking in nursing. *Journal of Nursing Education*, 39(8), 352-360.
- Schmidt, R. (1997). Managing Delphi Surveys Using Nonparametric Statistical Techniques. *Decision Sciences*, 28(3), 763-774.
- Simonian, Y. (2015). NAACLS Update. Cincinnati: CLEC. Retrieved 2015.
- Sizer, P. S., Felstehausen, V., Sawyer, S., Dornier, L., Matthews, P., & Cook, C. (2007). Eight Critical Skill Sets Required for Manual Therapy Competency. *Journal of Allied Health*, 36(1), 30-40.
- Smith, B. R., Agüero-Rosenfeld, M., Anastasi, J., Baron, B. B., Bock, J. L., & al., e. (2010). Educating medical students in laboratory medicine: a proposed curriculum. *American Journal for Clinical Pathology*, 133, 533-542.
- Staggers, N., Gassert, C. A., & Curran, C. (2001). Informatics Competencies for Nurses at Four Levels of Practice. *Journal of Nursing Education*, 40(7), 303-316.
- Staggers, N., Gassert, C. A., & Curran, C. (2002). A Delphi Study to Determine Informatics Competencies for Nurses at Four Levels of Practice. *Nursing Research*, 51(6), 383-390.

- Steinert, M. (2009). A dissensus based online Delphi approach: An explorative research tool. *Technological Forecasting and Social Change*, 76, 291-300.
- Stevens, C. D. (2000). Updating the immunology curriculum in clinical laboratory science. *Clinical Laboratory Science*, 13(2), 80-4.
- Suter, Michael (2011). Electronic Communication, June 17. PeaceHealth Laboratories. Springfield, OR.
- Tabachnik, B. G., & Fidell, L. S. (2007). Using Multivariate Statistics. Boston, MA: Pearson Educational, Inc. Allyn and Bacon.
- Tanabe, P. A., & Holladay, E. B. (2009). Board of Registry Study Guide for Clinical Laboratory Certification Examinations (5 ed.). Hong Kong: American Society of Clinical Pathology Board of Registry.
- Taylor, S., Bennett, K. M., Deignan, J. L., Hendrix, E. C., Orton, S. M., Verma, S., & Schutzbank, T. E. (2014). Molecular Pathology Curriculum for Medical Laboratory Scientists. A Report of the Association for Molecular Pathology Training and Education Committee. *The Journal of Molecular Diagnostics*, 16(3), 288-296.
- Tevacol, M., & Dennick, R. (2011). Making sense of Cronbach's alpha. *International Journal of Medical Education*, 2, 53-55.
- Thurstone, L. L. (1927). A Law of Comparative Judgment. *Psychological Review*, 34, 273-287.
- Tomasik, T. (2010). Reliability and validity of the Delphi method is guideline development for family physicians. *Quality in Primary Care*, 18, 317-26.
- Toohey, S. (1999). Designing Courses for Higher Education. Buckingham, England and Philadelphia, PA: The Society for Research into Higher Education and Open University Press.

- Tsongalis, G. J., & Coleman, W. B. (1997). *Molecular Diagnostics For The Clinical Laboratorian*. Totowa, NJ: Humana Press.
- Tsongalis, G. J., & Coleman, W. B. (2002). *Molecular Diagnostics. A Training and Study Guide*. Washington, DC: AACC Press.
- Turoff, M. (1970). The Design of a Policy Delphi. *Technological Forecasting and Social Change*, 2, 149-171.
- Turoff, M. (1975). The Policy Delphi. In H. A. Linstone, & M. Turoff, *The Delphi Method* (pp. 86-87).
- Turoff, M., & Hiltz, S. R. (2010, June 1). Computer Based Delphi Process. Retrieved from Murray Turoff's Homepage: <http://web.njit.edu/~turoff/Papers/delphi3.html>
- Turoff, M., Hiltz, S. R., Cho, H.-K., Li, Z., & Wang, Y. (2002). Social Decision Support Systems (SDSS). *Proceedings of the 35th Hawaii International Conference on System Sciences*. IEEE Computer Society.
- USDHHS. (2005). *The Clinical Laboratory Workforce: The Changing Picture of Supply, Demand, Education and Practice*. U. S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions.
- Valani, R. A., Yanchar, N., Grant, V., & Hancock, B. J. (2010). The development of a national pediatric trauma curriculum. *Medical Teacher*, 32, e115-119.
- VCU (2013, November 26). VCU Technology Services. Retrieved from Virginia Commonwealth University: <http://ts.vcu.edu/software-center/general-purpose/redcap/index.php>
- Vernon, W. (2009). The Delphi Technique. *International Journal of Therapy and Rehabilitation*, 16(2), 69-76.

- von der Gracht, H., Darkow, I.-L., Walter, S., Jahns, C., & Thomsen, E. (2008). Future of Logistics 2025 - Global Scenarios. European Business School. Wiesbaden: BrainNet Supply Management Group AG.
- Walker, A. M., & Selfe, J. (1996). The Delphi method: A useful tool for the allied health researcher. *British Journal of Therapy and Rehabilitation*, 3(12), 677-680.
- Wang, Y., Li, Z., Turoff, M., & Hiltz, S. R. (2003). Using Social Decision Support System Toolkit to Evaluate Achieved Course Objectives. AMCIS. Retrieved 7 5, 2012, from New Jersey Institute Dissertations: <http://www.library.njit.edu/etd/index.cfm>
- Ward-Cook, K., Daniels, M. G., & Guerogueiva, J. (2002). ASCP Board of Registry's 2001 Annual Survey of Medical Laboratory Science programs. *Laboratory Medicine*, 11(33), 831-836.
- Watson, J. D., & Crick, F. H. (1953). Molecular structure of nucleic acids. *Nature*, 171, 737.
- White, C., Turoff, M., & Van der Walle, B. (2007). A Dynamic Delphi Process Utilizing a Modified Thurstone Scaling Method: Collaborative Judgement in Emergency Response. Proceedings of ISCRAM 2007, 4th International Conference (pp. 7-15). Delft: Brussels University Press.
- Whitman, N. J. (1990). The Committee Meeting Alternative. *Journal of Nursing Administration*, 20(7/8), 30-36.
- Who's Doing What in Molecular Diagnostics? (February 2009). Kalorama. Retrieved from <http://www.reportlinker.com/p0116164/Who-s-Doing-What-in-Molecular-Diagnostics-Kalorama-Emmes-Survey-of-US-Laboratories.html?request=news>
- WPP (2013, November 14). Office of Research. Retrieved from Virginia Commonwealth University: http://www.research.vcu.edu/human_research/irb_wpp/VIII-1.htm

Xiao, J. D., Lee, D., & Vemuri, S. R. (1997). A Delphi evaluation of factors influencing length of stay in Australian hospitals. *International Journal of Planning and Management*, 12(3), 207-218.

Zinn, J., & Zalokowski, A. (1999). The Use of the Delphi Panel for Consensus Development on Indicators of Laboratory Performance. *Clinical Laboratory Management Review*, 136, 386-408.

Zipfinger, S. (2007). Computer-Aided Delphi. An Experimental Study of Comparing Round-Based with Real-Time Implementation Method. Linz: Trauner.

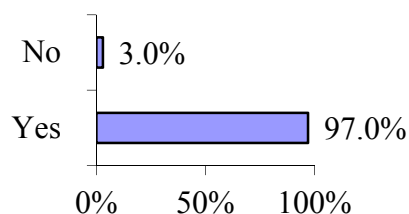
Appendix A

Results of an Informal 2005 Survey of NAACLS Accredited MLS Programs (Kraj, 2006).

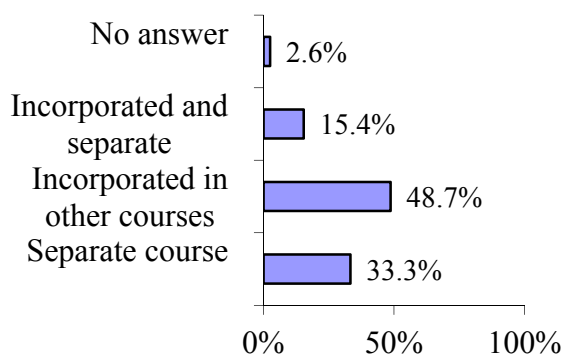
Appendix A

Results of an Informal 2005 Survey of NAACLS Accredited MLS Programs (Kraj, 2006).

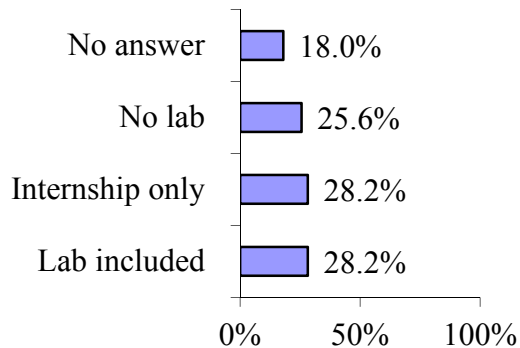
Does your program include teaching molecular diagnostics?



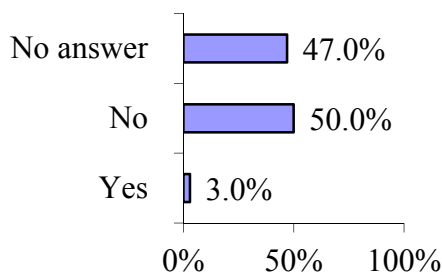
Is molecular diagnostics a separate subject or do you incorporate it in other disciplines?



Does the course include laboratory exercises?

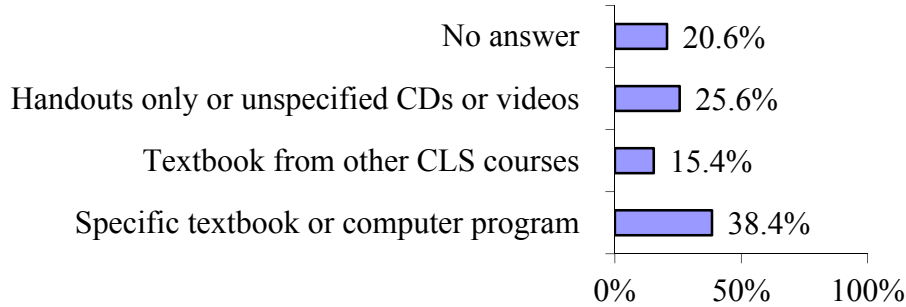


Are you planning to offer Diagnostic Molecular Scientist Track?

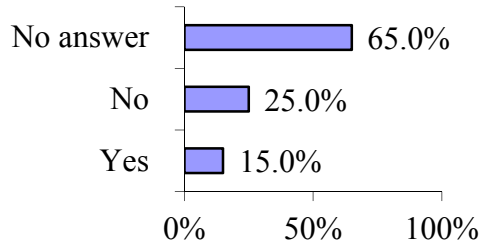


Appendix A - continued

What textbook or media are you using?



Have you heard about "Human Genetics Curricula for the Health Professionals" Project funded by the U.S. Dept. of Health and Human Resources?



Appendix B

Molecular Content in ASCLS Model for Clinical Laboratory Levels of Practice (ASCLS, Levels Of Practice Position Paper, 2009).

Appendix B

Molecular Content in ASCLS Model for Clinical Laboratory Levels of Practice (ASCLS, Levels Of Practice Position Paper, 2009).

Level	Practice Skills:	Education	Relevant Experience	Certification
IV	Micro ID including aerobes, anaerobes, or mixed cultures Blood Bank antibody identification Manual differential with the potential for higher level review Body Fluid differential with higher level review of abnormal results Simple molecular testing that follows established protocols including DNA Probes	Associate (plus training)	Yes	CLT / MLT
V	Advanced Techniques in Blood Bank Body Fluid Differential without Higher Level Review Immunology Advanced Techniques Microbiology Advanced molecular testing that follows established protocols including DNA Probes Advanced Techniques in Hematology / Bone Marrows Advanced Techniques in Coagulation Advanced Techniques in Chemistry (Electrophoresis, etc.) Advanced Techniques in Immunochemistry and Drug Testing (HPLC, etc.)	Baccalaureate	Entry Level	CLS / MT

Appendix B – continued

Level	Practice Skills:	Education	Relevant Experience	Certification
VI	<p>Advanced Techniques in Body Fluids</p> <ul style="list-style-type: none"> • <i>Micro Array</i> • <i>Flow Cytometry</i> • <i>PCR</i> <hr/> <p>Infection Control/Epidemiology</p> <hr/> <p>Method Evaluation/Test Development</p> <hr/> <p>Patient Education</p> <p>POC Oversight</p> <hr/> <p>Technical Supervision</p> <ul style="list-style-type: none"> • <i>Discipline Specific</i> • <i>Employee Supervision</i> • <i>Daily Operations, QC Review, etc.</i> <hr/> <p>Research Protocols</p> <hr/> <p>Safety Officer</p> <hr/> <p>Oversight of Student/Staff Education and Training</p> <hr/> <p>Technical Consultation</p> <hr/> <p>Informatics</p> <hr/> <p>Cellular Therapy - Stem Cell Transplantation</p> <hr/> <p>Educators:</p> <ul style="list-style-type: none"> • <i>Develop and teach didactic and laboratory sessions to reflect current practice</i> • <i>Assess student performance</i> • <i>Available to students for counseling</i> • <i>Engage in service and scholarly activities.</i> <hr/> <p><i>Cytogenetics</i></p> <hr/> <p>Advanced Molecular / PCR</p> <ul style="list-style-type: none"> • <i>Modify existing tests</i> • <i>Troubleshooting</i> • <i>Method evaluation</i> • <i>Research and development</i> <hr/> <p>Advanced Flow Cytometry (anything beyond a routine hematology analyzer)</p> <hr/> <p>Histocompatibility</p> <hr/> <p>Specialist in (BB, Chem, Heme, Coag, etc.)</p>	Bacca-laureate + additional education	Yes	CLS / MT
	<hr/> <p><i>Cytogenetics</i></p> <hr/> <p>Advanced Molecular / PCR</p> <ul style="list-style-type: none"> • <i>Modify existing tests</i> • <i>Troubleshooting</i> • <i>Method evaluation</i> • <i>Research and development</i> <hr/> <p>Advanced Flow Cytometry (anything beyond a routine hematology analyzer)</p> <hr/> <p>Histocompatibility</p> <hr/> <p>Specialist in (BB, Chem, Heme, Coag, etc.)</p>	Bacca-laureate + additional education	Yes	Specialty Certification

Note: Table modified from “Practice Levels and Educational Needs for Clinical Laboratory Personnel Position Paper” (ASCLS, Levels Of Practice Position Paper, 2009).

Appendix C

Examples of Rating Scales in Selected Delphi Studies

Relevant to Healthcare or Healthcare Education.

Appendix C

Examples of Rating Scales in Selected Delphi Studies

Relevant to Healthcare or Healthcare Education.

Author, publication year and title	Question/s	Rating scale
(Davis, 1978) Development of Competency-Based, Career-Entry Examination for Clinical Laboratory Personnel.	Consider/refine each item/competency from the perspective of:	<ul style="list-style-type: none"> • Item accuracy and format • Appropriateness for career-entry professionals • Assignment of taxonomic level • Corroboration of the reference to one or more of the competence statements
(McKenzie, 1994) Identification of Core Educational Goals and Related Outcome Measures for Development of Assessment Programs in Selected Schools of Allied Health.	Rate the importance of educational goals accompanied by assorted outcome measures	<ul style="list-style-type: none"> • 1 – not important, not valid, not feasible • 2 – • 3 – • 4 – very important, valid and very feasible
(Elder & Nick, 1997) Moving Toward a Core Curriculum in Schools of the Allied Health Professions: Knowledge and Skills Considered Important by Department Chairs of Four Disciplines.	Rate the items above the professional accreditation, important to graduates of the baccalaureate allied health programs	<ul style="list-style-type: none"> • 4 - Most important • 3 – • 2 – • 1 – • 0 – not important
(Zinn & Zalokowski, 1999) The Use of the Delphi Panel for Consensus Development on Indicators of Laboratory Performance.	Prioritize by clarifying and ranking laboratory performance areas on the basis of importance	1-6 scale 1 – most important

Appendix C – continued

Author, publication year and title	Question/s	Rating scale
(Scheffer & Rubenfeld, 2000) A consensus statement on critical thinking in nursing.	Provide feedback on the Definitions of Habits of the Mind and Skills of Critical Thinking in Nursing	<ul style="list-style-type: none"> • Agree • Disagree
(Staggers, Gassert, & Curran, 2002) Delphi Study to Determine Informatics Competencies for Nurses at Four Levels of Practice.	Assign 304 competencies to the informatics levels of nursing practice	4 levels of practice: <ul style="list-style-type: none"> • Beginning • Experienced • Specialists • Innovators
(Kantz, 2004) Use of a Web-based Delphi for identifying critical components of a professional science master's program in biotechnology	1. Assign the competencies accordingly	<ul style="list-style-type: none"> • Core curriculum • Track curriculum • Blank (competency not appropriate)
	2. Rate importance for inclusion in internship	<ul style="list-style-type: none"> • Not important • Important but not absolutely necessary • Important and necessary
	3. Decide if the listed positions are appropriate for entry level graduate	<ul style="list-style-type: none"> • Agree • Disagree
	4. Indicate the level of agreement with the roles identified for industry advisory board for professional science master's program	<ul style="list-style-type: none"> • 1 - Agree strongly • 2 - Agree • 3 - No opinion • 4 - Disagree • 5 - Disagree strongly
	5. Indicate the level of agreement with five goals identified as appropriate for the program	Same as above
	6. Indicate the level of agreement with skills identified for the core curriculum and tracks	Same as above

Appendix C – continued

Author, publication year and title	Question/s	Rating scale
(Perkins, et al., 2005) The Acute Care Undergraduate TEaching (ACUTE) Initiative: consensus development of core competencies in acute care for undergraduates in the United Kingdom.	Rate 88 themes/ competencies grouped into 12 domains	<ul style="list-style-type: none"> • 5 - very important • 4 - important • 3 - moderately important • 2 - of little importance • 1 - of no importance Items w/ median 4 or 5 considered core competencies. Items with median of 3 optional.
(Edgren, 2006) Developing a competency-based core curriculum in biomedical laboratory science: a Delphi study.	Rate the importance of competencies grouped into skills, knowledge, attitudes and generic skills	4 point Likert scale. Items with mean of 3.25 retained for further consideration in subsequent round with yes/no options (include/not include in the curriculum)
(Fried & Leao, 2007) Using Delphi Technique in a Consensual Curriculum for Periodontics.	Rate 89 topics identified as foundational to clinical experience for possible inclusion in periodontic curriculum	<ul style="list-style-type: none"> • Indispensable • Important • Relatively important • Of little importance • should not be included
(Sizer, et al., 2007) Eight Critical Skill Sets Required for Manual Therapy Competency.	Evaluate the importance of stand-alone skills defined by descriptor statements	<ul style="list-style-type: none"> • Essential • moderately important • moderately unimportant • not at all important
(Kirby, 2008) The future of clinical laboratory science: A Delphi study.	1. Indicate predicted time period for the event to occur	<ul style="list-style-type: none"> • Im – 1-3 yrs • M – 4-10 yrs • L – 11-20 yrs • Beyond 20 yrs • Never
	2. Indicate potential impact	<ul style="list-style-type: none"> • 1 – very low impact/very undesirable
	3. Rate desirability	<ul style="list-style-type: none"> • 7 – v. high impact/v. desirable
(Burke, et al., 2009) Developing a curriculum statement based on clinical practice.	Comment and rate the topics in genetics that should be included in general practice training	<ul style="list-style-type: none"> • Essential • Needs to be included • Useful for inclusion • Need not be included
(Russell, et al., 2011) Capturing Professionalism in Pre-Service Education: Professionalism Tool Development and Implementation.	Rank attributes of professionalism	<ul style="list-style-type: none"> • 1 - essential • 3 - important • 5 - not important Items with scores less or equal to 2.5 retained on the list

Appendix D

Email sent to survey testers with the link to Delphi I practice and the actual survey downloaded from REDCap.

Appendix D

Email sent to survey testers with the link to Delphi I practice and the actual survey downloaded from REDCap

Barbara Kraj <krajbj@mymail.vcu.edu>



help with research project - practice survey link

Barbara Kraj <krajbj@mymail.vcu.edu>
To: [...]
Cc: bkraj@gru.edu

Fri, Aug 8, 2014 at 1:20 PM

Dear,

Thank you for helping me with my doctoral research project on the importance of molecular diagnostics learning objectives in MLS curriculum. I am asking that you click the link below, enter your answers (for survey testing purposes) and then provide me with your feedback on the clarity of the questions and project explanation, time it took you to go through the survey, etc.

You may open the survey in your web browser by clicking the link below:
[Importance of MD Objectives - Delphi Round 1 practice](#)

If the link above does not work, try copying the link below into your web browser:
<https://redcap.vcu.edu/rc/surveys/?s=etwqQZ459Y>

I would appreciate if you take the survey by Wednesday, August 13.

Regards,

Barbara Kraj, MS, MLS(ASCP)^{CM}MB^{CM}
Virginia Commonwealth University
Ph.D. Program in Health Related Sciences

Importance of Molecular Diagnostics Learning Objectives - Delphi Round 1 practice

You are asked to complete this survey as a practicing medical laboratory professional with expertise relevant to medical molecular diagnostics.

Though molecular diagnostic testing has been mainstreamed in the clinical laboratory for over two decades, faculty of Medical/Clinical Laboratory Science programs have received little guidance pertaining to cognitive and psychomotor skills in this area necessary for entry to the profession. MLS program educators are faced with additional challenges including rapidly changing technology and increased costs in the area of molecular diagnostic testing. Few formal studies exist that have defined expected competencies in molecular diagnostics. The purpose of this study is to utilize Delphi technique to achieve a consensus among the practitioners in molecular diagnostic laboratories concerning their expectations for entry-level knowledge and competencies.

The Delphi technique gathers information in sequential rounds of surveys sent to the same experts to reach a consensus on the investigated subject, in this case the importance of inclusion of specific cognitive or psychomotor learning objectives in the medical laboratory science curriculum. There will be a maximum of three surveys which you will be asked to complete. You should be able to complete each survey in a short period of time, approximately 10-20 minutes. In subsequent surveys, each respondent will have an opportunity to either confirm or change his/her opinion on a particular learning objective after reviewing the overall results of the preceding survey. The items assigned low importance by the majority of the respondents will be removed from the subsequent surveys, and some items assigned high importance will be expanded to include more specific information.

You will be asked to provide your preferred e-mail address so that the next survey may be sent by the investigators to you directly; your e-mail address will only be used for the purpose of conducting this project and will not be shared with anyone. Once all of the data are collected, your e-mail address will be permanently deleted from the study files. The data gathered from this survey will be presented in aggregate at professional meetings and/or in publications. No data will be presented that identifies participants in any way. The study authors have no financial interest to disclose related to the surveys.

Your participation in this project is voluntary. Completion and submission of the survey is considered to be your consent to participate. If you agree to participate in this assessment, you have the right to refuse to respond to any question. You can stop participating in the survey effort at any time. Your individual responses will remain confidential and will not be linked to your identity.

Information collected in this study will be used for a doctoral dissertation conducted at Virginia Commonwealth University. If you have any questions about this project, please contact the investigator (doctoral candidate) Barbara Kraj, MS, MLS(ASCP)CM, MBCM at krajbj@vcu.edu or 706-267-4775 or dissertation advisor, Teresa Nadder, PhD, MLS(ASCP)CM, Chairman and Associate Professor, Department of Clinical Laboratory Science at VCU, at tsnadder@vcu.edu or 804-828-9469.

If you agree to participate in the project, please proceed with answering the following questions.

Participant Demographics

Preferred e-mail address of the participant _____

Education completed. Check all that apply.

- A.A. degree
- CLT/MLT certificate
- Baccalaureate degree
- MT/CLS/MLS post-baccalaureate certificate
- Master's degree
- Doctorate
- Other

Please specify "other" degree.

Professional credentials obtained. Check all that apply.

- MLS(ASCP)
- MT(ASCP)
- CLS(NCA)
- ASCP or NCA specialty
- ASCP or NCA categorical certification
- Other

ASCP or NCA specialty field

ASCP or NCA categorical certification field

Please specify "other" credential and field

If you DO NOT have a MB(ASCP) credential (Technologist in Molecular Biology), do you plan to obtain one in the next year?

- Yes
- No
- Undecided

Provide information on number of years you have worked in clinical laboratory (any area).

- Less than 5 years
- 5-10 years
- Over 10 years

Provide information on number of years you have performed molecular-based tests in clinical laboratory.

- Less than 5 years
- 5-10 years
- Over 10 years

Prior to starting to work in the clinical laboratory, did you perform molecular-based tests in a different setting (for example, in a basic science research laboratory or in industry)?

- Yes
- No

My current place of employment is located in:

- Alabama
- Alaska
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- Florida
- Georgia
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming
- Outside of USA

My current place of employment is best described as a:

- Hospital laboratory
- Academic center
- Reference laboratory
- Other

Please specify "other" place of employment.

The number of molecular-based assays performed in my laboratory is approximately:

- 1-3
- 4-10
- More than 10

Name the tests

(If possible, please provide manufacturer(s) in addition to

Name three most frequently run molecular tests

(If possible, please provide manufacturer(s) in addition to

Have you ever been a preceptor/instructor for a Medical Laboratory Science (MLS) student performing an internship in your laboratory?

- Yes
- No

Specify the areas in which you were an instructor. Check all that apply.

- Blood Bank
- Chemistry
- Hematology
- Immunology
- Microbiology
- Molecular testing

Please describe your satisfaction with overall performance of students trained in molecular testing in your laboratory.

- not satisfied
- somewhat satisfied
- satisfied
- very satisfied

Basic Concepts in Molecular Biology

Most MLS/CLS educational programs do not require molecular biology as a prerequisite for admission. Thus, the applicants' knowledge of basic molecular biology concepts upon admission may vary. This knowledge is however necessary to understand the scientific background of molecular diagnostic procedures. The amount of time a MLS/CLS faculty has to teach these concepts prior to focusing on the actual diagnostic procedures is limited.

On a scale from 0 to 4 (as described below) please rate the importance of teaching the following basic concepts in molecular biology.

General concepts of breakthrough discoveries made by molecular scientists chosen by course instructor.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Modes of single gene inheritance: autosomal dominant, autosomal recessive, X-linked dominant, X-linked recessive.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Chemical structure and bonds in DNA and RNA.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

DNA melting point and its relevance to DNA denaturation, renaturation, hybridization and annealing.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

The central dogma of molecular biology and the molecular processes occurring during the cell cycle

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Specific Cognitive and Psychomotor Learning Objectives in Molecular Diagnostics.

On a scale from 0 to 4 (as described below), please rate the importance of the following learning objectives corresponding to molecular testing skills that you think a graduating clinical/medical laboratory scientist should know upon entry to the profession.

Objectives relevant to general laboratory operations.

Recognize the differences in quality assurance practices utilized in clinical molecular diagnostic laboratories versus molecular biology laboratories.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Justify molecular laboratory workflow

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recommend proper transport for acceptable specimens for molecular pathology.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recommend proper storage conditions for specimens and purified nucleic acids according to Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP) guidelines.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Observe correct protocols for disposal of biohazard and chemical waste in the molecular laboratory.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Observe precautions against nucleic acids degradation and contamination.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Identify companies that manufacture molecular assays utilized in the clinical laboratory.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recognize the complexity of reporting patients' results including laboratory developed tests and the FDA Analyte Specific Reagents (ASR) Rule.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to pipetting skills

Demonstrate proper use of automated, variable or fixed volume micropipette.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Assess the accuracy of micropipettes by gravimetric procedure using water.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to nucleic acid isolation

Explain the purpose of each reagent used in the traditional organic DNA extraction procedure.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the purpose of each reagent used in the traditional guanidinium thiocyanate-phenol-chlorophorm RNA extraction procedure.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the principle of selected automated DNA and RNA isolation systems.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Extract DNA and RNA from blood or other specimens.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Assess purity of nucleic acid solutions using spectrophometric measurements.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Calculate nucleic acid concentrations of DNA and RNA solutions using spectrophometric measurements.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Objectives relevant to DNA Polymorphism

State clinical applications of various human gene polymorphisms.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Recommend proper temperature and buffer conditions for a specific restriction enzyme digestion of assigned amount of DNA.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Perform restriction enzyme digestion using properly calculated amounts of all components of the digestion mix.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Predict the sizes of DNA fragments obtained following restriction enzyme digestion.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to gel electrophoresis

State the principle of DNA gel electrophoresis.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Perform gel electrophoresis.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Interpret the outcomes of electrophoresis.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to Polymerase Chain Reaction method and modifications

Explain the principle of the Polymerase Chain Reaction.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Perform the Polymerase Chain Reaction.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Apply the principles of PCR primer design.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Compare and contrast the standard and real-time PCR

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Troubleshoot in case of unsuccessful end-point or real-time PCR product analysis outcome.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to specific molecular applications

Differentiate between target amplification and signal amplification.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Identify (the functions of) all parts of at least one molecular diagnostic system/instrument utilized in your laboratory, such as amplification, microarray or sequencing system.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Compare and contrast the principles of other molecular technologies not considered PCR.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Provide specific clinical applications of other molecular technologies not considered PCR.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Apply basic karyotyping terms to chromosomal localization of clinically significant genes.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of oncologic conditions.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of inherited disorders.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of most common polysomies (Down, Turner, Klinefelter, Patau syndromes).

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

List at least two clinical applications of pharmacogenomics.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Distinguish between low and high resolution DNA-based testing used to identify human leukocyte antigens (HLA).

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Discuss at least two clinical situations when molecular typing of blood group antigens is superior to classical hemagglutination methods.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

List Nucleic Acid Tests (NATs) approved by FDA for screening of donor blood for HIV1, HCV, HBV, and WNV.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Upon consideration of all learning objectives presented in this survey, would you expand any of these objectives or include any additional objectives for entry-level medical laboratory scientist curriculum? Please, specify:

Appendix E

Email sent to MLS Program Directors with the link to Delphi I and the actual survey downloaded from REDCap.

Appendix E

Email sent to MLS Program Directors with the link to Delphi I and the actual survey downloaded from REDCap

Barbara Kraj <krajbj@mymail.vcu.edu>



Survey on the Importance of Molecular Diagnostics Learning Objectives

Barbara Kraj <krajbj@mymail.vcu.edu>

Thu, Sep 4, 2014 at 9:07 AM

To: krajbj@vcu.edu

Bcc: [...]

As program director teaching molecular methods in a medical laboratory science program in Georgia for the past 8 years and a doctoral candidate at Virginia Commonwealth University, I am seeking participants/survey respondents for my research project on the assessment of the importance of specific entry-level cognitive and psychomotor learning objectives pertaining to molecular diagnostics. The intended survey respondent is a clinical laboratory professional working in an American medical laboratory and actively involved in or supervising the performance of diagnostic assays based on molecular technology (molecular bench technologists or molecular area supervisors). **If you do not perform molecular based tests yourself, I am asking you to serve as a “gatekeeper” and forward the following survey** to as many laboratories/professionals as possible. Feel free to forward the link to both molecular reference labs, as well as smaller labs where the only molecular test performed is detection of *N.gonorrhoe/C.trachomatis*.

Although not required, as a courtesy, please kindly let me know the number of laboratory professionals performing molecular assays who received the survey from you. Please, encourage them to help me collect the data to complete this project. Once the project is completed, I will share the learning objectives with educators and other stakeholders, to add my contribution to the improvement of the existing MLS content guidelines.

Upon clicking on the link, the participants will be able to read a more detailed description of the study and either proceed or opt out. Their identity will remain confidential.

If you have any questions pertaining to this project, please contact me at krajbj@vcu.edu or at 706-267-4775. My research advisor is the Chair and Associate Professor at VCU Department of Clinical Laboratory Sciences, Dr. Teresa Nadder. She may be reached at tsnadder@vcu.edu or at 804-828-9469.

Regards,

Barbara Kraj, MS, MLS(ASCP)^{CM}MB^{CM}

The survey may be opened in your web browser by clicking the link below:
[Importance of Molecular Diagnostics Learning Objectives - Delphi Round One](#)

If the link above does not work, try copying the link below into your web browser:
<https://redcap.vcu.edu/rc/surveys/?s=FRq9oxahSj>

The survey should be submitted by September 19, 2014.

Importance of Molecular Diagnostics Learning Objectives - Delphi Round One

You are asked to complete this survey as a practicing medical laboratory professional with expertise relevant to medical molecular diagnostics.

Though molecular diagnostic testing has been mainstreamed in the clinical laboratory for over two decades, faculty of Medical/Clinical Laboratory Science programs have received little guidance pertaining to cognitive and psychomotor skills in this area necessary for entry to the profession. MLS program educators are faced with additional challenges including rapidly changing technology and increased costs in the area of molecular diagnostic testing. Few formal studies exist that have defined expected competencies in molecular diagnostics. The purpose of this study is to utilize Delphi technique to achieve a consensus among the practitioners in American molecular diagnostic laboratories concerning their expectations for entry-level knowledge and competencies.

The Delphi technique gathers information in sequential rounds of surveys sent to the same experts to reach a consensus on the investigated subject, in this case the importance of inclusion of specific cognitive or psychomotor learning objectives in the medical laboratory science curriculum. There will be a maximum of three surveys (including this one) which you will be asked to complete. You should be able to complete each survey in less than 15 minutes. In subsequent surveys, each respondent will have an opportunity to either confirm or change his/her opinion on a particular learning objective after reviewing the overall results of the preceding survey. The items assigned low importance by the majority of the respondents will be removed from the subsequent surveys, and some items assigned high importance will be expanded to include more specific information.

You will be asked to provide your preferred e-mail address so that the next survey may be sent by the investigators to you directly; your e-mail address will only be used for the purpose of conducting this project and will not be shared with anyone. Once all of the data are collected, your e-mail address will be permanently deleted from the study files. The data gathered from this survey will be presented in aggregate at professional meetings and/or in publications. No data will be presented that identifies participants in any way. The study authors have no financial interest to disclose related to the surveys.

Your participation in this project is voluntary. Completion and submission of the survey is considered to be your consent to participate. If you agree to participate in this assessment, you have the right to refuse to respond to any question. You can stop participating in the survey effort at any time. Your individual responses will remain confidential and will not be linked to your identity.

Information collected in this study will be used for a doctoral dissertation conducted at Virginia Commonwealth University. If you have any questions about this project, please contact the investigator (doctoral candidate) Barbara Kraj, MS, MLS(ASCP), MB at krajbj@vcu.edu or 706-267-4775 or dissertation advisor, Teresa Nadder, PhD, MLS(ASCP), Chairman and Associate Professor, Department of Clinical Laboratory Sciences at VCU, at tsnadder@vcu.edu or 804-828-9469.

If you agree to participate in the project, please proceed with answering the following questions. We ask that the survey is completed by September 19, 2014.

Participant Demographics

Preferred e-mail address of the participant (A Program Director or another professional forwarded to you this survey. Your preferred e-mail address will be used by the investigator to send you the next survey directly. It will not be used for any other reason but to complete this project.) _____

Education completed. Check all that apply.

- A.A. degree
- CLT/MLT certificate
- Baccalaureate degree in Medical Technology (Clinical/Medical Laboratory Science)
- Other Baccalaureate degree
- MT/CLS/MLS post-baccalaureate certificate
- Master's degree
- Doctorate
- Other degree

Field of study of your highest degree

Please specify "other" degree.

Professional credentials obtained. Check all that apply.

- MLS(ASCP)
- MT(ASCP)
- CLS(NCA)
- ASCP or NCA specialist certification (such as SBB, SC, SCT, SH, SM)
- ASCP or NCA categorical certification (such as BB, C, CG, H, M, MB)
- Other

ASCP or NCA specialist credential

ASCP or NCA categorical credential

Please specify "other" credential and field

If you DO NOT have a MB(ASCP) credential (Technologist in Molecular Biology), do you plan to obtain one in the next year?

- Yes
- No
- Undecided

Provide information on number of years you have worked in clinical laboratory (any area).

- Less than 5 years
- 5-10 years
- Over 10 years

Provide information on number of years you have performed molecular-based tests in clinical laboratory.

- Less than 5 years
- 5-10 years
- Over 10 years

Prior to starting to work in the clinical laboratory, did you perform molecular-based tests in a different setting (for example, in a basic science research laboratory or in industry)?

- Yes
- No

My current place of employment is located in:

- Alabama
- Alaska
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- Florida
- Georgia
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming
- Outside of USA

My current place of employment is best described as a:

- Hospital laboratory
- Academic medical center
- Reference laboratory
- Other

Please specify "other" place of employment.

The number of molecular-based assays performed in my laboratory is approximately:

- 1-3
- 4-10
- More than 10

Name the tests

(If possible, please provide manufacturer(s) in addition to

Name three most frequently run molecular tests

(If possible, please provide manufacturer(s) in addition to

Have you ever been a preceptor/instructor for a Medical Laboratory Science (MLS) student performing an internship in your laboratory?

- Yes
- No

Specify the areas in which you were an instructor. Check all that apply.

- Blood Bank
- Chemistry
- Hematology
- Immunology
- Microbiology
- Molecular testing

Please describe your satisfaction with overall performance of students trained in molecular testing in your laboratory.

- not satisfied
- somewhat satisfied
- satisfied
- very satisfied

Basic Concepts in Molecular Biology

Most MLS/CLS educational programs do not require molecular biology as a prerequisite for admission. Thus, the applicants' knowledge of basic molecular biology concepts upon admission may vary. This knowledge is however necessary to understand the scientific background of molecular diagnostic procedures. The amount of time a MLS/CLS faculty has to teach these concepts prior to focusing on the actual diagnostic procedures is limited.

On a scale from 0 to 4 (as described below) please rate the importance of teaching the following basic concepts in molecular biology.

General concepts of breakthrough discoveries made by molecular scientists chosen by course instructor.

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- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Modes of single gene inheritance: autosomal dominant, autosomal recessive, X-linked dominant, X-linked recessive.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Chemical structure and bonds in DNA and RNA.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
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DNA melting point and its relevance to DNA denaturation, renaturation, hybridization and annealing.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

The central dogma of molecular biology and the molecular processes occurring during the cell cycle

- 0 - not important (should not be taught in the MLS curriculum at all)
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- 3 - very important
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Objectives relevant to general laboratory operations.

Recognize the differences in quality assurance practices utilized in clinical molecular diagnostic laboratories versus molecular biology laboratories.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Justify unidirectional (clean to dirty) workflow in the molecular laboratory

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recommend proper transport for acceptable specimens for molecular pathology.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recommend proper storage conditions for specimens and purified nucleic acids according to Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP) guidelines.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Observe correct protocols for disposal of biohazard and chemical waste in the molecular laboratory.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Observe precautions against nucleic acids' degradation and contamination.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Identify companies that manufacture molecular assays utilized in the clinical laboratory.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recognize the complexity of reporting patients' results including FDA regulation of laboratory developed tests and the FDA Analyte Specific Reagents (ASR) Rule.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to pipetting skills

Demonstrate proper use of automated, variable or fixed volume micropipettes.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Assess the accuracy of micropipettes by gravimetric procedure using water.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to nucleic acid isolation

Explain the purpose of each reagent used in the traditional organic DNA extraction procedure.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the purpose of each reagent used in the traditional guanidinium thiocyanate-phenol-chlorophorm RNA extraction procedure.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the principle of selected automated DNA and RNA isolation systems.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Extract DNA and RNA from blood or other specimens.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Assess purity of nucleic acid solutions using spectrophometric measurements.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Calculate nucleic acid concentrations in DNA and RNA solutions using spectrophometric measurements.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Objectives relevant to DNA Polymorphism

State clinical applications of various human gene polymorphisms.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Recommend proper temperature and buffer conditions for a specific restriction enzyme digestion of assigned amount of DNA.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Perform restriction enzyme digestion using properly calculated amounts of all components of the digestion mix.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Predict the sizes of DNA fragments obtained following restriction enzyme digestion.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to gel electrophoresis

State the principle of DNA gel electrophoresis.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Perform gel electrophoresis.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Interpret the outcomes of electrophoresis.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to Polymerase Chain Reaction method and modifications

Explain the principle of the Polymerase Chain Reaction.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Perform the Polymerase Chain Reaction.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Apply the principles of PCR primer design.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Compare and contrast the end-point and real-time PCR

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Troubleshoot in case of unsuccessful end-point or real-time PCR product analysis outcome.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Objectives relevant to specific molecular applications

Differentiate between target amplification and signal amplification.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Identify (the functions of) all parts of at least one molecular diagnostic system/instrument utilized in your laboratory, such as amplification, microarray or sequencing system.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Compare and contrast the principles of other molecular technologies not considered PCR.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Provide specific clinical applications of other molecular technologies not considered PCR.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Apply basic karyotyping terms to chromosomal localization of clinically significant genes.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of oncologic conditions.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of inherited disorders.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of most common polysomies (Down, Turner, Klinefelter, Patau syndromes).

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

List at least two clinical applications of pharmacogenomics.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Distinguish between low and high resolution DNA-based testing used to identify human leukocyte antigens (HLA).

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Discuss at least two clinical situations when molecular typing of blood group antigens is superior to classical hemagglutination methods.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

List Nucleic Acid Tests (NATs) approved by FDA for screening of donor blood for HIV1, HCV, HBV, and WNV.

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Upon consideration of all learning objectives presented in this survey, would you expand any of these objectives or include any additional objectives for entry-level medical laboratory scientist curriculum? Please, specify:

Appendix F

Delphi Round I Objectives Predetermined for Expansion in Round II

Appendix F

Delphi Round I Objectives Predetermined for Expansion in Round II.

Round I objective predetermined to be expanded in Round II if not excluded	Follow-up objectives rated in Round II if the original objective was considered at least moderately important by at least 70% of round I respondents (objective assigned a score of 2, 3 or 4 by at least 70% of Round I respondents)
Extract DNA and RNA from blood and other specimens.	Use manual DNA and RNA extraction protocols (ex. Qiagen, Invitrogen, etc.). Use automated DNA and RNA extraction protocols (ex. MagNaPure LC).
State clinical applications of various human gene polymorphisms.	State clinical applications of Single Nucleotide Polymorphisms. State clinical applications of Short Tandem Repeats. State clinical applications of Variable Number of Tandem Repeats State clinical applications of Restriction Fragment Length Polymorphism.
Perform DNA gel electrophoresis.	Set up a horizontal or vertical gel electrophoresis system. Prepare electrophoretic buffer and gel. Select nucleic acid size markers for electrophoresis considering the expected product length. Load samples onto the electrophoretic gel without loss of volume, spillover between the wells, or gel disruption. Observe safety precautions during electrophoretic gel staining and UV photography.
Interpret the outcomes of DNA electrophoresis.	Assess the length of separated DNA fragments. Determine zygosity of an allele. Determine the number of sequence repeats.

Appendix F – continued

Round I objective predetermined to be expanded in Round II if not excluded	Follow-up objectives rated in Round II if the original objective was considered at least moderately important by at least 70% of round I respondents (objective assigned a score of 2, 3 or 4 by at least 70% of Round I respondents)
Explain the principle of the Polymerase Chain Reaction.	<p>Provide temperature ranges appropriate for the molecular events of the denaturation, annealing and extension steps of a PCR cycle.</p> <p>Predict the amount of DNA amplification product based on the number of PCR cycles.</p> <p>Explain the role of each component of a standard PCR mixture in DNA amplification.</p> <p>Describe the operation of a thermal cycler.</p> <p>Distinguish among the positive, negative, internal, and reagent blank PCR controls.</p> <p>Explain the purpose of including Uracil N-Glycosylase as it relates to quality control.</p> <p>Differentiate between standard PCR and reverse transcriptase PCR.</p> <p>Provide at least one specific application of each: standard end-point PCR, real-time PCR, reverse-transcriptase PCR and multiplex PCR.</p>
Perform Polymerase Chain Reaction.	<p>Prepare PCR mix of assigned volume “from scratch” using appropriate calculations when given the concentrations of the stock solutions.</p> <p>Program a thermal cycler when provided with the number of PCR cycles, temperature conditions and duration of each reaction step.</p> <p>Calculate optimal annealing temperature for primers.</p>
Apply the principles of PCR primer design.	<p>Navigate the National Institute of Health GenBank database to download a sequence of a gene of interest.</p> <p>Given a sequence of DNA, select the best oligonucleotide PCR primers using the manual method.</p> <p>Given a sequence of DNA, select the best primers using computer primer design software.</p>
Compare and contrast the end-point and real-time PCR.	<p>Describe at least two fluorescence based detection systems, such as FRET or TaqMan.</p> <p>Interpret graphs representing melt curve analysis to identify presence and zygosity of gene mutations.</p>

Appendix F – continued

Round I objective predetermined to be expanded in Round II if not excluded	Follow-up objectives rated in Round II if the original objective was considered at least moderately important by at least 70% of round I respondents (objective assigned a score of 2, 3 or 4 by at least 70% of Round I respondents)	
Two objectives expanded in the second round by asking about the importance to include the following:		
Compare and contrast the principles of other molecular technologies not considered PCR and provide specific clinical applications of other molecular technologies not considered PCR (2 objectives)	Transcription Mediated Amplification (TMA)	Pyrosequencing
	Branched DNA (bDNA)	Next Generation Sequencing (NGS)
	Strand Displacement Amplification (SDA)	Microarrays
	Invader technology	Fluorescent <i>in situ</i> Hybridization (FISH)
	Automated Dideoxy (Sanger) Sequencing	
The objective expanded in the second round by asking about the importance to include the following:		
Identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents.	<i>Neisseria gonorrhoe/Chlamydia trachomatis</i>	Group A <i>Streptococcus</i>
	Human Immunodeficiency Virus	Influenza Virus
	Hepatitis C Virus (HCV)	Respiratory Syncytial Virus
	<i>Mycobacterium tuberculosis</i>	Human Rhinovirus/Enterovirus
	<i>Clostridium difficile</i>	<i>Bordetella pertussis</i>
	Human Papilloma Virus (HPV)	Other pathogens in respiratory panel (Adenovirus, Parainfluenza, etc.)
	Herpes Simplex Virus (HSV)	
	Cytomegalovirus (CMV)	Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)
	Epstein-Barr Virus (EBV)	Vancomycin Resistant Enterococcus (VRE)

Appendix F - continued

Round I objective predetermined to be expanded in Round II if not excluded	Follow up objectives rated in Round II if the original objective was considered at least moderately important by at least 70% of round I respondents (objective assigned a score of 2, 3 or 4 by at least 70% of round I respondents)	
Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of oncologic conditions.	The objective expanded in the second round by asking about the importance to include the following:	
	chronic myelogenous leukemia (CML)	breast cancer
	acute lymphocytic leukemia (ALL)	colon cancer
	Burkitt's lymphoma	bladder cancer
Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of inherited disorders.	The objective expanded in the second round by asking about the importance to include the following:	
	Factor II and Factor V Leiden	dinucleotide repeat expansion diseases
	hereditary hemochromatosis	Duchenne and Becker muscular dystrophy
	cystic fibrosis	Angelman/Prader-Willi

Appendix G

Email sent to Delphi I participants with narrative comments to review.

Appendix G

Email sent to Delphi I participants with narrative comments to review.

Barbara Kraj <krajbj@mymail.vcu.edu>



Follow-up on the Survey on the Importance of Molecular Diagnostics Learning Objectives

Barbara Kraj <krajbj@mymail.vcu.edu>
To: krajbj@vcu.edu
Cc: Teresa S Nadder/HSC/VCU <tsnadder@vcu.edu>
Bcc:[...]

Fri, Nov 14, 2014 at 6:45 AM

Dear Participant,

Thank you again for submitting your answers to the first Delphi round survey in the project on the Importance of Molecular Diagnostics Learning Objectives in Entry Level Medical Laboratory Science Curriculum conducted at Virginia Commonwealth University. The link to the second survey will be sent to you in a few days. In this second round per Delphi study design, each respondent will have an opportunity to either confirm or change his/her opinion on a particular learning objective after reviewing the overall results of the preceding survey. The counts and frequencies of each rating from the first round will be shown below each objective.

The last question in the first round Delphi survey asked the participants if, upon consideration of all learning objectives listed, they would expand any of these objectives or would they include any additional objectives for entry-level medical laboratory scientist curriculum. The participants' narrative answers to this last question are included in the attached document for your review.

Please be on a lookout for your personal Delphi Round Two survey link. It will be sent to you directly by the REDCap system at Virginia Commonwealth University. Once you receive your personal link, please do not forward it to anyone. I will send a confirmatory email to all participants to make sure the survey was successfully distributed.

If you have any questions about this project, please contact me at krajbj@vcu.edu or 706-267-4775 or Teresa Nadder, PhD, MLS(ASCP)^{CM}, my dissertation advisor (Chairman and Associate Professor, Department of Clinical Laboratory Science at VCU), at tsnadder@vcu.edu or 804-828-9469.

Regards,

Barbara Kraj, MS, MLS(ASCP)^{CM}, MBC^{CM}

Appendix G – continued.

E-mail attachment:

Kraj, B. Incorporation of Molecular Diagnostics into Clinical Laboratory Science Curriculum:

Clinical Facilities Expectations. An Asynchronous, Iterative, Online Delphi Study.

Delphi Round One Survey narrative comments 10-1-14.

The last question in the first round Delphi survey on the Importance of Molecular Diagnostics Learning Objectives in Entry Level Medical Laboratory Science Curriculum conducted at Virginia Commonwealth University asked the participants if, upon consideration of all learning objectives listed, they would expand any of these objectives or would they include any additional objectives for entry-level medical laboratory scientist curriculum. The participants' narrative answers to this last question were as follows:

List above is very extensive and if a majority of these were covered individuals would be way ahead once they started working.

Basic DNA sequencing methodologies/interpretation

Not all.

Laboratory Math (dilutions, DNA concentrations) Sequencing (Sanger, other methods)
Controls (amplification, sensitivity, internal)

Pharmacogenomics

Sample contamination and QA/QC procedures should be emphasized. I have observed that most positions that open in the Molecular Diagnostics area in the clinical labs have been given to more senior level MLS. Some of the areas of emphasis are so very specialized that it is difficult to cover each adequately in a lecture/lab undergraduate course, and the students become overwhelmed with the information.

Able to use a variety of pipettes produced by different manufacturers (Rainin, Eppendorf) with different aspirating/expelling mechanisms. Able to pipette in a way that limits cross contamination.

I would also present the amount of daily cleaning needed to keep the lab quality in good shape.

With my limited base of knowledge in molecular diagnostics, the concepts covered in this survey seem to encompass the fundamentals of molecular methods.

It would be useful for a Molecular Technologist to learn how to troubleshoot unexpected results, which can happen in every platform. i.e, crosscontamination, carryover, failed internal controls, low yield for DNA and RNA, etc. After all, I think you learn the most when something has gone wrong and you work to find the way to prevent it. These exercises would probably fit better in the practical part of the curriculum.

Basic understanding of extraction and components involved in PCR. Importance of specimen integrity and pipetting technique.

I think general molecular concepts should definitely be emphasized (especially if student has not taken a molecular biology course in undergrad), but even more importantly, teaching should focus on molecular techniques to provide optimal results and minimize error/contamination.

Be familiar with the clinical presentation of most common viral/bacterial analytes detected by PCR.

CAP compliance

Curriculum should be basic and prepare the student to learn the application in the field.

While it would be great to include all of these learning objectives in the molecular course curriculum I think it might be hard to squeeze it all in AND do a good job covering the material. I believe our MLS students only have 2 weeks of molecular lectures and they spend 1 week in the lab. If you haven't seen it yet, AMP (The Association for Molecular Pathology) published a paper recently in JMD similar to this.

For our particular purposes which is infectious disease, I think all the relevant topics were covered.

More information on infectious disease testing using molecular methods.

Since the science is moving so rapidly, I would suggest automated platforms for tests, new methods, and new FDA cleared assays. I would suggest that also included in the lectures is the need to correlate molecular results with diagnosis and disease. The presence of DNA does not always mean a disease process is present.

Knowledge of FDA approved versus ASR for infectious disease agents (e.g. HIV, HSV, NG/CT, HPV, etc.)

No. Believe that the basic infectious disease and amplification techniques, QC and workflow is entry level. Human chromosomal genetics, HLA and other molecular techniques beyond entry

level. Molecular is a technique like serology and the remainder should be an advanced specialty or masters level. We are not good at defining level of practice, we jump from B.S. to DCLS and should look at developing a better flow across levels of practice in all disciplines.

My main concern would be for the students to understand the theory of PCR and related molecular techniques. Otherwise, it is very difficult to troubleshoot problems in the lab. In addition, in order to understand PCR, you would need to begin with a review (I say review, because this information should be covered in a basic bio class) of DNA and RNA structures and processes. Although it is important to get some molecular labwork under their belts, there are multiple techniques for the same type of testing, so I'd say that a sampling of techniques is good . . . a conventional PCR, real time PCR, reverse transcriptase PCR, PFGE (maybe a watch-and-learn lab), Gen-Probe, etc. Having guest speakers who can illustrate the real-life applications of molecular techniques! Its' always good to know that the education that you're getting will actually be a benefit to someone, the world, the pharmaceutical industry, a patient, etc.

As molecular technology is applied so broadly to so many specialties the entry level scientist should have strongest training in the basics and a survey of the specialties and a robust understanding of the application of the techniques in diagnostic testing.

Although molecular testing is gaining popularity, in our area all molecular testing is a send out. It is sad to say that lab directors and pathologists here are questioning why we have to teach molecular diagnostics when the graduates are not using the information.

Focus in our program is on contamination control, basic Master mix preparation (listing components and describing how each one is utilized in a reaction), comparing molecular methods to other methods such a culture (advantages, disadvantages etc...). We also focus on Real-time PCR, describing the curve, how it can apply to Qualitative and Quant assays. We touch on mutations/translocations, etc. and examples. FYI-Our program does not include cytogenetics applications.

Pipetting technique is extremely important as well as preventing contamination. Basics on isolating RNA, DNA as well as PCR, etc. is important...once these are learned it is easier to understand the downstream testing and platforms.

Must include Next Generation platforms and applications.

At least make biochemistry, cell biology, and/or basic human genetics prerequisites for a molecular course

Appendix H

Delphi Round Two invitation text and survey sent by REDCap system on November 17, 2014.

Appendix H

Delphi Round Two invitation text and survey sent by REDCap system on November 17, 2014

Subject Line: Round Two of Delphi Survey on the Importance of Molecular Diagnostics Learning Objectives

Thank you very much for your participation in the first round of Delphi study on the importance of molecular diagnostics learning objectives in entry level medical laboratory science curriculum. Your expertise as a practicing medical laboratory professional with experience in medical molecular diagnostics is invaluable!

Recall that the purpose of this study is to utilize the Delphi technique to gather information in sequential rounds of surveys sent to the same experts to reach a consensus on the investigated subject. In subsequent surveys, each respondent has the opportunity to either confirm or change his/her opinion on a particular learning objective upon reviewing the overall results of the preceding survey.

At the end of this email you will find the link to the second Delphi round survey. Round One counts and frequencies of each rating are shown below each objective in Round Two. A list of all participants' comments made in the first round was emailed to you a few days prior for your review - if you have not received it - please contact the investigator using the email or phone number provided below.

You will be able to read more details about the structure of the second round survey upon clicking the provided link. You should be able to complete the survey in approximately 10-20 minutes.

Please submit the survey by December 1, 2014.

If you have any questions about this project, please contact the investigator (doctoral candidate) Barbara Kraj, MS, MLS(ASCP)^{CM}, MB^{CM} at krajbj@vcu.edu or 706-267-4775 or Teresa Nadder, PhD, MLS(ASCP)^{CM}, dissertation advisor (Chairman and Associate Professor, Department of Clinical Laboratory Science at VCU), at tsnadder@vcu.edu or 804-828-9469.

You may open the survey in your web browser by clicking the link below:
[Importance of Molecular Diagnostics Learning Objectives - Delphi Round Two](#)

If the link above does not work, try copying the link below into your web browser:

[XX](#)

This link is unique to you and should not be forwarded to others.

Importance of Molecular Diagnostics Learning Objectives

- Delphi Round Two

Welcome to Round Two of Delphi study on the importance of molecular diagnostics learning objectives in entry level medical laboratory science curriculum!

The purpose of this study is to utilize the iterative Delphi technique to achieve a consensus among the practitioners of molecular diagnostic laboratories concerning their expectations for entry-level knowledge and competencies.

In subsequent surveys, each respondent has the opportunity to either confirm or change his/her opinion on a particular learning objective upon reviewing the overall results of the preceding survey.

Please, be patient as you are answering the questions in this second survey. Though most of the questions are the same as in the first one, it is very important that you provide answers. This is the nature of the Delphi process. Upon completion of the second round, depending on the outcome, there may be a need for a FINAL, third round. To maintain the validity of this instrument, it is extremely important to minimize attrition; therefore, please make every effort to participate in all rounds of this project. You should be able to complete the second survey in approximately 10-20 minutes. Note that due to low importance assigned by the respondents, one learning objective was removed from the second round, and some items assigned high importance are now expanded to include more specific information.

You were asked to provide your e-mail address so that the second survey may be sent to you directly; your e-mail address will only be used for the purpose of conducting this project and will not be shared with anyone. If you anticipate a change in your email address, please notify us immediately.

In this second round you are receiving the survey directly via the preferred email address and the link is uniquely tied to your ID in the study. Due to this feature, you will not be asked for your demographic information again. Please, do not forward this unique link to anyone. As stated upon release of the first survey, once all data are collected, your e-mail address will be permanently deleted from the investigator's files.

Your participation in this project is voluntary. Completion and submission of the survey is considered to be your consent to participate. If you agree to participate in this assessment, you have the right to refuse to respond to any question. You can stop participating in the survey effort at any time. Your individual responses will remain confidential.

If you have any questions about this project, please contact the investigator (doctoral candidate) Barbara Kraj, MS, MLS(ASCP)CM, MBCM at krajbj@vcu.edu or 706-267-4775 or Teresa Nadder, PhD, MLS(ASCP)CM , dissertation advisor (Chairman and Associate Professor, Department of Clinical Laboratory Science at VCU), at tsnadder@vcu.edu or 804-828-9469.

Please submit this survey by December 1, 2014.

Preferred e-mail address of the participant (Please confirm the address in case it is needed to distribute the third and FINAL Delphi survey. If at any time your preferred email changes, please contact the principal investigator at krajbj@vcu.edu)

I. Basic Concepts in Molecular Biology

On a scale from 0 to 4 (as described below) please re-rate the importance of teaching the following basic concepts in molecular biology, necessary to understand the scientific background of molecular diagnostic procedures.

Before you assign your current rating, please review the results of the first round of Delphi provided for each concept.

General concepts of breakthrough discoveries made by molecular scientists chosen by course instructor. Delphi Round One counts/frequency: 0 - (2, 2.2%) 1 - (14, 15.1%) 2 - (46, 49.5%) 3 - (23, 24.7%) 4 - (8, 8.6%) Your round two rating of the importance of teaching this concept is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Modes of single gene inheritance: autosomal dominant, autosomal recessive, X-linked dominant, X-linked recessive. Delphi Round One counts/frequency: 0 - (4, 4.3%) 1 - (9, 9.6%) 2 - (27, 28.7%) 3 - (37, 39.4%) 4 - (17, 18.1%) Your round two rating of the importance of teaching this concept is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Chemical structure and bonds in DNA and RNA. Delphi Round One counts/frequency: 0 - (2, 2.1%) 1 - (5, 5.3%) 2 - (17, 18.1%) 3 - (38, 40.4%) 4 - (32, 34%) Your round two rating of the importance of teaching this concept is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

DNA melting point and its relevance to DNA denaturation, renaturation, hybridization and annealing. Delphi Round One counts/frequency: 0 - (1, 1.1%) 1 - (4, 4.3%) 2 - (10, 10.6%) 3 - (38, 40.4%) 4 - (41, 43.6%) Your round two rating of the importance of teaching this concept is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

The central dogma of molecular biology and the molecular processes occurring during the cell cycle Delphi Round One counts/frequency: 0 - (2, 2.1%) 1 - (6, 6.4%) 2 - (18, 19.1%) 3 - (38, 40.4%) 4 - (30, 31.9%) Your round two rating of the importance of teaching this concept is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

II. Specific Cognitive and Psychomotor Learning Objectives in Molecular Diagnostics.

On a scale from 0 to 4 (as described below), please re-rate the importance of the following learning objectives corresponding to molecular testing skills that you think a graduating clinical/medical laboratory scientist should know upon entry to the profession.

Before you assign your current rating, please review the results of the first round of Delphi provided for each objective.

OBJECTIVES RELEVANT TO GENERAL LABORATORY OPERATIONS

Recognize the differences in quality assurance practices utilized in clinical molecular diagnostic laboratories versus molecular biology laboratories. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (7, 7.4%) 2 - (18, 19.1%) 3 - (37, 39.4%) 4 - (32, 34%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Justify unidirectional (clean to dirty) workflow in the molecular laboratory Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (1, 1.1%) 2 - (10, 10.6%) 3 - (25, 26.6%) 4 - (58, 61.7%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recommend proper transport for acceptable specimens for molecular pathology. Delphi Round One counts/frequency: 0 - (2, 2.1%) 1 - (3, 3.2%) 2 - (15, 16%) 3 - (40, 42.6%) 4 - (34, 36.2%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recommend proper storage conditions for specimens and purified nucleic acids according to Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP) guidelines. Delphi Round One counts/frequency: 0 - (2, 2.2%) 1 - (2, 2.2%) 2 - (12, 12.9%) 3 - (37, 39.8%) 4 - (40, 43%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Observe correct protocols for disposal of biohazard and chemical waste in the molecular laboratory. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (2, 2.1%) 2 - (17, 18.1%) 3 - (47, 50%) 4 - (28, 29.8%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Observe precautions against nucleic acids' degradation and contamination. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (0, 0%) 2 - (4, 4.3%) 3 - (35, 37.2%) 4 - (55, 58.5%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Recognize the complexity of reporting patients' results including FDA regulation of laboratory developed tests and the FDA Analyte Specific Reagents (ASR) Rule. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (8, 8.5%) 2 - (23, 24.5%) 3 - (37, 39.4%) 4 - (26, 27.7%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO PIPETTING SKILLS

Demonstrate proper use of automated, variable or fixed volume micropipettes. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (2, 2.1%) 2 - (6, 6.4%) 3 - (30, 31.9%) 4 - (56, 59.6%) Your round two rating of the importance of this learning objective is:

Assess the accuracy of micropipettes by gravimetric procedure using water. Delphi Round One Counts/frequency: 0 - (5, 5.3%) 1 - (14, 14.9%) 2 - (25, 26.6%) 3 - (33, 35.1%) 4 - (17, 18.1%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO NUCLEIC ACID ISOLATION

Explain the purpose of each reagent used in the traditional organic DNA extraction procedure.

Delphi Round One counts/frequency: 0 - (1, 1.1%) 1 - (4, 4.3%) 2 - (33, 35.1%) 3 - (41, 43.6%) 4 - (15, 16%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the purpose of each reagent used in the traditional guanidinium

thiocyanate-phenol-chlorophorm RNA extraction procedure. Delphi Round One counts/frequency: 0 - (2, 2.2%) 1 - (13, 14%) 2 - (33, 35.5%) 3 - (33, 35.5%) 4 - (12, 12.9%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the principle of selected automated DNA and RNA isolation systems. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (8, 8.5%) 2 - (29, 30.9%) 3 - (44, 46.8%) 4 - (13, 13.8%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round 97.9% of the participants stated that it was at least moderately important to teach to extract DNA and RNA from blood and other specimens. Per study design, in this second round you are asked to rate two follow-up psychomotor objectives:

Use manual DNA and RNA extraction protocols (ex. Qiagen, Invitrogen, etc).

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Use automated DNA and RNA extraction protocols (ex. MagNaPure LC).

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO NUCLEIC ACID ISOLATION - Continued.

Before you assign your current rating, please review the results of the first round of Delphi provided for each objective.

Assess purity of nucleic acid solutions using spectrophotometric measurements. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (13, 14%) 2 - (29, 31.2%) 3 - (35, 37.6%) 4 - (16, 17.2%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Calculate nucleic acid concentrations in DNA and RNA solutions using spectrophotometric measurements. Delphi Round One counts/frequency: 0 - (0, 0%) 1 - (13, 13.8%) 2 - (35, 37.2%) 3 - (33, 35.1%) 4 - (13, 13.8%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

OBJECTIVES RELEVANT TO DNA POLYMORPHISM

In the first Delphi survey round 88.3% of the participants stated that it was at least moderately important to teach about clinical applications of various human gene polymorphisms. Per study design, in this second round you are asked to rate the importance of the following four cognitive objectives:

State clinical applications of Single Nucleotide Polymorphisms (SNP)

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

State clinical applications of Short Tandem Repeats (STR)

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

State clinical applications of Variable Number of Tandem Repeats (VNTR)

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

State clinical applications of Restriction Fragment Length Polymorphism (RFLP)

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

OBJECTIVES RELEVANT TO DNA POLYMORPHISM - Continued.

Before you assign your current rating, please review the results of the first round of Delphi provided for each objective.

Recommend proper temperature and buffer conditions for a specific restriction enzyme digestion of assigned amount of DNA. Delphi Round One counts/frequency: 0 - (2, 2.1%) 1 - (14, 14.9%) 2 - (33, 35.1%) 3 - (29, 30.9%) 4 - (16, 17%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Perform restriction enzyme digestion using properly calculated amounts of all components of the digestion mix. Delphi Round One counts/frequency: 0 - (2, 2.1%) 1 - (16, 17%) 2 - (32, 34%) 3 - (31, 33%) 4 - (13, 13.8%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

Predict the sizes of DNA fragments obtained following restriction enzyme digestion. Delphi Round One counts/frequency: 0 - (2, 2.2%), 1 - (20, 21.5%) 2 - (35, 37.6%) 3 - (27, 29%) 4 - (9, 9.7%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO GEL ELECTROPHORESIS

Before you assign your current rating, please review the results of the first round of Delphi provided for the first objective in this category.

State the principle of DNA gel electrophoresis.
Delphi Round One counts/frequency: 0 - (0, 0%), 1 - (5, 5.3%), 2 - (25, 26.6%), 3 - (33, 35.1%), 4 - (31, 33%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 91.3 % of the respondents stated that it was at least moderately important to teach to perform DNA gel electrophoresis. Per study design, in this second round you are asked to rate five follow-up objectives:

Set up a horizontal or vertical gel electrophoresis system

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Prepare electrophoretic buffer and gel.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Select nucleic acid size markers for electrophoresis considering the expected product length.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Load samples onto the electrophoretic gel without loss of volume, spillover between the wells, or gel disruption.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Observe safety precautions during electrophoretic gel staining and UV photography

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 94.7% of the respondents stated that it was at least moderately important to teach to interpret the outcomes of DNA electrophoresis. Per study design, in this second round you are asked to rate three follow-up cognitive objectives:

Assess the length of separated DNA fragments

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Determine zygosity of an allele

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Determine the number of sequence repeats

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO POLYMERASE CHAIN REACTION METHOD AND MODIFICATIONS

In the first Delphi survey round, 98.9 % stated that it was at least moderately important to explain the principle of the Polymerase Chain Reaction. Per study design, in this second round you are asked to rate eight follow-up cognitive objectives:

Provide temperature ranges appropriate for the molecular events of the denaturation, annealing and extension steps of a PCR cycle.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Predict the amount of DNA amplification product based on the number of PCR cycles.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the role of each component of a standard PCR mixture in DNA amplification.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Describe the operation of a thermal cycler.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Distinguish among the positive, negative, internal, and reagent blank PCR controls.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Explain the purpose of including Uracil N-Glycosylase as it relates to quality control.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Differentiate between standard PCR and reverse transcriptase PCR

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Provide at least one specific application of each:
standard end-point PCR, real-time PCR,
reverse-transcriptase PCR and multiplex PCR

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 95.7 % of the participants stated that it was at least moderately important to teach to perform Polymerase Chain Reaction. Per study design, in this second round you are asked to rate two follow-up psychomotor objectives:

Prepare PCR mix of assigned volume "from scratch" using appropriate calculations when given the concentrations of the stock solutions

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Program a thermal cycler when provided with the number of PCR cycles, temperature conditions and duration of each reaction step.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 90.4 % of the participants stated that it was at least moderately important to teach to apply the principles of PCR primer design. Per study design, in this second round you are asked to rate four follow-up cognitive objectives:

Calculate optimal annealing temperature for primers.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Navigate the National Institute of Health GenBank database to download a sequence of a gene of interest.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Given a sequence of DNA, select the best oligonucleotide PCR primers using the manual method

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Given a sequence of DNA, select the best primers using computer primer design software

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 96.8 % of the participants stated that it was at least moderately important to teach to compare and contrast the end-point and real-time PCR. Per study design, in this second round you are asked to rate two follow-up cognitive objectives:

Describe at least two fluorescence based detection systems, such as FRET or TaqMan.

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Interpret graphs representing melt curve analysis to identify presence and zygosity of gene mutations

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO POLYMERASE CHAIN REACTION METHOD AND MODIFICATIONS - continued.

Before you assign your current rating, please review the results of the first round of Delphi provided for the objective.

Troubleshoot in case of unsuccessful end-point or real-time PCR product analysis outcome. Delphi Round One Counts/frequency: 0 - (1, 1.1%), 1 - (2, 2.1%), 2 - (18, 19.1%), 3 - (39, 41.5%), 4 - (34, 36.2%)
Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO SPECIFIC MOLECULAR APPLICATIONS

Before you assign your current rating, please review the results of the first round of Delphi provided for the first two objectives in this category.

Differentiate between target amplification and signal amplification. Delphi Round One Counts/frequency: 0 - (2, 2.1%) 1 - (2, 2.1%) 2 - (21, 22.3%) 3 - (38, 40.4%) 4 - (31, 33%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Identify (the functions of) all parts of at least one molecular diagnostic system/instrument utilized in your laboratory, such as amplification, microarray or sequencing system. Delphi Round One Counts/frequency: 0 - (3, 3.2%) 1 - (6, 6.4%) 2 - (32, 34%) 3 - (37, 39.4%) 4 - (16, 17%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 93.6 % of the participants stated that it was at least moderately important to teach to compare and contrast the principles of other molecular technologies not considered PCR and 89.1 % of the participants stated that it was at least moderately important to provide specific clinical applications of other molecular technologies not considered PCR. Per study design, in this second round you are asked to rate the importance of inclusion of principles and applications of:

- Transcription Mediated Amplification (TMA)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Branched DNA (bDNA)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Strand Displacement Amplification (SDA)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Invader technology
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Automated Dideoxy (Sanger) Sequencing
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Pyrosequencing
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Next Generation Sequencing (NGS)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)

Microarrays

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Fluorescent in situ Hybridization (FISH)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 93.5 % of the participants stated that it was at least moderately important to teach to identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents. Per study design, in this second round you are asked to rate the importance of inclusion of the following pathogens:

Neisseria gonorrhoe/Chlamydia trachomatis

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Human Immunodeficiency Virus (HIV-1)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Hepatitis C Virus (HCV)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Mycobacterium tuberculosis

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Clostridium difficile

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Human Papilloma Virus (HPV)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Herpes Simplex Virus (HSV)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

- Cytomegalovirus (CMV)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Epstein-Barr Virus (EBV)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Group A Streptococcus
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Influenza Virus
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Respiratory Syncytial Virus (RSV)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Human Rhinovirus/Enterovirus
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Bordetella pertussis
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)
- Other pathogens in the respiratory panel (such as Adenovirus, Parainfluenza, etc.)
- 0 - not important (should not be included in the MLS curriculum at all)
 - 1 - of little importance
 - 2 - of moderate importance
 - 3 - very important
 - 4 - most important (absolutely must be included in the MLS curriculum)

Methicillin Resistant Staphylococcus aureus (MRSA)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Vancomycin Resistant Enterococcus (VRE)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO SPECIFIC MOLECULAR APPLICATIONS - continued.

Before you assign your current rating, please review the results of the first round of Delphi provided for the objective.

Apply basic karyotyping terms to chromosomal localization of clinically significant genes. Delphi Round One Counts/frequency: 0 - (3, 3.3%), 1 - (19, 20.9%), 2 - (37, 40.7%), 3 - (25, 27.5%), 4 - (7, 7.7%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 80 % of the participants stated that it was at least moderately important to teach to associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of oncologic conditions. Per study design, in this second round you are asked to rate the importance of inclusion of the following:

chronic myelogenous leukemia (CML)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

acute lymphocytic leukemia (ALL)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Burkitt's lymphoma

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

breast cancer

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

colon cancer

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

bladder cancer

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

In the first Delphi survey round, 83.7 % of the participants stated that it was at least moderately important to teach to associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of inherited disorders. Per study design, in this second round you are asked to rate the importance of inclusion of the following:

hypercoagulopathy (Factor II and Factor V Leiden)

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

hereditary hemochromatosis

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

cystic fibrosis

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

trinucleotide repeat expansion diseases

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Duchenne and Becker muscular dystrophy

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Angelman/Prader-Willi

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

OBJECTIVES RELEVANT TO SPECIFIC MOLECULAR APPLICATIONS - continued.

Before you assign your current rating, please review the results of the first round of Delphi provided for each objective.

Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of most common polysomies (Down, Turner, Klinefelter, Patau syndromes). Delphi round One Counts/frequency: 0 - (3, 3.3%) 1 - (12, 13%) 2 - (39, 42.4%) 3 - (30, 32.6%) 4 - (8, 8.7%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

List at least two clinical applications of pharmacogenomics. Delphi Round One Counts/frequency: 0 - (3, 3.3%) 1 - (15, 16.3%) 2 - (44, 47.8%) 3 - (19, 20.7%) 4 - (11, 12%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Distinguish between low and high resolution DNA-based testing used to identify human leukocyte antigens (HLA). Delphi Round One Counts/frequency: 0 - (1, 1.1%) 1 - 19, 20.9%) 2 - (41, 45.1%) 3 - (25, 27.5%) 4 - (5, 5.5%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

Discuss at least two clinical situations when molecular typing of blood group antigens is superior to classical hemagglutination methods. Delphi Round One Counts/frequency: 0 - (1, 1.1%) 1 - (16, 17.6%) 2 - (41, 45.1%) 3 - (27, 29.7%) 4 - (6, 6.6%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be included in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be included in the MLS curriculum)

List Nucleic Acid Tests (NATs) approved by FDA for screening of donor blood for HIV1, HCV, HBV, and WNV. Delphi Round One Counts/frequency: 0 - (3, 3.2%) 1 - (16, 17%) 2 - (44, 46.8%) 3 - (19, 20.2%) 4 - (12, 12.8%) Your round two rating of the importance of this learning objective is:

- 0 - not important (should not be taught in the MLS curriculum at all)
- 1 - of little importance
- 2 - of moderate importance
- 3 - very important
- 4 - most important (absolutely must be taught in the MLS curriculum)

III. Instructional time devoted to basic concepts and groups of learning objectives rated above

The amount of time a MLS/CLS faculty has to teach the above molecular biology basic concepts and content relevant to the specific molecular diagnostics learning objectives is limited.

Given that a semester lasts (on average) 16 weeks, please, select the most appropriate amount of time you think an MLS faculty should spend on teaching the following:

Basic molecular biology concepts listed at the beginning of this survey:

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Objectives pertaining to general laboratory operations:

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Objectives pertaining to pipetting skills:

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Objectives pertaining to nucleic acids' extraction:

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Objectives pertaining to DNA polymorphisms:

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Objectives pertaining to DNA gel electrophoresis:

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Objectives pertaining to PCR method and modifications:

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Objectives pertaining to specific clinical molecular applications listed in the last section of the survey

- 1-3 contact hours
- 4-6 contact hours
- More than 6 contact hours

Upon consideration of concepts and learning objectives presented in this Delphi Round Two survey, would you add any methodologies, pathogens and diseases/conditions other than already listed above to include in entry level medical laboratory scientist curriculum? Please, specify:

Appendix I

Molecular Biology Concepts and Cognitive (C) and Psychomotor (P) Learning Objectives

Pertaining to Molecular Diagnostics.

Appendix I

Molecular Biology Concepts and Cognitive (C) and Psychomotor (P) Learning Objectives
Pertaining to Molecular Diagnostics.

Molecular biology concepts and cognitive (C) and psychomotor (P) learning objectives
pertaining to molecular diagnostics are color coded according to the legend shown below:

Concepts or objectives rated as very or most important by at least 70% of the respondents in Round II
Concepts or objectives rated as very or most important by 50-69% of the respondents in Round II
Concepts or objectives rated as very or most important by 25-49% of the respondents in Round II
Concepts or objectives rated as very or most important by less than 25% of the respondents in Round II

Delphi Round I objectives expanded in Round II are typed in **blue bold font**.

Round I and Round II rating frequencies and median ratings of each concept or objective
are shown. Rating scale was as follows:

0 – not important (should not be taught in entry-level medical laboratory science
curriculum)

1 – of little importance

2 – of moderate importance

3 – very important

4 – most important (absolutely must be taught in the MLS curriculum)

Appendix I – continued

Concepts or Objectives		Round I Rating Frequency (%)					Round I respondents with ratings of 2, 3 and 4					Round II Rating Frequency (%)					Round II respondents with ratings of 3 and 4				
		0	1	2	3	4	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
Basic Concepts in Molecular Biology																					
1	General concepts of breakthrough discoveries made by molecular scientists chosen by course instructor.	2.2	15.1	49.5	24.7	8.6	83	2	0	12.9	71	16.1	0	16	2						
2	Modes of single gene inheritance: autosomal dominant, autosomal recessive, X-linked dominant, X-linked recessive.	4.3	9.6	28.7	39.4	18.1	86	3	0	1.6	28.6	60.3	9.5	70	3						
3	Chemical structure and bonds in DNA and RNA.	2.1	5.3	18.1	40.4	34	93	3	0	1.6	6.3	60.3	31.7	92	3						
4	DNA melting point and its relevance to DNA denaturation, renaturation, hybridization and annealing.	1.1	4.3	10.6	40.4	43.6	95	3	0	0	4.8	39.7	55.6	95	4						
5	The central dogma of molecular biology and the molecular processes occurring during the cell cycle.	2.1	6.4	19.1	40.4	31.9	91	3	0	3.2	12.7	66.7	17.5	84	3						
Specific Cognitive (C) and Psychomotor (P) Learning Objectives in Molecular Diagnostics																					
OBJECTIVES RELEVANT TO GENERAL LABORATORY OPERATIONS.																					
6	Recognize the differences in quality assurance practices utilized in clinical molecular diagnostic laboratories versus molecular biology laboratories.	0	7.4	19.1	39.4	34	93	3	0	0	15.9	58.7	25.4	84	3						
7	Justify unidirectional (clean to dirty) workflow in the molecular laboratory.	0	1.1	10.6	26.6	61.7	99	4	0	0	14.8	85.2	100	100	4						
8	Recommend proper transport for acceptable specimens for molecular pathology.	2.1	3.2	16	42.6	36.2	95	3	1.6	0	7.9	68.3	22.2	91	3						
9	Recommend proper storage conditions for specimens and purified nucleic acids according to Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP) guidelines.	2.2	2.2	12.9	39.8	43	96	3	0	1.6	3.2	46	49.2	95	3						
10	Observe correct protocols for disposal of biohazard and chemical waste in the molecular laboratory.	0	2.1	18.1	50	29.8	98	3	0	0	9.5	79.4	11.1	91	3						
11	Observe precautions against nucleic acids degradation and contamination.	0	0	4.3	37.2	58.5	100	4	0	0	1.6	20.6	77.8	98	4						
N/A	Identify companies that manufacture molecular assays utilized in the clinical laboratory.	9.6	29.8	42.6	11.7	6.4	61	2													
12	Recognize the complexity of reporting patients' results including regulation of laboratory developed tests and the FDA Analyte-Specific Reagents (ASR) Rule	0	8.5	24.5	39.4	27.7	92	3	0	3.2	15.9	71.4	9.5	81	3						
OBJECTIVES RELEVANT TO PIPETTING SKILLS.																					
13	Demonstrate proper use of automated, variable or fixed volume micropipettes.	0	2.1	6.4	31.9	59.6	98	4	0	0	6.3	19	74.6	94	4						
14	Assess the accuracy of micropipettes by gravimetric procedure using water.	5.3	14.9	26.6	35.1	18.1	80	3	0	9.5	31.7	52.4	6.3	59	3						
OBJECTIVES RELEVANT TO NUCLEIC ACIDS' ISOLATION																					
15	Explain the purpose of each reagent used in the traditional organic DNA extraction procedure.	1.1	4.3	35.1	43.6	16	95	3	0	3.2	28.6	68.3	0	68	3						
16	Explain the purpose of each reagent used in the traditional guanidinium thiocyanate-phenol-chloroform RNA extraction procedure.	2.2	14	35.5	35.5	12.9	84	2	1.6	3.2	57.1	36.5	1.6	38	2						
17	Explain the principle of selected automated DNA and RNA isolation systems.	0	8.5	30.9	46.8	13.8	92	3	0	0	33.3	65.1	1.6	67	3						
Extract DNA and RNA from blood and other specimens.																					
18	Use manual DNA and RNA extraction protocols (ex. Qiagen, Invitrogen, etc).	0	2.1	14.9	41.5	41.5	98	3													
19	Use automated DNA and RNA extraction protocols (ex. MagNaPure LC).	0	3.2	25.4	49.2	22.2	71	3	0	3.2	25.4	49.2	22.2	71	3						
		0	3.2	34.9	49.2	12.7	62	3	0	3.2	34.9	49.2	12.7	62	3						

Appendix I – continued

Concepts or Objectives	Round I Rating Frequency (%)										Round II Rating Frequency (%)																																
	0				1				2				3				4				0				1				2				3				4						
	Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4				Percentage (%) of respondents with ratings of 2, 3 and 4										
Specific, Cognitive (C) and Psychomotor (P) Learning Objectives in Molecular Diagnostics																																											
OBJECTIVES RELEVANT TO NUCLEIC ACID ISOLATION - Continued.																																											
20 Assess purity of nucleic acid solutions using spectrophotometric measurements.	P	0	14	31.2	37.6	17.2	86	3	0	1.6	41.9	41.9	14.5	56	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
21 Calculate nucleic acid concentrations of DNA and RNA solutions using spectrophotometric measurements.	P	0	13.8	37.2	35.1	13.8	86	2	0	1.6	42.9	46	9.5	56	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
OBJECTIVES RELEVANT TO DNA POLYMORPHISM																																											
State clinical applications of various human gene polymorphisms.	C	1.1	10.6	39.4	41.5	7.4	88	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2	0	3.3	41	45.9	9.8	56	3
22 State clinical applications of Single Nucleotide Polymorphisms (SNP).	C	0	3.3	41	45.9	9.8	56	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2	0	3.3	41	45.9	9.8	56	3
23 State clinical applications of Short Tandem Repeats (STR).	C	0	3.3	41	45.9	9.8	56	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2	0	3.3	41	45.9	9.8	56	3
24 State clinical applications of Variable Number of Tandem Repeats (VNTR).	C	0	3.3	41	45.9	9.8	56	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2	0	3.3	41	45.9	9.8	56	3
25 State clinical applications of Restriction Fragment Length Polymorphism (RFLP).	C	0	3.3	41	45.9	9.8	56	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2	0	3.3	41	45.9	9.8	56	3
OBJECTIVES RELEVANT TO DNA POLYMORPHISM - Continued.																																											
26 Recommend proper temperature and buffer conditions for a specific restriction enzyme digestion of assigned amount of DNA.	C	2.1	14.9	35.1	30.9	17	83	2	1.6	8.1	51.6	37.1	1.6	39	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
27 Perform restriction enzyme digestion using properly calculated amounts of all components of the digestion mix.	P	2.1	17	34	33	13.8	81	2	1.6	6.6	57.4	31.1	3.3	34	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
28 Predict the sizes of DNA fragments obtained following restriction enzyme digestion.	C	2.2	21.5	37.6	29	9.7	76	2	1.6	14.5	61.3	17.7	4.8	23	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
OBJECTIVES RELEVANT TO GEL ELECTROPHORESIS																																											
29 State the principle of DNA gel electrophoresis	C	0	5.3	26.6	35.1	33	95	3	0	22.6	45.2	32.3	78	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2	
Perform DNA gel electrophoresis.	P	2.2	6.5	33.3	33.3	24.7	91	3	0	22.6	45.2	32.3	78	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2	
30 Set up a horizontal or vertical gel electrophoresis system.	P	0	8.1	38.7	40.3	12.9	53	3	0	12.9	50	29	8.1	37	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
31 Prepare electrophoretic buffer and gel.	P	0	8.1	38.7	40.3	12.9	53	3	0	12.9	50	29	8.1	37	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
32 Select nucleic acid size markers for electrophoresis considering the expected product length.	P	0	8.1	38.7	40.3	12.9	53	3	0	12.9	50	29	8.1	37	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
33 Load samples onto the electrophoretic gel without loss of volume, spillover between the wells, or gel disruption.	P	0	8.1	38.7	40.3	12.9	53	3	0	12.9	50	29	8.1	37	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
34 Observe safety precautions during electrophoretic gel staining and UV photography.	P	0	8.1	38.7	40.3	12.9	53	3	0	12.9	50	29	8.1	37	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
Interpret the outcomes of DNA electrophoresis.																																											
35 Assess the length of separated DNA fragments.	C	0	5.3	27.7	35.1	31.9	95	3	0	3.2	45.2	35.5	16.1	52	3	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
36 Determine zygosity of an allele.	C	0	6.5	50	32.3	11.3	44	2	0	6.5	50	32.3	11.3	44	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2
37 Determine the number of sequence repeats.	C	0	8.1	56.5	33.9	1.6	36	2	0	8.1	56.5	33.9	1.6	36	2	0	3.3	41	45.9	9.8	56	3	0	9.8	39.3	45.9	4.9	51	3	0	11.7	45	41.7	1.7	43	2	0	6.6	45.9	41	6.6	48	2

Appendix I – continued

Concepts or Objectives	Round I Rating Frequency (%)					Round II Rating Frequency (%)					Percentage (%) of respondents with ratings of 3 and 4			
	Round I					Round II								
	0	1	2	3	4	0	1	2	3	4				
Specific Cognitive (C) and Psychomotor (P) Learning Objectives in Molecular Diagnostics OBJECTIVES RELEVANT TO POLYMERASE CHAIN REACTION METHOD AND MODIFICATIONS														
Explain the principle of the Polymerase Chain Reaction.	C													
38 Provide temperature ranges appropriate for the molecular events of the denaturation, annealing and extension steps of a PCR cycle.	C	0	1.1	9.6	19.1	70.2	99	4						
39 Predict the amount of DNA amplification product based on the number of PCR cycles.	C	0	4.9	11.5	50.8	32.8	84	3						
40 Explain the role of each component of a standard PCR mixture in DNA amplification.	C	0	6.6	41	47.5	4.9	52	3						
41 Describe the operation of a thermal cycler.	C	0	0	11.3	51.6	37.1	89	3						
42 Distinguish among the positive, negative, internal, and reagent blank PCR controls.	C	0	0	23	50.8	26.2	77	3						
43 Explain the purpose of including Uracil N-Glycosylase as it relates to quality control.	C	0	1.6	14.5	33.9	50	84	3.5						
44 Differentiate between standard PCR and reverse transcriptase PCR.	C	0	13.1	24.6	47.5	14.8	62	3						
45 Provide at least one specific application of each: standard end-point PCR, real-time PCR, reverse-transcriptase PCR and multiplex PCR.	C	0	4.8	9.7	53.2	32.3	86	3						
Perform Polymerase Chain Reaction.	P	0	4.3	9.8	25	60.9	96	4						
46 Prepare PCR mix of assigned volume "from scratch" using appropriate calculations when given the concentrations of the stock solutions.	P													
47 Program a thermal cycler when provided with the number of PCR cycles, temperature conditions and duration of each reaction step.	P													
Apply the principles of PCR primer design.	P	1.1	8.5	35.1	26.6	28.7	90	3						
48 Calculate optimal annealing temperature for primers.	P													
49 Navigate the National Institute of Health GenBank database to download a sequence of a gene of interest.	P													
50 Given a sequence of DNA, select the best oligonucleotide PCR primers using the manual method.	P													
51 Given a sequence of DNA, select the best primers using computer primer design software.	P													
Compare and contrast the end-point and real-time PCR.	C	0	3.2	23.7	37.6	35.5	97	3						
52 Describe at least two fluorescence based detection systems, such as FRET or TaqMan.	C													
53 Interpret graphs representing melt curve analysis to identify presence and zygosity of gene mutations.	C													
OBJECTIVES RELEVANT TO POLYMERASE CHAIN REACTION METHOD AND MODIFICATIONS - continued.														
54 Troubleshoot in case of unsuccessful end-point or real-time PCR product analysis outcome.	C	1.1	2.1	19.1	41.5	36.2	97	3	0	3.2	9.7	59.7	27.4	87

Appendix I – continued

Concepts or Objectives	Round I Rating Frequency (%)										Round II Rating Frequency (%)																													
	0				1				2				3				4				0				1				2				3				4			
	Percentage of Round I respondents with ratings of 2, 3 and 4										Percentage of Round II respondents with ratings of 3 and 4																													
Specific, Cognitive (C) and Psychomotor (P) Learning Objectives in Molecular Diagnostics																																								
OBJECTIVES RELEVANT TO SPECIFIC MOLECULAR APPLICATIONS																																								
55 Differentiate between target amplification and signal amplification.	C	2.1	22.3	40.4	33	96	3	0	3.2	14.5	67.7	14.5	82	3	3.3	14.8	42.6	37.7	1.6	39	2																			
56 Identify the functions of all parts of at least one molecular diagnostic system/instrument utilized in your laboratory, such as amplification, microarray or sequencing system.	C	3.2	6.4	34	39.4	17	90	3	0	4.8	25.8	62.9	6.5	69	3	3.2	22.6	48.4	22.6	3.2	26																			
Compare and contrast the principles of other molecular technologies not considered PCR and provide specific clinical applications of other molecular technologies not considered PCR - two objectives expanded in the second round by asking about the importance to include the following:	C	2.2	4.3	30.1	39.8	23.7	94	3	0	1.6	13.1	52.5	29.5	33	2	1.6	8.1	40.3	33.9	16.1	50																			
57 Transcription-Mediated Amplification (TMA)	C	2.2	8.7	39.1	33.7	16.3	89	2.5	3.3	14.8	42.6	37.7	1.6	39	2	3.2	22.6	48.4	22.6	3.2	26																			
58 Branched DNA (bDNA)	C								3.2	16.1	48.4	30.6	1.6	32	2	1.6	13.1	52.5	29.5	3.3	33																			
59 Strand Displacement Amplification (SDA)	C								1.6	8.1	40.3	33.9	16.1	50	2.5	3.3	15	40	36.7	3.5	40																			
60 Invader technology	C								1.6	8.2	24.6	52.5	13.1	66	3	0	4.8	35.5	51.6	8.1	60																			
61 Automated Dideoxy (Sanger) Sequencing	C								1.6	8.1	38.7	41.9	9.7	52	3																									
62 Pyrosequencing	C																																							
63 Next Generation Sequencing (NGS)	C																																							
64 Microarrays	C																																							
65 Fluorescent <i>in situ</i> Hybridization (FISH)	C																																							
Identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents – the objective expanded in the second round by asking about the importance to include the following agents:	C	2.2	4.3	34.4	41.9	17.2	94	3																																
66 <i>Neisseria gonorrhoeae/Chlamydia trachomatis</i>	C								0	3.2	25.8	56.5	14.5	71	3	0	4.8	21	51.6	22.6	74																			
67 Human Immunodeficiency Virus (HIV-1)	C								0	4.9	23	54.1	18	72	3	0	8.2	41	42.6	8.2	51																			
68 Hepatitis C Virus (HCV)	C								0	3.3	42.6	41	13.1	54	3	0	5.1	28.8	52.2	13.6	66																			
69 <i>Mycobacterium tuberculosis</i>	C								0	5.1	40.7	45.8	8.5	54	3	0	4.8	41.9	46.8	6.5	53																			
70 <i>Clostridium difficile</i>	C								0	6.6	47.5	39.3	6.6	46	2	0	8.2	49.2	34.4	8.2	43																			
71 Human Papilloma Virus (HPV)	C								0	3.3	27.9	50.8	18	69	3	0	6.6	32.8	52.5	8.2	61																			
72 Herpes Simplex Virus (HSV)	C								0	6.6	41	44.3	8.2	53	3	0	6.6	41	44.3	8.2	53																			
73 Cytomegalovirus (CMV)	C								0	4.9	41	42.6	11.5	54	3	0	6.7	55	33	5	38																			
74 Epstein-Barr Virus (EBV)	C								0	4.8	32.3	41.9	21	63	3	0	4.8	32.3	41.9	21	63																			
75 Group A <i>Streptococcus</i>	C								0	12.9	33.9	37.1	16.4	54	3	0	12.9	33.9	37.1	16.4	54																			
76 Influenza Virus	C																																							
77 Respiratory Syncytial Virus (RSV)	C																																							
78 Human Rhinovirus/Enterovirus	C																																							
79 <i>Bordetella pertussis</i>	C																																							
80 Other pathogens in the respiratory panel (such as Adenovirus, Parainfluenza, etc.)	C																																							
81 Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	C																																							
82 Vancomycin Resistant Enterococcus (VRE)	C																																							

Appendix I – continued

Concepts or Objectives		Round I Rating Frequency (%)					Round II Rating Frequency (%)					Percentage (%) of respondents with ratings				
		0	1	2	3	4	0	1	2	3	4	Round I Median	Round II Median			
Specific Cognitive (C) and Psychomotor (P) Learning Objectives in Molecular Diagnostics																
OBJECTIVES RELEVANT TO SPECIFIC MOLECULAR APPLICATIONS - continued.																
83	Apply basic karyotyping terms to chromosomal localization of clinically significant genes	C	3.3	20.9	40.7	27.5	7.7	7.6	2	3.2	8.1	71	16.1	1.6	18	2
Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of oncologic conditions - the objective expanded in the second round by asking about the importance to include the following:		C	3.3	16.7	37.8	34.4	7.8	80	2							
84	chronic myelogenous leukemia (CML)	C								1.6	1.6	44.3	37.7	14.8	53	3
85	acute lymphocytic leukemia (ALL)	C								1.6	3.3	47.5	34.4	13.1	48	2
86	Burkitt's lymphoma	C								1.6	9.8	60.7	19.7	8.2	28	2
87	breast cancer	C								0	8.1	37.1	37.1	17.7	55	3
88	colon cancer	C								0	10	43.3	33.3	13.3	47	2
89	bladder cancer	C								0	14.5	54.8	22.6	8.1	31	2
Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the diagnosis of inherited disorders - the objective expanded in the second round by asking about the importance to include the following:		C	3.3	13	42.4	32.6	8.7	84	2							
90	hypercoagulopathy (Factor II and Factor V Leiden)	C								0	6.5	45.2	38.7	9.7	48	2
91	hereditary hemochromatosis	C								0	8.2	59	29.5	3.3	33	2
92	cystic fibrosis	C								0	4.8	30.6	50	14.5	65	3
93	trinucleotide repeat expansion diseases	C								1.6	14.5	58.1	22.6	3.2	26	2
94	Duchenne and Becker muscular dystrophy	C								1.7	16.7	46.7	33.3	1.7	35	2
95	Angelman/Prader-Willi	C								1.6	17.7	54.8	25.8	0	26	2
OBJECTIVES RELEVANT TO SPECIFIC MOLECULAR APPLICATIONS - continued.																
96	Associate specific mutations and cytogenetic markers/chromosomal abnormalities with the most common polysomies (Down, Turner, Klinefelter, Patau syndromes).	C	3.3	13	42.4	32.6	8.7	84	2	0	8.2	57.4	32.8	1.6	34	2
97	List at least two clinical applications of pharmacogenomics.	C	3.3	16.3	47.8	20.7	12	81	2	1.6	6.5	67.7	21	3.2	24	2
98	Distinguish between low and high resolution DNA-based testing used to identify human leukocyte antigens (HLA).	C	1.1	20.9	45.1	27.5	5.5	78	2	3.3	10	75	8.3	3.3	12	2
99	Discuss at least two clinical situations when molecular typing of blood group antigens is superior to classical hemagglutination methods.	C	1.1	17.6	45.1	29.7	6.6	81	2	1.6	6.5	71	17.7	3.2	21	2
100	List Nucleic Acid Tests (NATs) approved by FDA for screening of donor blood for HIV1, HCV, HBV, and WNV.	C	3.2	17	46.8	20.2	12.8	80	2	0	3.3	85.2	8.2	3.3	12	2

Appendix J

Concepts and Learning Objectives Addressing Respondent Comments from Delphi Round I.

Appendix J

Concepts and Learning Objectives Addressing Respondent Comments from Delphi Round I

Delphi Round I Narrative Comments Made by Respondents	Related Learning Objective(s) (number assigned in Round II)
Basic DNA sequencing methodologies/interpretation	<ul style="list-style-type: none"> • Compare and contrast the principles of other molecular technologies not considered PCR (#61)
Laboratory Math (dilutions, DNA concentrations) Sequencing (Sanger, other methods) Controls (amplification, sensitivity, internal)	<ul style="list-style-type: none"> • Calculate nucleic acid concentrations of DNA and RNA solutions using spectrophotometric measurements (#21) • Compare and contrast the principles of other molecular technologies not considered PCR (#61) • Distinguish among the positive, negative, internal, and reagent blank PCR controls (#42)
Pharmacogenomics	<ul style="list-style-type: none"> • List at least two clinical applications of pharmacogenomics (#97)
Sample contamination and QA/QC procedures should be emphasized. I have observed that most positions that open in the Molecular Diagnostics area in the clinical labs have been given to more senior level MLS. Some of the areas of emphasis are so very specialized that it is difficult to cover each adequately in a lecture/lab undergraduate course, and the students become overwhelmed with the information.	<ul style="list-style-type: none"> • Distinguish among the positive, negative, internal, and reagent blank PCR controls (#42)

Appendix J – continued

Delphi Round I Narrative Comments Made by Respondents	Related Learning Objective(s) (number assigned in Round II)
<p>Able to use a variety of pipettes produced by different manufacturers (Rainin, Eppendorf) with different aspirating/expelling mechanisms. Able to pipette in a way that limits cross contamination.</p> <p>I would also present the amount of daily cleaning needed to keep the lab quality in good shape.</p>	<ul style="list-style-type: none"> • Demonstrate proper use of automated, variable or fixed volume micropipettes (#13) • Observe precautions against nucleic acids degradation and contamination (#11)
<p>It would be useful for a Molecular Technologist to learn how to troubleshoot unexpected results, which can happen in every platform. i.e. cross contamination, carryover, failed internal controls, low yield for DNA and RNA, etc. After all, I think you learn the most when something has gone wrong and you work to find the way to prevent it. These exercises would probably fit better in the practical part of the curriculum.</p>	<ul style="list-style-type: none"> • Troubleshoot in case of unsuccessful end-point or real-time PCR product analysis outcome (#54)
<p>Basic understanding of extraction and components involved in PCR. Importance of specimen integrity and pipetting technique.</p>	<ul style="list-style-type: none"> • Extract DNA and RNA from blood and other specimens (#18, 19) • Explain the role of each component of a standard PCR mixture in DNA amplification (#40) • Recommend proper storage conditions for specimens and purified nucleic acids according to Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP) guidelines (#9) • Observe precautions against nucleic acids degradation and contamination (#11) • Demonstrate proper use of automated, variable or fixed volume micropipettes (#13)

Appendix J – continued

Delphi Round I Narrative Comments Made by Respondents	Related Learning Objective(s) (number assigned in Round II)
I think general molecular concepts should definitely be emphasized (especially if student has not taken a molecular biology course in undergrad), but even more importantly, teaching should focus on molecular techniques to provide optimal results and minimize error/contamination.	<ul style="list-style-type: none"> • Basic Concepts in Molecular Biology (#1-5) • Observe precautions against nucleic acids degradation and contamination (#11) • Troubleshoot in case of unsuccessful end-point or real-time PCR product analysis outcome (#54)
Be familiar with the clinical presentation of most common viral/bacterial analytes detected by PCR.	Identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents (#66-82)
CAP compliance	<ul style="list-style-type: none"> • Recommend proper storage conditions for specimens and purified nucleic acids according to Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP) guidelines (#9)
More information on infectious disease testing using molecular methods.	<ul style="list-style-type: none"> • Identify methodologies and diagnostic equipment used in molecular assays developed to detect, quantify or genotype bacterial and viral agents (#66-82)
Since the science is moving so rapidly, I would suggest automated platforms for tests, new methods, and new FDA cleared assays. I would suggest that also included in the lectures is the need to correlate molecular results with diagnosis and disease. The presence of DNA does not always mean a disease process is present.	<ul style="list-style-type: none"> • Identify (the functions of) all parts of at least one molecular diagnostic system/instrument utilized in your laboratory, such as amplification, microarray or sequencing system (#56) • Compare and contrast the principles of other molecular technologies not considered PCR and provide specific clinical applications of other molecular technologies not considered PCR (#57-65)

Appendix J – continued

Delphi Round I Narrative Comments Made by Respondents	Related Learning Objective(s) (number assigned in Round II)
<p>My main concern would be for the students to understand the theory of PCR and related molecular techniques. Otherwise, it is very difficult to troubleshoot problems in the lab. In addition, in order to understand PCR, you would need to begin with a review (I say review, because this information should be covered in a basic bio class) of DNA and RNA structures and processes. Although it is important to get some molecular labwork under their belts, there are multiple techniques for the same type of testing, so I'd say that a sampling of techniques is good, a conventional PCR, real time PCR, reverse transcriptase PCR, PFGE (maybe a watch-and-learn lab), Gen-Probe, etc. Having guest speakers who can illustrate the real-life applications of molecular techniques! Its' always good to know that the education that you're getting will actually be a benefit to someone, the world, the pharmaceutical industry, a patient, etc.</p>	<ul style="list-style-type: none"> • Explain the principle of the Polymerase Chain Reaction (#38-45) • Chemical structure and bonds in DNA and RNA (#3) • DNA melting point and its relevance to DNA denaturation, renaturation, hybridization and annealing (#4)
<p>Focus in our program is on contamination control, basic Master mix preparation (listing components and describing how each one is utilized in a reaction), comparing molecular methods to other methods such a culture (advantages, disadvantages etc...). We also focus on Real-time PCR, describing the curve, how it can apply to Qualitative and Quant assays. We touch on mutations/translocations, etc. and examples. FYI-Our program does not include cytogenetics applications.</p>	<ul style="list-style-type: none"> • Observe precautions against nucleic acids degradation and contamination (#11) • Explain the principle of the Polymerase Chain Reaction (#40, 45) • Perform Polymerase Chain Reaction (#46)
<p>Pipetting technique is extremely important as well as preventing contamination. Basics on isolating RNA, DNA as well as PCR, etc. is important...once these are learned it is easier to understand the downstream testing and platforms</p>	<ul style="list-style-type: none"> • Demonstrate proper use of automated, variable or fixed volume micropipettes (#13)

Appendix J – continued

Delphi Round I Narrative Comments Made by Respondents	Related Learning Objective(s) (number assigned in Round II)
Must include Next Generation platforms and applications.	<ul style="list-style-type: none">• Compare and contrast the principles of other molecular technologies not considered PCR and provide specific clinical applications of other molecular technologies not considered PCR: NGS (#63)

Vita

Barbara Kraj (birth name: Ostrowska) was born on March 31, 1967 in Gliwice, Poland and is a naturalized United States citizen. She received a Bachelor and Master of Science degrees in Biology from the University of Silesia, Katowice, Poland in 1991 upon completion of a Master's Thesis at the Centre of Oncology, M. Sklodowska-Curie Memorial Institute, Department of Tumor Biology, Gliwice, Poland, where she worked as research assistant after graduation. She was an exchange visitor at the Wistar Institute of Anatomy and Biology, Philadelphia, PA from May 1993 to December 1994 and was trained in cell culture and molecular techniques in the melanoma laboratory of Dr. Meenhard Herlyn. Since 1998, Barbara Kraj has been working at Georgia Regents University (formerly the Medical College of Georgia) in Augusta, GA. She completed a post-baccalaureate certificate in Medical Technology at that institution in 2004 while working as a research associate in the Institute of Molecular Medicine and Genetics. Currently Barbara is an Associate Professor in the Department of Medical Laboratory, Imaging and Radiologic Sciences at GRU. She joined the faculty of Clinical Laboratory Science program in 2005 and has been teaching clinical molecular methods, professional issues and other courses at baccalaureate and masters levels. She is a certified medical laboratory scientist and technologist in molecular biology and as of April 2013 she has been serving as CLS program director.